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

FORM 20-F

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

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2018

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 6473921, Israel
(Address of principal executive offices)

Micha Ben Chorin, Chief Financial Officer
21 Ha'arba'a Street, Tel Aviv 6473921, 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 Global Market
Ordinary Shares, par value NIS 0.01 per share (2)	NASDAQ Global 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: 283,686,908 Ordinary Shares

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

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files).

Yes ☒ No ☐

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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 ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

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 ☒

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Unless the context otherwise requires, all references to "RedHill," "we," "us," "our," the "Company" and similar designations refer to RedHill Biopharma Ltd., a limited liability company incorporated under the laws of the State of Israel, and its direct and indirect subsidiaries, including RedHill Biopharma Inc., a wholly-owned subsidiary incorporated in Delaware in January 2017. The term "including" means "including but not limited to", whether or not explicitly so stated. The term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$", "$" or "U.S." refer to U.S. dollars, the lawful currency of the United States of America. Our functional and presentation currency is the U.S. dollar. Unless otherwise indicated, U.S. dollar amounts herein (other than amounts originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of February 25, 2019 ($1 = NIS 3.605). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated. Foreign currency transactions in currencies other than U.S. dollars are translated in this Annual Report into U.S. dollars using exchange rates in effect at the date of the transactions.

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

FORWARD-LOOKING STATEMENTS

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

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

- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to obtain additional financing;
- our receipt and timing of regulatory clarity and approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the initiation, timing, progress, and results of our research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts, as well as the extent and number of additional studies that we may be required to conduct;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our reliance on third parties to conduct key portions of our clinical trials, including data management services, and the potential for those third parties to not perform satisfactorily;
- our ability to establish and maintain corporate collaborations;
- that products we promote or commercialize may be withdrawn from the market by regulatory authorities and our need to comply with continuing laws, regulations and guidelines to maintain clearances and approvals for our products;

- our ability to acquire products approved for marketing in the U.S. that achieve commercial success and to maintain our own marketing and commercialization capabilities;
- the research, manufacturing, clinical development, commercialization, and market acceptance of our therapeutic candidates or commercial products;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in research, preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business, therapeutic candidates and commercial products;
- the impact of other companies and technologies that compete with us within our industry;
- our estimates of the markets, their size, characteristics and their potential for our therapeutic candidates and commercial products and our ability to serve those markets;
- 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 or violating the intellectual property rights of others;
- parties from whom we license or acquire our intellectual property defaulting in their obligations towards us;
- the failure by a licensor or a partner of ours to meet their respective obligations under our acquisition, in-license or other development or commercialization agreements or renegotiate the obligations under such agreements, or if other events occur that are not within our control, such as bankruptcy of a licensor or a partner;
- our ability to implement network systems and controls that are effective at preventing cyber-attacks, malware intrusions, malicious viruses and ransomware threats; and
- the impact of the political and security situation in Israel and in the U.S. on our business.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following table sets forth our selected financial data, which is derived from our financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. We have derived the selected financial data as of December 31, 2018, and 2017 and for the years ended December 31, 2018, 2017, and 2016 from our audited financial statements included elsewhere in this Annual Report on Form 20-F. We have derived the selected financial data as of December 31, 2016, 2015, and 2014 and for the years ended December 31, 2015, and 2014 from our financial statements not included in this Annual Report. You should read this selected financial data and other information provided in this Annual Report in conjunction with, and is qualified in its entirety by, our historical financial information including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report.

	Year Ended December 31				
	2018	2017	2016	2015	2014
Statements of Comprehensive Loss					
Net revenues	8,360	4,007	101	3	7,014
Cost of revenues	2,837	2,126	—	—	1,050
Gross profit	5,523	1,881	101	3	5,964
Research and development expenses, net	24,862	32,969	25,241	17,771	12,700
Selling, marketing and business development expenses	12,486	12,014	1,555	1,386	900
General and administrative expenses	7,506	8,025	3,848	2,748	3,111
Other (income) expenses	—	845	—	100	(100)
Operating loss	39,331	51,972	30,543	22,002	10,647
Financial income	678	6,505	1,548	1,124	319
Financial expenses	167	77	375	212	383
Financial (income) expenses, net	(511)	(6,428)	(1,173)	(912)	64
Loss and comprehensive loss	38,820	45,544	29,370	21,090	10,711
Loss per Ordinary Share (in U.S. dollars)					
Basic	0.17	0.26	0.23	0.19	0.12
Diluted	0.17	0.26	0.24	0.19	0.13
Weighted average number of Ordinary Shares used in computing loss per Ordinary Share	231,204,129	176,578,990	128,513,729	110,813,742	86,610,126
Weighted average number of Ordinary Shares used in computing diluted loss per share	231,204,129	176,578,990	128,808,543	111,714,566	87,222,188

	As of December 31 (U.S. Dollars, in thousands)				
	2018	2017	2016	2015	2014
Balance Sheet Data					
Cash and short-term investments	53,185	46,205	66,154	58,138	22,945
Working capital	46,407	39,846	62,459	54,996	24,299
Total assets	62,411	57,343	74,212	66,828	28,856
Total liabilities	11,225	12,278	11,511	6,751	3,845
Accumulated deficit	(169,086)	(132,944)	(89,635)	(61,944)	(42,218)
Equity	51,186	45,065	62,701	60,077	25,011

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report, including our financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares (the "Ordinary Shares") or our American Depositary Shares ("ADSs"). The risks and uncertainties described below in this annual report on Form 20-F for the year ended December 31, 2018 are not the only risks facing us. We may face additional risks and uncertainties not currently known to us or that we currently deem to be immaterial. Any of the risks described below or incorporated by reference in this Form 20-F, and any such additional risks, could materially adversely affect our reputation, business, financial condition or results of operations. In such case, you may lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

Since our incorporation in 2009, we have focused primarily on the development and acquisition of late-stage clinical development therapeutic candidates and more recently on the acquisition of rights to products for promotion and/or commercialization in the U.S. and we have a history of operating losses. We expect to incur additional losses in the future and may never be profitable.

Since our incorporation in 2009, we have focused primarily on the development and acquisition of late-stage clinical development therapeutic candidates. Most of our therapeutic candidates are in the late-stage clinical development and none of our therapeutic candidates is approved for sale. However, in December 2016 we obtained certain rights to promote, but not to sell or distribute, Donnatal® in certain U.S. territories pursuant to an exclusive agreement with a subsidiary of ADVANZ PHARMA ("ADVANZ") (f/k/a Concordia International Corp.). In 2017, we obtained certain rights to commercialize EnteraGam® (a prescription medical food product) in the U.S. and certain rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in certain U.S. territories, and in 2018 we obtained exclusive U.S. rights to co-promote Mytesi® (crofelemer 125 mg delayed-release tablets) in certain U.S. territories for the approved indication in people living with HIV/AIDS with respect to certain gastroenterologists and other healthcare practitioners.

Most of our therapeutic candidates will require additional clinical trials before we can obtain the regulatory approvals in order to initiate commercial sales of them, if at all. We have incurred losses since inception, principally as a result of research and development, selling, marketing and business development, and general and administrative expenses in support of our operations. We experienced net losses of approximately $38.8 million in 2018, $45.5 million in 2017, and $29.4 million in 2016. As of December 31, 2018, we had an accumulated deficit of approximately $169.1 million. We are expected to incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our therapeutic candidates, promoting Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, commercializing EnteraGam®, and prioritizing, selecting, and advancing other products that we may

promote or commercialize in the future. Our ability to generate sufficient revenues to sustain our business operations in accordance with our plan and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop our therapeutic candidates, obtain the required regulatory approvals in various territories and commercialize our therapeutic candidates, promote Donnatal®, Mytesi®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam® and products that we may acquire or for which we may acquire commercialization rights in the future. We may be unable to achieve any or all of these goals with regard to our therapeutic candidates, our commercial products or products we may commercialize. As a result, we may never achieve sufficient revenues to sustain our business operations in accordance with our plan or be profitable.

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 and rights to promote or commercialize products in certain U.S. territories, research and development, raising capital and recruiting scientific and management personnel and third-party partners. Except with respect to RHB-106 and related rights, which is out-licensed to Bausch Health Companies Inc. ("Bausch Health"), we have not yet demonstrated an ability to commercialize or obtain regulatory approval for our therapeutic candidates. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development or commercialization of our therapeutic candidates, promote Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, commercialize EnteraGam® and products that we may promote or commercialize in the future, obtain regulatory approvals, reimbursement by third-party payors, achieve market acceptance or competitive pricing for our therapeutic candidates or our current commercial products, Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and EnteraGam® (collectively, "our current commercial products"), and products that we may promote or commercialize in the future.

Our current working capital is not sufficient to complete our research and development with respect to any or all of our therapeutic candidates or to commercialize our products or products to which we have rights, including the promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialization of EnteraGam®. We will need to raise additional capital to achieve our strategic objectives of acquiring, in-licensing, developing and commercializing therapeutic candidates, promoting Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercializing EnteraGam® and other products that we may promote or commercialize in the future, and our failure to raise sufficient capital or on favorable terms would significantly impair our ability to fund our operations, develop our therapeutic candidates, promote products such as Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg or other products that we may promote in the future, commercialize EnteraGam® or the products we may commercialize in the future, attract development or commercial partners or retain key personnel.

As of December 31, 2018, we had cash and short-term investments of approximately $53.2 million, and as of December 31, 2017, we had cash and short-term investments of approximately $46.2 million. We have funded our operations primarily through public and private offerings of our securities. We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates, commercialization of in-licensed or acquired products, and we will also need to raise additional capital through equity or debt financing or non-dilutive financing. These amounts may not be sufficient to complete the research and development of all of our therapeutic candidates, and we are also not yet certain of the financial impact of our commercialization activities.

To date, our business has generated limited revenues and is not profitable. As we plan to continue expending funds in research and development, including clinical trials, as well as to continue to promote Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, commercialize EnteraGam® and acquire additional products, we will need to raise additional capital in the future through equity or debt financing or a non-dilutive 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 at all or on favorable terms, or securing a development or commercialization partner in the future as a result of, among other factors, our limited revenues from commercialization of the therapeutic candidates and promoting Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercializing EnteraGam® and products that we may

promote or commercialize in the future, as well as the inherent business risks associated with our company, our therapeutic candidates, our current commercial products and products that we may promote or commercialize in the future, and present and future market conditions. To the extent we are able to generate meaningful revenues from our current commercial products, we may still need to raise capital because the revenues from our current commercial products may not be sufficient to cover all of our operating expenses and may not be sufficient to cover our commercial operations expenses. In addition, global and local economic conditions may make it more difficult for us to raise needed capital or secure a development or commercialization partner in the future and may impact our liquidity. If we are unable to obtain sufficient future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research, development or commercialization programs for our therapeutic candidates or EnteraGam® or the promotion of Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and products that we may promote or commercialize in the future, any of which may have an adverse effect on our reputation, business, financial condition or results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

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

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

- the number of therapeutic candidates in development;
- the regulatory clarity and path of each of our therapeutic candidates;
- the progress, success, and cost of our clinical trials and research and development programs including manufacturing;
- our ability to successfully complete our clinical trials and research and development programs since the very advanced disease state and poor prognosis of the oncology patients in our oncology studies, including our ongoing Phase 2 cholangiocarcinoma study, make it particularly difficult to successfully treat the patients and to successfully complete the studies;
- the identification and acquisition of additional therapeutic candidates;
- the costs, timing, and outcome of regulatory review and obtaining regulatory clarity and approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of manufacturing, developing and maintaining sales, marketing, and distribution channels;
- our ability to successfully commercialize our therapeutic candidates, promote Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam® and products that we may promote or commercialize in the future, including through securing commercialization agreements with third parties and favorable pricing and market share or through securing and maintaining our own commercialization capabilities;
- the existence and entrance of generics into the market that could compete with our products and erode the profitability of the products we are promoting or commercializing;
- our ability to successfully commercialize products that we develop or acquire or for which we acquire commercialization rights; and
- our consumption of available resources, especially a more rapid consumption than currently anticipated, resulting in the need for additional funding sooner than anticipated.

Risks Related to Our Business and Regulatory Matters

If we or our development, co-promotional or commercialization partners are unable to obtain or maintain the U.S. Food and Drug Administration ("FDA") or other foreign regulatory clearance and approval for our therapeutic candidates or products we may promote or commercialize, we or our co-promotional or commercialization partners will be unable to commercialize our therapeutic candidates or products we may promote or commercialize.

To date, other than our limited experience in promoting Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercializing EnteraGam®, we have not marketed, distributed or sold any therapeutic candidate

or product. Several of the products that we currently promote or commercialize must obtain and maintain FDA and other foreign regulatory clearance and approval.

In June 2017, we commenced commercializing EnteraGam® in certain territories in the U.S., and in September 2017, we commenced promoting Esomeprazole Strontium DR Capsules 49.3 mg to gastroenterologists in certain U.S. territories. EnteraGam® is marketed as an FDA-regulated "medical food" product intended for the dietary management of chronic diarrhea and loose stools, which must be administered under medical supervision. The FDA could require that EnteraGam® obtain FDA approval in the future to remain in distribution in the United States if the FDA disagrees with the classification of EnteraGam® as a medical food.

In June 2017, we commenced promoting Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) in the U.S. Donnatal® is an anticholinergic and barbiturate combination drug product used as an adjunctive therapy for irritable bowel syndrome ("IBS"), a condition characterized by abdominal pain, bloating, and diarrhea or constipation. It may also be used as an adjunctive therapy for acute enterocolitis and duodenal ulcers.
Although we have certain rights to promote Donnatal® in certain U.S. territories, which is currently included in the FDA Drug Efficacy Study Implementation ("DESI") review program, we cannot guarantee that our co-promotion partner will continue to be allowed to sell or promote Donnatal® in the U.S. without future regulatory developments that may lead to the FDA requiring Donnatal® to seek a U.S. New Drug Application ("NDA") approval. See "—We or our co-promotional or commercialization partners are subject to risks related to the regulatory environment of the Drug Efficacy Study Implementation review program with respect to Donnatal®." In addition, future regulatory developments may lead to a loss of the right to commercialize EnteraGam® or the right to promote Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg.

Esomeprazole Strontium DR Capsules 49.3 mg is an FDA-approved proton pump inhibitor ("PPI") drug product indicated for adults for the treatment of gastroesophageal reflux disease ("GERD"), risk reduction of NSAID-associated gastric ulcer, *Helicobacter pylori* ("*H. pylori*") eradication to reduce the risk of duodenal ulcer recurrence and for pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

In July 2018, we commenced promoting Mytesi® (crofelemer), an FDA-approved anti-diarrheal prescription drug indicated for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy (ART).

Currently, we have seven therapeutic candidates, most in late-clinical stage development, for which we ultimately plan to seek FDA approval: TALICIA® (proposed tradename for RHB-105, if approved) for the treatment of *H. pylori* infection with two positive Phase 3 studies; RHB-104 for the treatment of Crohn's disease with positive top-line results from a first Phase 3 study and a completed proof-of-concept Phase 2a study for multiple sclerosis; RHB-204, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria ("NTM") infections; RHB-106 (out-licensed to Bausch Health) for bowel preparation; BEKINDA® (proposed tradename for RHB-102, if approved) with positive results from a first Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; YELIVA® (proposed tradename for ABC294640, if approved), with an ongoing Phase 2a study for cholangiocarcinoma and other ongoing studies; and RHB-107 (Upamostat; formerly MESUPRON), targeting cancer and inflammatory GI diseases. Our therapeutic candidates are subject to extensive governmental laws, regulations, and guidelines relating to development, clinical trials, manufacturing, marketing, promotion, and commercialization of pre- and post-approval prescription 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 maintaining, or the failure to obtain or maintain, required regulatory clearances and approvals will increase our costs and materially adversely affect our ability to generate meaningful revenues. Any regulatory clearance or approval to market a therapeutic candidate, our current commercial products, or other products that we may promote or commercialize may be subject to limitations on the indicated uses for marketing or may impose restrictive conditions of use, including cautionary information, thereby altering or eliminating the size of the market for the therapeutic candidate, our current commercial products, or other products that we may promote or commercialize in the future. We also are, and will be, subject to numerous regulatory requirements from both the FDA and other foreign regulatory authorities that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. Moreover, clearance or approval by one regulatory authority does not ensure clearance or approval by other regulatory authorities in separate jurisdictions. Each jurisdiction may have different approval processes

and requirements and may impose additional testing, development and manufacturing requirements for our therapeutic candidates, our current commercial products and products that we may promote or commercialize in the future.

Additionally, the FDA or other foreign regulatory authorities may change their clearance or approval policies or adopt new laws, regulations or guidelines in a manner that materially delays or impairs our ability to obtain the necessary regulatory clearances or approvals or our ability to commercialize our therapeutic candidates, promote Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, commercialize EnteraGam® and products that we may promote or commercialize in the future.

We may encounter delays in receipt of FDA approval, if any, for commercialization of TALICIA ® due to CMC, clinical, regulatory, supply or other issues.

We may encounter significant delays in receipt of FDA approval, if any, for commercialization of TALICIA ®. For example, the FDA may determine that the chemistry, manufacturing and controls ("CMC") of TALICIA ® are not satisfactory due to the manufacturing standards of the products or that additional CMC work, information or quality assurances are needed. The FDA may also consider the clinical studies conducted with TALICIA ® to date and the additional information provided to be inadequate, or insufficient, or require us to provide additional information, which may require us to conduct additional studies or otherwise significantly delay potential FDA approval of the NDA for TALICIA ®, if at all. In addition, we rely on the current manufacturer of TALICIA® for the manufacture of validation and registration batches in support of our potential submission of an NDA with the FDA. In addition, we rely on suppliers of active pharmaceutical ingredients and excipients. We cannot guarantee that our manufacturer, suppliers or other vendors will be able to perform as required, will not terminate their agreements with us, or otherwise will not perform satisfactorily. The delay in identifying, engaging, qualifying and training an alternative manufacturer or suppliers may be extended, leading to a significant delay. Furthermore, the FDA may also change its clearance or approval policies or adopt new laws, regulations or guidelines in a manner that materially delays or impairs our ability to obtain approval of the NDA for TALICIA®.

If any of these or other issues occur, we may face substantial additional expenses and otherwise experience delays in obtaining potential FDA approval of the NDA for TALICIA ® or may never obtain the FDA approval of the NDA for TALICIA®.

We or our co-promotional or commercialization partners are subject to risks related to the regulatory environment of the Drug Efficacy Study Implementation review program with respect to Donnatal®.

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

Based on our review of docketed correspondence with the FDA, our co-promotion partner, ADVANZ, is currently a party to the unresolved Notice of Opportunity Hearing for anticholinergic and barbiturate combination drug products. We make no assurances that the FDA will not seek to begin a hearing process to remove Donnatal® from the market or otherwise remove Donnatal® from the market at any time. If this were to happen, it could have a material adverse effect on our reputation, business, financial condition or results of operations. It is also the case that other manufacturers would try to take advantage of the regulatory uncertainty to launch unauthorized copies of Donnatal®. Any delay or inaction by the FDA or other regulatory body to remove unauthorized copies of Donnatal® from the market will harm our ability to successfully promote this product.

Our offering of EnteraGam® as a "medical food" in the U.S. may be challenged by regulatory authorities.

EnteraGam® is sold under physician supervision in the U.S. as a "medical food" on the basis of its meeting the criteria for "medical foods" in the Federal Food, Drug, and Cosmetic Act (the "FDCA") and FDA regulations. The term "medical food" is defined in the FDCA as a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. "Medical foods" are not required to undergo premarket review or approval by the FDA.

To our knowledge, EnteraGam® meets the criteria for "medical foods" established by the FDCA, and, to our knowledge to date, the labeling and promoting of EnteraGam® is consistent with FDA regulatory requirements. However, our offering of EnteraGam® as a "medical food" could be challenged by the FDA. The FDA has previously issued warning letters to other companies challenging the classification of their products as "medical foods." These letters, along with guidance written by the FDA regarding medical foods, indicate that the FDA may be applying a more narrow interpretation of what qualifies as a "medical food." Given this enhanced focus on "medical food" companies, we cannot provide any assurance that we will not also receive such a letter or other potential enforcement action, and the FDA could take the position that EnteraGam® may not be lawfully sold in the U.S. as a "medical food." If such a challenge were to occur, we could incur significant costs responding to such an enforcement action or claim and defending the status of EnteraGam® as a "medical food" and ultimately litigation. If we or Entera Health Inc. ("Entera Health") are not able to demonstrate to the FDA's satisfaction that EnteraGam® meets the regulatory requirements for "medical foods," we would need to suspend further commercialization of EnteraGam® in, and could be required to withdraw EnteraGam® from, the U.S. market. The drug development process can be lengthy and may involve the expenditure of substantial monetary and other resources.
Furthermore, the process is uncertain, as there can be no assurance that EnteraGam® will ultimately be approved by the FDA as a drug. The U.S. is the only territory in which we have rights to commercialize EnteraGam®, and the cessation of such sales, even for a limited period, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Clinical trials and related non-clinical studies may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We or our development or commercialization partners may not be able to commercialize our therapeutic candidates and products we may promote or commercialize without completing such trials in accordance with the applicable regulatory standards, even products that may have already been cleared or approved for marketing.

We have limited experience in conducting and managing the clinical trials that are required to obtain regulatory approvals and commence commercial sales of our therapeutic candidates. Clinical trials and related non-clinical studies are expensive, complex, can take many years and have uncertain outcomes. We cannot predict whether we, independently or through third parties, will encounter problems with any of the completed, ongoing or planned clinical trials that will cause delays, including suspension of a clinical trial, delay of data analysis or release of the final report. The clinical trials of our therapeutic candidates may take significantly longer to complete than estimated. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could materially delay or prevent the obtainment of a regulatory approval and 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 or failure in securing clinical investigators or trial sites for the clinical trials;
- delays or failure in receiving import or other government approvals to ensure appropriate drug supply;
- delays or failure in obtaining institutional review board (IRB) and other regulatory approvals to commence or continue a clinical trial;
- expiration of clinical trial material before or during our trials as a result of delays, including suspension of a clinical trial, degradation of, or other damage to, the clinical trial material;
- negative or inconclusive results or results that are not sufficiently positive from clinical trials;

- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the FDA or other foreign regulatory authorities may require us to conduct additional clinical trials or studies in connection with therapeutic candidates in development as well as for products that have already been cleared and approved for marketing;
- inability to monitor patients adequately during or after treatment;
- inability to retain patients;
- lack of technology to support clinical trials results;
- problems with investigator or patient compliance with the trial protocols;
- a therapeutic candidate may not prove safe or efficacious; there may be unexpected or even serious adverse events and side effects from the use of a therapeutic candidate;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities;
- the results may justify only limited or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of a therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials, which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory clearances or approvals.

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

If we are unable to develop a diagnostic test for Mycobacterium avium paratuberculosis ("MAP"), this may adversely impact our ability to develop or obtain approval for RHB-104.

We are expecting to continue to advance the development program for a companion diagnostic for the detection of MAP bacteria in Crohn's disease patients in collaboration with several U.S. universities and with Q^2 Solutions. However, we do not know if and when a diagnostic test for MAP will become available. If we are unable to develop a diagnostic test for MAP, this may adversely impact our ability to develop or obtain regulatory approval to market RHB-104.

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

Our drug development programs and the potential commercialization of our therapeutic candidates and products that we may promote or commercialize will require additional cash to fund expenses. As such, our strategy includes either selectively partnering or collaborating with multiple pharmaceutical and biotechnology companies to assist us in furthering development or potential commercialization of our therapeutic candidates, promoting or commercializing products, in whole or in part, in some or all jurisdictions or through securing our own commercialization capabilities. With respect to potential new third-party partners for the development or commercialization of our therapeutic candidates and development or commercialization of products that we may promote or commercialize, we may not be successful in entering into collaborations with third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development, commercialization or promotion agreements or otherwise raise substantial additional capital to secure our own commercialization capabilities, we may have to limit the size or scope of our activities or we may have to

delay or terminate one or more of our development or commercialization programs. Any failure to enter into development or commercialization agreements with respect to the development, marketing and commercialization of any therapeutic candidate or failure to develop, market and commercialize such therapeutic candidate independently may have an adverse effect on our reputation, business, financial condition or results of operations.

Any collaborative arrangements that we have established or may establish may not be successful, or we may otherwise not realize the anticipated benefits from these collaborations, including our out-licensing of RHB-106, as well as our promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg or commercialization of EnteraGam®. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on such third parties to achieve results which may be significant to us. In addition, any future collaborative arrangements may place the development or commercialization of our therapeutic candidates, promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg or commercialization of EnteraGam® or products that we may promote or commercialize in the future, outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Each of our collaborative arrangements requires us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory, market research, intellectual property, and commercialization. We do not control these third parties, but we rely on such third parties to achieve results, which may be significant to us. To date, we have out-licensed one of our therapeutic candidates, RHB-106, and related rights to Bausch Health. We do not control Bausch Health, but we rely on Bausch Health to clinically develop and, ultimately, if approved, commercialize RHB-106 and related rights. In addition, with respect to Donnatal®, Mytesi®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and EnteraGam®, we rely on ADVANZ, Napo Pharmaceuticals, Inc. ("Napo"), ParaPRO LLC ("ParaPRO") and Entera Health, respectively, as the party responsible for, among others, the manufacture, supply, generation of product information, and other operating responsibilities.

Relying upon collaborative arrangements to develop and commercialize our therapeutic candidates, such as RHB-106, products we promote, such as Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and EnteraGam®, which we commercialize, and other products that we may promote or commercialize in the future, subjects us to a number of risks, including but not limited to the following:

- our collaborators may default on their obligations to us and we may be forced to either terminate, litigate or renegotiate such arrangements;
- our collaborators may have claims that we breached our obligations to them which may result in termination, renegotiation, litigation or delays in performance of such arrangements;
- we may not be able to control the amount and timing of resources that our collaborators may devote to our therapeutic candidates, our current commercial products, Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, which are products that we promote, EnteraGam®, which is a product we commercialize, or products that we may promote or commercialize in the future;
- our collaborators may fail to comply with applicable laws, rules, or regulations when performing services for us, and we could be held liable for such violations;
- our collaborators may experience financial difficulties, making it difficult for them to fulfill their obligations to us, including payment obligations, or they may experience changes in business focus;
- our collaborators' partners may fail to secure adequate commercial supplies of our therapeutic candidates upon or after obtaining marketing approval, if at all, for Donnatal®, Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, or EnteraGam®, which is a product we commercialize, or of products that we may promote or commercialize;
- our collaborators' partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business or business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate or product developed either independently or in collaboration with others, including our competitors;
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our therapeutic candidates or may limit or terminate our rights to promote

Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam® in the U.S. or products we may promote or commercialize in the future;
- our collaborators may not wish to extend the terms of our agreements related to our commercial products beyond the existing terms, in which case, we will not have access to existing rights upon the expiration and will therefore not be able to promote or commercialize our candidates and products following the initial terms of our agreements; and
- our collaborators may wish to terminate the collaborative arrangements due to any disagreements or conflicts with us, a change in their assessment that the arrangement is no longer valuable, a change in control or in management or in strategy, changes in product development or business strategies of our collaborators.

In addition, our reliance upon our partners in connection with promotional activities subjects us to a number of additional risks, including but not limited to, the following:

- we do not control our partners' communications with the FDA, and the FDA may determine to withdraw the products from the market due to any action or inaction taken by our partners (see "–Donnatal®, Mytesi®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and EnteraGam® or products which we may promote or commercialize in the future may be withdrawn from the market at any time due to product withdrawal requests by the FDA or other foreign regulatory authorities");
- we rely on our partners to take enforcement action to protect the IP and regulatory protections, if any, of our commercial products. Their failure to diligently protect these products could materially affect our commercial success; in the case of Donnatal®, we rely on our partner to take action to proactively prevent unauthorized copies of the product from being marketed and sold and their failure to do so could materially affect our commercial success;
- we rely on our partners to be responsible for the manufacture of our current commercial products through third-party manufacturers with the requisite quality and manufacturing standards as required under applicable laws and regulations, and we also rely on those same partners to supply their respective products, which may result in us having those respective products in insufficient quantities or not delivered in as timely a manner as is necessary to achieve adequate or successful promotion and sale of their respective products in the U.S.;
- our same partners may significantly create or change reimbursement agreements or increase or decrease the price of their respective products to a level that could adversely affect our sales or revenues;
- we rely on those same partners for most decisions related to the product and for taking critical actions to support the product including with respect to promotion, sales and marketing, medical affairs and pharmacovigilance, and any action or inaction taken by those same partners may adversely affect the sales of their respective products;
- our partners may change or create new agreements with wholesalers, Pharmacy Benefit Managers or other important stakeholders, which may significantly impact our ability to achieve commercial success, or they may fail to negotiate reimbursement agreements with payors which could also negatively affect our commercial success;
- our partners may change the price of their respective products to a level that could adversely affect our sales or revenues;
- those same partners may not be successful in maintaining or expanding reimbursement from government or third-party payors, such as insurance companies, health maintenance organizations and other health plan administrators, which may adversely affect the sales of their respective products; and
- those same partners may terminate their agreements with us after an agreed upon period for reasons set forth in those same partners' respective agreements with us.

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

As a result of ADVANZ's rebranding, recapitalization in September 2018 and its delisting from the NASDAQ Stock Market in July 2018, we are subject to the additional risks that ADVANZ may delay, reduce or cease payments to us under the ADVANZ Co-Promotion Agreement or otherwise be unable or unwilling to meet its obligations to us under the ADVANZ Co-Promotion Agreement, including its manufacture, supply, and other operating responsibilities. If any of these scenarios materialize, it could have an adverse effect on our reputation, business, financial condition or results of operations.

Our co-promotion agreement with Napo for the promotion of Mytesi® is short-term, and Napo will continue to control the sale of Mytesi® and have the right to set policies concerning pricing and other terms of sale that may impact the adoption and use of Mytesi®.

We entered into the co-promotion agreement with Napo on June 28, 2018, and initiated U.S. promotion of Mytesi® in July 2018. The agreement, as amended, will expire, without renewal or a follow-on agreement, on January 28, 2020, without us ever realizing benefits from the agreement. We have not realized and may not in the future realize any meaningful revenue from our activities under the agreement and any launch of our promotional activities may fail. Our promotional activities under the agreement are also limited to the promotion of the product to gastroenterologists and other gastro/intestinal specialty healthcare providers, and we did not obtain the right to promote Mytesi® to other healthcare providers, such as infectious disease specialists who may have greater numbers of patients with HIV and HIV specialists who are high prescribers of antiretroviral therapies medications. We will only receive compensation from Napo if sales of Mytesi® are attributable to our promotional activities within the territory agreed upon with Napo. In addition, we rely upon Napo, a third party, to manufacture, sell, and manage all regulatory and other issues related to Mytesi®. Napo's failure to properly execute any of its legal or other responsibilities, in a manner that complies with all applicable governing laws and regulations, may subject us to various regulatory and litigation risks. In addition, Napo's failure to manufacture Mytesi® in sufficient quantities and in a timely manner would impair our ability to successfully promote this product.

Donnatal®, Mytesi®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and EnteraGam® or products which we may promote or commercialize in the future may be withdrawn from the market at any time due to product withdrawal requests by the FDA or other foreign regulatory authorities.

Products we acquire or to which we acquire certain commercialization rights may be subject to withdrawal requests by the FDA or other foreign regulatory authorities for various reasons. For instance, certain products, such as Donnatal®, may be subject to regulatory review under the DESI program, through which the FDA may determine such products to be ineffective and impose limitations or require withdrawal of the product from the market. Donnatal® is currently subject to the FDA's DESI proceedings to determine its effectiveness and the right to continue to be marketed in the U.S., and there is no assurance as to the outcome of such proceedings. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®. In addition, the process and timing of any FDA DESI proceedings with respect to Donnatal® are unclear. Historically, the FDA has generally permitted products to stay on the market during these proceedings, although there is no assurance as to the time of commencement of such proceedings or whether the FDA will, in fact, grant such permission to any future DESI-related proceedings, thereby resulting in our current commercial products being subject to withdrawal requests by the FDA. The status of EnteraGam® as a "medical food" in the U.S. may be challenged by regulatory authorities, which may result in its withdrawal from the market until additional regulatory requirements are met. Regulatory authorities in other jurisdictions may have similar procedures that may subject any product we may promote or commercialize to limitations or withdrawal requests. In addition, the FDA or other foreign regulatory authorities may determine that the chemistry, manufacturing and controls ("CMC") of marketed products that we develop, acquire or to which we acquire commercialization rights, such as our current commercial products, is unsatisfactory due to the manufacturing standards of the products. If either of these or any regulatory action is taken, our current commercial products or any product we promote or commercialize in the future could be withdrawn from the market at any time. In addition, we may suffer from delays in further commercialization of any product we promote or commercialize.

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

Part of our strategy is to identify and acquire rights to products that have been cleared or approved for marketing in the U.S. or elsewhere, and in particular, those with a therapeutic focus on GI. Specifically, we seek to acquire rights to products that are already commercialized, which would enable us to commercialize such products independently and further establish our own marketing and commercialization capabilities in the U.S. We have entered into the ADVANZ Co-Promotion Agreement pursuant to which we were granted certain rights to promote Donnatal® in certain U.S. territories, which was our first agreement to commercialize a product being marketed in the U.S. We have also entered into a license

agreement with Entera Health pursuant to which we were granted the exclusive rights to commercialize EnteraGam® in certain U.S. territories, an agreement with ParaPRO pursuant to which we were granted the exclusive rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg to gastroenterologists in certain U.S. territories and a co-promotion agreement with Napo pursuant to which we were granted the exclusive right to co-promote Mytesi® in certain U.S. territories to certain gastroenterologists and other healthcare practitioners for the approved indication in people living with HIV/AIDS. However, there can be no assurance as to our ability to identify and acquire rights to any additional products, in particular, those with a therapeutic focus on GI. If we are not successful in acquiring any additional products, or in commercializing EnteraGam®, or in promoting Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, we may not be able to further establish or maintain our own marketing and commercialization capabilities in the U.S. This may limit our ability to commercialize products on our own and may require us to contract with third-party development or commercialization partners on terms which may not be commercially favorable to us. Additionally, these efforts to further establish and maintain our commercial capabilities in the U.S. could be found to be more costly than our forecast and have an adverse effect on our reputation, business, financial condition or results of operations.

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

If we are unable to maintain, train and build an effective sales and marketing infrastructure, or establish and maintain compliant and adequate sales and marketing capabilities, we will not be able to commercialize and grow our products and product candidates successfully.

To further establish and maintain our own marketing and commercialization capabilities in the U.S. we may need to expand, among other things, our development, regulatory, manufacturing, marketing, and sales capabilities and to increase or maintain our personnel to accommodate sales. We may not be able to secure sales personnel or organizations that are adequate in number or expertise to successfully and lawfully market and sell our products in the U.S. If we are unable to expand our sales and marketing capability, train our sales force effectively or provide any other capabilities necessary to commercialize our products and therapeutic candidates, we may need to contract with third parties to market and sell our products.

Our employees and sales personnel must comply with applicable regulatory requirements and restrictions, including, but not limited to, “fair balance” promotion of our products and state and federal anti-kickback laws. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, we may not be able to increase our product revenue, may generate increased expenses and may be subject to regulatory and compliance investigation and enforcement.

The FDA also requires that our sales and marketing efforts, as well as promotions, comply with various laws and regulations. Prescription drug promotions must be consistent with and not contrary to labeling, present “fair balance” between risks and benefits, be truthful and not false or misleading, be adequately substantiated (when required), and include adequate directions for use.

In addition to the requirements applicable to approved drug products, we may also be subject to enforcement action in connection with any promotion of an investigational new drug. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug candidate.

If the FDA investigates our marketing and promotional materials or other communications and finds that any of our current or future commercial products are being marketed or promoted in violation of the applicable regulatory restrictions, we could be subject to FDA enforcement action. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable drug promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any approved drug products we may promote or commercialize.

Expanding and maintaining our commercial infrastructure for our commercial capabilities in the U.S. is a significant undertaking that requires substantial financial and managerial resources, and we may encounter delays or may not be successful in our efforts.

While we are currently promoting Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in certain U.S. territories, we only began to promote products in the U.S. in 2017 and have limited experience in promoting products. We are currently commercializing EnteraGam® in the U.S., and we likewise have only recently begun to commercialize products in the U.S., and we have limited experience in marketing and selling products. Establishing, maintaining and/or expanding the necessary capabilities are competitive and time-consuming, and the commercialization of EnteraGam® and promotion of Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg require a significant expenditure of operating, financial and management resources. Even with those investments, we may not be able to effectively promote Donnatal® Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, commercialize EnteraGam®, or we may incur more expenditures than anticipated in order to maximize our sales. We cannot guarantee that we will be able to establish, maintain and/or expand our sales, marketing, distribution, and market access capabilities and enter into and maintain any agreements necessary for commercialization with payers and third-party providers on acceptable terms, if at all. If we are unable to establish, maintain and/or expand such capabilities, either on our own or by entering into agreements with others, or are unable to do so in an efficient manner or on a timely basis, we will not be able to maximize our commercialization of EnteraGam® or promotion of Donnatal®, Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, which would adversely affect our business, operating results or financial condition.

Even if the promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and/or commercialization of EnteraGam® are successful, we may fail to further our business strategy as anticipated or to achieve anticipated benefits and success. We may incur higher than expected costs in connection with our promotion of Donnatal®, Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg or commercialization of EnteraGam®, and we may encounter general economic or business conditions that adversely affect these products. In addition, Donnatal® continues to face pressure from competitive products and from non-FDA approved copies of Donnatal® being distributed in the United States.

In addition, if we incur higher than expected costs in connection with our promotion of Donnatal®, Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, or commercialization of EnteraGam®, we may need to reduce or terminate our commercial activities, which may have a material adverse effect on our business, operating results or financial condition.

We have no history of independently commercializing any of our therapeutic candidates that may be approved in the future and may have difficulty promoting Donnatal®, Mytesi® or Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, commercializing EnteraGam®, or promoting or commercializing any therapeutic candidates or products to which we may acquire the rights in the future.

We have limited experience in commercializing therapeutic candidates or marketed products on our own, which may materially increase marketing and sales expenses or cause us to be ineffective in these efforts. In June 2017, we began promoting Donnatal® and commercializing EnteraGam® in the U.S., in September 2017, we began promoting Esomeprazole Strontium Delayed-Release Capsules 49.3 mg to gastroenterologists in certain U.S. territories and in July 2018, we began the promotion of Mytesi® to certain gastroenterologists and other healthcare practitioners in certain U.S. territories. There can be no assurance we will successfully commercialize our therapeutic candidates, such as TALICIA®, if approved in the future, or promote Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, or successfully commercialize EnteraGam® or any products we may promote or commercialize in the future.

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

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

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

In addition, our ability to bring our therapeutic candidates to market depends on the quality and integrity of data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third-party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated. Furthermore, the FDA may consider clinical studies inadequate where steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias. For example, one potential source of bias in clinical studies is a clinical investigator with a financial stake in the outcome of the study. Accordingly, we (or the applicant of the IND or Biologics License Application, as applicable) must submit for all applicable clinical investigators either: (i) a completed Form FDA 3454 attesting to the absence of financial interests and arrangements described in the regulations, dated and signed by the chief financial officer or other responsible corporate official; or (ii) for any investigators for whom a Form FDA 3454 is not submitted, a Form FDA 3455 disclosing completely and accurately the following:

- any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of a covered clinical trial, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
- any significant payments of other sorts from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- any proprietary interest in the tested product held by any clinical investigator involved in a study;
- any significant equity interest in the sponsor of the covered study held by any clinical investigator involved in any clinical study; and
- any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

The FDA may refuse to file an NDA that does not contain the required certifications and disclosures or an attestation by the applicant that the applicant has acted with due diligence to obtain the information but was unable to do so and stating the reason. Additionally, FDA refusal of an NDA on potential bias grounds may have a material adverse effect on our reputation, business, and the credibility of our other therapeutic candidates and/or commercial products.

We rely on contract research organizations for the management of clinical data generated from our studies, and such contract research organizations may not perform satisfactorily.

We rely on contract research organizations to provide monitors for and to manage data for our studies, including the ERADICATE Hp2 study and the MAP US study. Our reliance on these contract research organizations for data management reduces our control over clinical data management. While we have agreements governing their activities, we have limited influence over their actual performance. The ERADICATE Hp2 study enrolled 455 patients at 55 clinical sites across the U.S., and the MAP US study enrolled 331 patients across clinical sites in several countries. If these contract research organizations do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, we may be required to replace them, or our clinical studies may be extended, delayed or terminated. In addition, such failure of our contract research organizations would pose risks to the accuracy and usability of clinical data from our clinical studies. Replacing a contract research organization may result in a delay of our clinical studies and generation of data from such studies. In addition, we face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by contract research organizations, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology, including those regarding TALICIA® or RHB-104.

We rely on data from third parties in connection with the sale of our commercial products and our assessment of product acquisition opportunities, and this data may be inaccurate or may not accurately reflect the sales of commercial products, which may affect the revenues of some of our commercial products and our allocation of resources, which may adversely affect our business and the reputation of the commercial products that we promote.

We rely on data from third parties, including data providers, in connection with our commercial business. Revenues for our promotion of some of our commercial products, as well as our assessment of opportunities to acquire rights to products, are dependent on the volume of sales of our commercial products, which is calculated based on information obtained from third parties. Although we take steps to verify this data, the information we receive may be inaccurate or incomplete. In the event the information we receive is inaccurate or incomplete, this may affect our reported revenue for a reporting period or our decisions of whether to acquire rights to certain products.

If third parties do not manufacture TALICIA® or our other therapeutic candidates or do not manufacture and sell any products we may promote or commercialize, including our current commercial products, in sufficient quantities, in the required timeframe, and at an acceptable cost and quality, clinical development and commercialization of TALICIA® or our other therapeutic candidates or promotion of products we may promote or commercialize could be delayed and sales of any product we may promote or commercialize may be adversely affected.

We do not currently own or operate manufacturing facilities. We rely on, and expect to continue to rely on, third parties to manufacture clinical and commercial quantities of TALICIA® or our other therapeutic candidates and products that we may promote or commercialize. For TALICIA®, we rely on the manufacturer of TALICIA® for the manufacture of validation and registration batches in support of our potential submission of an NDA with the FDA and, if approved for marketing, for marketing and commercial sale of TALICIA®. For Donnatal®, we rely on ADVANZ, which has a manufacturing agreement with a third party to provide sufficient quantities of Donnatal® in the required timeframe. For EnteraGam® we rely on Entera Health and the manufacturer, The Lauridsen Group, Inc., to provide sufficient quantities of EnteraGam® in the required timeframe, and for Esomeprazole Strontium Delayed-Release Capsules 49.3 mg we rely on ParaPRO, which has a manufacturing agreement with a third party to provide sufficient quantities of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in the required timeframe. For Mytesi®, we rely on Napo, which has a manufacturing agreement with a third party to provide sufficient quantities of Mytesi® in the required timeframe. Our reliance on third parties includes our reliance on them for quality assurance related to regulatory compliance. Our current and anticipated future reliance upon others for the manufacture of our therapeutic candidates and any products that we may promote or commercialize may adversely affect our future operations and our ability to develop therapeutic candidates and commercialize any therapeutic candidates and any products that we may promote or commercialize on a timely and competitive basis.

We may not be able to maintain our existing or future third-party manufacturing arrangements on acceptable terms, if at all. If for some reason our manufacturers or our development or commercialization partners' manufacturers do not perform as agreed or expected or terminate or fail to renew their agreements with us for any reason, we or our partners may be

required to replace them, in which event we may incur added costs and delays in identifying, engaging, qualifying under applicable regulatory requirements and training any such replacements and entering into agreements with such replacements on acceptable terms. Obtaining the necessary FDA or other regulatory approvals or other qualifications required for changes in manufacturing sites, methods or processes under applicable regulatory requirements could result in a significant interruption of supply. In the case of the manufacturer of TALICIA®, in particular, the delay in identifying, engaging, qualifying and training its replacement may be extended, leading to a significant interruption of supply. Any such additional costs and delays may adversely impact our ability to obtain regulatory clearances and approvals to commercialize TALICIA® or our other therapeutic candidates or any product we may promote or commercialize or make such commercialization or marketing economically unfeasible.

We rely on third parties to manufacture and supply us with high quality active pharmaceutical ingredients ("APIs") in the quantities we require on a timely basis.

We currently do not manufacture any APIs ourselves. Instead, we rely on third-party vendors for the development, manufacture, and supply of our APIs that are used to formulate our therapeutic candidates and products we may promote or commercialize. If these suppliers are incapable or unwilling to meet our current or future needs on acceptable terms or at all, we could experience a delay in obtaining regulatory clearances or approvals for our therapeutic candidates or products that we may promote or commercialize or in conducting clinical trials of our therapeutic candidates and incur additional costs or experience an adverse effect on our sale of any product we may promote or commercialize.

While there may be several alternative suppliers of APIs on the market, for most of our products (but not Mytesi®, as discussed below), we have yet to conclude extensive investigations into the quality or availability of their APIs. In addition, we do not believe that there are alternative suppliers of APIs for Mytesi®, and we are wholly dependent upon Napo's ability to source or procure the API; the raw material used to manufacture Mytesi® is a crude plant latex ("CPL"), derived from the *Croton lechleri* tree, which is found in countries in South America, principally Peru. The ability of Napo's contract suppliers to harvest CPL is governed by the terms of their respective agreements with local government authorities. Although CPL is available from multiple suppliers, to our knowledge, Napo only has contracts with a small number of suppliers to obtain CPL and arrange its shipment to its contract manufacturer. Accordingly, if Napo's contract suppliers do not or are unable to comply with the terms of their respective agreements with Napo, and Napo is not able to negotiate new agreements with alternate suppliers on terms that it deems commercially reasonable, it may harm our co-promotion of Mytesi®. The countries from which CPL is obtained could also change their laws and regulations regarding the export of the natural products or impose or increase taxes or duties payable by exporters of such products. Restrictions could be imposed on the harvesting of the natural products or additional requirements could be implemented for the replanting and regeneration of the raw material. Such events could have a significant impact on our co-promotion of Mytesi®. As a result of each of the foregoing circumstances related to Mytesi® and the APIs of other products that we promote or commercialize, we can provide no assurances that supply sources will not be interrupted from time to time. Changing API suppliers or finding and qualifying new API suppliers can be costly and take a significant amount of time. Many APIs require significant lead-time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next.

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

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

To date, our therapeutic candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials as well as for other regulatory purposes by third-party manufacturers. If the FDA or other regulatory agencies approve any of our therapeutic candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved therapeutic candidates. In addition, we rely on, and we expect to continue to rely on, third-party manufacturers to produce commercial quantities of our current commercial products or any product that we may gain the rights to in the future to promote or commercialize. These manufacturers

may not be able to successfully increase or maintain the manufacturing capacity for any of our therapeutic candidates that may be approved in the future, our current commercial products or any product we may gain the rights to in order to promote or commercialize in the future, in a timely or economic manner, or at all. Except for current FDA regulations with respect to "medical foods," the significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. Foreign regulatory agencies may also require the approval of additional validation studies for scaling up the manufacturing process of any of our products, including "medical foods." If the third-party manufacturers are unable to successfully increase or maintain the manufacturing capacity for a therapeutic candidate or for products that we may promote or commercialize, or if we are unable to secure replacement third-party manufacturers or 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 which could have a material adverse effect on our reputation, business, financial condition or results of operations.

