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, 2012
OR

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

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

Date of event requiring this shell company report _____

Commission file number 001-35773

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

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

Israel
(Jurisdiction of incorporation or organization)

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

Ori Shilo, Deputy Chief Executive Officer Finance and Operations
21 Ha'arba'a Street, Tel Aviv 64739, Israel
Tel: 972-3-541-3131; Fax: 972-3-541-3144
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

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

None
(Title of Class)

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

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 52,990,361

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 ☒

TABLE OF CONTENTS

Unless the context otherwise requires, all references to "RedHill," "we," "us," "our," the "Company" and similar designations refer to RedHill Biopharma Ltd. The term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$" or "$" refer to U.S. dollars, the lawful currency of the U.S. Our functional and presentation currency is the U.S. dollar. Foreign currency transactions in currencies other than the U.S. dollar are translated in this Annual Report into U.S. dollars using exchange rates in effect at the date of the transactions.

FORWARD-LOOKING STATEMENTS

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

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

- the initiation, timing, progress and results of our 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 approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing the intellectual property rights of others;
- estimates of our expenses, future revenues capital requirements and our needs for additional financing;
- competitive companies, technologies and our industry; and
- the impact of the political and security situation in Israel on our business.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected financial data, which is derived from our financial statements prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, or IFRS. We have derived the selected financial data as of December 31, 2009, 2010, 2011 and 2012 and for the period from August 3, 2009 (date of incorporation) through December 31, 2009 and for the years ended December 31, 2010, 2011 and 2012, from our audited financial statements included elsewhere in this Annual Report on Form 20-F. You should read this selected financial data in conjunction with, and it is qualified in its entirety by, our historical financial information and other information provided in this Annual Report including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report. The unaudited selected financial data were prepared on a basis consistent with our audited financial statements and include, in the opinion of our management, all adjustments necessary for the fair presentation of the financial information contained in those statements.

	Year ended December 31			Period from August 3, 2009 to December 31, 2009
	2012	2011	2010	
	(U.S. dollars in thousands, except share and per share data) (audited)			
Statement of Comprehensive Loss				
Revenues	16	23	-	-
Research and development expenses	(6,455)	(5,414)	(736)	(86)
General and administrative expenses	(2,601)	(2,482)	(518)	(43)
Other income (expenses)	-	-	(479)	28
Operating loss	(9,040)	(7,873)	(1,733)	(101)
Financial income	197	570	65	2
Financial expenses	(1,483)	(8,200)	(876)	(6)
Financial expenses – net	(1,286)	(7,630)	(811)	(4)
Loss and comprehensive loss	(10,326)	(15,503)	(2,544)	(105)
Loss per ordinary share – basic and diluted (in U.S. dollars)	(0.20)	(0.32)	(0.27)	(0.01)
Number of ordinary shares used in computing loss per ordinary share	52,595,128	48,087,362	9,600,000	8,896,000

	As of December 31			
	2012	2011	2010	2009
	(U.S. dollars in thousands) (audited)			
Balance Sheet Data:				
Cash and short term investments	18,365	18,647	9,152	782
Working capital	17,485	18,223	9,161	770
Total assets	20,096	20,186	10,510	891
Total liabilities	1,078	1,399	12,104	21
Accumulated deficit	(23,887)	(15,209)	(2,569)	(105)
Equity	19,018	18,787	(1,594)	870

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 consolidated financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares or our American Depositary Shares. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares and American Depositary Shares to decline, and you could lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical development stage biopharmaceutical company. Since our incorporation in 2009, we have been focused on acquiring and in-licensing therapeutic products and performing research and development. All of our therapeutic candidates are in the clinical development stage, and none has been approved for marketing or is being marketed or commercialized. Many, if not all, of our therapeutic candidates require additional clinical trials before we can obtain the regulatory approvals in order to initiate commercial sales. We have incurred losses since inception, principally as a result of research and development and general administrative expenses in support of our operations. We experienced net losses of approximately $10.3 million in 2012, net losses of approximately $15.5 million in 2011, and net losses of approximately $2.5 million in 2010. As of December 31, 2012, we had an accumulated deficit of approximately $23.9 million. We may incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our therapeutic candidates. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop our therapeutic candidates, obtain the required regulatory approvals in various territories and then commercialize our therapeutic candidates. We may be unable to achieve any or all of these goals with regard to our therapeutic candidates. As a result, we may never be profitable or achieve significant and/or sustained revenues.

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

We have a limited operating history and our operations to date have been limited primarily to acquiring and in-licensing therapeutic candidates, research and development, raising capital and recruiting scientific and management personnel and third party partners. We have not yet demonstrated an ability to commercialize or obtain regulatory approval for any of our therapeutic candidates. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development and/or commercialize our therapeutic candidates, obtain regulatory approvals, or achieve market acceptance or favorable pricing for our therapeutic candidates.

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

We have funded our operations primarily through public and private offerings of our securities. We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and raising additional capital. As of December 31, 2012, we had cash and short term investments of approximately $18.4 million. This amount is not sufficient to complete the research and development of all of our therapeutic candidates, and accordingly we may need to raise additional capital in the coming year.

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

Our long term capital requirements are subject to numerous risks.

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

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

Risks Related to Our Business and Regulatory Matters

If we and/or our commercialization partners are unable to obtain U.S. Food and Drug Administration and/or other foreign regulatory authority approval for our therapeutic candidates, we and/or our commercialization partners will be unable to commercialize our therapeutic candidates.

To date, we have not marketed, distributed or sold any therapeutic candidate or other product. Currently, we have six therapeutic candidates in clinical development, "RHB-101" for the treatment of hypertension, heart failure and left ventricular dysfunction; "RHB-102" for the prevention of chemotherapy and radiotherapy induced nausea and vomiting; "RHB-103" for the treatment of acute migraine headaches; "RHB-104" for the treatment of Crohn's disease; "RHB-105" for the treatment of *Helicobacter pylori* infection, a major cause of peptic ulcer disease; and "RHB-106" for bowel preparation prior to abdominal procedures such as surgery or colonoscopy. Our therapeutic candidates are subject to extensive governmental laws, regulations and guidelines relating to development, clinical trials, manufacturing and commercialization of drugs. We may not be able to obtain marketing approval for any of our therapeutic candidates in a timely manner or at all.

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

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

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

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

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in receiving import or other government approvals to ensure appropriate drug supply;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- negative or inconclusive results from clinical trials;
- the U.S. Food and Drug Administration or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the U.S. Food and Drug Administration or other foreign regulatory authorities may require us to conduct additional clinical trials and/or studies;
- an 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 product;
- 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 U.S. Food and Drug Administration or other foreign regulatory authorities;
- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory approvals.

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

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

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

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

Each of our collaborative arrangements requires us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory, market research, and intellectual property. We do not control these third parties, but we rely on them to achieve results which may be significant to us. Relying upon collaborative arrangements to develop and commercialize our therapeutic candidates subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our therapeutic candidates;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may experience financial difficulties or changes in business focus;
- our collaborators partners may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;

- our collaborators partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our therapeutic candidates.

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

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

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

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

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

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

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

In October 2012, we and our clinical manufacturer for RHB-104 mutually terminated our relationship after we concluded that another manufacturer would be better suited to conduct the scale up required to produce our clinical trial material in sufficient quantities and fulfill our timeline. We do not believe that this action delayed or will delay the initiation of our clinical studies with RHB-104 or will cause us to incur additional significant costs. However, it is possible that in the future we may be required to terminate other third party manufacturers, which may cause us to incur additional costs or delays.

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

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

While there may be several alternative suppliers of API in the market, we have not conducted extensive investigation 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, reliable supplies of our API, we may not be able to produce enough supplies of our therapeutic candidates, which could affect our business, financial condition or results of operation.

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

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

We and our third-party manufacturers are, and will be, subject to regulations of the U.S. Food and Drug Administration and other foreign regulatory authorities.

We and our contract manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the U.S. Food and Drug Administration or other foreign regulatory authorities setting forth current good manufacturing practices. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates. We and our manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our manufacturers are and will be subject to unannounced inspections by the U.S. Food and Drug Administration, 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, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates, and materially and adversely affect our business, financial condition and results of operations.

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

Even if our therapeutic candidates receive regulatory approval, we or our commercialization partners, as applicable, will be subject to ongoing reporting obligations, including pharmacovigilance, and the therapeutic candidates and the manufacturing operations will be subject to continuing regulatory review, including inspections by the U.S. Food and Drug Administration or other foreign regulatory authorities. The results of this ongoing review may result in the withdrawal of a therapeutic candidate from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate. In addition, the manufacturer and the manufacturing facilities that we or our commercialization partners use to produce any therapeutic candidate will be subject to periodic review and inspection by the U.S. Food and Drug Administration and other foreign regulatory authorities. Later discovery of previously unknown problems with any therapeutic candidate, manufacturer or manufacturing process, or failure to comply with rules and regulatory requirements, may result in actions such as:

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;
- warning letters from the U.S. Food and Drug Administration or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we or our commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties;
- adverse publicity; or
- if we, or our commercialization partners, suppliers, third party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we or our commercialization partners may lose marketing approval for any of our therapeutic candidates if any of our therapeutic candidates are approved, resulting in decreased or lost revenue from milestones, product sales or royalties.

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

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

We depend on our ability to identify and in-license therapeutic candidates to achieve commercial success.

Our six therapeutic candidates were all acquired by us or licensed to us by third parties. We evaluate internally and with external consultants each therapeutic candidate. However, there can be no assurance as to our ability accurately or consistently select therapeutic candidates that have the highest likelihood to achieve commercial success.

If we cannot meet our obligations under our acquisition or in-license agreements or we cannot renegotiate our obligations, we could lose the rights to our therapeutic candidates and/or experience delays in developing our therapeutic candidates, which could have a material adverse effect on our business.

We acquired our rights to three of our therapeutic candidates, RHB-104, RHB-105 and RHB-106, from a third party pursuant to an asset and purchase agreement. In addition, we in-license our rights to three other therapeutic candidates, RHB-101, RHB-102, and RHB-103 pursuant to license agreements in which we received exclusive worldwide perpetual licenses to certain patent rights and know-how related to these therapeutic candidates. These agreements require us to make payments and satisfy various performance obligations in order to maintain our rights and licenses with respect to these products. If we do not meet our obligations under these agreements, 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. In addition, our agreement with IntelGenx Corp. requires us to renegotiate certain provisions of the contract in the event the agreed-to budget is exceeded by a certain amount. In the event we are required to renegotiate this agreement, there is no guarantee that we will agree upon new terms promptly, or at all, which could delay the development of RHB-103.

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, we could lose the rights to our therapeutic candidates which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

We face several risks associated with international business.

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

Risks Related to Our Industry

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

Even if our therapeutic candidates are approved for commercialization, they may not become commercially viable products. For example, if we or our commercialization partners receive regulatory approval to market a therapeutic candidate, approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect the marketability and profitability of the therapeutic candidate. In addition, a new therapeutic candidate may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate may not result in commercial success for various reasons, including:

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

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

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

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

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

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

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

In 2010, the U.S. Congress adopted important legislation regarding health insurance, the provision of health care, and conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients. Under the new legislation, substantial changes are going to be made to the current system for paying for healthcare in the U.S., including changes made in order to extend medical benefits to those who currently lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. Such legislation is one of the most comprehensive and significant reforms ever experienced by the U.S. in the health care field and is expected to have meaningful ramifications on tens of millions of citizens in the U.S. Such legislation is expected to impact the scope of health care insurance, the insurance refunds from the insurance companies and possibly also the costs of medical products. At this stage, we are unable to estimate the extent of the direct and/or indirect impact of the new legislation on us.

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

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

Several states and private entities mounted legal challenges to the healthcare reform legislation. That litigation culminated in a decision from the U.S. Supreme Court on July 26, 2012 that generally upheld the healthcare reform legislation as constitutional. However, the Supreme Court held that the legislation improperly required the States to expand their Medicaid programs to cover more individuals. As a result, the States now have a choice as to whether they will expand the numbers of individuals covered by their respective State Medicaid programs. Some States have already indicated that they will not expand their Medicaid programs and will develop other cost saving and coverage measures to provide care to currently uninsured residents. Many of these efforts to date have included the institution of Medicaid managed care programs. The manner in which these cost saving measures are implemented could have a materially adverse effect on our financial performance.

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

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved therapeutic candidates, if any, from governmental or other third-party payors, both in the U.S. and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that the use of an approved therapeutic candidate is:

- a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

In the U.S., there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our therapeutic candidates in the U.S. We believe that legislation that reduces reimbursement for our therapeutic candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our therapeutic candidates, if approved. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our therapeutic candidates, if approved. At this stage, we are unable to estimate the extent of the direct and/or indirect impact of any such federal and state proposals.

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

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

The clinical trials that we conduct, and the testing, manufacture, marketing and commercial sale of our therapeutic candidates, involve and will involve an inherent risk that significant liability claims may be asserted against us. We currently have a product liability policy that includes coverage for our clinical trials and has an aggregate limit of liability of US $10,000,000. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our therapeutic candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and therapeutic candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our therapeutic candidates.

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

The biopharmaceutical industry, like other industries and businesses, continues to face the effects of the challenging economic environment. Patients experiencing the effects of the challenging economic environment, including high unemployment levels and increases in co-pays, may switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. Challenging economic conditions in the U.S. have increased the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many states, to 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 biopharmaceutical products, as well as government-imposed access restrictions in certain countries. All of the aforesaid may make it more difficult for us to commercialize our therapeutic candidates.

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

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

Risks Related to Intellectual Property

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

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

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

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

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the 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 act to manufacture and/or market our therapeutic candidates in infringement of our patent protected rights. Such manufacture and/or market of our therapeutic candidates in infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our therapeutic candidates, thereby reducing our anticipated profits.

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

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

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

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

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

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

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

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

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

Risks Related to our Ordinary Shares and American Depositary Shares

We may be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes in 2012 or in any subsequent year which may have negative tax consequences for U.S. investors.

We will be treated as a PFIC for U.S. federal income tax purposes in any taxable year in which either (i) at least 75% of our gross income is "passive income" or (ii) on average at least 50% of our assets by value produce passive income or are held for the production of passive income. Based on our estimated gross income, the average value of our gross assets, and the nature of our business, we believe that we may be classified as a PFIC in the current taxable year and in future years. In addition, because we have valued our goodwill based on the market value of our equity, a decrease in the price of our ordinary shares may result in our becoming a PFIC. If we are treated as a PFIC for any taxable year during which a U.S. investor held our ordinary shares or American Depositary Shares, certain adverse U.S. federal income tax consequences could apply to the U.S. investor. See "Item 10. Additional Information – E. Taxation – Foreign Exchange Regulations – Passive Foreign Investment Companies."

The market price of our ordinary shares and our American Depositary Shares 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 and our American Depository Shares on The Nasdaq Capital Market in particular, are subject to fluctuation, and changes in our share price may be unrelated to our operating performance. The market price of our ordinary shares on the Tel Aviv Stock Exchange has fluctuated in the past, and we expect it will continue to do so. It is likely that the market price of our American Depositary Shares will likewise be subject to wide fluctuations. The market price of our ordinary shares and American Depositary Shares are and will be subject to a number of factors, including:

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

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

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

Future sales of our ordinary shares or American Depositary Shares could reduce the market price of our ordinary shares and American Depositary Shares.

All of our outstanding ordinary shares are registered and available for sale in Israel. In addition, as of February 19, 2013, we had outstanding 7,151,150 tradable Series 1 warrants which are traded on the Tel Aviv Stock Exchange and exercisable for an aggregate of 7,151,150 ordinary shares, 6,421,500 non-tradable warrants to purchase an aggregate of 6,421,500 ordinary shares and 12,015,000 options to purchase 12,015,000 ordinary shares under our 2010 Stock Option Plan. See "Item 6. Directors, Senior Management and Employees – E. Share Ownership – Stock Option Plans." Substantial sales of our ordinary shares or American Depositary Shares, 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 American Depositary Shares 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 American Depositary Shares on their respective exchanges.

Our ordinary shares and our American Depositary Shares are traded on different markets and this may result in price variations.

Our ordinary shares have been traded on the Tel Aviv Stock Exchange since February 2011, and our American Depositary Shares have been listed on The Nasdaq Capital Market since December 27, 2012. Trading in our securities on these markets take place in different currencies (U.S. dollars on The Nasdaq Capital Market and New Israeli Shekels, or NIS, on the Tel Aviv Stock Exchange), 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.

Our American Depositary Shares have only recently began trading on The Nasdaq Capital Market, and an active market may not develop, which may limit the ability of our investors to sell our American Depositary Shares in the U.S.

Our American Depositary Shares have only recently begun trading on The Nasdaq Capital Market, and an active trading market for our American Depositary Shares may never develop or may not be sustained if one develops. If an active market for our American Depositary Shares does not develop, it may be difficult to sell your American Depositary Shares.

We may incur significant additional increased costs as a result of the listing of our American Depositary Shares on The Nasdaq Capital Market, and our management may be required to devote substantial time to new compliance initiatives as well as to compliance with ongoing U.S. and Israeli reporting requirements.

As a public company in the U.S., we may 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 Tel-Aviv Stock Exchange. These may include costs associated with reporting requirements of the Securities and Exchange Commission and the Nasdaq Marketplace Rules. 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. These laws, rules and regulations make it more difficult, and has made it more costly for us to obtain certain types of insurance, including director and officer liability insurance. 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.

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

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the Nasdaq Marketplace Rules for domestic issuers. For instance, we follow home country practice in Israel with regard to, among other things, composition of the board of directors, which does not require that a majority of a company's board of directors be independent, director nomination procedure and quorum at shareholders' meetings. In addition, we follow our home country law, instead of the Nasdaq Marketplace Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on the Nasdaq Capital Market may provide less protection than is accorded to investors under the Marketplace Rules of The Nasdaq Stock Market applicable to domestic issuers.

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

As a result of becoming a U.S. Securities and Exchange Commission registrant, we are obligated to develop and maintain proper and effective internal controls over financial reporting. We may not complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our ordinary shares.

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. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, depending on the market value of our shares held by the public and legal and regulatory requirements, our independent registered public accounting firm will be required to issue an opinion on management's assessment of those matters, which will be tested in connection with the filing of our second annual report on Form 20-F after the listing of our ADSs on The Nasdaq Capital Market.

We have not completed the challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common shares to decline.

Because we became a reporting company under the Securities Exchange Act of 1934, as amended, by means of filing a Form 20-F, we may not be able to attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering, we do not expect security analysts of major brokerage firms to provide coverage of our company in the near future. In addition, major investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we were to become a public reporting company by means of an initial public offering. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our American Depositary Shares.

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

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

The depositary for the American Depositary Shares has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the American Depositary Shares, after deducting its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your American Depositary Shares 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 American Depositary Shares. For example, it would be unlawful to make a distribution to a holder of American Depositary Shares 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 American Depositary Shares, 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 American Depositary Shares, ordinary shares, rights or anything else to holders of American Depositary Shares. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the American Depositary Shares.

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

Holders of our American Depositary Shares do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the American Depositary Shares. 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 shareholder meeting is convened, holders of our American Depositary Shares 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 American Depositary Shares 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 American Depositary Shares 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 American Depositary Shares. 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 American Depositary Shares may not be able to exercise their right to vote and they may lack recourse if their American Depositary Shares are not voted as they requested. In addition, in the capacity as an American Depositary Share holder, they are not able to call a shareholders' meeting.

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

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

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

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

Risks Related to our Operations in Israel

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

We are incorporated under the laws of the State of Israel, our principle 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 winter of 2012, Israel was engaged in an armed conflict with Hamas, a militia group and political party operating in the Gaza Strip. This conflict involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. Recent political uprisings and civil resistance demonstrations 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, or the Arab Spring in general, will develop and how it will affect the political and security situation in the Middle East. This instability may lead to deterioration of the political relationships that exist between Israel and these countries, and have raised concerns regarding security in the region and the potential for armed conflict. In addition, it is widely believed that Iran, which has previously threatened to attack Israel, has been stepping up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy generally and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary.

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

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

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

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

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

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

Provisions of our 2010 Stock 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 Stock Option Plan provides that all options granted by us prior the completion of our initial public offering and options granted subject to completion of our initial public offering and options which we granted after September 24, 2012, will be fully accelerated upon a "takeover" of the Company. A "takeover" is defined in our 2010 Stock Option Plan as an event in which any person, entity or group that was not an "interested party", as defined in the Israeli Securities Law – 1968, on the date of the initial public offering of our securities, shall become a "controlling shareholder". A "controlling shareholder" for these purposes means a controlling shareholder as defined in the Israel Securities Law, 1968, or any person, entity or group becoming a holder, as defined in the Israel Securities Law, 1968, of 25% or more of our voting rights. See "Item 6. Directors, Senior Management and Employees – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law – 1968.

The Israeli Companies Law, 1999, or the Israeli Companies Law, regulates mergers, requires tender offers for acquisitions of shares 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 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 rights 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 or class of shares, 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 6 months following the completion of the tender offer, petition the court to alter the consideration for the acquisition. At the request of an offeree of a full tender offer which was accepted, the court may determine that the consideration for the shares purchased under the tender offer was lower than their fair value and compel the offeror to pay to the offerees the fair value of the shares. Such application to the court may be filed as a class action.

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

Pursuant to our articles of association, the size of our board of directors shall be no less than 5 persons but no more than 7, excluding at least two external directors. The directors, except for our external directors, are divided into three classes, as nearly equal in number as possible. At each annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three year term that expires at the annual general meeting held in the third year following such election. This process continues indefinitely. Such provisions of our articles of association make it more difficult for a third party to effect a change in control or takeover attempt that our management and board of directors oppose.

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

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, or an acquisition of a significant portion of our shares, even if such an acquisition or merger would be beneficial to us or to our shareholders. See "Item 10. Additional Information - B. Memorandum and Articles of Association."

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

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

Your obligations and responsibilities as a shareholder are governed by Israeli law which may differ in some respects from the obligations and responsibilities of shareholders of U.S. companies. Israeli law may impose obligations and responsibilities on a shareholder of an Israeli company that are not imposed upon shareholders of corporations in the 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 stockholder 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 and our Articles of Association provide that a company may not exempt or indemnify a director or an office holder nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of (a) a breach by the director or officer of his duty of loyalty, except for insurance and indemnification where the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the company; (b) a breach by the director or officer of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence; (c) any act or omission done with the intent to derive an illegal personal benefit; or (d) any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director. 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 consolidated shareholders' equity, per our most recent consolidated annual financial statements, or $3 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 providing coverage for up to $10 million a year, 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 stockholders 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 shareholders.

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," our Series 1 Warrants are traded on the Tel Aviv Stock Exchange under the symbol "RDHL.W1," and our ADSs are traded on the Nasdaq Capital Market under the symbol "RDHL".

Our capital expenditures for the years ended December 31, 2012, 2011 and 2010 were $5,000, $139,000 and $8,000, respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of therapeutic candidates acquired through asset purchases or in-licensing. In particular, we acquire or in-license and develop patent-protected new formulations and combinations of existing drugs in advanced stages of development.

Our strategy is to acquire the therapeutic candidates for relatively small down and milestone payments and relatively high royalties. From inceptions we invested total of 1.35 Million on acquisitions.

Depending on the specific development program, our therapeutic candidates are designed to provide improvements over existing drugs by improving their safety profile, reducing side effects, lowering the number of administrations, using a more convenient administration form, providing a cost advantage and/or exhibiting greater efficacy. Where applicable, we intend to seek U.S. Food and Drug Administration 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 six late clinical development therapeutic candidates, two of which have completed bioequivalence clinical trials subject to review and approval by the U.S. Food and Drug Administration and, in some cases, regulatory authorities in other countries.

We generate our pipeline of therapeutic candidates by identifying, rigorously validating and in-licensing or acquiring products that are consistent with our products strategy and that we believe exhibit a relatively high probability of therapeutic and commercial success. Our therapeutic candidates have not yet been approved for marketing and, to date, there have been no meaningful sales. Upon and subject to receipt of the requisite approvals, we intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and territorial basis. We may also evaluate, on a case by case basis, co-development and similar arrangements and the commercialization of our therapeutic candidates independently.

Our Strategy

Our goal is to become a significant player in the development of pharmaceuticals that represent improvements, enhancements and/or innovative uses of existing drugs.

Key elements of our strategy are to:

- identify and acquire rights to products from companies in the pharmaceutical field, which have encountered cash flow or operational problems or that decide to divest one or more of their products for various reasons. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field.

- produce enhancements of existing pharmaceutical products, including broadening their range of indications or launching innovative and advantageous pharmaceutical products based on existing products. 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 study 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.

- acquire rights to and develop products that are intended to treat pronounced clinical needs, have patent protection, and have target markets totaling tens of millions to billions of dollars.

- acquire rights to and develop products based on different technologies designed to reduce our dependency on any specific product technology.

- capitalize on the U.S. Food and Drug Administration's 505(b)(2) regulatory pathway to obtain more timely and efficient approval of our formulations of previously approved products, when applicable. Under the 505(b)(2) process, we are able to seek U.S. Food and Drug Administration 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 U.S. Food and Drug Administration. This enables us to partially rely on the U.S. Food and Drug Administration's findings of safety and/or efficacy for previously approved drugs, thus avoiding the duplication of costly and time consuming preclinical and various human studies. See "Government Regulations and Funding - Section 505(b)(2) New Drug Applications."

- cooperate with third parties to develop and/or commercialize therapeutic candidates in order to share costs and leverage the expertise of others.

Our six current clinical stage therapeutic candidates include "RHB-101", "RHB-102", "RHB-103", "RHB-104", "RHB-105" and "RHB-106", each of which are described below.

Our Therapeutic Candidates

RHB–101

RHB-101 is intended for the treatment of hypertension, heart failure and left ventricular dysfunction (following myocardial infraction) by means of controlled release of an active ingredient known as carvedilol, which is designed to be administered to patients on a once-daily basis. Carvedilol is a nonselective β-adrenergic blocking agent with α1-blocking activity providing its clinical effect through two different mechanisms. β-adrenergic blockade slows the heart rate and promotes its effect by decreasing the work or output of the heart. α1 adrenergic blockade is effected within the vascular system and lowers blood pressure. We believe that our once-daily RHB-101 is an improvement over existing generic carvedilol-containing drugs, which are administered several times per day.

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

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

Competition and Market

The pharmaceutical market targeted by RHB-101 has over 200 million users worldwide according to a 2012 report by Scrip Intelligence. According to the 2007 annual report of GlaxoSmithKline, generic products have entered this market since 2007. In 2011, the target worldwide market of RHB-101 reached a total value in excess of $500 million according to sales market data integrated from a 2012 report by Scrip Intelligence, the 2011 annual report of GlaxoSmithKline and European 2011 sales data for carvedilol from IMS Health, a provider of information for the health care industry. At present, the market can be divided into two parts:

The first part of the market includes generic drugs based on the immediate release of the generic active ingredient known as carvedilol (such as Coreg® produced by GlaxoSmithKline). These drugs are administered to patients twice a day, due to their relatively short active span, as opposed to the once daily administration of RHB-101. Administration once per day instead of several times per day has the potential to be a significant advantage, including improved compliance, especially for the elderly who commonly take a relatively large number of drugs over long periods of time.