We and our third-party manufacturers or our partners' manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities, such as applicable current good manufacturing practices and other quality-based regulations.

We and our third-party manufacturers or our partners' manufacturers are, and will be, required to adhere to laws, regulations, and guidelines of the FDA and other foreign regulatory authorities setting forth current good manufacturing practices ("cGMP"). These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates with varying cGMP rigors depending on what phase each of our respective therapeutic candidates is in with respect to its drug development process and any products we may promote or commercialize, including our current commercial products. We and our third-party manufacturers and our partners' manufacturers may not be able to comply with applicable laws, regulations, and guidelines. We and our third-party manufacturers and our partners' manufacturers are, and will be, subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the U.S. Our failure, or the failure of our third-party manufacturers or our partners' manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates and commercially-marketed products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates and commercially-marketed products, and materially and adversely affect our reputation, business, financial condition or results of operations.

Our therapeutic candidates, our current commercial products, and any product we may promote or commercialize in the future, even if all regulatory clearances and approvals are obtained, will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations, and guidelines, we could lose those clearances and approvals, and our reputation, business, financial condition or results of operations may be materially and adversely affected.

We and/or our commercialization partners, as applicable, will be subject to ongoing reporting obligations with respect to our therapeutic candidates, even if they receive regulatory clearance or approval, and with respect to our current commercial products and any cleared or approved product that we may gain the rights to promote or commercialize in the future, including pharmacovigilance. In addition, the manufacturing of our therapeutic candidates, our current commercial products, and any other product we may promote or commercialize, whether currently or in the future, will be subject to continuing regulatory review, including inspections by the FDA and other foreign regulatory authorities. The results of any ongoing review may result in withdrawal from the market of a therapeutic candidate or one of our current commercial products, Donnatal®, Mytesi®, EnteraGam®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, or another product we may promote or commercialize, interruption of manufacturing operations or imposition of labeling or marketing limitations for such therapeutic candidate or product. Since many more patients are exposed to drugs following their marketing clearance or approval, serious adverse reactions that were not observed in clinical trials may occur during the commercial marketing of the therapeutic candidate or any product we may promote or commercialize, including our current commercial products.

If a product receives regulatory approval, the approval may be limited, which could restrict the commercial value of the product. As a condition of approval or after approval (if the FDA becomes aware of new safety information), the FDA may require us to implement a Risk Evaluation and Mitigation Strategy (REMS), which may include distribution or use restrictions to manage a known or potential serious risk associated with the product. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of a given drug. Once adopted, REMS are subject to periodic assessment and modification. Additionally, the FDA may require post-approval, "Phase 4" clinical trials to generate additional information on safety and/or efficacy. The results of such post-marketing studies may be negative and could cause the Agency to, among other things, further limit marketing efforts or a product's approved uses.

As we develop our therapeutic candidates or commercialize our products, we may also periodically discuss with the FDA and other regulatory authorities certain clinical, regulatory and manufacturing matters and, our views may, at times, differ from those of the FDA and other regulatory authorities. For example, the FDA may seek to regulate our therapeutic candidates or any product we may promote or commercialize that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. If the FDA raises questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in such combination drug products, we may be required to provide additional information, which may require us to conduct additional preclinical studies or clinical trials. If we and/or our commercialization partners, as applicable, are required to conduct additional clinical trials or other testing of our therapeutic candidates or of our current commercial products, or any other product we may promote or commercialize, we may face substantial additional expenses, be delayed in obtaining marketing clearance or approval, if required by the FDA, or may never obtain marketing clearance or approval for such therapeutic candidate or product we may promote or commercialize, including Donnatal®. In addition, Donnatal® is currently subject to the FDA's DESI proceedings to determine its effectiveness and the right to continue to be marketed in the U.S., and there is no assurance as to the outcome of such proceedings. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®.

In addition, in 2011, the FDA granted RHB-104 orphan drug designation for the treatment of Crohn's disease in the pediatric population, and, in 2017, the FDA granted YELIVA® orphan drug designation for the treatment of cholangiocarcinoma and granted RHB-107 orphan drug designation for the treatment of pancreatic cancer. If we fail to maintain these orphan drug designations, we will lose our associated marketing exclusivity, and our competitors may sell competing products and our revenues could be reduced.

In 2014, the FDA granted TALICIA® a Qualified Infectious Disease Product ("QIDP") designation for the treatment of *H. pylori* infection. In 2017, we announced that RHB-204 had been granted QIDP designation by the FDA for the treatment of NTM infections. If either TALICIA® or RHB-204 fails to maintain its QIDP designation, it could significantly increase the development time for TALICIA® for the treatment of *H. pylori* infection and RHB-204 for NTM infections, as the case may be.

Third-party manufacturers and the manufacturing facilities that we and our development or commercialization partners use to manufacture any therapeutic candidate and any other products that we may promote or commercialize, including our current commercial products, will be subject to periodic review and inspection by the FDA and may be subject to similar review by other regulatory authorities. Later discovery of previously unknown problems with any therapeutic candidate or product we may promote or commercialize, including our current commercial products, manufacturer or manufacturing process, or failure to comply with rules and regulatory requirements, may result in actions, including but not limited to the following:

- restrictions on such therapeutic candidate, marketed product, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate or marketed product from the market;
- suspension or withdrawal of regulatory approvals;

- refusal to approve pending applications or supplements to approved applications that we or our development or commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates or products that we may promote or commercialize;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

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

Modifications to our therapeutic candidates, or to any product that we may promote or commercialize, may require new regulatory clearances or approvals or may require us or our development or commercialization partners, as applicable, to recall or cease marketing any of our cleared or approved products, if any, or delay further studies of our therapeutic candidates in human subjects until clearances or approvals are obtained.

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

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

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

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

As part of our overall strategy, we pursue opportunities to in-license or acquire therapeutic candidates and products that have been approved or cleared for marketing in the U.S. We may compete for in-license and acquisition opportunities with

other companies, including established and well-capitalized companies. As a result, we may be unable to in-license or acquire additional therapeutic candidates or products that have been approved or cleared for marketing in the U.S. at all or on favorable terms. Our failure to further in-license or acquire therapeutic candidates or products that have been approved or cleared for marketing in the U.S. in the future may materially hinder our ability to grow and could materially harm our reputation, business, financial condition or results of operations.

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

We acquired our rights to three of our therapeutic candidates, TALICIA®, RHB-104, and RHB-106, from a third party pursuant to an asset purchase agreement. In addition, we in-licensed our rights to three other therapeutic candidates, BEKINDA®, YELIVA®, and RHB-107 pursuant to license agreements in which we received exclusive perpetual licenses to certain patent rights and know-how related to these therapeutic candidates. We have also obtained certain rights to promote Donnatal® in certain U.S. territories under a co-promotion agreement, the exclusive U.S. rights to commercialize EnteraGam® in certain U.S. territories pursuant to a license agreement, the exclusive rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg to gastroenterologists in certain U.S. territories pursuant to an agreement and the exclusive right to co-promote Mytesi® to certain gastroenterologists and other healthcare practitioners in certain U.S. territories under a co-promotion agreement. These agreements require us to make payments and satisfy various performance obligations in order to maintain our rights and licenses with respect to these therapeutic candidates and marketed products. If we or our collaborators do not meet our or their respective obligations under these agreements, or if other events occur that are not within our control, such as the bankruptcy of a licensor, we could lose the rights to our therapeutic candidates, experience delays in developing or commercializing our therapeutic candidates or incur additional costs, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations.

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

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, compliance-related data, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans, and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber-fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the

information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

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

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

We face several risks associated with international business.

We operate our business in multiple international jurisdictions. Such operations could be materially affected by changes in foreign exchange rates, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to, our therapeutic candidates and products we may promote or commercialize, including our current commercial products, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations. Additionally, because our corporate headquarters are in Israel while our commercial office is in the U.S., there is additional risk in our ability as a company to control the activities occurring in the U.S., due to the geographic separation within the company.

Uncertain geopolitical conditions could have a material adverse effect on our promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg.

We rely on ParaPRO to manage all aspects of manufacturing, including entering into agreements with third parties to provide sufficient quantities of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in the required timeframe. This includes both the API and the finished dosage. Major aspects of manufacturing have taken place in South Korea and may continue in the foreseeable future. Accordingly, geopolitical and military conditions in South Korea and the surrounding region may directly affect our promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg.

In the past, there have been heightened security concerns regarding North Korea's nuclear weapons and long-range ballistic missile programs. This has resulted in increased uncertainty regarding both North Korea's actions and those of the U.S. If a party will take an aggressive action, including acts of war, we may not receive sufficient quantities of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in the required timeframe, and our promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg may be adversely affected.

Risks Related to Our Industry

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

None of our therapeutic candidates have been cleared or approved for marketing, and none of our therapeutic candidates is currently being marketed or commercialized in any jurisdiction. We were granted certain rights to promote our current commercial products in certain U.S. territories and to commercialize EnteraGam® Even if any of our therapeutic candidates or any product we may promote or commercialize receive, have received or do not require regulatory clearance or approval, it may not become a commercially viable product. For example, even if we or our development or commercialization partners receive regulatory clearance or approval to market a therapeutic candidate or receive regulatory clearance or approval to promote or commercialize any product, the clearance or approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions, which could materially and adversely affect their marketability and profitability. In addition, a new therapeutic candidate may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate or any product that we may promote or commercialize, may not result in commercial success for various reasons, including but not limited to:

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

Physicians, various other health care providers, patients, payors or the medical community, in general, may be unwilling to accept, utilize or recommend any of our approved therapeutic candidates and any product we may promote or commercialize. If we are unable, either on our own or through third parties, to manufacture, commercialize or market our

proposed formulations, therapeutic candidates or any product we may promote or commercialize when planned, or to develop them commercially, we may not achieve any market acceptance or generate meaningful revenue.

Unexpected product safety or efficacy concerns may arise and cause any product we may promote or commercialize to fail to gain or lose market acceptance.

Unexpected safety or efficacy concerns can arise with respect to any product we may promote or commercialize, whether or not scientifically justified, potentially resulting in product recalls, withdrawals and/or declining sales, as well as product liability, consumer fraud and/or other claims. The market perception and reputation of any product we may promote or commercialize, and their safety and efficacy are important to our business and the continued acceptance of any product we may promote or commercialize. Any negative publicity about any of our products, such as the pricing of any product we may promote or commercialize, discovery of safety issues with any product we may promote or commercialize, adverse events involving any product we may promote or commercialize, or even public rumors about such events, could have a material adverse effect on our reputation, business, financial condition or results of operations. In addition, the discovery of one or more significant problems with a product similar to any product we may promote or commercialize that implicate (or are perceived to implicate) an entire class of products or the withdrawal or recall of such similar products could have an adverse effect on the commercialization of any product we may promote or commercialize. New data about any product we may promote or commercialize, or products similar to any product we may promote or commercialize, could cause us reputational harm and could negatively impact demand for any product we may promote or commercialize due to real or perceived side effects or uncertainty regarding safety or efficacy and, in some cases, could result in product withdrawal. Any of the foregoing could have a material adverse effect on our reputation, business, financial condition or results of operations.

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

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

New drug delivery mechanisms, drug delivery technologies, new drugs and new treatments that have been developed or that are in the process of being developed or will be developed by others may render our therapeutic candidates and products we may promote or commercialize noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our therapeutic candidates and products we may promote or commercialize. In addition, our current commercial products and products we may promote or commercialize may compete with products of third parties for market share, and generic drugs or products that treat the same indications as our current commercial products or products we may promote or commercialize can have an adverse effect on our revenues by reducing our market share or requiring us to reduce the price of the products we market. We are aware of at least two products that are, to our understanding, unauthorized copies of Donnatal® that currently are being sold in the U.S. The FDA has not taken action against these products and this has had a negative effect on our commercial success. We understand that ADVANZ is pursuing legal remedies in an attempt to stop the sale of unauthorized copies of Donnatal®.

Technological competition from, and commercial capabilities of, pharmaceutical and biotechnology companies, universities, governmental entities, and others is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources, and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant

competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing, and other resources.

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

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

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) and on March 30, 2010, the signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of healthcare, conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients, and other healthcare policy reforms. Through the law-making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made to extend medical benefits to certain Americans who lacked insurance coverage and to contain or reduce healthcare costs (such as by reducing or conditioning reimbursement amounts for healthcare services and drugs, and imposing additional taxes, fees, and rebate obligations on pharmaceutical and medical device companies). This legislation was one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions were designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. This environment has caused changes in the purchasing habits of consumers and providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. This attention may result in our therapeutic candidates and products we may promote or commercialize, including our current commercial products, being chosen less frequently or the pricing being substantially lowered. At this stage, it is difficult to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid, and the State Children's Health Insurance Program), creation of government-sponsored healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, including our current commercial products, those we and our development or commercialization partners are currently developing and/or those that we may promote or commercialize in the future. If reimbursement for our approved therapeutic candidates, products we currently commercialize or promote, or any product we may promote or commercialize is substantially reduced or otherwise adversely affected in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our reputation, business, financial condition or results of operations.

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

for which we receive marketing approval in the future, could have a material adverse effect on our reputation, business, financial condition or results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, the states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have not expanded their Medicaid programs and have chosen to develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our reputation, business, financial condition or results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, replace, or repeal the Healthcare Reform Law and judicial challenges continue, and may increase in light of the current administration and legislative environment. We cannot predict the impact on our business of future legislative and legal challenges to the Healthcare Reform Law or other changes to the current laws and regulations. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for therapeutics affected by the legislation. From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing coverage, reimbursement, and marketing of pharmaceutical products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

Since taking office, President Trump has continued to support the repeal of all or portions of the Healthcare Reform Law. President Trump has also issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Healthcare Reform Law and in which he directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Healthcare Reform Law to the maximum extent permitted by law. Congress has enacted legislation that repeals certain portions of the Healthcare Reform Law, including but not limited to the Tax Cuts and Jobs Act, passed in December 2017, which included a provision that eliminates the penalty under the Healthcare Reform Law's individual mandate, effective January 1, 2019, as well as the Bipartisan Budget Act of 2018, passed in February 2018, which, among other things, repealed the Independent Payment Advisory Board (which was established by the Healthcare Reform Law and was intended to reduce the rate of growth in Medicare spending). There have also been more recent examples of judicial challenges, such as federal judges attempting to invalidate the entire Healthcare Reform Law based on the individual mandate. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold.

Third-party payors may not adequately reimburse customers for any of our therapeutic candidates that are approved or cleared for marketing or for products that we may promote or commercialize, including our current commercial products, and may impose coverage restrictions or limitations that affect their use.

Our revenues and profits depend heavily upon the availability of adequate reimbursement for the use of our approved or cleared therapeutic candidates, our current commercial products, and any products that we may promote or commercialize, from governmental or other third-party payors, both in the U.S. and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that the use of an approved or cleared therapeutic candidate or product 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 or for any product that we may promote or commercialize, including our current commercial products, from any government or other third-party payor is a time-consuming and costly process that could require us or our development or commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our therapeutic candidates or any product that we currently, or may, promote or commercialize to each payor. Even when a payor determines that a therapeutic candidate or a product that we promote or commercialize is eligible for reimbursement under its criteria, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities, or may impose restrictions, such as prior authorization requirements, or may simply deny coverage altogether. Reimbursement rates may vary according to the use of the therapeutic candidate or the use of any product that we promote or commercialize and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for products or services, and may reflect budgetary constraints or imperfections in Medicare, Medicaid or other data used to calculate these rates. In particular, reimbursement for our products may not be available from Medicare or Medicaid, and reimbursement from other third-party payors may be limited, reduced or revoked. For example, reimbursement for Donnatal® has been limited and is mostly available only through private payors, with certain restrictions, such as prior authorization requirements. Commercial coverage for Esomeprazole Strontium Delayed-Release Capsules 49.3 mg has been limited, and the class as a whole is highly genericized with certain products available inexpensively and over the counter, and many payors manage the pricing of the generics as well. In addition, because EnteraGam® is a "medical food" it is subject to unique FDA regulations and requirements that may limit its market potential. Overall, our ability to get reimbursement coverage for our commercial products has historically been limited. Successful commercialization of our current commercial products requires a conducive reimbursement environment. If our products do not receive adequate reimbursement coverage, or if reimbursement coverage is reduced or otherwise adversely affected, then their respective commercial prospects could be severely limited. Although certain payors may currently provide some form of coverage for our commercial products, payors may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, may impose restrictions or limitations on coverage, or may reduce reimbursement rates for our products. If we fail to establish broad adoption of and reimbursement for our commercial products, or if we are unable to maintain any existing reimbursement from payors, our ability to generate revenue could be harmed and this could have a material adverse effect on our reputation, business, financial condition or results of operations. In addition to our existing commercial products, any new product we may promote or commercialize in the future may require that we expend substantial time and resources in order to obtain and retain reimbursement, and any of these efforts may not be successful.

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

Furthermore, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both the Centers for Medicare and Medicaid Services and other third-party payors may have sufficient market power to demand significant price reductions. Price reductions or other significant coverage policies or payment limitations could materially and adversely affect our reputation, business, financial condition or results of operations.

We are subject to U.S. federal and state healthcare laws and regulations relating to our business, and our failure to comply with such laws could have a material adverse effect on our reputation, business, financial condition or results of operations.

We are subject to additional healthcare regulation and enforcement by the U.S. federal government and the states in which we conduct or will conduct our business. Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of our therapeutic candidates, current commercial products, or any products we may promote or commercialize. Our arrangements with third-party payors, customers, employees, or others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or family member has a financial relationship with the entity providing the designated health service, unless an exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- the so-called federal "Sunshine Act", which requires certain pharmaceutical and medical device companies to monitor and report certain financial relationships with physicians and other healthcare providers to the Centers for Medicare and Medicaid Services for disclosure to the public;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations, which impose obligations on certain covered entities and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals, regulatory authorities, and potentially the media of certain breaches of security of individually identifiable health information;
- HIPAA's fraud and abuse provision, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the FDCA, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Compliance efforts may involve substantial costs, and if our operations or business arrangements with third parties are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any violations of these

laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition or results of operations.

The Healthcare Reform Law also imposes reporting requirements on certain medical device and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not reported. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. Some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code and the AdvaMed Code of Ethics), which apply to pharmaceutical and medical device companies' interactions with healthcare providers; some mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

Most recently, there has been a trend in federal and state legislation aimed at requiring pharmaceutical companies to disclose information about their production and marketing costs, and ultimately lowering costs for drug products. Several states have passed or introduced bills that would require disclosure of certain pricing information for prescription drugs that have no threshold amount or are above a certain annual wholesale acquisition cost. In June 2016, Vermont became the first state to pass legislation requiring certain drug companies to disclose information relating to justification of certain price increases. The U.S. Congress has also introduced bills targeting prescription drug price transparency, and two such bills, the Patient Right to Know Drug Prices Act (for private plans) and the Know the Lowest Price Act (for Medicare Parts C and D), were signed into law on October 10, 2018. These laws and any other such implementation of legislation requiring publication of drug costs could materially and adversely impact our reputation, business, financial condition or results of operations by promoting a reduction in drug prices. As such, patients may choose to use other low-cost, established drugs or therapies.

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

Our marketing, promotional and business practices, including with respect to pricing, as well as the manner in which sales forces interact with purchasers, prescribers and patients, are subject to extensive regulation, including but not limited to, state and federal anti-kickback laws and any material failure to comply could result in significant sanctions against us.

The marketing, promotional, and business practices, including with respect to pricing, of pharmaceutical companies, as well as the manner in which companies' in-house or third-party sales forces interact with purchasers, prescribers, and patients, are subject to extensive regulation, the enforcement of which may result in the imposition of civil and/or criminal penalties, injunctions, and/or limitations on marketing practices for some of our products and/or pricing restrictions or mandated price reductions for some of our products. Many companies have been the subject of claims related to these practices asserted by state or federal authorities. These claims have resulted in fines and other consequences, such as entering into corporate integrity agreements with the U.S. government. Companies may not promote drugs for "off-label" uses, that is, uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. A company that is found to have improperly promoted drug products for off-label uses may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, an enforcement action against us could cause management's attention to be diverted from our business operations and damage our reputation.

We must comply with the U.S. Foreign Corrupt Practices Act.

The U.S. Foreign Corrupt Practices Act (the "FCPA") applies to companies, such as us, with a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The FCPA to which various of our operations may be subject generally prohibits companies and their intermediaries from engaging in bribery or making other improper payments to officials for the purpose of obtaining or retaining business. In various jurisdictions, our operations require that we and third parties acting on our behalf routinely interact with government officials, including medical personnel who may be considered government officials for purposes of these laws because they are employees of state-owned or controlled facilities. Our policies mandate compliance with these anti-bribery laws; however, we operate in many parts of the world that have experienced governmental and/or private corruption to some degree. As a result, the existence and implementation of a robust anti-corruption program cannot eliminate all risks that unauthorized reckless or criminal acts have been or will be committed by our employees or agents. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties. Violations of the FCPA, or allegations of such violations, could disrupt our business and result in a material adverse effect on our financial condition, results of operations or cash flows.

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

The clinical trials that we conduct and the testing, manufacturing, marketing, and commercial sale and use or misuse of our therapeutic candidates and any products we may promote or commercialize, involve and will involve an inherent risk that significant liability claims may be asserted against us or our development or commercial partners. Product liability claims, or other claims related to our therapeutic candidates and any products we may promote or commercialize, regardless of merit or their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. A product liability claim could also significantly harm our reputation and the market price of our shares and delay market acceptance of our therapeutic candidates and decrease demand for any products that we promote or commercialize, including our current commercial products. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for approved products;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- litigation costs;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We currently have a product liability policy that includes coverage for our clinical trials and our commercial operations. However, our insurance may prove inadequate to cover claims or litigation costs, especially in the case of wrongful death claims. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our therapeutic candidates or products we may promote or commercialize.

Our clinical trials may indicate unexpected serious adverse events or other adverse events and/or undesirable side effects that may harm our business prospects, operating results or financial condition. Serious adverse events identified during one of our Expanded Access Programs (EAPs) may present additional risks that may adversely affect our development of the therapeutic candidates involved in the applicable EAP.

As is the case with pharmaceuticals generally, certain side effects and adverse events may emerge as safety risks associated with the use of our therapeutic candidates. Similarly, serious adverse events (SAEs) have occurred and may occur in the future in connection with our clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and

prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on reputation, business, financial condition or results of operations.

Patients who receive access to investigational new drugs that have not yet received regulatory marketing approval through expanded access programs may be suffering from life-threatening illnesses and poor prognosis and may have exhausted all other available therapies. The risk for serious adverse events in this patient population is high, which could have a negative impact on the prospects of our therapeutic candidates that are provided under the EAP.

Serious adverse events or other undesirable side effects in connection with the use of our therapeutic candidates provided under the EAP could cause significant delays or an inability to successfully develop or commercialize such therapeutic candidates, which would materially harm our business. In particular, any such serious adverse events or other undesirable side effects could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of our investigational new drugs that have not yet received regulatory marketing approval are observed in patients who were granted expanded access to our investigational new drugs under the EAP, further clinical development of such product candidate may be delayed or we may not be able to continue development of such product candidates at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our therapeutic candidates could also result in the delay or denial of regulatory approval by the FDA or other regulatory authorities or in a more restrictive label than we expect.

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

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

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

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

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we may collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of patients, clinical trial participants and employees. We also have outsourced elements of our information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee, vendor, or business partner error, malfeasance or other disruptions. We, our partners, vendors, and other third-party providers could be susceptible to attacks on our and their information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups. Any such breach could compromise our and their networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Risks Related to Intellectual Property

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

Our success depends, in part, on our ability, and the ability of our development or commercialization partners to obtain patent protection for our therapeutic candidates and any products that we may promote or commercialize, maintain the confidentiality of our trade secrets and know-how, operate without infringing or violating on the proprietary rights of others and prevent others from infringing or violating on our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to our therapeutic candidates, inventions and improvements that may be important to the continuing development of our therapeutic candidates, and we plan to try to do the same with products we may acquire, promote or commercialize in the future, where this is possible.

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

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

in published applications, and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

After the completion of development and registration of our patents, third parties may still manufacture or market products in infringement of our patent-protected rights. Such manufacture or market of products in infringement of our patent-protected rights is likely to cause us damage and lead to a reduction in the prices of our therapeutic candidates or any product we may promote or commercialize, including our current commercial products, thereby reducing our potential profits.

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

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

We are reliant on our licensing partner, Bausch Health, to prosecute, maintain and defend the patents and other intellectual property rights of RHB-106, which we have licensed to Bausch Health. If Bausch Health does not prosecute, maintain and defend the patents and other intellectual property rights of RHB-106, it could materially harm our ability to obtain suitable patent protection covering RHB-106 or ensure freedom to commercialize RHB-106 in view of third-party patent rights, thereby materially reducing our potential profits from RHB-106.

In addition, Donnatal®, for which we were granted certain rights to promote Donnatal® in certain U.S. territories, and EnteraGam®, for which we were granted the exclusive U.S. rights to EnteraGam® for all indications for human use, are not protected by patents. The third GI-specialty product, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, includes the active ingredient esomeprazole strontium, which is protected by a process patent covering methods of preparing esomeprazole salts. The fourth GI-specialty product, Mytesi® (crofelemer), is protected by three methods of use patents that protect only the approved first therapeutic use of crofelemer as described on the Mytesi® label. If the FDA proceedings related to Donnatal® designed to determine its effectiveness will be ongoing, only products that receive an NDA from the FDA, DESI products and those actively participating in the hearing process of the FDA may be marketed. However, other competing products may freely enter the market, and we and our partners may not have sufficient intellectual property rights in Donnatal® to protect it from such competition. See *"*—Risks Related to Our Business and Regulatory Matters – Donnatal®, Mytesi®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and EnteraGam® or products which we may promote or commercialize in the future may be withdrawn from the market at any time due to product withdrawal requests by the FDA or other foreign regulatory authorities

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 them, such as our development or commercialization partners, employees, contractors, and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade

secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

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

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

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

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a therapeutic candidate and any products that we may promote or commercialize 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 or the ability to exclude others using proprietary rights could have a material adverse effect on our reputation, business, financial condition or results of operations.

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

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

Risks Related to our Ordinary Shares and ADSs

It is possible that we may be treated as a "passive foreign investment company", which could result in adverse U.S. federal income tax consequences to U.S. investors.

There is some uncertainty in the determination of our PFIC status, and it is possible that we may be treated as a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. Because the value of our assets for purposes of this determination will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies") holds Ordinary Shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Each U.S. Holder is urged to consult its own tax advisor regarding these issues.

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

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

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

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

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time, experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, following periods of market volatility,

shareholders have often instituted securities class action litigation and derivative actions. If we were involved in securities or other litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful.

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

All of our outstanding Ordinary Shares are registered and available for sale in Israel. In addition, as of December 31, 2018, we had options to purchase 29,400,235 Ordinary Shares under our Amended and Restated Award Plan (2010) (the "2010 Award Plan") outstanding, options to purchase 3,000 ADSs (each representing 10 Ordinary Shares) outside the 2010 Award Plan and non-tradable warrants to purchase an aggregate of 2,025,458 ADSs (each representing 10 Ordinary Shares) outstanding. In addition, as of December 31, 2018, there were 38,518,375 Ordinary Shares reserved for issuance under our 2010 Award Plan (including Ordinary Shares subject to outstanding options under such plan). Substantial sales of our Ordinary Shares or ADSs, or the perception that such sales may occur in the future, including sales of Ordinary Shares issuable upon the exercise of options, warrants or other equity-based securities, may cause the market price of our Ordinary Shares or ADSs to decline. Moreover, the issuance of shares underlying our options and warrants will also have a dilutive effect on our shareholders, which could further reduce the price of our Ordinary Shares and ADSs on their respective exchanges.

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

Our Ordinary Shares have been traded on the TASE since February 2011, and our ADSs were listed on the NASDAQ Capital Market from December 27, 2012, through July 19, 2018, and have been listed on the NASDAQ Global Market since July 20, 2018. Trading in our securities on these markets takes place in different currencies (U.S. dollars on the NASDAQ and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the U.S. and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

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

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

While our ADSs began trading on the NASDAQ Capital Market in December 2012, and on the NASDAQ Global Market in July 2018, and our Ordinary Shares began trading on the TASE in February 2011, we cannot assure you that we will maintain compliance with all of the requirements for our ADSs and our Ordinary Shares to remain listed. Additionally, there can be no assurance that trading of our ADSs and our Ordinary Shares on such markets will be sustained or desirable.

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

As a public company in the U.S. and Israel, we incur significant accounting, legal and other expenses as a result of the listing of our securities on both the NASDAQ and the TASE. These include costs associated with the reporting requirements of the Securities and Exchange Commission (the "SEC") and the requirements of the NASDAQ Listing Rules, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"). These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, travel costs, stock exchange listing fees, and shareholder reporting, and made some activities more time-consuming and costly. Any future changes in the laws and regulations affecting public companies in the U.S. and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the NASDAQ Listing Rules, as well as applicable Israeli reporting requirements, will result in increased costs to

us as we respond to such changes. These laws, rules, and regulations could make it more difficult and costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers and may require us to pay more for such positions.

As of December 31, 2018, we no longer qualify as an "emerging growth company" as defined in the JOBS Act. As such, certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act (and the rules and regulations of the SEC thereunder) ceased to apply, and we have begun to incur and expect to incur additional expenses and devote increased management time, effort and attention toward ensuring compliance with such reporting requirements, which are significant.

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

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the NASDAQ Listing Rules for domestic issuers. For instance, we follow the home country practice in Israel with regard to, among other things, director nomination procedures and quorum at shareholders' meetings. In addition, we follow our home country law, instead of the NASDAQ Listing Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans, an issuance that will result in a change in control, certain transactions other than a public offering involving issuances of a 20% or more interest in us and certain acquisitions of the stock or assets of another company. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. domestic issuer listed on the NASDAQ Stock Market may provide less protection than is accorded to investors under the NASDAQ Listing Rules applicable to domestic issuers.

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

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

We have documented and tested our internal control systems and procedures in order for us to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, which requires us to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting, and requires our auditor's attestation report on the effectiveness of our internal control over financial reporting. The continuous process of strengthening our internal control and complying with Section 404 of the Sarbanes-Oxley Act is complicated, expensive and time-consuming. While our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2018, our internal control over financial reporting was effective, we cannot predict the outcome of our testing or any subsequent testing by our auditor in future periods. If we fail to maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting. Even if we do conclude that our internal control over financial reporting is effective, our independent registered public accounting firm may still issue a report that is qualified or adverse if it is not satisfied with our internal control. Failure to maintain effective internal control over financial reporting could result in investigation or sanctions by regulatory authorities and could have a material adverse effect on our reputation, business, financial condition, results of operations or investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our Ordinary Shares and ADSs to decline.

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

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

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

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

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

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

The depositary for our ADSs gives us a discretionary proxy to vote our Ordinary Shares underlying ADSs if a holder of our ADSs does not give voting instructions, except in limited circumstances.

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

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

The effect of this discretionary proxy is that a holder of our ADSs cannot prevent our Ordinary Shares underlying such ADSs from being voted by us in our discretion, absent the situations described above. Holders of our Ordinary Shares are not subject to this discretionary proxy.

Risks Related to our Operations in Israel

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

We are incorporated under the laws of the State of Israel, and our principal offices are located in central 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, including Hezbollah in Lebanon (and Syria) and Hamas in the Gaza Strip, both of which involved missile strikes in various parts of Israel causing the disruption of economic activities. Our principal offices are located within the range of rockets that could be fired from Lebanon, Syria or the Gaza Strip into Israel. In addition, Israel faces many threats from more distant neighbors, in particular, Iran. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. 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 or results of operations and could make it more difficult for us to raise capital.

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 is currently committed to cover the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there is no assurance that this government coverage will be maintained, or if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business.

Several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies. In addition, there have been increased efforts by activists to cause companies and consumers to boycott Israeli goods based on Israeli government policies. Such business restrictions and boycotts, particularly if they become more widespread, may materially and adversely impact our business.

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 our revenues and royalty payments from our agreements with our development or commercialization partners are in U.S. dollars, and we expect our revenues from future licensing and co-promotion agreements to be denominated mainly in U.S. dollars or in Euros. We pay a substantial portion of our expenses in U.S. dollars; however, a portion of our expenses, including salaries of our employees in Israel and payment to

part of our 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 currency fluctuation risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

Provisions of the RedHill Biopharma Ltd. 2010 Award Plan, Israeli law, our articles of association and our change in control retention plan 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 in control, even when the terms of such a transaction are favorable to us and our shareholders.

Our 2010 Award Plan provides that all options granted by us will be fully accelerated upon a "hostile takeover" of us. A "hostile takeover" is defined in our 2010 Award Plan as an event in which any person, entity or group that was not an "interested party", as defined in the Israeli Securities Law – 1968, on the date of the initial public offering of our Ordinary Shares on the TASE, will become a "controlling shareholder" as defined in the Israel Securities Law, 1968, or a "holder," as defined in the Israeli Securities Law – 1968, of 25% or more of our voting rights or any merger or consolidation involving us, in each case without a resolution by our board of directors supporting the transaction. In addition, if a "Significant Event" occurs and following which the employment of a grantee with us or a related company is terminated by us or a related company other than for "Cause", and unless the applicable agreement provides otherwise, all the outstanding options held by or for the benefit of any such grantee will be accelerated and immediately vested and exercisable. A "Significant Event" is defined in our 2010 Award Plan as a consolidation or merger with or into another corporation approved by our board of directors in which we are the continuing or surviving corporation or in which the continuing or surviving corporation assumes the option or substitutes it with an appropriate option in the surviving corporation.

The Israeli Companies Law, 1999, or the Israeli Companies Law, regulates mergers, requires tender offers for acquisitions of shares or voting rights above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, a majority of each class of securities of the target company must approve a merger. Moreover, the Israeli Companies Law provides that certain purchases of securities of a public company are subject to tender offer rules. As a general rule, the Israeli Companies Law prohibits any acquisition of shares or voting power in a public company that would result in the purchaser holding 25% or more, or more than 45% of the voting power in the company, if there is no other person holding 25% or more, or more than 45% of the voting power in a company, respectively, without conducting a special tender offer. The Israeli Companies Law further provides that a purchase of shares or voting power of a public company or a class of shares of a public company which will result in the purchaser's holding 90% or more of the company's shares, class of shares or voting rights, is prohibited unless the purchaser conducts a full tender offer for all of the company's shares or class of shares. The purchaser will be allowed to purchase all of the company's shares or class of shares (including those shares held by shareholders who did not respond to the offer), if either (i) the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, or (ii) the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class. The shareholders, including those who indicated their acceptance of the tender offer (except if otherwise detailed in the tender offer document), may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition. At the request of an offeree of a full tender offer which was accepted, the court may determine that the consideration for the shares purchased under the tender offer was lower than their fair value and compel the offeror to pay to the offerees the fair value of the shares. Such an application to the court may be filed as a class action.

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

Pursuant to our articles of association, the size of our board of directors may be no less than five persons and no more than eleven, including any external directors whose appointment is required under law. The directors who are not external

directors are divided into three classes, as nearly equal in number as possible. At each annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three-year term that expires at the annual general meeting held in the third year following such election (other than any director originally nominated for election by virtue of the nomination right granted to any investor who purchased, in the Company's public offering which closed on December 27, 2016, together with its affiliates, at least $15 million of ADSs and warrants (excluding the proceeds, if any, from the exercise of warrants, whose term of office may expire earlier depending on the beneficial ownership by the investor of the Company's shares)). 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.

In addition, we have adopted a change in control employee retention plan providing for compensation to Company officers and employees in the event of a change in control (as defined by the plan), subject to the satisfaction of various conditions. See "Item 6 B. – Compensation – Change in Control Retention Plan."

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.

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

We are incorporated in Israel. Most of our directors and executive officers reside outside of the U.S., and most of our assets and most of the assets of our directors and executive officers may be 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 a U.S. or Israeli court. It may also be difficult to effect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel.

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

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

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

The Israeli Companies Law and our articles of association permit us to indemnify our directors and officers for acts performed by them in their capacity as directors and officers. The Israeli Companies Law provides that a company may not exempt or indemnify a director or an officer nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of: (a) a breach by the director or officer of his duty of loyalty, except for insurance and indemnification where the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the company; (b) a breach by the director or officer of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence; (c) any act or omission done with the intent to derive an illegal personal benefit; or (d) any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director. Our articles of association provide that we may exempt or indemnify a director or an officer to the maximum extent permissible under law.

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

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

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is RedHill Biopharma Ltd. Our 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, and on July 20, 2018, our ADSs were listed on the NASDAQ Global Market. Our Ordinary Shares are traded on the Tel-Aviv Stock Exchange under the symbol "RDHL," and our ADSs are traded on the NASDAQ Global Market under the same symbol "RDHL."

The Securities and Exchange Commission, or SEC, maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://sec.gov.

Our web site address is http://www.redhillbio.com. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

Our capital expenditures for the years ended December 31, 2018, 2017, and 2016 were approximately $23,000, $146,000 and $85,000 respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are a specialty biopharmaceutical company, primarily focused on proprietary drugs for gastrointestinal ("GI") diseases. From inception to the end of the period covered by this Annual Report, we invested a total of $5.3 million on in-licensing and acquisitions of therapeutic candidates and related technologies.

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

We generate our pipeline of therapeutic candidates by identifying, rigorously validating and in-licensing or acquiring products that are consistent with our product strategy and that we believe exhibit a relatively high probability of therapeutic and commercial success. None of our therapeutic candidates has been approved for marketing and, to date; our therapeutic candidates have not generated meaningful sales. We intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and territorial basis. We also evaluate, on a case-by-case basis, co-development and similar arrangements and the independent commercialization of our therapeutic candidates in the U.S.

In addition to our primary focus on the development of clinical-stage GI products, we have established commercial presence and capabilities in the U.S., intended primarily to support potential future launch of our GI-related therapeutic candidates currently under development in the U.S. We pursue our GI-focused sales force in the U.S. currently promotes Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide), Mytesi® (crofelemer 125 mg delayed-release tablets) and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercializes EnteraGam® (serum-derived bovine immunoglobulin/protein isolate ("SBI")).

Our Strategy

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

Key elements of our strategy are to:

- identify and acquire rights to products from pharmaceutical companies that have encountered cash flow or operational problems or that decide to divest one or more of their products for various reasons. Specifically, we seek to acquire rights to and develop products that are intended to treat pronounced clinical needs, have patent or other protections, and have potential target markets totaling tens of millions to billions of dollars. Additionally, we seek to acquire rights to and develop products based on different technologies designed to reduce our dependency on any specific product or technology. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field;
- advance our initiative to become a revenue-generating, GI-focused, specialty biopharmaceutical company with a commercial presence in the U.S. to support potential future commercialization of our therapeutic candidates and products approved for marketing by identifying and acquiring rights to products that have been approved for marketing in the U.S. from pharmaceutical companies that are interested in divesting one or more of their products. Specifically, we seek to acquire rights to products that are already commercialized in the U.S., preferably with a therapeutic focus on GI, which would enable us to commercialize such products independently through our own marketing and commercialization capabilities. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field;
- enhance existing pharmaceutical products, including broadening their range of indications, or launching innovative and advantageous pharmaceutical products, based on existing active ingredients. Because there is a large knowledge base regarding existing products, the preclinical, clinical and regulatory requirements needed to

obtain marketing approval for enhanced formulations are relatively well-defined. In particular, clinical trial designs, inclusion criteria and endpoints previously accepted by regulators may sometimes be re-used. In addition to reducing costs and time to market, we believe that targeting therapeutics with proven safety and efficacy profiles provides us a better prospect of clinical success;

- where applicable, utilize the FDA's 505(b)(2) regulatory pathway to potentially obtain more timely and efficient approval of our formulations of previously approved products. Under the 505(b)(2) process, we are able to seek FDA approval of a new dosage form, strength, route of administration, formulation, dosage regimen, or indication of a pharmaceutical product that has previously been approved by the FDA. This process enables us to partially rely on the FDA findings of safety or efficacy for previously approved drugs, thus avoiding the duplication of costly and time-consuming preclinical and various human studies. See "Item 4. Information on the Company – B. Business Overview – Government Regulations and Funding – Section 505(b)(2) New Drug Applications"; and
- cooperate with third parties to develop or commercialize therapeutic candidates in order to share costs and leverage the expertise of others.

Our Therapeutic Candidates

Summary

The ongoing development programs of our seven therapeutic candidates, most in late-stage clinical development, include "TALICIA®", "RHB-104", "RHB-204", "BEKINDA®", "RHB-106", "YELIVA®" and "RHB-107" and related research and development programs, the most advanced of which are described below.

Name of Therapeutic Candidate	Proposed Indication	Potential Advantages Over Most Existing Treatments, if Approved	Development Stage	Rights to the Product
TALICIA®	*H. pylori* infection	Improved efficacy; all-in-one pill	First Phase 3 study in the U.S. completed; confirmatory Phase 3 study in the U.S. ongoing	Acquired all rights to the composition and its use for the treatment of a GI disorder associated with *H. pylori*, worldwide and exclusive. We filed our own IP applications directed to the proposed commercial formulation and use
RHB-104	Crohn's disease	Novel mechanism of action and improved clinical benefit (targeting suspected underlying cause of Crohn's disease)	First Phase 3 study in N. America, Israel, Australia, New Zealand, and Europe ongoing; open label extension Phase 3 study ongoing	We filed patent applications internationally directed to the proposed commercial formulation and use
RHB-104	Multiple sclerosis (MS)	Oral formulation and novel mechanism of action	Phase IIa proof of concept study in Israel completed	We filed patent applications internationally directed to the proposed use of triple antibiotic therapy to treat RRMS
RHB-204	Pulmonary nontuberculous mycobacteria (NTM) infections caused by Mycobacterium avium complex (MAC)	Oral formulation targeting a major cause of pulmonary NTM infections	A single pivotal Phase 3 study planned in support of an NDA filing; initiation expected second half of 2019	We filed patent applications internationally directed to the proposed commercial formulation and use
BEKINDA® 24 mg	Acute gastroenteritis and gastritis	No other approved 5-HT3 serotonin receptor inhibitor for this indication; once-daily dosing	First Phase 3 study in the U.S. completed; confirmatory Phase 3 study in planning	We filed patent applications internationally to protect the proposed commercial formulation and its use
BEKINDA® 12 mg	IBS-D	Potential 5-HT3 serotonin receptor inhibitor with improved safety, while maintaining efficacy	Phase 2 in the U.S. completed; final results announced in January 2018	We filed patent applications internationally to protect the proposed commercial formulation and its use
RHB-106	Bowel preparation	Oral pill, avoid severe bad taste of chemical solutions, no known nephrotoxicity issues	Licensed to Bausch Health	Worldwide rights licensed to Bausch Health
YELIVA®	Advanced unresectable cholangiocarcinoma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Phase 2a study in the U.S. ongoing (ABC-108)	Worldwide exclusive license
YELIVA®	Refractory or relapsed multiple myeloma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Investigator-initiated Phase 1b/2 study in the U.S. ongoing (ABC-103)	Worldwide exclusive license
YELIVA®	Advanced hepatocellular carcinoma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Investigator-sponsored Phase 2 study in the U.S. ongoing (ABC-106)	Worldwide exclusive license
RHB-107 (Upamostat; formerly MESUPRON)	Gastrointestinal and other solid tumors	An orally-dosed small molecule compound with an established clinical safety profile; first-in-class specific inhibitor of five human serine proteases	Completed Phase 2 studies in pancreatic cancer and breast cancer; pre-clinical studies ongoing	Worldwide exclusive license; excludes China, Hong Kong, Taiwan, and Macao

TALICIA® (proposed tradename for RHB-105, if approved)

TALICIA® is an investigational new drug intended for the eradication of *H. pylori* bacterial infection in the GI tract. TALICIA® is a combination of three approved drug products – omeprazole, which is a proton pump inhibitor (prevents

the secretion of hydrogen ions necessary for digestion of food in the stomach), amoxicillin and rifabutin, which are antibiotics. TALICIA® is administered to patients orally.

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

Gastric cancer is one of the most commonly diagnosed cancers worldwide and one of the most common causes of cancer-related deaths, accounting for approximately 780,000 deaths annually, according to the World Health Organization ("WHO"). According to a 2010 report by Polk DB *et al.* published in Nature Reviews Cancer, *H. pylori*-induced gastritis is the strongest singular risk factor for cancers of the stomach, and eradication of *H. pylori* significantly decreases the risk of developing cancer in infected individuals without pre-malignant lesions.

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

TALICIA® is targeting a significantly broader indication than that of existing *H. pylori* therapies, as a treatment of *H. pylori* infection, regardless of ulcer status.

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

Market and Competition

The first-line therapies for *H. pylori* infection recommended by the American College of Gastroenterology in 2017 commonly include clarithromycin or metronidazole antibiotics with amoxicillin and a proton pump inhibitor. Such current standard-of-care treatments fail in approximately 30-40% of the patients due to the development of antibiotic resistance, based on "The Toronto Consensus for the Treatment of *Helicobacter pylori* Infection in Adults" by Fallone *et al.* published in Gastroenterology in 2016 and reports by Prof. David Y. Graham, M.D., *et al.* published in Nature Clinical Practice Gastroenterology & Hepatology in 2008 and in Gut in 2010 and by Malfertheiner P. *et al.* published in Gut in 2012.

As published in the 2006 study report by Dr. T.J. Borody, et al. in Alimentary Pharmacology & Therapeutics, the potential advantage of TALICIA® over the current first-line therapies was shown in a Phase 2 study comprised of 130 subjects. In the study, a different formulation of TALICIA®, using the same antibiotic ingredients and a similar proton pump inhibitor, was shown to eradicate *H. pylori* in over 90% of treated patients who failed previous eradication attempts using standard-of-care treatments. Furthermore, final results from the first Phase 3 study in the U.S. (the "ERADICATE Hp Study") conducted by us demonstrated 89.4% efficacy in eradicating *H. pylori* infection with TALICIA® in 118 dyspepsia patients with confirmed *H. pylori* infection.

H. pylori bacterial infection affects over 50% of the adult population worldwide, according to a 2018 report by Kakelar HM et al., published in Gastric Cancer, and approximately 35% of the U.S. population, according to a report by Hooi JKY et al. published in 2017 in Gastroenterology. In the U.S., we estimate that approximately 2.5 million patients per annum are treated for *H. pylori* eradication, based on a 2018 analysis by Foster Rosenblatt, a provider of analytic consulting and management development services for the life sciences industry. Based on the analysis by Foster Rosenblatt, we estimate the potential global and U.S. market for TALICIA® was approximately $4.8 billion and $1.4 billion in 2018, respectively.