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

In 2011, sales of Coreg CR® in the U.S. reached approximately $240 million according to the 2011 annual report of GlaxoSmithKline. Coreg CR® is not marketed in Europe. The European market of immediate release carvedilol in 2011 was in excess of $200 million according to IMS Health. In 2010, the sale of generic immediate release of carvedilol reached $273 million in the U.S. alone according to data published by IMS Health. Consolidating sales data for both segments of the market indicate that the worldwide target market of RHB-101 is in excess of $500 million.

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

Clinical Development

We are currently reassessing RHB-101's development strategy, including its regulatory path, for the possible obtainment of marketing approvals in the U.S., pursuant to the 505(b)(2) regulatory path, and in Europe, based on a number of clinical trials previously conducted by us and Egalet a/s. In addition, we are currently searching for a strategic partner to jointly develop RHB-101.

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

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Number of subjects	Nature and status of the trial	Schedule	Total accrued cost as of December 31, 2012
CL-EG-01	Phase I	Pharmacokinetic (PK) comparison of once-daily administration of the product in 25 mg concentration against carvedilol, and the impact of food on the product's absorption in the human body	Shandon Clinic, Ireland	30	30	The trial was performed and indicated that food does not have any impact on the absorption of the product	Ended in 2004	-
CL-EG- 02	Phase I	PK comparison of repeat product administration in 25 mg concentration against carvedilol	Shandon Clinic, Ireland	30	30	The trial was performed and indicated that there is PK similarity between the products	Ended in 2004	-
CL-EG- 04	Phase I	PK comparison of once-daily administration of two different product formulations in a concentration of 50 mg against carvedilol	Shandon Clinic, Ireland	12	12	The trial was performed and indicated that one of the formulations is pharmacokinetically preferable	Ended in 2007	-
CL-EG- 09	Phase I	PK comparison of once-daily administration of two different formulations of the product in a concentration of 12.5 mg against carvedilol	Shandon Clinic, Ireland	14	14	The trial was performed and indicated that one of the formulations is pharmacokinetically preferable	Ended in 2007	-
PLT-11	Pilot	Feasibility check of PK comparison of the product with Coreg CR®	RA Chem Pharma India	36	36	The trial was performed and provided initial and partial information on potential comparison with Coreg CR®	Ended in 2011	Approx. $60,000
To be determined	We are examining the relevant regulatory strategy	Under examination	To be determined	To be determined	-	Under examination	Under examination	

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

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

RHB-102

RHB-102 is a once-daily controlled release oral formulation of ondansetron, a leading member of the family of 5HT-3 serotonin receptor inhibitors. It is intended to prevent chemotherapy and radiotherapy induced nausea and vomiting.

RHB-102 utilizes a technology called CDT® that uses salts to provide a controlled release of ondansetron. The CDT® platform enables controlled release drug design (*i.e.*, measured rate of introduction of active drug) at a relatively low manufacturing cost.

We acquired the rights to RHB-102 under a May 2, 2010 agreement with SCOLR Pharma Inc., pursuant to which we received a worldwide, exclusive and perpetual license to various patent rights and know-how related to RHB-102. See "– Acquisition and License Agreements – License Agreement for RHB-102."

Competition and Market

Nausea and vomiting prevention (anti-emetic) treatments account for a large market share of oncology-support treatments. In 2010, the worldwide market for treatments for prevention of chemotherapy-induced nausea and vomiting exceeded $2 billion. Of this market, 5-HT3 serotonin receptor inhibitors are estimated at approximately $1 billion in 2010 (RHB-102 belongs to this family of inhibitors) according to BCC Research, a leading market intelligence and information resource.

To the best of our knowledge, the main competitors of RHB-102 are other 5-HT3 serotonin receptor inhibitors. This class of medication is derived from the active ingredient ondansetron (such as the generic drug marketed in the U.S. under the trade name Zofran®, produced by GlaxoSmithKline). Additional first-generation generic drugs from the same family contain the active ingredient granisetron (marketed in the U.S. under the name Kytril®, produced by Hoffman-La Roche Ltd.) or the active ingredient dolasetron (marketed in the U.S. under the name of Anzemet®, produced by Sanofi-Aventis Groupe). In addition, a second-generation drug containing the active ingredient palonosetron is still under patent and marketed in the U.S. under the name Aloxi, by Eisai Pharmaceuticals Inc., or Eisai.

Zofran® is a leading 5HT-3 serotonin receptor inhibitor drug, reaching worldwide sales of approximately $400 million in 2011 according to integration of data from IMS Health and the 2011 annual report of GlaxoSmithKline. This drug contains the active ingredient ondansetron and became generic in December 2006. The drug is available in oral tablet and intravenous (IV) formulations. The price of the drug varies broadly and reaches up to $85 for a single chemotherapy treatment.

Granisetron and dolasetron are additional first-generation generic drugs from the same family of 5HT-3 serotonin receptor inhibitors. Although there are no significant differences in the mechanisms of action between them and ondansetron, sales of ondansetron products exceed those of granisetron and dolasetron. The generic drugs containing these active ingredients are available both orally and intravenously and by transdermal patch. The price of the Kytril® and Anzemet® drugs varies roughly between $100 and $180 for each chemotherapy treatment. Their relatively high cost is one of the reasons that ondansetron-based drugs are more widely used.

Aloxi® is a second-generation drug from the same family of inhibitors. To the best of our knowledge, it is currently administered only intravenously (IV) in the U.S. It has longer duration of action in the body and is the only drug in this family that was approved for use with an indication of nausea and vomiting prevention for more than 24 hours from the chemotherapy treatment (delayed onset). This means that the drug continues to be effective from the time of its administration for more than the ensuing 24 hours. The price of this drug is significantly higher than Zofran® and is estimated at approximately $400 per treatment. To the best of our knowledge, an oral version of this drug was approved in August 2008 in the U.S., but is not currently marketed in the U.S.

The potential advantages of RHB-102 compared to Zofran® are significant. A single dose of RHB-102 is anticipated to prevent chemotherapy or radiotherapy induced nausea and vomiting over a time window of approximately 24 hours. This effectiveness period is significantly longer than the effective time of Zofran® 8mg, which is indicated to be administered several times a day. This is potentially advantageous for cancer patients undergoing radiation treatments who would prefer to avoid the need to take additional drugs (tablets) during the day after the treatment, when they may suffer attacks of nausea and vomiting.

The potential advantages of RHB-102 compared to Aloxi®, the only drug that has a relatively long-term effect (beyond 24 hours, as stated above), is the delivery method and price. Aloxi® is a drug that in the United States is delivered intravenously (IV) and costs approximately $400 per dose. RHB-102 is planned to be delivered orally, in tablet form. Oral administration is expected to allow independent self-administration by patient, save patient travel time to the clinic or hospital and reduce health care professional work load, thus significantly lowering its cost as opposed to currently available IV alternatives. To the best of our knowledge, there are several plans to develop new products in the area of nausea and vomiting prevention, including the development of a product that directly competes with RHB-102, for controlled release of ondansetron, based on a different technology of controlled release, by the Eurand N.V. (which merged with Axcan Pharma, and changed its name after the merger to Aptalis Pharma Inc.). To the best of our knowledge, this product completed Phase II trials.

Clinical Development

In April 2012, we completed a comparative bioavailability trial, comparing the bioavailability of RHB-102 (24mg) administered once to Zofran® 8mg tablet administered three times over a 24 hour period. The final results of the study, which we received in June 2012, showed that one dose of RHB-102 (24mg) provides patients with comparable exposure to Zofran® 8mg tablet administered three times over a 24 hour period. Together with literature data on the relationship between the efficacy and pharmacokinetics of ondansetron, RedHill believes that these results indicate that the efficacy and safety of the two pharmaceutical products would be expected to be similar.

In order to carry out clinical trials for RHB-102, in November 2011 we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with Algorithme Pharma Inc., a Canadian clinical research organization specializing in the performance of clinical trials. Algorithme Pharma Inc. performed the clinical trials described above for RHB-102 from February to April 2012. See "– Master Service Agreement with 7810962 Canada Inc."

In light of the positive results of the clinical trial, we are currently in discussions with the U.S. Food and Drug Administration regarding the U.S. marketing approval pathway for RHB-102.

The following chart summarizes the clinical trial history and status of RHB-102:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Number of subjects	Nature and status of the trial	Schedule	Accrued cost as of December 31, 2012
Biovail 838332783283	Phase I	PK test of three different formulations of the product in a concentration of 24 mg compared to Zofran 8 mg administered 3 times per day	Biovail Contact Research, Canada	30	30	The trial was performed and indicated that one of the formulations is suitable for continuing the development process	Ended in 2007	-
ODO-P1-494	Comparative Bioavailablity	Comparison between once-daily administration of several formulations of RHB-102 to administration of Zofran® 8mg three times per day, 8 hours apart	Algorithme Pharma, Canada	26	26	Successfully completed the study in compliance with the trial's bioequivalence and safety objectives, meeting its objectives of bioequivalence as defined by U.S. Food and Drug Administration	Ended in Q2 2012	Approx. $1.3 million
TBD	Supplementary Pharmacokinetics	Comparison of the bioavailability of RHB-102 with and without food	Algorithme Pharma, Canada	14	TBD	Under examination	Planned to begin in H1 2013	
TBD	Supplementary Pharmacokinetics	Study of ondansetron plasma accumulation over multiple day dosing of RHB-102	Algorithme Pharma, Canada	TBD	TBD	Under examination	Planned to begin in 2013	

Supplemental studies will be required as part of the RHB-102 global development program and regulatory strategy.

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

RHB-103

RHB-103 is an oral thin film formulation of rizatriptan intended for the treatment of acute migraine headaches. Migraine is a neurovascular disorder (related to nerves and blood vessels) characterized by recurrent headaches in one side or both sides of the head. In general, migraine headaches are accompanied by nausea and increased sensitivity to light and sound. Migraines are generally treated through the usage of triptans, a class of molecules that narrow (constrict) blood vessels in the brain in order to relieve swelling and other migraine symptoms. Examples of triptans include sumatriptan, zolmitriptan and rizatriptan, the basis of RHB-103. RHB-103 rapidly dissolves in the mouth.

The product 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 RHB-103 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 RHB-103. See "– License Agreement for RHB-103" for more information regarding this agreement.

Competition and Market

To the best of our knowledge, the main marketing competitors of RHB-103 are oral drugs from the triptan family, such as rizatriptan from Merck and Co., Inc., which is marketed in the U.S. under the name of Maxalt®, and sumatriptan, produced by GlaxoSmithKline and marketed in the U.S. as Imitrex® and in generic form since 2006. The target market for RHB-103 is the triptan market, which was estimated at approximately $2.1 billion worldwide in 2011 according to a 2011 report by Business Insights.

According to the 2011 annual report of Merck and Co., Inc., the direct sales of Maxalt® worldwide in 2011 accounted for $639 million. According to an article in the journal Current Pain and Headache Reports 2004 by Dr. David W. Dodick et. al., Rizatriptan (Maxalt®) is considered one of the oral triptans with the highest effectiveness among the triptan family. According to HTA (Health Technology Assessment), the price of one 10 mg tablet is approximately $37. The U.S. patent of Maxalt® is expected to expire in the U.S. in December 2012. It should be noted that, to the best of our knowledge, and based on investigations performed by us, we were prevented from marketing RHB-103 in the U.S. until December 2012, due to the validity of the existing patent of Merck & Co. Inc.

Until December 2012, sumatriptan was the only generic triptan competitor on the market. While its price is generally lower than the rizatriptan based drugs on the market, it ranks lower than these drugs in terms of effectiveness. We believe that this limited efficacy will likely also be true with respect to the single-use, battery-powered patch that actively delivers sumatriptan which was approved by the FDA in January 2013 and will be marketed as as Zecuity™ by NuPathe, Inc. beginning in the fourth quarter of 2013.

In December 2012, the patent on rizatriptan expired and as of the date of this filing, nine generic versions of Maxalt® and a few generic versions of MaxaltMLT® are available for prescription, including one by PAR Pharmaceutical and one by Mylan.

We believe that RHB-103 will compare favorably to the other triptan drugs due to the fact that it is delivered through oral dissolution, rather than through conventional tablets. This feature should be especially appealing to pediatric and geriatric populations that often struggle with swallowing capsules with water.

Clinical Development

In April 2012, we and IntelGenx, Corp. completed a bioequivalence clinical trial in Canada, subject to the U.S. Food and Drug Administration review and approval, in order to examine the pharmacokinetic equivalence between the soluble film of RHB-103 and rizatriptan of Merck & Co. Inc. (Maxalt MLT®), using 26 volunteers. The final results of the clinical trial, which we received in August 2012, demonstrated that RHB-103 met its specified endpoints and the U.S. Food and Drug Administration criteria in all parameters for bioequivalence with rizatriptan of Merck & Co. Inc. (Maxalt MLT®).

On November 7, 2012, we and IntelGenx Corp. held a pre-New Drug Application, or pre-NDA, meeting with the FDA.

Based on this clinical trial and the outcome of the pre-NDA meeting, we and IntelGenx Corp. intend to file an NDA with the U.S. Food and Drug Administration for U.S. marketing approval under the 505(b)(2) regulatory path during the first quarter of 2013.

The following chart summarizes the clinical trial history status of RHB-103:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Number of subjects	Nature and status of the trial	Schedule	Accrued cost as of December 31, 2012
PLT—008-09	Phase I	PK comparison with a parallel product	RA Chem Pharma, India	10	10	The trial was performed and indicated similarity between the PK profile of the product and the profile of the reference product	Ended in 2009	-
RZA-P9-688	Comparative Bioequivalence	PK comparison with Maxalt MLT®	Algorithme Pharma, Canada	26	26	Successfully completed the study demonstrating bioequivalence as defined by U.S. Food and Drug Administration	Ended in Q2 2012	Approx. $800,000

Supplemental studies may be required as part of the RHB-103 global development program and regulatory strategy.

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

RHB-104

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

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

To date, Crohn's disease has been considered to be an autoimmune disease, but the exact pathological mechanism is unclear. According to Dr. Robert Greenstein's article published in The Lancet Infectious Diseases in 2003, the hypothesis that Crohn's disease is caused by an interaction between MAP bacteria and the immune systems of individuals having a predisposition to the pathological inflammatory reaction is supported by increasing evidence. This hypothesis is further supported by an increasing number of scientific and clinical studies published in peer reviewed journals since a National Institute of Allergy and Infectious Diseases conference in 1998 that focused on MAP in Crohn's disease.

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

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

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

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

On February 12, 2012, we entered into an agreement with Quest Diagnostics Ltd. to develop a commercial diagnostic test for detecting the presence of MAP bacteria in the blood based upon the rights we acquired from University of Central Florida Research Foundation, Inc. We intend to use this test in connection with our planned RHB-104 clinical trials and potentially in future commercial applications of RHB-104.

Market

According to a report on the epidemiology of Inflammatory Bowel Disease published by Datamonitor in August 2012, there were approximately 534,000 Crohn's patients in the U.S. in 2011, which number is expected to increase by 12% to approximately 598,800 by 2021. The disease is now considered to be the second most common chronic inflammatory disorder after rheumatoid arthritis. According to Dr. Andrew Yu in an article published in Current Medical Research Opinions in 2008, the total direct medical cost of Crohn's disease in the U.S. was estimated to be $7.8 billion to $11.2 billion in 2006. Including indirect costs, the total economic burden of Crohn's disease was estimated to be $10.9 billion to $15.5 billion.

The MAP bacterium is suspected of being a major factor in causing the inflammatory symptoms of Crohn's disease patients. According to a study by Professor Saleh Naser et. al. in 2004 in The Lancet Infectious Diseases, approximately 40-50% of Crohn's disease patients have been found to be infected with these bacteria. These patients represent our target market. EvaluatePharma, a source for commercial analysis of the pharmaceutical and biotech sector, estimates the market for diagnosis and drug treatment of Crohn's disease to have been approximately $3 billion worldwide in 2011 and estimates the worldwide market for diagnosis and drug treatment of Crohn's disease to reach $5 billion by 2016.

Competition

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

Currently available drugs on the market for the treatment of Crohn's disease offer only symptomatic relief, the effects of which are largely temporary and accompanied by numerous adverse effects. A report of these side effects is shown in the following chart published by Dr. Carol Nacy et. al. in a report from the American Academy of Microbiology that was published in June 2007.

Drug Family	Example of Drug from the Family	Effect	Common Side Effects
Corticosteroids	Prednisone	Relatively good effectiveness, for some patients only.	Headaches, swinging moods, muscle and bone weakness, heart failure, diabetes and risk of infections.
Immunomodulatory drugs	6-Mercaptopurine Methotrexate	High effectiveness, but only for a certain time and for some patients.	Suppresses the immune system causing risks of infection or even cancer, negative side effects on the liver, kidneys and blood.
Biological agents –Anti-TNF-α drugs. The TNF (Tumor Necrosis Factor) is a component of the immune system.	Remicade, (Infliximab) Humira	Administered intravenously (IV) every 2-8 weeks. Effective for some patients (30-40%). Effectiveness decreases over time.	Suppresses a central component of the immune system. Risk of infectious diseases, cancer and damage to the nervous system.

We may also be exposed to potentially competitive products which may be under development to treat Crohn's disease, including Sequella's CM Analog, an innovative cellular therapy with stem cells by Hospital Clinic in Barcelona, Spain, which is in early stage of development, and new anti-TNFα therapies which may be under development to treat Crohn's disease.

Clinical Development

We are currently preparing two clinical trials, one in the U.S. and one Europe, before submitting applications for marketing approval for RHB-104 from the U.S. Food and Drug Administration through the 505(b)(2) regulatory path. These trials, based on the analysis and data of a Phase III trial conducted in Australia, are designed as a Phase III trial for Crohn's disease patients in North America and Israel, and a Phase III trial for Crohn's disease patients in six countries in Europe. In the Phase III clinical trial in Australia, sponsored by Pharmacia and published by Professor Warwick Selby in 2007 in the medical journal Gastroenterology, the main objective was to evaluate the ratio of patients with recurrent symptoms of the disease in the 12th, 24th and 36th month of disease, out of the patients who had achieved remission after 16 weeks of treatment. The main secondary objective was the rate of patients whose clinical condition improved within the first 16 weeks. Although the study did not meet the main objective of showing a difference in relapse rate with long-term treatment, there was a statistically significant difference between the treatment groups in the percentage of subjects in remission at week 16. Professor Marcel Behr and Professor James Hanley from McGill University published a re-analysis of the study in The Lancet Infectious Diseases in June 2008 based on the intent-to-treat (ITT) principle and found that there was a significant statistical advantage for the active therapy over the placebo throughout the period of administration that disappeared once the active therapy was discontinued.

The trial of RHB-104 in North America and Israel will be led by Professor David Y. Graham, MD, from Baylor College of Medicine, Houston, Texas, U.S., while the clinical trial of RHB 104 in Europe will be led by Professor Colm O'Morain, MD, of Meath and Adelaide Hospital, Dublin, Ireland.

We are also currently examining the possibility of carrying out clinical trials on pediatric patients that suffer from Crohn's disease, a population for which RHB-104 received "Orphan Drug" status in 2011. Upon the successful completion of these trials, we intend to apply for regulatory approval of a pediatric indication of RHB-104.

On October 21, 2012, we entered into an agreement, with our Canadian service provider which entered into a back-to-back agreement with Corealis Pharma, Inc., a Canadian drug manufacturer, to manufacture and supply RHB-104 for our clinical trials. See " – Manufacturing Agreement Related to RHB-104."

In June 2011, we entered into an agreement with our Canadian service provider, which entered into a back-to-back agreement with PharmaNet Canada Inc. for the provision of clinical trial services for the RHB-104 adult studies in North America and Europe. In March 2012, our Canadian service provider entered into another agreement with PharmaNet Canada Inc. for the provision of clinical trial services for a pediatric trial of RHB-104. We have not yet set a date for starting the pediatric clinical trial, nor have we applied for U.S. Food and Drug Administration approval to undertake this trial. See "– Master Service Agreements with Canadian service provider" and see also "– Clinical Services Agreement related to RHB-104."

Subsequent to our discussions with the U.S. Food and Drug Administration for approval to conduct the North American trial based upon an Investigative New Drug (IND) approved by the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration, and after 30 days, the IND became effective. Based upon the response from the U.S. Food and Drug Administration on issues relating to the clinical study, additional changes have been made to the clinical study in North America and Israel.

Approximately 240 Crohn's disease subjects are expected to participate in the clinical trial in North America and Israel. Half of the patients will receive RHB-104 and half will receive a placebo drug over a period of approximately six months to determine efficacy, followed by an additional follow-up period of approximately six months to confirm safety. A further Clinical Trial Application (CTA) may be submitted in Europe in the coming months.

The following chart summarizes the clinical trial history and status of RHB-104:

Clinical trial name	**Development phase of the clinical trial**	**Purpose of the clinical trial**	**Clinical trial site**	**Planned number of subjects of the trial**	**Number. of subjects**	**Nature and status of the trial**	**Schedule**	**Accrued cost as of December 31, 2012**
Borody 2002	Phase IIa	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	12	12	Performed	Ended in 2002	-
Borody 2005	Phase II	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	52	52	Performed	Ended 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	211	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	24	Trial compared two formulations to determine the optimum formulation for RHB-104	Ended in 2007	Biovail PK study 2007
To be determined	Phase III (N. America and Israel – "MAP US")	Examining the product's effectiveness in alleviating symptoms of Crohn's disease in patients	To be determined	240		Preparations for Phase III trial in North America and Israel	Expected to commence in Q2 2013	$2.5 million
To be determined	Phase III (Europe – "MAP Europe")	Examining the product's effectiveness in alleviating Crohn's disease patients	To be determined	To be determined		Under examination	-	
To be determined	Pediatric trial	Examining the product's effectiveness in alleviating Crohn's disease in pediatric patients	To be determined	To be determined		Under examination	-	

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

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

Multiple Sclerosis

We are also exploring, through preliminary research, the potential impact of RHB-104 in treating Multiple Sclerosis, or MS, indication. To date, we have performed three pre-clinical studies in an experimental autoimmune encephalomyelitis (EAE) mouse model of MS. The first pre-clinical 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 pre-clinical 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 pre-clinical study measured relapses, demonstrating RHB-104's efficacy in significantly reducing the incidence of relapse, compared with the control group. Following these pre-clinical studies, we are making advanced preparations for starting a Phase IIa proof of concept clinical trial to be run in Israel. Such clinical trial is currently expected to commence in Q1 2013 and to conclude during the second quarter of 2014, with interim results expected during the first quarter of 2014.

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.

Trial name	**Development phase**	**Purpose of the trial**	**Clinical trial sites**	**Planned number of subjects of the trial**	**Number. of subjects currently enrolled**	**Nature and status of the trial**	**Schedule**	**Accrued cost as of December 31, 2012**
Experimental Autoimmune Encephalomyelitis (EAE) Mouse T-cell Function Study	Pre-Clinical	Measure cytokine production as a measure of inflammation in EAE mice treated with RHB-104 vs. negative controls	-			Completed 2012		
Experimental Autoimmune Encephalomyelitis (EAE) Prophylaxis Study	Pre-Clinical	Scoring EAE severity in mice treated prophylactically with RHB-104 vs. negative controls	-			Completed 2012		
Experimental Autoimmune Encephalomyelitis (EAE) Relapse Study	Pre-Clinical	Scoring EAE severity in mice treated with RHB-104 vs. negative and positive controls	-			Completed 2012		
Lipopolysaccharide (LPS)-induced cytokine production study	Pre-Clinical	Measure LPS induced cytokine production in C57BL/6 mice treated with RHB-104 vs. negative and positive controls	-			Completed 2013		
CEASE-MS	Phase IIa	Exploratory	Israel	16	0	Start-up	Expected to commence in Q1 2013	70,000

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

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

RHB-105

RHB-105 is intended for the treatment of *Helicobacter pylori* bacterial infection in the gastrointestinal tract. RHB-105 is a combination of three approved drug products – omeprazole, which is a proton pump inhibitor (the natural body pump that produces the gastric acids used for digesting the food in the stomach), and amoxicillin and rifabutin which are antibiotics. RHB-105 is administered to patients orally.

Chronic infection with *Helicobacter pylori* irritates the mucosal lining of the stomach and small intestine. This condition is further exacerbated by the acidic environment within the upper gastro intestinal tract, and can eventually result in a peptic ulcer. According to a 2004 article in The Emerging Infectious Diseases by William M. Duck et. al., patients with a peptic ulcer may complain of abdominal pain, nausea, vomiting and weight loss. In addition, these bacteria are a major risk factor for the development of stomach cancer.

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

Competition and Market

The most popular treatments of *Helicobacter pylori* type bacteria combine clarithromycin or metronidazole antibiotics with amoxicillin and a proton pump inhibitor. Such current standard of care treatments fail in more than 20% of the patients due to the development of antibiotic resistance, as reported by Dr. Lennita Wannmacher in a 2011 report submitted to the World Health Organization. The potential advantage of RHB-105 over these drugs (such as PrevPac® of Takeda Pharmaceuticals NA) was shown in a Phase II study comprising 130 subjects, in which RHB-105 was shown to eradicate *Helicobacter pylori* in over 90% of treated patients who failed previous eradication attempts using the current standard of care treatment, as published in the 2006 study report by Dr. TJ. Borody, et. al. in Alimentary Pharmacology & Therapeutics.

Approximately three million *Helicobacter pylori* infected patients are treated per annum in the U.S. according to a 2007 report by Colin W. Howden, MD, et. al. in The American Journal of Managed Care. Based on this figure, combined with the price of current treatments, we estimate that the U.S. market of RHB-105 to be between $1 billion and $1.5 billion.

Clinical Development

RHB-105 completed a Phase II clinical trial in Australia and is planned to undergo a Phase II/III study in North America, which is currently anticipated to commence during the second quarter of 2013, subject to receipt of necessary regulatory approvals. We intend to seek marketing approval for RHB-105 from the U.S. Food and Drug Administration through the 505(b)(2) regulatory path.

We entered into an agreement with Professor David Y. Graham, MD, from Baylor College of Medicine, Houston, Texas, U.S., to serve as the lead investigator of the clinical trial of RHB-105.

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

Clinical trial name	**Development phase of the clinical trial**	**Purpose of the clinical trial**	**Clinical trial site**	**Planned number. of subjects of the trial**	**Number of Subjects**	**Nature and status of the trial**	**Schedule**	**Accrued cost as of December 31, 2012**
-	Phase IIa	Examining the product's effectiveness in treating *Helicobacter pylori* infections in patients for whom standard of care had failed to treat the infection	Center for Digestive Disease, Australia	130	130	The trial was performed and indicated that the treatment is effective for bacteria patients for whom standard of care had failed to treat the infection	Ended in 2005	-
To be determined	Phase II/III	Examining the effectiveness, safety and pharmacokinetics of the final formulation	To be determined	To be determined		Preparations for Phase II/III trial in North America	Expected to commence in Q2 2013	$0.6 million

Supplemental studies will be required as part of the RHB-105 global development program and regulatory strategy.

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

RHB-106

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

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

Competition and Market

According to a 2012 report by EvaluatePharma, the world market of products intended for cleansing the gastrointestinal system was estimated at approximately $1.4 billion in 2011.

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

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

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

A leading product among the PEG 3350 family of products is MoviPrep®, marketed by Salix Pharmaceuticals, Inc. in the U.S. and by Norgine in Europe. Its price in the U.S. varies from $40 to $60 per dose. It requires drinking of about 2 liters of solution and some users report it has an unpleasant taste. EvaluatePharma estimates that the annual worldwide sales of MoviPrep® and the parallel product marketed outside of the U.S. (Movicol®) in 2011 were approximately $400 million. The potential advantage of RHB-106 over the current competitor products of the PEG 3350 type (such as MoviPrep®), as well as over PicoPrep™, is that it is tasteless, eliminates the need to drink several liters of solution, and spares the patient the exposure to the harsh tastes that may accompany these products. RHB-106 also does not fall under the black box warning against nephrotoxicity issued by the U.S. Food and Drug Administration in December 2008 with respect to currently marketed capsule preparations which are based on sodium phosphate.