Clinical Development

A Phase 2 clinical trial in Australia was completed with a different formulation of TALICIA®, using the same antibiotic ingredients and a similar proton pump inhibitor. A first Phase 3 trial in the U.S., the ERADICATE Hp Study, which was completed in 2015, showed 89.4% eradication of *H. pylori* with TALICIA® therapy while open-label standard-of-care yielded an *H. pylori* eradication rate of 63% in placebo subjects.

We met with the FDA in April 2016 to discuss the results of the ERADICATE Hp Study and the proposed design of the confirmatory Phase 3 study for the treatment of *H. pylori* infection. In light of the feedback received from the FDA, in January 2017 we entered into an agreement with ICON Clinical Research Limited to perform clinical trial services for the confirmatory Phase 3 study. Pursuant to a recommendation from the FDA, we completed a successful supportive pharmacokinetic (PK) program in May 2017 prior to initiating the confirmatory Phase 3 study.

In June 2017, we initiated a confirmatory Phase 3 study with TALICIA® for the treatment of *H. pylori* infection (the "ERADICATE Hp2 study"). The ERADICATE Hp2 study is a two-arm, randomized, double-blind, active comparator-controlled study, that investigated 455 dyspepsia patients with confirmed *H. pylori* infection at 55 clinical sites across the U.S. Subjects were randomized 1:1 to receive four capsules, three times daily, of either TALICIA® or the active comparator, a dual therapy amoxicillin and omeprazole regimen at equivalent doses, for a period of 14 days.

In December 2018, we announced positive top-line results from the ERADICATE Hp2 study. The study successfully met its primary endpoint with a high degree of statistical significance, demonstrating 84% eradication of *H. pylori* infection with TALICIA® versus 58% in the active comparator arm in the intent-to-treat population ($p<0.0001$). No safety issues were reported in the study and TALICIA® was found to be well tolerated.

Preliminary *H. pylori* culture results taken throughout the ERADICATE Hp2 study from patients across 20 U.S. states confirmed the high resistance of *H. pylori* to the antibiotics most commonly used for treatment, clarithromycin (17% resistance) and metronidazole (44% resistance). Importantly, no resistance to rifabutin, a key component in TALICIA®'s unique and proprietary formulation, was detected in the study.

Moreover, consistent with the literature describing the diminished efficacy of standard-of-care therapies, results from the open-label part of the ERADICATE Hp2 Phase 3 study showed 60% eradication of *H. pylori* with these therapies.

Results from the ERADICATE Hp2 study showed consistent 21- 29% treatment benefit of TALICIA® versus the active comparator across all *H. pylori* culture susceptibility and resistance subgroups, including amoxicillin, clarithromycin, and metronidazole.

We will continue to analyze the data from the ERADICATE Hp2 study, including antibiotic susceptibility and resistance, and plan to meet with the FDA to present the data and discuss the path towards potential marketing approval of TALICIA® in the U.S.

Subject to any additional regulatory feedback, the ERADICATE Hp2 study is expected to complete the clinical package required for a potential submission of an NDA with the FDA for TALICIA® in the first half of 2019.

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

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
-	Phase 2a	Examining the therapeutic candidate's effectiveness in treating *H. pylori* infection in patients for whom standard of care had failed to treat the infection	Center for Digestive Disease, Australia	130	The trial was completed and indicated that the treatment is effective for *H. pylori*-infected patients for whom standard of care had failed to treat the infection	Completed in 2005
-	Comparative Bioavailability	Comparing the bioavailability of TALICIA® to the bioavailability of an equivalent dose of commercially available active ingredients	Algorithme Pharma, Canada	16	Completed	Completed in 2013
ERADICATE Hp Study	Phase 3	Examining the effectiveness, safety, and PK of the final formulation	13 sites in the U.S.	118	Completed	Completed in 2015
-	Comparative Bioavailability	Comparing the bioavailability of TALICIA® in fed and fasted state and to the bioavailability of the active comparator for the confirmatory Phase 3 study	Algorithme Pharma, Canada	18	Completed	Completed in 2017
ERADICATE Hp2 Study	Phase 3	Assess the safety and efficacy of TALICIA® as compared to active comparator	65 sites in the U.S.	455	Positive top-line results announced in December 2018	Final results expected in the first quarter of 2019

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

RHB-104

Crohn's Disease

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

RHB-104 is a patented combination of clarithromycin, clofazimine, and rifabutin, three generic antibiotic ingredients, in a single capsule. The compound was developed to treat MAP infections in Crohn's disease. We announced positive top-line safety and efficacy results from the first Phase 3 study with RHB-104 for Crohn's disease (the "MAP US study") in July 2018, and have an ongoing open-label extension Phase 3 study (the "MAP US2 study") to evaluate the safety and efficacy of RHB-104 in subjects who remain with active Crohn's disease (CDAI ≥ 150) after 26 weeks of blinded study therapy in the Phase 3 MAP US study.

To date, Crohn's disease has been considered an autoimmune disease, but the exact pathological mechanism is unclear. Dr. Robert J. Greenstein suggested in *The Lancet Infectious Diseases*, 2003 that Crohn's disease is caused by MAP, the same organism responsible for causing a major disease in animal agriculture production, domestic and wild animals. This hypothesis is supported by an expanding number of scientific and clinical studies published in peer-reviewed journals since a National Institute of Allergy and Infectious Diseases conference that focused on MAP in Crohn's disease took place in 1998. Specific genetic loci like NOD2/CARD15 have been implicated in the pathogenesis of Crohn's disease with

mutations in NOD2 suspected of leading to defective recognition of MAP and increased compensatory immune activation in patients with Crohn's disease. Advances in diagnostic technology have led to increasingly higher identification of MAP, with studies, such as Bull TJ *et al*. J Clin Microbiol, 2003 and Shafran I *et al.* Dig Dis Sci, 2002, demonstrating a high prevalence of MAP in Crohn's disease patients. However, there is currently no FDA-approved commercial diagnostic test for MAP.

In 2011, we obtained FDA "Orphan Drug" status for RHB-104 for the treatment of Crohn's disease in the pediatric population. See "Item 4. Information on the Company – B. Business Overview – Government Regulations and Funding – Orphan Drug Designation."

The formulation for RHB-104 and manufacturing of the all-in-one capsules for our clinical trials have been completed. Stability testing of the clinical trial material is ongoing.

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

We continue to pursue the development program for a companion diagnostic for the detection of MAP bacteria in Crohn's disease patients in collaboration with U.S. universities and diagnostic companies. These efforts are in part based on detecting the presence of MAP bacterial DNA in the blood, the rights for which we acquired from UCF. We do not know if or when such a diagnostic test would become available.

Market and Competition

According to GlobalData, a provider of market intelligence for the pharmaceutical sector, there were approximately 1.69 million diagnosed prevalent cases of Crohn's disease in the seven major markets (U.S., France, Germany, Italy, Spain, UK, Japan) in 2018. This number of prevalent cases is expected to increase to 1.85 million by 2022.

According to GlobalData, the 2018 sales of drug treatments for Crohn's disease were estimated at approximately $10.5 billion in the seven major markets and are expected to exceed $12.8 billion in 2022 in the seven major markets.

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

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

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

We may also be exposed to potentially competitive products, which may be under development to treat Crohn's disease, including new biological therapies and other new therapies. Additionally, Salix Pharmaceuticals (a wholly owned subsidiary of Bausch Health) together with Alfasigma S.p.A announced that they will initiate a late-stage clinical program to study a formulation of the antibiotic rifaximin (Xifaxan®) for the treatment of Crohn's disease.

Clinical Development

A Phase 3 clinical trial for RHB-104 was conducted in Australia, sponsored by Pharmacia, a Swedish company (which merged with Pfizer), with the primary endpoint of evaluating the ratio of patients with recurrent symptoms of Crohn's disease following the initial induction of remission with 16 weeks of treatment with prednisolone initiated at 40 mg / day and weaned over the 16-week period. Subjects were subsequently assessed at 52, 104 and 156 weeks. The main secondary objective was the percentage of patients who achieved clinical remission at 16 weeks. The results of the trial were published by Professor Warwick Selby *et al*. in 2007 in the medical journal *Gastroenterology*. Although the study did not meet the main objective of showing a difference in relapse rate with long-term treatment, there was a statistically significant difference between the treatment groups in the percentage of subjects in remission at week 16. Professor Marcel Behr and Professor James Hanley from McGill University published a re-analysis of the study in *The Lancet Infectious Diseases* in June 2008, based on the intent-to-treat (ITT) principle and found that there was a significant statistical advantage for the active therapy over the placebo throughout the two-year period of administration that disappeared once the active therapy was discontinued.

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

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

In July 2018, we announced positive top-line results from the MAP US study, a randomized, double-blind, placebo-controlled first Phase 3 study with RHB-104 for Crohn's disease. The Phase 3 study enrolled 331 subjects with moderately to severely active Crohn's disease (defined as Crohn's Disease Active Index ("CDAI") between 220 and 450) in the U.S., Canada, Europe, Australia, New Zealand, and Israel. Subjects were randomized 1:1 to receive RHB-104 or placebo as an add-on therapy to baseline standard-of-care medications, including 5-ASAs, corticosteroids, immunomodulators or anti-TNF agents.

Our MAP US study successfully met its primary endpoint, as well as key secondary endpoints. Top-line results in the intent-to-treat (ITT) population demonstrated superiority of RHB-104 over placebo in achieving remission at week 26, defined as CDAI value of less than 150, the primary endpoint of the study. The proportion of patients meeting the primary endpoint was significantly greater in the RHB-104 group compared to placebo at week 26 (37% vs. 23%, p= 0.007). Moreover, while the secondary endpoints were not powered for significance in this induction of remission trial, key secondary endpoints were nevertheless met with statistically and clinically meaningful outcomes, demonstrating consistent benefit to Crohn's disease patients treated with RHB-104. RHB-104 was found to be generally safe and well tolerated.

The top-line results were provided to us by an independent third party following an independent analysis and remain subject to completion of the independent review and analysis of the underlying data, including all safety, secondary and other outcome measures, and completion of the Clinical Study Report. We believe that additional clinical studies will most likely be required to support an NDA for RHB-104, if filed. We plan to meet with key opinion leaders and the FDA to present the data package and discuss the development path to potential approval and also continue discussions with potential partners for RHB-104.

In addition, an open-label extension Phase 3 study (the "MAP US2 study") is ongoing to evaluate the safety and efficacy of RHB-104 in subjects who remain with active Crohn's disease (CDAI $\geq$ 150) after 26 weeks of blinded study therapy in the Phase 3 MAP US study. These subjects had the opportunity to receive treatment with RHB-104 for a 52-week period in the open-label MAP US2 study. We expect that the data collected in the MAP US2 study will be supplemental to the MAP US study data. The MAP US2 study's primary endpoint is disease remission at week 16, defined as CDAI of less than 150. In July 2018, the MAP US2 study completed enrollment of 54 subjects in the U.S., Canada, Europe, Israel, and New Zealand.

We have conducted several supportive studies with the current formulation of RHB-104, and a long-term population pharmacokinetic study is ongoing as part of the MAP US study.

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

Clinical trial author/designation	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
Borody 2002	Phase 2a	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	12	Performed	Completed 2002
Borody 2005	Phase 2	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	52	Performed	Completed 2005
Selby	Phase 3	Examining the effect of the treatment with the product on Crohn's disease patients	20 clinical centers in Australia	213	The trial was performed and indicated promising improvement rates, although it did not meet the main trial objective, as defined	Published in 2007
Biovail PK Study 2007	PK Study	Optimize the formulation of RHB-104 on a PK basis	Toronto, Ontario	24	The trial compared two formulations to determine the optimum formulation for RHB-104	Completed 2007
MAP US Study	Phase 3	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	U.S., Canada. Israel, Australia, New Zealand, and Europe	331	Positive top-line results announced in July 2018.	Final results expected in the first quarter of 2019
Food Effect Study	PK Study	Determine the effect of food on the bioavailability of RHB-104 in healthy volunteers	Algorithme Pharma, Canada	84	Completed	Completed 2014
Drug-Drug Interaction Study	PK Study	To assess the net PK effect of multiple doses of RHB-104 on CYP3A4 enzymes in healthy volunteers	Algorithme Pharma, Canada	36	Ended	Ended 2014
MAP US2 Study	Phase 3	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	U.S., Canada, Israel, New Zealand, and Europe	54	Ongoing	Ongoing

Expanded Access Programs (EAP) for Treatment of Crohn's Disease

Responding to a number of requests from investigators in the MAP US study, we recently opened up an EAP for the use of RHB-104 for treatment of Crohn's Disease outside of clinical trials. Treating physicians are required to submit to us expanded access requests on behalf of patients in addition to obtaining the local regulatory approval for the proposed use of the investigational medicinal product. Our medical professionals evaluate each request and respond based on the scientific evidence available at the time of the request and specific criteria set by us. We cannot predict how long this program will continue, and we may decide for various reasons, including but not limited to, resources and availability of RHB-104, not to continue with the EAP for RHB-104.

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

Multiple Sclerosis ("MS")

MS is an inflammatory, demyelinating, and neurodegenerative disease of the central nervous system of uncertain etiology that exhibits characteristics of both infectious and autoimmune pathology. There is a growing consensus in the medical community that a dysregulated immune system plays a critical role in the pathogenesis of MS. In a study published in PLOS One (April 2011 | Volume 6 | Issue 4 | e18482) by Cusso *et al*., among 50 MS patients and 56 healthy patients, MAP was detected in 42% and 12% respectively.

Clinical Development

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

Following these preclinical studies, in June 2013, we initiated a Phase 2a proof-of-concept study with RHB-104 for relapsing-remitting multiple sclerosis ("RRMS") (the "CEASE MS" study) at two clinical sites in Israel. The study was completed, and the final results (48 weeks) were announced in December 2016. The final results (48 weeks) were consistent with the interim results (24 weeks), suggesting meaningful positive safety and clinical signals upon 24 weeks of treatment with RHB-104 as an add-on therapy, including an encouraging relapse-free rate, Expanded Disability Status Scale scores and MRI results, which support further clinical development.

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

Trial name	Development phase	Purpose of the trial	Clinical trial sites	Planned number of subjects of the trial	Status of the trial
EAE Mouse T-cell Function Study	Pre-Clinical	Measure cytokine production as a measure of inflammation in EAE mice treated with RHB-104 vs. negative controls	-	-	Completed 2012
EAE Prophylaxis Study	Pre-Clinical	Scoring EAE severity in mice treated prophylactically with RHB-104 vs. negative controls	-	-	Completed 2012
EAE Relapse Study	Pre-Clinical	Scoring EAE severity in mice treated with RHB-104 vs. negative and positive controls	-	-	Completed 2012
Lipopolysaccharide (LPS)-induced cytokine production study	Pre-Clinical	Measure LPS-induced cytokine production in C57BL/6 mice treated with RHB-104 vs. negative and positive controls	-	-	Completed 2013
CEASE-MS	Phase 2a	Proof of concept study to assess the safety and efficacy of RHB-104 in RRMS	Israel	18	Completed 2016; final results announced in December 2016

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

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

RHB-204

Nontuberculous Mycobacteria Infections

In light of our discussions with the FDA on our design of a single pivotal Phase 3 study in support of a potential NDA filing for the treatment of pulmonary nontuberculous mycobacteria (NTM) caused by *mycobacterium avium complex* (MAC), we plan, subject to completion of a supportive non-clinical program and further input from the FDA, to initiate a pivotal Phase 3 study with RHB-204 in the second half of 2019.

The study will be intended to assess the efficacy and safety of RHB-204 as a first-line treatment for pulmonary NTM infections caused by MAC.

In January 2017, we announced that RHB -204 had been granted QIDP designation by the FDA for the treatment of NTM infections, including eligibility for an extended market exclusivity period, if approved for marketing in the U.S.

RHB-204 is a patented fixed-dose combination product of three antibiotics intended to simplify administration and optimize compliance. Each capsule contains the same three antibiotics as RHB-104 (clarithromycin, clofazimine, and rifabutin), but at doses unique from RHB-104. Clarithromycin and rifabutin were selected because mycobacteria live within host cells, and these agents have intracellular activity against MAC. Further, rifabutin enhances the antimicrobial activity of clarithromycin due to increased levels of clarithromycin's active metabolite. Selection of clofazimine was based on its activity against MAC, preferential accumulation in macrophages and bactericidal activity demonstrated in a mouse model of tuberculosis.

Market and Competition

Pulmonary NTM is an orphan disease affecting an estimated 110,000 patients in the U.S. in 2017, according to a 2017 analysis by Foster Rosenblatt. The incidence and prevalence of NTM lung disease are increasing worldwide, while treatment options remain limited, lengthy and challenging, according to Ryu YJ *et* (Tuberc Respir Dis, 2016).

NTM are naturally occurring organisms found in water and soil, which can cause chronic pulmonary infection. According to Prevots DR (Am J Respir Crit Care Med, 2010), approximately 80% of pulmonary NTM cases in the U.S. are associated with MAC. In some people, infection with NTM may lead to a progressive lung disease characterized by cough, shortness of breath, fatigue and weight loss. NTM disease is more common in the older adult population and individuals with a compromised immune system or underlying lung disease.

According to the American Lung Association, NTM are relatively resistant to antibiotics and can become more resistant if only one antibiotic is used. Effective treatment of NTM caused by MAC requires three drugs for at least 12 months of treatment. Currently recommended treatment regimens, drug resistance patterns, and treatment outcomes differ according to the NTM species, and management is a lengthy complicated process with limited therapeutic options (Ryu YJ et al. 2016). Adherence to the guidelines for treating NTM lung disease is suboptimal, and potentially harmful antibiotics regimens are commonly prescribed. Management of NTM disease requires prolonged use of costly combinations of multiple drugs with a significant potential for toxicity.

In September 2018, FDA approved Arikayce ® (amikacin liposome inhalation suspension), a new drug developed by Insmed Incorporated, for the treatment of lung disease caused by MAC in a limited population of refractory patients which does not respond to conventional treatment. To the best of our knowledge, this is the first treatment approved specifically for pulmonary NTM infections caused by MAC. Arikayce® is indicated as a second-line therapy in refractory patients as part of a combination antibacterial drug regimen. The Arikayce® prescribing information includes a Boxed Warning regarding the increased risk of respiratory conditions, including hypersensitivity pneumonitis, bronchospasm, exacerbation of underlying lung disease and hemoptysis that have led to hospitalizations in some cases.

Additional drug candidates are currently under development for the treatment of NTM infections, including Molgradex (Savara Inc.), an inhaled formulation of recombinant human GM-CSF, which is being evaluated in an ongoing Phase 2a study.

RHB-204 is targeting an annual potential U.S. market for pulmonary NTM, estimated to have exceeded $500 million in 2017, based on an analysis by Foster Rosenblatt.

Clinical Development

Although each of the three components of RHB-204 is approved individually and has been tested extensively in humans (e.g. see RHB-104), the formulation and doses represented by RHB-204 have not been tested. Current plans are to start a pivotal trial for pulmonary NTM lung infection in the second half of 2019. The appropriate regulatory path is currently under discussion.

The following chart summarizes the development history and status of RHB-204:

Trial name	Development phase	Purpose of the trial	Clinical trial sites	Planned number of subjects of the trial	Status of the trial
CleaR-MAC Trial	Phase 3	Registration for pulmonary NTM treatment	25	100	In planning for the second half of 2019

BEKINDA® (RHB-102)

BEKINDA® is an investigational once-daily bi-modal extended-release oral formulation of ondansetron, a leading member of the family of 5-HT3 serotonin receptor inhibitors. We are developing BEKINDA® in multiple dosage strengths. BEKINDA® is under development for the intended use in the following indications, which are novel and not yet FDA-approved indications for ondansetron targeting large potential markets:

1) Acute gastroenteritis and gastritis - 24 mg strength

2) Irritable Bowel Syndrome with Diarrhea (IBS-D) - lower dose strength for long-term administration

BEKINDA® utilizes a technology called CDT® that uses salts to provide an extended release of ondansetron. The CDT® platform enables extended drug release (i.e., the measured rate of introduction of active drug) at a relatively low manufacturing cost. Patents that we licensed from Temple University, relating to the CDT® technology, expired in the first quarter of 2018. The proposed commercial formulation and its use are protected by Company-filed patent applications and are being pursued internationally.

Acute Gastroenteritis and Gastritis

Acute gastroenteritis and gastritis both involve inflammation of the mucous membranes of the GI tract. Symptoms of gastroenteritis and gastritis include nausea, vomiting, diarrhea, and abdominal pain. Acute gastroenteritis and gastritis are a major cause of emergency room visits, particularly for pediatrics. If approved, BEKINDA® could potentially decrease the number of emergency room visits for patients suffering from acute gastroenteritis and gastritis by offering them an effective and long-lasting treatment, which can be taken in the comfort of their home.

Market and Competition

A single dose of BEKINDA® is intended to treat nausea and vomiting over a time window of approximately 24 hours. If approved for such use, this would be potentially advantageous for acute gastroenteritis and gastritis patients as it could help eliminate the need to take additional drugs (tablets) during the day or receiving intravenously administered drugs.

If BEKINDA® is approved for the treatment of acute gastroenteritis and gastritis, it could potentially hold substantial advantages over existing treatments. If approved, BEKINDA® could be prescribed by primary care physicians to patients early on, potentially preventing emergency room visits, dehydration and the need to provide IV fluids.

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

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

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

Clinical Development

In June 2017, we announced positive top-line results from the randomized, double-blind, placebo-controlled Phase 3 study (the "GUARD study") with BEKINDA® (RHB-102) 24 mg, which tested it for use in connection with acute gastroenteritis and gastritis. The study successfully met its primary endpoint of efficacy in acute gastroenteritis and gastritis. BEKINDA® 24 mg was also found to be safe and well tolerated in this indication. The GUARD study evaluated the safety and efficacy of BEKINDA® 24 mg in treating acute gastroenteritis and gastritis in 321 adults and children over the age of 12. The primary endpoint of the study was the proportion of patients without further vomiting, without rescue medication, and who were not given intravenous hydration from 30 minutes post first dose of the study drug until 24 hours post dose, compared to placebo. In September 2017, we met with the FDA to discuss the study results and the clinical and regulatory path towards potential marketing approval of BEKINDA® 24 mg in the U.S. Following the guidance provided at the meeting and additional guidance provided thereafter, we are currently working to design a confirmatory Phase 3 study to support a potential NDA with BEKINDA® 24 mg for acute gastroenteritis and gastritis.

Final results from the GUARD study showed improvement to the primary efficacy outcome by 21% in the Intent to Treat (ITT) population; 65.6% of BEKINDA® treated patients as compared to 54.3% of placebo patients (p=0.04; n=192 in the BEKINDA® group and n=129 in the placebo group). In the Per Protocol (PP) population, which included patients who met all protocol entry criteria and for which the diagnosis of gastroenteritis was confirmed (n=177 in the BEKINDA® group and n=122 in the placebo group), BEKINDA® improved the efficacy outcome by 27%; 69.5% of patients in the BEKINDA® group vs. 54.9% in the placebo group, (p=0.01). An imbalance in baseline nausea was noted, with worse nausea in the BEKINDA® treated group. In a post hoc analysis, when results were adjusted for baseline nausea, the p-value for the ITT population was 0.0152, and for the PP population was 0.0037. BEKINDA® 24 mg was also shown to be safe and well tolerated; electrocardiogram results showed no adverse changes with treatment. The benefit observed with BEKINDA® is evident across the spectrum of severity of nausea at baseline, including in patients with very severe nausea, suggesting that the drug works regardless of the initial severity of gastroenteritis.

The lead investigator for the Phase 3 study was Dr. Robert A. Silverman, MD, MS, Associate Professor at the Hofstra North Shore-LIJ School of Medicine and an emergency medicine specialist.

The following chart summarizes the clinical trial history and status of BEKINDA® for gastroenteritis and gastritis:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
GUARD Study	Phase 3	Randomized double-blind placebo-controlled Phase 3 study in acute gastroenteritis and gastritis	21 sites in the U.S.	321	Evaluated the safety and efficacy of BEKINDA® in acute gastroenteritis and gastritis	Completed 2017
TBD	Confirmatory Phase 3	Support a potential NDA with BEKINDA® 24 mg for acute gastroenteritis and gastritis	TBD	TBD	TBD	TBD

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

Irritable Bowel Syndrome with Diarrhea (IBS-D)

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

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

In light of the activity of ondansetron demonstrated in the preliminary studies described above, and because of its extended-release properties and once-daily dosing, we believe BEKINDA® is a promising candidate for the treatment of IBS-D.

Market and Competition

IBS is one of the most common GI disorders. According to publications by Saito YA. *et al.* (The American Journal of Gastroenterology, 2002) and by Lovell RM *et al.* (Clinical Gastroenterology and Hepatology, 2012), it is estimated that up to 30 million Americans may suffer from IBS. Of the three subtypes of IBS, IBS-D is the most prevalent diagnosed subtype in the seven major markets, with an estimated 8.3 million diagnosed prevalent cases in 2018, according to a report by GlobalData.

According to a report from EvaluatePharma, the U.S. potential market for IBS-D treatments was estimated to reach approximately $980 million in 2019 and exceed $1 billion in 2020.

To the best of our knowledge, there is one other 5-HT3 serotonin receptor inhibitor indicated for this indication in the U.S. – alosetron (currently marketed under the brand name Lotronex® by Sebela Pharmaceuticals and generic versions marketed by Actavis plc, Hikma and Amneal Pharmaceuticals). However, alosetron is approved only for the treatment of IBS in women with severe chronic IBS-D and its indication is restricted to those patients for whom the benefit-to-risk balance is most favorable due to infrequent, but severe, adverse reactions. The active ingredient in BEKINDA®, ondansetron, is approved by the U.S. FDA as an oncology support antiemetic and has a good safety profile. Therefore, we believe that BEKINDA®, if approved for the treatment of IBS-D in the U.S., may provide improved safety while maintaining efficacy and has the potential to be a preferred 5-HT3 serotonin receptor inhibitor treatment for patients suffering from IBS-D. According to EvaluatePharma, the 2019 U.S. sales of Lotronex® are estimated to reach approximately $70 million in 2018. Ramosetron, another 5-HT3 serotonin receptor inhibitor (marketed under the brand name Irribow® by Astellas Pharma Inc. and generic versions marketed by Pfizer Japan, Takeda Pharmaceuticals, Fuji Pharma and additional companies), is

marketed for the treatment of IBS-D and for chemotherapy-induced nausea and vomiting in Japan, South Korea, China and India, and for and postoperative nausea and vomiting in South Korea. To the best of our knowledge, there is currently no clinical development of ramosetron for marketing approval in the U.S. for any indication.

To the best of our knowledge, one of the main competitors of BEKINDA® for the treatment of IBS-D is Xifaxan® (rifaximin), marketed in the U.S. by Bausch Health. Xifaxan® is an antibiotic treatment that was approved for the treatment of IBS-D in 2015. Xifaxan® is also approved in the U.S. for the treatment of hepatic encephalopathy and traveler's diarrhea and for the reduction in risk of overt hepatic encephalopathy recurrence in adults. According to a report by GlobalData, it is believed that Xifaxan® is a gut-selective, broad-spectrum antibiotic with in vitro activity against both gram-positive and gram-negative bacteria. According to a report by EvaluatePharma, the worldwide annual sales of Xifaxan® for the treatment of IBS-D were estimated to reach approximately $590 million in 2019.

Viberzi® (eluxadoline) is another drug for the treatment of IBS-D approved by the FDA in 2015. Viberzi® is a locally-acting mu-opioid receptor agonist and a delta-opioid receptor antagonist marketed in the U.S. by Ironwood Pharmaceuticals and Allergan plc. According to EvaluatePharma, the worldwide sales of Viberzi® are estimated to reach approximately $200 million in 2019.

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

Clinical Development

In January 2018, we announced positive final results from the Phase 2 clinical study of BEKINDA® (RHB-102) 12 mg for the treatment of IBS-D. The randomized, double-blind, placebo-controlled Phase 2 study evaluated the safety and efficacy of BEKINDA® 12 mg in 126 subjects over 18 years old at 16 clinical sites in the U.S. The BEKINDA® 12 mg Phase 2 study successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency. BEKINDA® 12 mg was also shown to be safe and well tolerated. No serious adverse events or new or unexpected safety issues were noted in the study.

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

- proportion of patients in each treatment group who are pain responders, per FDA guidance definition;
- proportion of patients in each treatment group who are overall responders, per FDA guidance definition; and
- differences between treatment groups in:
    - abdominal pain
    - abdominal discomfort
    - frequency of defecation
    - incidence and severity of adverse events.

The BEKINDA® 12 mg Phase 2 study successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency response (in accordance with the FDA guidance definition) by an absolute difference of 20.7%, with 56.0% responders of subjects treated with BEKINDA® (n=75) vs. 35.3% responders of the placebo subjects (n=51) (p=0.036). While not powered for statistical significance of the secondary efficacy endpoints, the study suggested clinically meaningful improvement in both secondary efficacy endpoints of abdominal pain response and overall response (combined stool consistency and abdominal pain response). Final results from the Phase 2 study demonstrated that BEKINDA® 12 mg improved the overall worst abdominal pain response rate by 11.5% vs. placebo (50.7% with BEKINDA® 12 mg (n=75) vs. 39.2% with placebo (n=51); (p=0.278)) and the overall response improved by an absolute difference of 14.5% in favor of the BEKINDA® 12 mg arm (40.0% with BEKINDA® 12 mg (n=75) vs. 25.5% with placebo (n=51); (p=0.135)).

BEKINDA® 12 mg was also shown to be safe and well tolerated. No serious adverse events or new or unexpected safety issues were noted in the study. In September 2018, we announced that we concluded a positive End-of-Phase 2/Pre-Phase 3 (Type B) meeting with the FDA discussing the clinical and regulatory pathway towards potential FDA approval of BEKINDA® 12 mg for the treatment of IBS-D. We plan to finalize the design of two pivotal Phase 3 studies with BEKINDA® for the treatment of IBS-D.

The following chart summarizes the clinical trial history and status of BEKINDA® for IBS-D:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
-	Phase 2	Randomized double-blind placebo-controlled Phase 2 study in IBS-D	16 sites in the U.S.	126	Evaluating the safety and efficacy of BEKINDA® 12 mg in IBS-D	Completed 2018
TBD	Phase 3	Randomized double-blind placebo-controlled Phase 3 study in IBS-D	TBD	TBD	TBD	TBD

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

RHB-106

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

As noted above, we acquired the rights to RHB-106 pursuant to an agreement with Giaconda Limited. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Acquisition of RHB-104, TALICIA® and RHB-106."

On February 27, 2014, we entered into a licensing agreement with Salix Pharmaceuticals, Ltd. ("Salix"), which was later acquired by Valeant Pharmaceuticals International, Inc. ("Valeant"), and subsequently renamed to Bausch Health, pursuant to which we licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation and rights to other purgative developments. Pursuant to this agreement, we received an upfront payment of $7 million and are entitled to an additional potential $5 million in subsequent milestone payments. In March 2018, the 2014 license agreement was amended, among other things, to clarify the development efforts to be used by Bausch Health, provide for enhanced involvement by us in certain intellectual property matters and increase the lower end of the range of royalty payments to be paid to us on net sales from low single digits to high single digits, such that the total potential royalties range from high single digits up to low double digits. We continue to assist Bausch Health in the development of RHB-106, as needed. We have agreed to pay a percentage of the amounts we will potentially receive from Bausch Health to the third party from which we acquired the rights to RHB-106. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Exclusive License Agreement with Bausch Health Companies Inc."

Market and Competition

According to a report by EvaluatePharma, the worldwide market of laxative products was estimated at approximately $1.2 billion in 2018.

To the best of our knowledge, the main competitors of RHB-106 are GI cleansing products based on polyethylene glycol (PEG 3350). These products are delivered in the form of a water-soluble powder and require users to drink between 2-4 liters of solution before the performance of the gastroenterological procedure. In addition to the need to drink considerable amounts of solution, a common side effect that raises difficulties with users is the accompanying harsh and unpleasant

taste, leading to potential difficulties with patient compliance. RHB-106 offers the potential for improved patient compliance because it is tasteless and eliminates the need for drinking several liters of the ill-flavored electrolyte solution. RHB-106 also potentially has an advantage compared to currently available tablet products in the field in that it does not contain sodium phosphate, an active ingredient linked with a risk of nephrotoxicity.

Competing products in the U.S. include PrepoPik® (marketed by Ferring Pharmaceuticals; marketed under the name PicoPrep® in other countries), which is based on an active chemical ingredient called sodium picosulfate, the same active ingredient used in RHB-106. PrepoPik® is given in the form of a water-soluble powder and requires drinking quantities of fluids. Clenpiq™ is another product by Ferring Pharmaceuticals, which includes the active ingredient sodium picosulfate. Clenpiq™ (sodium picosulfate, magnesium oxide, and anhydrous citric acid) is a ready-to-drink cranberry-flavored oral solution for cleansing of the colon in adults undergoing a colonoscopy. Another product, Suprep®, marketed by BrainTree Laboratories Inc., is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. Suprep®'s active ingredients include sodium sulfate, potassium sulfate and magnesium sulfate in oral solution, and it is administered as a split-dose regimen.

Products administered in the form of tablets or capsules that were released on the market in the U.S., such as OsmoPrep® (marketed by Bausch Health), are based on a chemical substance called sodium phosphate. In December 2008, the FDA published a severe warning against the use of these products due to rare but severe side effects linked to kidney damage. As a consequence of this development, the FDA required in 2008 that oral sodium phosphate products carry a severe warning (black box label).

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

Plenvu® is a new PEG-based bowel preparation oral solution, which was approved by FDA in May 2018 and is marketed by Bausch Health in the U.S. and by Norgine B.V. in Europe. It is administered as a two-day split dose regimen.

Clinical Development

Following the acquisition of Salix by Valeant (now Bausch Health), and a recent amendment to our agreement with them, to the best of our knowledge, Bausch Health is continuing the development program based on such agreement and amendment.

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	Number of subjects of the trial	Nature and status of the trial	Performance schedule
-	Phase 2a	Comparison of the product's effectiveness and safety with an existing product	Center for Digestive Disease, Australia	60	Completed	Completed in 2005

YELIVA® (Opaganib, ABC294640)

YELIVA® is an investigational new drug that is a proprietary, first-in-class, orally-administered SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple oncology, inflammatory and GI indications. The compound originally designated as ABC294640 received an international non-proprietary name, opaganib, in the Recommended INN: List 79, 2018.

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

On March 30, 2015, we entered into an exclusive worldwide license agreement with Apogee Biotechnology Corporation (Apogee), pursuant to which Apogee granted us the exclusive worldwide development and commercialization rights to ABC294640 (which we then renamed to YELIVA® and, as noted above, received an international non-proprietary name, opaganib, in 2018) and additional intellectual property for all indications. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for YELIVA®."

Market and Competition

YELIVA® is currently being developed for several potential indications, including for the treatment of cholangiocarcinoma (bile duct cancer), refractory or relapsed multiple myeloma and advanced hepatocellular carcinoma ("HCC)."

Cholangiocarcinoma (bile duct cancer) is a highly lethal malignancy. According to the American Cancer Society report from January 2016, approximately 8,000 people are diagnosed with intrahepatic and extrahepatic bile duct cancers annually in the U.S., with recent studies showing an increased incidence of cholangiocarcinoma, mainly attributed to recent advancements in the diagnosis of this disease (Gores GJ, Hepatology, 2003). Surgery with complete resection is currently known to be the only curative therapy for cholangiocarcinoma; however, only a minority of patients are classified as having a resectable tumor at the time of diagnosis. Additional treatment options include radiation therapy and chemotherapy, but the efficacy of these treatments in cholangiocarcinoma patients is also limited and the prognosis for relapse patients who have failed initial chemotherapy is very poor, with an overall median survival of approximately one year (Valle J, et al. New Eng J, Med 2010). The 5-year relative survival rates of intrahepatic and extrahepatic cholangiocarcinoma patients range between 2% to 30%, depending on the tumor type and stage at diagnosis, according to the American Cancer Society. There are several drugs in late-stage clinical development for cholangiocarcinoma.

The American Cancer Society estimated that approximately 32,110 new cases of multiple myeloma would be diagnosed in the U.S. in 2019 and approximately 12,960 deaths are expected to occur. The risk of multiple myeloma increases as people age. The total worldwide sales of multiple myeloma therapies were estimated to exceed $22 billion in 2019 according to GlobalData. There are several drugs in late-stage clinical development for multiple myeloma.

Hepatocellular carcinoma is the most dominant form of liver cancer, accounting for approximately 85% of liver cancer cases, according to GlobalData. According to the WHO International Agency for Research on Cancer GLOBOCAN 2018 report, liver cancer is the fourth most common cause of cancer-related deaths worldwide. The annual worldwide incidence of liver cancer was estimated to have reached approximately 841,000 cases in 2018. In the U.S., the American Cancer Society estimates that over 42,000 patients will be diagnosed with liver cancer in 2019, with an expected mortality of 31,780 people. According to GlobalData, the market for the treatment of HCC in the seven major markets is estimated to exceed $730 million in 2019. There are several drugs in late-stage clinical development for HCC.

Clinical Development

ABC-108: Advanced Unresectable Cholangiocarcinoma

A single-arm Phase 2a clinical study to explore the activity of YELIVA® as a single agent in patients with advanced, unresectable, intrahepatic and extrahepatic cholangiocarcinoma was initiated in December 2017. The study is being conducted at Mayo Clinic major campuses in Arizona and Minnesota, the University of Texas MD Anderson Cancer Center, Huntsman Cancer Institute, the University of Utah Health and Emory University, Georgia. In September 2018, we announced that the study achieved its pre-specified efficacy goal (one of the first 12 evaluable patients was noted to have stable disease (based RECIST 1.1 criteria) of at least 4 months) for the first stage of the two-stage study design, and as a result, the study has continued to its second stage. The study is designed to enroll up to 70 patients, in order to achieve

enrollment of 39 patients evaluable for efficacy as defined by the Modified Intent to Treat (mITT) population criteria. Enrollment is expected to be completed by the end of 2019.

The primary objective is to determine the response rate (RR) of cholangiocarcinoma defined as objective responses (OR), i.e. complete and partial responses (CR, PR) plus stable disease (SD) of at least 4 months to treatment with YELIVA®.

In April 2017, the FDA granted YELIVA ® (ABC294640) orphan drug designation for the treatment of cholangiocarcinoma. The orphan drug designation allows us to benefit from various development incentives to develop YELIVA ® for this indication, including tax credits for qualified clinical testing, the waiver of a prescription drug user fee (PDUFA) upon submission of a potential NDA and, if approved, a seven-year marketing exclusivity period (subject to certain exceptions) for the treatment of cholangiocarcinoma.

EAP for the Treatment of Advanced Unresectable Cholangiocarcinoma

An EAP is for eligible participants who do not qualify for participation in, or who are otherwise unable to access, the ongoing clinical trial ABC-108 for advanced unresectable cholangiocarcinoma. This program is designed to provide access to YELIVA® for the treatment of cholangiocarcinoma prior to approval by the local regulatory agency. We cannot predict how long this program will continue, and we may decide for various reasons, including but not limited to resources and availability of YELIVA®, not to continue with the EAP.

ABC-103: Refractory or Relapsed Multiple Myeloma

A Phase 1b/2 study with YELIVA ® for the treatment of refractory or relapsed multiple myeloma was initiated in the third quarter of 2016 and is ongoing at Duke University Medical Center. Enrollment for the Phase 1b portion of the study has been completed with a total of 11 patients enrolled and treated in three dose cohorts. Results from the Phase 1b portion of the study did not show any dose-limiting toxicities. Additionally, while efficacy was not the primary endpoint of the Phase 1 study, it was observed that out of 10 evaluable subjects, two subjects had stable disease for over four months and one patient achieved a very good partial response (VGPR). The study is supported by a $2 million grant from the National Cancer Institute ("NCI") Small Business Innovation Research Program awarded to Apogee Biotechnology Corporation, in conjunction with Duke University, with additional support from us.

The primary endpoints of the first portion of the study (Phase 1) are to assess safety and determine the maximum tolerated dose in this group of patients. Secondary objectives include assessment of antitumor activity and determination of the PK and pharmacodynamic (PD) properties of YELIVA® in refractory or relapsed multiple myeloma patients.

The primary endpoints of the second portion of the study (Phase 2) are to assess the overall treatment response rate and overall survival. Secondary objectives include evaluating the treatment response of YELIVA ® in patients with refractory or relapsed multiple myeloma after three cycles of treatment and evaluation of pharmacodynamic markers.

ABC-101: Advanced Solid Tumors

A Phase 1 study, first-in-man evaluation of YELIVA ® in advanced solid tumors was completed in the summer of 2015. Final results demonstrated that the study, conducted at the Medical University of South Carolina (MUSC), successfully met its primary and secondary endpoints, demonstrating that the compound is well tolerated and can be safely administered to cancer patients at doses predicted to have therapeutic activity.

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

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

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

ABC-106: Advanced Hepatocellular Carcinoma

An investigator-sponsored Phase 2 study to evaluate the safety and efficacy of YELIVA® as a second-line monotherapy in patients with advanced hepatocellular carcinoma *("*HCC") is ongoing at the Medical University of South Carolina ("MUSC") Hollings Cancer Center, the Mayo Clinic campus in Arizona and the University of Maryland. The study is planned to enroll up to 39 patients who have experienced tumor progression following treatment with first-line single-agent sorafenib (Nexavar®).

The study is being led by Dr. Carolyn Britten and is being conducted at the Medical University of South Carolina (MUSC) and the University of Maryland and Mayo campus at Arizona.

The study is supported by a grant from the NCI, awarded to MUSC, which is intended to fund a broad range of studies on the feasibility of targeting sphingolipid metabolism for the treatment of a variety of solid tumor cancers. We are supplying YELIVA® to this study.

ABC-104: Oncology Support, Radioprotectant: Prevention of Radiation-Associated Mucositis in the Treatment of Head and Neck Cancer

A Phase 1b study is in planning to evaluate YELIVA® as a radioprotectant in head and neck cancer patients undergoing therapeutic radiotherapy.

ABC-105: Moderate to Severe Ulcerative Colitis ("UC")

A Phase 2 study is in planning to evaluate the efficacy of YELIVA® in patients with moderate to severe UC by the proportion of patients who are in remission at the end of treatment.

ABC-109: Food Effect Study in Healthy Subjects

A Phase 1, randomized, open-label, single-dose, 3-treatment, 3-period, 6-sequence crossover study designed primarily to evaluate the effect of a standardized meal on the absorption and bioavailability of YELIVA® in healthy subjects, was completed in the U.S. in January 2018. The study also evaluated the effect of the administration of a solution of YELIVA® via nasogastric (NG) tube on the absorption and bioavailability of YELIVA®. Twenty-three eligible, healthy, male and female adult subjects were randomized to receive YELIVA® orally in a state of fast, fed or as a solution by NG tube (after tube feeding). 17 subjects received all three treatments. All three treatments, though maximum concentration was lower when the drug was given orally in the fed state as compared to fasted, nasogastric administration after tube feeding led to intermediate results. Subjects experienced fewer gastrointestinal side effects when the drug was given in the fed state than fasted, but the pharmacodynamic effect, as reflected in decrease in sphingosine-1-phosphate, the product of the target enzyme, was no lower after fed than fasted administration. Thus, the results indicated that YELIVA® may be given after eating, with improved tolerance and no loss of pharmacodynamic effect.

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

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
ABC-108	Phase 2a	A study for the treatment of advanced, unresectable intra-hepatic, perihilar and extrahepatic cholangiocarcinoma	Multicenter study across the U.S.	Up to 70	Ongoing	Ongoing
ABC-103	Phase 1b/2	Safety and efficacy study in patients with refractory or relapsed multiple myeloma that have previously been treated with proteasome inhibitors and immunomodulatory drugs	Duke University, North Carolina, U.S.	Up to 77	Ongoing	Ongoing
ABC-101	Phase 1	Safety, PK and pharmacodynamic study in patients with advanced solid tumors	Medical University of South Carolina, Charleston, U.S.	22	Completed. Final results indicate the study drug is well tolerated and can be safely administered to cancer patients	Completed 2015
ABC-106	Phase 2	Investigator-Sponsored Safety and Efficacy Study in Patients with Advanced Hepatocellular Carcinoma Who Have Progressed on Sorafenib	Medical University of South Carolina, Charleston, U.S. and collaborating sites (Multicenter, U.S.)	From 12 to 39	Ongoing	Ongoing
ABC-104	Phase 1b	Safety and efficacy study in the prevention of mucositis in combination with radiotherapy for treatment of squamous head and neck carcinoma	Multicenter study across the U.S.	Up to 32	TBD	TBD
ABC-105	Phase 2	A study for the treatment of moderate to severe ulcerative colitis	Multicenter study	Up to 94	TBD	TBD
ABC-109	Phase 1	Assessment of the effect of a food on the absorption and bioavailability of ABC294640, also as a solution via nasogastric (NG) tube under fed conditions	ICON Early Phase Services, San-Antonio, TX, U.S.	23	Completed	Completed 2018

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

RHB-107 (Upamostat; formerly MESUPRON)

RHB-107 (Upamostat; formerly MESUPRON) (INN: upamostat) is an investigational new drug, which we are seeking to market as a proprietary small molecule, first-in-class, potent serine protease inhibitor administered by oral capsule.

We believe that RHB-107 has a unique potency and specificity that suggests it may be a new non-cytotoxic approach to cancer therapy, as well as other indications of high unmet need such as inflammatory digestive diseases and inflammatory lung diseases.

As mentioned under "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for RHB-107", on June 30, 2014, we signed an exclusive license agreement for this oncology therapeutic candidate. Under this agreement, we are responsible for all development, regulatory and commercialization of RHB-107 in the entire world, excluding China, Taiwan, Macao, and Hong Kong.

In October 2017, the FDA granted RHB-107 orphan drug designation for the treatment of pancreatic cancer. The orphan drug designation allows us to benefit from various development incentives to develop RHB-107 (Upamostat; formerly MESUPRON) for this indication, including tax credits for qualified clinical testing, waiver of a PDUFA upon submission of a potential marketing application and, if approved, a seven-year marketing exclusivity period (subject to certain exceptions) for the treatment of pancreatic cancer.

Market and Competition

RHB-107 is an investigational new drug, to be marketed upon approval as an orally-administered protease inhibitor with several potential mechanisms of action to inhibit tumor invasion and metastasis and has been developed for the treatment of solid tumor cancers, including GI cancers, with the focus on locally advanced non-metastatic pancreatic cancer.

Data from non-clinical studies indicate that WX-UK1, the active metabolite of RHB-107, is a potent and specific inhibitor of five human serine proteases (trypsin-3, trypsin-2, trypsin-1, matriptase-1, and trypsin-6). Several of these serine proteases are associated with cancer progression and metastasis. The non-clinical studies suggest new potential therapeutic applications of WX-UK1 in oncology and inflammatory gastrointestinal diseases.