Clinical Development

Giaconda Limited completed a Phase IIa clinical trial in which 62 patients who underwent elective colonoscopies were prospectively randomized to receive either a hypertonic solution with PicoPrep™ (sodium picosulphate) capsules, PicoPrep™ capsules alone, standard Glycoprep™ (PEG) or PicoPrep™ sachets. The clinical trial showed that the PicoPrep™ capsules were the preferred option by the patients and resulted in a lower number of mild adverse events than the other preparations. In terms of "ease of completion", more subjects in the PicoPrep™ capsule arm, as compared to the GlycoPrep™ arm, rated this bowel preparation as easy to complete.

RHB-106 is currently in the formulation stage. We intend to seek marketing approval from the U.S. Food and Drug Administration through the 505(b)(2) regulatory path.

The following chart summarizes the clinical trial history and status of RHB-106:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical site	Planned number of subjects of the trial	Number of subjects	Nature and status of the trial	Performance schedule	Accrued cost as of December 31, 2012
-	Phase IIa	Comparison of the product's effectiveness and safety with an existing products	Center for Digestive Disease, Australia	60	60	Performed	Ended in 2005	-
To be determined	To be determined	Comparison of the product's effectiveness and safety (in its final formulation) with an existing product	To be determined	To be determined	-	To be determined	To be determined	Approx. $200,000

Supplemental studies will be required as part of the RHB-106 global development program and regulatory strategy.

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

Summary

A summary of our therapeutic candidates is provided below:

Name of Product	Relevant Indication	Potential Advantages Over Most Existing Treatments	Development Stage	Rights in the Product
RHB-101	Cardiovascular	Once-daily	Under review	Worldwide, exclusive license
RHB-102	Oncology support	Reduced number of drug administrations	In preparation for application for marketing approval	Worldwide, exclusive license
RHB-103	Acute migraine	Discrete dosage form and ease of use	In preparation for application for marketing approval	Worldwide, exclusive license and co-development
RHB-104	Crohn's disease	Novel mechanism of action and improved clinical benefit	In preparation for Phase III studies	Acquired all rights to the product, worldwide and exclusive
RHB-104	Multiple Sclerosis (MS)	Oral formulation targeting underlying cause of MS	In preparation for Phase IIa study	Acquired all rights to the product, worldwide and exclusive
RHB-105	*Helicobacter pylori* infection	Improved effectiveness	In preparation for Phase II/III studies	Acquired all rights to the product, worldwide and exclusive
RHB-106	Bowel preparation	An oral pill. Avoids severe bad taste No known nephrotoxicity issues	In preparation for Phase II/III studies	Acquired all rights to the product, worldwide and exclusive

Acquisition and License Agreements

License Agreement for RHB-101

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

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

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

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

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

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

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

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

License Agreement for RHB-102

On May 2, 2010, we entered into an agreement with SCOLR Pharma, Inc., a publicly traded Seattle based pharmaceutical company, that granted us a worldwide, exclusive and perpetual license to use patents and know how relating to an oral formulation for sustained release of ondansetron, a generic active chemical substance, for any pharmaceutical indication or treatment usage, diagnostic usage or any other use in human beings or in animals. The name given to the product by us is RHB-102.

The license granted to us includes the right to grant sublicenses. The license covers the development, manufacture, commercialization, use, sale, offer for sale and import of products for all uses, including medical uses, diagnostics, and other uses in human beings and/or animals. However, under the license agreement SCOLR Pharma, Inc. retained certain rights and is entitled to make use of the know- how for purposes other than RHB-102 and/or products outside of RHB-102's field of use, which is defined as all indications, including therapeutic, diagnostic and other human and or animal uses.

In consideration for the granting of the license, we paid SCOLR Pharma, Inc. an up-front payment of $100,000. Furthermore, we are obligated under the license to pay to SCOLR Pharma, Inc. additional amounts, as follows:

- $250,000 upon the receipt of U.S. Food and Drug Administration approval for marketing the product;
- $250,000 upon the first sale of the product; and
- royalty payments.

Royalties are payable to SCOLR Pharma, Inc. at a rate of 8% of our net sales or sublicensing fees, for the shorter of:

- expiration of the last patent granted under the license;
- 10 years from the date of the sale of the first product by us or any third party; and
- a date when the total of all payments made to SCOLR Pharma, Inc. reach an aggregate of $30 million.

The agreement requires us to make a good faith, continuous and diligent effort to allocate appropriate financial resources to prepare, initiate and complete the clinical development of RHB-102 and file an application for regulatory marketing approval in accordance with industry standards. If we do not comply with this undertaking, SCOLR Pharma, Inc. may terminate the license, except if our failure is due to development failures, negative regulatory decisions, and/or other reasons beyond our control.

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

Furthermore, if we have not received U.S. Food and Drug Administration approval for the marketing of the product within 36 months, or if product sales do not occur within 48 months following the transfer of the know- how to us, which was 30 days following the date of the agreement, SCOLR Pharma, Inc. may terminate the agreement, unless we elect to pay the relevant milestone payment within 45 days from the date SCOLR Pharma, Inc. notifies us of its intention to terminate the agreement.

License Agreement for RHB-103

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^{TM} technology and which we call RHB-103.

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, 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 U.S. Food and Drug Administration for marketing of the product, and we agreed to finance the balance of the development in the amount of approximately $849,000, subject to deviations of 10%.

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 $600,000 and we are required to make additional milestone payments of up to $700,000 as follows:

- $200,000 upon the filing of an NDA and acceptance of the filing by the U.S. Food and Drug Administration; and
- $500,000 upon receipt of U.S. Food and Drug Administration marketing approval for the product.

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

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

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

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. The agreement excluded from the transfer the rights to two other products of Giaconda Limited that are not related to RHB-104, RHB-105 and RHB-106. However, to the extent that the intellectual property associated with these two other products shall be required for the research, development, manufacture, registration, import/export, use, commercialization, distribution, sale and/or offer for sale of any of RHB-104, RHB-105 and RHB-106, Giaconda Limited granted us an exclusive worldwide assignable right to such intellectual property for such purposes. The closing under this agreement occurred on August 26, 2010.

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

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

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

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

License Agreement for MAP diagnostic test related to RHB-104

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

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

We intend to use this test in order to identify the MAP status of the subjects in the clinical study, thereby allowing a correlation of MAP status and treatment response to RHB-104.

Under the license agreement, we received an exclusive license for all indications and medical uses of the test in exchange for a one-time payment of $45,000. Furthermore, we agreed to pay royalties of 7% of future sales, or an annual minimum amount noted below, as well as 20% of payments we receive from granting sublicenses.

The agreement provides that the annual minimum royalty payment amount shall be $10,000 in year two, $15,000 in year three, $20,000 in year four and $35,000 every year thereafter. These annual minimum payment amounts shall be deducted from future royalty payments.

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

License Agreement for RHB-107 and RHB-108

On October 21, 2012, we signed a term sheet for an exclusive worldwide licensing agreement with SCOLR Pharma Inc. Subject to completion of due diligence and execution of a binding agreement, the agreement would provide us a worldwide, perpetual, exclusive license for all indications for two proprietary therapeutic candidates, both 12 hour extended release proprietary formulations of currently available pharmaceutical products. The first therapeutic candidate is extended release ibuprofen, which to the best of our knowledge, has completed a Phase III study in the U.S. To the best of our knowledge, prior to the NDA submission to the U.S. Food and Drug Administration, we will be required to complete an "Actual Use study," the purpose of which is to assess safety under conditions resembling non-prescription use (OTC). The second therapeutic candidate is extended release pseudoephedrine, which has, to the best of our knowledge, completed a pivotal bioequivalence trial. To the best of our knowledge, an Abbreviated New Drug Application was submitted to the U.S. Food and Drug Administration and a complete response letter was received citing certain deficiencies. We would have the primary responsibility for development and commercialization of the therapeutic candidates in cooperation with SCOLR Pharma Inc. would receive royalties in the event either therapeutic candidate generates commercial sales. For extended release ibuprofen, SCOLR Pharma Inc. would be entitled to a royalty of between 20% and 50%, depending on the distribution channel and territory, and for extended release pseudoephedrine, SCOLR Pharma Inc. would be entitled to a royalty of between 8% and 15% depending on the distribution channel. The consummation of this licensing transaction is subject to our further due diligence as well as a negotiation and execution of a definitive agreement. The term sheet establishes various mechanisms, including payment-related mechanisms, in the event the agreement is not executed; however, we are entitled not to enter into an agreement, with no payment to SCOLR Pharma, in the event that material deviations emerge during the due diligence process. The term sheet also includes a framework for potential future cooperation between the parties with respect to other products. Our discussions with SCOLR Pharma continue and we cannot guarantee that we will in fact enter into a definitive agreement with SCOLR Pharma Inc. or that the terms that we ultimately agree to will be similar to the terms described in the term sheet.

Master Service Agreement with 7810962 Canada Inc.

On April 28, 2011, we entered into a master service agreement, which was later amended, with 7810962 Canada Inc., our Canadian service provider for various project management services. According to the agreement, as amended, we agreed to pay our Canadian service provider a monthly fee of $10,000. The agreement allowed our Canadian service provider to enter into service agreements with third parties for the relevant services. The agreement may be terminated by either party upon 30 days' advance notice.

The agreement with our Canadian service provider provides that certain research and development services related to our projects will be carried out pursuant to our specific requests and upon the signing of specific agreements for each project. Such agreements shall include a description of the required services, service terms and fees. To date, we, through our Canadian service provider, have entered into manufacturing, clinical services and regulatory agreements with respect to RHB-102, RHB-104, RHB-105 and RHB-106.

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, 2012 we estimated, that in the future we may receive from our Canadian service provider discounts of approximately $0.5 million. As of December 31, 2012, we had not recorded any research and development expense deductions.

Manufacturing Agreements

Manufacturing Agreement Related to RHB-102

On March 21, 2011, we entered into an agreement with a U.S. drug manufacturer, Pharmaceutics International, Inc., for the manufacture and supply of RHB-102 for our clinical trial. On May 24, 2012 and on July 13, 2012, we entered into further agreements with Pharmaceutics International, Inc. to manufacture, test and supply registration batches of RHB-102.

The agreement provides for Pharmaceutics International, Inc. to manufacture sufficient amounts of RHB-102 for our clinical trials and other planned tests pursuant to our specifications and in accordance with regulatory requirements.

Pursuant to this agreement, as amended, the manufacturer is entitled to receive up to approximately $1.2 million payable upon the completion of milestones during the production periods and reimbursement of certain expenses. Milestone payments will be triggered upon the manufacturer performing various services, such as API and raw materials sourcing, formulation and manufacturing work, development, manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next few years.

Manufacturing Agreements Related to RHB-104

On April 28, 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with Uman Pharma, Inc., a Canadian drug manufacturer, to manufacture and supply RHB-104 for the clinical trials.

The agreement provided for Uman Pharma, Inc. to manufacture sufficient amounts of RHB-104 for our clinical trials, NDA submission batches, and other planned tests pursuant to our specifications and in accordance with regulatory requirements. All manufacturing will be done under good manufacturing practices (GMP), as proscribed by the U.S. Food and Drug Administration.

Pursuant to the agreement, as amended, the manufacturer is entitled to receive approximately $1.4 million, payable upon the completion of milestones during the production periods and reimbursement of certain expenses. Milestone payments will be triggered upon the manufacturer performing various services, such as sourcing, formulation and manufacturing work, development, manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next few years.

On October 14, 2012, we mutually terminated this agreement with our Canadian service provider, resulting in the concurrent termination of the related back-to-back agreement between the Canadian service provider and Uman Pharma Inc. Through the end of October, we paid Uman Pharma approximately $1.1 million. No additional amounts are payable to Uman Pharma.

On October 21, 2012, we entered into a new agreement with our Canadian service provider which, in turn, entered into a back-to-back agreement with Corealis Pharma Inc. to complete the manufacturing and supply of RHB-104 for our clinical trials. Pursuant to this agreement, the manufacturer is entitled to receive approximately $350,000 upon the completion of milestones during the production and stability tests periods and the reimbursement of various expenses. All manufacturing will be done under GMP. Milestone payments will be triggered upon the performance by the manufacturer of various services, such as manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next few years. The total costs of the two manufacturing agreements with the Canadian service provider are expected to be approximately $1.8 million. See "– Master Service Agreement with 7810962 Canada Inc." for a description of our agreement with our Canadian service provider.

Manufacturing Agreement Related to RHB-105

On July 5, 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with Corealis Pharma Inc., a Canadian drug manufacturer, to formulate, manufacture and supply a clinical trial batch of RHB-105.

The agreement provides for Corealis Pharma Inc. to manufacture sufficient amounts of RHB-105 for our clinical trials and other planned tests pursuant to our specifications and in accordance with regulatory requirements.

Pursuant to this agreement, as amended, the manufacturer is entitled to receive approximately $500,000 payable upon the completion of milestones during the production periods and for reimbursement of certain expenses. Milestone payments will be triggered upon the performance by the manufacturer of various services, such as raw materials formulation and manufacturing work, development, manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next few years.

The agreement will remain in force until terminated. This agreement provides that either party may terminate the agreement (i) if the other party is in material breach and does not cure within thirty (30) days or (ii) upon a bankruptcy or liquidation event with respect to the other party.

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

Manufacturing Agreement Related to RHB-106

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

The agreement provides for Pharmaceutics International Inc. to manufacture sufficient amounts of RHB-106 for our clinical trials and other planned tests pursuant to our specifications and in accordance with regulatory requirements.

Pursuant to this agreement, as amended, the manufacturer is entitled to receive approximately $400,000, payable in upon the completion of milestones during the production periods and reimbursement of certain expenses over a period of approximately 3 years. Milestone payments will be triggered upon the performance by the manufacturer of various services, such as raw materials sourcing, formulation and manufacturing work, development, manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next few years.

Either party may terminate the agreement if the other party is in material breach and does not cure within sixty (60) days (ten (10) days in connection with monetary obligations). We may terminate the agreement at any time and for any reason upon providing thirty (30) days written notice to Pharmaceutics International Inc. Pharmaceutics International Inc. may terminate the agreement if we fail to authorize purchase of material needed in connection with the services.

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 PharmaNet Canada Inc., a subsidiary of an international CRO company, and other related entities, for the purpose of performing the clinical trials for RHB-104

PharmaNet Canada Inc. specializes in the performance of clinical trials and pursuant to the agreement will be responsible for the performance of the clinical trials, including entering into agreements with medical centers to perform the trials, supervision of the performance and progress of the trials and the analysis of the results, all pursuant and subject to applicable regulatory requirements.

Pursuant to this agreement and subsequent amendments, PharmaNet Canada Inc. is entitled to receive $8 million in connection with the Phase III clinical trial in North America and the Phase III clinical trial in Europe, as well as reimbursement of costs and investigator grants to be paid during the trials. The payments will be spread out over the period of the clinical trials and based upon quarterly administration fees, payments of up to approximately $4 million during the course of the clinical trials subject to the satisfaction of certain milestones and reimbursements of certain expenses. These fees, however, may vary widely from time to time in accordance with the final clinical trials protocol and payments to be made to third parties, such as investigator grants and payments for various laboratory tests during the clinical trials, including tests to identify the MAP bacterium.

The agreement includes a timetable for the recruitment of patients, performance of the trials 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 trials.

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.

In March, 2012, 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 pediatric trial of RHB-104.

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

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology, its therapeutic applications, and related technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments.

We have rights either through assignment, asset purchase or in-licensing to a total of 104 issued patents and 21 patent applications in 12 different patent families. The patents and patent applications are registered in various jurisdictions, the details of each family of patents being provided below. In addition, we have licensed rights to various platform technologies on a non-exclusive basis.

RHB-101

One family of our patents and patent applications is in-licensed by us and is comprised of ten issued patents and one patent application. This family is entitled "Controlled Release Solid Dispersion of carvedilol" and relates to RHB-101. The patent family has a priority date of September 21, 2001 and assuming no extension or adjustment of term, the patents in this family will expire September 23, 2022. This patent family is licensed from Egalet a/s as part of our licensing agreement and relates to controlled release pharmaceutical composition for oral use comprising a solid dispersion of:

- a t least one therapeutically, prophylactically and/or diagnostically active substance (including carvedilol), which is at least partially in an amorphous form,
- a pharmaceutically acceptable polymer that has plasticizing properties, and
- optionally, a stabilizing agent, the active substance having a limited water solubility, and the composition being designed to release the active substance with a substantially zero order release.

This family of patents includes one patent application filed in the U.S., and patents granted in Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, the United Kingdom, Ireland and Italy.

A second family of our patents and patent applications is in-licensed by us from Egalet a/s and is comprised of one patent application which has been granted a Notice of Allowance in the U.S. related to a controlled release pharmaceutical composition for oral use comprising carvedilol. This family is entitled "Controlled Release Carvedilol Compositions" and also relates to RHB-101. The patent family has a priority date of November 8, 2002, and the U.S. application once granted will expire June 6, 2024, including a patent term adjustment of 219 days.

RHB-102

A third family is in-licensed by us and is comprised of three issued patents in the U.S., Canada and Mexico, and two pending patent applications in Europe and Hong Kong. Nineteen countries are designated in the European application. This family is entitled "Monolithic tablet for controlled drug release" and has priority date of March 9, 1998. The non-U.S. patents in this family will expire March 2, 2019 and the U.S. patent will expire on March 9, 2018. This family is in-licensed from SCOLR Pharma, Inc. as part of our licensing agreement and relates to a swellable hydrophilic matrix tablet that delivers drugs in a controlled manner over a long period of time. The drug is disposed in a matrix composed of HPMC or polyethylene oxide, in the presence of a salt, which may be a combination of salts.

A fourth patent family is in-licensed by us and is comprised of 24 issued patents and two pending patent applications. This family is entitled "Amino Acid Modulated extended Release Dosage Form" and has an earliest priority date of December 20, 1999 for the U.S. patents, and the earliest US patent will expire December 20, 2019. The non-U.S. patents will expire February 20, 2022. The patent has been granted in the U.S., Canada, Australia and Europe and two patent applications are still pending in Japan.

This family is licensed from SCOLR Pharma, Inc. and covers an extended release tablet comprising a plurality of granules of an effective amount of a pharmaceutically active compound, at least one amino acid, and an intragranular polymer in which the granule is dispersed within a hydrophilic extragranular polymer matrix which is more rapidly hydrating than the intragranular polymer.

RHB-103

A fifth patent family is in-licensed by us from IntelGenx Corp. and is comprised of three issued patents in the U.S. and one pending patent application. As part of the agreement with IntelGenx Corp., we were granted a worldwide, exclusive and perpetual license which includes the right to grant sub-licenses to these patents and applications. These patents and applications cover various aspects of the VersaFilm^{TM} technology that is the basis for RHB-103. The central U.S. patent (7,132,113) for a multi-layer film formulation comprising the combination of a hydroxypropyl cellulose and a modified starch was issued November 7, 2006 and expires in 2022.

RHB-104

A sixth family of our patents and patent applications is owned by us and is comprised of thirty five issued patents (including U.S., Australia, Canada, Israel, Japan, New Zealand, Norway, Philippines, South Africa, Austria, Belgium, Switzerland, Lichtenstein, Cyprus, Germany, Denmark, Spain, Finland, France, the United Kingdom, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal and Sweden) and two pending patent applications. This family is entitled "Method and composition for treating inflammatory bowel disease" and relates to RHB-104. The patent family has priority rights dating to April 1, 1997 and the patents in this family will expire April 1, 2018. This patent family was acquired from Giaconda Limited as part of our asset purchase agreement with them.

This family relates to a method and composition of medications used to treat inflammatory bowel disease, which includes Crohn's disease. It further provides combinations of anti-atypical mycobacterial agents effective against the atypical mycobacterial strains. It also provides a method of potentially immunizing patients with extracts of non-pathogenic mycobacteria.

A seventh family of our patents and patent applications is owned by us and is comprised of seven patent applications in Australia, Canada, Europe (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Switzerland/Liechtenstein, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hungary, Ireland, Iceland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Slovakia, Sweden and Turkey), Israel, Japan, South Africa and the Philippines, and one granted patent in New Zealand. In the U.S., we have received a notice of issuance. In Europe we have the option, once the European application is granted, to validate the European patent in a total of 35 countries. This patent family was acquired from Giaconda Limited as part of our asset purchase agreement with them and is related to RHB-104.

The family is entitled "Method and composition for treating inflammatory bowel disease" and covers improved compositions comprising rifabutin, clarithromycin, and clofazimine for use in the treatment of Inflammatory Bowel Diseases. In one instance, the compositions may comprise a formulation of rifabutin, clarithromycin, and clofazimine in a single dosage form, such as a capsule, tablet, etc., with one or more specific excipients.

The family also covers a method for formulating the compositions to provide a solid oral dosage form of the composition which has improved efficacy and a reduced likelihood of side effects.

RHB-105

An eighth family of our patents and patent applications is owned by us and comprised of twenty issued patents (including the U.S., Australia, Canada, Austria, Belgium, Switzerland/Liechtenstein, Cyprus, Germany, Denmark, Spain, France, the United Kingdom, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal and Sweden). This eighth family is entitled "Improved Method of Eradication of *H.pylori*" and relates to RHB-105. The patent family has priority rights dating to April 30, 1998 and the patents in this family will expire April 30, 2019. This patent family was acquired as part of the asset purchase agreement with Giaconda Limited.

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

RHB-106

A ninth family of our patents and patent applications is owned by us and is comprised of seven issued patents in the U.S., Australia, Canada and New Zealand and one application in Europe (designating Austria, Belgium, Switzerland/Liechtenstein, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Luxembourg, Monaco, Netherlands, Portugal and Sweden). This ninth family is entitled "Improved Preparation for colonic evacuation" and relates to RHB-106. The patent family has priority rights dating to November 3, 1995 and the non-U.S. patents in this family will expire November 1, 2016 and the U.S. patents October 31, 2016.

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

A tenth family is owned by us and at present includes one U.S. provisional application. The title of this application is "A formulation and method of manufacturing a formulation for use in colonic evacuation" and relates to a new formulation of RHB 106. The U.S. provisional application was filed July 27, 2012.

RHB-104 - new indications

An eleventh family is owned by us and is comprised of two U.S. provisional patent applications. The title of these applications is "A composition and method for treating an autoimmune disease" and relates to new indications for RHB-104. The first U.S. provisional application was filed September 20, 2011 and the second U.S. provisional application was filed September 21, 2011. On September 19, 2012, we completed a PCT filing and additional filings occurred in select non-PCT countries.

Protocol for detection of the Intracellular Infection Mycobacterium avium paratuberculosis in blood

A twelfth family of patents is a single patent licensed from the University of Central Florida Research Foundation Inc. (UCF) and is entitled Protocol for detection of the Intracellular Infection Myobacterium avium paratuberculosis in blood. It was granted in the U.S. (7,488,580 B1) and has a priority date of March 8, 2006, expiring in 2026. This patent relates to a method and kit for detection of intracellular MAP infection in blood and blood derivative samples from humans by culture and PCR. The technology can screen for MAP in blood samples from patients having inflammatory and non-inflammatory bowel disease, and the results used to identify those patients for appropriate treatment with antibiotics. The method and kit allows monitoring and evaluation of the outcome of antibiotic therapy.

The patent positions of companies like 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.

Government Regulations and Funding

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

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

U.S. Food and Drug Administration Approval Process

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

- Completion of pre-clinical laboratory and animal testing;
- The submission to the U.S. Food and Drug Administration of an investigational new drug, or IND, application which must be evaluated and found acceptable by the U.S. Food and Drug Administration before human clinical trials may commence;
- Performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- Submission and approval of an NDA.

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

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

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

Phase I. In Phase 1 clinical studies, the product is tested in a small number of patients with the target condition or disease or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the product candidate in humans, side effects associated with increasing doses, and, in some cases, to gain early evidence on efficacy. The number of participants included in Phase 1 studies is generally in the range of 20 to 80.

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

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

Phase IV. Phase IV clinical trials are studies required of, or agreed to by, a sponsor that are conducted after the U.S. Food and Drug Administration has approved a product for marketing. These studies are used to gain additional information from the treatment of patients in the intended therapeutic indication and to verify a clinical benefit in the case of drugs approved under accelerated approval regulations. If the U.S. Food and Drug Administration 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 U.S. Food and Drug Administration's good clinical practices, or GCP, requirements. The U.S. Food and Drug Administration may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with U.S. Food and Drug Administration requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

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

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the U.S. Food and Drug Administration in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, controls 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 U.S. Food and Drug Administration.

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

After the U.S. Food and Drug Administration evaluates the NDA and inspects manufacturing facilities where the drug product and/or its API will be produced, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the U.S. Food and Drug Administration nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The U.S. Food and Drug Administration 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 U.S. Food and Drug Administration also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include phase 4 clinical studies and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug.

If the U.S. Food and Drug Administration approves one of our product candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the U.S. Food and Drug Administration, 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 U.S. Food and Drug Administration periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need U.S. Food and Drug Administration review and approval before the change can be implemented. For example, if we change the manufacturer of a product or its API, the U.S. Food and Drug Administration may require stability or other data from the new manufacturer, which will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the U.S. Food and Drug Administration, we may not label or promote the product for an indication that has not been approved. Securing U.S. Food and Drug Administration approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the U.S. Food and Drug Administration 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 product candidates. Future U.S. Food and Drug Administration 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, U.S. Food and Drug Administration-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 U.S. Food and Drug Administration'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 U.S. Food and Drug Administration approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the Food, Drug, and Cosmetic Act, or FDC, was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the U.S. Food and Drug Administration's conclusions from prior review of such studies. The U.S. Food and Drug Administration may require companies to perform additional studies or measurements to support any changes from the approved product. The U.S. Food and Drug Administration 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 U.S. Food and Drug Administration's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the U.S. Food and Drug Administration concerning any patents listed for the approved product in the U.S. Food and Drug Administration'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 U.S. Food and Drug Administration, the Orphan Drug Act provides tax credits for clinical research, U.S. Food and Drug Administration assistance with protocol design, eligibility for U.S. Food and Drug Administration grants to fund clinical studies, waiver of the U.S. Food and Drug Administration application fee, and a period of seven years of marketing exclusivity for the product following U.S. Food and Drug Administration marketing approval.

C. Organizational Structure

Not applicable.

D. Property, Plant and Equipment

On February 23, 2011 we entered into a lease agreement for the lease of offices in the "Platinum" building at 21 Ha'arba'ah Street, Tel Aviv, Israel. Pursuant to the lease agreement, we lease approximately 310 square meters of office space, a 27 square meter warehouse and six parking spaces. The monthly rent is NIS 48,000 (approximately $13,000, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), linked to the Israeli Consumer Price Index of January 2011. The lease term under the agreement is as of March 1, 2011 up to February 28, 2016, with an option to extend the lease term by three additional years. As security for its obligations under the Lease Agreement, we provided a bank guarantee in the amount of NIS 280,000 ($76,000, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013). Since April 2011, these offices have served as our corporate headquarters.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

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

Company Overview

We are an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of therapeutic candidates acquired through asset purchases or in-licensing. In particular, we acquire or in-license and develop patent-protected new formulations and combinations of existing drugs in advanced stages of development.