Pancreatic cancer is characterized as a disease with very high unmet need in oncology. The American Cancer Society estimates that 6,770 new cases of pancreatic cancer will be diagnosed in 2019, with an expected mortality of 45,750 in 2019, representing one of the poorest prognoses across the GI cancers. The total worldwide sales of pancreatic cancer therapies were estimated to reach approximately $1.6 billion in 2019, according to GlobalData.

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

Clinical Development

Several Phase 1 studies and two Phase 2 proof-of-concept studies have been completed with RHB-107. The first Phase 2 trial in locally advanced non-metastatic pancreatic cancer and the second trial in metastatic breast cancer established the therapeutic candidate's safety and tolerability profile. The Phase 2 trials with RHB-107 in both indications failed to demonstrate significant improvement in either progression-free survival or overall survival.

None of the prior studies used any molecular markers to target certain patient populations. Using technologies developed since the original clinical trials were performed, we are currently planning several preclinical studies, including biomarker analysis and mechanism of action studies. We expect that the findings from these studies can help us determine the patient populations to be studied in subsequent clinical trials.

We are working on several oncology projects evaluating multiple clinical candidates, including RHB-107 as a component spanning oncology and inflammatory digestive disease indications where strong unmet medical need exists. We have recently received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent that will recite claims directed to a combination of YELIVA®, RHB-107, and a known antibiotic. The claims in the patent will also be directed to methods of treating cancer, or preventing cancer, by administering YELIVA ® and a known antibiotic. Upon issuance, in addition to the existing intellectual property protection covering the individual compounds, we believe the new patent will provide us with intellectual property protection covering our combination for the potential treatment of cancer, prevention of cancer recurrence or progression and inhibition of growth and proliferation of cancer cells.

In March 2018, we announced that a new mechanism of action for RHB-107, inhibition of trypsin-3 was identified. We are currently evaluating potential utilization of RHB-107 in several GI indications.

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

Ebola Virus Disease Therapy

We completed the first part of a pre-clinical in-vivo study (2 out of the 3 proposed actives). The results are being evaluated in conjunction with the U.S. National Institute of Allergy and Infectious Diseases. The second part of the study (all three actives combined) has not yet been initiated. In May 2018, we received a new U.S. Patent for our experimental Ebola therapy.

Our Commercial Activities in the U.S.

Our U.S. commercial operations are intended to set the stage for the potential launch of our proprietary, late-clinical stage products, if approved by the FDA.

We have established an office for our U.S. commercial operations in Raleigh, North Carolina. Our GI-focused sales force consists of approximately 40 sales representatives. The net revenues for the fiscal year ended December 31, 2018, and from initiation of our promotional activities in mid-June 2017 through December 31, 2017, were approximately $8.4 million and $4.0 million, respectively. We continue to pursue the acquisition of additional commercial GI products, including, without limitation, through licensing or promotion transaction, asset purchase, joint venture with, acquisition of, or merger with or other business combination with, companies with rights to commercial GI assets and are continuously working to expand U.S. managed care access and coverage to our commercial products, where appropriate. We plan to pursue such GI opportunities in the U.S. and, if available, in other jurisdictions; however, we intend to focus our commercial activities in the U.S. By the end of 2018, we were promoting and commercializing four GI products in the U.S.

Donnatal®

In December 2016, we entered into the Co-Promotion Agreement with ADVANZ for the promotion of Donnatal® (Phenobarbital, Hycosamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) in the U.S. The prescription drug product is sold in two formulations: an immediate-release tablet and an immediate-release fast-acting liquid (tablets and elixir). Donnatal® is an anticholinergic and barbiturate combination drug product used as an adjunctive therapy for IBS, a condition characterized by abdominal pain, bloating, and diarrhea or constipation. It may also be used as an adjunctive therapy for acute enterocolitis and duodenal ulcers. We commenced promotional activities for Donnatal® in June 2017.

Regulatory status

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

Donnatal® has been found safe but not for efficacy for its labeled uses. As a DESI drug, Donnatal® is classified as "possibly effective" as an adjunctive therapy in the treatment of IBS (irritable colon, spastic colon, and mucous colitis) and acute enterocolitis. Donnatal® may also be useful as adjunctive therapy in the treatment of duodenal ulcer. It has not been shown conclusively whether anticholinergic/antispasmodic drugs aid in the healing of duodenal ulcers, decrease the rate of recurrences or prevent complications. Donnatal® slows the natural movements of the gut by relaxing the mucous in the stomach and intestines and acts on the brain to produce a calming effect.

The FDA has said that all products marketed as drugs under the DESI Program are new drugs, requiring FDA approval of an NDA or an abbreviated NDA for marketing. The agency has issued guidance that outlines its priorities for enforcement action relating to a particular drug's effect on public safety and other factors. The FDA has used enforcement discretion concerning many DESI drugs, particularly where there is a pending hearing on a final determination regarding efficacy that has not yet been made. There is a long and complicated regulatory history involving Donnatal®, but currently, there is an open hearing request for anticholinergic and barbiturate combination drug products, of which Donnatal® is one. While ADVANZ is ultimately responsible for regulatory compliance as the application holder, if the FDA convenes a hearing and concludes the product has not been shown to be effective, it may take enforcement action, including requiring Donnatal® to be removed from the market. Several copies of Donnatal® are being sold in the market without going through the FDA approval process. To the best of our knowledge, the FDA has not taken any enforcement action against these copies of Donnatal®.

Market and Competition

IBS is one of the most common GI disorders. According to publications by Saito YA. *et al.* (The American Journal of Gastroenterology, 2002) and by Lovell RM *et al.* (Clinical Gastroenterology and Hepatology, 2012), it is estimated that up to 30 million Americans may suffer from IBS.

According to a report from GlobalData, the U.S. potential market for IBS treatments was estimated to reach approximately $1.89 billion in 2019 and exceed $2 billion in 2020.

To the best of our knowledge, at least two third parties are distributing unapproved generic versions of Donnatal® (tablets and elixir) in the U.S. ADVANZ reported in its third quarter 2018 Management's Discussion and Analysis report (dated November 14, 2018) that it has ongoing legal proceedings against third parties for listing and distributing non-FDA approved copies of Donnatal®. To the best of our knowledge, both proceedings are still ongoing.

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

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

Mytesi®

In June 2018, we entered into a co-promotion agreement with Napo, a wholly-owned subsidiary of Jaguar Health, Inc., granting us exclusive U.S. rights to co-promote Mytesi® (crofelemer 125 mg delayed-release tablets) for the approved indication in people living with HIV/AIDS with respect to certain gastroenterologists and other healthcare practitioners in certain U.S. territories. Mytesi® is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. In July 2018, we initiated the promotion of Mytesi® in the U.S. The initial term of the co-promotion agreement was for six months, which was subsequently extended by amendments to the co-promotion agreement entered in November 2018 and again in January 2019 to end in January 2020.

Napo owns the NDA initially filed by Salix and approved on December 31, 2012. Napo must complete the post-marketing commitments pursuant to the FDA regulations for this product, including a carcinogenicity study that is ongoing; and a pediatric study protocol (evaluation of pharmacokinetics, efficacy for symptomatic relief of non-infectious diarrhea, and safety with different doses of crofelemer over a four-week period in HIV-positive pediatric patients, ages 1 month to 17 years, on anti-retroviral therapy), which has not yet been submitted.

Market and Competition

Mytesi® is the only FDA-approved diarrhea treatment, which has been studied and approved specifically in adults with HIV/AIDS. To the best of our knowledge, there are currently no advanced clinical studies ongoing in the U.S. with new therapeutics for the indication of symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS.

According to the CDC, there were approximately 1 million people living with diagnosed HIV in the U.S. in 2016. Based on an analysis by Foster Rosenblatt, we estimate that approximately 15,000 HIV patients suffer from non-infectious diarrhea annually.

EnteraGam®

In April 2017, we entered into a license agreement with Entera Health pursuant to which we were granted exclusive U.S. commercialization rights to EnteraGam®. EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is promoted as an FDA-regulated "medical food" product intended for the dietary management of chronic diarrhea and loose stools. EnteraGam® must be administered under medical supervision. We initiated commercialization activities for EnteraGam® in June 2017.

Regulatory status

EnteraGam® is currently sold under physician supervision in the U.S. as a "medical food," on the basis of its meeting the criteria for "medical foods" in the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA regulations. The term "medical food" is defined in the FDCA as a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. "Medical foods" are not required to undergo premarket review or approval by the FDA. To our knowledge, EnteraGam® meets the criteria for "medical foods" established by the FDCA, and to date, the labeling and promoting of EnteraGam® is consistent with FDA regulatory requirements. However, our offering of EnteraGam® as a "medical food" could be challenged by the FDA. See "—Our offering of EnteraGam® as a "medical food" in the U.S. may be challenged by regulatory authorities." The ingredients in EnteraGam® are generally recognized as safe (GRAS) for use in the general population.

Market and Competition

EnteraGam® is a medical food product that provides dietary management for patients with chronic diarrhea and loose stools due to specific intestinal disorders, such as IBS-D, IBD, HIV-associated enteropathy and chronic diarrhea.

EnteraGam® can be added safely to any therapy taken by patients suffering from chronic diarrhea and loose stools, including patients who suffer from IBS-D, Crohn's disease and ulcerative colitis. According to a report from EvaluatePharma, the U.S. potential market for IBS-D treatments is estimated to reach approximately $980 million in 2019 and exceed $1 billion in 2020.

There are several competing medical foods marketed in the U.S. intended for the treatment of diarrhea or loose stools associated with IBS, IBD or other conditions. One of the leading competitors is VSL#3® (marketed by Alfasigma USA Inc.), a high potency probiotic medical food used in addition to certain medications for the dietary management of ulcerative colitis, IBS and pouchitis. Other competing medical foods include UltraInflamX® and UltraInflamX Plus 360°® (Metagenics), a medical food formulated to provide support for patients with compromised gut function resulting from inflammatory bowel disease, Banatrol Plus® (Medtrition Inc.), a medical food formulated for patients under medical supervision experiencing diarrhea and loose stools associated with the flu, antibiotics, tube feeding, oncology treatment,

Clostridium difficile (C. diff) and aging, Tolerex® (Nestle Health Science), a medical food intended for patients suffering from severely impaired GI function, Modulen® (Nestle Health Science), a whole-protein, powdered formulation for the dietary management of the active phase of Crohn's disease, and IBGard® (IM HealthScience), a medical food formulated for dietary management of IBS. There are also several competing products being sold by other companies that source the raw material from the same manufacturer of EnteraGam®, although we are the only ones licensed to sell under the EnteraGam® brand.

Other competing products include over-the-counter ("OTC") probiotic dietary supplements such as Culturelle®, prescription anticholinergics such as Lomotil® (Pfizer U.S.) and Motofen® (Sebela Pharmaceuticals) and prescription and OTC anti-diarrheal medications, such as Imodium® (loperamide).

Esomeprazole Strontium Delayed-Release Capsules 49.3 mg

In August 2017, we entered into a commercialization agreement with ParaPRO, an Indiana-based specialty pharmaceutical company, granting us the exclusive rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg to gastroenterologists in certain U.S. territories. Esomeprazole Strontium Delayed-Release Capsules 49.3 mg is an FDA-approved prescription PPI drug product indicated for adults for the treatment of GERD, risk reduction of NSAID-associated gastric ulcer, *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence and for pathological hypersecretory conditions, including Zollinger-Ellison syndrome. In September 2017, we initiated the promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in selected U.S. territories.

Regulatory status

We promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in the U.S., which was approved by the FDA in 2013 under the 505(b)(2) regulatory path, with Nexium as the Reference Listed Drug. Since we have not licensed or purchased the rights to the NDA and instead only promote the product with limited rights under the agreement with ParaPRO, we rely on ParaPRO for ensuring regulatory compliance and to maintain the approved NDA. To the best of our knowledge, there have been two supplements approved to the NDA, one due to safety concerns and class labeling of PPIs initiated by the FDA in 2016 and the first supplement, again requested by the FDA in October 30, 2014, under Section 505(o)(4) of the FDCA, with new safety information that the FDA believed should be included in the labeling for Esomeprazole Strontium Delayed-Release Capsules 49.3 mg. This information pertains to the risk of Vitamin B12 deficiency with long-term daily treatment of PPIs and the risk of concomitant dosing of mycophenolate mofetil with PPIs resulting in reduced systemic exposure of mycophenolate mofetil as reported in current literature.

Market and Competition

GERD is considered the most common disease encountered by gastroenterologists (Katz PO *et al*. Am J Gastroenterol, 2013). According to GlobalData, the number of prevalent cases of GERD in the U.S. in 2019 is estimated to exceed 66 million.

The 2012 American College of Gastroenterology guidelines for treatment of GERD recommend treatment with an 8-week course of PPIs for symptom relief and healing of erosive esophagitis. Other treatments for GERD include antacids, H2-receptor blockers and other medications which are available in OTC and prescription strength.

There are currently no generic formulations of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg available in the U.S. The main competitors of Esomeprazole Strontium Delayed-Release Capsuled 49.3 mg are numerous OTC and prescription PPIs marketed in the U.S. These include branded and generic, prescription and OTC omeprazole (Prilosec®), branded and generic, prescription and OTC lansoprazole (Prevacid®) and branded and generic, prescription and OTC esomeprazole magnesium (Nexium®). Prescription dexlansoprazole (Dexilant®, marketed by Takeda Pharmaceuticals) is the only other PPI other than Esomeprazole Strontium Delayed-Release Capsules 49.3 mg that is not available in generic form. PPIs are one of the most commonly prescribed classes of medications in the U.S.; with an estimated market value exceeding $20 billion in 2016 (Symphony Health (accessed August 2017)).

Acquisition, Commercialization and License Agreements

Acquisition of RHB-104, TALICIA® 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, TALICIA® and RHB-106, respectively. Giaconda Limited further transferred to us products in process, product samples and raw materials, as well as certain rights of first refusal with respect to intellectual property in relation to digestive condition treatments. The agreement excluded the transfer of the rights to two products of Giaconda Limited that are not related to RHB-104, TALICIA® and RHB-106. However, to the extent that the intellectual property associated with these two other products may be required for the research, development, manufacture, registration, import/export, use, commercialization, distribution, sale or offer for sale of any of RHB-104, TALICIA® and RHB-106, Giaconda Limited granted us an exclusive worldwide assignable right to such intellectual property for such purposes. The closing of this transaction occurred on August 26, 2010.

We paid Giaconda Limited in consideration for the assets purchased by us an initial amount of $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 consideration (including royalties received by us) from sublicensees, in each case, only after we recoup the amounts and expenses exceeding an approved budget.

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

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

The agreement also requires us to make a good faith, continuous and commercially reasonable effort to allocate appropriate financial resources to prepare, initiate and complete the clinical development of the products (with the exception of Picoconda by virtue of the Salix license agreement dated February 27, 2014) and file an application for regulatory marketing approval in accordance with industry standards. Development failures, negative regulatory decisions, or other reasons beyond our control will not constitute a breach of this obligation. Should we breach this obligation with respect to the development of any of the products and fail to cure the breach within 90 days from the date that Giaconda Limited sends us a default notice, Giaconda Limited may buy back all of the intellectual property rights with respect to such product for the original purchase price, plus the related development costs incurred by us through the date of the buy-back.

In connection with the license agreement with Salix (later acquired by Bausch Health), dated February 27, 2014, described below, we amended the asset purchase agreement and related agreements by excluding from the non-compete undertakings of Giaconda Limited and certain of its affiliate products, technology and related activities in the purgative field and excluded from such non-compete undertakings certain of Giaconda Limited's affiliates. Subsequently, we recognized revenues in 2014 and paid Giaconda Limited an additional amount of $1 million. On February 27, 2014, we amended the asset purchase agreement with Giaconda Limited to cancel the buyback right and agreed that we would pay Giaconda Limited 20% of all amounts received by us from Bausch Health under the license agreement, without first recouping amounts and expenses and notwithstanding the expiration of any relevant patents.

Exclusive License Agreement with Bausch Health Companies Inc.

On February 27, 2014, we entered into a worldwide exclusive license agreement with Salix (now Bausch Health), as amended on February 26, 2018, pursuant to which Salix licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation and rights to other purgative developments. Pursuant to the agreement, we granted Salix the right to develop and commercialize RHB-106 or the related rights.

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

Pursuant to the agreement, before it was amended on February 26, 2018, we received an up-front payment of $7 million and were entitled to an additional amount of up to $5 million in subsequent milestone payments. In addition, we were entitled to receive tiered royalties on net sales, ranging from low single-digit up to low double-digits.

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

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

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

On February 26, 2018, we entered into an amendment to the agreement that clarifies the development efforts to be used by Bausch Health, as well as provides for our enhanced involvement in certain intellectual property matters. In addition, the parties have agreed to increase the lower end of the range of royalty payments to be paid to us on net sales from low single digits to high single digits, such that the potential royalties now range from high single digits up to low double digits. Milestone payments remain unchanged. We have agreed to pay a percentage of the amounts received by us from Bausch Health to the third party from which we acquired the rights to RHB-106.

License Agreement for YELIVA®

On March 30, 2015, we entered into an exclusive license agreement with Apogee, a privately-held biotech company located in Hummelstown, Pennsylvania, U.S., under which Apogee granted us the exclusive, worldwide development and commercialization rights to ABC294640 (which we then renamed to YELIVA ® and received an international non-proprietary name, opaganib, in 2018) and additional intellectual property rights. YELIVA ® is a proprietary, first-in-class, orally-administered SK2 inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple oncology, inflammatory and GI indications. Under the terms of the agreement, as amended, we agreed to pay Apogee initial milestone payments of $3 million. In addition, we undertook to pay up to an additional $2 million in potential development milestone payments and potential tiered royalties starting in the low double-digits. Such potential royalties are due until the later of: (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2018, we paid Apogee the initial amount of $3 million. The license agreement will stay in effect as of its effective date unless terminated earlier as described in the agreement. We are entitled to terminate the agreement at any time upon 30 days' prior written notice to Apogee. The agreement also provides for the right of termination for each party in the event of a material breach committed by the other party.

License Agreement for RHB-107 (Upamostat; formerly MESUPRON)

On June 30, 2014, we entered into an exclusive license agreement with Wilex AG (which later changed its name to Heidelberg Pharma AG, "Heidelberg"), a German biopharmaceutical company focused on oncology, under which Heidelberg granted us the exclusive worldwide (excluding China, Hong Kong, Taiwan, and Macao) development and commercialization rights for all indications to RHB-107.

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

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

Exclusive Co-Promotion Agreement for Donnatal®

On December 30, 2016, we entered into an exclusive co-promotion agreement with a subsidiary of ADVANZ, an international specialty pharmaceutical company focused on generic and legacy pharmaceutical products and orphan drugs, as part of our strategic initiative to become a revenue-generating, GI-focused, specialty pharmaceutical company with a commercial presence in the U.S. to support potential future commercialization of our therapeutic candidates.

Under the agreement, we are responsible for certain promotional activities related to Donnatal® in certain U.S. territories, and ADVANZ continues to be responsible for, among other things, the manufacturing and supply and pricing of Donnatal ® in all territories. We and ADVANZ share the revenues generated from the promotion of Donnatal® by us based upon an agreed upon split. There are no upfront or milestone payments required to be paid by us under the agreement. The initial term of the agreement is three years. We may terminate the agreement upon three months' notice for reasons set forth in the agreement. ADVANZ may terminate the agreement after an agreed upon period and for reasons set forth in the agreement.

Co-Promotion Agreement for Mytesi®

In June 2018, we entered into a co-promotion agreement with Napo, a human health company developing and commercializing novel gastrointestinal prescription products from plants used traditionally in rainforest areas. Napo is a wholly-owned subsidiary of Jaguar Health, Inc. Under this agreement, Napo granted us exclusive U.S. rights to co-promote Mytesi® (crofelemer 125 mg delayed-release tablets) for the approved indication in people living with HIV/AIDS with respect to certain gastroenterologists and other healthcare practitioners in certain U.S. territories. Mytesi® is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. The initial term of the co-promotion agreement was for six months, which was extended by the parties in November 2018 and January 2019 to end in January 2020. In July 2018, we initiated the promotion of Mytesi® in the U.S.

Exclusive License Agreement for EnteraGam®

In April 2017, we entered into a license agreement with Entera Health, a U.S. privately owned company. Under the license agreement, we were also granted an exclusive license to use the related EnteraGam® trademarks, URL and other related intellectual property for the sale and distribution of EnteraGam® in the U.S. during the term of the agreement. We are required to pay Entera Health royalties based on net sales as provided in the agreement. The initial term of the agreement is four years. Each party may terminate the agreement upon an agreed prior written notice to the other party for various reasons stipulated in the agreement.

Commercialization Agreement for Esomeprazole Strontium Delayed-Release Capsules 49.3 mg

In August 2017, we entered into an agreement with ParaPRO LLC ("ParaPRO") granting us the exclusive rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg to gastroenterologists in certain U.S. territories. Under the agreement, we agreed on a co-promotion plan with ParaPRO, and are responsible, together with ParaPRO for the promotion of the product to gastroenterologists for all labeled indications for the product in certain U.S. territories. In the event of the sale into the agreed territories of a generic equivalent for the product, we may limit or discontinue all or part of our ongoing promotional activities. ParaPRO agreed to provide us promotional material, training and samples (or equivalents) of the product, and it is responsible to take all actions in relation to the commercialization of the product in the territory and all aspects of managed care, and we are responsible for the promotion of the product. The agreement provides that all regulatory matters relating to the commercialization of the product during the term of this agreement are the responsibility of ParaPRO, subject to our right to communicate with regulatory authorities with respect to matters

relating to us and our performance under the agreement. The initial term of the agreement is four years. Each party may terminate the agreement upon prior written notice to the other party for reasons set forth in the agreement.

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 (UCF) pursuant to which we were granted an exclusive license for all indications and medical uses to a patent-protected diagnostic test aimed at identifying the presence of MAP bacterial DNA in peripheral blood through DNA testing. The license covers the future commercial use of the test, including its manufacture, marketing, sale, and commercialization.

Under the agreement, we may grant sublicenses for the test with the consent of the UCF, from whom consent may not be unreasonably withheld.

To date, in consideration for the license, we have made payments in the aggregate amount of $195,000 and are required to make additional annual minimum royalty payments of $35,000 in each subsequent year until the last patent covered by the agreement expires. These annual minimum payment amounts will be deducted from future royalty payments.

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

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

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

On December 27, 2014, we entered into a license agreement with the University of Minnesota (UoM) pursuant to which we were granted an exclusive license for all indications and medical uses to a patent-protected designation of certain DNA sequencing.

Master Service Agreement with 7810962 Canada Inc.

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

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

Furthermore, pursuant to the agreement, the Canadian service provider may provide us with a discount on 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, 2018, the estimated discount we will receive from our Canadian service provider is approximately $0.3 million.

Clinical Services Agreements

Clinical Services Agreement related to RHB-104

On June 15, 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with PharmaNet Canada Inc., (subsequently a subsidiary of inVentiv Health Clinical, Inc., which became Syneos), an international CRO company for the purpose of performing the clinical trial for RHB-104. Syneos is a leading provider of global drug development services to pharmaceutical and biotechnology companies, offering therapeutically specialized capabilities for Phase 1-4 clinical development, and pursuant to the agreement, is responsible for the performance of the clinical trial, including entering into agreements with medical centers to perform the trial, supervision of the performance and progress of the trial and the analysis of the results, all pursuant and subject to applicable regulatory requirements.

Pursuant to this agreement and subsequent amendments, Syneos is entitled to receive compensation in connection with the MAP US study, as well as reimbursement of investigator grant costs and pass-through costs to be paid during the trial. The payments are spread over the period of the clinical trial based upon quarterly administration fees and milestone payments based on patient recruitment, completion of subject dosing and report preparation, investigators' grants paid to research centers that participate in the trial, as well as reimbursement of certain expenses. These fees, however, are partial costs for the RHB-104 program and may increase in accordance with the final clinical trial protocol, length of the study and payments to be made to third parties, such as investigator grants costs and additional service providers, including other clinical research organizations.

The agreement includes a timetable for the recruitment of patients, performance of the trial and analysis of results, including a timetable for the performance of ongoing patient follow-up.

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 February 2017, we entered into an agreement with our Canadian service provider, which entered into a back-to-back agreement with Syneos for the provision of clinical trial services for the MAP US2 study.

Expanded Access Program (EAP)

We have adopted an EAP, allowing patients with life-threatening diseases potential access to our investigational new drugs that have not yet received regulatory marketing approval. Expanded access (sometimes referred to as "compassionate use") is possible outside of our clinical trials, under certain eligibility criteria, when a certain investigational new drug is needed to treat a life-threatening condition and when there is some clinical evidence suggesting that the drug might be effective for that condition. Patients who qualify for our EAP do not meet the eligibility criteria or are incapable of participating in our clinical trials for such therapeutic candidate or there is no clinical trial accessible to such patients. Following the adoption of the program, we continue to receive patient requests to obtain access to our investigational drugs. Subject to the evaluation of eligibility and all other necessary regulatory, reporting and other conditions and approvals required in all relevant jurisdictions, we provide certain patients with an investigational new drug under the EAP.

Intellectual Property

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

vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments. We have rights, either through assignment, asset purchase or in-licensing, to a total of approximately 200 issued patents and 100 patent applications. The patents and patent applications are registered in the U.S. and other key jurisdictions, the details of each family of patents being provided below. In addition, we have licensed rights to various platform technologies on a non-exclusive basis.

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

TALICIA®

The patent portfolio protecting TALICIA® currently includes four U.S. patents, two pending U.S. patent applications, and over 20 foreign patents and patent applications. The second-generation patents (all but two noted above) provide patent protection through 2034.

RHB-104 – Inflammatory Bowel Disease

The patent portfolio protecting RHB-104 and its use in treating inflammatory bowel disease currently includes six U.S. patents, one pending U.S. patent application, and 33 foreign patents and patent applications, providing patent protection through 2029.

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

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

RHB-104 – Multiple Sclerosis ("MS")

The patent portfolio protecting use of RHB-104 for treating relapsing-remitting multiple sclerosis includes one U.S. patent and over 20 foreign patents and patent applications, providing patent protection through 2032.

RHB-204 – Nontuberculous Mycobacterium (NTM) Infections

The patent portfolio protecting RHB-204 currently includes two U.S. patents, one pending U.S. patent application and one pending European patent application, providing protection through 2029.

BEKINDA® - Gastritis, Gastroenteritis and IBS-D

The patent portfolio protecting BEKINDA® and its use currently includes two U.S. patents, two pending U.S. patent applications, and over 30 foreign patents and patent applications, providing patent protection through 2034.

RHB-106 - Bowel Preparation

The patent portfolio protecting RHB-106 and its use currently includes one issued U.S. patent, one pending U.S. patent application, and 12 foreign patents and patent applications, providing patent protection through 2033.

We are party to an exclusive agreement by which Bausch Health licensed us the exclusive worldwide rights to the RHB-106 patent portfolio. As part of the agreement, Bausch Health is responsible for the patent families related to RHB-106.

YELIVA® - Oncology, inflammatory and GI Indications

This patent portfolio was in-licensed by us from Apogee Biotechnology Corp. YELIVA® (ABC294640) is a first-in-class, proprietary SK2 inhibitor, administered orally, with anti-cancer and anti-inflammatory activities, targeting a number of potential oncology, inflammatory and GI indications. These patents relate to sphingosine kinase inhibitors, pharmaceutical compositions, methods of preparing the inhibitors, methods of treating inflammatory diseases using the inhibitors, methods of treating cancer using the inhibitors, and methods for inhibiting sphingosine kinase.

The patent portfolio covering YELIVA® includes 4 U.S. patents and over 18 foreign patents and patent applications, providing patent protection through 2028.

RHB-107 (Upamostat; formerly MESUPRON) – Oncology

This patent portfolio was in-licensed by us from Wilex AG, now known as Heidelberg Pharma AG. RHB-107 is a first-in-class protease inhibitor administered by oral capsule. The RHB-107 patent portfolio includes patents directed to the new chemical entity, WX-671, WX-UK1, the active metabolite of WX-671, pharmaceutical compositions comprising WX-671 (RHB-107), methods of synthesizing WX-671 and WX-UK1, and methods of use. The portfolio includes 15 issued U.S. patents and over 60 foreign patents and patent applications, providing patent protection through 2027.

Ebola

The patent portfolio covers RedHill's proprietary experimental therapy for the treatment of Ebola virus disease. The portfolio consists of one U.S. patent, 1 pending U.S. patent application, and 7 pending international patent applications.

Government Regulations and Funding

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

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

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

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

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

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

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

The clinical testing of a therapeutic drug candidate generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. However, safety information should be submitted before initiation of a subsequent clinical phase. A fourth, or post-approval phase may include additional clinical studies. The phases are generally as follows:

Phase 1. In Phase 1 clinical studies, the therapeutic drug candidate is tested in a small number of healthy volunteers, though in cases where the therapeutic drug candidate may make the volunteer ill, clinical patients with the targeted condition may be used. These "dose-escalation" studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the therapeutic drug candidate in humans, side effects associated with increasing doses, and, in some cases, to gain early evidence on efficacy. The number of participants included in Phase 1 studies is generally in the range of 20 to 80.

Phase 2. In Phase 2 studies, in addition to safety, the sponsor evaluates the efficacy of the therapeutic drug candidate on targeted indications to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. Phase 2 studies typically are larger than Phase 1 but smaller than Phase 3 studies and may involve several hundred participants.

Phase 3. Phase 3 studies typically involve an expanded patient population at geographically-dispersed test sites and involve control groups taking a reference compound or a placebo (an inactive compound identical in appearance to the study compound). They are performed after preliminary evidence suggesting the effectiveness of the product candidate has been obtained and are designed to evaluate clinical safety and efficacy further, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for a potential product approval. Phase 3 studies usually involve several hundred to several thousand participants.

Phase 4. Phase 4 clinical trials are post-marketing studies designed to collect additional safety data as well as potentially expand a product indication. Post-marketing commitments may be required of, or agreed to by, a sponsor after the FDA has approved a therapeutic drug candidate for marketing. These studies are used to gain additional information from the treatment of patients in the intended therapeutic indication and to verify a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement. These clinical trials are often referred to as Phase 4 post-approval or post-marketing commitments. Failure to promptly conduct Phase 4 clinical trials could result in the inability to deliver the product into interstate commerce, misbranding charges, and civil monetary penalties.

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

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

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

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within ten months of a completed submission for 90% of the submissions received, unless the application relates to an unmet medical need in a serious or life-threatening indication, in which case the goal may be within six months of a completed NDA submission. However, PDUFA goal dates are not legal mandates, and the FDA response may occur several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive, and the FDA or any advisory committee it appoints may interpret data differently than the applicant.

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

Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug product candidate.

If the FDA approves one of our therapeutic drug candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report to the FDA, among other things, certain adverse reactions and production problems, and provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and recordkeeping requirements. If we seek to make certain changes to an approved therapeutic drug, such as certain manufacturing changes, we may need the FDA to review and approve before the change can be implemented. For example, if we change the manufacturer of a product or its API, the FDA may require stability or other data from the new manufacturer, which will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. At their discretion, physicians may prescribe approved pharmaceutical products for indications that pharmaceutical products have not been approved for use by the FDA. However, we may not label or promote pharmaceutical products for an indication that has not been approved. Securing FDA approval for new indications of an approved therapeutic drug requires a Section 505(b)(2) filing, is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

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

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval of new indications or new formulations of previously-approved therapeutic drugs, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA, somewhat similar to the process for approval of the original indication or reference drug and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. Section 505(b)(2) of the Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) was enacted to allow a company to avoid duplicative testing by permitting the applicant to leverage previously performed pertinent clinical and non-clinical studies into the current NDA submission. Some examples of therapeutic drug candidates that may be allowed to follow a 505(b)(2) path to approval are candidates that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the NDA. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development,

process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

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

Orphan Drug Designation

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

GAIN Act

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

Other Healthcare Laws and Compliance Requirements

In the U.S., we are subject to various federal and state laws and regulations regarding fraud and abuse in the healthcare industry, as well as industry standards and guidance, such as the codes issued by the Pharmaceutical Research and Manufacturers of America (or "PhRMA Codes"), which some states reference or incorporate in their statutes and regulations. These laws, regulations, standards, and guidance may impact, among other things, our sales and marketing activities and our relationships with healthcare providers and patients. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claim Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from the federal government, including Medicare, Medicaid, or other third-party payors, that are false or fraudulent;
- HIPAA, which imposes federal criminal and civil liability for executing, or attempting to execute, a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the Physician Payments Sunshine Act, that requires applicable manufacturers of covered drugs to disclose payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, also imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, state laws that require pharmaceutical manufacturers to report certain pricing or payment information, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are not preempted by HIPAA, thus complicating compliance efforts.

The Healthcare Reform Law broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and certain other criminal healthcare fraud statutes. Specifically, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only federal healthcare programs such as the Medicare and Medicaid programs.

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to comply with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect the arrangements we may have with sales personnel, healthcare providers, and patients. Our risk of being found in violation of these laws is increased by the fact that some of these laws are open to a variety of interpretations. If our past or present operations, practices, or activities are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, damages, fines, disgorgement, contractual remedies, reputational harm, diminished profits and future earnings, if any, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

C. Organizational Structure

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

D. Property, Plant and Equipment

We lease approximately 826 square meters of office space, a 27-square meter warehouse and eleven parking spaces in the "Platinum" building at 21 Ha'arba'a Street, Tel Aviv, Israel. The projected yearly gross rental expenses are approximately $410,000 per year. During 2018, we subleased a portion of the office space to a tenant for approximately $42,000. The term under our lease agreement will expire on January 31, 2026. These offices have served as our corporate headquarters since April 2011.

The Company also entered into an operating lease agreement for the U.S. offices it uses. The agreement will expire on March 31, 2023. The projected yearly rental expenses are approximately $169,000 per year.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report. The following discussion contains

forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly those in "Item 3. Key Information – D. Risk Factors."

Company Overview

We are a specialty biopharmaceutical company primarily focused on proprietary drugs for GI diseases. From our inception to the end of the period covered by this Annual Report, we invested a total of $5.3 million on in-licensing and acquisitions of therapeutic candidates and related technologies.

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

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

In addition to our primary focus on the development of clinical-stage GI products, we have established commercial presence and capabilities in the U.S., intended primarily to support potential future launch of our GI-related therapeutic candidates currently under development in the U.S. We pursue our commercial activities in the U.S. through RedHill Biopharma Inc., a wholly-owned subsidiary we formed in Delaware in January 2017. Through this subsidiary, we currently promote four GI products in the U.S., Donnatal®, Mytesi®, EnteraGam® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg under agreements with third parties.

We have funded our operations primarily through public and private offerings of our securities. Because our therapeutic candidates and products are currently in development, and because we have not yet generated sufficient revenues from the promotion of Donnatal®, Mytesi®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and from commercialization of EnteraGam® with no anticipation of profits in the near future, we cannot estimate when and if we will generate sufficient revenues to sustain our business operations in accordance with our plan, or profits in the future from our therapeutic candidates and commercial products.

The following is a description of our seven therapeutic candidates, most in late-stage clinical development, and four commercial products:

Therapeutic Candidates

TALICIA® (RHB-105) is intended for the treatment of *H. pylori* bacterial infection in the GI tract. TALICIA® is a combination of three approved drug products – omeprazole, which is a proton pump inhibitor (prevents the secretion of hydrogen ions necessary for digestion of food in the stomach), amoxicillin and rifabutin, which are antibiotics. TALICIA® is administered to patients orally. In December 2018, we announced positive top-line results from the ERADICATE Hp2 study. Subject to any additional regulatory feedback, the ERADICATE Hp2 study is expected to complete the clinical package required for a potential submission of an NDA with the FDA for TALICIA® in the first half of 2019. We acquired ownership rights in patents, tangible assets, production files, and regulatory approvals and other data and certain third-party agreements related to TALICIA® pursuant to the Asset Purchase Agreement with Giaconda Limited described above.

See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Acquisition of RHB-104, TALICIA®, and RHB-106."

RHB-104 is intended to treat Crohn's disease, which is a serious inflammatory disease of the GI system that may cause severe abdominal pain and bloody diarrhea, malnutrition and potentially life-threatening complications. RHB-104 is a patented combination of clarithromycin, clofazimine, and rifabutin, three generic antibiotic ingredients, in a single capsule. The compound was developed to treat Crohn's disease through the targeting of MAP infection. We announced positive top-line safety and efficacy results from the Phase 3 MAP US study in July 2018 and have an ongoing Phase 3 MAP US2 study to evaluate the safety and efficacy of RHB-104 in subjects who remain with active Crohn's disease (CDAI ≥ 150) after 26 weeks of blinded study therapy in the MAP US study. 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, TALICIA® 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, Commercialization and License Agreements – Acquisition of RHB-104, TALICIA®, and RHB-106."

RHB-204 is a patented fixed-dose combination product of three antibiotics that will simplify administration and optimize compliance. Each capsule contains the same components as RHB-104 (clarithromycin, clofazimine, and rifabutin) but at unique doses. Final dose selection for the pending pivotal trial is ongoing, and current plans are to start a pivotal trial for NTM lung infection in H2 2019. The appropriate regulatory path is currently under discussion.

BEKINDA® (RHB-102) is a once-daily bi-modal extended-release oral formulation of ondansetron, a leading member of the family of 5-HT3 serotonin receptor inhibitors, intended to treat nausea, vomiting and diarrhea symptoms experienced in some people suffering from acute gastroenteritis, gastritis, and IBS-D. On May 2, 2010, we received a worldwide, exclusive and perpetual license to use patents and know-how relating to CDT® technology from SCOLR Pharma, Inc. in exchange for an up-front payment of $100,000. SCOLR announced during 2013 that it had ceased business operations, and we entered into a License Agreement with Temple University to secure direct rights to patents related to the CDT® platform. SCOLR had itself licensed those patents from Temple University, the original owner of the patents.

YELIVA® (ABC294640) is a proprietary, first-in-class, orally-administered SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple oncology, inflammatory and GI indications. The compound originally designated as ABC294640 received an international non-proprietary name, opaganib, in the Recommended INN: List 79, 2018. On March 30, 2015, we entered into an exclusive worldwide license agreement with Apogee, pursuant to which Apogee granted us the exclusive worldwide development and commercialization rights to ABC294640 (which we then renamed to YELIVA® and as noted above, received an international non-proprietary name, opaganib, in 2018) and additional intellectual property for all indications. Under the terms of the agreement, as amended, we agreed to pay Apogee initial milestone payments of $3 million, of which the total amount has been paid, as well as up to $2 million in potential development milestone payments, and tiered royalties starting in the low double-digits. For more information regarding this agreement, see "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for YELIVA®."

RHB-107 (Upamostat; formerly MESUPRON) (INN: upamostat) is a proprietary small molecule, first-in-class, potent serine protease inhibitor administered by oral capsule. We believe that RHB-107 has a unique potency and specificity that suggests it may be a new non-cytotoxic approach to cancer therapy, as well as other indications of high unmet need such as inflammatory digestive diseases and inflammatory lung diseases. On June 30, 2014, we acquired from Heidelberg the exclusive development and commercialization rights to RHB-107, excluding China, Hong Kong, Taiwan, and Macao, for all indications. We made an upfront payment to Heidelberg of $1.0 million with potential tiered royalties on net revenues, ranging from mid-teens up to 30%. We are responsible for all development, regulatory and commercialization of RHB-107. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for RHB-107."

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

interventions, such as a laparotomy. We acquired ownership rights in patents, tangible assets, production files, and regulatory approvals and other data and rights in certain third-party agreements related to RHB-106 pursuant to the Asset Purchase Agreement with Giaconda Limited described above. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Acquisition of RHB-104, TALICIA®, and RHB-106." On February 27, 2014, we entered into a licensing agreement with Salix (later acquired by Bausch Health) pursuant to which Bausch Health is granted the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation, and rights to other purgative developments.

Commercial Products

Donnatal® is an anticholinergic and barbiturate combination drug product used as an adjunctive therapy for IBS. On December 30, 2016, we entered into the Co-Promotion Agreement with a subsidiary of ADVANZ, pursuant to which we were granted certain rights to promote Donnatal® in certain U.S. territories. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Exclusive Co-Promotion Agreement for Donnatal®." We commenced promotional activities for Donnatal® in June 2017 and recorded revenues of $0.7 million for the year ended 2017 and $3.5 million for the year ended 2018 from promotion of Donnatal®.

Mytesi® is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Co-Promotion Agreement for Mytesi®." We initiated the promotion of Mytesi® in the U.S. in July 2018 and recorded an immaterial amount of revenues for the year ended December 31, 2018 from promotion of Mytesi®.

Esomeprazole Strontium Delayed-Release Capsules 49.3 mg is an FDA-approved prescription PPI drug product indicated for adults for the treatment of GERD, risk reduction of NSAID-associated gastric ulcer, *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence and for pathological hypersecretory conditions, including Zollinger-Ellison syndrome. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Commercialization - Agreement for Esomeprazole Strontium Delayed-Release Capsules 49.3 mg." We initiated the promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in selected U.S. territories in September 2017 and recorded an immaterial amount of revenues for the year ended December 31, 2017, and $0.2 million for the year ended December 31, 2018, from promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg.

EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is promoted as an FDA-regulated "medical food" product intended for the dietary management of chronic diarrhea and loose stools. EnteraGam® must be administered under medical supervision. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – License Agreement for EnteraGam®." We initiated commercialization activities for EnteraGam® in June 2017 and recorded revenues of $3.2 million for the year ended December 31, 2017, and $4.7 million for the year ended December 31, 2018, from commercialization of EnteraGam®.

Components of Statements of Comprehensive Loss

Revenues

In 2018 and 2017, revenues consisted of revenues with respect to commercialization and promotional activities of our commercial products, as described above. In 2016, we recorded revenues with respect to a certain licensing agreement.

Cost of Revenues

Direct costs related to the revenues, such as cost of goods sold and royalties to third parties.

Research and Development Expenses

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

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees, directors and consultants and professional services. Other significant general and administrative expenses include office related expenses, travel, conferences, and others.

Selling, Marketing and Business Development Expenses

Selling, Marketing and Business Development expenses consist primarily of compensation for employees and consultants dedicated for marketing activities with the Company's commercialized and promoted products and professional services. Other significant selling, marketing and business development expenses include product samples, car fleet, travel, conferences, office-related expenses and others.

Financial Income and Expenses

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

Critical Accounting Policies and Estimates

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

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

Recent Accounting Pronouncements

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

A. Operating Results

History of Losses

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

of 2017, we started to accumulate losses also from our commercial operations. As of December 31, 2018, we had an accumulated deficit of approximately $169.1 million.

We expect to continue to fund our operations over the next several years through public or private equity offerings, debt financings, non-dilutive financings, commercialization of our therapeutic candidates, products we may promote or commercialize, or through revenues from the promotion of Donnatal®, Mytesi®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and from the commercialization of EnteraGam®.

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.

Three Months Ended

	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31
	2016				2017				2018			
Statements of operations	U.S. dollars in thousands											
Net revenues	—	1	—	100	—	483	1,523	2,001	2,445	2,350	2,206	1,359
Cost of revenues	—	—	—	—	—	272	935	919	930	725	598	584
Research and development expenses, net	4,676	6,031	7,038	7,496	8,137	8,434	8,106	8,292	6,416	6,044	6,624	5,778
Selling, marketing and business development	312	424	402	417	605	3,376	4,189	3,844	3,170	3,123	3,040	3,153
General and administrative expenses	915	740	1,014	1,179	1,315	1,940	2,258	2,512	1,924	2,015	1,680	1,887
Other expenses	—	—	—	—	45	—	—	800	—	—	—	—
Operating loss	5,903	7,194	8,454	8,992	10,102	13,539	13,965	14,366	9,995	9,557	9,736	10,043
Financial income	380	666	109	1,013	1,556	2,523	150	3,966	134	156	133	2,403
Financial expenses	1	24	599	371	50	7	1,697	13	74	1,717	480	44
Net loss	5,524	6,552	8,944	8,350	8,596	11,023	15,512	10,413	9,935	11,118	10,083	7,684

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

Segment Information

Commencing 2017, the Company has two segments, Commercial Operations and Research & Development. The Commercial Operations segment covers all areas relating to the commercial sales and operating expenses directly related to that activity. The Research and Development segment includes all activities related to the research and development of therapeutic candidates.

Below is a table summarizing the financial results of the two segments for the years ended December 31, 2018 and December 31, 2017.

	Year Ended December 31, 2018			Year Ended December 31, 2017		
December 31, 2018:	Commercial Operations	Research and Development	Consolidated	Commercial Operations	Research and Development	Consolidated
	U.S. dollars in thousands			U.S. dollars in thousands		
Net revenues	8,360	—	8,360	4,007	—	4,007
Cost of revenues	2,837	—	2,837	2,126	—	2,126
Gross profit	5,523	—	5,523	1,881	—	1,881
Research and development expenses, net	—	24,862	24,862	—	32,969	32,969
Selling, marketing and business development expenses	11,329	1,157	12,486	10,520	1,494	12,014
General and administrative expenses	2,795	4,711	7,506	2,680	5,345	8,025
Other expenses	—	—	—	—	845	845
Operating loss	8,601	30,730	39,331	11,319	40,653	51,972

Comparison of the Year Ended December 31, 2018 to the Year Ended December 31, 2017

Net Revenues

Net Revenues for the year ended December 31, 2018 were $8.4 million, compared to $4.0 million for the year ended December 31, 2017. The increase was due to the advancement of promotional activities for Donnatal® and commercialization activities for EnteraGam®, initiated mid-June 2017.

Cost of Revenues

Cost of Revenues for the year ended December 31, 2018 was $2.8 million, compared to $2.1 million for the year ended December 31, 2017. The increase was due to higher cost of goods sold and amounts paid for royalties relating to commercialization activities.

Gross Profit

Gross Profit for the year ended December 31, 2018, was $5.5 million, compared to $1.9 million for the year ended December 31, 2017. Gross margin increased from 47% to 66%. The increase was due to net revenues and cost of revenues, discussed above.

Research and Development Expenses

Research and Development Expenses for the year ended December 31, 2018, were $24.9 million, compared to $33.0 million for the year ended December 31, 2017. The decrease was mainly due to the implementation of the Company's cost reduction plan, the finalization of the Phase 3 study with RHB-104 and completion of the clinical studies with BEKINDA®.

Selling, Marketing and Business Development Expenses

Selling, Marketing and Business Development Expenses for the year ended December 31, 2018, were $12.5 million, compared to $12.0 million for the year ended December 31, 2017. The increase was mainly due to the expenses related to commencement of U.S. commercial operations in June 2017, offset by the continued implementation of the Company's cost reduction plan.

General and Administrative Expenses

General and Administrative Expenses for the year ended December 31, 2018, were approximately $7.5 million, compared to $8.0 million for the year ended December 31, 2017. The decrease was due to the continued implementation of the Company's cost reduction plan and optimization measures.

Operating Loss

Operating Loss for the year ended December 31, 2018, was $39.3 million, compared to $52.0 million for the year ended December 31, 2017. The decrease was due to the increase in gross margin and a decrease in operating expenses.