Depending on the specific development program, our therapeutic candidates are designed to provide improvements over existing drugs by improving the safety profile, reducing side effects, lowering the number of daily administrations, using a more convenient administration form, providing a cost advantage and/or exhibiting greater efficacy. Where applicable, we intend to seek U.S. Food and Drug Administration 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 six late clinical development therapeutic candidates, two of which have completed bioequivalence clinical trials subject to review and approval by the U.S. Food and Drug Administration.

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

The following is a description of our six therapeutic candidates:

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

RHB-102 is a patented formulation once-daily controlled release oral formulation of ondansetron, in combination with salts, intended for the prevention of chemotherapy and radiotherapy induced nausea and vomiting, by means of an oral formulation of ondansetron. RHB-102 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 RHB-102 from SCOLR Pharma, Inc. in exchange for an up-front payment of $100,000, milestone payments of up to $500,000 and future royalties, for a fixed period of time as determined under the agreement, of 8% of our net sales or sublicense fees. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements - License Agreement for RHB-102."

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 RHB-103 and to grant sublicenses. In consideration for the license, we made up-front and milestone payments in the aggregate amount of $600,000 and are required to make additional milestone payments of up to $700.000. In addition, we are required to make royalty payments to IntelGenx Corp. of 20% of net sales if the product is marketed by us and 40% of net sublicense fees if the product is marketed by sublicensees. However, in certain events the royalty payments could range between 20% to 70% of net sublicense fees. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for RHB-103."

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 of Inflammatory Bowel Disease (IBD) but has focused on Crohn's disease patients. 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."

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

RHB-106 is a patented formulation in tablet form intended for the preparation and cleansing of the gastrointestinal tract prior to the performance of abdominal procedures. We acquired ownership rights in patents, tangible assets, production files and regulatory approvals and other data and 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."

Components of Statement of Comprehensive Loss

Revenues

In 2012 and in 2011, we recorded non-significant revenues for the first time, in connection with royalty payments received from a third party licensee of limited rights to a patent that we acquired from Giaconda Limited. Our therapeutic candidates are currently in development and, therefore, we cannot estimate when and if we will generate significant revenues in the future.

Research and Development Expenses

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

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for directors, employees and consultants in executive and operational functions. Other significant general and administration costs include office related expenses, professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

Financial Income and Expense

Financial income and expense consist of non-cash financing expenses in connection with the revaluation of mandatory convertible loans that we entered into during 2010. The fair value of these loans was measured at the time of initial issuance. Subsequent to initial recognition of the fair value of these loans, changes in fair value were charged to financial expense or financial income. Immediately before the completion of our initial public offering, all of these loans were automatically converted into ordinary shares and warrants. See "Item 10. Additional Information – C. Material Contracts – Loan Agreements – August 2010 Mandatory Convertible Loan Agreements." Other financial income and expense include revaluing certain royalty liabilities due to investors in our mandatory convertible loans, interest earned on our cash, cash equivalents and short-term bank deposits, bank fees and other transactional costs and expense or income resulting from fluctuations of the U.S. dollar and other currencies, in which a portion of our assets and liabilities are denominated in NIS. In 2012, the majority of the finance expenses were accretion and settlement of royalty obligations to investors. In 2011, the majority of the finance expenses were generated from the revaluation to fair value of the mandatory convertible loans upon their conversion to shares and warrants prior to our initial public offering.

Critical Accounting Policies and Estimates

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

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

Recent Accounting Pronouncements

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

A. Operating Results

History of Losses

Since inception in 2009, we have generated significant losses mainly in connection with the research and development of our therapeutic candidates. Such research and development activities are expected to expand over time and will require further resources if we are to be successful. As a result, we expect to continue incurring operating losses, which may be substantial over the next several years, and will need to obtain additional funds to further develop our research and development programs. As of December 31, 2012, we had an accumulated deficit of approximately $23.9 million.

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

As of December 31, 2012, we had approximately $18.4 million of cash, cash equivalents and short term investments.

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 presentation of the information shown. Operating results for any quarter are not necessarily indicative of results for a full fiscal year.

Three Months Ended

	March 31	June 30	Sept. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31
	2010				2011				2012			
	(U.S. dollars in thousands - Unaudited)											
Statements of operations												
Revenues	-	-	-	-	6	3	11	3	4	5	3	4
Research and development expenses	39	86	202	409	843	1,176	1,540	1,855	2,330	1,498	1,379	1,248
General and administrative expenses	37	106	173	202	509	679	687	607	607	573	550	871
Other expenses (income)	-	58	60	361	-	-	-	-	-	-	-	-
Operating loss	76	250	435	972	1,346	1,852	2,216	2,459	2,933	2,066	1,926	2,115
Financial income	1	1	16	404	765	381	20	5	258	40	57	(158)
Financial expenses	4	7	1,222	-	8,045	57	533	166	59	247	98	1.079
Net loss	79	256	1,641	569	8,626	1,528	2,729	2,620	2,734	2,273	1,967	2,352

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

Comparison of the Year Ended December 31, 2012 to the Year Ended December 31, 2011

Research and Development Expenses

Research and development expenses for the year ended December 31, 2012 were $6.5 million, an increase of $1.1 million, or 20%, compared to $5.4 million for the year ended December 31, 2011. The increase resulted primarily from approximately $1.2 million in manufacturing and clinical trial costs related to the development of RHB-102, RHB-103, RHB-104 and RHB-105 and clinical trials costs related to RHB-102 and RHB-103.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2012 were $2.6 million, an increase of $0.1 million, or 0.4%, compared to $2.5 million for the year ended December 31, 2011. The increase resulted primarily from major increase in professional services mainly due to the NASDAQ listing that was mostly offset by a decrease in share-based payments expenses.

Operating Loss

During the year ended December 31, 2012 and 2011, our operating loss was approximately $9.0 million and $7.9 million, respectively. This increase in operating loss was mainly due to an increase in our research and development activities mentioned above.

Financing Income and Expenses

We recognized net financial expenses of $1.3 for the year ended December 31, 2012, compared to net financial expenses of $7.6 million for the year ended December 31, 2011. The expenses for the year of 2012 represented primarily a non-cash financing expense of $1.5 million due to the accretion and settlement of royalty obligations to investors. The expenses for the year of 2011 represented primarily one-time non-cash financing expense of $7.9 million related to the revaluation of our mandatory convertible loans at fair value at the time of their conversion into shares prior to our initial public offering.

Comparison of the Year Ended December 31, 2011 to the Year Ended December 31, 2010

Revenues

During the year ended December 31, 2011, we recorded revenues for the first time in the amount of $23,000, in connection with royalty payments received from a third party licensee of limited rights to a patent that we acquired from Giaconda Limited. In the year ended December 31, 2010, we had no such revenue.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2011 were $5.4 million, compared to $0.7 million for the year ended December 31, 2010. This increase resulted primarily from an increase of $2.3 million in manufacturing and supply costs related to the clinical trials of RHB-102, RHB-103, RHB-104, RHB-105 and RHB-106, fees paid to third parties engaged to conduct our clinical trials for RHB-104 and a $2.1 million increase in salaries and consulting fees (including an increase from share-based payments made to several employees and consultants in the amount of $1.4 million) mainly due to an increase of the number of employees and consultants and option grants in connection with and following our initial public offering.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2011 were $2.5 million, compared to $0.5 million for the year ended December 31, 2010. This increase resulted mainly from an increase of $1.6 million in our payroll and consultant expenses, mainly due to higher share-based payments of $1.4 million in connection with and following our initial public offering, and the transfer of our operations to offices in Tel Aviv in April 2011.

Other Income and Expenses

In 2011, we had no other expenses, compared to $0.5 million for the year ended December 31, 2010 that was related to financing agent fees paid in connection with our mandatory convertible loans.

Operating Loss

In 2011, our operating loss amounted to approximately $7.9 million, compared to $1.7 million in 2010. The increase was due to growth in our activities, which was reflected mainly in an increase in research and development expenses and general and administrative expenses described above, including an increase of share-based payments of $2.8 million in connection with and following our initial public offering.

Financing Income and Expenses

We recognized net financial expenses of $7.6 million in the year ended December 31, 2011, compared to net financial expense of $0.8 million for the year ended December 31, 2010. This increase resulted primarily from a one-time non-cash financing expense of $7.49 million in the year ended December 31, 2011 related to the revaluation of our mandatory convertible loans at fair value at the time of their conversion into shares prior to our initial public offering. In addition, the increase in financial expenses was offset by an increase of $0.5 million in financial income resulting primarily from changes in foreign exchange rates on our cash balances, which had a positive effect on our net assets during the year ended December 31, 2011.

B. Liquidity and Capital Resources

Liquidity and Capital Resources

Our therapeutic candidates are in the research and development stage and therefore do not generate significant revenues. To date, our activities have been financed by raising capital. Since inception, we have raised an aggregate of approximately $12.6 million from private investors pursuant to investment and/or loan agreements prior to the initial public offering on the Tel Aviv Stock Exchange, gross proceeds of approximately $14 million from our initial public offering on the Tel Aviv Stock Exchange, gross proceeds of approximately $700,000 from the exercise of options and warrants following the listing, and gross process of approximately $6.5 million in a private financing shortly prior to the listing on NASDAQ. As December 31, 2012, we had approximately $18.4 million of cash, cash equivalents and short term investments.

Below is a summary of our material financing transactions since our inception:

From September to November 2009, we entered into investment agreements pursuant to which we raised an aggregate of $975,000 from the issuance of 649,673 preferred shares and 129,935 warrants exercisable into preferred shares at an exercise price of $0.45 per preferred share.

From June 2010 to August 2010, we entered into loan agreements with a number of investors, pursuant to which we received gross proceeds of approximately $3.5 million. The loans issued under these loan agreements accrued interest at an annual rate of 8% and were payable upon conversion of the loans. Under the terms of the loan agreements, we agreed to pay the investors certain royalty payments with regard to possible future sales of two of our therapeutic candidates. The loan agreements were subsequently replaced in their entirety by a mandatory convertible loan agreement, other than the obligation to pay royalties to the investors which remain in effect. On December 26, 2012, we acquired these royalty rights from all of the investors and then terminated them in consideration for the issuance of 2,317,186 ordinary shares. The mandatory convertible loan agreement subsequently was converted into shares and warrants immediately prior to the completion of our initial public offering on the Tel Aviv Stock Exchange. See "Item 10. – C. Material Contracts – Loan Agreements – August 2010 Mandatory Convertible Loan Agreements."

On November 7, 2010, we entered into additional mandatory convertible loan agreements with a number of investors pursuant to which we received proceeds of approximately $7.6 million. The loans accrued interest at an annual rate of 8%. Such loans were subsequently converted into shares and warrants immediately prior to the completion of our initial public offering on the Tel Aviv Stock Exchange. See "Item 10. – C. Material Contracts – Loan Agreements – November 2010 Mandatory Convertible Loan Agreement."

In January 2011, we received gross proceeds of an aggregate of $584,000 in connection with the exercise of all warrants issued under our 2009 investment agreements for 1,299,347 preferred shares.

In February 3, 2011, we raised gross proceeds of approximately $14 million in connection with our initial public offering on the Tel Aviv Stock Exchange of 14,302,300 ordinary shares and 7,151,150 tradable Series 1 Warrants. Each tradable Series 1 Warrant is exercisable through February 2, 2014 into one ordinary share (i) at a dollar-linked exercise price of NIS 3.8 (approximately $1.03 based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) through February 2, 2012 and (ii) at a dollar-linked exercise price of NIS 4.6 (approximately $1.25, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) from February 3, 2012 to February 2, 2014. The tradable Series 1 Warrants expire on February 2, 2014.

Since our initial public offering, investors in our mandatory convertible loans have exercised warrants for an aggregate gross amount of approximately $600,000

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 $1.08 based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) and non-tradable warrants to purchase up to 3,240,640 ordinary shares at exercise prices ranging from $1.18 to $1.54, depending on the date of exercise. In connection with this private placement we received an aggregate investment amount of approximately $6.56 million. Investors included existing shareholders, including two of our directors, Dr. Cabilly and Mr. Suesskind.

The warrants will be exercisable for a period of two (2) years until January 10, 2015. The exercise price for each warrant share (the "Warrant Price") will be calculated as follows: (i) in the event the holder exercises the warrant by July 10, 2013 (the "Initial Exercise Period"), the Warrant exercise price will be $1.18 ; (ii) in the event the holder exercises the holder's warrant within six (6) months following the end of the Initial Exercise Period (the "Second Exercise Period"), the Warrant exercise price will be $1.34; and (iii) in the event the holder exercises the holder's warrant following the end of the Second Exercise Period and until January 10, 2015, the warrant exercise price will be $1.54.

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

- the regulatory path of each of our therapeutic candidates;
- our ability to successfully commercialize our therapeutic candidates, including securing commercialization agreements with third parties and favorable pricing and market share;
- the progress, success and cost of our clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing sales, marketing and distribution channels;
- our 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 the Company is unable to commercialize or out-license its therapeutic candidates or obtain future financing, the Company may be forced to delay, reduce the scope of, or eliminate one or more of its research and development programs related to the therapeutic candidates, which may have material adverse effect on the Company's business, financial condition and results of operations.

Cash Flow

Operating activities

For the year ended December 31, 2012, net cash flow used in operating activities was approximately $6.8 million compared to approximately $4.7 million for the year ended December 31, 2011 and $1.6 million for the year ended December 31, 2010. The increase in net cash flow used in operating activities was a direct result of the significant increase in our operations, reflected, by increased payments for research and development activities and increased payment of salaries, consultant fees, and payments to other service providers.

Investment activities

Net cash flow used in investing activities for the year ended December 31, 2012 totaled approximately $3 million compared to approximately $4.7 million for the year ended December 31, 2011 and $1million for the year ended December 31, 2010. For the year ended December 31, 2012, we invested a total of $1 million in the purchasing of marketable securities and we received proceeds of $1.6 million from sale of marketable securities and $2.5 million from withdrawal from bank deposits to cash and cash equivalents For the year ended December 31, 2011, we invested a total of $4.5 million in bank deposits and in purchasing of marketable securities. For the year ended December 31, 2010, we invested $1.1 million to acquire rights to pharmaceutical products.

Financing activities

Net cash flow resulting from financing activities for the year ended December 31, 2012 amounted to approximately $6.6 million, compared with approximately $13.8 million for the year ended December 31, 2011 and $11.1 million for the year ended December 31, 2010. In 2012, most of the cash flows from financing activities resulted from investment agreements for the issuance ordinary shares and warrants in consideration of an aggregate investment amount of approximately $6.2 million, while in 2011; most of the cash flows from financing activities were derived from cash raised in our initial public offering. In 2010, our cash flows from financing activities were derived from our mandatory convertible loans.

C. Research and Development, Patents and Licenses

Our research and development expenses consist primarily of costs of clinical trials, salaries and consulting fees (including share-based payments), and fees paid to external service providers. We primarily use external service providers to manufacture our therapeutic candidates and to perform clinical trials with our therapeutic candidates. 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.

Clinical trial expenses

Set forth below is a summary of the gross external clinical trial costs allocated to our therapeutic candidates on an individual basis for the years ended December 31, 2010, 2011 and 2012.

	Year Ended December 31,			
	2010	2011	2012	Total Costs Since Project Inception
	U.S. dollars in millions			
RHB-101	-	0.2	-	0.2
RHB-102	0.1	0.3	1.0	1.4
RHB-103	-	0.2	0.6	0.8
RHB-104	-	1.4	1.6	3.0
RHB-105	-	0.2	0.3	0.5
RHB-106	-	0.2	0.1	0.3
Total gross direct project costs	0.1	2.5	3.6	6.2

Research and development expenses

From our inception through December 31, 2012, we have incurred research and development expenses of approximately $12.7 million. Set below is a summary of our research and development expenses based on the type of expenditure.

	Amount invested in R&D (U.S. dollars in millions)		From incorporation date until December 31, 2012
	2011	2012	
Payroll and related expenses	0.4	0.5	1.0
Professional services	0.7	0.9	2.0
Share-based payments	1.4	0.9	2.3
Clinical trials	2.5	3.6	6.2
Patents expenses	0.2	0.3	0.6
Other	0.2	0.3	0.6
Total	5.4	6.5	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, as well as available resources and the ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future commercialization arrangements, when such commercialization arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See "Item 3. Key Information – D. Risk Factors – If we and/or our commercialization partners are unable to obtain U.S. Food and Drug Administration and/or other foreign regulatory authority approval for our therapeutic candidates, we and/or our commercialization partners will be unable to commercialize our therapeutic candidates."

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

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

D. **Trend Information**

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

E. **Off-Balance Sheet Arrangements**

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

F. **Tabular Disclosure of Contractual Obligations**

The following table summarizes our significant contractual obligations on December 31, 2012:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
			(U.S. dollars in thousands) (Unaudited)		
Office lease obligations	455	117	312	26	-
Accounts payable and accrued expenses	1,078	1,078			
Total	1,533	1,195	312	26	-

The foregoing table does not include our in-license agreements with Egalet a/s, SCLOR Pharma, Inc. and IntelGenx Corp., our agreement with the University of Central Florida Research Foundation, Inc., and our asset sale agreement with Giaconda Limited, pursuant to which we are obligated to make various payments upon the achievement of agreed upon milestones and/or make certain royalty payments since we are unable to currently estimate the actual amount or timing of these payments. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay, in addition to royalties on our net income, an aggregate amount of approximately $1.9 million. All of our in-licensing agreements are terminable at-will by us upon prior written notice of 30 days. See "Item 4. Information on the Company — Business Overview — Acquisition and License Agreements."

The foregoing table also does not include payments payable under our manufacturing agreements or payments under our clinical services agreements, all of which are contingent upon the completion of milestones. See "Item 4. Information on the Company - Business Overview - Manufacturing Agreements" and "Item 4. Information on the Company – Business Overview – Clinical Services Agreement Related to RHB-104."

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	47	Chief Executive Officer and Chairman of the board of directors
Ori Shilo	46	Deputy Chief Executive Officer Finance and Operations, and Director
Reza Fathi, Ph.D.	58	Senior Vice President Research and Development
Gilead Raday	38	Senior Vice President Corporate and Product Development
Adi Frish	43	Senior Vice President Business Development and Licensing
Guy Goldberg	37	Chief Business Officer
Ira N. Kalfus, M.D.	51	Chief Medical Officer
Uri Hananel Aharon	32	Chief Accounting Officer
Directors		
Dr. Shmuel Cabilly (2)	63	Director
Eric Swenden	69	Director
Dr. Kenneth Reed	59	Director
Dan Suesskind (1)	69	Director
Ofer Tsimchi (1), (2)	53	External Director
Aliza Rotbard (1), (2)	67	External Director

Member of our audit committee that also serves as our financial statements committee.

Member of our compensation committee.

Executive officers

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

Ori Shilo has served as our Deputy Chief Executive Officer Finance and Operations since November 1, 2010 and as a director since August 3, 2009. From 2009 to 2010, Mr. Shilo served as our Vice President Finance and Operations. From 2000 to 2010, Mr. Shilo served as Chief Executive Officer of P.C.M.I. Ltd. Mr. Shilo is currently a director at P.C.M.I. Ltd. and G. Shilo Holdings Ltd. Mr. Shilo holds a B.A in Business Administration from the Academic College for Management in Rishon Lezion, Israel and an MBA in Business Administration from the Ben Gurion University in Beer Sheva, Israel. The board of directors has determined that Mr. Shilo is a financial and accounting expert under Israeli law.

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

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

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

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

Ira N. Kalfus, M.D. has served as our Chief Medical Officer since August 15, 2010. Dr. Kalfus has over 22 years' experience in the healthcare industry, and has been a biotech and drug development consultant since 2006. From 2006-2008, Dr. Kalfus was a consultant and then Vice President, Medical Affairs at Lev Pharmaceuticals Inc., a development stage biopharmaceutical company. Dr. Kalfus led the clinical development of CINRYZE, the first approved C1 inhibitor therapy for Hereditary Angioedema. Lev Pharmaceuticals was acquired by ViroPharma Incorporated in 2008 for $530 million. Dr. Kalfus has been a medical director and clinical peer reviewer for US Healthcare, Aetna, and Group Health Insurance. From 1990-2004, Dr. Kalfus practiced internal medicine in New York. He also served as President of the Staff Society at the LIJ Division of the North Shore LIJ Health System. Dr. Kalfus received his B.A. in Biology from Columbia University and his M.D. from the Albert Einstein College of Medicine.

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

Directors

Dr. Shmuel Cabilly has served as a member of our board of directors since August 26, 2010, and has served on our compensation committee since May 5, 2011. Dr. Cabilly currently serves on the board of directors of BioKine Therapeutics Ltd., Irody Inc., Biologic Design Ltd., Silenseed Ltd., Mobydom Ltd., Neuroderm Ltd., Dentack Implants Ltd., Ofakim Hi-Tech Ventures Ltd., Meytag Hi-Tech Ventures Ltd., Dia Cardio Ltd., Pixcell Medical Technologies Ltd., Medasense Biometrics Ltd., L.R.S. Ltd., Algomia Ltd. Velocee Inc., A.G.M. Biological Products Development Ltd. Ornim Inc. N.E.D. Next Dimension Ltd., OPLON B.V., ONECALL CONTACT CENTERS LTD., Coeruleus Ltd., Efranat Ltd. BioCep Ltd., Health Watch Technologies Ltd., and VIDAC Pharma Ltd. Dr. Cabilly holds a BSC Biology from the Ben Gurion University of Beer Sheva, Israel, an MSC in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel and a PhD in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel.

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

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

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

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

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

B. Compensation

The aggregate compensation paid, and benefits in-kind granted to or accrued on behalf of all of our directors and senior management for their services, in all capacities, to us during the year ended December 31, 2012 was approximately $1.5 million. This amount included approximately $44,000 for long-term benefits paid to retirement plans on behalf of our senior management during the year ended December 31, 2012. No additional amounts have been set aside or accrued by us to provide pension, retirement or similar benefits.

Employment Agreements

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

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

Director Compensation

Under the Israeli Companies Law, 5754-1999, and related regulations, external directors are entitled to a fixed annual compensation and an additional payment for each meeting attended. We currently pay our external directors, Mr. Ofer Tsimchi and Ms. Aliza Rotbard, an annual fee of NIS 42,200 (approximately $11,500, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) and a fee of NIS 2,820 (approximately $770, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) per meeting (or a smaller amount in case they do not physically attend the meeting). In addition, each of Mr. Tsimchi and Ms. Rotbard received options to purchase 150,000 ordinary shares at an exercise price of $1.05 per share, which expire in 2018.

In 2010, each of Mr. Swenden and Dr. Reed received options to purchase 90,000 ordinary shares at an exercise of $0.165 per share, which expire in 2017, and Dr. Cabilly received an option to purchase 90,000 ordinary shares at an exercise of $0.50 per share, which expire in 2017 (the numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange). These options vest over a period of 3 years, a third of which vested at the first anniversary, and the remaining of which vest in 8 subsequent equal quarterly installments.

In 2011, the following options were granted upon completion of our initial public offering:

- Mr. Sweden: options to purchase 150,000 ordinary shares at an exercise price of $0.50 per share, which expire in 2018;
- Mr. Suesskind: options to purchase 860,000 ordinary shares at an exercise price of $0.50 per share, which expire in 2018;
- Dr. Reed: options to purchase 150,000 ordinary shares at an exercise price of $0.50 per share, which expire in 2018; and
- Dr. Cabilly: options to purchase 150,000 ordinary shares at an exercise price of $0.50 per share, which expire in 2018.

A third of these options vested on February 3, 2012, and the remaining options vest in 8 subsequent equal quarterly installments (subject to rounding) commencing March 31, 2012.

On January 19, 2011, our shareholders approved a recommendation from the board of directors to cause all options granted to our directors, prior to our initial public offering and at the time of our initial public offering, to immediately vest in the event of a "takeover" as defined in our 2010 Stock Option Plan. See "– F. Share Ownership – Stock Option Plans." In addition, on September 24, 2012 our board of directors approved the amendment of all options granted to our directors after completion of our IPO to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all such options will immediately vest in full. The amendment was approved by our shareholders on November 6, 2012. See " – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law – 1968.

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

Executives and Directors Compensation

Employment Agreement with Mr. Dror Ben-Asher

On November 1, 2010 we entered into an employment agreement with Mr. Dror Ben-Asher, pursuant to which he serves as our Chief Executive Officer. Mr. Ben-Asher also currently serves as Chairman of our board of directors.

Pursuant to the terms of the agreement, Mr. Ben-Asher is entitled to a monthly salary of NIS 55,000 (approximately $14,920, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), a car allowance of NIS 5,000 (approximately $1,360, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), reimbursement for all mobile phone expenses, contributions to a pension fund/directors' insurance fund, advanced study fund, disability insurance and leave days, all as provided for in his employment agreement.

The agreement further provides that if the agreement is terminated in connection with a "hostile takeover," Mr. Ben-Asher shall 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 in the employment agreement as an occurrence where a person, entity or group that was not an interested party under the Israeli Securities on the date of the initial public offering of our ordinary shares, becomes a "controlling shareholder," within the meaning of such term 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. See " – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law. In addition, on January 19, 2011, we amended the terms of Mr. Ben-Asher's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Mr. Ben-Asher prior to the IPO, including the options granted subject to completion of our IPO shall immediately vest in full. In addition, on September 24, 2012, our board of directors approved the amendment of the terms of Mr. Ben-Asher's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Mr. Ben-Asher after completion of our IPO shall immediately vest in full. The September 24, 2012 amendment was approved by our shareholders on November 6, 2012. See " – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law – 1968.

We may terminate the employment agreement with Mr. Ben-Asher upon 180-days prior notice, while Mr. Ben-Asher may terminate the agreement upon 90-days prior notice.

On May 30, 2010 Mr. Ben-Asher was granted 7 year options to purchase 750,000 ordinary shares at an exercise price of $0.165 per share. 250,000 of these options vested on February 2, 2011, and the remaining 500,000 options vest in 8 subsequent quarterly installments of 62,500 options commencing March 31, 2011 (which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange).

Upon completion of the initial public offering, Mr. Ben-Asher was granted 7 year options to purchase 1,540,000 ordinary shares at an exercise price of $0.50 per share. 513,333 of these options vested on February 3, 2012, and the remaining 1,026,667 options vest in 8 subsequent equal quarterly installments of 128,333 options (except for one installment of 128,337) commencing March 31, 2012.

On February 15, 2012 we amended Mr. Ben-Asher's employment agreement in order to increase his car allowance, as of January 1, 2011, from NIS 5,000 (approximately $1,360, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) to NIS 6,000 (approximately $1,630, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013).

On February 15, 2012 we granted Mr. Ben-Asher 7 year options to purchase 600,000 ordinary shares at an exercise price of $0.72. These options vest in 6 equal installments of 100,000 options every 6 months following January 1, 2012.

Employment Agreement with Mr. Ori Shilo

On November 1, 2010, we entered into an employment agreement with Mr. Ori Shilo, pursuant to which Mr. Shilo serves as our Deputy Chief Executive Officer Finance and Operations. Mr. Shilo also currently serves as one of our directors.

Pursuant to the terms of the agreement, Mr. Shilo is entitled to a monthly salary of NIS 45,000 (approximately $12,210, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), a car allowance of NIS 4,000 (approximately $1,090 , based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), reimbursement for all mobile phone expenses, contributions to a pension fund/directors' insurance fund, advanced study fund, disability insurance and leave days, all as provided for in his employment agreement.