Financial Income, net

Financial Income, net for the year ended December 31, 2018, was $0.5 million, compared to $6.4 million for the year ended December 31, 2017. The decrease was mainly related to a fair value gain on derivative financial instruments.

Comparison of the Year Ended December 31, 2017 to the Year Ended December 31, 2016

Net Revenues

Net Revenues for the year ended December 31, 2017, were $4.0 million, compared to $0.1 million for the year ended December 31, 2016. The increase was due to the initiation of the Company's U.S. promotional activities in mid-June 2017.

Cost of Revenues

Cost of Revenues for the year ended December 31, 2017, was $2.1 million, due to cost of goods sold and royalties relating to commercialization activities. There was no cost of revenues for the year ended December 31, 2016.

Gross Profit

Gross Profit for the year ended December 31, 2017, was $1.9 million, compared to $0.1 million for the year ended December 31, 2016. The increase was due to the initiation of the Company's U.S. promotional activities in mid-June 2017.

Research and Development Expenses

Research and Development Expenses for the year ended December 31, 2017, were $33.0 million, compared to $25.2 million for the year ended December 31, 2016. The increase was mainly due to the then ongoing Phase 3 study with TALICIA® and from the Phase 1/2 studies with YELIVA® for multiple indications.

Selling, Marketing and Business Development Expenses

Selling, Marketing and Business Development Expenses for the year ended December 31, 2017, were $12.0 million, compared to $1.6 million for the year ended December 31, 2016, which was comprised only of business development expenses. The increase was mainly due to the establishment and advancement of the Company's U.S. commercial operations. The Company recognized selling and marketing expenses for the first time in 2017.

General and Administrative Expenses

General and Administrative Expenses for the year ended December 31, 2017, were approximately $8.0 million, compared to $3.8 million for the year ended December 31, 2016. The increase was mainly due to the establishment and advancement of the Company's U.S. commercial operations in 2017.

Operating Loss

Operating Loss for the year ended December 31, 2017, was $52.0 million, compared to $30.5 million for the year ended December 31, 2016. The increase was due to an increase in the Company's research and development activities as well as the establishment and advancement of the Company's U.S commercial operations in 2017, as detailed above.

Financial Income, net

Financial Income, net for the year ended December 31, 2017, was $6.4 million, compared to $1.2 million for the year ended December 31, 2016. The increase was mainly related to a fair value gain on derivative financial instruments.

B. Liquidity and Capital Resources

Liquidity and Capital Resources

Our therapeutic candidates are in research and development stage, and therefore we do not generate significant revenues yet. Since 2017, through our U.S. subsidiary, we commercialize or promote four GI products in the U.S., Donnatal®,

Mytesi®, EnteraGam® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg under agreements with third parties. These commercial operations are still generating operational losses.

Since inception, we have funded our operations primarily through public and private offerings of our equity securities, investor loans, and a payment received under our Exclusive License Agreement with Salix (now Bausch Health). As of December 31, 2018, we had approximately $53.2 million of cash, cash equivalents, and short-term investments.

On February 3, 2011, we raised gross proceeds of approximately $14 million in connection with our initial public offering on the TASE of 14,302,300 Ordinary Shares and 7,151,150 tradable Series 1 Warrants. By February 2, 2014, the tradable Series 1 Warrants were exercised for an aggregate amount of $4 million.

On January 10, 2013, we issued in a private placement 6,481,280 Ordinary Shares at a price per share of NIS 4.00 (approximately $1.06 based on the representative U.S. dollar – NIS rate of exchange of 3.78 on January 10, 2013) and non-tradable warrants to purchase up to 3,240,640 Ordinary Shares. By January 10, 2015, the warrant expiration date, 682,200 warrants had been exercised for an aggregate amount of approximately $1.0 million. The remaining unexercised warrants expired.

On January 8, 2014, we issued in a private placement a total of 894,740 units, each unit consisting of one ADS and a three-year warrant to purchase 0.4 of an ADS, at a purchase price of $9.50 per unit, for an aggregate gross amount of $8.5 million. We also issued warrants to purchase an aggregate of 357,896 ADSs, at an exercise price of $11 per ADS. On January 10, 2017, warrants to purchase an aggregate of 252,632 ADSs were exercised for aggregate proceeds of approximately $2.63 million, and the unexercised warrants expired.

On January 21, 2014, we issued in a private placement a total of 10,458,740 Ordinary Shares at a purchase price of NIS 3.9 per share and three-year warrants to purchase an aggregate of 4,183,496 Ordinary Shares at an exercise price of NIS 4.9 per share, linked to changes in the NIS-U.S. dollar exchange rate, for an aggregate gross amount of $11.7 million (based on the representative U.S. dollar–NIS rate of exchange of 3.49 on January 22, 2014). On January 21, 2017, all of these warrants expired unexercised.

On February 27, 2014, we entered into a Worldwide Exclusive License Agreement with Salix (now Bausch Health), pursuant to which we granted exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation and rights to other purgative developments. Under the license agreement, Salix paid an upfront payment of $7.0 million. We are also entitled to milestone payments and royalties based on net sales of RHB-106. See "Item 4. Information on the Company – B. Business Overview – Acquisition, Commercialization and License Agreements – Exclusive License Agreement with Bausch Health Companies Inc."

On February 13, 2015, we sold an aggregate of 1,150,000 ADSs in an underwritten public offering of our ADSs in the U.S. at a public offering price of $12.50 per ADS, for gross proceeds to us of approximately $14.4 million.

On July 22, 2015, we sold an aggregate of 2,739,143 ADSs in an underwritten public offering of our ADSs in the U.S. at a public offering price of $16.25 per ADS, for gross proceeds to us of approximately $44.5 million, before underwriting discounts and commissions and other offering expenses.

On December 27, 2016, we sold 2,250,000 ADSs and warrants to purchase 1,125,000 ADSs in an underwritten public offering for gross proceeds of approximately $23 million. Concurrent with the underwritten public offering, we sold 1,463,415 ADSs and warrants to purchase 731,708 ADSs in a concurrent registered direct offering for gross proceeds of approximately $15 million. The offering price in both offerings was $10.25 for a fixed combination of one ADS and a warrant to purchase 0.5 of an ADS. The warrants in both offerings have a per ADS exercise price of $13.33 and have a term of three years. Following the partial exercise by the underwriters of their option, our underwritten public offering and the concurrent registered direct offering totaled 3,846,519 ADSs and warrants to purchase 2,025,458 ADSs, representing aggregate gross proceeds from both offerings of approximately $39.4 million.

On November 13, 2017, we sold 4,090,909 ADSs in an underwritten public offering of our ADSs in the U.S. at a public offering price of $5.50 per ADS for gross proceeds of approximately $22.5 million before underwriting discounts and commissions and other offering expenses.

On August 9, 2018, we sold 4,166,667 ADSs in an underwritten public offering of our ADSs in the U.S. at a public offering price of $6.00 per ADS, for gross proceeds of approximately $25 million before underwriting discounts and commissions and other offering expenses.

On December 11, 2018, we sold 2,857,143 ADSs in an underwritten public offering of our ADSs in the U.S. at a public offering price of $7.00 per ADS, for gross proceeds of approximately $20 million before underwriting discounts and commissions and other offering expenses.

Revenues generated from our U.S. commercial activities were approximately $8.4 million for the year ended December 31, 2018, and approximately $4.0 million for the year ended December 31, 2017.

We estimate that so long as sufficient revenues to sustain our business operations in accordance with our plan are not generated from our therapeutic candidates, out-licensing transactions or promotion or commercialization of our current commercial products or products that we may promote or commercialize in the future, we will need to raise substantial additional funds, 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 commercial operations. However, additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors including but not limited to:

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

If we are unable to commercialize or out-license our therapeutic candidates, obtain future financing or generate sufficient revenues to sustain our business operations in accordance with our plan from our commercial products, we may be forced to delay, reduce the scope of, or eliminate one or more of our research and development programs related to the therapeutic candidates, which may have material adverse effect on our reputation, business, financial condition or results of operations. See “Item 3. Key Information – D. Risk Factors – Risks Related to Our Financial Condition and Capital Requirements”. Our current working capital is not sufficient to complete our research and development with respect to any or all of our therapeutic candidates or to commercialize our products or products to which we have rights, including the promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialization of EnteraGam®. We will need to raise additional capital to achieve our strategic objectives of acquiring, in-licensing, developing and commercializing therapeutic candidates, promoting Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercializing EnteraGam® and other products that we may promote or commercialize in the future, and our failure to raise sufficient capital or on favorable terms would significantly impair our ability to fund our operations, develop our therapeutic candidates, promote products such as Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg or other products that we may promote in the future, commercialize EnteraGam® or the products we may commercialize in the future, attract development or commercial partners or retain key personnel.

We implemented a cost reduction plan to gradually reduce our 2018 quarterly cash used in operating activities to approximately $8.5 million on average. We believe this, should allow our capital resources to be sufficient to fund our operations for more than the next 12 months.

Cash Flow

Net Cash Used in Operating Activities

Net Cash Used in Operating Activities for the year ended December 31, 2018, was $34.5 million, compared to $44.8 million for the year ended December 31, 2017. The decrease in Net Cash Used in Operating Activities was a direct result of the decrease in Operating Loss, as detailed above.

Net Cash Used in Investing Activities

Net Cash provided by Investing Activities for the year ended December 31, 2018, was $5.4 million, compared to Net Cash used in Investing Activities of $18.6 million for the year ended December 31, 2017. The change from the comparable period was mainly due to a change in investment in current bank deposits and financial assets at fair value through profit or loss.

Net Cash Provided by Financing Activities

Net Cash Provided by Financing Activities for the year ended December 31, 2018, was $41.8 million, compared to $25.7 million for the year ended December 31, 2017, both resulting mainly from the proceeds of our public offerings.

We did not have any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies, as of December 31, 2018.

C. Research and Development, Patents and Licenses

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

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, the rate of patient recruitment and the ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future commercialization arrangements, when such commercialization arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See "Item 3. Key Information – D. Risk Factors – If we or our development or commercialization partners are unable to obtain or maintain FDA or other foreign regulatory clearance and approval for our therapeutic candidates or products we may promote or commercialize, we or our commercialization partners will be unable to commercialize our therapeutic candidates or products we may promote or commercialize."

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 stay material 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 high certainty if and when we would recognize any substantial revenues from our projects.

D. Trend Information

We are a specialty biopharmaceutical company primarily focused on proprietary drugs for GI diseases.

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

In December 2016, we were granted certain rights to promote Donnatal® in certain U.S. territories, a specialty GI product currently included in the FDA DESI review program, in April 2017, we entered into an exclusive license agreement with Entera Health, granting us exclusive license to use the EnteraGam® trademarks, trade names and other Entera Health proprietary rights relating to EnteraGam® for the sale and distribution of the product in the U.S., and in August 2017, we entered into a commercialization agreement with ParaPRO granting us the exclusive rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg to gastroenterologists in certain U.S. territories. In June 2018, we entered into a co-promotion agreement with Napo, granting us exclusive U.S. rights to co-promote Mytesi® (crofelemer 125 mg delayed-release tablets) for the approved indication in people living with HIV/AIDS with respect to certain gastroenterologists and other healthcare practitioners in certain U.S. territories. The foregoing agreements are part of our goal to build our own marketing and commercialization capabilities in the U.S. to support future commercialization of our therapeutic candidates.

Our primary focus is currently on the development of clinical-stage GI therapeutic candidates, and we have also established commercial presence and capabilities, promoting several GI products in the U.S., intended primarily to support potential future launch of our GI-related therapeutic candidates currently under development. Recently, we have increased our focus on the preparations for commercialization of our therapeutic candidates. As we prepare to potentially submit an NDA with the FDA for TALICIA® in the first half of 2019 and plan to progress in our clinical studies of our other therapeutic candidates, including RHB-104 for Crohn's disease and RHB-204 for pulmonary nontuberculous mycobacteria ("NTM") infections, we have begun preparations for a potential commercial launch of TALICIA® and discussions with potential partners for the potential commercialization of TALICIA® and potential development and commercialization of RHB-104 and RHB-204, with the goal to generate revenues from our therapeutic candidates and support their development and commercialization. At the same time, as we continue to try to increase revenues generated by our commercial products, we continue to pursue opportunities to in-license or acquire GI therapeutic candidates and products that have been approved or cleared for marketing in the U.S.

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, 2018:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(U.S. dollars in thousands) (Unaudited)				
Office and vehicle lease obligations	1,846	994	793	60	—
Accounts payable, accrued expenses and other current liabilities	10,381	10,381	—	—	—
Total	12,227	11,375	793	60	—

The foregoing table does not include our in-license agreements with Heidelberg, Apogee, our asset sale agreement with Giaconda Limited and our agreement with UCF or University of Minnesota, pursuant to which we are obligated to make various payments upon the achievement of agreed upon milestones or make certain royalty payments since we are unable to estimate the actual amount or timing of these payments currently. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay, in addition to the amounts in the above table and royalties on our net income, an aggregate amount of approximately $2.3 million for milestones achieved. All of our in-licensing agreements are terminable at-will by us upon prior written notice. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements."

The foregoing table does not include our manufacturing agreements pursuant to which we are obligated to make various payments upon the achievement of agreed-upon milestones. We are unable to currently estimate the actual amount or timing of these payments. If all of the milestones are achieved over the life of the manufacturing agreements, we will be required to pay, in addition to the above table and royalties on our net income, an aggregate amount of approximately $1.8 million. All of our manufacturing agreements are terminable at-will by us upon short prior written notice.

The foregoing table does not reflect an amendment to the office lease for our offices in Tel-Aviv, signed in January 2019. Under the amendment, the term of the lease was extended through January 31, 2026, and an annual lease payment is approximately $0.4 million.

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

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management[1]

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	53	Chief Executive Officer and Chairman of the Board of Directors
Micha Ben Chorin	50	Chief Financial Officer
Reza Fathi, Ph.D.	64	Senior Vice President Research and Development
Gilead Raday	44	Chief Operating Officer
Adi Frish	49	Senior Vice President Business Development and Licensing
Guy Goldberg	43	Chief Business Officer
Directors		
Dr. Shmuel Cabilly (2)	69	Director
Eric Swenden	75	Director
Dr. Kenneth Reed	65	Director

Dan Suesskind (1)	75	Director
Rick D. Scruggs	59	Director
Ofer Tsimchi (1), (2)	59	Director
Nurit Benjamini (1), (2)	52	Director
Nicolas A. Weinstein	37	Director

(1) Member of our audit committee that also serves as our financial statements committee.
(2) Member of our compensation committee.

Executive officers

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

Micha Ben Chorin has served as our Chief Financial Officer since March 1, 2016. Prior to joining RedHill he was a member of the team that built GVT (currently Telefonica Brazil). During his seven years as Chief Financial Officer at GVT, he led its financial department through pivotal financial transactions and preparations for its successful IPO. From 2014 until 2016, Mr. Ben Chorin served as Chief Financial Officer of Pyramid Analytics a business intelligence (BI) software company. From 2009 until 2013, he served as CFO of Starhome B.V., a leading international roaming vendor, from 2005 until 2009 as CFO of Winetworks, and from 1998 until 2005 Mr. Ben Chorin served as Chief Financial Officer at GVT (currently Telefonica Brazil). Mr. Ben Chorin holds a B.A. from Tel-Aviv University and is a Certified Public Accountant.

[1] Senior management includes: members of the Company's administrative, supervisory or management bodies, or nominees for such positions.

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

Gilead Raday has served as our Chief Operating Officer since April 1, 2016. From December 5, 2012, until March 31, 2016, Mr. Raday served as Senior Vice President Corporate and Product Development. From November 2010 to December 2012, Mr. Raday served as our Vice President Corporate and Product Development. From January 2010 until October 2010, Mr. Raday served as Interim Chief Executive Officer of Sepal Pharma Plc., an oncology drug development company, and from January 2009 to December 2009, he was an independent consultant, specializing in business development and project management in the field of life sciences. From 2004 to 2008, Mr. Raday was a partner in Charles Street Securities Europe, LLP, an investment banking firm, where he was responsible for the field of life sciences. Mr. Raday previously served on the boards of Sepal Pharma Plc., ViDAC Limited, Morria Biopharmaceuticals Plc., Vaccine Research International Plc., TKsignal Plc., and Miras Medical Imaging Plc. He received his M.Sc. in Neurobiology from the Hebrew University of Jerusalem, Israel, and an M.Phil. in Biotechnology Management from Cambridge University, U.K.

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

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

Directors

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

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

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

Dan Suesskind has served as a member of our board of directors since February 21, 2011, and has served on our audit committee and investment committee since May 5, 2011. From 1977 to 2008, Mr. Suesskind served as the Chief Financial Officer of Teva Pharmaceutical Industries Ltd. Mr. Suesskind served as a director of Teva Pharmaceutical Industries Ltd. from 1981 to 2001 and again from 2010 to 2014 and from 2017 to 2018. In addition, Mr. Suesskind currently serves on the board of directors of Israel Corporation Ltd. the Jerusalem Foundation well as a member of the board of trustees of the Hebrew University and the Ben Gurion University. Mr. Suesskind is one of the founders and a member of the steering committee of the Israeli Forum of Chief Financial Officers. Mr. Suesskind holds a B.A. in Economics and Political Science from the Hebrew University of Jerusalem, Israel, and an M.B.A. from the University of Massachusetts. The board of directors has determined that Mr. Suesskind is a financial and accounting expert under Israeli law.

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

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

Nurit Benjamini has served as a director on our board of directors and a chairperson of our audit committee and a member of our compensation committee since February 16, 2016, and has served on our investment committee since February 22, 2017. Since December 2013, Ms. Benjamini has served as the Chief Financial Officer of TabTale Ltd. a company that creates fresh mobile content for everyone. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wix.com (NASDAQ: WIX). Ms. Benjamini serves as an external director of BiolineRx Ltd. (NASDAQ/TASE: BLRX), and as the chairperson of its audit committee, and on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (NASDAQ/TASE: ALLT). Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

Nicolas Weinstein has served as a member of our board of directors since May 11, 2017. Mr. Weinstein served as Managing Director of Water Bear Investments LLC, a healthcare and real estate investment services company since January 2017. From 2014 to 2015, Mr. Weinstein served as country head in Chile for Abbott Laboratories / CFR Pharmaceuticals. In 2014, Mr. Weinstein served as VP Marketing & Sales of CFR Pharmaceuticals, and from 2012 to 2013, he served as VP Business Development of CFR Pharmaceuticals. From 2008 to 2010, Mr. Weinstein served as VP Marketing & Sales of CFR Pharmaceuticals. Mr. Weinstein currently leads the healthcare and venture investments of EMC2 Fund Ltd. ("EMC2") and its partnership interests in Olive Tree Ventures Limited Partnership (Israel) and Puma Bioventures (a U.S. biotech fund). Mr. Weinstein is a director in investee companies of EMC2, including Aquila Diagnostics, Medasense, Via Surgical, Harbo, and Selfpoint. Mr. Weinstein holds an M.Sc. in Finance from Universidad Adolfo Ibanez (Chile) and an MBA from the Kellogg School of Management (2012). Mr. Weinstein has been nominated to our board of directors by

EMC2 pursuant to the right we granted to any investor that invested at least $15 million in the Company in our December 2016 public offering to nominate one person to our board of directors, subject to various conditions described in the prospectus that we filed with the Securities Exchange Commission.

B. Compensation

The aggregate compensation paid, and benefits-in-kind granted to or accrued on behalf of all of our directors and executive officers for their services, in all capacities, to us during the year ended December 31, 2018, was approximately $2.6 million. Out of that amount $1.8 million was paid as salary, $0.4 million was attributed to the value of the options granted to senior management during 2018, approximately $0.1 million was attributed to retirement plans and $0.3 million attributed to other long-term benefits. No additional amounts have been set aside or accrued by us to provide pension, retirement or similar benefits.

The compensation terms for our directors and officers are derived from their employment agreements and comply with our Compensation Policy for Executive Officers and Directors as approved by our shareholders on June 8, 2016 (the "Compensation Policy").

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2018. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2018.

Name and Position of Director or Officer	Base Salary or Other Payment (1)	Value of Social benefits (2)	Value of Equity Based Compensation Granted (3)	All Other Compensation (4)	Total
Amounts in U.S. dollars are based on 2018 monthly average representative U.S. dollar – NIS rate of exchange					
Dror Ben-Asher, Chief Executive Officer and Chairman of the Board of Directors (5)	351,781	72,386	132,631	18,787	575,585
Adi Frish, Senior Vice President Business Development and Licensing	264,082	69,152	65,617	15,291	414,141
Guy Goldberg, Chief Business Officer	280,595	53,020	65,617	12,525	411,756
Micha Ben Chorin, Chief Financial Officer	260,191	68,688	65,617	14,784	409,280
Gilead Raday, Chief Operating Officer	266,463	50,948	65,617	15,656	398,683

(1) "Base Salary or Other Payment" means the aggregate yearly gross monthly salaries or other payments with respect to the Company's Executive Officers and members of the board of directors for the year 2018.
(2) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law.
(3) Consists of the fair value of the equity-based compensation granted during 2018 in exchange for the directors and officers services recognized as an expense in profit or loss and is carried to the accumulated deficit under equity. The total amount recognized as an expense over the vesting period of the options.
(4) "All Other Compensation" includes, among other things, car-related expenses (including tax gross-up), communication expenses, basic health insurance, and holiday presents.
(5) Mr. Ben-Asher's employment terms as the Company's Chief Executive Officer provide that Mr. Ben-Asher is entitled to a monthly base gross salary of NIS 105,000 (approximately $29,126). Mr. Ben-Asher is further entitled to vacation days, sick days and convalescence pay in accordance with the market practice and applicable law, monthly remuneration for a study fund, contribution by the Company to an insurance policy and pension fund, and additional benefits, including communication expenses. In addition, Mr. Ben-Asher is entitled to reimbursement of car-related expenses from the Company. Mr. Ben-Asher's employment terms include an advance notice period of 180 days by the Company and 90 days by Mr. Ben-Asher. During such advance notice period, Mr. Ben-Asher will be entitled to all of the compensation elements, and to the continuation of vesting of any options or restricted shares granted to him. Additionally, in the event Mr. Ben-Asher's employment is terminated in connection with a "hostile takeover," he will be entitled to a special one-time bonus equal to his then current monthly salary and retirement benefits, including payments to an advanced study fund and pension arrangement and car expense reimbursement, multiplied by 12. A "hostile takeover" is defined as an occurrence where a person, entity or group that was not an interested

party under the Israeli Securities Law 1968 on the date of the initial public offering of our Ordinary Shares, becomes a "controlling shareholder," as defined in the Israeli Securities Law 1968, or a "holder," as defined in the Israel Securities Law 1968, of 25% or more of the voting rights in the Company. In addition, in case of a "hostile takeover", all options granted to Mr. Ben-Asher will immediately vest in full.

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

Employment Agreements

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

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

Director Compensation

We currently pay our non-executive directors an annual cash fee of NIS 83,480 (approximately $23,157) and a cash fee of NIS 4,390 (approximately $1,218) per meeting (or a smaller amount in the case where they do not physically attend the meeting).

Change in Control Retention Plan

We have adopted a change in control employee retention plan providing for compensation to Company employees, other than to the chief executive officer, in the event of a change in control (as defined by the plan), subject to the satisfaction of various conditions. Compensation to employees would be up to 12 months' salary depending on employee seniority and years with the Company.

Compensation Policy

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

The Compensation Policy is in effect for three years from the 2016 annual general meeting. Our Compensation Policy principles were designed to grant proper, fair and well-considered remuneration to our officers, in alignment with our long-term best interests and overall organizational strategy. Part of the rationale is that our Compensation Policy should encourage our officers to identify with our objectives, and an increase in officer satisfaction and motivation should retain the employment of high-quality officers in our service over the long term.

C. Board Practices

Appointment of Directors and Terms of Officers

Pursuant to our articles of association, the size of our board of directors shall be no less than five persons and no more than eleven persons, including any external directors whose appointment is required by law. The directors who are not external directors are divided into three classes, as nearly equal in number as possible. At each annual general meeting, which is required to be held annually, but not more than fifteen months after the prior annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three-year term that expires at the annual general meeting held in the third year following such election (other than any director originally nominated for election by virtue of the nomination right granted to EMC2 for purchasing in the Company's public offering

which closed on December 27, 2016, together with its affiliates, more than $15 million of ADSs and warrants, whose term of office as director may expire earlier depending on the beneficial ownership of EMC2 at least 75 days prior to our annual general meeting of shareholders for the year 2019, as described below). This process continues indefinitely. A simple majority shareholder vote may elect directors for a term of less than three years in order to ensure that the three groups of directors have as equal number of directors as possible as provided above. The directors of the first class, currently consisting of Dr. Shmuel Cabilly, Dan Suesskind and Nurit Benjamini, will hold office until our annual general meeting to be held in the year 2019. The directors of the second class, currently consisting of Dror Ben-Asher, Rick Scruggs and Nicolas Weinstein, will hold office until our annual general meeting to be held in the year 2020, and the directors of the third class, currently consisting of Dr. Kenneth Reed, Eric Swenden and Ofer Tsimchi, will hold office until our annual general meeting to be held in the year 2021. 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. The foregoing notwithstanding, the term of office of Mr. Weinstein, who was nominated for election by EMC2, shall become subject to early expiration in 2019 if EMC2 does not meet a 4% beneficial ownership of our outstanding shares threshold at least 75 days prior to our annual general meeting of shareholders for 2019. See "Item 6. "Directors, Senior Management and Employees – C. Board Practices – Independent and External Directors – Israeli Companies Law Requirements" below for a description of the adoption by the Company of the corporate governance exemptions set forth in Regulation 5D of the Israeli Companies Regulations (Relief for Public Companies with Shares Listed for Trading on a Stock Market Outside of Israel), 5760-2000, including with respect to external directors.

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

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

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

Under the Israeli Companies Law, a "special majority" requires (i) the vote of at least a majority of the shares held by shareholders who are not controlling shareholders or have a personal interest in the proposal (shares held by abstaining shareholders are not be taken into account); or (ii) that the aggregate number of shares voting against the proposal held by such shareholders does not exceed 2% of the company's voting shareholders.

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

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

Independent and External Directors - Israeli Companies Law Requirements

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

Under the Israeli Companies Law, except as provided below, companies incorporated under the laws of Israel whose shares are either (i) listed for trading on a stock exchange or (ii) have been offered to the public in or outside of Israel and are held by the public (Public Company) are required to appoint at least two external directors.

Our board of directors has resolved to adopt the corporate governance exception set forth in Regulation 5D of the Israeli Companies Regulations (the "Regulation"). In accordance with the Regulation, a public company with securities listed on certain foreign exchanges, including the NASDAQ Stock Market, that satisfies the applicable foreign country laws and regulations that apply to companies organized in that country relating to the appointment of independent directors and composition of audit and compensation committees and have no controlling shareholder are exempt from the requirement to appoint external directors or comply with the audit committee and compensation committee composition requirements

under the Israeli Companies Law. In accordance with our board of directors' resolution, pursuant to the Regulation, we intend to comply with the NASDAQ Listing Rules in connection with a majority of independent directors on the board of directors and in connection with the composition of each of the audit committee and the compensation committee, in lieu of such requirements of the Israeli Companies Law.

The Israeli Companies Law provides that a person may not be appointed as an external director if the person is a relative of the controlling shareholder or if the person or the person's relative, partner, employer, someone to whom he is subordinated directly or indirectly or any entity under the person's control, has, as of the date of the person's appointment to serve as external director, or had, during the two years preceding that date, any affiliation with us, our controlling shareholder, any relative of our controlling shareholder, as of the date of the person's appointment to serve as external director, or any entity in which, currently or within the two years preceding the appointment date, the controlling shareholder was the company or the company's controlling shareholder; and in a company without a controlling shareholder or without a shareholder holding 25% or more of the voting rights in the company, any affiliation to the chairman of the board of directors, to the general manager (Chief Executive Officer), to a shareholder holding 5% or more of the company's shares or voting rights, or to the chief officer in the financial or economic field as of the date of the person's appointment. The term "affiliation" includes:

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

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

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

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

No person can serve as an external director if the person's positions or other businesses create, or may create, a conflict of interests with the person's responsibilities as a director or may impair his ability to serve as a director. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

Except for the cessation of classification of directors as external directors in connection with the adoption by certain companies listed on foreign stock exchanges, including the NASDAQ Stock Market, of the corporate governance exceptions set forth in the Regulation, as described above, until the lapse of two years from termination of office, a company, its controlling shareholder, or a company controlled by him may not engage an external director, his spouse, or child to serve as an officer in the company or in any entity controlled by the controlling shareholder and cannot employ or receive professional services for consideration from that person, and may not grant such person any benefit either directly or indirectly, including through a corporation controlled by that person. The same restrictions apply to relatives other than a spouse or a child, but such limitations may only apply for one year from the date such external director ceased to be engaged in such capacity. In addition, if at the time an external director is appointed all current members of the board of directors who are neither controlling shareholders nor relatives of controlling shareholders are of the same gender, then the external director to be appointed must be of the other gender.

Under the Israeli Companies Law, a public company is required to appoint as an external director, a person who has "professional expertise" or a person who has "financial and accounting expertise," provided that at least one of the external directors must have "financial and accounting expertise." However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the NASDAQ Stock Market for membership on the audit committee and (3) has financial and accounting expertise as defined in the Israeli Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. The determination of 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 of 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 appropriate in light of the company's type, size, the scope and complexity of its activities and other factors. Once a company has made this determination, it must ensure that the necessary appointments to the board of directors are made in accordance with this determination. Our board of directors determined that two directors with "accounting and financial expertise" is appropriate for us. Our board of directors currently has five directors with such "accounting and financial expertise."

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

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

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

Committees

Israeli Companies Law Requirements

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

Audit Committee

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

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

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

The role of the audit committee under the Israel Companies Law is to examine suspected flaws in our business management, in consultation with the internal auditor or our independent accountants and suggest an 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:

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

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

An amendment to the Israeli Companies Law allows a company whose audit committee's composition meets the requirements set for the composition of a compensation committee (as further detailed below) to have one committee acting as both audit and compensation committees. As of the date of this Annual Report, we have not elected to have one committee acting as both the audit and the compensation committees.

Compensation Committee

According to the Israeli Companies Law, the board of directors of a public company must establish a compensation committee. Except in the case of companies listed on foreign stock exchanges, including the NASDAQ Stock Market, which have adopted the corporate governance exceptions set forth in the Regulation, such as us, as described under "- Independent and External Directors - Israeli Companies Law Requirements", who are exempt from the compensation committee composition requirements under the Companies Law, the Israeli Companies Law requires that the compensation committee must consist of at least three directors and include all of the external directors who must constitute a majority of its members. The remaining members must be qualified to serve on the audit committee pursuant to the Israeli Companies Law requirements described above. The compensation committee chairman must be an external director and any persons not qualified from serving as a member of the compensation committee may not be present at the compensation committee meetings during the discussion and at the time decisions are made, unless the chairman of the compensation committee determines that the presence of such person is required to present a matter to the meeting or if such person qualifies under an available exemption in the Israeli Companies Law.

Our compensation committee, which consists of Ofer Tsimchi (chairman), Dr. Shmuel Cabilly and Nurit Benjamini, administers issues relating to our global compensation plan with respect to our employees, directors, and consultants. Our compensation committee is responsible for making recommendations to the board of directors regarding the issuance of share options and compensation terms for our directors and officers and for determining salaries and incentive compensation for our executive officers and incentive compensation for our other employees and consultants. Each of the members of the compensation committee is "independent" as such term is defined in the NASDAQ Listing Rules.

Investment Committee

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

NASDAQ Stock Market Requirements

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

The independence requirements of Rule 10A-3 of the Exchange Act implement two basic criteria for determining independence:

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

The SEC has defined "affiliate" for non-investment companies as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." The term "control" is intended to be consistent with the other definitions of this term under the Exchange Act, as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the

ownership of voting securities, by contract, or otherwise." A safe harbor has been adopted by the SEC, under which a person who is not an executive officer or 10% shareholder of the issuer would be deemed not to have control of the issuer.

In accordance with the Sarbanes-Oxley Act of 2002 and the NASDAQ Listing Rules, the audit committee is directly responsible for the appointment, compensation, and performance of our independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal control 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 Nurit Benjamini, Ofer Tsimchi and Dan Suesskind, with Ms. Benjamini serving as chairperson. All members of our audit committee meet the requirements for financial literacy under the NASDAQ Listing Rules. Our board of directors has determined that each of Mr. Ofer Tsimchi and Ms. Nurit Benjamini is an audit committee financial expert as defined by the SEC rules and all members of the audit committee have the requisite financial experience as defined by the NASDAQ Listing Rules. Each of the members of the audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

Corporate Governance Practices

Internal Auditor

Under the Israeli Companies Law, the board of directors must appoint an internal auditor proposed by the audit committee. The role of the internal auditor is, among others, to examine whether our actions comply with the law and orderly business procedure. Under the Israeli Companies Law, the internal auditor may not be an interested party, an officer or a director, a relative of an interested party, or a relative of an officer or a director, nor may the internal auditor be our independent accountant or its representative. In January 2018, Ms. Sharon Cohen, Lead Engagement Partner, Head of LS & HC Industry at Deloitte Israel, was elected to serve as our internal auditor.

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

Fiduciary Duties of Officers

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

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

- information on the appropriateness of a given action brought for the directors' or officer's approval or performed by such person by virtue of such person's position; and
- all other important information pertaining to the previous actions.

The duty of loyalty requires a director or an officer to act in good faith and for the benefit of the company and includes a duty to:

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

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

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

Under the Israeli Companies Law, an extraordinary transaction is a transaction:

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

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

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

Controlling Shareholder Transactions and Actions

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

of office and employment, require the approval of the audit committee, the board of directors and the shareholders of the company, in that order. The shareholders' approval must include either:

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

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

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

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

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

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

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

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

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

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

Exemption, Insurance, and Indemnification of Directors and Officers

Exemption of Officers and Directors

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

Directors' and Officers' Insurance

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

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

In June 2016, our shareholders approved our Compensation Policy, which includes, among other things, provisions relating to directors' and officers' liability insurance. Pursuant to the Compensation Policy, we may obtain a liability insurance policy, which would apply to our and/or our subsidiaries' directors and officers, as they may be, from time to time, subject to the following terms and conditions: (a) the total insurance coverage under the insurance policy may not exceed $50 million; and (b) the annual premium payable by us for the insurance premium may not exceed $400,000 annually. In addition, pursuant to our Compensation Policy, should we sell our operations (in whole or in part) or in case of merger, spin-off or any other significant business combination involving us or part or all of our assets, we may obtain a director's and officers' liability insurance policy (run-off) for our directors and officers in office with regard to the relevant operations, subject to the following terms and conditions: (a) the insurance term may not exceed seven years; (b) the coverage amount may not exceed $50 million; (c) the premium payable by us may not exceed $400,000 annually. The Compensation Policy is in effect for three years from the 2016 annual general meeting.

Subsequent to the approval of the terms of our Compensation Policy, our compensation committee and board of directors resolved to purchase a directors' and officers' liability insurance policy, pursuant to which the total amount of insurance covered under the policy is $17 million and an additional $33 million, subject to shareholder approval. This insurance is renewed on an annual basis. Pursuant to the foregoing approvals, we carry directors' and officers' liability insurance.

Indemnification of Officers and Directors

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

- a provision authorizing the company to indemnify an officer or director for future events with respect to a monetary liability imposed on him in favor of another person pursuant to a judgment (including a judgment given in a settlement or an arbitrator's award approved by the court), so long as such indemnification is limited to types of events which, in the board of directors' opinion, are foreseeable at the time of granting the indemnity

undertaking given the company's actual business, and in such amount or standard as the board of directors deems reasonable under the circumstances. Such undertaking must specify the events that, in the board of directors' opinion, are foreseeable in view of the company's actual business at the time of the undertaking and the amount or the standards that the board of directors deemed reasonable at the time;

- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation expenses, including counsel fees, incurred by an officer or director in which he is ordered to pay by a court, in proceedings that the company institutes against him or instituted on behalf of the company or by another person, or in a criminal charge of which he was acquitted, or a criminal charge in which he was convicted of 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 indemnify an officer or director retroactively.

Limitations on Insurance, Exemption and Indemnification

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

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

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

Letters of Indemnification

We may provide a commitment to indemnify in advance any director or officer of ours in the course of such person's position as our director or officer, all subject to the letter of indemnification, as approved by our shareholders from time to time and in accordance with our articles of association. We may provide retroactive indemnification to any officer to the extent allowed by the Israeli Companies Law. As approved by our shareholders on July 18, 2013, the amount of the advance indemnity is limited to the higher of 25% of our then shareholders' equity, per our most recent annual financial statements, or $5 million.

As part of the indemnification letters, we exempted our directors and officers, in advance, to the extent permitted by 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 by law, we do not exempt an officer or director in advance from his liability to us for a breach of the duty

of care upon distribution, to the extent applicable to the officer or director, if any. The letter also exempts an officer or director from any liability for any damage incurred by him, either directly or indirectly, due to the breach of the officer or director's duty of care *vis-à-vis* us, by his acts in his capacity as an officer or director prior to the letter of exemption and indemnification becoming effective.

D. Employees

As of December 31, 2018, we had 75 employees, of which fourteen employees provide services in Israel and sixty-one in the U.S. In addition, we also received services from sixteen consultants, of which ten in the U.S., five in Canada and one in Belgium.

	As of December 31,					
	2016		2017		2018	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management and administration	11	4	12	—	12	—
Research and development	2	10	2	17	2	16
Commercial operations	—	—	60	3	61	—

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

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

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding Ordinary Shares as of February 25, 2019, 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 283,686,908 Ordinary Shares outstanding as of such date. The number of Ordinary Shares beneficially owned by a person includes Ordinary Shares subject to options or warrants held by that person that were currently exercisable at, or exercisable within 60 days of February 25, 2019. The Ordinary Shares issuable under these options and warrants are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options and warrants but not

the percentage ownership of any other person. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of the Ordinary Shares.

	Number of Shares Beneficially Held	Percent of Class
Directors		
Dr. Kenneth Reed (1)	6,722,270	2.37 %
Dr. Shmuel Cabilly (2)	5,378,268	1.89 %
Eric Swenden (3)	1,565,340	*
Dan Suesskind (4)	1,293,590	*
Nicolas A. Weinstein (5)	320,130	*
Ofer Tsimchi (6)	280,000	*
Rick D. Scruggs (7)	205,000	*
Nurit Benjamini (8)	205,000	*
Executive officers		
Dror Ben-Asher (9)	6,431,280	2.24 %
Reza Fathi, Ph.D. (10)	1,626,250	*
Adi Frish (11)	1,186,250	*
Gilead Raday (12)	997,960	*
Guy Goldberg (13)	956,250	*
Micha Ben Chorin (14)	412,500	*
All directors and executive officers as a group (14 persons)	27,580,088	9.39 %

* Less than 1.0%

(1) Includes options to purchase 275,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.48 per share, and the options expire between 2020 and 2024. Number of shares beneficially held also includes shares held by family members.

(2) Includes options to purchase 335,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.48 per share, and the options expire between 2021 and 2024.

(3) Includes options to purchase 181,250 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.48 per share, and the options expire between 2020 and 2024. Also includes warrants to purchase 475,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these warrants is $1.33 per share, and the options expire in December 2019.

(4) Includes options to purchase 275,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.48 per share, and the options expire between 2020 and 2024.

(5) Includes options to purchase 40,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options is $1.09 per share, and the options expire in 2024.

(6) Includes options to purchase 280,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.48 per share, and the options expire between 2021 and 2024.

(7) Includes options to purchase 205,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.28 per share, and the options expire between 2023 and 2024.

(8) Includes options to purchase 205,000 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $1.09 and $1.28 per share, and the options expire between 2023 and 2024.

(9) Includes options to purchase 3,146,250 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $0.65 and $1.48 per share, and the options expire between 2020 and 2025. Does not include options to purchase 600,000 Ordinary Shares at an exercise price of $1.08 per Ordinary Share, the allocation of which is subject to approval of our shareholders, which would replace options to acquire the same number of Ordinary Shares previously held by Mr. Ben-Asher which had an exercise price of $0.72 per Ordinary Share and an expiration date in February 2019. This allocation of options has been approved by our compensation committee and board of directors which also approved the extension of options held by other optionees whose options were expiring in February 2019 and whose extended options will have the same terms as Mr. Ben-Asher's options. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(10) Includes options to purchase 1,358,250 Ordinary exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $0.75 and $1.56 per share, and the options expire between 2020 and 2028. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.
(11) Includes options to purchase 1,006,250 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $0.75 and $1.56 per share, and the options expire between 2020 and 2025.
(12) Includes options to purchase 997,960 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $0.75 and $1.56 per share, and the options expire between 2020 and 2025.
(13) Includes options to purchase 956,250 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $0.65 and $1.56 per share, and the options expire between 2020 and 2025.
(14) Includes options to purchase 412,500 Ordinary Shares exercisable within 60 days of February 25, 2019. The exercise price of these options ranges between $0.65 and $1.41 per share, and the options expire between 2023 and 2025.

Award Plans

2010 Award Plan

In 2010, we adopted the RedHill Biopharma Ltd. 2010 Option Plan (later amended and restated as the 2010 Award Plan). The 2010 Award Plan provides for the granting of ordinary shares, ADSs, stock options under various tax regimes in Israel and the U.S., restricted shares, and other share-based awards 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 Award Plan provides for awards to be issued at the determination of our board of directors in accordance with applicable laws. As of February 25, 2019, there were 29,360,235 Ordinary Shares issuable upon the exercise of outstanding awards under the 2010 Award Plan. See footnote (6) to "– E. Share Ownership" above for a description of an allocation of options to Mr. Ben Asher which is subject to shareholder approval.

Administration of Our 2010 Award Plan

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

Options granted under 2010 Award Plan as amended generally vest over a period of 4 years and expire ten (10) years after the grant date. The 2010 Award 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 Award Plan) the right to exercise all the options granted to the grantee, the grantee's vested and unvested options will expire immediately, on the earlier of:

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

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

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

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

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

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

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding Ordinary Shares as of February 25, 2019, by each person or entity known to beneficially own 5.0% or more of our outstanding Ordinary Shares. The information with respect to beneficial ownership of the Ordinary Shares is given based on information reported in such shareholder's Schedule 13G, and if no Schedule 13G was filed, based on the information provided to us by the shareholders.

The information in this table is based on 283,686,908 Ordinary Shares outstanding as of such date. In determining the number of Ordinary Shares beneficially owned by a person, we include any shares as to which the person has sole or shared voting power or investment power, as well as any Ordinary Shares subject to options or warrants held by that person that were currently exercisable at, or exercisable within 60 days of February 25, 2019. The Ordinary Shares issuable under these options and warrants are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options and warrants but not the percentage ownership of any other person. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of Ordinary Shares.

	Number of Shares Beneficially Held	Percent of Class
First Investments Holding Ltd. (1)	39,285,710	13.85 %
683 Capital Partners, LP (2)	36,938,400	13.02 %
EMC2 Fund Ltd. (3)	22,223,950 (4)	7.81 %

(1) The address of First Investments Holding Ltd. is2nd Floor, Strathvale House, 90 North Church Street, P.O. Box 1103.
(2) 683 Capital Partners, LP, a Delaware limited partnership, holds ADSs. Based on information filed with the SEC, 683 Capital Management, LLC, a Delaware limited liability company, is the investment manager of 683 Capital Partners, LP. The principal business address of each of 683 Capital Partners, LP and 683 Capital Management, LLC is 3 Columbus Circle, Suite 2205, New York, NY 10019.
(3) EMC2 holds the ADSs and warrants to purchase ADSs. The address of EMC2 is Bayside Executive Park, Building No. 1, West Bay Street, PO Box SP-63131, Nassau, the Bahamas. Based on information provided to us, EMC2 is controlled by Banque Pictet & Cie SA.
(4) Includes warrants to purchase 731,708 ADSs with an exercise price of $13.33 and an expiration date of December 26, 2019, purchased by EMC2 in a registered direct offering that closed on December 27, 2016. See "Item 5.

Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

On February 6, 2019, 22,149,844 ADSs (equivalent to 221,498,440 Ordinary Shares, or approximately 78% of our total issued and outstanding Ordinary Shares), were held of record by three record holders in the U.S., of which one holder had a U.S. address. As of February 25, 2019, there was one shareholder of record of our Ordinary Shares who was located in Israel. The number of record holders is not at all representative of the number of beneficial holders of our ADSs or Ordinary Shares because many of the ADSs and Ordinary Shares are held by brokers or other nominees.

B. Related Party Transactions

November 2017 Public Offering

In our underwritten public offering which closed on November 13, 2017, (i) Mr. Eric Swenden, one of our directors, purchased 90,909 ADSs, (ii) Dr. Shmuel Cabilly, one of our directors, purchased 90,909 ADSs, and (iii) Mr. Nicolas Weinstein, one of our directors, purchased 27,272 ADSs. The terms of the issuance, as well as the discount received by the underwriters for these shares, were the same as those offered to the public. For more information on the underwritten public offering, please see "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources."

December 2016 Public Offering

In our underwritten public offering which closed on December 27, 2016, Mr. Eric Swenden, one of our directors, purchased 95,000 ADSs and warrants to purchase 47,500 ADSs. The terms of the issuance, as well as the discount received by the underwriters for these shares, were the same as those offered to the public. In a concurrent registered direct offering, EMC2 purchased 1,463,415 ADSs and warrants to purchase 731,708 ADSs at the same price as the public offering price. For more information on the underwritten public offering, please see "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Financial Statements and Other Financial Information

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

Legal Proceedings

From time to time, we may become a 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, if any, 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, if any, 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, 2018.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares have been trading on the TASE under the symbol "RDHL" since February 2011. Our ADSs were traded on the NASDAQ Capital Market under the symbol "RDHL" from December 27, 2012, and were listed on the NASDAQ Global Market under the same symbol since July 20, 2018.

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed and traded on the TASE, and our ADSs, each representing ten Ordinary Share and evidenced by an American depositary receipt, or ADR, are traded on the NASDAQ Global 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

The transfer agent and registrar for our ADSs is The Bank of New York Mellon, and its address is 101 Barclay Street, New York, NY.

Objects and Purposes

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

Private Placements

Under the Israeli Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded

securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder will increase or as a result of it a person will become a substantial shareholder, then, in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" is defined as a shareholder who holds five percent or more of the company's outstanding share capital, assuming the exercise of all of the securities convertible into shares held by that person. In order for the private placement to be on "market terms" the board of directors has to determine, on the basis of detailed explanation, that the private placement is on market terms, unless proven otherwise.

Board of Directors

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

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

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

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

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

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

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

Description of Securities

Ordinary Shares

The following is a description of our Ordinary Shares. Our authorized share capital is 600,000,000 Ordinary Shares, par value NIS 0.01 per share.

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

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

Notices. Under the Israeli Companies Law and our articles of association, we are required to publish notices in two Hebrew-language daily newspapers or our website at least 21 calendar days' prior notice of a shareholders' meeting. However, under regulations promulgated under the Israeli Companies Law, we are required to publish a notice in two daily newspapers at least 35 calendar days prior any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Israeli Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Israeli Companies Law. An amendment to these regulations exempts us from the requirements of the Israeli proxy regulation, under certain circumstances.

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

Election of Directors. The number of directors on the board of directors shall be no less than five and no more than eleven, including any external directors whose appointment is required by law. The general meeting is entitled, at any time and from time to time, in a resolution approved by a majority of 75% or more of the votes cast by those shareholders present and voting at the meeting in person, by proxy or by a voting instrument, not taking into consideration abstaining votes, to change the minimum or maximum number of directors as stated above as well as to amend the board classification under our Articles. A simple majority shareholder vote is required to elect a director for a term of less than three years. 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 a dividend or bonus shares, are to be paid pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie among the shareholders and he may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above deems fit.

Voting, Shareholders' Meetings and Resolutions. Holders of Ordinary Shares are entitled to one vote for each Ordinary Share held on all matters submitted to a vote of shareholders. The quorum required for an ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, or who has sent us a voting instrument indicating the way in which he is voting, who hold or represent, in the aggregate, at least 25% of the voting rights of our outstanding share capital. A meeting adjourned for lack of a quorum is adjourned to the following day at the same time and place or any time and place as prescribed by the board of directors in the notice to the shareholders. At the reconvened meeting one

shareholder at least, present in person or by proxy constitutes a quorum except where such meeting was called at the demand of shareholders. With the agreement of a meeting at which a quorum is present, the chairman may, and on the demand of the meeting he must, adjourn the meeting from time to time and from place to place, as the meeting resolves. Annual general meetings of shareholders are held once every year within a period of not more than 15 months after the last preceding annual general shareholders' meeting. The board of directors may call special general meetings of shareholders. The Israeli Companies Law provides that a special general meeting of shareholders may be called by the board of directors or by a request of two directors or 25% of the directors in office, whichever is the lower, or by shareholders holding at least 5% of our issued share capital and at least 1% of the voting rights, or of shareholders holding at least 5% of our voting rights.

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

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

Acquisitions under Israeli Law

Full Tender Offer

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

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

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

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

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

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

Special Tender Offer

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

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

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

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

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

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

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

Merger

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

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

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control (See "Management – Audit Committee – Approval of Transactions with Related Parties" for a definition of means of control) of the other party to the merger or anyone 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." In addition, provisions of our articles of our association relating to the election of our directors for terms of three years 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. See "Item 6. Directors, Senior Management and Employees – C. Board Practices – Appointment of Directors and Terms of Officers."

C. Material Contracts

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

D. Exchange Controls

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

E. Taxation

Israeli Tax Considerations

General

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

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

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

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income at the rate of 23% for the 2018 tax year.

Taxation of Shareholders

Capital Gains

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

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

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income (23% in 2018 and thereafter), and a marginal tax rate of up to 50% in 2019 for individuals, including an excess tax (as discussed below).

Notwithstanding the foregoing, capital gains generated from the sale of our Shares by a non-Israeli shareholder may be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Shares were purchased upon or after the registration of the Shares on the stock exchange (this condition will not apply to shares purchased on or after January 1, 2009) and (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

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

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

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

Dividends

Dividends distributed by a company to a shareholder who is an Israeli resident individual will generally be 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 generally be exempt from Israeli income tax provided that the income from which such dividend is distributed, derived or accrued within Israel.

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

Excess Tax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds a certain threshold in a tax year ((NIS 649,560 for 2019, linked to the Israeli Consumer Price Index) will be subject to an additional tax at the rate of 3% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Estate and Gift Tax

Israel does not currently impose estate or gift taxes.

Foreign Exchange Regulations

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

U.S. Federal Income Tax Considerations

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

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

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

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

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

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

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

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

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

Distributions

Subject to the discussion under "Item 10. Additional Information – E. Taxation – U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies" below, the gross amount of any distribution, including the amount of any Israeli taxes withheld from such distribution, see "Item 10. Additional Information – E. Taxation – Israeli Tax Considerations", actually or constructively received by a U.S. Holder with respect to our Ordinary Shares (or, in the case of ADSs, received by the depositary) will be taxable to the U.S. Holder as foreign source dividend income to the extent of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. The U.S. Holder will not be eligible for any dividends received deduction in respect of the dividends paid by us. Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of the U.S. Holder's adjusted tax basis in its Ordinary Shares or ADSs. Distributions in excess of such adjusted tax basis will generally be taxable to the U.S. Holder as capital gain from the sale or exchange of property as described below under "Sale or Other Disposition of Ordinary Shares or ADSs." If we do not report to a U.S. Holder the portion of a distribution that exceeds earnings and profits, then the distribution will generally be taxable as a dividend. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution.

Under the Code, certain dividends received by non-corporate U.S. Holders will be subject to a maximum federal income tax rate of 20%. This reduced income tax rate is only applicable to dividends paid by a "qualified foreign corporation" that is not a PFIC for the year in which the dividend is paid or for the preceding taxable year, and only with respect to Ordinary Shares or ADSs held by a qualified U.S. Holder (i.e., a non-corporate holder) for a minimum holding period (generally 61 days during the 121-day period beginning 60 days before the ex-dividend date). As discussed below, however, we believe we may be a "passive foreign investment company" (see "Item 10. Additional Information – E. Taxation – U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies" below) for our current taxable year and future taxable years. Accordingly, dividends paid by us to individual U.S. Holders may not be eligible for the reduced income tax rate applicable to qualified dividends. You should consult your own tax advisor regarding the availability of this preferential tax rate under your particular circumstances.

The amount of any distribution paid in a currency other than U.S. dollars (a "foreign currency"), including the amount of any withholding tax thereon, will be included in the gross income of a U.S. Holder in an amount equal to the U.S. dollar value of the foreign currency calculated by reference to the exchange rate in effect on the date of the U.S. Holder's (or, in the case of ADSs, the depositary's) receipt of the dividend, regardless of whether the foreign currency is converted into

U.S. dollars. If the foreign currency is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize a foreign currency gain or loss in respect of the dividend. If the foreign currency received in the distribution is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the foreign currency will be treated as U.S. source ordinary income or loss.

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

Sale or Other Disposition of Ordinary Shares or ADSs

Subject to the discussion under "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies" below, if a U.S. Holder sells or otherwise disposes of its Ordinary Shares or ADSs, gain or loss will be recognized for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and such holder's adjusted basis in the Ordinary Shares or ADSs. Such gain or loss generally will be a capital gain or loss and will be a long-term capital gain or loss if the holder had held the Ordinary Shares or ADSs for more than one year at the time of the sale or other disposition. Long-term capital gains realized by non-corporate U.S. Holders are generally subject to a preferential U.S. federal income tax rate. In general, gain or loss recognized by a U.S. Holder on the sale or other disposition or our Ordinary Shares or ADSs will be U.S. source gain or loss for purposes of the foreign tax credit limitation. As discussed below in "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies," however, we may be a PFIC for our current taxable year and future taxable years. If we are a PFIC, any such gain will be subject to the PFIC rules, as discussed below, rather than being taxed as a capital gain.

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

As discussed above under the heading "Item 10. Additional Information – E. Taxation – Israeli Tax Considerations – Taxation of Shareholders," a U.S. Holder who holds Ordinary Shares or ADSs through an Israeli broker or other Israeli intermediary may be subject to Israeli withholding tax on any capital gains recognized on a sale or other disposition of the Ordinary Shares or ADSs if the U.S. Holder does not obtain approval of an exemption from the Israeli Tax Authorities or claim any allowable refunds or reductions. U.S. Holders are advised that any Israeli tax paid under circumstances in which an exemption from (or a refund of or a reduction in) such tax was available will not be creditable for U.S. federal income tax purposes. U.S. Holders are advised to consult their Israeli broker or intermediary regarding the procedures for obtaining an exemption or reduction.

Medicare Tax on Unearned Income

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

Passive Foreign Investment Companies

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

- at least 75% of its gross income for such taxable year is passive income; or

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

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

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

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

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

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

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

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

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the general tax treatment for PFICs discussed above. If you make a mark-to-market election for the ADSs, you will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of your taxable year over your adjusted basis in such Ordinary Shares. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the

taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for the ADSs. Your basis in the ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid mark-to-market election, the tax rules that apply to distributions by corporations which are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a mark-to-market election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "Sale or Other Disposition of Ordinary Shares or ADSs."

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

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

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

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

Backup Withholding and Information Reporting

Payments of dividends with respect to Ordinary Shares or ADSs and the proceeds from the sale, retirement, or other disposition of Ordinary Shares or ADSs made by a U.S. paying agent or other U.S. intermediary will be reported to the IRS and to the U.S. Holder as may be required under applicable U.S. Treasury regulations. We, or an agent, a broker, or any paying agent, as the case may be, may be required to withhold tax (backup withholding), currently at the rate of 24%, if a non-corporate U.S. Holder that is not otherwise exempt fails to provide an accurate taxpayer identification number and comply with other IRS requirements concerning information reporting. Certain U.S. Holders (including, among others, corporations and tax-exempt organizations) are not subject to backup withholding. Any amount of backup withholding withheld may be used as a credit against your U.S. federal income tax liability provided that the required information is

furnished to the IRS. U.S. Holders should consult their own tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining an exemption.

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our Ordinary Shares or ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies," each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than $100,000 for our Ordinary Shares or ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

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

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act, applicable to foreign private issuers, and under those requirements, we file reports with the SEC. Those other reports or other information are available to the public through the SEC's website at *http://www.sec.gov*.

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

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

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

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Risk of Interest Rate Fluctuation and Credit Exposure Risk

At present, our credit and interest risk arise from cash and cash equivalents, deposits with banks and a portfolio of corporate bonds as well as accounts receivable. A substantial portion of our liquid instruments is invested in short-term deposits and corporate bonds 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 low. 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, mainly corporate bonds, held by us and classified in our financial statements 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 is denominated in NIS and in Euro. Our NIS expenses consist principally of payments to employees or service providers and office-related expenses in Israel. Our Euro expenses consist primarily of payments to vendors related to our therapeutic candidates. We also hold 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 on our assets and liabilities as of December 31, 2018:

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	22	55	29,004	(55)	(22)
Bank deposits	4	10	8,271	(10)	(4)
Accounts receivable (except prepaid expenses)	3	8	1,895	(8)	(3)
Accounts payable and accrued expenses	(6)	(15)	(10,381)	15	6
Total loss	23	58		(58)	(23)

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 the American Depositary Shares, or ADSs, represents 10 Ordinary Shares. The ADSs trade on the NASDAQ Global 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 Shareholders 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 Shareholders
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 Shareholders
$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 the 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 us or share its revenue with us from the fees collected from American Depositary Shareholders or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the American Depositary Share program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

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

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

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

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

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act of 1934, as amended. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors (as appropriate); and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013).

Based on our assessment and this framework, our management concluded that the Company's internal control over financial reporting was effective as of December 31, 2018. Our auditor, Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, has provided an attestation report on our internal control over financial reporting, which is included herein.

(c) Attestation Report of Registered Public Accounting Firm

Our independent registered public accounting firm has audited the consolidated financial statements included in this annual report on Form 20-F, and as part of its audit, has issued its audit report on the effectiveness of our internal control over financial reporting. This report is included in pages F-2 and F-3 of this annual report on Form 20-F and is incorporated herein by reference.

(d) Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2018, 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 Ofer Tsimchi, Dan Suesskind, and Nurit Benjamini are audit committee financial experts. Mr. Tsimchi, Mr. Suesskind, and Ms. Benjamini are independent directors for the purposes of the NASDAQ Listing Rules.

ITEM 16B. CODE OF ETHICS

As of the date of this Annual Report, we have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, https://ir.redhillbio.com/static-files/9be49636-4b2f-453e-ac3e-7b759b984c40.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

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

	Year Ended December 31,	
Services Rendered	**2018**	**2017**
	(U.S. dollars in thousands)	
Audit (1)	185	115
Audit-related services (2)	85	47
Tax (3)	22	33
Total	292	195

(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 related to work regarding prospectus supplements and ongoing consultation.
(3) Tax fees relate to tax compliance, planning, and advice.

Audit Committee Pre-Approval Policies and Procedures

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

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

Not applicable.

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

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

NASDAQ Stock Listing Rules and Home Country Practices

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

- *Shareholder Approval* - We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Israeli Companies Law, which are different from the shareholder approval requirements of 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 in control of a company, certain transactions other than a public offering involving issuances of 20% or more of the shares or voting power in a company, and certain acquisitions of the stock or assets of another company involving issuances of 20% or more of the shares or voting power in a company or if any director, officer or holder of 5% or more of the shares or voting power of the company has a 5% or greater interest in the company or assets to be acquired or consideration to be paid and the transaction could result in an increase in the outstanding common shares or voting power by 5% or more;
- Under the Israeli Companies Law, shareholder approval is required for any transaction, including any grant of equity-based compensation, to a director or a controlling shareholder, but is not generally required to establish or amend an equity-based compensation plan. Similarly, shareholder approval is required for a private placement that is deemed an "extraordinary private placement" or that involves a director or controlling shareholder. A "extraordinary private placement" is a private placement in which a company issues securities representing 20% or more of its voting rights prior to the issuance and the consideration received pursuant to such issuance is not comprised, in whole or in part, solely of cash or securities registered for trade on an exchange or which is not made pursuant to market conditions, and as a result of which the shareholdings of a 5% holder of the shares or voting rights of the company increases or as a result of which a person will become a holder of 5% of the shares or voting rights of the company or a controlling shareholder after the issuance;
- *Quorum* - As permitted under the Israeli Companies Law, pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and at an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the NASDAQ Listing Rules; and
- *Nominations Committee* - As permitted by the Israeli Companies Law, our board of directors selects director nominees subject to the terms of our articles of association which provide that incumbent directors are re-nominated for additional terms. Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the NASDAQ Listing Rules.

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

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 17. FINANCIAL STATEMENTS

Not applicable.

ITEM 18. FINANCIAL STATEMENTS

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

ITEM 19. EXHIBITS

See Exhibit Index on page 141.

Glossary of Terms

Certain standards and other terms that are used in this Annual Report are defined below:

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

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

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

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

CMC - chemistry, manufacturing and controls of pharmaceutical products.

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

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

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

FDA – United States Food and Drug Administration.

FDCA – Federal Food, Drug, and Cosmetic Act of 1938, as amended.

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

GERD - gastroesophageal reflux disease.

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

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

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

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

MAA - Marketing Authorization Application - the equivalent European Union (EU) process to the U.S. new drug application (NDA – see below) process. It is an application submitted by a drug sponsor seeking permission to bring a newly-developed medicinal product to the market. An MAA may be filed with the European Medicines Agency (EMA)

or one or more Member States, depending on the applicable and selected procedure: centralized, mutual recognition or decentralized.

***Mycobacterium avium subspecies paratuberculosis* (MAP) -** an obligate pathogenic bacterium in the genus Mycobacterium. MAP is the causative agent of Johne's disease, a chronic granulomatous ileitis occurring mainly in ruminants. MAP has been suspected as the cause of Crohn disease in humans.

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

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

Ondansetron - a drug in a 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 Designation - the designation of Orphan Drug Designation to drugs that are in the process of development for the treatment of rare diseases, affecting fewer than 200,000 people in the United States. This status provides tax reductions and the exclusive rights to the cure for a specific condition for a period of seven years post-approval.

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

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

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

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

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

REDHILL BIOPHARMA LTD

EXHIBIT INDEX

1.1	Articles of Association of the Registrant, as amended (unofficial English translation).
2.1	Form of Deposit Agreement among the Registrant, the Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued hereunder (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
2.2	Form of American Depositary Receipt (Incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
4.1*	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).
4.2	Amendment to Asset Purchase Agreement by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) dated February 27, 2014.
4.3*	License Agreement, dated February 27, 2014, by and between the Registrant and Bausch Health (f/k/a Salix Pharmaceuticals, Inc.) (Incorporated by reference to Exhibit 4.6 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.4†	Amendment #1 dated March 20, 2018 to the License Agreement, dated February 27, 2014, by and between the Registrant and Bausch Health (f/k/a Salix Pharmaceuticals, Inc.).
4.5*	Exclusive License Agreement, dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp (Incorporated by reference to Exhibit 4.7 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.6†	Amendment #1 dated January 23, 2017, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp.
4.7*	Amendment #2 dated June 22, 2017, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp. (incorporated by reference to Exhibit 4.5 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 22, 2018),
4.8*	Amendment #3 dated February 6, 2018, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp. (incorporated by reference to Exhibit 4.6 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 22, 2018).
4.9†	Amendment #4 dated January 3, 2019, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp.
4.10	Amendment #5 dated January 23, 2019, to the Exclusive License Agreement dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp.

4.11* Exclusive Commercialization Agreement, dated December 30, 2016, by and between Registrant and Concordia Pharmaceuticals Inc. (incorporated by reference to Exhibit 4.24 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 23, 2017).

4.12† Amendment #1 dated August 26, 2018, to the Exclusive Commercialization Agreement, dated December 30, 2016, by and between Registrant and a subsidiary of ADVANZ PHARMA (f/k/a Concordia Pharmaceuticals Inc.).

4.13* Exclusive License Agreement, dated April 5, 2017, by and between Registrant and Entera Health Inc. (incorporated by reference to Exhibit 4.19 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 22, 2018).

4.14 Amendment #1 dated July 25, 2018, to the Exclusive License Agreement by and between Registrant and Entera Health Inc.

4.15† Amendment #2 dated September 29, 2018, to the Exclusive License Agreement by and between Registrant and Entera Health Inc.

4.16 Form of Letter of Exemption and Indemnity adopted on July 2013 (unofficial English translation) (incorporated by reference to Exhibit B to Exhibit 99.1 to Form 6-K disseminated with the Securities and Exchange Commission, dated June 26, 2013).

4.17 Amended and Restated Award Plan (2010) (incorporated by reference to Appendix B of the 6-K filed with the Securities and Exchange Commission on April 3, 2017).

8.1 Subsidiary List (incorporated by reference to Exhibit 8.1 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 22, 2018),

12.1 Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

12.2 Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

13. Certification by Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

15.1 Consent of Independent Registered Public Accounting Firm

101. The following financial statements from the Company's 20-F for the fiscal year ended December 31, 2018 formatted in XBRL: (i) Consolidated Statements of Comprehensive Loss, (ii) Consolidated Statements of Financial Position, (iii) Consolidated Statements of Changes in Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to the Consolidated Financial Statements.

* Confidential treatment granted with respect to certain portions of this Exhibit.

†Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

SIGNATURE

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

REDHILL BIOPHARMA LTD

By:/s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: Chief Executive Officer and Chairman of the Board of Directors

By:/s/ Micha Ben-Chorin
Name: Micha Ben Chorin
Title: Chief Financial Officer

Date: February 25, 2019

REDHILL BIOPHARMA LTD.
2018 CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of **REDHILL BIOPHARMA LTD.**

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated statements of financial position of RedHill Biopharma Ltd. and its subsidiary (The "Company") as of December 31, 2018 and 2017, and the related consolidated statements of comprehensive loss, of changes in equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 15(b). Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other

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procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

Tel-Aviv, Israel
February 25, 2019

We have served as the Company's auditor since 2010.

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year Ended December 31,		
		2018	2017	2016
		U.S. dollars in thousands		
NET REVENUES	18	8,360	4,007	101
COST OF REVENUES		2,837	2,126	—
GROSS PROFIT		5,523	1,881	101
RESEARCH AND DEVELOPMENT EXPENSES, net	19	24,862	32,969	25,241
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	20	12,486	12,014	1,555
GENERAL AND ADMINISTRATIVE EXPENSES	21	7,506	8,025	3,848
OTHER EXPENSES	10	—	845	—
OPERATING LOSS		39,331	51,972	30,543
FINANCIAL INCOME		678	6,505	1,548
FINANCIAL EXPENSES		167	77	375
FINANCIAL INCOME, net	22	(511)	(6,428)	(1,173)
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		38,820	45,544	29,370
LOSS PER ORDINARY SHARE (U.S. dollars)	24			
Basic		0.17	0.26	0.23
Diluted		0.17	0.26	0.24

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

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2018	December 31, 2017
		U.S. dollars in thousands	
CURRENT ASSETS:			
Cash and cash equivalents	5	29,005	16,455
Bank deposits	5	8,271	13,163
Financial assets at fair value through profit or loss	6	15,909	16,587
Trade receivables		958	1,528
Prepaid expenses and other receivables	7	1,876	3,290
Inventory	8	769	653
		56,788	51,676
NON-CURRENT ASSETS:			
Bank deposits		140	152
Fixed assets	9	163	230
Intangible assets	10	5,320	5,285
		5,623	5,667
TOTAL ASSETS		62,411	57,343
CURRENT LIABILITIES:			
Accounts payable		3,324	4,805
Accrued expenses and other current liabilities	12	7,057	6,025
Payable in respect of intangible asset purchase	13a(3)	—	1,000
		10,381	11,830
NON-CURRENT LIABILITIES:			
Derivative financial instruments	16	344	448
Royalty obligation	13a(3)	500	—
		844	448
TOTAL LIABILITIES		11,225	12,278
EQUITY:	15		
Ordinary shares		767	575
Additional paid-in capital		219,505	177,434
Accumulated deficit		(169,086)	(132,944)
TOTAL EQUITY		51,186	45,065
TOTAL LIABILITIES AND EQUITY		62,411	57,343

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

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2016	343	120,621	1,057	(61,944)	60,077
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2016:					
Share-based compensation to employees and service providers	—	—	—	1,679	1,679
Issuance of ordinary shares, net of expenses	96	29,956	—	—	30,052
Exercise of options into ordinary shares	2	261	—	—	263
Comprehensive loss	—	—	—	(29,370)	(29,370)
BALANCE AT DECEMBER 31, 2016	441	150,838	1,057	(89,635)	62,701
BALANCE AT JANUARY 1, 2017	441	150,838	1,057	(89,635)	62,701
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2017:					
Share-based compensation to employees and service providers	—	—	—	2,235	2,235
Issuance of ordinary shares, net of expenses	119	22,097		—	22,216
Exercise of warrants and options into ordinary shares	15	3,442	—	—	3,457
Warrants expiration	—	1,057	(1,057)	—	—
Comprehensive loss	—	—	—	(45,544)	(45,544)
BALANCE AT DECEMBER 31, 2017	575	177,434	—	(132,944)	45,065
BALANCE AT JANUARY 1, 2018	575	177,434	—	(132,944)	45,065
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2018:					
Share-based compensation to employees and service providers	—	—	—	2,678	2,678
Issuance of ordinary shares, net of expenses	190	41,712		—	41,902
Exercise of options into ordinary shares	2	359	—	—	361
Comprehensive loss	—	—	—	(38,820)	(38,820)
BALANCE AT DECEMBER 31, 2018	767	219,505	—	(169,086)	51,186

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

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
OPERATING ACTIVITIES:			
Comprehensive loss	(38,820)	(45,544)	(29,370)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	2,678	2,235	1,679
Depreciation	90	81	44
Write-off of intangible assets	—	845	—
Fair value adjustments on derivative financial instruments	(104)	(5,687)	(1,152)
Fair value losses (gains) on financial assets at fair value through profit or loss	137	127	(67)
Revaluation of bank deposits	35	(123)	(274)
Issuance costs in respect of warrants	—	—	368
Exchange differences in respect of cash and cash equivalents	103	(367)	(39)
	2,939	(2,889)	559
Changes in assets and liability items:			
Decrease (increase) in trade receivables	570	(1,429)	99
Decrease (increase) in prepaid expenses and other receivables	1,414	(1,728)	612
Decrease (increase) in inventory	(116)	(653)	—
Increase (decrease) in accounts payable	(1,481)	4,745	(60)
Increase (decrease) in accrued expenses and other current liabilities	1,032	2,729	(98)
	1,419	3,664	553
Net cash used in operating activities	**(34,462)**	**(44,769)**	**(28,258)**
INVESTING ACTIVITIES:			
Purchase of fixed assets	(23)	(146)	(85)
Purchase of intangible assets	(35)	(1,035)	(35)
Change in investment in current bank deposits	4,869	(13,000)	36,838
Purchase of financial assets at fair value through profit or loss	(6,976)	(21,923)	(12,246)
Proceeds from sale of financial assets at fair value through profit or loss	7,517	17,522	—
Net cash provided by (used in) investing activities	**5,352**	**(18,582)**	**24,472**
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, net of expenses	41,902	22,216	35,754
Exercise of warrants and options into ordinary shares, net of expenses	361	3,437	263
Repayment of payable in respect of intangible asset purchase	(500)	—	—
Net cash provided by financing activities	**41,763**	**25,653**	**36,017**
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,653	(37,698)	32,231
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(103)	367	39
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	16,455	53,786	21,516
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	29,005	16,455	53,786
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	728	469	408

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

REDHILL BIOPHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 - GENERAL:

a. General

1) RedHill Biopharma Ltd. (the "Company"), incorporated in Israel on August 3, 2009, together with its wholly-owned subsidiary RedHill Biopharma Inc. (the "Company's subsidiary"), incorporated in Delaware, U.S. on January 19, 2017, is a specialty biopharmaceutical company, primarily focused on late-stage clinical development and commercialization of proprietary drugs for gastrointestinal ("GI") diseases.

The Company is primarily engaged in the research and development of its therapeutic candidates and, since January 2017, has pursued its commercial activities in the U.S. through the Company's subsidiary.

In February 2011, the Company listed its securities on the Tel-Aviv Stock Exchange ("TASE") and from December 2012 through July 2018, the Company's American Depositary Shares ("ADSs") were listed on the NASDAQ Capital Market. Since July 2018, the Company's ADSs have been listed on the NASDAQ Global Market ("NASDAQ").

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

2) U.S. rights to commercialize and co-promote

In April 2017, the Company signed an exclusive license agreement with a privately held U.S. company, granting the Company certain commercialization rights to commercialize EnteraGam®. Under the license agreement, the Company is required to pay royalties based on net sales, as provided in the agreement. The initial term of the agreement is four years. See also note 2o(2).

In December 2016, the Company entered into an agreement with an international specialty pharmaceutical company, granting the Company certain rights to promote Donnatal® in certain U.S. territories. In addition, in August 2017 and June 2018, the Company entered into agreements with U.S. companies, granting the Company certain rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and Mytesi®, respectively, in certain U.S. territories. According to these agreements, fees are paid to the Company based on units sold of the products during each period. The initial terms of the agreements are between a year and a half and four years. See also note 2o(1).

3) To date the Company has out-licensed on an exclusive worldwide basis only one of its therapeutic candidates and has generated limited revenues from its commercial activities. Accordingly, there is no assurance that the Company's business will generate sustainable positive cash flows. Through December 31, 2018, the Company has an accumulated deficit, and its activities have been funded primarily through public and private offerings of the Company's securities.

The Company plans to further fund its future operations through commercialization and out-licensing of its therapeutic candidates, commercialization of in-licensed or acquired products and raising additional capital through equity or debt financing or through non-dilutive financing. The Company's current cash resources are not sufficient to complete the research and development of

all of the Company's therapeutic candidates and to fully support its commercial operations until generation of sustainable positive cash flows. Management expects that the Company will incur additional losses as it continues to focus its resources on advancing the development of its therapeutic candidates, as well as advancing its commercial operations, 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 out-license, sell or commercialize its therapeutic candidates, generate sufficient and sustainable revenues from its commercial operations, 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 or commercialization programs, any of which may have a material adverse effect on the Company's business, financial condition or results of operations.

b. Approval of financial statements

These financial statements were approved by the Board of Directors on February 25, 2019.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a. Basis for presentation of the financial statements

The consolidated financial statements of the Company as of December 31, 2018 and 2017 and for each of the three years for the period ended on December 31, 2018 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 consolidated 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 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 transactions and balances

1) Functional and presentation currency

Items included in the consolidated financial statements are measured using the currency of the primary economic environment in which the Company and its subsidiary operate (the "Functional

Currency"). The consolidated 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 Shekel ("NIS")) are translated into the Functional Currency using the exchange rates at the dates of the transactions. Foreign exchange differences resulting from the settlement of such transactions and from the translation of period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recorded in the Statements of Comprehensive Loss under Financing Income or Financial Expenses.

c. Principles of consolidation

Commencing 2017, the Company's consolidated financial statements include the accounts of the Company and its subsidiary. All material intercompany balances and transactions have been eliminated upon consolidation.

d. 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.

e. Trade receivables

Trade receivables are recognized initially at the amount of consideration that is unconditional, unless they contain significant financing components. Subsequent to the initial recognition, they are measured at amortized cost using the effective interest rate method, less any impairment loss.

f. Inventory

The Company's inventory represents items held for sale in the ordinary course of business, in the process of production for a sale in the ordinary course of business or materials or supplies to be used in the production process, to the extent they are recoverable. The inventory is stated at the lower of cost or net realizable value with cost determined using the first-in, first-out method.

The Company continually evaluates inventory for potential loss due to excess quantity or obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates that the carrying value of a product may not be recoverable, a charge is recorded to reduce the inventory to its current net realizable value.

g. Fixed assets

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

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

	%
Computer equipment	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.

h. Research and development

1) Research and development assets acquired by the Company, the development of which has not yet been completed, 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 and development expenses are charged to profit or loss as incurred. An intangible asset arising from the development of the Company's therapeutic candidates is recognized if all of the following conditions are met:

- it is technically feasible to complete the intangible asset so that it will be available for use;
- management intends to complete the intangible asset and use it or sell it;
- there is an ability to use or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits; and
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available and costs associated with the intangible asset during development can be measured reliably.

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

As of December 31, 2018, the Company had not yet capitalized any development costs.

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

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

i. Impairment of non-financial assets

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

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For 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 Statements of Financial Position.

j. Financial assets

As of January 1, 2018, the Company adopted IFRS 9 "Financial Instruments"**.**

1) Classification

The financial assets of the Company are classified into the following categories: financial assets at fair value through profit or loss, and financial assets at amortized cost. The classification is done on the basis of the Company's business model for managing the financial asset and the contractual cash flow characteristics of the financial asset.

a) Financial assets at amortized cost

Financial assets at amortized cost are assets held within a business model whose objective is to hold assets in order to collect contractual cash flows and the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are included in current assets, except for those with maturities greater than 12 months after the statements of financial position date (for which they are classified as noncurrent assets).

Financial assets at amortized cost of the Company are included in trade receivables, other receivables and bank deposits in the Statements of Financial Position.

b) Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss of the Company are assets not measured at amortized cost in accordance with (1)(a) above. Assets in this category are classified as current assets if they are expected to be settled within 12 months; otherwise, they are classified as noncurrent.

2) Recognition and measurement

Regular purchases and sales of financial assets are recognized on the settlement date, which is the date on which the asset is delivered to the Company or delivered by the Company. Investments are initially recognized at fair value plus transaction costs for all financial assets not recorded at fair value through profit or loss, except for trade receivables, that are recognized initially at the amount of consideration that is unconditional unless they contain significant financing components.

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

Gains or losses arising from changes in the fair value of financial assets at fair value through profit or loss are presented in the Statement of Comprehensive Loss under "Financial Expenses (Income), net".

3) Impairment

The Company recognizes a loss allowance for expected credit losses on financial assets at amortized cost.

At each reporting date, the Company assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. If the financial instrument is determined to have low credit risk at the reporting date, the Company assumes that the credit risk on a financial instrument has not increased significantly since initial recognition.

The Company measures the loss allowance for expected credit losses on trade receivables that are within the scope of IFRS 15 and on financial instruments for which the credit risk has increased significantly since initial recognition based on lifetime expected credit losses. Otherwise, the Company measures the loss allowance at an amount equal to 12-month expected credit losses at the current reporting date.

Prior to the effective date and adoption of IFRS 9, the financial assets of the Company were classified into the following categories: financial assets at fair value through profit or loss, and loans and receivables. The classification depended on the purpose for which the financial assets were acquired, also, prior to the adoption of IFRS 9, the Company assessed at December 31, 2017 whether there is any objective evidence that a financial asset or group of financial assets was impaired.

k. Financial liabilities

Financial liabilities are initially recognized at their fair value minus, in the case of a financial liability not at fair value through profit or loss, transaction costs that are directly attributable to the issue of the financial liability.

Financial liabilities are subsequently measured at amortized cost, except for derivative financial instruments, which are subsequently measured at fair value through profit or loss.
Financial liabilities are classified as current liabilities if payment is due within one year or less, otherwise they are classified as non-current liabilities.

The Company's financial liabilities at amortized cost are included in accounts payable, accrued expenses and other current liabilities and payable in respect of intangible asset.

The derivative financial instruments represent warrants that confer the right to net share settlement.

The Company removes a financial liability (or a part of a financial liability) from its Statement of Financial Position when, and only when, it is extinguished (when the obligation specified in the contract is discharged, canceled or expired).

The Company accounts for a substantial modification of the terms of an existing financial liability or a part of it as an extinguishment of the original financial liability and the recognition of a new financial liability. The difference between the carrying amount of a financial liability (or part of a financial liability) extinguished and the consideration paid, including any non-cash assets transferred or liabilities assumed, is recognized in profit or loss.

l. Share capital

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

m. Employee benefits

1) Pension and retirement benefit obligations

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

Labor laws and agreements in Israel as well as the Company's practice, require the Company to pay severance pay and/or pensions to employees dismissed or retired, in certain circumstances.

The Company has a severance pay plan in accordance with Section 14 of the Israeli Severance Pay Law which is treated as a defined contribution plan. According to the plan, the Company regularly makes payments to severance pay or pension funds without having a legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay the related payments to employees' service in 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.

The Company's subsidiary provides, at will, benefit contributions for its employees.

2) Vacation and recreation pay

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

n. Share-based payments

The Company operates several equity-settled, share-based compensation plans to employees (as defined in IFRS 2 "Share-Based Payments") and service providers. As part of the plans, the Company grants employees and service providers, from time to time and at its discretion, options to purchase Company shares. The fair value of the employee and service provider services received in exchange for the grant of the options is recognized as an expense in profit or loss and is recorded as accumulated deficit within equity. The total amount recognized as an expense over the vesting period of the options (the period during which all vesting conditions are expected to be met) is determined by reference to the fair value of the options granted at the date of grant.

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

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

When exercising options, the Company issues new shares. The proceeds, less direct attributable transaction costs, are recognized as share capital (par value) and share premium.

o. Revenue from contracts with customers

As of January 1, 2017, the Company early adopted IFRS 15, with full retrospective application. The adoption of IFRS 15 did not have an effect on either revenue recognized in prior periods, nor to accumulated deficit as of January 1, 2015.

IFRS 15 introduces a five-step model for recognizing revenue from contracts with customers, as follows:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to the performance obligations in the contract; and
- recognize revenue when (or as) the entity satisfies a performance obligation.

1) Revenues from promotional services

The Company recognizes revenue from promotional services as it satisfies its performance obligation over time, in an amount equal to the consideration to which it expects to be entitled to, taking into consideration the constraint on variable considerations stipulated in IFRS 15.

2) Revenues from the sale of products

Principal versus agent considerations:

When a third party is involved in providing goods or services to a customer, the Company analyzes whether the Company acts as a principal or an agent in the transaction, based on whether the Company obtains control of the product before it is transferred to the customer, using the indicators provided in IFRS 15.

In connection with the commercialization of EnteraGam®, the Company is determined to be the principal in the arrangement, rather than an agent of Entera Health Inc. ("Entera Health"), since the Company controls the product before transferring it to a customer. Therefore, revenue in the amount the Company is entitled to receive from its customers is recognized on a gross basis, from which royalties payable to Entera Health are accounted for in cost of revenues.

The Company recognizes revenues from the sale of EnteraGam® at a point in time when control over the product is transferred to customers (upon delivery).

The transaction price in these arrangements is the consideration to which the Company expects to be entitled from the customer, reduced by estimates of rebates, discounts, allowances and provision for product returns, given or expected to be given, which vary by product arrangement and buying groups. The Company estimates its variable consideration using the most likely amount method using actual in-market data received pre- and post- end of the accounting period and are applied to inventory held at wholesalers and pharmacies. The Company will continue to refine these estimates and methodologies over time as the breadth of in-market data increases.

3) Revenues from out-licensing of the Company's therapeutic candidates

Revenue incurred in connection with the out-licensing of a right to use the Company's intellectual property is recognized at a point in time when control over the license is transferred to the licensee.

The transaction price contains variable considerations contingent upon the licensee achieving certain milestones, as well as sales-based royalties, in accordance with the relevant agreement.

Variable payments, contingent on achieving additional milestones, are included in the transaction price based on most likely amount method. Amounts included in the transaction price are recognized

only when it is highly probable that a significant reversal of cumulative revenues will not occur, usually upon achievement of a specific milestone, in accordance with the relevant agreement.

Sales-based royalties are not included in the transaction price; rather they are recognized as the related sale occurs, due to the specific exception for sales-based royalties in licensing of intellectual property.

4) Practical expedients and exemptions

The Company expenses sales commissions when incurred since the amortization period of the asset that the Company otherwise would have recognized would have been for less than one year. These costs are recorded as selling and marketing expenses.

p. Advertising and promotional expenses

Advertising and promotional costs include, among others, distribution of free samples of the commercialized products. These costs are recognized as an expense when incurred.

q. 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 Statements of Comprehensive Loss on a straight-line basis over the period of the lease.

r. Loss per ordinary share

The computation of basic loss per share is based on the Company's loss divided by the weighted average number of ordinary shares outstanding during the period.

In calculating the diluted loss per share, the Company adds the weighted average of the number of shares to be issued to the average number of shares outstanding used to calculate the basic loss per share, assuming all shares that have a potentially dilutive effect have been exercised into shares.

s. 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 these financial statements.

Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the date of the Statements of Financial Position and are expected to apply when the related deferred income tax asset will be realized, or the deferred income tax liability will be settled. Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Since the Company is unable to assess whether it will have taxable income in the foreseeable future, no deferred tax assets were recorded in these financial statements.

t. Standards and interpretations to existing standards that are not yet in effect and have not been early adopted by the Company

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

IFRS 16 was issued in January 2016. It will result in almost all leases being recognized on the balance sheet by lessees, as the distinction between operating and finance leases is removed. Under the new standard, an asset (the right to use the leased item) and a financial liability to pay rentals are recognized. The only exceptions are short-term and low-value leases.

The Company has reviewed all of the Company's and its subsidiary's leasing arrangements over the last year in light of the new lease accounting rules in IFRS 16. The standard will affect primarily the accounting for the Company's operating leases. As at the reporting date, the Company has non-cancellable operating lease commitments of $1.8 million, see note 13b.

The Company expects to recognize right-of-use assets and lease liabilities of approximately $1.7 million on January 1, 2019.

The Company will apply the standard from its mandatory adoption date of January 1, 2019. The Company intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption.

The Company expects that net loss will increase by an immaterial amount for 2019 as a result of adopting the new rules. Operating cash flows for 2019 will increase, and financing cash flows will decrease by approximately $0.9 million as repayment of the principal portion of the lease liabilities will be classified as cash flows from financing activities.

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

The Company reviews once a year or when indications of impairment are present, whether research and development related assets are to be impaired. See note 2i.

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

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amounts of each asset are based on the Company's estimates as to the development of the therapeutic candidates, changes in the potential market, market competition and timetables for regulatory approvals.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT:

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 risks), 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 results of operations and financial position.

Risk management is performed by the Chief Financial Officer of the Company who identifies and evaluates financial risks in close cooperation with the Company's Chief Executive Officer.

The Company's finance department is responsible for carrying out financial risk management activities in accordance with policies approved by its board of directors (the "Board of Directors"). The Board of Directors provides general guidelines for overall financial 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 market risk and credit risk, the Company has invested the majority of its cash balances in low-risk investments, such as (i) highly-rated bank deposits with terms of up to one-year term with exit points and (ii) a managed portfolio of selected corporate bonds comprised of a diversified mix of highly-rated bonds. No more than 10% of the total value of the Company's corporate bonds portfolio is invested in a single bond issuer.

(a) Market risks

The Company might be exposed to foreign exchange risk as a result of its payments to employees and service providers and investment of some liquidity in currencies other than the U.S. dollar (i.e., the Functional Currency). The Company manages the foreign exchange risk by aligning the currencies for holding liquidity with the currencies of expected expenses, based on the expected cash flows of the Company. Had the Functional Currency of the Company been stronger by 5% against the NIS, assuming all other variables remained constant, the Company would have recognized an additional expense of $58,„000 $56,000 and $78,000 in profit or loss for the years ended, December 31, 2018, 2017 and 2016, respectively. The foreign exchange risks associated with these balances are immaterial.

(b) Credit and interest risks

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

the short term and with highly-rated institutions, the credit and interest risks associated with these balances are low.

Credit risk is the risk that customers may fail to pay their debts. The Company manages credit risk by setting credit limits, performing controls and monitoring qualitative and quantitative indicators of trade receivable balances such as the period of credit taken and overdue payments. Customer credit risk also arises as a result of the concentration of the Company's revenues with its largest customers. See also note 23b.

(c) Liquidity risk

Prudent liquidity risk management requires maintaining sufficient cash or the availability of funding through an adequate amount of committed credit facilities. Management monitors rolling forecasts of the Company's liquidity reserve (comprising of cash and cash equivalents, deposits and financial assets through profit or loss). This is generally carried out based on the expected cash flow in accordance with practice and limits set by the management of the Company.

As of December 31, 2018, the Company has generated revenues from commercialization and promotional activities; however, and as no sufficient revenue from the commercial operations was generated to compensate for operating expenses and as sales, royalties or commercialization revenues from the therapeutic candidates have not yet been generated, the Company is exposed to liquidity risk.

As of December 31, 2018, the Company's non-derivative financial liabilities, include accounts payable, accrued expenses, and other current liabilities for a period of less than 1 year.

2) Capital risk management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders, maintain optimal capital structure, and to reduce the cost of capital.

3) Fair value estimation

The following is an analysis of financial instruments measured at fair value using valuation methods. The different levels have been defined as follows:

- quoted prices (unadjusted) in active markets for identical assets or liabilities (level 1);
- inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices) (level 2); and
- 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 the Statements of Financial Position. A market is regarded as active if quoted prices are

readily and regularly available from an exchange, dealer, broker, industry group, pricing service, or regulatory agency, and those prices represent actual and regularly occurring market transactions on an arm's length basis. These instruments are included in level 1.

The fair value of financial instruments that are not traded in an active market is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity-specific estimates. If all significant inputs required to determine the fair value of an instrument are observable, then the instrument is included in level 2.

If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

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

	Level 1	Level 3	Total
	U.S. dollars in thousands		
December 31, 2018:			
Assets -			
Financial assets at fair value through profit or loss	15,909	—	15,909
Liabilities -			
Derivative financial instruments	—	344	344
December 31, 2017:			
Assets -			
Financial assets at fair value through profit or loss	16,587	—	16,587
Liabilities -			
Derivative financial instruments	—	448	448

The following table presents the change in derivative liabilities measured at level 3 for the years ended December 31, 2018 and 2017:

	Derivative financial instruments	
	Year Ended December 31,	
	2018	2017
	U.S. dollars in thousands	
Balance at beginning of the year	448	6,155
Exercise of derivative into shares	—	(20)
Fair value adjustments recognized in profit or loss	(104)	(5,687)
Balance at end of the year	344	448

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

For more information regarding the derivative financial instruments, see note 16.

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NOTE 5 – CASH, CASH EQUIVALENTS AND BANK DEPOSITS:

a. Cash and cash equivalents

	December 31,	
	2018	2017
	U.S. dollars in thousands	
Cash in bank	7,736	8,305
Short-term bank deposits	21,269	8,150
	29,005	16,455

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

b. Bank deposits

The bank deposits include deposits invested for terms of three months to one year and bear interest at an average annual rate of 2.03%.

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

These financial assets as of December 31, 2018 represent a portfolio of marketable debt securities.

The Company's business model regarding this portfolio is to realize cash flows through the sale of its assets, rather than hold these assets to collect their contractual cash flows or both to collect contractual cash flows and to sell these financial assets. The Company is primarily focused on fair value information and uses that information to assess the assets' performance and to make decisions. Therefore, this portfolio is classified as financial assets at fair value through profit or loss.

The fair value of the securities is based on their exchange market price at the end of each trading day and reporting period.

NOTE 7 - PREPAID EXPENSES AND OTHER RECEIVABLES:

	December 31,	
	2018	2017
	U.S. dollars in thousands	
Advance to suppliers	1,319	2,426
Discount from service provider	241	537
Prepaid expenses	120	130
Government institutions	196	197
	1,876	3,290

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

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NOTE 8 - INVENTORY:

	December 31,	
	2018	2017
	U.S. dollars in thousands	
Raw materials	507	—
Finished goods	262	653
	769	653

During the years ended December 31, 2018 and 2017, the Company recognized amounts of $1 million and $0.8 million, respectively, in inventory cost as part of cost of revenues.

NOTE 9- FIXED ASSETS:

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

	Cost		Accumulated depreciation		Depreciated balance	
	December 31		December 31		December 31	
	2018	2017	2018	2017	2018	2017
	U.S. dollars in thousands					
Office furniture and equipment (including computers)	372	349	235	163	137	186
Leasehold improvements	132	132	106	88	26	44
	504	481	341	251	163	230

NOTE 10 - INTANGIBLE ASSETS:

The intangible assets represent R&D assets with respect to intellectual property rights of the therapeutic candidates purchased by the Company under licensing agreements or under asset acquisition agreements. The changes in those assets are as follows:

	Year Ended December 31,	
	2018	2017
	U.S. dollars in thousands	
Cost:		
Balance at beginning of year	5,285	6,195
Additions during the year	35	35
Deductions during the year	—	(945)
Balance at end of year	5,320	5,285

In February 2017, the Company deducted from the intangible assets cost an amount of $100,000, written off in prior years, due to final termination notice provided to a Danish company for the exclusive rights to a non-core therapeutic candidate that was intended to treat congestive heart failure, left atrium dysfunction and high blood pressure.

In February 2017, the Company recognized a loss in the amount of $45,000 paid to a private German company for the exclusive option to acquire rights to an oncology therapeutic candidate. As the Company did not exercise or extend its option to acquire these rights, the entire amount was deducted from the intangible assets' cost and recorded as a loss in the Consolidated Statement of Comprehensive Loss under Other Expenses.

In December 2017, the Company recognized a loss in the amount of $800,000, paid to a Canadian company for the exclusive rights to a non-core migraine therapeutic candidate. Given the Company's increasing focus on GI diseases, in particular its two key Phase 3 GI programs, a termination notice was issued to the Canadian company and the entire amount was deducted from the intangible assets cost and recorded as a loss in the Consolidated Statement of Comprehensive Loss under Other Expenses.

For further details regarding the intangible assets, see note 13.

NOTE 11 - LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT:

a. Labor laws and agreements in Israel require the Company to pay severance pay and/or pensions to an employee dismissed or retiring from their employment in certain circumstances.

b. The Company's pension liability and the Company's liability for payment of severance pay for employees in Israel for whom the liability is within the scope of Section 14 of the Severance Pay Law, is covered by ongoing deposits with defined contribution plans. The amounts deposited are not included in the Statements of Financial Position.