The agreement further provides that if the agreement is terminated in connection with a "hostile takeover", Mr. Shilo will be entitled to a special one-time bonus equal to his then current monthly salary and retirement benefits, including payments to an advanced study fund and pension arrangement and car expense reimbursement, multiplied by 12. In addition, on January 19, 2011, we amended the terms of Mr. Shilo's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Mr. Shilo prior to the IPO, including the options granted subject to completion of our IPO shall immediately vest in full. In addition, on September 24, 2012, our board of directors approved the amendment of the terms of Mr. Shilo's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Mr. Shilo after completion of our IPO shall immediately vest in full. The September 24, 2012 amendment was approved by our shareholders on November 6, 2012. See " – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law – 1968.

We may terminate the employment agreement with Mr. Shilo upon 180-days prior notice, while Mr. Shilo may terminate the agreement upon 90-days prior notice.

On May 30, 2010 Mr. Shilo was granted 7 year options to purchase 750,000 ordinary shares at an exercise price of $0.165 per share. 250,000 of these options vested on February 2, 2011, and the remaining 500,000 options vest in 8 subsequent quarterly installments of 62,500 options commencing March 31, 2011 (which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange).

Upon completion of the initial public offering, Mr. Shilo was granted 7 year options to purchase 1,220,000 ordinary shares at an exercise price of $0.50 per share. 406,667 of these options vested on February 3, 2012, and the remaining 813,333 options vesting in 8 subsequent equal quarterly installments of 101,666 options (except for one installment of 101,671) commencing March 31, 2012.

On February 15, 2012 we amended Mr. Shilo's employment agreement in order to increase his car allowance, as of January 1, 2011, from NIS 4,000 (approximately $1,090, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) to NIS 5,000 (approximately $1,360, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013).

On February 15, 2012, we granted Mr. Shilo 7 year options to purchase 400,000 ordinary shares at an exercise price of $0.72. These options vest in 6 equal installments of 66,667 options (except for one installment of 66,665) every 6 months following January 1, 2012.

Employment Agreement with Mr. Gilead Raday

On November 1, 2010, we entered into an employment agreement with Mr. Gilead Raday, pursuant to which Mr. Raday serves as our Senior Vice President Corporate and Product Development.

Pursuant to the terms of the agreement, Mr. Raday is entitled to a monthly salary of NIS 30,000 (approximately $8,140, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), a car allowance of NIS 3,000 (approximately $810, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), reimbursement for all mobile phone expenses up to NIS 400 a month (approximately $110, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), contributions to a pension fund/directors' insurance fund, advanced study fund, disability insurance and leave days, all as provided for in his employment agreement.

The agreement further provides that if the agreement is terminated in connection with a "hostile takeover", Mr. Raday 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 6. In addition, on January 19, 2011, we amended the terms of Mr. Raday's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Mr. Raday prior to the IPO, including the options granted subject to completion of our IPO shall immediately vest in full. In addition, on September 24, 2012, our board of directors approved the amendment of the terms of Mr. Raday's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Mr. Raday after completion of our IPO shall immediately vest in full. The September 24, 2012 amendment was approved by our shareholders on November 6, 2012. See " – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law – 1968. Mr. Raday's employment agreement may be terminated by either us or Mr. Raday upon 60-day prior notice.

On August 24, 2010, Mr. Raday was granted 7 year options to purchase 310,000 ordinary shares at an exercise price of $0.165 per share. 103,333 of these options vested on February 2, 2011, and the remaining 206,667 options vest in 8 subsequent quarterly installments of 25,833 options (except for one installment of 25,836) commencing March 31, 2011 (which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange).

Upon completion of the initial public offering, Mr. Raday was granted 7 year options to purchase 500,000 ordinary shares at an exercise price of $0.50 per share. 166,667 of these options vested on February 3, 2012, and the remaining 333,333 options vesting in 8 subsequent equal quarterly installments of 41,667 options (except for one installment of 41,664) commencing March 31, 2012.

On January 5, 2012, we amended Mr. Raday's employment agreement in order to increase his car allowance from NIS 3,000 (approximately $810, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) to NIS 4,000 (approximately $1,090, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) and his monthly salary from NIS 30,000 (approximately $8,140, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) to NIS 36,000 (approximately $9,770, based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013), each as of January 1, 2012.

On January 5, 2012, we granted Mr. Raday 7 year options to purchase 75,000 ordinary shares at an exercise price of $0.72. These options vest in 6 equal installments of 12,500 options every 6 months following January 1, 2012.

Consultancy Services Agreement with Reza Fathi, PhD

On May 11, 2010 we entered into a consulting agreement with Reza Fathi, PhD, to serve as our director of research operations

Pursuant to the terms of the agreement, Dr. Fathi is entitled to a monthly payment of $4,000 and reimbursement of expenses in the fixed amount of $100. On August 25, 2010, we amended this agreement and Dr. Fathi was appointed as our Senior Vice President R&D as of August 1, 2010, and his monthly payment was increased to $10,000. On January 1, 2011, we amended the agreement in order to increase Dr. Fathi's, monthly payment to $13,000 and expense reimbursement amount of $300. On October 1, 2011, we amended the agreement again in order to increase Dr. Fathi's monthly payment to $16,000.

The agreement further provides that if the agreement is terminated in connection with a "hostile takeover", Dr. Fathi will be entitled to a special one-time bonus in the amount of his then current monthly consultancy payment, multiplied by 6. In addition, on January 19, 2011, we amended the terms of Dr. Fathi's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Dr. Fathi prior to the IPO, including the options granted subject to completion of our IPO shall immediately vest in full. In addition, on September 24, 2012, our board of directors approved the amendment of the terms of Dr. Fathi's options to provide that in the event any person, entity or group that was not an interested party at the time of our IPO becomes a "controlling shareholder", as defined in our 2010 Option Plan, all options granted to Dr. Fathi after completion of our IPO shall immediately vest in full. The September 24, 2012 amendment was approved by our shareholders on November 6, 2012. See " – E. Share Ownership – Stock Option Plan" for a description of interested parties under the Israeli Securities Law – 1968. Dr. Fathi's employment agreement may be terminated by either us or Dr. Fathi upon 60-days prior notice.

On May 30, 2010, Dr. Fathi was granted 7 year options to purchase 90,000 ordinary shares at an exercise price of $0.165 per share. 30,000 of these options vested on February 2, 2011, and the remaining 60,000 options vest in 8 quarterly subsequent installments of 7,500 options commencing March 31, 2011 (which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange).

On August 6, 2010, Dr. Fathi was granted 7 year options to purchase 180,000 ordinary shares respectively at an exercise price of $0.165 per share. 60,000 of these options vested on May 30, 2011, and the remaining 120,000 options vest in 8 subsequent equal quarterly installments of 15,000 options commencing June 30, 2011 (which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange).

Upon completion of our initial public offering, Dr. Fathi was granted 7 year options to purchase 500,000 ordinary shares at an exercise price of $0.50 per share. 166,667 of these options vested on February 3, 2012, and the remaining 333,333 options vest in 8 subsequent equal quarterly installments of 41,667 options (except for one installment of 41,664) commencing March 31, 2012.

On January 5, 2012, we granted Dr. Fathi 7 year options to purchase 200,000 ordinary shares at an exercise price of $0.72. These options vest in 6 equal installments of 33,333 options (except for one installment of 33,335) every 6 months following January 1, 2012.

C. Board Practices

Appointment of Directors and Terms of Officers

Pursuant to our articles of association, the size of our board of directors shall be no less than 5 persons but no more than 7, excluding at least two external directors. The directors, except for our external directors, are divided into three classes, as nearly equal in number as possible. At each annual general meeting, which is required to be held annually, but not more than fifteen months after the prior annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three year term that expires at the annual general meeting held in the third year following such election. This process continues indefinitely. The directors of the first class, currently consisting of Dror Ben-Asher and Ori Shilo, will hold office until our annual general meeting to be held in the year 2014. The directors of the second class, currently consisting of Dr. Kenneth Reed, and Eric Swenden, will hold office until our annual general meeting to be held in the year 2015, and the directors of the third class, currently consisting of Dr. Shmuel Cabili and Dan Suesskind, will hold office until our annual general meeting to be held in the year 2013. Until the next annual general meeting, the board of directors may elect new directors to fill vacancies, or increase the number of members of the board of directors up to the maximum number provided in our articles of association. Any director so appointed may hold office until the first general shareholders' meeting convened after the appointment.

Pursuant to the Israeli Companies Law, 1999, one may not be elected and may not serve as a director in a public company if he or she does not have the required qualifications and the ability to dedicate an appropriate amount of time for the performance of his duties as a director in the company, taking into consideration, among other things, the special needs and size of the company. In addition, a public company may convene an annual general meeting of shareholders to elect a director, and may elect such director, only if prior to such shareholders meeting, the nominee declares, among other things, that he or she possesses all of the required qualifications to serve as a director (and lists such qualifications in such declaration) and has the ability to dedicate an appropriate amount of time for the performance of his duties as a director of the company.

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

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

We have service contracts with two of our directors, Dror Ben-Asher and Ori Shilo that provide for benefits upon termination of their employment as directors. For more information, see " – B. Compensation – Executives and Director Compensation."

Independent and External Directors - Israeli Companies Law Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

Ms. Aliza Rotbard and Mr. Ofer Tsimchi currently serve as our external directors.

Committees

Israeli Companies Law Requirements

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

Audit Committee

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

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

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

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

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

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

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

Compensation Committee

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

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

Investment Committee

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

Nasdaq Stock Market Requirements

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

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

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

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

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

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

Corporate Governance Practices

Internal Auditor

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

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

Fiduciary Duties of Office Holders

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

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

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

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

- refrain from any action involving a conflict of interest between the performance of the office holder's duties in the company and his personal affairs;
- refrain from any activity that is competitive with the company's business;

- refrain from usurping any business opportunity of the company to receive a personal gain for the office holder or others; and
- disclose to the company any information or documents relating to a company's affairs which the office holder has received due to his position as an office holder.

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

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

Under Israeli law, an extraordinary transaction is a transaction:

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

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

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

Controlling Shareholder Transactions and Actions

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

- a majority of the shareholders who have no personal interest in the transaction and who are participating in the voting, in person, by proxy or by written ballot, at the meeting (votes abstaining shall not be taken into account); or

- the total number of shares voted against the proposal by shareholders without a personal interest does not exceed 2% of the aggregate voting rights in the Company.

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

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

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

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

The Israeli Companies Law further provides that an acquisition of shares 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.

Regulations under the Israeli Companies Law provide that the Israeli Companies Law's tender offer rules do not apply to a company whose shares are publicly traded outside of Israel, if, pursuant to the applicable foreign laws or stock exchange rules, there is a restriction on the acquisition of any level of control of the company, or if the acquisition of any level of control of the company requires the purchaser to make a tender offer to the public shareholders. It is the view of the Israeli Securities Authority that U.S. securities laws and stock exchange rules do not impose the required restriction on the acquisition of any level of control of a company, and therefore the Israeli Companies Law's special tender offer rules would apply to a company whose shares are publicly traded in the U.S.

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

- any amendment to the articles of association;

- an increase in the company's authorized share capital;

- a merger; or

- approval of certain transactions with control persons and other related parties, which require shareholder approval.

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

Exemption, Insurance and Indemnification of Directors and Officers

Office Holder Exemption

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

Office Holder Insurance

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

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

On February 15, 2012, at our general meeting of shareholders, our shareholders authorized us to purchase, from time to time, liability insurance to cover officers and directors, except for officers and directors who are controlling shareholders, together with their relatives, and interested controlling shareholders. Pursuant to this authorization, we may purchase this insurance commencing on the date of the approval of the general shareholders' meeting and ending on the 2015 annual general shareholders' meeting, to be convened in 2016, provided that:

- the policy provides up to $13,000,000 of liability coverage per period and per event; and
- that the annual insurance premium is not more than $15,000 (the "Framework Resolution").

On September 24, 2012, our Board of Directors approved an amendment of the Framework Resolution for our directors and officers liability insurance policy, pursuant to which we may purchase, from time to time, liability coverage of up to $30 million with a total annual insurance premium of up to $130,000. The liability insurance policy will also cover directors and/or officers who are considered controlling shareholders. The Board of Directors resolved that the amended insurance framework would be effective from the date the amended framework is approved by our general meeting of shareholders and ending at our annual general meeting for the year 2016 to be convened in 2017.

On November 6, 2012, at our general meeting of shareholders, our shareholders approved the proposed amendment to the Framework Resolution, pursuant to which we may acquire a new insurance policy shortly prior to the time of the listing of our shares on Nasdaq and thereafter. Further to such approval, our audit committee and board of directors will approve, on a yearly basis, that the new insurance policy complies with the terms of the amended Framework Resolution and that they are fair and reasonable under the circumstances, taking into account our exposure and the market conditions.

Subsequent to the amendment to the Framework Resolution, our audit committee and board of directors resolved in November 2012 to purchase directors and officers liability insurance policy, pursuant to which the amount of insurance covered under the policy would be $20 million and the total annual policy premium would be $69,000.

Pursuant to the foregoing approvals, we carry directors and officers liability insurance.

Indemnification of Office Holders

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

- a provision authorizing the company to indemnify an officer or director for future events with respect to a monetary liability imposed on him in favor of another person pursuant to a judgment (including a judgment given in a settlement or an arbitrator's award approved by the court), so long as such indemnification is limited to types of events which, in the board of directors' opinion, are foreseeable at the time of granting the indemnity undertaking given the company's actual business, and in such amount or standard as the board of directors deems reasonable under the circumstances. Such undertaking must specify the events that, in the board of directors' opinion, are foreseeable in view of the company's actual business at the time of the undertaking and the amount or the standards that the board of directors deemed reasonable at the time;

- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation expenses, including counsel fees, incurred by an officer or director in which he is ordered to pay by a court, in proceedings that the company institutes against him or instituted on behalf of the company or by another person, or in a criminal charge from which he was acquitted, or a criminal charge in which he was convicted for a criminal offense that does not require proof of criminal intent;

- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation fees, including attorney's fees, incurred by an officer or director due to an investigation or proceeding filed against him by an authority that is authorized to conduct such investigation or proceeding, and that resulted without filing an indictment against him and without imposing on him financial obligation in lieu of a criminal proceeding, or that resulted without filing an indictment against him but with imposing on him a financial obligation as an alternative to a criminal proceeding in respect of an offense that does not require the proof of criminal intent or in connection with a monetary sanction;

- a provision authorizing the company to indemnify an officer or director for future events with respect to a Party Harmed by the Breach;

- a provision authorizing the company to indemnify an officer or director for future events with respect to expenses incurred by such officer or director in connection with an administrative proceeding, including reasonable litigation expenses, including legal fees; and

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

Limitations on Insurance, Exemption and Indemnification

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

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

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

Letters of Indemnification

We have issued our officers and directors letters of indemnification, pursuant to which we have agreed to indemnify each officer and director in advance for any liability or expense imposed on or incurred by him in connection with acts performed by him in the capacity of an officer or director, subject to the provisions of the letters of indemnification agreement. The amount of the advance indemnity is limited to the higher of 25% of our then consolidated shareholders' equity per our most recent consolidated annual financial statements or $3 million.

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

D. Employees

As of February 19, 2013, we had 7 employees and we also received services from 9 consultants who provide services to us in the U.S., Canada and Belgium.

	As of December 31,					
	2010		2011		2012	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management and administration	3	1	5	1	6	2
Research and development	1	6	1	6	1	6

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 19, 2013 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 61,788,827 ordinary shares outstanding as of such date. The number of ordinary shares beneficially owned by a person includes ordinary shares subject to options or warrants held by that person that were currently exercisable at, or exercisable within 60 days of, February 19, 2013. The ordinary shares issuable under these options and warrants are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options and warrants but not the percentage ownership of any other person. None of the holders of the ordinary shares listed in this table have voting rights different from other holders of the ordinary shares.

	Number of Shares Beneficially Held	Percent of Class
Directors		
Eric Swenden (1)	5,104,246	7.68%
Dr. Kenneth Reed (2)	4,146,472	6.69%
Dr. Shmuel Cabilly (3)	4,575,678	7.25%
Dan Suesskind (4)	806,150	1.29%
Ofer Tsimchi (5)	100,000	*
Aliza Rotbard (6)	100,000	*
Executive officers		
Dror Ben-Asher (7)	4,870,001	7.62%
Ori Shilo (8)	4,422,715	6.94%
Gilead Raday (9)	711,250	1.14%
Reza Fathi, Ph.D. (10)	702,500	1.12%
Adi Frish (11)	375,000	*
Ira Kalfus (12)	365,535	*
Uri Hananel Aharon (13)	89,750	*
Guy Goldberg	-	-
All directors and executive officers as a group (14 persons)	26,369,297	41.87%

* Less than 1.0%

(1) Consists of (i) options to purchase 202,500 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) tradable series 1 warrants to purchase 273,000 ordinary shares and non-tradable warrants to purchase 297,161 ordinary shares. The exercise price of these options range between $0.165 and $0.5 per share, and the options expiry date range between 2017 and 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(2) Consists of (i) options to purchase 210,000 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) tradable series 1 warrants to purchase 12,000 ordinary shares. The exercise price of these options range between $0.165 and $0.5 per share, and the options expiry date range between 2017 and 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(3) Consists of (i) options to purchase 187,500 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) tradable series 1 warrants to purchase 497,500 ordinary shares and non-tradable warrants to purchase 668,801 ordinary shares. The exercise price of these options is $0.5 per share, and the options expiry date range between 2017 and 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(4) Consists of (i) options to purchase 645,000 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) non-tradable warrants to purchase 37,050 ordinary shares. The exercise price of these options is $0.5 per share, and the options expire in 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(5) Consists of options to purchase 100,000 ordinary shares exercisable within 60 days of February 19, 2013. The exercise price of these options is $1.05 per share, and the options expire in 2018.

(6) Consists of options to purchase 100,000 ordinary shares exercisable within 60 days of February 19, 2013. The exercise price of these options is $1.05 per share, and the options expire in 2018.

(7) Consists of (i) options to purchase 2,117,500 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) tradable series 1 warrants to purchase 22,671 ordinary shares. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(8) Consists of (i) options to purchase 1,827,500 Ordinary exercisable within 60 days of February 19, 2013 and (ii) tradable series 1 warrants to purchase 33,883 ordinary shares and non-tradable warrants to purchase 59,432 ordinary shares. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(9) Consists of options to purchase 711,250 ordinary shares exercisable within 60 days of February 19, 2013. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019.

(10) Consists of options to purchase 702,500 ordinary shares exercisable within 60 days of February 19, 2013. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019.

(11) Consists of options to purchase 375,000 ordinary shares exercisable within 60 days of February 19, 2013. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019.

(12) Consists of (i) options to purchase 224,167 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) non-tradable warrants to purchase 17,480 ordinary shares. The exercise price of these options range between $0.165 and $0.69 per share, and the options expiry date range between 2017 and 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants. Consists of options to purchase 75,000 ordinary shares exercisable within 60 days of February [ ], 2013. The exercise price of these options is $0.69 per share, and the options expire in 2018.

(13) Consists of options to purchase 87,500 ordinary shares exercisable within 60 days of February 19, 2012. The exercise price of these options is $0.69 per share, and the options expire in 2018.

Stock 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 19, 2013, there were 12,015,000 ordinary shares issuable upon the exercise of outstanding options under the 2010 Option Plan.

Administration of Our Option Plan

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

Options granted under our 2010 Option Plan generally vest over a period of 3 years and expire 7 years after the grant date. The 2010 Option Plan, however, permits options to have a term of up to 10 years. If we terminate a grantee for cause (as such term is defined in the 2010 Option Plan) the right to exercise all the options granted to the grantee, the grantee's vested and unvested options will expire immediately, on the earlier of:

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

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

Under our 2010 Option Plan, in the event any person, entity or group that was not an interested party at the time of our initial public offering becoming a controlling shareholder, options that granted by us to such grantee will be accelerated, so that the grantee will be entitled to exercise all of those options. 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.

A "controlling shareholder" in this paragraph is a controlling shareholder, as defined in the Israel Securities Law, 1968, or any person, entity or group becoming a holder, as defined in the Israel Securities Law, 1968, of 25% or more of the voting rights in us. This option acceleration clause, however, only applies with respect to the 3,080,000 options granted to our employees and consultants before our initial public offering in Israel and to the 6,210,000 options allocated upon completion of our initial public offering in Israel to our employees and consultants.

Under our 2010 Option Plan, options which we granted after September 24, 2012 will be accelerated, so that the grantee will be entitled to exercise all of such options, in the event any person, entity or group that was not an interested party at the time of our initial public offering becomes a controlling shareholder. A "controlling shareholder" in this paragraph is a controlling shareholder, as defined in the Israel Securities Law, 1968. The board of directors also approved that options granted to our directors under our 2010 Option Plan after completion of our initial public offering and prior to September 24, 2012 will also be accelerated under the same circumstances and it was approved by our shareholders on November 6, 2012 . See " – B. Compensation – Executives and Directors Compensation."

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

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

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of February 19, 2013, 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 provided to us by the shareholders.

The information in this table is based on 61,788,827 ordinary shares outstanding as of such date. The number of ordinary shares beneficially owned by a person includes ordinary shares subject to options held by that person that were currently exercisable at, or exercisable within 60 days of February 19, 2013. The ordinary shares issuable under these options are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options 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 Class
Mr. Dror Ben-Asher (1)	4,870,001	7.62%
Mr. Eric Swenden (2)	5,104,246	7.68%
Mr. Ori Shilo (3)	4,422,715	6.94%
Dr. Kenneth Reed (4)	4,146,472	6.69%
Dr. Shmuel Cabilly (5)	4,081,678	6.52%

(1) Consists of (i) options to purchase 2,117,500 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) Tradable Series 1 Warrants to purchase 22,671 ordinary shares. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(2) Consists of (i) options to purchase 202,500 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) Tradable Series 1 Warrants to purchase 273,000 ordinary shares and non-tradable warrants to purchase 297,161 ordinary shares. The exercise price of these options range between $0.165 and $0.5 per share, and the options expiry date range between 2017 and 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(3) Consists of (i) options to purchase 1,827,500 ordinary shares exercisable within 60 days of_ February 19, 2013 and (ii) Tradable Series 1 Warrants to purchase 33,883 ordinary shares and non-tradable warrants to purchase 59,432 ordinary shares. The exercise price of these options range between $0.165 and $0.72 per share, and the options expiry date range between 2017 and 2019. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(4) Consists of (i) options to purchase 210,000 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) Tradable Series 1 Warrants to purchase 12,000 ordinary shares. The exercise price of these options range between $0.165 and $0.5 per share, and the options expiry date range between 2017 and 2018. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(5) Consists of (i) options to purchase 187,500 ordinary shares exercisable within 60 days of February 19, 2013 and (ii) tradable series 1 warrants to purchase 668,801 ordinary shares and non-tradable warrants to purchase 668,801 ordinary shares. The exercise price of these options is $0.5 per share, and the options expiry date range between 2017 and 2018. See “Item 10. Additional Information – A. Share Capital” for more information regarding the warrants. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

As of February 13, 2013, there were approximately 20 shareholders of record with a United States address. As of February 13, 2013, these United States record holders held approximately 816,907 ordinary shares directly and an additional 3,509,290 ordinary shares in the form of ADSs, representing in the aggregate approximately 7.0% of our then outstanding share capital.

At the time of our incorporation in 2009, ProSeed Capital Holdings CVA held approximately 46% of our outstanding shares. Following the issuance by us of additional shares, including in connection with our initial public offering in Israel, and the distribution by ProSeed Capital Holdings CVA in November 2011 of substantially of all of its shares in us to its shareholders, it currently holds less than one percent of our shares.

At the time of our incorporation in 2009, Benjamin Van Oudenhove, the chief executive officer and chairman of ProSeed Capital Holdings CVA, held approximately 10.5% of our outstanding shares, in addition to his indirect holdings through ProSeed Capital Holdings CVA. Following the issuances of additional shares, including in connection with our initial public offering in Israel, he currently beneficially holds less than 5% of our shares.

B. Related Party Transactions

Consulting Agreement with ProSeed Capital Holdings CVA

On June 3, 2010, we entered into a consulting agreement with ProSeed Capital Holdings CVA, which at the time was one of our major shareholders and whose security holders included a number of our own shareholders, pursuant to which ProSeed Capital Holdings CVA agreed to promote our business with potential investors and partners. According to the agreement, ProSeed Capital Holdings CVA was entitled to success fees in the amount of 6%, plus value added tax, if necessary, of any investment where the investor was introduced to us by ProSeed Capital Holdings CVA. ProSeed Capital Holdings CVA was to be entitled to such commission for a period of 18 months from the date of termination of the agreement. In accordance with the terms of this agreement, we paid ProSeed Capital Holdings CVA $66,000 and $75,000 in 2011 and 2010, respectively. This agreement was terminated by the parties on September 5, 2010.

In December 2011, ProSeed Capital Holdings CVA distributed substantially all of its holdings in us to its security holders. Until such distribution, ProSeed Capital Holdings CVA was considered, pursuant to instructions from the Israeli Securities Authority, as jointly holding our shares together with ProSeed Capital Holdings CVA's security holders, Dror Ben-Asher, Ori Shilo, Eric Swenden, Benjamin Van Oudenhove and Pascal Weerts. Accordingly, such persons were deemed as interested parties for reporting and the approval of transactions under Israeli law. See "Item 7. Major Shareholders and Related Party Transactions – A. Major Shareholders"

Agreement with R.E. Investments

On August 7, 2010, we entered into an agreement with R.E. Investments, an entity owned by Benjamin Van Oudenhove, pursuant to which R.E. Investments provides us with strategic consulting services in the fields of finance, mergers and acquisitions and business development, with an emphasis on Europe.

Pursuant to this agreement, R.E. Investments is entitled to success fees of 3%, plus value added tax, if necessary, of the value of any transaction resulting from its introductions. R.E. Investments is entitled to such payment for a period of 12 months from the date of termination of the agreement. Pursuant to this agreement, we paid R.E. Investments $4,000 and $56,000 in 2011 and 2010, respectively.

On November 6, 2012, we entered into an amendment to this agreement pursuant to which the success fees were increased to 5%, plus value added tax, if applicable, of the value of any transaction resulting from the introductions made by R.E. Investments from November 6, 2012 through December 31, 2012 which result in investments in the Company

In the agreement, R.E. Investments agreed that so long as it serves as our consultant, and for a period of 2 years from the date of termination of the agreement, it will not interfere in our relationship with customers, suppliers, employees, consultants, investment partners, investors and creditors during this period.

Pursuant to the agreement, R.E. Investments was granted options to acquire 400,000 of our ordinary shares at an exercise price of $0.55 per share and Mr. Van Oudenhove was granted options to acquire 100,000 of our ordinary shares at an exercise price of $0.55 per share (all which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange). All of these unexercised options granted to R. E. Investments and Mr. Van Oudenhove will lapse upon the earlier of our merger or acquisition or on September 1, 2012. On August 29, 2012 all these options were exercised into 500,000 ordinary shares.

Agreement with Pascal Weerts

On October 1, 2010, we entered into a consultancy agreement with Pascal Weerts through UpperWest BVBA, one of our shareholders. This agreement was amended on December 1, 2010 and on October 1, 2011 and January 5, 2012. Pursuant to this agreement, Mr. Weerts is entitled, in consideration for his provision to us of consulting services as Director of Corporate and Legal Affairs, to $8,000 per month and an expense reimbursement of $200 per month. Either of the parties may terminate this agreement upon 30 days' notice.