The amounts charged as an expense with respect to defined contribution plans in 2018, 2017 and 2016 were $182,000, $155,000 and $121,000, respectively.

NOTE 12 - ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES:

	December 31,	
	2018	2017
	U.S. dollars in thousands	
Accrued expenses	5,599	4,969
Employees and related liabilities	1,380	1,045
Government institutions	78	11
	7,057	6,025

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

NOTE 13 - COMMITMENTS:

a. Agreements to purchase intellectual property

1) On August 11, 2010, the Company entered into an agreement with private Australian company in an asset purchase agreement to acquire intellectual property relating to three therapeutic candidates for the treatment of gastrointestinal conditions. Pursuant to the asset purchase agreement, as amended, the Company paid the Australian company an initial amount of $500,000 and undertook to pay future payments in the range of 7% - 20% from the Company's revenues that may be generated from the sale and sublicense of the therapeutic candidates, less certain deductible amounts, as detailed in the agreement. Such potential payments are due until termination or expiration of the last of the patents transferred to the Company pursuant to the agreement (each on a product-by-product basis).

In 2014, the Company entered into a licensing agreement with Salix Pharmaceuticals, Ltd., which was later acquired by Valeant Pharmaceuticals International, Inc. and subsequently renamed to Bausch Health Companies Inc. ("Bausch Health"), pursuant to which Bausch Health licensed from the Company the exclusive worldwide rights to one of the above-mentioned therapeutic candidates. Under the license agreement, Bausch Health paid an upfront payment of $7 million with subsequent potential milestone payments up to a total of $5 million. In March 2018, the 2014 license agreement was amended, among other things, to increase the lower end of the range of potential royalty payments to be paid to the Company on net sales from low single digits to high single digits, such that the total potential royalties payments will range from high single digits up to low double digits. Following the execution of the 2014 license agreement, the Company recognized revenues in 2014 in the amount of the upfront payment and subsequently paid the Australian company an additional amount of $1 million. The additional amount paid was recognized as cost of revenues in the Statement of Comprehensive Loss.

Through December 31, 2018, the Company has paid the Australian company in total $1.5 million, as mentioned above.

2) On June 30, 2014, the Company entered into an agreement with a German publicly-traded company that granted the Company the exclusive worldwide (excluding China, Hong Kong, Taiwan and Macao) development and commercialization rights to all indications to a therapeutic candidate. Under the terms of the agreement, the Company paid the German company an upfront payment of $1 million and agreed to pay the German company potential tiered royalties, less certain deductible amounts as detailed in the agreement, ranging from mid-teens and up to 30%. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2018, the Company has paid the German company only the initial amount mentioned above.

3) On March 30, 2015, the Company entered into an agreement with a U.S.-based private company that granted the Company the exclusive worldwide development and commercialization rights for all indications to a therapeutic candidate, and additional intellectual property rights, targeting multiple oncology, inflammatory and GI indications. Under the terms of the agreement, the Company undertook to pay the U.S. company an initial amount of $1.5 million and an additional amount of $2 million to be paid on a specific date. In addition, the Company undertook to pay up to $2 million in potential development milestone payments, and potential tiered royalties on revenues, less certain deductible amounts starting in the low double-digits as detailed in the agreement. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2018, the Company paid the U.S. company a total of $3 million.

Following an amendment to the agreement from February 2018, during December 2018 the Company elected to convert the current payment of the remaining $0.5 million into increased future potential royalty payments. As of December 31, 2018, the Company recognized an amount of $0.5 million as a non-current liability with respect to the increase in potential royalty payments.

b. Operating lease agreements

The Company and its subsidiary lease offices and vehicles under non-cancellable operating leases expiring within two to five years. The office and vehicle obligations are payable as follows:

	December 31, 2018
	U.S. dollars in thousands
Less than 1 year	994
2-5 years	853
	1,847

As of December 31, 2018, an amount of $140,000 was deposited with a bank to secure the lease obligations.

In January 2019, the Company signed an amendment to its Israeli office lease agreement. According to the amendment, the Company obliged to lease the offices through January 31, 2026 for an annual lease amount of approximately $0.4 million.

NOTE 14 - INCOME TAX:

a. Taxation of the Company in Israel

1) Measurement of results for tax purposes

The Company elected to compute its taxable income in accordance with Income Tax Regulations (Rules for Accounting for Foreign Investors Companies and Certain Partnerships and Setting their Taxable Income), 1986. Accordingly, the Company's taxable income or loss is calculated in U.S. dollars.

The results of the Company are measured for tax purposes in accordance with Accounting Principles Generally Accepted in Israel (Israeli GAAP). These financial statements are prepared in accordance with IFRS. The differences between IFRS and Israeli GAAP, both on an annual and a cumulative basis cause differences between taxable results and the results reflected in these financial statements.

2) Tax rates

The net income of the Company is subject to the Israeli corporate tax rate. Israeli corporate tax rates for 2018, 2017 and 2016 were 23%, 24% and 25%, respectively.

b. U.S. subsidiary

The Company's subsidiary is incorporated in the U.S and is taxed under U.S. tax laws. The applicable corporate tax rate in 2017 was 34%. On December 22, 2017, the Tax Cuts and Jobs Act (the "2017 Act") was enacted and the applicable tax rate was reduced to 21% from 2018 and thereafter.

As a general rule, inter-company transactions between the Israel-resident Company and its U.S-resident subsidiary are subject to the reporting provisions of the Income Tax Regulations, section 85-A, 2006.

c. Carry forward losses

As of December 31, 2018, the Company had net operating losses carried forward ("NOLs") of approximately $135 million. Under Israeli tax laws, carry forward tax losses have no expiration date.

As of December 31, 2018, the U.S. subsidiary had net operating losses carried forward of approximately $18 million, of which approximately $10 million which expires in 2037, and approximately $8 million which does not expire, but is limited to offset 80% of the net income in the year it is utilized.

Under U.S. tax laws, for NOLs arising after December 31, 2017, the 2017 Act limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income. In addition, NOLs arising after 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018 will not be subject to the foregoing taxable income limitation and will continue to have a two-year carryback and twenty-year carryforward period.

Deferred tax assets on losses for tax purposes carried forward to subsequent years are recognized if utilization of the related tax benefit against a future taxable income is expected. The Company has not created deferred taxes on its carryforward losses since their utilization is not expected in the foreseeable future.

d. Deductible temporary differences

The amount of cumulative deductible temporary differences, other than carryforward losses (as mentioned in c. above), for which deferred tax assets have not been recognized in the Statements of Financial Position as of December 31, 2018 and 2017, were $27 million and $28 million, respectively. These temporary differences have no expiration dates.

e. Tax assessments

The Company has not been assessed for tax purposes since its incorporation. The Company's tax assessments for 2013 are therefore considered final.

NOTE 15 - EQUITY:

a. **Share capital**

1) Composition

Company share capital is composed of ordinary shares of NIS 0.01 par value, as follows:

	Number of shares	
	December 31,	
	2018	2017
	In thousands	
Authorized	600,000	300,000
Issued and paid	283,687	212,729

The Company's ordinary shares are traded on the TASE, and the Company's ADSs are traded on the NASDAQ under the symbol "RDHL". Each ADS represents 10 ordinary shares. The last reported market price for the Company's securities on December 31, 2018 was $5.55 per ADS on the NASDAQ and $0.54 per share on the TASE (based on the exchange rate reported by the Bank of Israel for that date).

On May 2, 2018, a general meeting of the Company's shareholders approved the increase of the authorized share capital of the Company to 600,000,000 ordinary shares.

2) Exercise of warrants and options

During 2018 and 2017, the Company issued 719,374 and 2,988,750 ordinary shares for $0.4 million and $0.8 million, respectively, resulting from exercises of options that had been issued to employees, consultants and directors of the Company.

In January 2017, the Company received notification of exercise with respect to non-tradable warrants that had been issued in 2014 to investors in the form of private placements. Accordingly, the Company issued 2,526,320 ordinary shares for approximately $2.63 million.

3) In January 2017, the underwriters for the Company's December 2016 underwritten public offering partially exercised their option and purchased 133,103 ADSs for approximately $1.28 million. Following the partial exercise of the underwriters' option, the underwritten public offering and the concurrent registered direct offering totaled 3,846,519 ADSs and warrants to purchase 2,025,458 ADSs, representing aggregate gross proceeds from both offerings of approximately $39.4 million before deducting underwriting discounts and commissions, placement agent fees and other offering expenses.

4) In November 2017, the Company completed an underwritten public offering in the U.S. of an aggregate of 4,090,909 ADSs for gross proceeds to the Company of approximately $22.5 million. Net proceeds to the Company from the offering, following underwriting discounts and other offering expenses of approximately $1.5 million, were approximately $21 million.

5) In August 2018, the Company completed an underwritten offering in the U.S. of an aggregate 4,166,667 ADSs, each representing ten of its ordinary shares, for gross proceeds to the Company of approximately $25 million. Net proceeds to the Company from the offering, following underwriting commissions and other offering expenses, were approximately $23.5 million

6) In December 2018, the Company completed an underwritten offering in the U.S. of an aggregate 2,857,143 ADSs, each representing ten of its ordinary shares, for gross proceeds to the Company of approximately $20 million. Net proceeds to the Company from the offering, following underwriting commissions and other offering expenses, were approximately $18.4 million

b. Warrants

In January 2017, warrants issued under investment agreements from January 21, 2014, that were exercisable into 4,183,496 ordinary shares, expired along with any right or claim of the holders.

REDHILL BIOPHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 16 - DERIVATIVE FINANCIAL INSTRUMENTS:

a. Warrants issued in 2014

The warrants were classified as a financial liability due to a net settlement provision. In January 2017, the Company issued 2,526,320 ordinary shares for approximately $2.63 million resulting from exercises of these warrants. The remaining unexercised warrants to purchase 1,052,640 ordinary shares expired along with any right or claim whatsoever of the holders.

b. Warrants issued in 2016

The warrants, issued under December 2016 offering, were classified as a financial liability due to a net settlement provision. These warrants are exercisable into 2,025,458 ADSs. The warrants have a three-year term and may be exercised either for cash or on a cashless basis at an exercise price of $13.33 per ADS.

The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the warrants upon issuance was computed based on the price of an ADS and based on the following parameters: risk-free interest rate of 1.56% and an average standard deviation of 53.13%. The fair value of the warrants as of December 31, 2018, was computed based on the price of an ADS as of December 31, 2018 and based on the following parameters: risk-free interest rate of 2.63% and an average standard deviation of 60.55%.

NOTE 17 - SHARE-BASED PAYMENTS:

On May 30, 2010, a general meeting of shareholders approved the option plan of the Company (the "Option Plan"), after being approved by the Board of Directors. In 2017 the Option Plan was amended and restated as the 2010 Award Plan (the "Award Plan"). As of December 31, 2018, the Award Plan allows the Company to allocate up to 38,518,375 options to employees, consultants and directors and are reserved by the Board of Directors for issuance under the Award Plan. The terms and conditions of the grants were determined by the Board of Directors and are according to the Award Plan.

a. The following is information on options granted in 2018:

	Number of options granted				
	According to the Award Plan of the Company			Exercise price for 1 ordinary	Fair value of options on date of grant in U.S. dollars
Date of grant	Other than to directors (1)	To directors (1)(2)	Total	share ($)	in thousands (3)
January 2018	1,455,000	—	1,455,000	0.56	433
March 2018	3,210,000	—	3,210,000	0.65	808
May 2018	—	500,000	500,000	0.65	111
August 2018	630,000	—	630,000	0.84	238
November 2018	210,000	—	210,000	0.90	102
	5,505,000	500,000	6,005,000		1,692

1) The options will vest as follows: for directors, employees and consultants of the Company and the Company's subsidiary who had provided services exceeding one year as of the grant date, options will vest in 16 equal quarterly installments over a four-year period. For directors, employees and consultants of the Company and the Company's subsidiary who had not provided services exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest will vest over 12 equal quarterly installments. During the contractual term, the options will be exercisable, either in full or in part, from the vesting date until the end of 10 years from the date of grant.
The options include both options exercisable into the Company's ordinary shares and options exercisable to the Company's ADSs.

2) The general meeting of the Company's shareholders held on May 2, 2018 (the "May 2018 AGM"), subsequent to approval of the Company's Board of Directors, granted 500,000 options under the Company's stock options plan to the Company's Chairman of the Board of Directors and Chief Executive Officer.

3) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $0.48 - $0.88, expected volatility: 50.99% - 58.4%, risk-free interest rate: 2.65% - 3.19% and the expected term was derived based on the contractual term of the options, the expected exercise behavior and expected post-vesting forfeiture rates. the expected volatility assumption used in based on the historical volatility of the Company's share.

b. During 2018, the Board of Directors approved a three years extension of the exercise period of fully-vested options exercisable into the Company's ordinary shares granted to employees and consultants that were originally scheduled to expire in February 2018, March 2018, August 2018, January 2019 and February 2019. Accordingly, 2,844,210 options, 120,000 options, 260,000 options, 750,000 options and 400,000 options, respectively, were extended with new terms: the exercise price will increase by 50% to $0.75, $1.575, $1.035, $1.08 and $1.08 per ordinary share, respectively, and will not be exercisable within one year of the extension. These options originally had a term of seven years. The total incremental fair value of the options as of the date of the extension was approximately $0.4 million and was recorded to the Statement of Comprehensive Loss immediately.

c. The May 2018 AGM, subsequent to approval of the Company's Board of Directors, granted three year extensions of the exercise period of 1,540,000 fully-vested options exercisable into the Company's ordinary shares and 150,000 fully-vested options exercisable into the Company's ordinary shares granted to the Company's Chairman of the Board of Directors and Chief Executive Officer and to a non-executive director of the Company, respectively, that were originally scheduled to expire in February 2018 and May 2018, respectively. These options originally had a term of seven years, and the extensions are under the same terms as detailed in b above. The total incremental fair value of the options on the date of May 2018 AGM was $0.1 million and was recorded to the Statements of Comprehensive Loss immediately.

In December 2018, the Board of Directors of the Company also approved the extension of the exercise period of 600,000 options to the Company's Chief Executive Officer that were originally scheduled to

expire in February 2019, under the same terms detailed above, subject to the approval of the Company's shareholders. These options also originally had a term of seven years.

d. The following is information on options granted in 2017:

	Number of options granted				
	According to the Award Plan of the Company				
Date of grant	Other than to directors (1)	To directors (1)	Total	Exercise price for 1 ordinary share ($)	Fair value of options on date of grant in U.S. dollars in thousands (2)
March 2017	3,650,000	—	3,650,000	1.08	1,777
May 2017	—	640,000	640,000	1.08	290
May 2017	—	500,000	500,000	1.09	227
July 2017	2,445,000	—	2,445,000	0.98	1,205
	6,095,000	1,140,000	7,235,000		3,499

1) The options will vest as follows: for directors, employees and consultants of the Company who had provided services exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For directors, employees and consultants of the Company who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments. During the contractual term the options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant. 2017 grants include both options exercisable into the Company's ordinary shares and options exercisable to the Company's ADSs.

2) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $0.98 - $1.09, expected volatility: 49.48% - 58.09%, risk-free interest rate: 2.05% - 2.23% and the expected term was derived based on the contractual term of the options, the expected exercise behavior and expected post-vesting forfeiture rates. The expected volatility assumption used is based on the historical volatility of the Company's share.

e. Changes in the number of options and weighted averages of exercise prices are as follows:

	Year Ended December 31,			
	2018		2017	
	Number of options	Weighted average of exercise price ($)	Number of options	Weighted average of exercise price ($)
Outstanding at beginning of year	25,781,798	1.05	22,025,548	0.95
Exercised	(719,374)	0.02	(2,988,750)	0.27
Expired and forfeited	(1,707,189)	0.96	(490,000)	1.37
Granted	6,005,000	0.66	7,235,000	1.05
Outstanding at end of year	29,360,235	1.05	25,781,798	1.05
Exercisable at end of year	12,962,574	1.25	16,842,697	0.99

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

December 31,					
2018			2017		
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
29,360,235	$0.56-$1.61	4.3	25,781,798	$0.5-$1.61	3.5

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

Year Ended December 31,		
2018	2017	2016
U.S. dollars in thousands		
2,678	2,235	1,679

The remaining compensation expenses as of December 31, 2018 are $1.8 million and will be expensed in full by December 2022.

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 Award Plan. Options granted to option holders who are related parties of the Company are governed by Section 3(i) to the Ordinance.

NOTE 18 – NET REVENUES:

	Year Ended December 31,		
	2018	2017	2016
	U.S dollars in thousands		
Licensing	—	—	100
Commercialization of product	4,671	3,240	—
Promotional services	3,689	767	—
Other revenues			1
	8,360	4,007	101

In 2018 and 2017, revenues consist solely revenues with respect to commercialization and promotional activities of the company's commercial products, as detailed in note 1a(2).

REDHILL BIOPHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 19 - RESEARCH AND DEVELOPMENT EXPENSES, net:

	Year Ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
Payroll and related expenses	552	653	652
Professional services	2,297	2,218	1,816
Share-based payments	872	793	841
Clinical and pre-clinical trials	20,373	27,940	20,732
Intellectual property development	290	401	428
Other	478	964	772
	24,862	32,969	25,241

NOTE 20 – SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES:

	Year Ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
Payroll and related expenses	7,540	5,012	301
Share-based payments	575	387	65
Professional services	1,626	1,778	947
Samples	—	1,569	—
Travel and related expenses	1,822	2,236	81
Office-related expenses	495	395	86
Other	428	637	75
	12,486	12,014	1,555

NOTE 21 – GENERAL AND ADMINISTRATIVE EXPENSES:

	Year Ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
Payroll and related expenses	3,880	3,311	1,082
Share-based payments	1,231	1,054	773
Professional services	1,461	2,246	1,391
Office-related expenses	547	567	300
Other	387	847	302
	7,506	8,025	3,848

REDHILL BIOPHARMA LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

NOTE 22- FINANCIAL INCOME, net:

	Year Ended December 31,		
	2018	2017	2016
	U.S dollars in thousands		
Financial income:			
Fair value gains on derivative financial instruments	104	5,687	1,152
Gains on financial assets at fair value through profit or loss	295	189	80
Gains from changes in exchange rates	—	332	34
Interest from bank deposits	279	297	282
	678	6,505	1,548
Financial expenses:			
Loss from changes in exchange rates	125	—	—
Issuance cost with respect of warrants	—	—	368
Other	42	77	7
	167	77	375
Financial income, net	(511)	(6,428)	(1,173)

NOTE 23 – SEGMENT INFORMATION

Commencing 2017, the Company has two segments, Commercial Operations and Research & Development. In line with the reporting to the Chief Executive Officer, the performance of these segments is reviewed at revenues, gross profit and operating expenses levels. The Commercial Operations segment covers all areas relating to the commercial sales and operating expenses directly related to that activity and is being performed by the Company's U.S. subsidiary. The Research and Development segment includes all activities related to the research and development of therapeutic candidates and is being performed by the Company. There is no segmentation of the Statements of Financial Position. Charges such as depreciation, impairment and other non-cash expenses are charged to the relevant segment.

a. Segment information

	Year Ended December 31, 2018			Year Ended December 31, 2017		
	Commercial Operations	Research and Development	Consolidated	Commercial Operations	Research and Development	Consolidated
	U.S. dollars in thousands			U.S. dollars in thousands		
Net revenues	8,360	—	8,360	4,007	—	4,007
Cost of revenues	2,837	—	2,837	2,126	—	2,126
Gross profit	5,523	—	5,523	1,881	—	1,881
Research and development expenses, net	—	24,862	24,862	—	32,969	32,969
Selling, marketing and business development expenses	11,329	1,157	12,486	10,520	1,494	12,014
General and administrative expenses	2,795	4,711	7,506	2,680	5,345	8,025
Other expenses	—	—	—	—	845	845
Operating loss	8,601	30,730	39,331	11,319	40,653	51,972

b. Major customers

The percentages of total net revenues for the year ended December 31, 2018 and the year ended December 31, 2017 from one customer were 46% and 59%, respectively and from another customer were 42% and 19% respectively. The Company's revenues were entirely in the U.S. and the payment terms for all customers are 30 to 60 days.

NOTE 24- LOSS PER ORDINARY SHARE:

a. Basic

The basic loss per share is calculated by dividing the loss by the weighted average number of ordinary shares in issue during the period.

The following is data taken into account in the computation of basic loss per share:

	Year Ended December 31,		
	2018	2017	2016
Loss (U.S. dollars in thousands)	38,820	45,544	29,370
Weighted average number of ordinary shares outstanding during the period (in thousands)	231,204	176,579	128,514
Basic loss per share (U.S. dollars)	0.17	0.26	0.23

b. Diluted

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding, assuming conversion of all potentially dilutive ordinary shares, using the treasury stock method. The Company has two categories of potentially dilutive ordinary shares: warrants issued to investors and options issued to employees and service providers. The effect of options issued to employees and service providers, for all reporting years, is anti-dilutive. In 2017 and 2018, the effect of warrants is anti-dilutive.

	Year Ended December 31,		
	2018	2017	2016
Loss (U.S. dollars in thousands)	38,820	45,544	29,370
Adjustment for financial income of warrants	—	—	1,208
Loss used to determine diluted loss per share	38,820	45,544	30,578
Weighted average number of ordinary shares outstanding during the period (in thousands)	231,204	176,579	128,514
Adjustment for warrants	—	—	295
Weighted average number of ordinary shares for diluted loss per share (in thousands)	231,204	176,579	128,809
Diluted loss per share (U.S. dollars)	0.17	0.26	0.24

NOTE 25 - RELATED PARTIES:

a. Key management in 2018 includes members of the Board of Directors and the Chief Executive Officer

	Year Ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
Key management compensation:			
Salaries and other short-term employee benefits	734	677	576
Post-employment benefits	36	35	32
Share-based payments	510	557	504
Other long-term benefits	26	7	11

b. Balances with related parties:

	December 31,	
	2018	2017
	U.S. dollars in thousand	
Current liabilities -		
Credit balance in "accrued expenses and other current liabilities"	178	199
Non-current liabilities -		
Derivative financial instruments	8	11

NOTE 26 – EVENT SUBSEQUENT TO DECEMBER 31, 2018:

On February 25, 2019, the Board of Directors of the Company approved a grant of 178,000 options to purchase ADSs to employees of the Company's subsidiary and 100,000 options to purchase ordinary shares to advisory board members and an employee of the Company, under the Company's stock options plan. The estimated fair value of the options on the grant date was $0.8 million.

Exhibit 1.1

These Articles of Association are an unofficial translation of the Articles of Association in Hebrew adopted by the Company.

Articles of Association

of

Redhill Biopharma Ltd.
("Company")

As approved by in the annual general meeting of shareholders on May 2, 2018

Table of Contents

1. Introduction

1.1 In these Articles, each of the terms set forth below shall have the meaning set forth opposite it:

Law -	The provisions of any law applicable in the State of Israel.
Administrative Proceeding -	A proceeding pursuant to Chapter H3 (Imposing Monetary Sanction by the ISA), H4 (Imposing Administrative Enforcement Measures by the Administrative Enforcement Committee) and/or I1 (Conditioned Arrangement for Avoidance of Taking Action of for Stopping Action) of the Securities Law, as amended from time to time
The Companies Law -	The Companies Law, 5759 – 1999; or any provision of law superseding same.
The Securities Law -	The Securities Law, 5728 – 1968; or any provision of law superseding same.
Business Day -	A day on which most of the banks in Israel are open for the performance of transactions.
Writing -	Print and any other form of imprinting words including documents transmitted in writing via facsimile, by telegraph, telex, email, computer or in any other electronic means of communication, creating or allowing the creation of any copy and/or printed output of the document.
Securities -	As defined in Section 1 of the Securities Law.
Incapacitated -	A person declared incapacitated pursuant to the Legal Capacity and Guardianship Law, 5722 – 1962.
Companies Ordinance -	The Companies Ordinance [New Version], 5743 – 1983, or any provision of law superseding same.
Simple Majority -	A majority of over one half of the votes of the shareholders entitled to vote who have voted in person or by proxy or by means of a voting paper, other than abstainees.
A majority of 75% -	A majority of 75% or more of the votes of the shareholders entitled to vote who have voted in person or by proxy or by means of a voting paper, other than abstainees.
Articles of Association -	The Company's articles of association as per the wording herein or as duly modified, from time to time, either expressly or under any law.
The Companies Regulations -	Regulations enacted by virtue of the Companies Law and/or by virtue of the Companies Ordinance.
Securities Regulations -	Regulations enacted by virtue of the Securities Law.

Related Corporation - A corporation controlling the Company directly and/or indirectly and/or any corporation directly and/or indirectly controlled by such corporation and/or any corporation controlled by the Company, directly and/or indirectly.

1.2 In these Articles, reference to any organ or officeholder is to organs or officeholders of the company.

1.3 The provisions of sections 3-10 of the Interpretation Law, 5741 – 1981, shall also apply, *mutatis mutandis*, to the interpretation of these Articles, where there is no other provision in respect of such matter and where such matter or the context thereof, contain nothing which does not comply with such applicability.

Save for the provisions of this Article, any word or term in these Articles shall have the meaning imparted to them in the Companies Law, and where there is no such meaning in the Companies Law, then the meaning imparted to them in the Companies Regulations, and where there is no such meaning, then the meaning imparted to them in the Securities Law, and where there is no such meaning, then the meaning imparted to them in the Securities Regulations and where there is no such meaning, then the meaning imparted to them in any other law, all where the meaning imparted as aforesaid is not in conflict with the context where such word or expression appears or with the purpose of the relevant provision in these Articles.

In case of reference in these Articles to a provision of law, and such provision has been revised or revoked, such provision shall be deemed valid and as though it were part of the Articles, unless in consequence of such revision or cancellation, such provision has no effect.

The provisions of these Articles are designed to add to and contract out the provisions stipulated in the Companies Law. In the event that any of the provisions of these Articles is in contravention of that permitted under law, the provisions of these Articles shall be interpreted to the extent possible in accordance with the provisions of the law.

2. **A Public Company**

The Company is a public company.

3. **Donations**

The Company may make donations, even if the donation is not made as part of commercial considerations.

4. **Company's Objectives**

The Company shall engage in any lawful business.

5. **Limitation of Liability**

The liability of the shareholders of the Company is limited, each of them to full payment of the amount that he has undertaken to pay for the shares allocated to him at the time of the allocation.

6. **Amendments to the Articles of Association**

The Company may amend any of the provisions of these Articles or substitute these Articles for other Articles, by means of a resolution passed by the a simple majority at a general meeting, apart from the provisions of Sub-Articles 14.1, 14.2, 19.1 and 19.2 herein, the amendment or replacement of which is subject to a resolution to be passed by a majority of 75% at a general meeting.

Chapter Two - The Share Capital of the Company

7. Share Capital.[1]

7.1 The Company's registered share capital is NIS 6,000,000, divided into 600,000,000 registered Ordinary Shares of NIS 0.01 par value each (hereinafter: "**share", "ordinary share", "shares" or "ordinary shares",** as the case may be). Each share confers a right to receive invitations to participate in and vote at the general meetings. A shareholder shall have one vote for every fully paid up share that he holds. All Shares have equal rights *inter se* with respect to dividend, distribution of bonus shares or any other distribution, capital refund and participation in distribution of surplus of Company assets upon liquidation.

7.2 The provisions of these Articles in relation to shares, shall also apply, *mutatis mutandis*, to other securities to be issued by the Company.

8. **Issuance of Shares and Other Securities**

8.1 No Priority Right - the existing shareholders of the Company shall not have a priority right, a right of preference, or any other right whatsoever to acquire the Company's securities. The board of directors may, at its exclusive discretion, first offer the Company's securities to all or any of the current shareholders.

8.2 Redeemable Securities

The Company may issue redeemable securities, with rights attached to them and subject to such terms and conditions as shall be prescribed by the board of directors.

8.3 Commissions - the Company may pay any person a commission (including underwriting fees) in consideration of underwriting services, marketing or distribution of the Company's securities, either conditionally or unconditionally, on such terms and conditions as shall be prescribed by the board of directors. Payment as aforementioned in this Article can be made either in cash or in securities of the Company, or some of them in one way and some of them in another way.

8.4 The board of directors may introduce distinctions between holders of the Company's securities in relation to the terms and conditions of allocation of the Company's securities and the rights attached to such securities and may also vary such terms and conditions, including waiving some of them. The board of directors

1 Subject to the provisions of Section 46.B. of the Securities Law, pursuant to which so long as the Company's shares are listed for trading on the Stock Exchange, the Company's share capital will consist of one class of shares.

may further issue calls to the holders of securities for payment of the money that has not yet been paid for the securities held by them.

8.5 Any payment on account of a share shall be credited initially on account of the nominal value and only then on account of the premium for each share, unless otherwise prescribed in the terms of the allocation.

8.6 A shareholder will not be entitled to his rights as a shareholder, including to a dividend, unless he has paid the amounts in full in accordance with the terms of the allocation, with the addition of interest, linkage and expenses, if there were any, and all if not otherwise prescribed in the terms of the allocation.

8.7 The board of directors may forfeit as well as sell, re-allocate or otherwise transfer any security as it shall decide, in respect of which the full consideration has not been paid, including for nil consideration.

8.8 The forfeiture of a security shall result, at the time of such forfeiture, in the revocation of any right in the Company and any claim or demand against it in relation to such security, except for such rights and obligations as are excluded from this rule in accordance with these Articles or which the law confers on or imposes on a former shareholder.

9. **The Register of Shareholders of the Company and Issue of Share Certificates**

9.1 The secretary of the Company or whoever is appointed for such purpose by the board of directors of the Company shall be responsible for keeping a Register of the Company's Shareholders. A shareholder is entitled to receive from the Company, free of charge, within two months after the allocation or the registration of the transfer (unless the terms of the issue stipulate another period of time), one certificate or a number of certificates, at the Company's discretion, in respect of all the shares that are registered in his name, which shall specify the number of shares, and any other detail that is important in the opinion of the board of directors. In the event of a jointly held share, the Company shall not be required to issue more than one certificate to all the joint holders, and delivery of such a certificate to one of the joint holders shall be deemed to be delivery to all of them.

9.2 The board of directors may close the register of shareholders for a total period of up to 30 days annually.

9.3 Every certificate shall bear the seal or stamp of the Company or its printed name and shall bear the signature of one director and the Company secretary, or of two directors or of any other person who has been appointed by the board of directors for such purpose.

9.4 The Company may issue a new certificate *in lieu of* a certificate that was issued and was lost, defaced, or destroyed, on the basis of such proof and guarantees as the Company may require, and after payment of an amount that shall be prescribed by the board of directors and the Company may also, in accordance with a resolution of the board of directors, replace existing certificates with new certificates free of charge subject to such conditions as the board of directors shall stipulate.

9.5 Where two or more persons are registered as the joint holders of a share, each of them may confirm receipt of a dividend or other payments for such share and his confirmation will bind all holders of such share.

9.6 The Company is entitled to recognize a holder of a share as a trustee and to issue a share certificate in the name of the trustee provided that the trustee has notified the Company of the identity of the beneficiary of the trust. The Company will not be bound to or be required to, recognize a right that is based on the rules of equity or a right that is subject to a condition, or a future right or a partial right to a share, or any other right in relation to a share, other than the absolute right of the registered holder in respect of any share, unless this is done on the basis of a judicial decision or in accordance with the requirements of any law.

10. **Transfer of the Company's Shares**[2]

10.1 The Company shares are transferable.

10.2 No transfer will be registered of shares that are registered in the register of shareholders in the name of a registered shareholder, unless an original, signed deed of transfer of the shares has been submitted to the Company (hereinafter: "**deed of transfer"**), unless otherwise stipulated by the board of directors of the Company. The deed of transfer shall be drawn up in the form set out hereunder or in such other format as is as similar as possible to it or in another format which shall be approved by the board of directors.

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Deed of Transfer

I, _____ Identity Card No. / Corporate No. _____ (hereinafter: **"the transferor**") of _____ hereby transfer to _____ Identity Card No. / Corporate No. _____ (hereinafter: "**the transferee**") of _____ in consideration of the sum of NIS _____ that he has paid to me, _____ shares, each having a nominal value of NIS _____, which are marked by the numbers _____ to _____ inclusive, of _____Ltd. (hereinafter: "**the Company**"), and they shall be in the possession of the transferee, his estate administrators, guardians, and his duly authorized representatives, in accordance with the conditions under which I personally held the shares at the time of signature of this deed, and I, the transferee, agree to accept the said shares in accordance with the conditions set out above and subject to the Company 's Articles, such as they are from time to time.

In Witness Whereof we have signed, this __ day of the month of _____, in the year _____

Transferor -
Name: _____
Signature: _____

Transferee
Name: _____
Signature: _____

Witness to the Transferor's Signature:
Name: _____, Advocate
Signature: _____

Witness to the Transferee's Signature:
Name: _____, Advocate
Signature: _____

2 So long as the Company shares are listed for trading on the stock exchange, the Company shares will be registered in the name of the nominee company and the share transfer will be carried out via the nominee company and not as prescribed in Sub-Articles 10.1-10.4 of these Articles.

Neither a transfer of non-fully paid up shares or of shares over which the Company has a lien or a charge shall be valid unless it has been approved by the board of directors, which may, at its absolute discretion and without giving any reasons, refuse to register such a transfer.

The board of directors may refuse a transfer of shares as aforesaid and the board of directors may also make such a transfer of shares conditional on an undertaking by the transferee, in such scope and in such manner as the board of directors shall stipulate, or settle the transferor's liabilities in respect of such shares or the liabilities in respect of which the Company has a lien or a charge over such shares.

10.3 The transferor shall continue to be deemed to be the holder of the shares being transferred until such time as the name of the transferee is registered in the Company's register of shareholders.

10.4 A deed of transfer shall be submitted to the registered office of the Company for registration together with the certificates of registration of the shares that are about to be transferred (if such certificates have been issued) and any other proof which the Company shall require as to the title of the transferor to such shares or his right to transfer them.

10.5 A joint shareholder who wishes to transfer his right in a share but is not in possession of the share certificate, will not be bound to attach the share certificate to the transfer deed provided that in the transfer deed it is stated that the transferor is not in possession of the share certificate in respect of the share in which his right is being transferred and that the share being transferred is held jointly with others, together with their particulars.

10.6 The Company may require payment of a fee for registration of the transfer of such an amount or at such rate as the board of directors shall determine from time to time.

10.7 Upon the death of a holder of shares in the Company, the Company will recognize guardians, estate administrators or executors, and if there are no such persons, the lawful heirs of the shareholder, as parties with the sole right to the shares of the shareholder, after the entitlement thereto is substantiated in such manner as shall be determined by the board of directors.

10.8 In the event that a deceased shareholder held shares jointly with others, the Company will recognize the survivor as a shareholder in respect of the said shares, unless all the joint holders of the share have notified the Company in writing prior to the death of one of them, of their wish that the provisions of this Article shall not apply, provided that this shall not absolve the estate of a joint holder of a share from any obligation whatsoever that the joint holder would have had in respect of such share had he not passed away.

10.9 A person who acquires a right to shares by virtue of being a guardian, estate administrator, heir of a shareholder, a receiver, liquidator or trustee in bankruptcy of a shareholder or in accordance with any other legal provision, may, if and when he proves his right as such may be required by the board of directors, be registered

as the shareholder or may transfer such shares to another person, subject to the provisions of the Articles in relation to a transfer.

10.10 A person who acquires a right to a Share as a result of a transfer thereof by operation of law, will be entitled to a dividend and to the other rights in respect of such share and he may also accept and give receipts for a dividend or for other payments payable in respect of such share; however, he will not be entitled to receive notices regarding the general meetings of the Company (insofar as such a right exists), and to participate at or vote at such meetings in connection with such share or to exercise any right whatsoever, which the share confers, except as aforesaid, until after he is registered in the register of shareholders.

11. **Bearer Share Warrant**

The Company will not issue bearer share warrants.

12. **Lien on Shares**

12.1 The Company shall have a first charge and a lien over all the shares that are not fully paid up, which are registered in the name of any shareholder, and over the proceeds of sale thereof, in relation to monies (whether or not the time for payment thereof has fallen due), payment of which has already been called or which are to be paid at a fixed time in respect of such shares. The Company shall also have a first charge over all the shares (except fully paid up shares) that are registered in the name of any shareholder as security for monies that are due from him or from his assets, whether his liability is individual or jointly with others. The said charge shall also apply over such dividends as have been declared from time to time in respect of such shares.

12.2 The board of directors may sell the shares to which the charge applies for the purpose of realizing the charge and lien, or any part thereof, in any manner as it sees fit. No such sale shall proceed until after written notification has been given to such shareholder as to the intention of the Company to sell them, and the amounts have not been paid within fourteen days after such notification. The net proceeds of any such sale, after payment of the sale expenses, shall be utilized in discharging the debts or obligations of such shareholder and the balance (if any remains) shall be paid to him.

12.3 Where a sale of shares has occurred in order to realize a charge or a lien by the *prima facie* exercise of the powers vested as aforesaid, the board of directors may register such shares in the register of shareholders, in the name of the purchaser, and the purchaser will be under no obligation to examine the propriety of the transaction or the way in which the purchase price is used. Following registration of the said shares in the register of shareholders in the name of the purchaser, no person shall have the right to challenge the validity of the sale.

13. **Alteration of Share Capital**[3]

The general meeting may resolve at any time to take one of the following actions, provided that a resolution of the general meeting as aforesaid has been adopted by a simple majority.

3 Subject to the provisions of Section 46.B. of the Securities Law, pursuant to which so long as the Company's shares are listed for trading on the Stock Exchange, the Company's share capital will consist of one class of shares.

13.1 Increase of the Registered Share Capital

To increase the registered share capital of the Company, irrespective of whether or not all the shares registered at that time have been issued. The increased capital will be divided into ordinary shares with equal rights.

13.2 Consolidation and Division of Share Capital

To consolidate and re-divide some or all of its share capital into shares of a greater or smaller nominal value than that which is specified in the Articles. In a case in which, as a result of such consolidation, shareholders whose shares have been consolidated are left with fractions of shares, the board of directors may, if it receives approval thereto from the general meeting in the resolution as to consolidation of capital as aforesaid:

A. Sell the aggregate of all the fractions, and for this purpose appoint a trustee in whose name the share certificates containing the fractions shall be issued, and the trustee shall sell the said fractions, and the proceeds received less commissions and expenses shall be distributed to eligible shareholders. The board of directors will be entitled to decide that shareholders who are entitled to the consideration, which is less than an amount that it shall stipulate, will not receive a consideration from the sale of the said fractions, and their share in the sale proceeds shall be distributed among such shareholders who are entitled to a consideration that exceeds the stipulated amount, *pro rata* to the consideration to which they are entitled;

B. To allocate to all holders of shares in respect of whom the consolidation and the re-division leaves them with a fraction of a share, shares of the class of shares which, before such consolidation, are fully paid up, in such a number that their consolidation with the fraction will be sufficient for one complete consolidated share, and such an allocation shall be deemed as being effective immediately prior to such consolidation;

C. Determine that shareholders shall not be entitled to receive a consolidated share in respect of a fraction of a consolidated share, which derives from the consolidation of half or less of the number of shares whose consolidation creates one consolidated share, and they shall be entitled to receive a consolidated share in respect of a fraction of a consolidated share which derives from the consolidation of more than half of the number of shares whose consolidation creates one consolidated share.

In the event that an action taken in accordance with sub-paragraphs (b) or (c) above requires the issue of additional shares, payment therefor shall be made in the manner in which bonus shares may be repaid. Consolidation and division as aforesaid shall not be deemed to be a variation of the rights of the shares forming the subject of the consolidation and division.

13.3 Cancellation of Un-allocated Registered Share Capital

To cancel registered share capital which has not yet been allocated provided that the Company is under no obligation to allocate such shares.

13.4 Split of Share Capital

To split some or all of the Company's share capital, into shares with a smaller nominal value than that which is prescribed in the articles of association by division of some or all of the Company shares, at that time.

Chapter Three - General Meetings

14. **Powers of the General Meeting**

14.1 Subjects within the authority of the General Meeting

Resolutions of the Company in respect of the following matters shall be passed by the general meeting:

14.1.1 Changes to the Articles.

14.1.2 Exercise of the powers of the board of directors, provided that the general meeting has decided by a majority of 75% of the votes of shareholders who are entitled to vote and have voted either in person or by proxy, that the board of directors is incapable of exercising its powers and further that the exercise of its powers is essential for the proper management of the Company.

14.1.3 Approval of actions or transactions requiring approval of the general meeting pursuant to the provisions of Sections 255 and 268 to 275 of the Companies Law.

14.1.4 Any decision that, by law or under the Articles, must be passed by a resolution of a general meeting.

14.1.5 Any power which, by law, is vested in the general meeting.

14.2 Power of the General Meeting to Transfer Powers between the Company's Organs

The general meeting may by a majority of 75% of the votes of shareholders who are entitled to vote and have voted either in person or by proxy, assume such powers as are vested in another organ and may also transfer powers that are vested in the general manager to the authority of the board of directors, and all either in respect of a particular matter or for a particular period of time which shall not exceed the period of time required under the circumstances.

15. **Annual and Special General Meetings**

15.1 Notice of a General Meeting

The Company is not obliged to give notice of a general meeting to shareholders except in so far as this is mandatory by law.

The notice of a general meeting shall specify the place and the time for the convening of the meeting, its agenda, a summary of the proposed resolutions and any other detail as may be required under law.

16. **Proceedings at General Meetings**

16.1 Quorum

No general meeting may proceed unless a quorum is present at the time of the deliberation. Two shareholders who are present in person or by proxy and who hold or represent at least twenty five percent (25%) of the voting rights in the Company shall constitute a quorum. For the purpose of a quorum, a shareholder or his proxy, who also acts as proxy for other shareholders, shall be deemed to be two or more shareholders, depending on the number of shareholders that he represents.

16.2 Postponement of the General Meeting in the Absence of a Quorum

Where half an hour has elapsed from the time designated for the meeting and no quorum is present, the meeting shall be postponed to the business day following the day of the meeting, at the same time and at the same place or to such other day, time and place as shall be prescribed by the board of directors in a notification to the shareholders. The Company shall give notice, via an immediate report, of postponement of the meeting and the time of the holding of the adjourned meeting.

Where no quorum is present at such adjourned meeting as aforesaid, at least one shareholder, who is present either in person or by a proxy, shall be deemed as a quorum, except where such meeting has been called at the demand of shareholders.

16.3 Chairman of the General Meeting

The Chairman of the board of directors shall chair any general meeting, and, in his absence, it shall be chaired by whoever is appointed for such purpose by the board of directors. In the absence of a chairman, or if he has not appeared at the meeting after 15 minutes from the time designated for the meeting, the shareholders present at the meeting shall, in person or by proxy, elect one of the directors or the officeholders of the Company present at the meeting as chairman, or if no director or officeholder is present, or where all of them refuse to chair the meeting, one of the shareholders present, or one of the officeholders present, shall be elected to chair the meeting.

The chairman of the meeting shall not have an additional or casting vote.

The decision by the chairman that a resolution at the general meeting was passed unanimously or by a specific majority or was rejected and the minutes of the general meeting signed by the chairman shall serve as *prima facie* evidence of that stated therein.

17. **Votes of Shareholders**

17.1 Majority - resolutions at the general meeting shall be passed by a simple majority unless another majority is required by law or in accordance with the provisions of Articles 6, 14.1.2, 14.2, 19.1, 19.2.5 and 19.2.6 of these Articles. Checking the majority will be carried out by means of counting of votes, where each shareholder will have one vote per each share held by him.

17.2 Confirmation of title - a shareholder must furnish the Company with confirmation of title at least two business days prior to the date of the general meeting. The Company may waive such requirement.

17.3 Vote of a legally incapacitated party - a legally incapacitated party may only vote by a trustee, natural guardian or other legal guardian. Such persons may vote either in person or by proxy.

17.4 Vote of joint holders of a share - where two or more shareholders are the joint holders of a share, one of them shall vote, either in person or by proxy. Where more than one joint holder wish to participate in a vote, only the first of the joint holders will be able to vote. For such purpose the first of the joint holders shall be deemed to be the person whose name is recorded first in the register of shareholders.

17.5 The manner of voting and the counting of votes shall be done in accordance with the provisions of the Companies Law. A resolution at a general meeting shall be passed if it has received such majority as it is required to receive under law or in accordance with the provisions of these Articles.

18. **Appointment of a Voting Proxy**

18.1 Voting by Proxy

A shareholder may appoint a proxy to participate in and vote in his place, either at a particular general meeting or generally at the general meetings of the Company, provided that the written document authorizing the appointment of a proxy has been delivered to the Company at least 48 hours prior to the date of the general meeting, unless the Company has waived such requirement. A proxy need not be a shareholder of the Company.

If such proxy is not for a particular general meeting, a proxy that has been deposited prior to one general meeting shall also hold good for other subsequent general meetings.

The foregoing shall also apply to a shareholder that is a corporation and which appoints a person to participate in and vote in its place at the general meeting.

18.2 Format of the Proxy

The proxy shall be signed by the shareholder or by the person who is duly authorized in writing for such purpose, and where the appointing party is a corporation it shall be signed in such manner as binds such corporation. The Company may require that it be furnished with written confirmation to its satisfaction as to the fact of the due authority of the signatories to bind such corporation. A proxy shall be drawn up in the form specified hereunder. The Company secretary or the board of directors of the Company may, at their discretion, accept a proxy in a different form, including in the English language, provided that the variations are not fundamental. The Company will only accept an original proxy or a copy of the proxy, provided that the same is duly authenticated by a notary or by an attorney at law holding an Israeli license.

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Proxy

To: _____ **Date:_____**
[Name of Company
Corporate address:]
Dear Sir or Madam;

Re: Annual / special general meeting of _____ (the "Company")
to be held on _____ (The "Meeting")

I the undersigned _____, Identity Card/Registration No. _____, of _____Street _____ being the registered holder of _____(*) ordinary shares of NIS____ par value each, hereby empower _____ Identity Card No. (**)_____ and/or _____ Identity Card No. _____and/or _____Identity Card No. _____to participate in and vote on my behalf and instead of me at the aforementioned meeting and at any adjourned meeting of the aforesaid meeting of the Company/at any general meeting of the Company, until I notify you otherwise.

_____
Signature

_____

(*) A registered shareholder may issue a number of proxies, each of them in reference to another quantity of shares of the Company held by him, provided that he shall not issue proxies for a quantity of shares that is greater than the quantity of shares held by him.

(**) In the event that the proxy does not hold an Israeli Identity Card, both the passport number and the country of its issue shall be stated instead.

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18.3 Validity of Proxy

A vote in accordance with a proxy shall be lawful even if the appointing party has previously died or has become legally incapacitated or has become bankrupt or, in the event of a corporation - has been wound up, or has cancelled the proxy, or transferred the share in respect of which it was given, other than if notification in writing that such an event has occurred has been received at the registered office of the Company prior to the meeting.