On October 1, 2010, Mr. Weerts was granted 7 year options to purchase 60,000 ordinary shares at an exercise price of $0.165 per share. 20,000 of these options vested on October 1, 2011 with the remaining 40,000 options vesting in 8 subsequent installments of 5,000 options every three months following October 1 (which numbers reflect adjustments made following the distribution of bonus shares to our shareholders at the time of our initial public offering on the Tel Aviv Stock Exchange).

Upon completion of our initial public offering, Mr. Weerts was granted 7 year options to purchase 90,000 ordinary shares at an exercise price of $0.50 per share. 30,000 of these options vested on February 3, 2012, with the remaining 60,000 options vesting in 8 subsequent equal installments of 7,500 options every three months following February 3, 2012.

On January 5, 2012, we granted Mr. Weerts 7 year options to purchase 75,000 ordinary shares at an exercise price of $0.72 per share. These options vest in 6 equal installments of 12,500 options every 6 months following January 1, 2012.

August 2010 Mandatory Convertible Loan Agreements

From June 2010 to August 2010, we entered into a loan agreement with a number of investors, under which Mr. Swenden invested $650,000, Dr. Cabilly invested $500,000, Dr. Reed invested $350,000, and Amram Hayut, a brother-in-law of Mr. Shilo, invested $85,000, out of a total amount of approximately $3.5 million. Under the terms of the loan agreement, we agreed to pay the investors certain royalty payments with regard to two of our therapeutic candidates. In August 2010, the loan agreement was replaced in its entirely by a new convertible loan agreement under which all the loans thereunder, accrued interest at an annual rate of 8% and was converted into ordinary shares and ordinary share warrants upon the completion of our initial public offering. However, the obligation to pay the investors the royalty payments described above remains in full force and effect. Our board of directors approved a proposed acquisition and termination of the royalty rights granted to the investors. See "Item 10. Additional Information – C. Material Contracts – Loan Agreements – August 2010 Mandatory Convertible Loan Agreements" for more information.

November 2010 Mandatory Convertible Loan Agreement

In November 2010, we entered into a convertible loan agreement with a number of investors, under which Dr. Reed invested $500,000, Mr. Swenden invested $200,000 and Mr. Shilo invested $170,000, out of a total amount of approximately $7.6 million. Under the terms of the convertible loan agreement, the loan accrued interest at an annual rate of 8% and was converted into ordinary shares and ordinary share warrants upon the completion of the initial public offering. See "Item 10. Additional Information – C. Material Contracts – Loan Agreements – November 2010 Mandatory Convertible Loan Agreement" for more information.

February 2011 Initial Public Offering

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

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

November 2012 Private Placement

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

Acquisition of Royalties Rights

On January 10, 2013, we issued an aggregate of 2,317,186 ordinary shares in exchange for the acquisition and termination of the royalty rights granted to investors pursuant to the August 2010 mandatory convertible loan agreement. In connection with such transaction, each investor will receive a number of shares on a pro-rata basis in accordance with their respective royalty rights. As part of the transaction, the following three directors who were investors in the August 2010 mandatory convertible loan agreement were issued ordinary shares: Dr. Kenneth Reed - 233,688 ordinary shares; Mr. Eric Swenden - 433,993 ordinary shares; and Dr. Shmuel Cabilly - 333,841ordinary shares, and Mr. Amram Hayut, a brother-in-law of Mr. Shilo, received 56,753 ordinary shares, out of a total amount of approximately $3.5 million. For more information on the royalty right acquisition, please see “Item 10. Additional Information – C. Material Contracts – Loan Agreements – August 2010 Mandatory Convertible Loan Agreements”.

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, 2012.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

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

Ordinary Shares

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

	NIS		$ U.S.	
	Price Per Ordinary Share		Price Per Ordinary Share	
	High	Low	High	Low
Annual				
2012	4.19	1.71	1.08	0.45
2011	3.80	1.82	1.05	0.49
Quarterly				
First Quarter 2013 (through February 14)	4.29	3.91	1.15	1.03
Fourth Quarter 2012	4.19	3.04	1.08	0.78
Third Quarter 2012	2.99	2.19	0.76	0.55
Second Quarter 2012	2.95	1.91	0.78	0.51
First Quarter 2012	2.52	1.71	0.66	0.45
Fourth Quarter 2011	2.80	2.17	0.77	0.57
Third Quarter 2011	3.00	1.82	0.88	0.49
Second Quarter 2011	3.55	2.71	1.02	0.78
First Quarter 2011	3.80	3.00	1.05	0.82
Most Recent Six Months				
February 2013 (through February 14)	4.10	3.91	1.11	1.06
January 2013	4.29	3.91	1.15	1.03
December 2012	4.00	3.80	1.06	1.01
November 2012	4.02	3.59	1.05	0.93
October 2012	4.19	3.04	1.08	0.78
September 2012	2.99	2.23	0.76	0.55
August 2012	2.38	2.19	0.60	0.55

On February 14, 2013, the last reported sales price of our ordinary shares on the Tel Aviv Stock Exchange was NIS 4.04 per share, or $1.10 per share (based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013).

Our tradable Series 1 Warrants are also traded on the Tel Aviv Stock Exchange. Currently there are 7,151,150 tradable Series 1 Warrants outstanding, each of which is exercisable into one ordinary share at a per share price of NIS 4.60 or $1.25 (based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013). The exercise price is linked to the last known representative rate of the U.S. dollar on the exercise date as published by the Bank of Israel. The base rate for linkage is the representative rate of the U.S. dollar published by the Bank of Israel on January 28, 2011 (NIS 3.68 = $1). On February 14, 2013, the last reported sales price of our tradable Series 1 Warrants on the Tel Aviv Stock Exchange was NIS 1.20, or $0.33 per Warrant (based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013).

ADSs

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Capital Market in U.S. dollars beginning from December 27, 2012 through to February 14, 2013.

	U.S.$	
	Price Per ADS	
	High	Low
Most Recent Three Months:		
February 2013 (through February 14)	12.29	10.71
January 2013	13.60	11.00
December 2012 (from December 27) *	-	-

*There was no trading of our ADSs on the Nasdaq Capital Market during December 2012.

On February 14, 2013, the last reported sales price of our ADSs on the Nasdaq Capital Market was $10.71 per ADS.

B. Plan of Distribution

Not applicable.

C. Markets

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

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable

B. Memorandum and Articles of Association

Securities Registers

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

Objects and Purposes

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

Private Placements

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

Board of Directors

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

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

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

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

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

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

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

Description of Securities

Ordinary Shares

The following is a description of our ordinary shares. Our authorized share capital is 100,000,000 ordinary shares, par value NIS 0.01 per share.

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

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

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

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

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

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

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

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

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

Private Placements

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

Acquisitions under Israeli Law

Full Tender Offer

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

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

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

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

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

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

Special tender offer

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

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

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

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

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

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

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

Merger

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

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

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

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

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

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

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

Anti-takeover Measures

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

C. **Material Contracts**

Loan Agreements

August 2010 Mandatory Convertible Loan Agreements

From June 2010 to August 2010, we entered into loan agreements with a number of investors, pursuant to which we received gross proceeds of approximately $3.5 million. The loans we received under these loan agreements accrued interest at an annual rate of 8%, which was payable upon the conversion of the loans. We agreed to use the proceeds from this financing to finance the acquisition of additional products, licensing transactions, clinical trials and current expenditures (general corporate activity).

Under the terms of the loan agreements, we agreed to pay the investors 5% of the proceeds of (i) net sales by us or our sublicensees or distributors; and (ii) down payments and milestone payments from sublicenses or distributor transactions paid to us in connection with the first two new products purchased by us subsequent to the closing of this loan financing. Such royalties are payable (i) with regard to net sales over a period of 5 years from the date of the first commercial sale of either of these products; and (ii) with regard to down payments and milestone payments over a period of 5 years commencing from August 11, 2010. Following approvals from our board of directors and shareholders, it was determined that the investors would be entitled to royalties with respect to RHB-103 for the treatment of acute migraine headaches and RHB-104 for the treatment of Crohn's disease.

On August 31, 2010, each of these loan agreements was replaced in their entirety by a new convertible loan agreement, pursuant to which the loans accrued interest at an annual rate of 8% and were automatically convertible into ordinary shares and ordinary share warrants upon the occurrence of specified events, including an initial public offering of our shares. However, the obligation to pay the investors the royalty payments described above remained in full force and effect.

Immediately prior to the completion of our initial public offering on the Tel Aviv Stock Exchange, all outstanding loans under the loan agreements, together with accrued interest, were converted into (i) 6,281,858 ordinary shares at a conversion price of NIS 2.11 (approximately $0.57 based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) per share and (ii) warrants exercisable for an aggregate number of ordinary shares equal to approximately $1 million (representing 30% of the aggregate original loan amount) divided by the exercise price, as determined below. Investors became entitled to receive their pro rata share of the shares and warrants based on their respective loan amounts. The exercise price for the warrants was calculated as follows:

- for warrants exercised within 6 months of our initial public offering on the Tel Aviv Stock Exchange, the exercise price per share would have been 130% of the conversion price per share, or $0.74;

- for warrants exercised between 6 and 12 months following our initial public offering on the Tel Aviv Stock Exchange, the exercise price per share would have been 140% of the conversion price per share, or $0.8;

- for warrants exercised between 12 months following our initial public offering on the Tel Aviv Stock Exchange through their expiration date which is August 11, 2013, the exercise price per share is 150% of the conversion price per share, or $0.86.

In December 2012, our shareholders approved an acquisition and termination of the royalty rights granted to investors pursuant to the August 2010 mandatory convertible loan agreement in consideration for the issuance of an aggregate of 2,317,186 ordinary shares, pursuant to which each investor will receive a number of shares on a pro-rata basis in accordance with their respective royalty rights (the "Royalty Acquisition"). The Royalty Acquisition closed on January 10, 2013.

November 2010 Mandatory Convertible Loan Agreement

On November 7, 2010, we completed a financing of approximately $7.6 million pursuant to a convertible loan agreement we signed with investors. Under this convertible loan agreement, the loan accrued interest at an annual rate of 8% and was automatically convertible into ordinary shares and ordinary share warrants upon the occurrence of specified events, including an initial public offering of our shares.

Immediately prior to the completion of our initial public offering on the Tel Aviv Stock Exchange, outstanding loans under this convertible loan agreement, together with accrued interest, were converted into (i) 13,536,456 ordinary shares at a conversion price of NIS 2.11 (approximately $0.57 based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) per share and (ii) warrants exercisable for an aggregate number of ordinary shares equal to approximately $2.3 million (representing 30% of the aggregate original loan amount) divided by the exercise price of the warrants, as calculated in the same manner as the warrants described above. The warrant contain the same terms as the warrants described above other than their expiration date which is November 9, 2013. Investors became entitled to receive their pro rata share of the shares and warrants based on their respective loan amounts.

Underwriting Agreement

In connection with our February 2011 initial public offering of shares on the Tel Aviv Stock Exchange, on January 30, 2011, we entered into an underwriting agreement with Poalim I.B.I. Underwriting and Issuing Ltd. as the leading underwriter and Apex Underwriting and Issue Management Ltd., Excellence Nessuah Underwriting (1993) Ltd., Meitav Issuing Finance Ltd. and Rosario Underwriting Services (A.S.) Ltd.

Pursuant to this agreement, the underwriters agreed to irrevocably acquire from us, each according to a rate set forth in the agreement, an aggregate of 16,400 units (each unit comprised of 100 shares and 50 warrants) offered according to the prospectus with respect to which we would provide notice if no requests had been submitted for the acquisition thereof, or if the full price had not been paid to us with respect thereto, in connection with the public offering. Since requests were received for the purchase of all the securities offered to the public under the prospectus, the underwriters were not required to acquire any securities.

In consideration for the undertakings and services of the principal managers and underwriters pursuant to the Underwriting Agreement, including issue coordination services, we paid, by means of the leading underwriter, a total of approximately $913,000 placement agent fee and cost reimbursement of approximately $198,000. We also provided the underwriters with certain indemnification undertakings in connection with the public offering.

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

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our ordinary shares. In May 1998, a new "general permit" was issued under the Israeli Currency Control Law, 1978, which removed most of the restrictions that previously existed under the law and enabled Israeli citizens to freely invest outside of Israel and freely convert Israeli currency into non-Israeli currencies. Dividends, if any, paid to holders of our ordinary shares, and any amounts payable upon our dissolution, liquidation or winding up, as well as the proceeds of any sale in Israel of our ordinary shares to an Israeli resident, may be paid in non-Israeli currency or, if paid in Israeli currency, may be converted into U.S. dollars at the rate of exchange prevailing at the time of conversion.

E. Taxation

Israeli Tax Considerations

General

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

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of our Shares. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, or foreign companies, Israeli residents holding 25% or more of their shares or having the right to 25% or more of their income or profit, 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

The Israeli corporate tax rate applicable to Israeli resident companies in 2012 is 25%.

Taxation of Shareholders

Capital Gains

Capital gains tax is imposed on the disposal of capital assets by an Israeli resident and on the disposal of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposal.

As of January 1, 2012, the real capital 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%. In addition, capital gains generated by an individual claiming deduction of financing expenses in respect of such gain will be taxed at the rate of 30%.

Individual and corporate shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income - 25% for corporations in 2012 and a marginal tax rate of up to 48% in 2012 for individuals (an additional 2% tax rate would be levied on individuals whose taxable income from Israeli sources exceeds NIS 811,560 (approximately $220,293 based on the representative U.S. dollar – NIS rate of exchange of 3.684 on February 17, 2013) in 2013). 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 (not applicable in respect of Shares purchased on or after January 1, 2009), (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed, and (iii) if the seller is a corporation, less than 25% of its means of control or the rights to its profit or income are held by or attributed to Israeli resident shareholders. 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 (the "U.S.- Israel Double Tax Treaty") exempts a U.S. resident 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.

Withholding Obligations - Either the purchaser, the Israeli stockbroker or the financial institution through which the Shares are held, are obligated, subject to the above mentioned exemptions, to withhold tax upon the sale of Shares at a 25% tax rate for corporations and individuals.

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 June 30 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

As of January 1, 2012, 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.

As of January 1, 2012, dividends distributed by an Israeli resident company to a non-Israeli resident (either individual or corporation) are generally subject to 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. Thus, 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 section (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate applicable to an Approved Enterprise/Benefited Enterprise/Preferred Enterprise – 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.

We are obligated to withhold tax upon the distribution of dividends at the following withholding tax rates: (A) for securities registered and held by a clearing corporation: (i) Israeli resident corporations – 0%, (ii) Israeli resident individuals – 25%, and (iii) non-Israeli residents - 25%, unless reduced under the provisions of an applicable double tax treaty; and (B) in all other cases: (i) Israeli resident corporations – 0%, (ii) Israeli resident individuals – 25% or 30% tax rate if the dividend recipient is a Controlling Shareholder at the time of the distribution or at any time during the preceding 12 months period)), and (iii) non-Israeli residents - 25% or 30% tax rate as referred to above with respect to Israeli resident individuals, unless reduced under 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 that apply to U.S. Holders who hold our Shares as capital assets for tax purposes. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended (the "Code"), current and proposed Treasury regulations promulgated thereunder, and administrative and judicial decisions as of the date hereof, all of which are subject to change, possibly on a retroactive basis. This summary does not address all U.S. federal income tax matters that may be relevant to a particular perspective holder or all tax considerations that may be relevant with respect to an investment in our Shares.

This summary does not address tax considerations applicable to a holder of our Shares 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;
- investors subject to the alternative minimum tax;
- tax-exempt organizations;
- traders that have elected mark-to-market accounting;
- investors that hold Shares as part of a "straddle", "hedge", or "conversion transaction" with other investments;
- regulated investment companies;
- investors that actually or constructively own 10 percent or more of our voting shares;
- investors 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
- U.S. Holders, as defined below, 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 Shares.

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 the Shares.

- For purposes of this summary, a "U.S. Holder" means a beneficial owner of a Share 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 Shares, 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 Shares through such entities should consult their own tax advisors.

In general, if you hold American Depositary Shares, you will be treated as the holder of the underlying shares represented by those American Depositary Shares for U.S. federal income tax purposes. Accordingly, no gain or loss will be recognized if you exchange American Depositary Shares for the underlying Shares represented by those American Depositary Shares.

Distributions

Subject to the discussion under "Passive Foreign Investment Companies" below, the gross amount of any distribution, including the amount of any Israeli taxes withheld from these distributions (see "Israeli Tax Considerations"), actually or constructively received by a U.S. Holder with respect to Shares 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 domestic corporations. 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 Shares. 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 Shares." If we do not report to a U.S. Holder the portion of a distribution that exceeds earnings and profits, the distribution will generally be taxable as a dividend even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. 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 before January 1, 2013 will be subject to a maximum income tax rate of 15%. This reduced income tax rate is only applicable to dividends paid by a "qualified foreign corporation" that is not a PFIC and only with respect to shares 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). We should be considered a qualified foreign corporation if we are not treated as a PFIC because (i) we are eligible for the benefits of a comprehensive tax treaty between Israel and the U.S., which includes an exchange of information program, and (ii) the American Depositary Shares are readily tradable on an established securities market in the U.S. As discussed below, however, we may be classified as a "passive foreign investment company" (see "Passive Foreign Investment Companies" below). Accordingly, dividends paid by us to individual U.S. Holders may not be eligible for the reduced income tax rate applicable to qualified dividends.

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 American Depositary Shares, 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 (including, in the case of a U.S. corporation that owns 10 percent or more of our voting stock, the possible application of Section 902 of the Code).

Sale or Other Disposition of Shares

If a U.S. Holder sells or otherwise disposes of its Shares, 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 Shares. Subject to the discussion below under the heading "Passive Foreign Investment Companies," 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 Shares 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 Shares will be U.S. source gain or loss for purposes of the foreign tax credit limitation.

If a U.S. Holder receives foreign currency upon a sale or exchange of Shares, gain or loss will be recognized in the manner described above under "Distributions." In addition, gain or loss, if any, recognized on the subsequent sale, conversion, or disposition of such foreign currency will be U.S. source ordinary income or loss for foreign tax credit limitation purposes. 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.

A U.S. Holder who holds Shares 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 Shares 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

For taxable years beginning after December 31, 2012, certain U.S. Holders that are individuals, estates or trusts will be required to pay an additional 3.8% tax on their investment income, including dividends paid on the Shares and capital gains from the sale or other disposition of the Shares.

Passive Foreign Investment Companies

For U.S. federal income tax purposes, we will be considered a passive foreign investment company ("PFIC") for any taxable year in which either 75% or more of our gross income is passive income, or at least 50% of the average value of all of our assets for the taxable year produce or are held for the production of passive income. For this purpose, passive income includes dividends, interest, royalties, rents, annuities, and the excess of gains over losses from the disposition of assets which produce passive income. If we were determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to U.S. Holders owning Shares.

Based on our estimated gross income, the average value of our gross assets, and the nature of our business, we believe that we may be classified as a PFIC in the current taxable year and in future years. Our status as a PFIC will depend on the composition of our assets and activities in each year and because this is a factual determination there can be no assurance that we will not be considered a PFIC for the current taxable year or for any future taxable year. If we are treated as a PFIC in any year during which a U.S. Holder owns Shares, certain adverse tax consequences could apply, as described below. If we are treated as a PFIC for any taxable year,

- a U.S. Holder would be required to allocate income recognized upon receiving certain dividends or gain recognized upon the disposition of Shares ratably over its holding period for such Shares,
- the amount allocated to each year during which we are considered a PFIC other than the year of the dividend payment or disposition would be subject to tax at the highest individual or corporate tax rate, as the case may be, and an interest charge would be imposed with respect to the resulting tax liability allocated to each such year,
- the amount allocated to the year of the dividend payment or disposition would be taxable as ordinary income,
- a U.S. Holder would be required to make an annual return on IRS Form 8621 regarding distributions received and gains realized with respect to the Shares, and
- the favorable dividend rate discussed above with respect to dividends paid to certain non-corporate U.S. Holders prior to January 1, 2013 would not apply.

As described below, certain elections may be available that would result in alternative treatments (such as mark-to-market or qualified electing fund treatment) to U.S. Holders of our Shares. A U.S. Holder that makes an election to treat us as a qualified electing fund (an "electing U.S. Holder") is required for each taxable year to include in income a pro rata share of the ordinary earnings of the qualified electing fund as ordinary income and a pro rata share of the net capital gain of the qualified electing fund as long-term capital gain, subject to a separate election to defer payment of taxes, which deferral is subject to an interest charge. A U.S. Holder may make a qualified electing fund election only if we furnish the U.S. Holder with certain tax information. We have agreed to supply an electing U.S. Holder with the information necessary to report income and gain pursuant to a qualified election in the event we are classified as a PFIC. Alternatively, another method to avoid the aforementioned treatment is for a U.S. Holder to make a timely mark-to-market election in respect of its Shares. If a U.S. Holder elects to mark-to-market its Shares, the excess of the fair market value of the Shares at the close of each tax year over such U.S. Holder's adjusted tax basis in such Shares will be included in income. If the fair market value of the Shares is less than the U.S. Holder's adjusted tax basis in its Shares at the close of the tax year, the U.S. Holder may generally deduct the excess of the adjusted tax basis of the Shares over their fair market value at such time. However, such deductions generally would be limited to the net mark-to-market gains, if any, that were included in income by such holder with respect to our Shares in prior years. Income recognized and deductions allowed under the mark-to-market provisions, as well as any gain or loss on the disposition of Shares with respect to which the mark-to-market election is made, are treated as ordinary income or loss.

You are urged to consult your own tax advisor regarding the possibility of us being classified as a PFIC and the potential tax consequences arising from the ownership and disposition of an interest in a PFIC.

Backup Withholding and Information Reporting

Payments of dividends with respect to Shares and the proceeds from the sale, retirement, or other disposition of Shares 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 tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining an exemption.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

As a foreign private issuer, we are exempt from the rules under the Securities Exchange Act of 1934, as amended, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Securities Exchange Act of 1934, as amended. In addition, we are not required under the Securities Exchange Act of 1934, as amended, to file annual, quarterly and current reports and financial statements with the Securities and Exchange Commission as frequently or as promptly as U.S. companies whose securities are registered under the Securities Exchange Act of 1934, as amended. However, we are required to comply with the informational requirements of the Securities Exchange Act of 1934, as amended, and, accordingly, file current reports on Form 6-K, annual reports on Form 20-F and other information with the Securities and Exchange Commission.

In addition, since our ordinary shares are traded on the Tel Aviv Stock Exchange, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the Tel Aviv Stock Exchange and the Israeli Securities Authority, as required under Chapter Six of the Israel Securities Law, 1968. Copies of our filings with the Israeli Securities Authority can be retrieved electronically through the MAGNA distribution site of the Israeli Securities Authority (*www.magna.isa.gov.il*) and the Tel Aviv Stock Exchange website (*www.maya.tase.co.il*).

We maintain a corporate website at *www.redhillbio.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Risk of Interest Rate Fluctuation and Credit Exposure Risk

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

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

Market Price Risk

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

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, our functional and reporting currency, mainly against the NIS and other currencies. Although the U.S. dollar is our functional currency and reporting currency, a portion of our expenses are denominated in NIS. Our NIS expenses consist principally of payments to employees or service providers and short term investments in currencies other than the U.S. dollar. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against the NIS it may have a negative impact on our results of operations. We manage our foreign exchange risk by aligning the currencies for holding short term investments with the currencies of expected expenses, based on our expected cash flows.

Portfolio diversification is performed based on risk level limits that we set. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

(A) Set forth below is a sensitivity test to possible changes in U.S. dollars/ NIS exchange rate as of December 31, 2012:

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	13	33	16,814	(33)	(13)
Bank deposits	-	1	561	(1)	-
Financial asset at fair value	21	53	1,065	(53)	(21)
Accounts receivable	2	4	198	(4)	(2)
Accounts payable and accrued expenses	(7)	(17)	(1,078)	17	7
Total loss	30	74		(74)	(30)

(B) As of the date of this Annual Report, our interest rate risk exposure is in respect to bank deposits, which expose us to risk due to change in fair value interest rates. As of December 31, 2012, these deposits carry annual interest of 0.52%-1.83%. Under these low interest rates, reasonable changes in interest rates are expected have negligible impact on the fair value of these assets.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable

C. Other Securities

Not applicable

D. American Depositary Shares

Each of our American Depositary Shares, or ADSs, represents 10 of our ordinary shares. Our ADSs trade on The Nasdaq Capital Market.

The form of the deposit agreement for the ADSs and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286, and at the principal office of our custodians, Bank Leumi Le-Israel, 34 Yehuda Halevi St., Tel-Aviv 65546, Israel and Bank Hapoalim B.M., 104 Hayarkon Street, Tel Aviv 63432, Israel.

Fees and Expenses

Persons depositing or withdrawing shares or American Depositary Share holders must pay:	***For:***
$5.00 (or less) per 100 American Depositary Shares (or portion of 100 American Depositary Shares)	• Issuance of American Depositary Shares, including issuances resulting from a distribution of shares or rights or other property • Cancellation of American Depositary Shares for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per American Depositary Share	• Any cash distribution to American Depositary Share holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of American Depositary Shares	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to American Depositary Share holders
$0.05 (or less) per American Depositary Shares per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) • converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any American Depositary Share or share underlying an American Depositary Share, for example, stock transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

The depositary collects its fees for delivery and surrender of American Depositary Shares directly from investors depositing shares or surrendering American Depositary Shares for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse and/or share revenue from the fees collected from American Depositary Share holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the American Depositary Share program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable

ITEM 15. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures**

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed on Form 20-F and filed with the Securities and Exchange Commission is recorded, processed, summarized and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our Chief Executive Officer and Deputy CEO Finance and Operations, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d) - 15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective at such reasonable assurance level.

(b) **Management's Annual Report on Internal Control over Financial Reporting**

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

(c) **Attestation Report of Registered Public Accounting Firm**

See statement in section (b).

(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, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Aliza Rotbard, Dan Suesskind and Ofer Tsimchi are audit committee financial experts. Ms. Rotbard, Mr. Tsimchi and Mr. Suesskind are independent directors for the purposes of the Nasdaq rules.

ITEM 16B. CODE OF ETHICS

As of the date of this Annual Report, we have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, http://ir.redhillbio.com/governance.cfm

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

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

	Year Ended December 31,	
	2011	2012
Services Rendered	(U.S. dollars in thousands)	
Audit (1)	52	70
Audit related services (2)	-	157
Tax (3)	-	-
Total	52	227

(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 a public listing.
(3) Tax fees relate to tax compliance, planning and advice.

Audit Committee Pre-Approval Policies and Procedures

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

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

Not applicable.

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

Not applicable

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT.

Not applicable

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq Stock Market Listing Rules and Home Country Practices

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of Nasdaq Marketplace Rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. We rely on this "foreign private issuer exemption" with respect to the following items:

- *Independent Directors* - Our board of directors includes two external directors in accordance with the Israeli Companies Law, but does not require that a majority of our board members be independent as required by the Nasdaq Listing Rules. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only our independent directors are present.

- *Shareholder Approval* - We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Israeli Companies Law, which are different from the shareholder approval requirements under the Nasdaq Listing Rules. The NASDAQ Listing Rules require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans and arrangements, issuances that will result in a change of control of a company, certain transactions other than a public offering involving issuances of 20% or more of the shares or voting power in a company, and certain acquisitions of the stock or assets of another company involving issuances of 20% or more of the shares or voting power in a company or if any director, officer or holder of 5% or more of the shares or voting power of the company has a 5% or greater interest in the company or assets to be acquired or consideration to be paid and the transaction could result in an increase in the outstanding common shares or voting power by 5% or more.

  Under the Israeli Companies Law, shareholder approval is required for any transaction, including any grant of equity-based compensation, to a director or a controlling shareholder, but is not generally required to establish or amend an equity based compensation plan. Similarly, shareholder approval is required for a private placement that is deemed a "extraordinary private placement" or that involves a director or controlling shareholder. A "extraordinary private placement" is a private placement in which a company issues securities representing 20% or more of its voting rights prior to the issuance and the consideration received pursuant to such issuance is not comprised, in whole or in part, solely of cash or securities registered for trade on an exchange or which is not made pursuant to market conditions, and as a result of which the shareholdings of a 5% holder of the shares or voting rights of the company increases or as a result of which a person will become a holder of 5% of the shares or voting rights of the company or a controlling shareholder after the issuance.

- *Quorum* - As permitted under the Israeli Companies Law, pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the Nasdaq Listing Rules.

- *Nominations Committee* - As permitted under the Israeli Companies Law, our board of directors selects director nominees subject to the terms of our articles of association which provide that incumbent directors are re-nominated for additional terms. Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the Nasdaq Listing Rules.

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Stock Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq Marketplace Rules related to corporate governance. We also comply with Israeli corporate governance requirements under the Israeli Companies Law applicable to public companies.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable

ITEM 17. FINANCIAL STATEMENTS

Not applicable

ITEM 18. FINANCIAL STATEMENTS

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

ITEM 19. EXHIBITS

See Exhibit Index on page 110.

Glossary of Industry Terms

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

5-HT3 family receptor inhibitors - play a role in mediating nausea and vomiting, and as such, demonstrate anti-emetic efficacy.

Bioequivalence - the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. To be considered "bioequivalent", certain standards specified by the US Food and Drug Administration must be met.

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

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

Clinical trial material (CTM) manufacturing - manufacturing of study supplies provided by the study sponsor to the clinical investigator.

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

Helicobacter pylori - a Gram-negative bacterium found in the stomach. It was identified in 1982 by Dr. Barry Marshall and Dr. Robin Warren and is associated with peptic ulcer disease and development of gastric cancer.

IND - Investigational New Drug - a status assigned by the Food and Drug Administration to a drug before allowing its use in humans, so that experimental clinical trials may be conducted.

MAP bacterium (*Mycobacterium avium subspecies paratuberculosis* (MAP)) - an obligate pathogenic bacterium in the genus Mycobacterium.

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

Ondansetron - Ondansetron is a drug in class of medications called serotonin 5-HT_3 receptor antagonists. Ondansetron works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.

Orphan Drug Status - the designation of Orphan Drug status to drugs that are in the process of development for the treatment of rare diseases. This status provides tax reductions and the exclusive rights to the cure for a specific condition for a period of seven years post-approval.

Pivotal Bioequivalence (BE) Clinical Trial - a study the data from which is submitted to the Food and Drug Administration in support of a marketing application of a test drug that is being compared to a referenced existing (already approved) drug. Sufficient similarity between the test and the reference drug is required, according to certain standards specified by the Food and Drug Administration, which must be met.

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

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

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

RedHill Biopharma Ltd.
Index to Financial Statements
as of December 31, 2012

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the shareholders of
REDHILL BIOPHARMA LTD.

We have audited the accompanying statements of financial position of RedHill Biopharma Ltd. (the "Company") as of December 31, 2012 and 2011 and the related statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended on December 31, 2012. 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 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, 2012 and 2011 and the results of its operations, changes in equity and cash flows for each of the three years in the period ended on December 31, 2012, in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Tel-Aviv, Israel
February 19, 2013

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

REDHILL BIOPHARMA LTD.

STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31		
		2012	2011	2010
		U.S. dollars in thousands		
REVENUE		16	23	-
RESEARCH AND DEVELOPMENT EXPENSES	17	(6,455)	(5,414)	(736)
GENERAL AND ADMINISTRATIVE EXPENSES	18	(2,601)	(2,482)	(518)
OTHER EXPENSES	19	-	-	(479)
OPERATING LOSS		(9,040)	(7,873)	(1,733)
FINANCIAL INCOME		197	570	65
FINANCIAL EXPENSES		(1,483)	(8,200)	(876)
FINANCIAL EXPENSES NET	20	(1,286)	(7,630)	(811)
LOSS AND COMPREHENSIVE LOSS		(10,326)	(15,503)	(2,544)
LOSS PER ORDINARY SHARE – basic and diluted	21	(0.20)	(0.32)	(0.27)

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

REDHILL BIOPHARMA LTD.

STATEMENTS OF FINANCIAL POSITION

	Note	December 31	
		2012	2011
		U.S. dollars in thousands	
CURRENT ASSETS:			
Cash and cash equivalents	5	16,814	14,070
Bank deposits	5	486	3,013
Financial assets at fair value through profit or loss	6	1,065	1,564
Prepaid expenses and receivables	7	198	89
		18,563	18,736
NON-CURRENT ASSETS:			
Restricted bank deposit		75	73
Fixed assets	8	113	132
Intangible assets	9	1,345	1,245
		1,533	1,450
Total assets		20,096	20,186
CURRENT LIABILITIES -			
Accounts payable and accrued expenses	11	1,078	513
NON-CURRENT LIABILITIES:			
Royalty obligations to investors	12	-	886
Total liabilities		1,078	1,399
COMMITMENTS	13		
EQUITY:	15		
Ordinary shares		143	142
Ordinary shares to be issued		8,020	-
Additional paid-in capital		31,469	31,168
Warrants		3,273	2,686
Accumulated deficit		(23,887)	(15,209)
Total equity		19,018	18,787
Total liabilities and equity		20,096	20,186

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

REDHILL BIOPHARMA LTD.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Convertible preferred shares	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	US dollars in thousands					
BALANCE AT JANUARY 1, 2010	3	2	925	45	(105)	870
CHANGES DURING THE YEAR ENDED DECEMBER 31,2010:						
Comprehensive loss	-	-	-	-	(2,544)	(2,544)
Share-based compensation to employees and service providers	-	-	-	-	80	80
BALANCE AT DECEMBER 31, 2010	3	2	925	45	(2,569)	(1,594)
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2011:						
Comprehensive loss	-	-	-	-	(15,503)	(15,503)
Exercise of warrants into convertible preferred shares	-	*	629	(45)	-	584
Conversion of convertible preferred shares into ordinary shares	2	(2)			-	
Distribution of bonus shares	42		(42)		-	
Conversion of mandatory convertible loans to equity	53	-	17,381	1,749	-	19,183
Issuance of ordinary shares and warrants under public offering	39	-	11,352	1,271	-	12,662
Exercise of warrants into ordinary shares	3		923	(334)	-	592
Share-based compensation to employees and service providers	-	-	-	-	2,863	2,863
BALANCE AT DECEMBER 31, 2011	142		31,168	2,686	(15,209)	18,787

* Represents amount less than $1 thousand.

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

REDHILL BIOPHARMA LTD.
STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Ordinary shares to be issued	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	US dollars in thousands					
BALANCE AT JANUARY 1, 2012	142		31,168	2,686	(15,209)	18,787
CHANGES DURING THE YEAR ENDED DECEMBER 31,2012:						
Comprehensive loss	-	-	-	-	(10,326)	(10,326)
Exercise of options into ordinary shares	1	-	301	-	-	302
Cash receipt on account of ordinary shares and warrants, see note 15a(8)	-	5,661	-	587		6,248
Settlement of the royalty obligations, see note 12d	-	2,359	-	-	-	2,359
Share-based compensation to employees and service providers	-	-	-	-	1,648	1,648
BALANCE AT DECEMBER 31, 2012	143	8,020	31,469	3,273	(23,887)	19, 018

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

REDHILL BIOPHARMA LTD.

STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2012	2011	2010
	US dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Loss	(10,326)	(15,503)	(2,544)
Adjustments in respect of income and expenses not involving cash flows:			
Share-based compensation to employees and service providers	1,648	2,863	80
Fair value losses on mandatory convertible loans	-	7,938	545
Depreciation	24	15	-
Fair value losses (gains) on financial assets at fair value through profit or loss	(57)	29	(7)
Revaluation of bank deposits	(4)	9	(2)
Accretion and settlement of royalty obligations to investors	1,473	168	327
Exchange differences in respect of cash and cash equivalents	(12)	(640)	(10)
Changes in asset and liability items:			
Decrease (increase) in prepaid expenses and receivables	(109)	61	(141)
Increase in accounts payable and accrued expenses	568	369	120
Net cash used in operating activities	(6,795)	(4,691)	(1,632)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(8)	(136)	(8)
Purchase of intangible assets	(100)	(45)	(1,100)
Changes in investment in bank deposits	2,529	(3,080)	-
Acquisition of financial assets at fair value through profit or loss	(1,032)	(1,506)	-
Proceeds from sale of financial assets at fair value through profit or loss	1,588	-	92
Net cash used in investing activities	2,977	(4,767)	(1,016)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds on account of shares and warrants, net	6,248	-	-
Proceeds from issuance of shares and warrants under February 2, 2011 prospectus, net of issuance expenses	-	12,662	-
Exercise of warrants and options into shares, net of expenses	302	1,176	-
Proceeds from mandatory convertible loans and royalty obligations to investors	-	-	11,091
Net cash provided by financing activities	6,550	13,838	11,091
INCREASE IN CASH AND CASH EQUIVALENTS	2,732	4,380	8,443
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	12	640	10
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	14,070	9,050	597
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	16,814	14,070	9,050
Supplementary information on interest received in cash	126	14	-
Supplementary Information on financing activities not involving cash flows :			
Settlement of the royalty obligations	2,359	-	-
Conversion of mandatory convertible loans	-	19,183	-

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

NOTE 1 – GENERAL INFORMATION:

a. General

RedHill Biopharma Ltd. (the "Company") was incorporated in Israel on August 3, 2009 and is active in the pharmaceutical industry. The Company is focused primarily on the development and acquisition of therapeutic candidates (the "drugs") acquired through asset purchases or in-licensing. In particular, the Company acquires or in-licenses and develops patent-protected new formulations and combinations of existing drugs in advanced stages of development with the objective of obtaining marketing approvals for these drugs. Additionally, the Company's strategy is to commercialize these drugs (in cooperation and/or through pharmaceutical and biotechnology companies) and to acquire rights in additional drugs.

In February 2011, the Company listed its securities on the Tel Aviv Stock Exchange (TASE) and they have been traded on the TASE since that time. Since December 2012, the Company's American Depositary Shares ("ADSs") are also listed on the NASDAQ Capital Market. See note 15.

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

The Company is still in research and development of its therapeutic candidates. Accordingly the Company is unable to estimate if and when its business will generate positive cash flow. Through December 31, 2012, the Company has accumulated an operating loss and its activities have been funded through public and private offerings of the Company's securities.

The Company plans to fund its future operations through commercialization of its therapeutic candidates, out-licensing certain programs and raising additional capital. The Company's current cash resources are not sufficient to complete the research and development of all of the Company's therapeutic candidates. Management expects that the Company will incur more losses, as it continues to focus its resources on advancing its therapeutic candidates based on a prioritized plan that will result in negative cash flows from operating activities. The Company believes its existing capital resources should be sufficient to fund its current and planned operations for at least the next 12 months.

If the Company is unable to commercialize or out-license its therapeutic candidates or obtaining future financing, the Company may be forced to delay, reduce the scope of, or eliminate one or more of its research and development programs related to the therapeutic candidates, 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 February19, 2013.

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, 2012 and 2011 and for each of the three years in the period ended on December 31, 2012 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 prevailing at the dates of the transactions. Foreign exchange differences resulting from the settlement of such transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recorded to the statement of comprehensive loss among financing income or expenses.

c. Cash and cash equivalents

Cash and cash equivalents include cash on hand and unrestricted short-term bank deposits with maturities of three months or less.

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

d. Fixed assets

Fixed assets are recognized as assets only if (a) it is probable that future economic benefits associated with the item will flow to the Company and (b) the cost of the item can be measured reliably.

Fixed assets items are initially recognized at acquisition cost. Fixed assets items are stated at cost less accumulated depreciation and impairment losses.
Depreciation is computed by the straight- line method, to reduce the cost of fixed assets to their residual value over their estimated useful lives as follows:

	%
Computers	33
Office furniture and equipment	8-15

Leasehold improvements are depreciated by the straight-line method over the shorter of the term of the lease or the estimated useful life of the improvements.
The assets' residual values, useful lives and depreciation method are reviewed, and adjusted if appropriate at least once a year.

e. Research and development:

1) Research and development assets acquired by the Company, the development of which has not been completed yet, are stated at cost and are not amortized; these assets are tested for impairment once a year. At the time these assets will be available for use, they will be amortized by the straight line method over their useful lives.

2) Research expenses are charged to profit or loss as incurred. An intangible asset arising from development of the Company's drugs is recognized if all of the following conditions are met:
   - It is technically feasible to complete the intangible assets so that it will be available for use;
   - Management intends to complete the intangible asset and use it or sell it;
   - There is an ability to use or sell the intangible asset;
   - It can be demonstrated how the intangible asset will generate probable future economic benefits;
   - Adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and costs associated to 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, 2012 and 2011, the Company has not yet capitalized development costs.

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

3) Amounts paid to purchase intellectual property of drugs are capitalized and carried as intangible assets. Amounts due for future payment, based on the agreement, will be accrued upon reaching the relevant milestones.

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

f. Impairment of non-financial assets

Depreciable assets are tested for impairment if any events have occurred or changes in circumstances have taken place, which might indicate that their carrying amounts may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Nonfinancial assets that were subject to impairment are reviewed for possible reversal of the impairment recognized in respect thereof at each date of statement of financial position.

Research and development assets, the development of which has not been completed yet, are not amortized and are tested for impairment on an annual basis.

g. Financial assets:

1) Classification

The financial assets of the Company are classified into the following categories: financial assets at fair value through profit or loss and loans and receivables. The classification depends on the purpose for which the financial assets were acquired. The Company's management determines the classification of its financial assets at initial recognition.

a) Financial assets at fair value through profit or loss

This category includes financial assets that are managed and their performance is evaluated on a fair value basis. Thus upon their initial recognition, these assets are designated by management at fair value through profit or loss. Assets in this category are classified as current assets if expected to be settled within 12 months; otherwise, they are classified as noncurrent.

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

b) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for 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 comprise "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 trade date, which is the date on which the asset is delivered to the Company or delivered by the Company. Investments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss.

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

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

h. Financial liabilities:

1) Classification:

a) Financial liabilities at fair value through profit or loss

This category includes financial liabilities designated by management as at fair value through profit or loss. Financial liabilities at fair value through profit or loss of the Company were the mandatory convertible loans exercisable into a variable number of shares and warrants.

Gains or losses arising from changes in the fair value of those financial liabilities at fair value through profit or loss are presented in the statement of comprehensive loss under "financial income or expenses".

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

b) Other Financial Liabilities

Other financial liabilities are initially measured at fair value, net of transaction costs. In subsequent periods, the other financial liabilities are presented at amortized cost. Any difference between the consideration (net of transaction costs) and the redemption value is carried to profit or loss over the term of the liability, using the effective interest method.

Financial liabilities are classified as current liabilities, unless the Company has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period, for which they are classified as noncurrent liabilities.

2) Derecognition of financial liabilities

A financial liability is derecognized when the obligation under the liability is settled, cancelled or expired. The financial liability is settled when the Company:

- Repays the liability by cash payment, other financial assets, issuance of shares, goods or services, or
- Is legally released from the liability.

Where an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and the recognition of a new liability with the difference in the respective carrying amount recognized in profit or loss. Where the replacement or change is immaterial, they are accounted for as changes to the terms of the original financial liability.

i. 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.

j. Share capital

The Company's ordinary shares and convertible preferred 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.

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

k. Employee benefits:

1) Pension and retirement benefit obligations

In any matter related to payment of pension and severance pay to employees 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 dismissed or retiring from their employer in certain circumstances.

The Company has a severance pay plan in accordance with Section 14 of the Israeli Severance Pay Law with the plan handled as a defined contribution plan. According to the plan, the Company regularly makes payments to severance pay or pension funds without having a legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employees 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 the law, each employee is entitled to vacation days and recreation pay, both computed on an annual basis. The entitlement is based on the period of employment. The Company records a liability and an expense for vacation and recreation fees, based on the benefit accumulated for each employee.

l. Share-based payments

The Company operates a number of equity-settled, share-based compensation plans to employees (as defined in IFRS 2 "Share-Based Payments") and service providers. As part of the plans, the Company grants employees and service providers, from time to time and at its discretion, options to purchase Company shares. The fair value of the employee and service provider services received in exchange for the grant of the options is recognized as an expense in profit or loss and is carried to accumulated deficit under equity. The total amount recognized as an expense over the vesting period of the options (the period during which all vesting conditions are expected to be met) was determined as follows:

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

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

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

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

When exercising options, the Company issues new shares, with proceeds, less directly-attributable transaction costs, recognized as share capital (par value) and share premium.

m. Provisions

Provisions are recognized when the Company has a present legal or constructive obligation as a result of past events and it is probable that an outflow of resources will be required to settle the obligation. Provisions are measured by discounting the future cash outflow at a pretax interest rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The carrying amount of the provision is adjusted in each reporting period in order to reflect the passage of time and the changes in the carrying amounts are carried to the profit and loss.

n. Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable for providing rights to use the Company's intangible assets. Revenue is presented net of VAT, returns, credits and discounts.

Revenue is recognized when the amount of revenue can be reliably measured; it is probable that future economic benefits will flow to the Company and the stage of completion of a transaction as of the reporting period end can be measured reliably. The amount of revenue is not considered to be reliably measurable until all conditions associated with the transaction are settled.

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.

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

p. Loss per ordinary share

The computation of basic loss per share is based, as a general rule, on the Company's loss divided by the weighted average number of ordinary shares outstanding during the period.

In calculating the diluted loss per share, the Company adds to the average number of shares outstanding that was used to calculate the basic loss per share the weighted average of the number of shares to be issued assuming all shares that have a potentially dilutive effect have been converted into shares. The potential shares, as above are only taken into account in cases where their effect is dilutive (increasing the loss per share). Since the addition of potential shares reduces loss per share, these potential shares are not taken into account, and basic and diluted loss per share is identical.

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. However, deferred tax liabilities are not recognized if they arise from the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss.

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 is realized or the deferred income tax liability is 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 taxes were recorded in these financial statements.

r. Standards and interpretations to existing standards that are not yet effective and have not been early adopted by the Company

1) International Financial Reporting Standard No. 9 "Financial Instruments" (hereafter - IFRS 9)
   The first part of IFRS 9, dealing with the classification and measurement of financial assets, was issued in November 2009 (hereinafter first part of IFRS 9) and the second part of IFRS 9, which includes guidance on financial liabilities and derecognition of financial instruments was issued in 2010. IFRS 9 replaces certain parts of IAS 39 "Financial Instruments: Recognition and Measurement" (hereinafter IAS 39) relating to the classification and measurement of financial instruments. IFRS 9 requires that financial assets will be classified into one of the following two categories: financial assets measured after initial recognition at fair value and financial assets measured after initial recognition at amortized cost. The decision on classification is made on the date of initial recognition, based on the entity's business model and the characteristics and the projected contractual cash flows from the asset. As to financial liabilities, IFRS 9 retains most guidance of IAS 39, with the main change being that entities with financial liabilities designated at fair value through profit or loss (FVTPL) recognize changes in the fair value due to changes in the liability’s credit risk (own credit risk) directly in other comprehensive income (OCI), unless this creates an accounting mismatch.

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

As to amounts recognized as above in other comprehensive income, the income or loss will not be recycled. However, it is possible to transfer accumulated income or loss between equity items.

In December 2011, an amendment to IFRS 9 and IFRS 7 "Financial Instruments: Disclosures" (hereinafter the amendment). The amendment deferred the mandatory effective date of the IFRS 9 and the transition provision for implementation, and added certain disclosure requirements for the transition (hereinafter the additional disclosures).
According to IFRS 9 after the amendment, both parts of IFRS 9 will apply to annual periods commencing on January 1, 2015 and thereafter. Entities can elect to early adopt IFRS 9, but it is not permitted to adopt early the second part of IFRS 9 without implementing the first part of IFRS 9 on the same date. On the other hand, it is possible to early adopt the first part of IFRS 9 without being required to implement the second part of IFRS 9 on the same date.

Entities adopting IFRS 9 for reporting periods:

1) Prior to January 1, 2012 are neither required to restate comparatives on first-time implementation and provide the additional disclosures.
2) Beginning January 1, 2013 and prior to January 1, 2013 will be required to restate comparatives and provide the additional disclosures.
3) Beginning on January 1, 2013 or thereafter will not be required to restate comparatives but will be required to provide additional disclosures.

The Company is assessing the expected effect of IFRS 9 on the financial statements and the timing of adoption.

2) IFRS 13 "Fair Value Measurement" (hereinafter IFRS 13)

IFRS 13 aims to improve consistency and reduce complexity by providing a precise definition of 'fair value' and a single source of fair value measurement and disclosure requirements for use across IFRSs. The requirements do not extend the use of fair value accounting, but provide guidance on how it should be applied where its use is already required or permitted by other standards within IFRSs. IFRS 13 should be applied for annual periods commencing on January 1, 2013 or thereafter. Early adoption is permitted with a related disclosure. IFRS 13 is applied prospectively as of the beginning of the annual period in which it is initially applied. The disclosure requirements of the new guidance do not need to be applied in comparative information for periods before initial application of IFRS 13.

The Company is assessing the expected effect of IFRS 13 on the financial statements.

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 next financial year are in respect of impairment of intangible assets:

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

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

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amounts of cash generating units are based on Company's estimates as to the development of the drugs, 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 Deputy Chief Executive Officer Finance and Operations of the Company, who identifies and evaluates financial risks in close cooperation with the Company's Chief Executive Officer.

The Company's finance department is responsible for carrying out risk management activities in accordance with policies approved by its Board of Directors. The Board of Directors provides guidelines for overall risk management, as well as policies dealing with specific areas, such as exchange rate risk, interest rate risk, credit risk, use of financial instruments, and investment of excess cash. In order to minimize the risk exposure to market risk and credit risk the Company invested the majority of its cash balances in highly-rated bank deposits with maturities of less than a year, and the remaining balance is invested in high rated marketable securities.

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

(a) Market risks

Foreign exchange risk - the Company might be exposed to foreign exchange risk as a result of making payments to employees or service providers and investment of some liquidity in currencies other than the US dollar (i.e. the functional, reporting and presentation currency of the Company). The Company manages the foreign exchange risk by aligning the currencies for holding liquidity with the currencies of expected expenses, based on the expected cash flows of the Company. Had the functional currency of the Company been stronger by 5% against the NIS, assuming all other variable remained constant, the Company would have recognized an additional expense of $74 thousand and $393 thousand in profit or loss for the years ended, December 31, 2012 and 2011, respectively.

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

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

(b) Credit and interest risks

Credit and interest risk arises from cash and cash equivalents, deposits with banks as well as accounts receivable. A substantial portion of liquid instruments of the Company are invested in short-term deposits in highly-rated banks. The Company estimates that since the liquid instruments are mainly invested for the short-term and with highly-rated institutions, the credit and interest risk associated with these balances is immaterial.

(c) Liquidity risk

Prudent liquidity risk management implies 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 cash and cash equivalents and deposits). This is generally carried out based on the expected cash flows in accordance with practice and limits set by the management of the Company.

The Company is in an R&D stage and has not yet generated significant revenue from the sale of drugs 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.

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

The table presented below classifies the Company's financial liabilities into relevant maturity groupings based on the remaining period to the contractual maturity date. The amounts presented in the table represent the contractual undiscounted cash flows.

	Less than 1 year	Between 1 and 5 years	More than 5 years
	US dollars in thousands		
As of December 31, 2012:			
Accounts payable and Accrued expenses	1,078	-	-
As of December 31, 2011:			
Accounts payable and Accrued expenses	513	-	-
Royalty obligations to investors	-	1,929	1,143
	513	1,929	1,143

2) Capital risk management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders and to maintain an optimal capital structure to reduce the cost of capital. It should be indicated that the Company is in the development stage and has not yet generated significant revenue from the sale of drugs or from royalties.

3) Fair value estimation

The table below analyses financial instruments carried at fair value through profit of loss, by 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.

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

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.

As of December 31, 2012 and 2011, the financial instruments of the company presented at fair value are financial assets at fair value through profit or loss in the amounts of 1,065 and 1,564, accordingly. Those instruments are classified as level 1.

The following table presents the change in instruments measured at level 3 for the year ended December 31, 2011:

	Financial liabilities at fair value through profit or loss
	US dollars in thousands
Balance at January 1, 2011:	11,245
Amounts recognized in profit or loss	7,938
Conversion of the mandatory convertible Loans	(19,183)
Balance at December 31, 2011	-

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

b. Classification of financial instruments by Groups:

	Assets at fair value through profit or loss	Loans and receivables	Total
	US dollars in thousands		
As of December 31 ,2012:			
Cash and cash equivalents		16,814	16,814
Bank deposits		561	561
Financial assets at fair value through profit or loss	1,065		1,065
Receivables (except prepaid expenses)		84	84
	1,065	17,459	18,524
As of December 31 ,2011:			
Cash and cash equivalents		14,070	14,070
Bank deposits		3,086	3,086
Financial assets at fair value through profit or loss	1,564		1,564
Receivable (excluding prepaid expenses)		19	19
	1,564	17,175	18,739

	Financial liabilities at amortized cost
As of December 31, 2012:	
Accounts payable and accrued expenses	1,078
As of December 31, 2011:	
Accounts payable and accrued expenses	513
Royalty obligations to investors	886
	1,399

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

c. Composition of financial instruments by currency:

As of December 31, 2012:

	Dollar	Foreign currency (mainly NIS)	Total
	US dollars in thousands		
Assets:			
Cash and cash equivalents	15,849	965	16,814
Bank deposits	473	88	561
Financial assets at fair value through profit or loss	-	1,065	1,065
Receivable (except prepaid expenses)	-	84	84
	16,322	2,202	18,524
Liabilities:			
Accounts payable and accrued expenses	734	344	1,078
	15,588	1,858	17,446

As of December 31, 2011:

	Dollar	Foreign currency (mainly NIS)	Total
	US dollars in thousands		
Assets:			
Cash and cash equivalents	9,857	4,213	14,070
Bank deposits	3,000	86	3,086
Financial assets at fair value through profit or loss	-	1,564	1,564
Receivables (excluding prepaid expenses)	-	19	19
	12,857	5,882	18,739
Liabilities:			
Accounts payable and accrued expenses	338	175	513
Royalty obligations to investors	886	-	886
	1,224	175	1,399
	11,633	5,707	17,340

NOTE 5 - CASH AND CASH EQUIVALENTS AND BANK DEPOSITS:

a. Cash and Cash Equivalents:

	December 31	
	2012	2011
	US dollars in thousands	
Cash in bank	6,703	3,030
Short-term bank deposits	10,111	11,040
	16,814	14,070

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

b. Bank Deposits

The bank deposits are for terms of three months to one year and bear interest at annual rates of between 0.95% - 1.83%.

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

These financial assets as of December 31, 2012 and 2011 represent a portfolio of Israeli, NIS denominated marketable securities, which is managed and valued by the Company based on the fair value of all portfolio securities.

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

NOTE 7 - PREPAID EXPENSES AND RECEIVABLES:

	December 31	
	2012	2011
	US dollars in thousands	
Prepaid expenses	114	70
Government institutions	81	16
Other	3	3
	198	89

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

The maximal exposure to credit risks as of statement of the financial position date in respect of the receivable balances is the fair value of the entire receivables in respect of those balances net of nonmonetary balances (arising from prepaid expense). The Company does not hold collaterals in connection with these receivables.

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	
	2012	2011	2012	2011	2012	2011
	US dollars in thousands					
Office furniture and equipment (including computers)	70	65	22	9	48	56
Leasehold improvements	82	82	17	6	65	76
	152	147	39	15	113	132

NOTE 9 - INTANGIBLE ASSETS

The intangible assets represent R&D assets with respect to intellectual property rights in drugs purchased by the Company under licensing agreements or under asset acquisition agreements. The changes in those assets are as follows:

	Year ended December 31		
	2012	2011	2010
	US dollars in thousands		
Cost:			
Balance at beginning of period	1,245	1,200	100
Additions during the period	100	45	1,100
Balance at end of period	1,345	1,245	1,200

For further details, see note 13.

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 employer dismissed or retiring from their employ 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 2012 and 2011were $58 thousand and $51 thousand, respectively. Of those amounts, approximately half were charged to general and administrative expenses and half to research and development expenses.

NOTE 11 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

	December 31	
	2012	2011
	US dollars in thousands	
Trade payables	313	337
Expenses payable	571	52
Employees and employees institutions	150	85
Government institutions	44	39
	1,078	513

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

NOTE 12 - MANDATORY CONVERTIBLE LOANS AND ROYALTY OBLIGATIONS TO INVESTORS:

a. First convertible loans:

1) In August 2010, the Company, raised $3.5 million from investors (part of which were shareholders) in the form of convertible loans ("the first convertible loans"). The loans were denominated in dollars, bore interest at an annual rate of 8%, were convertible into the Company's ordinary shares and warrants, and in any case were not repayable in cash.

2) Under the first convertible loans agreement, in addition to the terms described in (1) above, the investors were entitled to royalties equal to 5% of future revenue from two therapeutic candidates purchased by the Company, in connection with both Net Sales and advances or milestones as part of licensing transaction as follows:

   a) Royalty income on net sales and/or royalty income on sales by licensed reseller and/or distributors were to be paid over 5 years upon the commencement of commercial sales of one of the therapeutic candidates.

   b) Royalty income from down payments and milestones were to be paid over a period of 5 years commencing from August 11, 2010 (the closing date of the first convertible loan).

   The right to royalties also existed following any conversion of the convertible loans.

NOTE 12 – MANDATORY CONVERTIBLE LOANS AND ROYALTY OBLIGATION TO INVESTORS (continued):

3) The consideration received for the first convertible loans was divided into two components for measurement purposes mandatory convertible loans based on their fair value and the balance was assigned to royalties' obligation which is carried at amortized cost (using the embedded effective interest on the date of issuance).

The effective interest rate on the royalties' obligation is 27.98%.

b. Second convertible loans

In November 2010, the Company completed an additional capital round raising $7.6 million in mandatory convertible loans to Israeli and foreign investors (hereinafter - the second convertible loans). The terms of the loans are the same as the terms of the first convertible loans, except for the entitlement for royalties.

c. Conversion of the mandatory convertible loans

Based on the convertible loans terms, just prior to the Company's Initial Public Offering, all of the mandatory convertible loans were automatically converted into 19,818,314 Company's ordinary shares and to warrants. The conversion ratio was $0.5721 of convertible loan (and all accrued interest) into 1 ordinary share, as stipulated by the loans agreements. As to the terms of the warrants, see note 15c(1).

d. Acquisition and termination of the royalty rights

On December 26, 2012, a General Shareholders Meeting of the Company approved the acquisition and termination of the royalty rights granted to investors pursuant to the August 2010 mandatory convertible loan agreement in exchange for the issuance of an aggregate of 2,317,186 Company ordinary shares, with each investor entitled to receive a number of shares on a pro-rata basis in accordance with their respective royalty rights. The royalty obligation was presented as amortized cost. At date of the approval the Company got relief from its royalty obligations and the associated liability was derecognized. The fair value of the shares to be issued is $2,359 thousand. The increase, prior to settlement, in the royalty obligations amortized cost resulted primarily from interest accretion and from management's estimate with regard to future royalties. The excess between the fair value of the shares over the amortized cost of the liability as of the approval date was recorded on the statement of comprehensive loss under financial expenses. Since the shares were not issued as of December 31, 2012, the fair value of the shares is included in equity under ordinary shares to be issued. The shares were issued on January 10, 2013.

NOTE 13 - COMMITMENTS:

a. Agreements to purchase intellectual property of drugs:

1) On November 18, 2009, the Company entered into an agreement with a Danish company to provide the Company with the exclusive rights to a drug that treats congestive heart failure, left atrium dysfunction and high blood pressure. According to the agreement, the Company will pay the Danish company an initial amount of $100 thousand, and later will transfer to the Danish company additional amounts of up to $700 thousand based on achieving regulatory milestones as agreed between the parties. Under the agreement, the Company agreed to pay the Danish company royalties at 30% of the Company's revenues generated by the drug, less specified amounts incurred in the 12 years from the date marketing begins, or until the patent expires, whichever is the earliest in each country where the drug will be marketed. According to the agreement, the Company will obtain exclusive global rights for completing development and for production, commercialization, marketing and selling the drug. Through December 31, 2012, the Company paid the Danish company $100 thousand.

2) On May 2, 2010, the Company entered into an agreement with a US publically traded company that grants the Company an exclusive license to use rights in a drug that treat chemotherapy, radiation and surgery induced nausea and vomiting. Under the agreement, the Company will pay the US company an initial amount of $100 thousand, and will later pay the US company an amount of up to $500 thousand, based on regulatory milestones set between the parties. Under the agreement, the Company agreed to pay the US company royalties equal to 8% of Company revenues from selling the drug, less certain amounts as detailed in the agreement, during a period which is the shorter of: (1) expiry of the last patent granted under the license; (2) ten years from the beginning of marketing the drug by the Company or any third party; and (3) the date in which the amount of all payments to the US company reach $30 million. Through December 31, 2012, the Company paid $100 thousand to the US company.

3) On August 26, 2010, the Company entered into an agreement with a Canadian based company which is traded in the US and Canada, to a co-develop a drug for the treatment of migraines. Under the agreement, the Company paid the Canadian company an initial amount of $500 thousand on the date of signing the agreement, and later will transfer additional amounts of up to $800 thousand based on achieving milestones as agreed between the parties. In addition, the Company will participate in additional drug research and development costs of up to $934 thousand.

Under the agreement, the Company will pay a 60% royalty to the Canadian company for the first $2 million in revenue. For revenues beyond the $2 million, the Company will pay royalties at 20% - 40% of the Company's income from the drug. The agreement is for an indefinite period. Through December 31, 2012, the Company paid the Canadian Company for the license of the drug under the agreement a total of approximately $600 thousand. In addition, through December 31, 2012, the Company participated in the drug research and development costs in the amount of $800 thousand that was recorded in the statements of comprehensive loss under research and development expenses.

NOTE 13 - COMMITMENTS (continued):

4) On August 11, 2010, the Company entered into an agreement with an Australian company listed on the Australian stock exchange in an asset purchase agreement to acquire intellectual property of the Australian company relating to three therapeutic candidates for the treatment of intestinal and digestion conditions. Under the purchase agreement, the Company will pay the Australian company an initial amount of $500 thousand and later, another payment in the range of 7% - 20% of Company revenues from the sale of the drugs. Through December 31, 2012, the Company paid the Australian company a total of $500 thousand.

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

   Under the agreement, in addition to an initial payment of $45 thousand, the Company will pay the Academic Institution royalties in the range of 7% - 20% of the amount received by the Company from revenues resulting from rights to the test and other potential payments in immaterial amounts. Through December 31, 2012, the Company paid the Academic Institution a total amount of $45 thousand.

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

6) In October 2012 a term sheet was entered into between the Company and a US pharmaceutical company for the acquisition by the Company of exclusive rights to two proprietary extended release therapeutic candidates. The signing of a detailed agreement is subject to due diligence to be conducted by the Company. For the first extended release therapeutic candidates, the US company would be entitled to a royalty of between 20%-50% depending on distribution channel and territory and for the second the US company would be entitled to royalty of 8%-15% depending on distribution channel.

b. Operating lease agreement

The Company entered into operating lease agreement for the offices it uses. The agreement will expire on February 28, 2016 (hereafter – date of end of rental period) with an option to extend the rental period by additional 3 years. The projected rental payments until the end of the rent period, at rates in effect at December 31, 2012, are $155 thousand per year.

As of December 31, 2012 an amount of $75 thousand was deposited with a bank to secure the lease payments.

NOTE 14 - INCOME TAX:

a. Measurement of results for tax purposes

The results of the Company are measured for tax purposes in NIS and in accordance with Accounting Principles Generally Accepted in Israel (Israeli GAAP). These financial statements are prepared in dollars and in accordance with IFRS. The difference between the NIS and the exchange rate of the dollar and differences 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 the normal corporate tax rate. Corporate tax rate for 2012 was 25% (2011 - 24%).

On December 6, 2011, the Law for Changing the Tax Burden (Legislative Amendments), 2011, was published in Reshumot (the official gazette of the Israeli government), halting the phased reduction in corporate tax rates that was enacted in 2009, and setting the corporate tax rate at 25% in 2012 and thereafter.

c. Carry forward losses

The balance of carry forward losses as of December 31, 2012 is $10 million. These tax loss carry forwards 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 carry forward losses since their utilization is not expected in the foreseeable future.

d. Deductible temporary differences

The amount of cumulative deductible temporary differences, other than loss carry forwards (as mentioned in c. above), for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2012 and 2011, were $4.5 million and $2.5 million, respectively. These temporary differences have no expiration dates.

e. Tax assessments

The Company has not been assessed for tax purposes since its incorporation.

NOTE 15 - EQUITY:

a. Share capital:

1) Composition

Company share capital is composed of ordinary shares and of NIS 0.01 par value, as follows:

	Number of shares	
	December 31	
	2012	2011
	In thousands	
Authorized share capital	100,000	100,000
Issued and paid share capital	52,990	52,320

As of December 31, 2012, the market price on the Tel Aviv Stock Exchange of the Company's ordinary shares was $1.02. As of December 31, 2012, the Company's ADSs were listed on the NASDAQ Capital Market and their trading commenced on January 7, 2013, Each ADSs represents 10 ordinary shares.

2) Rights attached to Company shares:

Ordinary shares provide holders the rights to participate and vote in shareholders meetings, a right to appoint directors, a right to receive a share of earnings and a right to participate in remaining assets upon liquidation after convertible preferred shares.

3) Changes in share capital:

(a) On January 27, 2011, the general meeting of the Company ratified replacing the existing articles of incorporation with a new one that better fits a public company. Under the new articles, the outstanding preferred shares were converted into ordinary shares and the authorized share capital was consolidated into a single type of ordinary shares, NIS 0.01 par value per share.

(b) On January 16, 2011, the Company's Board of Directors resolved to increase the issued and outstanding share capital of the Company to NIS 1 million, divided into 100,000,000 ordinary shares, NIS 0.01 par value per share..

(c) On January 16, 2011, the Board of Directors of the Company resolved to distribute bonus shares based on a 1:10 ratio, such that each shareholder received 9 bonus shares for each share held by that shareholder. The distribution of bonus shares was performed on February 3, 2011.

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

4) In September 2009 and November 2009, the Company entered into investment agreements with a number of investors. Under these agreements, the Company issued to the investors 649,673 convertible preferred shares and 129,935 warrants exercisable into convertible preferred shares. Issuance proceeds amounted to $975 thousand and were divided between convertible preferred shares and warrants.

   In January 2011, all warrants that were issued to investors during 2009 were exercised into preferred shares. Accordingly, the Company issued 1,299,347 convertible preferred shares for $584 thousand.

5) As to the conversion of all mandatory convertible loans into 19,818,314 ordinary shares and to warrants - see note 12c.
   In June to August 2011, the Company received notifications on the exercise of part of the above warrants. Accordingly, the Company issued 803,667 ordinary shares for $592 thousand, net of issuance costs.

6) As to the issuance of 14,302,300 ordinary shares and 7,151,150 warrants in a public offering - see b. below.

7) In April to August 2012, the Company received notifications on the exercise of the 600,000 non-tradable options issued to service providers and a notice on the exercise of 70,000 options that were issued to a consultant in August 2010. Accordingly, the Company issued 670,000 ordinary shares for $302 thousand.

8) In December 2012, the Company entered into investment agreements with a group of investors for the issuance of 6,481,280 ordinary shares and 3,240,640 warrants exercisable into ordinary shares in consideration of an aggregate investment amount of approximately $6.56 million. Through December 31, 2012, the Company received with respect to the investment agreements a total of approximately $6,248 thousand, net of direct issuance cost of $ 212 thousand. This amount was allocated to ordinary shares to be issued and warrants based on their fair value. As of December 31, 2012, the shares were not issued, thus the cash received in respect thereof is included in equity under ordinary shares to be issued. The shares were issued on January 10, 2013. As to the terms of the warrants - see c(3) below.

b. Public offering

On February 3, 2011, the Company completed a public offering of securities on the TASE under a prospectus dated February 2, 2011. As part of the offering, the Company issued 14,302,300 Ordinary shares and 7,151,150 warrants (Series 1). The price of a package of 100 shares and 50 warrants was NIS 361 ($98.1 at the exchange rate on the date of issuance).

Issuance proceeds (gross) amounted to $14 million, less direct issuance costs of $1.3 million, thereby amounting to $12.7 million. Issuance proceeds (net) was allocated to the issued shares and warrants based on the fair value of each of these equity instruments and was recognized in equity.

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

c. Warrants:

1) The warrants that were issued to investors as part of the conversion of the mandatory convertible loans are exercisable on any trading day until expiration. Expiration date of the warrants will be the earlier of: (1) three years after the date of issuance (February 3, 2011) or (2) a transaction for transferring control over the company, as this term is defined in the convertible loan agreements.

As of December 31, 2012, warrants outstanding are exercisable into 3,180,861 ordinary shares for a total exercise price of $2.7 million. In accordance with the term of the warrants, the number of shares resulting from the exercise of the warrants is based upon the date of exercise. The number of the shares is subject to reduction based on the time elapsed from the date of issuing the warrants to the exercise thereof.

2) The warrants (Series 1) are exercisable since their listing and through February 2, 2014, with each warrant (Series 1) is exercisable into one ordinary share for $1.03 since the date of listing and through February 2, 2012, and for $1.25 from February 3, 2012 to February 2, 2014. The warrants (Series 1) not exercised by February 2, 2014 will expire.

As of December 31, 2012, 7,151,150 warrants (Series 1) are outstanding.

3) The warrants issued under the investment agreement, as described in a(8) above, are exercisable unto 3,240,640 ordinary shares, for a period of 24 months. Exercise price of each warrant ranges from $1.18 to $1.54, depending on the date of exercise.

NOTE 16 - SHARE-BASED PAYMENTS

On May 30, 2010, the general meeting of shareholders approved the option plan of the Company for 2010 (the "Option Plan"), after being approved by the Board of Directors on February 2, 2010. The terms and conditions of the grants were determined by the Board of Directors and according to the plan. The Company is allowed to allocate 3,080,000 (adjusted to reflect the distribution of bonus shares) options to employees and directors.

On August 6, 2010, the Company's Board of Directors approved a grant of 500,000 (adjusted to reflect the distribution of bonus shares) options to Company service providers beyond the scope of the Company's Option Plan.

NOTE 16 - SHARE-BASED PAYMENTS

On November 1, 2010, the Board of Directors resolved to enlarge the Option Plan of the Company by 7,000,000 additional options (adjusted to reflect the distribution of bonus shares). In addition, on January 19, 2011, the Board of Directors resolved to increase the Option Plan of the Company such that the Company is permitted to grant an additional 12,000,000 options of the Company.

a. Following is information on options granted in 2011:

	Number of options granted					
	According to option plan of the Company		To service providers, not under option plan of the Company			The fair value of options on date of grant in US$ thousands
Date of grant	Other than directors (1)	To directors (1)	(2)	Total	Exercise price to 1 ordinary share ($)	(3)
January 2011	*4,900,000	1,310,000		6,210,000	0.50	3,992
January 2011	-	-	100,000	100,000	0.55	43
March 2011	120,000	-	-	120,000	1.05	66
May 2011		300,000	-	300,000	1.05	164
August 2011	350,000	-	-	350,000	0.69	96
	5,370,000	1,610,000	100,000	7,080,000		4,361

* 2,760,000 options were allocated to officers who also serve as directors.

1) The options will vest as follows: 1/3 of the options after one year from the date of grant, and subsequently, 1/12 of the shares at the end of each calendar quarter over the following two years. Unexercised options will expire on the earlier of: a sale of all or most Company assets or shares; the Company being merged or consolidated into another Company;

   or after 7 years since their date of grant. In addition, in certain circumstances, the Company's Board of Directors has the authority to decide on an early vesting of some of the options granted to the option holder or compensating the option holder, including by extending the life of the options. Each of the options is exercisable at a ratio of 1 option to 1 ordinary share.

2) The options granted not under the Company's Option Plan will vest as follows: half after 6 months since the date of grant and the remainder after one year since the date of grant. Unexercised options will expire on the earlier of : a sale of all or most Company assets or shares; the Company being merged or consolidated into another Company; or an initial public offering of Company shares through September 1, 2012. On January 16, 2011, the Board of Directors approved an amendment indicating that the options will not expire automatically upon a public offering of Company shares.

   Each of these options is exercisable at a ratio of 1 option to 1 ordinary share.

NOTE 16 - SHARE-BASED PAYMENTS (continued):

3) The fair value of the options on the date of grant was computed using the binomial model. The underlying data use for computing the fair value of the options are mainly as follows: ordinary share price, based on share price in the public offering: $0.53-$0.97, expected volatility: 68.4%-72.8%, risk-free interest rate: 1.65%-2.89% (the risk-free interest rate is determined based on rates of return on maturity of unlinked US treasury bonds with time to maturity that equals the average life of the options); expected dividend at $0 and expected life to exercise of 7 years.

b. Options granted in 2012:

	Number of options granted					
	According to option plan of the Company		To service providers, not under option plan of the Company	Total	Exercise price to 1 ordinary share ($)	The fair value of options on date of grant in US$ thousands (2)
Date of grant	Other than directors (1)	To directors (1)				
January 2012	825,000	-		825,000	0.72	289
February 2012	*1,000,000	-	-	1,000,000	0.72	271
June 2012	200,000	-	-	200,000	0.70	75
	2,025,000	-	-	2,025,000		635

*the options were allocated to officers who also serve as directors.

1) The options will vest as follows: In the first year, 1/3 of the options after one year from the date of grant, or 1/6 of the total number of options at the end of each calendar half year. In the second and third years, 1/6 of the remaining options at the end of each calendar half year or 6 month period.

2) The fair value of the options on the date of grant was computed using the binomial model. The underlying data use for computing the fair value of the options are mainly as follows: ordinary share price, based on share price in the public offering: $0.52-$0.675, expected volatility: 67.53%-68.49%, risk-free interest rate: 1.06%-1.43% (the risk-free interest rate is determined based on rates of return on maturity of unlinked US treasury bonds with time to maturity that equals the average life of the options); expected dividend at $0 and expected life to exercise of 7 years.

NOTE 16 - SHARE-BASED PAYMENTS (continued):

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

	Year ended December 31			
	2012		2011	
	Number of options	Weighted average of exercise price	Number of options	Weighted average of exercise price
Outstanding at beginning of year	10,660,000	0.43	3,580,000	0.22
Exercised	(670,000)		-	-
Granted	2,025,000	0.72	7,080,000	0.54
Outstanding at end of year	12,015,000	0.47	10,660,000	0.43
Exercisable at end of year	7,816,667	0.38	2,443,750	0.24

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

December 31, 2012			December 31, 2011		
Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life	Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life
12,015,000	0.17-1.05	5.03	10,660,000	0.17-1.05	5.64

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

Year ended December 31		
2012	2011	2010
US dollars in thousands		
1,648	2,863	80

The remaining compensation expenses as of December 31, 2012 are $608 thousand and will be expensed in full by June 2015.

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 plan.

Options granted to option holder who are related parties of the Company are governed by Section 3(i) to the Ordinance.

NOTE 17 - RESEARCH AND DEVELOPMENT EXPENSES:

	Year ended December 31		
	2012	**2011**	**2009**
	US dollars in thousands		
Payroll and related expenses	529	468	45
Professional services	933	698	351
Share-based payments	862	1,384	20
Clinical trials	3,620	2,463	135
Patents expenses	240	193	120
Other	271	208	65
	6,455	5,414	736

NOTE 18 - GENERAL AND ADMINISTRATIVE EXPENSES:

	Year ended December 31		
	2012	**2011**	**2010**
	US dollars in thousands		
Payroll and related expenses	517	467	*266
Share-based payments	787	1,479	60
Professional services	879	301	112
Office related expenses	122	103	14
Other	296	132	66
	2,601	2,482	518

* Including a management fee of $180 thousand in 2010.

NOTE 19 - OTHER EXPENSES:

In the year ended December 31, 2010, the expenses were due to fees for recruiting investors.

NOTE 20 - FINANCIAL EXPENSES, net:

	Year ended December 31		
	2012	2011	2010
	US dollars in thousands		
Financial income:			
Fair value gain on financial assets at fair value through profit or loss	57	-	7
Income from changes in exchange rates	21	556	56
Other	119	14	2
	197	570	65
Financial expenses:			
Fair value losses on mandatory convertible loans	-	7,938	545
Accretion and settlement of royalty obligations to investors	1,473	168	327
Fair value losses on financial assets at fair value through profit or loss	-	29	-
Other	10	65	4
	1,483	8,200	876
Financial expenses - net	1,286	7,630	811

NOTE 21 - LOSS PER ORDINARY SHARE:

The basic loss per share is computed by dividing the Company's loss by the weighted average number of ordinary shares outstanding during the period.
The diluted loss per share is identical to the basic loss per share since the effect of potential dilutive shares in anti-dilutive.

Set forth below are data taken into account in the computation of loss per share:

	Year ended December 31		
	2012	2011	2010
Loss as reported in the financial statements (in thousands of dollars)	10,326	15,503	2,544
Weighted average of ordinary shares outstanding during the period (in thousands)	52,595	48,087	9,600
Basic and diluted loss per share (dollars)	0.20	0.32	0.27

NOTE 22 - RELATED PARTIES

a. Key management includes members of the Board of Directors, the Chief Executive Officer and Deputy Chief Executive Officer Finance and Operations.

	Year ended December 31		
	US dollars in thousands		
	2012	2011	2010
Key management compensation:			
Salaries and other short-term employee benefits	373	467	86
Post-employment benefits	44	48	8
Share-based payments	974	1,814	50
Other long-term benefits	22	25	4
Transactions with Key management:			
Accretion and settlement of royalty obligations to investors	637	73	146
Fair value on mandatory convertible loans	-	1,697	139

b. Balances with related parties:

	December 31	
	2012	2011
	US dollars in thousand	
Current liabilities - credit balance in "accounts payable"	131	79
Noncurrent liabilities:		
	-	-
Balance of Royalty obligations to investors *	-	383

* See also note 12.

NOTE 23 - EVENTS SUBSEQUENT TO DECEMBER 31, 2012:

In January 2013, the Company was informed by its Canadian service provider ("service provider") that a review by governmental authorities was successfully completed and, subject to a final approval, the service provider may be granted with incentives with regard to past research and development operations. Subject to such final approval, the Company is entitled to certain discounts in respect of past payments to the service provider for research and development services, estimated to be approximately $300 thousand with an additional future discount of approximately $200 thousand resulting from research and development operations in 2012.

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 (unofficial English translation) (incorporated by reference to Exhibit 1.1 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
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†	Exclusive License Agreement, dated November 18, 2009, by and between the Registrant and Egalet a/s (RHB-101) (incorporated by reference to Exhibit 4.1 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.2	Exclusive License Agreement, dated May 2, 2010, by and between the Registrant and SCOLR Pharma Inc. (RHB-102) (incorporated by reference to Exhibit 4.2 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.3†	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).
4.4†	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).
4.5†	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†	Fee Agreement, dated June 3, 2010, by and between the Registrant and ProSeed Capital Holdings CVA (incorporated by reference to Exhibit 4.6 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.7†	Termination of Fee Agreement, dated August 6, 2010, by and between the Registrant and ProSeed Capital Holdings CVA (incorporated by reference to Exhibit 4.7 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.8	Independent Consulting Agreement, dated as of August 23, 2010, by and between the Registrant and R.E. Investments (incorporated by reference to Exhibit 4.8 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.9	Form Loan Agreement, dated between June to August 2010, by and between the Registrant and each of the lenders (incorporated by reference to Exhibit 4.9 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).

4.10	Form of Term of Convertible Loan, dated August 31, 2010, by and between the Registrant and each of the lenders of the Loan Agreement Letter (incorporated by reference to Exhibit 4.10 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.11	Form of Convertible Loan Agreement, November 7, 2010 by and between the Registrant and each of the lenders (incorporated by reference to Exhibit 4.11 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.12†	Master Service Agreement, dated April 28, 2011, by and between the Registrant. and 7810962 Canada Inc. and amendments (incorporated by reference to Exhibit 4.12 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.13†	Manufacturing Agreement, dated April 28, 2011, by and between 7810962 Canada Inc. and the Registrant (regarding RHB-104) and amendments (incorporated by reference to Exhibit 4.13 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.14†	Manufacturing Agreement, dated October 21, 2012, by and between 7810962 Canada Inc. and the Registrant (regarding RHB-104) (incorporated by reference to Exhibit 4.14 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.15†	Clinical Services Agreement, dated June 15, 2011, by and between RedHill and 7810962 Canada Inc. and amendment (regarding RHB-104) (incorporated by reference to Exhibit 4.15 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.16	Underwriting Agreement made and entered on January 30, 2011, by and between the Registrant and to Poalim I.B.I Underwriting & Issuing Ltd. (Free English translation accompanied by the Hebrew original) (incorporated by reference to Exhibit 4.16 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.17	Form of Letter of Exemption and Indemnity adopted on January 2010, as amended in February 2012 (Free English translation accompanied by the Hebrew original) (incorporated by reference to Exhibit 4.17 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.18	Option Plan (2010), as amended (incorporated by reference to Exhibit 4.18 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.19	Form of Share Purchase Agreement, dated November 26, 2012 by and between the Registrant and each of the investors (incorporated by reference to Exhibit 4.19 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 18, 2012).
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.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

SIGNATURE

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

REDHILL BIOPHARMA LTD

By: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: Chief Executive Officer and Chairman of the Board of Directors

By: /s/ Ori Shilo
Name: Ori Shilo
Title: Deputy Chief Executive Officer Finance and Operations

Date: February 19, 2013

Exhibit 12.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

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)) 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) 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

c) 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 19, 2013

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

I, Ori Shilo certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd..;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

c) 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 19, 2013

/s/ Ori Shilo
Ori Shilo
Deputy Chief Executive Officer Finance and Operations

Exhibit 13

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RedHill Biopharma Ltd. (the "Company") on Form 20-F for the period ended December 31, 2012 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 19, 2013

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

/s/ Ori Shilo
Ori Shilo
Deputy Chief Executive Officer Finance and Operations