18.4 Disqualification of Proxies

Subject to the provisions of any law, the Company secretary will be entitled at his discretion, to disqualify proxies if a reasonable concern exists that they are forged or that they have been furnished in respect of shares for which other proxies have been issued.

18.5 Voting by Voting Papers

In accordance with these Articles and the provisions of the Companies Law and the regulations enacted thereunder, the Company shareholders shall be given the option to vote at general meetings of the Company by means of voting papers, on all such matters as are obligatory by law as well as on such matters in respect of which the board of directors shall decide from time to time to allow a vote by means of voting papers.

Chapter Four - The Board of Directors

19. **Appointment of Directors and Termination of Their Office**

19.1 The number of directors - the number of directors of the Company shall not be less than five (5) and not more than eleven (11) (including anyoutside directors whose appointment is required under law), unless otherwise decided by the general meeting by a majority of 75%.

19.2 Appointment of Directors at an Annual Meeting and their Replacement

19.2.1 The Company directors serving in office (who are not outside directors), will be divided into three groups, one third each, which will hereinafter be referred to as: the "**First third to the Third Third**"). If the number of directors is not a multiplication of three, each of the two groups - the first third to the second third - will include another number, being a number which is closest to and more than a third, while the group of the third third will consist of the remaining directors (who are not outside directors). The initial division into thirds will be carried out pursuant to the board of directors' resolution with respect to such division, and the rule that will apply is that the division be carried out in accordance with the director's seniority on the board of directors, the most senior directors being included in the first third, and so forth. Should the number of directors vary, the number of directors in each group will vary in accordance with the aforesaid rule.

19.2.2 At the first annual meeting of the Company shareholders to be held after the Company has become a public company (in 2011), the office of the directors included in the first third will terminate and they will be put up for re-appointment at that meeting.

At the second annual meeting of the Company shareholders to be held after the Company has become a public company (in 2012), the office of the directors included in the second third will terminate and they will be put up for re-appointment at that meeting.

At the third annual meeting of the Company shareholders to be held after the Company has become a public company (in 2013), the office of the directors included in the third third will terminate and they will be put up for re-appointment at that meeting.

At the three subsequent annual general meetings the aforesaid mechanism will reapply, and so on and so forth.

Any director elected as aforesaid, will be elected for a three-year term (unless his office is terminated in accordance with the provisions of these Articles), so that every year the office of a group of one third of the board of directors will terminate, as aforesaid.

Directors may be elected for a term of less than three years in order to ensure that the three groups of directors have as equal number of directors as possible as provided in Sub-Article 19.2.1 above.

Notwithstanding the foregoing, the term of office of any director elected to the Company's board of directors, and originally nominated for election by virtue of the nomination right granted to any investor who purchased, in the Company's public offering which closed on December 27, 2016, together

with its affiliates (as such term is defined in Rule 405 of the Securities Act of 1933, as amended), at least $15 million of ADSs and warrants (excluding the proceeds, if any, from the exercise of warrants), shall automatically expire at the first annual meeting of the Company shareholders following the annual meeting of the Company shareholders held in May 2017 unless such investor, at least 75 days prior to such first following annual meeting of shareholders evidences to the Company its beneficial ownership, together with its affiliates, of at least 4% of the Company's outstanding shares. If not so expired at the first annual meeting of the Company shareholders following the annual meeting held in May 2017, the term of office of such director shall automatically expire at the second annual meeting of the Company shareholders following the annual meeting of the Company shareholders held in May 2017 unless such investor, at least 75 days prior to such second following annual meeting of shareholders, evidences to the Company its beneficial ownership, together with its affiliates, of at least 4% of the Company's outstanding shares. In any event, the term of office of such director shall automatically expire at the third annual meeting of the Company shareholders following the annual meeting held in May 2017 unless re-elected by the Company's shareholders.

The elected directors shall assume their office commencing from the end of the meeting at which they were elected unless a later date is stipulated in the resolution on their appointment.

19.2.3 The appointment of members of the board of directors (who are not outside directors), will be carried out by the shareholders present at the meeting, in person or by proxy, or by means of a voting paper, by a simple majority of the votes of the shareholders as aforesaid.

19.2.4 If a director who was put up for re-appointment at the general meeting convened to deliberate same is not re-elected, the Company will convene another general meeting, at which another proposed director will be put up for the approval of the meeting. Notwithstanding the foregoing, the office of the director who has not been re-appointed or his alternate (insofar as he has appointed an alternate in accordance with the provisions of these Articles), will expire on the earlier of: (1) The additional general meeting as aforesaid; or (2) seventy days from the date of the annual general meeting as aforesaid in Sub-Article 19.2.2 above. It shall further be clarified that a director appointed as aforesaid will belong to the group of the third to which the director he replaced belonged, so that his office will expire on the date of the general meeting at which the office of the other directors of that third group will expire.

19.2.5 The general meeting may, at any time, by a majority of 75%, dismiss a director and it may decide at that time to appoint another person in his place by a majority of 75%. A director whose dismissal is on the agenda of the meeting will be given a reasonable opportunity to present his position before such meeting.

19.2.6 A special meeting of the Company may appoint directors for the Company *in lieu of* directors whose office has terminated and also in any case in which the number of members of the board of directors falls below the minimum that has been stipulated in these Articles or by the general

meeting by a majority of 75% of the shareholders' votes. It should be clarified that a director appointed as aforesaid will belong to the group of the third to which the director he replaced belonged, so that his office will expire on the date of the general meeting at which the office of the other directors of that third group will expire.

19.2.7 The foregoing provisions of Sub-Articles 19.2.1 - 19.2.6 shall not apply to the appointment and term in office of outside directors, in respect of whom the provisions of the Companies Law shall apply.

19.2.8 Subject to the provisions of the law in relation to the expiry of the office of a director, but notwithstanding the provisions of Section 230 of the Companies Law, the office of a director shall not be terminated, other than as provided in this Article.

19.3 Appointment of Directors by the Board of Directors

The board of directors may appoint a director or additional directors for the Company, whether in order to fill an office that has become vacant for any reason whatsoever or whether in the capacity of a director or additional directors, provided that the number of directors shall not exceed the maximum number of members of the board of directors. Any director so appointed shall serve up to the first annual meeting held subsequent to his appointment. In the event that the number of directors has fallen below the minimum number of directors, as prescribed in Sub-Article 19.1 above, the remaining directors may only act to convene a general meeting of the Company for the purpose of appointing the vacant positions of directors and up to the date of such meeting, act to conduct the Company's affairs in connection with matters that are pressing.

19.4 Date of Commencement of the Office of a Director - the elected directors shall assume their offices commencing at the end of the general meeting at which they were elected or on the date of their appointment by the board of directors as provided above in Sub-Article 19.3, as the case may be, unless a later date is prescribed in the resolution on their appointment.

19.5 Alternate Director - subject to the provisions of the law, a director may from time to time appoint an alternate director for himself (hereinafter: "**alternate director**"), dismiss such an alternate director, and may also appoint another alternate director *in lieu of* any alternate director whose office has been vacated for any reason, either for a specific meeting or permanently.

19.6 A Director's Proxy - any director and any alternate director may appoint a proxy who shall participate and vote in their name at, any meeting of the board of directors or of a board of directors' committee. Such an appointment may be general or for the purpose of one or a number of meetings. Where a director or an alternate director is present at such a meeting the proxy may not vote *in lieu of* the director who appointed him. Such an appointment shall be valid in accordance with the contents thereof or until its revocation by the appointor. A director or an alternate director of the Company may serve as a proxy as aforesaid.

19.7 Termination of the Office of a Director - in the event of a director's position becoming vacant, the remaining directors may continue acting for as long as the number of remaining directors does not fall below the minimum number of directors that has

been determined in these Articles or prescribed by the general meeting. If the number of directors has fallen below the foregoing, the remaining directors may only act in order to convene a general meeting of the Company.

19.8 Holding a Meeting by means of Communication and Without Convening

At a meeting that has been held by the use of any means of communication, it is sufficient that all of the directors who are entitled to participate in the proceedings and in a vote, shall be able to hear each other.

The board of directors may also pass resolutions without actually convening, provided that all of the directors who are entitled to participate in the discussion and to vote on the matter put forward for resolution have agreed not to meet to discuss such matter. Where resolutions have been passed as aforesaid, minutes of such resolutions shall be prepared, including the resolution not to convene and shall be signed by the chairman of the board of directors. The provisions of these Articles shall apply *mutatis mutandis* to such a resolution. A resolution that has been passed in accordance with this Article shall be valid in all respects as though it had been passed at a duly convened and conducted meeting of the board of directors.

19.9 Remuneration of Members of the Board of Directors - subject to the provisions of the Companies Law the Company may remunerate the Directors for fulfilling their functions as directors.

20. **Chairman of the Board of Directors**

20.1 Appointment - the board of directors shall elect one of its members to serve as chairman of the board of directors and will also designate the term in which he is to serve in his office, in the appointing resolution. If not stipulated otherwise in the resolution as to his appointment, the chairman of the board of directors shall serve in such capacity until another person is appointed in his place or until he ceases serving as a director, whichever is the earlier. Where the chairman of the board of directors has ceased serving in office as a director of the Company, the board of directors, at the first board of directors meeting held subsequently, shall elect a new chairman.

20.2 No Casting Vote - In the event of a tie of votes in a resolution of the board of directors, neither the chairman of the board of directors nor any person that has been elected to conduct the meeting, shall have an additional vote.

21. **Directors' Actions**

21.1 Convening a Meeting of the Board of Directors

Any notification of a meeting of the board of directors may be given verbally or in writing provided that such notification is given at least three business days prior to the date designated for the meeting, unless at least 75% of the members of the board of directors, their alternates or their proxies have agreed to shorten the said period of time. The aforesaid notwithstanding, the board of directors may convene for a meeting without notice only in urgent cases and with the consent of a majority of the directors.

Notification as aforesaid shall be given in writing, by facsimile, by electronic mail or by other means of communication and all to such address or the facsimile number, electronic mail address or the address to which notifications can be sent by other means of communication, as the case may be, which the Director furnished to the Company upon his appointment, or in a subsequent written notification to the Company and shall include reasonable details regarding the issues brought up for discussion at the meeting

Where an alternate or a proxy has been appointed, notification shall be given to such alternate or proxy unless the director has given notice that he wishes that notice shall also be given to him.

21.2 Quorum - the quorum for meetings shall be a majority of members of the board of directors who are not precluded by law from participating in a meeting, or any other quorum as will be prescribed by a majority of the members of the board of directors from time to time.

21.3 Validity of Actions of the Directors in the case of a Disqualified Director - All such actions as have been taken in good faith at a meeting of the board of directors or by a committee of the board of directors or by any person acting as a director shall be valid, even if it is subsequently discovered that there was a flaw in the appointment of a director or of such a person acting as aforesaid, or that they or one of them was disqualified, as though such a person had actually been duly appointed and was qualified to be a director.

21.4 Committees of the Board of Directors

Subject to the provisions of the Companies Law, the board of directors may appoint board of directors' committees.

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

22. **Validity of Actions and Approval of Transactions**

22.1 Subject to the provisions of any law, all such actions as have been taken by the board of directors or by a committee of the board of directors or by any person acting as a director, or as a member of a committee of the board of directors, or by the general manager, as the case may be, shall be valid even if it is subsequently discovered that there was any flaw in the appointment of the board of directors, a committee of the board of directors, the director who was a member of the committee or the general manager, as the case may be, or that any of the aforesaid officeholders was disqualified from serving in his position.

22.2 Subject to the provisions of the Companies Law:

22.2.1 If a person holds shares in the Company and if a person is an officeholder of the Company, a stakeholder, or an officeholder of any other corporation, including a corporation in which the Company is a stakeholder, or which is a shareholder of the Company, it shall not disqualify the officeholder from serving as an officeholder of the Company. Likewise, an officeholder shall not be disqualified from serving as an officeholder of the Company due to his contractual engagement or due to the contractual engagement of any corporation as aforesaid with the Company in any matter whatsoever and in any manner whatsoever.

22.2.2 The office of a person as an officeholder in the Company shall not disqualify him and/or a relative of his and/or another corporation in which he is a stakeholder from entering into transactions in which the officeholder has a personal interest in any way with the Company.

22.2.3 An officeholder may participate in and vote at discussions in respect of the approval of transactions or acts in which he has a *prima facie* personal interest, as prescribed in Sub-Articles 22.2.1 and 22.2.2.

22.3 Subject to the provisions of the Companies Law, a general notice that is given to the board of directors by an officeholder or a controlling shareholder of the Company with regard to his personal interest in a particular entity, while giving details of his personal interest, shall amount to disclosure on the part of the officeholder or the controlling shareholder to the Company with regard to his personal interest as aforesaid, for the purpose of the entering into any transaction which is not exceptional, with such an entity.

Chapter Five – Officeholders, Secretary, Internal Auditor and Auditor

23. **General Manager**

23.1 The board of directors may, from time to time, appoint a general manager for the Company and may further appoint more than one general manager. The board of directors may further dismiss the general manager or replace him at any time it deems fit, subject to the provisions of any agreement between him and the Company. The general manager will be responsible for the day-to-day management of the Company's affairs within the framework of the policy determined by the board of directors and subject to its directives.

23.2 The general manager will have all the powers of management and performance that were vested, pursuant to the Law or these Articles, or by virtue thereof, in another organ of the Company, apart from such powers as have been transferred from him to the board of directors. The general manager will be supervised by the board of directors.

23.3 The general manager may, subject to the approval of the board of directors, delegate some of his powers to another, who is his subordinate; the approval may be general and in advance.

23.4 Without derogating from the provisions of the Companies Law and any law, the general manager will submit to the board of directors, reports on such issues, on such dates and in such scope as shall be determined by the board of directors,

either by means of a specific resolution or within the ambit of the board of directors' procedures.

23.5 The general manager will give notice to the chairman of the board of directors, without delay, of any exceptional matter that is material to the Company. If the Company has no chairman of the board of directors or if the chairman of the board of directors is unable to fulfill his function, the general manager will give a notice to that effect to all members of the board of directors.

23.6 The general manager may from time to time appoint officeholders for the Company (apart from directors and general manager), for permanent, temporary or special functions, as the general manager finds fit and the general manager may further terminate the services of one or more of the foregoing at any time.

24. **Internal Auditor**

24.1 The Company's board of directors will appoint an internal auditor, at the recommendation of the audit committee.

24.2 The officer in charge of the internal auditor at the organization will be the chairman of the board of directors.

24.3 The internal auditor will submit for the approval of the audit committee a proposed annual or periodic work plan and the audit committee will approve it with such amendments as it finds fit.

25. **Secretary**

The board of directors may appoint a Company secretary, on such terms as it shall deem appropriate, and appoint a deputy secretary and determine the scope of their functions and their authorities. Where a Company secretary has not been appointed, the general manager, or whoever he designates to this end, and in the absence of a general manager, whoever is empowered for such purpose by the board of directors, shall perform the secretary's functions that are prescribed under any law, in accordance with these Articles and in accordance with a resolution of the board of directors.

The Company secretary will be responsible for all the documents that are kept at the registered office of the Company and for maintaining all the registers that the Company maintains by law.

26. **Auditor**

26.1 Subject to the provisions of the Companies Law, the general meeting may appoint an auditor for a period that exceeds one year, as the general meeting shall decide.

26.2 The board of directors, following receipt of the audit committee's or the financial statement committee's (as determined by the board of directors) recommendations shall determine the remuneration of the Company's auditor for audit work as well as his remuneration for other services that are not audit work, unless otherwise determined by the general meeting of the Company.

Chapter Six - Preservation of the Capital of the Company and its Distribution

27. **Distribution and Allocation of Bonus Shares**

The Company's resolution on distribution of dividend, bonus shares or any other distribution, including any distribution that does not comply with the profit test prescribed in the Companies Law and the terms thereof, shall be passed by the board of directors of the Company.

28. **Dividends and Bonus Shares**

28.1 Right to a Dividend or to Bonus Shares

28.1.1 A dividend or bonus shares shall be distributed to whoever is registered in the register of shareholders of the Company on the date of the resolution as to such distribution or on such other date as shall be prescribed in such resolution.[4]

28.2 Payment of the Dividend

28.2.1 The board of directors may resolve that the dividend be paid, in whole or in part, in cash or by means of distribution of assets in kind, including in securities or in any other manner, at its discretion.

The Company's board of directors may, before resolving to distribute any dividend, allocate out of the profits, any amounts as it shall deem fit for a general fund or a reserve fund for the distribution of dividend, distribution of bonus shares or for any other purpose whatsoever, as the board of directors shall resolve at its discretion.

Pending the realization of the said funds, the board of directors may invest any sums so allocated and the monies in the funds in any investment whatsoever, as it shall deem fit, deal with such investments, alter them or make any other use thereof, and it may subdivide the reserve fund into special funds and use any fund or any part thereof for the Company's affairs, without holding it separately from the other assets of the Company, all at the discretion of the board of directors and under such terms as it shall determine.

28.2.2 The Method of Payment[5]

If no other provisions have been prescribed in the resolution as to distribution of the dividend it will be permissible to pay any dividend, after deduction of the requisite tax under any law, by check to the beneficiary only, which shall be sent by registered mail to the registered address of the shareholder that is entitled to it, or by bank transfer. Any such check shall be drawn in favor of the person to whom it has been sent. A dividend in kind shall be distributed as stipulated in the distribution resolution.

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4 It shall be clarified that so long as the Company shares are listed for trading on the Stock Exchange, any dividend or bonus shares will be distributed to whoever is registered in the register of shareholders of the Company on the effective date determined on the date of the resolution.

5 It should be clarified that so long as the Company shares are listed for trading on the Stock Exchange the provisions of this Sub-Article 28.2.2 shall not apply.

In the event of joint registered shareholders, the check shall be sent to the shareholder whose name is recorded first in the register of shareholders in relation to the joint ownership.

Sending of a check to a person whose name, on the effective date, is registered in the register of shareholders as the holder of a share, or in the event of joint holders - of one of the joint holders, shall constitute discharge in respect of all the payments made in relation to such share.

The Company may resolve that a check below a certain amount, shall not be sent and amounts of the dividend that should have been paid as aforesaid shall be treated as unclaimed dividend.

The Company may offset against the dividend to which a shareholder is entitled, any debt of such shareholder to the Company, whether or not the time for payment thereof has fallen due.

28.2.3 Unclaimed Dividend

The board of directors may invest any amount of dividend that has not been claimed for a period of one year after having been declared, or use it otherwise for the benefit of the Company until it is claimed. The Company will not be compelled to pay interest or linkage in respect of an unclaimed dividend.

After one year has elapsed from the due date of any unclaimed dividend, the Company may use the unclaimed dividend as aforesaid for any purpose whatsoever and the shareholder who is entitled to such unclaimed dividend will have no claim and/or demand in relation thereto.

28.3 Method of Capitalization of Profits into Capital Funds and Distribution of Bonus Shares

28.3.1 Funds

The board of directors may, at its discretion, set aside into special capital funds, any amount out of the Company's profits, or arising from a revaluation of its assets, or its *pro rata* stake in the revaluation of assets of its affiliated companies and determine the designation of such funds. The board of directors may also cancel such funds.

28.3.2 Distribution of Bonus Shares – Subject to the provisions of the Companies Law, the board of directors may resolve to allocate bonus shares and render share capital as part of the Company's profits, within the meaning thereof in Section 302 (b) of the Companies Law, from premium on shares or from any other source contained in its equity, referred to in its last financial statements, in such sum as shall be determined by the board of directors and which shall not fall below the nominal value of the bonus shares.

Allocated bonus shares shall be deemed as fully repaid.

The board of directors resolving to allocate bonus shares may resolve that the Company will transfer to a special fund designated for future distribution

of bonus shares, such amount as the rendering thereof into share capital will be sufficient to allocate to whoever, at that time, for any reason whatsoever, has a right to purchase shares in the Company (including a right exercisable only on a subsequent date), bonus shares which would have been due to him had he exercised the right to purchase the shares on the eve of the effective date for the right to receive the bonus shares (hereinafter, in this Article: the "**effective date**"). If after the effective date, the holder of the said right should exercise his right to purchase all or any of the shares, the Company will allocate bonus shares to him, having a par value and to which he would have been entitled had he exercised the right to purchase the shares which he actually purchased, on the eve of the effective date. The bonus shares will entitle their owners to participate in distribution of dividends as of the date designated by the board of directors. For the purpose of determining the amount to be transferred to the said special fund, any amount transferred to this fund for previous distributions of bonus shares shall be treated as having already been capitalized, where shares entitling the holders of the right to purchase shares, have been allocated therefrom, for bonus shares.

For the purpose of distribution of bonus shares, the board of directors may, as it sees fit, resolve any difficulty that might arise and make adjustments, such as deciding that fractions of a share shall not be distributed, issue certificates in respect of an aggregate quantity of share fractions, sell such fractions and pay the proceeds from the sale thereof to those entitled to receive the fractions of the bonus shares and may also decide that cash payments shall be made to the shareholders, or that fractions of a lesser value than a stipulated amount (and if not stipulated then amounts which are less than NIS 50) shall not be brought into account in making such adjustments. Notwithstanding the foregoing, a shareholder will be entitled to apply to the Company and ask that such payment be made to him at the Company's offices.

29. **Acquisition of Company Shares**

The Company may acquire its own securities. Where the Company has acquired securities as aforesaid it may cancel them.

Chapter Seven - Exemption, Indemnification and Insurance of Officeholders

30. **Exemption of Officeholders**

The Company may exempt an officeholder therein, in advance or *post factum,* from some or all of his liability for damage as a result of breach of a duty of care *vis-à-vis* the Company, to the maximum extent that is permissible under any law.

31. **Indemnification of Officeholders**

The Company may indemnify its officeholders to the maximum extent permissible under any law. Without derogating from the generality of the foregoing, the following provisions shall apply:

31.1 The Company may indemnify an officeholder therein in respect of a liability, payment or expense imposed on him or that he has incurred as a result of an action, which he took by virtue of his being an officeholder of the Company, as follows:

31.1.1 Any financial liability imposed on him in favor of another person under a judgment, including a judgment entered under a settlement or an award approved by a court.

31.1.2 Reasonable litigation fees, including lawyer's fee, incurred by the officeholder due to any investigation or proceeding conducted against him by any authority competent to conduct an investigation or proceeding, at the end of which no indictment was filed against him and no financial liability was levied on him as an alternative for a criminal proceeding, or at the end of which no indictment was filed against him but a financial liability was levied as an alternative for a criminal proceeding in an offense not requiring proof of *mens rea* or in connection with a monetary sanction.

31.1.3 Reasonable litigation expenses, including lawyer's fees paid by the officeholder, or with which he was charged by the Court, in a proceeding filed against him by the Company or on its behalf or by any other person, or in criminal charges from which he was acquitted, or in criminal charges in which he was convicted of an offense which does not require proof of *mens rea*.

31.1.4 A payment for the party harmed by the breach, as aforesaid in Section 52(54)(a)(1)(a) of the Securities Law (the "**Party Harmed by the Breach**").

31.1.5 Expenses incurred by an officer in connection with an Administrative Proceeding conducted in his matter, including reasonable litigation expenses, including legal fees.

31.1.6 Any other liability or expense for which it is permitted and/or will be permitted by law to indemnify an officeholder.

31.2 Advance Indemnification

The Company may give an undertaking in advance to indemnify an officeholder for a liability, payment or expense as specified above in Sub-Article 31.1.1., provided that such advance indemnity undertaking shall be limited to such events as, in the opinion of the board of directors, are anticipated in view of the Company's actual activity at the time of giving the indemnity undertaking, and to such amount or criterion as the board of directors have determined to be reasonable under the circumstances of the case, and further provided that such undertaking shall state the events that in the opinion of the board of directors are anticipated in view of the Company's actual activity at the time of giving such undertaking as well as the amount or criterion that the board of directors have determined to be reasonable in the circumstances of the case. And the Company may also give an indemnity undertaking in advance to an officeholder in respect of liabilities or an expense as specified in Articles 31.1.2, 31.1.3, 31.1.4, and 31.1.5 above.

31.3 Retroactive Indemnification

The Company may indemnify an officeholder therein *ex post facto*.

32. **Officeholders' Insurance**

32.1 The Company may insure its officeholders to the maximum extent permitted under any law. Without derogating from the generality of the foregoing, the Company may enter into a contract for insuring the liability of an officeholder in the Company in respect of a liability or a payment that may be imposed on him as a result of an action that he has taken in his capacity as officeholder in the Company, in any of the following cases:

32.1.1 Breach of the duty of care to the Company or to any other person;

32.1.2 Breach of a fiduciary duty *vis-à-vis* the Company, provided that the Officeholder acted in good faith and had reasonable grounds to assume that his act would not compromise the Company's best interests;

32.1.3 Financial liability imposed on him in favor of another person;

32.1.4 Payment to the Party Harmed by the Breach;

32.1.5 Expenses incurred by an officer in connection with an Administrative Proceeding conducted in his matter, including reasonable litigation expenses, including legal fees;

32.1.6 Any other event for which it is permitted and/or will be permitted pursuant to the law to insure the liability of an officeholder.

33. **Exemption, Indemnification and Insurance - General**

33.1 It is neither the intention of the foregoing provisions in relation to exemption, indemnification and insurance, nor will there be any future intention, to restrict the Company in any way from entering into a contract in relation to exemption, insurance or indemnification of the parties specified hereunder:

33.1.1 A person who is not an officeholder of the Company, including employees, contractors or consultants of the Company who are not officeholders of the Company;

33.1.2 Officeholders in other companies. The Company may enter into a contract in relation to exemption, indemnification and insurance of officeholders in companies under its control, related companies and other companies in which it has any interest, to the maximum extent permitted under any law, and in this context the foregoing provisions in relation to exemption, indemnification and insurance of officeholders in the Company shall apply, *mutatis mutandis*.

33.2 It should be clarified that in this Chapter, an undertaking in relation to exemption, indemnification and insurance of an officeholder as aforesaid may also be valid after the office of such officeholder in the Company has terminated.

Chapter Eight - Merger, Winding Up and Reorganization of the Company

34. **Merger**

34.1 The requisite majority for approval of a merger by the general meeting shall be a simple majority.

35. **Liquidation**

35.1 If the Company is wound up, whether voluntarily or otherwise, the liquidator may, with the approval of a general meeting, distribute *in specie* parts of the Company's assets among the shareholders, and he may, with like approval, deposit such part of the Company's assets with trustees for the benefit of the shareholders, as the liquidator, with such approval, shall deem appropriate.

35.2 Subject to special rights of shares, where shares have been issued with special rights, the Company's shares shall have equal rights *inter se* in relation to the amounts of capital that have been paid or that have been credited as paid in respect of the nominal value of the shares, in connection with the surrender of capital and participation in a distribution of surplus assets of the Company upon liquidation.

36. **Reorganization of the Company**

36.1 Upon the sale of assets of the Company, the board of directors, or the liquidators (in the case of liquidation) may, if they have been duly authorized to do so in a resolution that has been passed by a simple majority at the general meeting of the Company, accept shares that are either fully or partially paid up, debentures or securities of another company, either Israeli or foreign, whether it has been incorporated or is about to be incorporated, for the purchase of all or any of the Company's assets, and the directors (if the Company's profits so allow) or the liquidators (in case of a liquidation), may distribute, among the shareholders, the shares or securities as aforesaid or any other assets of the Company without realizing them, or deposit them with trustees on behalf of the shareholders.

36.2 The general meeting may, by a resolution to be passed by the general meeting of the Company by a simple majority, decide as to a valuation of the securities or assets as aforesaid at such price and in such manner as the general meeting shall decide, and all the shareholders will be bound to accept any valuation or distribution that has been authorized as aforesaid and to waive their rights in this context, except, in the event that the Company is about to be wound-up or is in the process of winding-up, for such legal rights (if any) which, under the provisions of the law, cannot be amended, revised, or contracted out.

Chapter Nine - Notifications

37. **Notices**

37.1 A notification or any other document may be delivered by the Company to any shareholder who appears in the register of shareholders of the Company, either personally or by sending by registered mail addressed in accordance with the registered address of such shareholder in the register of shareholders or to such address as the shareholder has notified in writing to the Company as his address for the delivery of notifications, or by publication of notices in two newspapers in Israel, or by means of publishing an immediate report on the Magna system.

37.2 All notices to be given to the shareholders shall, in relation to shares that are jointly held, be given to such person whose name appears first in the register of shareholders and any notification that is given in such manner shall be sufficient notification to all the joint shareholders.

37.3 Any notification or other document which is delivered or sent to a shareholder in accordance with these Articles shall be deemed to have been duly delivered and sent in respect of all the shares held by him (whether as regards Shares held by him alone or by him jointly with others), even where such shareholder has passed away at that time or became insolvent, or an order has been issued for its winding up, or a trustee or liquidator or receiver has been appointed for his shares (whether or not the Company was aware of the occurrence of such event), until another person is registered in the register of shareholders instead of him as the holder thereof, and delivery or sending of a notification or document as aforesaid shall be deemed to be sufficient delivery or dispatch to any person who has a right to such shares.

37.4 Any notification or other document that has been sent by the Company in the mail to an address in Israel shall be deemed to have been delivered within 48 hours from the day on which the letter containing such notification or document was dispatched at the post office or within 96 hours in the event that the address is overseas, and for the purpose of proving delivery, it shall be sufficient to prove that the letter containing the notification or the document was duly addressed and was dispatched at the post office. Any notice or document delivered by means of notifications in newspapers or via an immediate report on the Magna system, will be deemed to have been delivered on the date of publishing the notice or on the date of publishing the immediate report as aforesaid.

37.5 The Company is not obliged to give notice of a general meeting to shareholders except in so far as this is mandatory by law. The notice of a general meeting shall specify the place and the time for the convening of the meeting, its agenda, a summary of the proposed resolutions and any other specification as is required under law.

37.6 Accidental omission in giving notice of a general meeting to any shareholder or non-receipt of a notification as to a meeting or other notification by any shareholder shall not invalidate a resolution that has been passed at such meeting, or cause the invalidation of processes based on such notification.

37.7 Notices to directors may be given in any manner to be determined by the board of directors.

37.8 Any shareholder and any member of the board of directors may waive his right to receive notification, or his right to receive notification within a specific period of time, and may agree that a general meeting of the Company or a meeting of the board of directors, as the case may be, shall convene and be held despite his not having received notification or despite such notification not having been received by him within the required time.

* * *

Exhibit 4.10

Confidential

Amendment #5
To
EXCLUSIVE LICENSE AGREEMENT
Apogee Biotechnology Corporation
and
RedHill Biopharma Ltd.

This Amendment is entered into effective as of the date of the last signature below (the "**Effective Date**") by and between RedHill Biopharma Ltd. ("**RedHill**") and Apogee Biotechnology Corporation ("**Apogee**") to amend the terms of that Exclusive License Agreement entered into by the parties effective March 30, 2015 ("**Agreement**").

NOW, THEREFORE, the mutual covenants set forth herein, the parties agree to amend the terms of the Agreement as follows:

1. Annex A is hereby amended and modified by adding to the list of Patents therein the following Patent:

- U.S. Provisional Patent Application Serial No. 62/792,996, filed January 16, 2019 which shall hereafter be a "Patent", as defined in and for all purposes of the Agreement.

2. The Parties hereby agree that subject to the modifications specifically stated in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to the Agreement to be executed by their duly authorized representatives as of the Effective Date.

Apogee Biotechnology Corp.

Signature:*/s/ Charles D. Smith*
Name: Charles D. Smith
Title: President and CEO
01/23/2019

RedHill Biopharma Ltd.

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

Signature:*/s/ Micha Ben Chorin*
Name: Micha Ben-Chorin
Title: CFO

Exhibit 4.12

Confidential

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

AMENDMENT NO. 1 TO EXCLUSIVE COMMERCIALIZATION AGREEMENT

This Amendment No.1 to Exclusive Commercialization Agreement is made effective as of August 24, 2018 by and between RedHill Biopharma Ltd. ("**RedHill**") and Concordia Pharmaceuticals Inc., by way of its Barbados branch ("**Concordia**").

WITNESETH

WHEREAS, Concordia and RedHill entered into an Exclusive Commercialization Agreement dated December 30, 2016 (the "**Main Agreement**");

WHEREAS, Concordia and RedHill desire to amend the Main Agreement;

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, the Parties hereby agree as follows:

1. All terms not otherwise defined herein shall have the meaning ascribed thereto in the Main Agreement, unless the context requires otherwise.

2. In accordance with Section 20.6 of the Main Agreement, the Main Agreement is amended as follows:

2.1. Section 1.4 of the Main Agreement is hereby amended effective October 1, 2018 by the deletion of the second sentence thereof so that Section 1.4 in its entirety is as follows:

*"1.4 "**Applicable Percentage**" means* [****]"

2.2. The following provision shall be added to the Main Agreement as a new Section 9.6:

"Concordia shall pay RedHill two (2) one-time payments as follows: (i) $[****] to be paid on or before [****]; and (ii) $ [****] for [****] to be paid on or before [****]. In consideration for [****] RedHill: (i) has provided [****]; and (ii) continue, until September 30, 2018, Promotion and commercialization of the Product for the Field of Use (with the number of representatives throughout geographical territories) substantially similar to that provided through the first half of 2018; subject, *inter alia*, to reassignment and prompt replacement of representatives and other ordinary course and commercially reasonable changes in the geographical territories.

2.3. The following provision shall be added to the Main Agreement as the last sentence of Section 9.2:

"All amounts paid or payable by Concordia to RedHill pursuant to the applicable Quarterly Report shall, absent fraud or manifest error, be considered final and binding and shall not be subject to dispute or adjustment."

3. Except as specifically amended herein, the provisions of the Main Agreement shall continue in full force and effect.

4. This Amendment No. 1 may be executed in any number of counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first above written.

RedHill Biopharma Ltd.

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

By:*/s/ Micha Ben Chorin*
Name: Micha Ben Chorin
Title: CFO
August 26, 2018

Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch

By:*/s/ Robert Ford*
Name: Robert Ford
Title: Managing Director & Vice-President, Legal Affairs

Exhibit 4.14

First Addendum
Exclusive Licensing Agreement

This First Addendum to the Agreement (as defined below) is made and entered into between Licensor and Licensee as of the Effective Date of the Agreement.

RECITALS

WHEREAS, the Licensor and Licensee are parties to an Exclusive License Agreement made and entered into as of April 4, 2017 (the "Agreement").

WHEREAS, the Licensed Product was sold by Licensor in the Territory since August 2013 up to the RedHill Launch which occurred June 12, 2017 (the "Licensor Sales").

WHEREAS, Licensee has been selling the License Product exclusively in the Territory pursuant to the terms and conditions of the Agreement since the RedHill Launch (the "Licensee Sales").

WHEREAS, the Licensor and Licensee both desire to enter into this First Addendum to the Agreement to establish the responsibilities of each party as they relate to customer returns of the Licensed Product ("Returns") which may occur during and after the Term of the Agreement.

NOW, THEREFORE, in consideration of the mutual promises and conditions contained in this First Addendum and in the Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by, the parties agree as follows:

1.0 Definitions. Capitalized terms not otherwise defined herein shall have the meaning ascribed to them in the **Agreement.**

2.0 Returns. The parties hereby agree that the responsibilities, conditions and process for returns as outlined in Attachment A to this First Addendum are hereby agreed to and incorporated into this First Addendum and the Agreement in their entirety.

3.0 Survival. The *terms* and conditions of this First Addendum shall survive the Expiration Date and the **Termination Date.**

IN WITNESS WHEREOF, the parties hereto have caused *this* First Addendum to the Agreement to be executed as of the Effective Date.

LICENSOR

Entera Health, Inc.
By: */s/ Aage Lauridsen*
Date: July 25, 2018
Title: CEO

LICENSEE

RedHill Biopharma, Inc.

By:	*/s/ Dror Ben-Asher*	*/s/ Micha Ben Chorin*
Date:	July 18, 2018	July 18, 2018
Title:	CEO	CFO

First Addendum
Exclusive License Agreement

Attachment A

Returns

The actual processing of all Returns will be the responsibility of Licensee through the earlier of the Expiration Date or Termination Date. Thereafter processing of such returns shall be the responsibility of the Licensor or its designated future licensee. Either party may use a logistics vendor to fulfill its processing responsibilities.

The cost of any credit issued to the customer relating to a Return shall be the responsibility of the Licensor for any Licensor sales and the Licensee for any Licensee sales.

The cost that Licensor will reimburse to Licensee for Returns of Licensor sales processed by Licensee will be limited to the sales price of the Licensed Product at the time of the Licensor sale (i.e., Licensor WAC) less 10%. The cost that Licensee will reimburse to Licensor for Returns of Licensee sales processed by Licensor will be limited to the sales price of the Licensed Product at the time of the Licensee sale (i.e., Licensee WAC) less 10%. For the avoidance of doubt, the cost of any credit issued to a customer relating to a Return which is the responsibility of the Licensee shall be deducted from Net Sales.

Any Licensor Sales Returned to Licensee will be destroyed in the manner required by the SOP of Licensor or shipped to Licensor for disposal, at Licensor's option. Licensor will be responsible for the cost of disposal and shipping. Any Licensee Sales Returned to Licensor will be destroyed in the manner required by the SOP of Licensee or shipped to Licensee for disposal, at Licensee's option. Licensee will be responsible for the cost of disposal and shipping.

Below is a listing of lots produced and their designation as Licensor Sales or Licensee Sales. Lots 6JO2PT, 6JO2PTA, and 6JO3PT contain both Licensor Sales and Licensee Sales and shall be designated as a "Shared Lot". All Licensor sales from the Shared Lots were made to Foundation Care. Licensee sales from Shared Lots were made to Foundation Care and additional customers. For simplicity, any returns of units from the Shared Lots from Foundation Care will be the responsibility of Licensor; returns of units from the Shared Lots from all other customers will be the responsibility of the Licensee.

Reimbursable costs of Returns will be invoiced monthly by the processing party. Payment terms shall be net thirty (30) calendar days from the date of invoice. Any undisputed past due payments over 15 days beyond due date shall bear interest at a per annum rate equal to (a) the Prime Rate plus two percent (2.0%) per annum, or the maximum interest rate permissible under law, whichever is less. All payments to be made in USD.

Entera Health Lots "Licensor Sales"				RedHill Lots "Licensee Sales"
				6J03PTA 6J04PT
3D01PT	3L02PT	5H02PTA	6B05PTA	
3D01PTA	3L02PTA	5H03PT	6B06PT	And, all future Licensed Product sales up to and including the earlier of Expiration Date or Termination Date
3D01PTB	4M02PTA	5H03PTA	6B06PTA	
3D01PTC	4M02PTB	5H04PT	6B07PT	
3E02PT	4M03PT	5H04PTA	6B07PTA	
3E02PTA	4M03PTA	5K03PT	6B08PT	
3E03PT	4P01PT	5K03PTA	6B08PT	
3E03PTA	4P01PTA	5K04PT	6H03PT	
3E04PT	4P02PTA	5K04PTA	6H03PT	
3G04PT	4P02PTB	5K05PT	6H04PT	
3G04PTA	5H01PT	5K05PTA	6H04PTA	
3L01PT	5H01PTA	5K06PT	6J01PT	
3L01PTA	5H02PT	5K06PTA	6J01PTA	
3L01PTB		6B05PT		

And all future Licensed Product sales after the earlier of the Expiration Date or the Termination Date

Exhibit 4.15

Confidential

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

AMENDMENT TO EXCLUSIVE LICENSE AGREEMENT

This Amendment to the Exclusive License Agreement (the "Amendment') is entered into as of September 7, 2018 (the "Amendment Effective Date") by and between Entera Health, Inc., an Iowa Corporation, having an address at 2425 SE Oak Tree Court, Ankeny, Iowa 50021 (the "Licensor"), and RedHill Biopharma, Inc. a Delaware corporation, having an address at 8045 Arco Corporate Drive, Suite 120, Raleigh, North Carolina 27617, along with all Affiliates thereof (as defined in that certain Exclusive License Agreement dated as of April 4, 2017 between the parties hereto (the "Agreement")) ("Licensee"). Unless otherwise specifically defined in this Amendment, any term used in this Amendment which is defined in the Agreement shall have the meaning assigned to it in the Agreement.

WHEREAS, on August 16, 2018, [****] of the Agreement; and

WHEREAS, pursuant to Section 17.4 of the Agreement, Licensor may [****]; and

WHEREAS, the Licensee [****].

NOW, THEREFORE, in consideration of the premises and of the mutual covenants above, and for good and valuable consideration, the adequacy and sufficiency of which is hereby acknowledged, the parties agree as follows:

l. Replacement of Section 1.6: The Agreement is hereby amended and modified by deleting Section 1.6 in its entirety and replacing such deleted section with a new Section 1.6 as set forth below:

1 . 6 "Contract Year" shall mean: (a) until October 1, 2018, a period of twelve (12) successive months commencing on the RedHill Launch Date (as defined below); and (b) from and after October 1, 2018, each period of twelve (12) successive months.

2. Addition of New Section 4.4: The Agreement is hereby amended and modified by adding a new Section 4.4 to the Agreement, as set forth below:

4.4 Licensee hereby agrees that the minimum amount of Licensed Product that Licensee shall purchase from Licensor in any one order shall comprise a [****] of Licensed Product, containing 30 sachets per box.

3. Addition of New Section 4.5: The Agreement is hereby amended and modified by adding a new Section 4.5 to the Agreement, as set forth below:

4.5 Licensee hereby agrees that, once per month, personnel of Licensee chosen at the full and sole discretion of the Licensee and who are intimately involved and familiar with Licensee's sales and commercialization efforts with respect to Licensed Product shall be available for, and participate in, monthly update teleconference calls, with personnel of Licensor. During such calls, Licensee personnel shall provide, within reason, monthly updates of sales efforts, progress, trends, forecasts, and the like, with respect to Licensed Product, and shall answer all questions reasonably related thereto submitted or asked by Licensor. The information and updates provided by Licensee shall include, without limitation, information and updates concerning the numbers of open territories, total prescriptions, new prescriptions, calls made, and sample calls made, in furtherance of the commercialization and sales activities for the Licensed Product. Licensee personnel shall participate on such calls for a duration reasonably requested by Licensor, up to one hour per monthly call. For the avoidance of any doubt, any and all operational decisions regarding the Licensed Product remain at the full and sole discretion of the Licensee and Licensor shall not intervene or attempt to intervene, in such decisions in any manner whatsoever.

4. Replacement of Section 17.4: The Agreement is hereby amended and modified by deleting Section 17.4 in its entirety and replacing such deleted section with a new Section 17.4 as set forth below:

17.4 Either of Licensor or Licensee may terminate this Agreement if Licensee fails to meet the Minimum Net Sales target in any Contract Year provided the terminating party delivers termination notice to the other party within [****] from the date Licensee notifies Licensor of an applicable failure. Either Licensor or Licensee may terminate this Agreement in the event of each and every such failure, and any failure to provide notice of termination within the timelines stipulated above in respect of any particular failure shall not preclude either party from later terminating such Agreement in respect of a later failure. Either Licensor or Licensee shall also be entitled to terminate this Agreement at any time, upon [****] prior written notice to the other party provided Licensor delivers termination notice to Licensee within [****] from the date Licensee provides the reports detailed below evidencing a failure to meet the sales targets provided below, if Licensee fails to meet any one or more of the following sales targets applicable to any one or more of the time periods as set forth below:

(a) [****] of Licensed Product during [****].
(b) [****] of Licensed Product during [****].
(c) [****] of Licensed Product [****].
(d) [****] of Licensed Product [****].

Termination of this Agreement shall constitute the only remedy Licensor is entitled to for such commercial failures described in this Section 17.4, with no further liability by Licensee whatsoever in connection with such commercial failures.

Without limiting any other obligation of Licensee in this Agreement, Licensee shall provide reports of all

sales of Licensed Product made during each calendar quarter sufficient to enable Licensor to determine whether Licensee has met the foregoing sales milestones within [****] during the Contract Term.

5. Replacement of Section 17.8 (a): The Agreement is hereby amended and modified by deleting Section 17.8(a) in its entirety and replacing such deleted section with a new Section 17.8(a) as set forth below:

(a) Within [****] before the Expiration Date or within [****] after the Termination Date, Licensee shall provide Licensor with a statement indicating the number and description of Licensed Products which it has on hand as of the date of expiration or termination and the amount of such inventory necessary to fill Licensee's existing customer orders with such documentation provided to Licensor. Licensee shall have the right to sell Licensed Products it has on hand to fulfill Licensee's existing customer orders, as aforesaid, under the License, subject to payment of Royalties. Furthermore, Licensee shall have the option, exercisable upon notice to Licensor within [****]following the date of expiration or termination, to require Licensor to repurchase from Licensee all such remaining Licensed Products (or the part thereof that is not needed to fulfill Licensee's existing customer orders, as aforesaid) that are in a sellable condition, meaning that all such Licensed Products: (i) are undamaged, unopened, unadulterated, unmodified, and in substantially identical condition as when such Licensed Products arrived at the Licensee's facilities; and (b) have at least [****] remaining shelf-life, at the price paid by Licensee. In the event that any such remaining Licensed Products bear, incorporate, or embody any trademarks or other intellectual property rights of Licensee, Licensee hereby grants a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid up, assignable, sublicensable license to Licensor to undertake any and all actions, including, without limitation, to sell and offer to sell such remaining Licensed Products bearing or incorporating such Licensee intellectual property rights, with respect to such remaining Licensed Products solely to the extent reasonably necessary, convenient, or advisable to enable Licensor to undertake any and all sales and commercialization activities for such remaining Licensed Products.

6. Entire Agreement: This Amendment, together with the Agreement, constitutes the entire agreement between the parties with respect to the subject matter of the Agreement, as amended by this Amendment. The Agreement, together with this Amendment supersedes all prior agreements, whether written or oral, with respect to the subject matter of the Agreement, as amended, provided that nothing herein shall affect the Supply Agreement or any other document or instrument referenced in the Agreement, except as modified herein. Each party confirms that it is not relying on any representations, warranties or covenants of the other party except as specifically set out in the Agreement as amended. The parties hereby agree that subject to the modifications specifically stated in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect. This Amendment shall be governed by the same choice of law and subject to the same venue and dispute resolution provisions as set forth in the Agreement.

[Signature Page Next Page]

IN WITNESS WHEREOF, the parties have entered into this Amendment to the Exclusive License Agreement as of the Amendment Effective Date by their duly authorized representatives.

LICENSOR	L.ICENSEE	
ENTERA HEALTH, INC.	REDHILL BIOPHARMA, INC.	
By: /s/ Alex Walden Date: Sept. 29, 2018 Title: VP, Finance	By: */s/ Dror Ben-Asher* Name: Dror Ben-Asher Title: CEO Date: Sept.27, 2018	*/s/ Micha Ben Chorin* CFO

Exhibit 4.2

Confidential

AMENDMENT TO ASSET PURCHASE AGREEMENT

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

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

WHEREAS, Professor Thomas J. Borody, of Ground Floor, 44 East Street, Five Dock, New South Wales, Australia 2046 ("**Borody**"), and RedHill in connection with the execution and delivery of the Original Asset Purchase Agreement and the consummation of the transactions contemplated thereby, entered into, and are now the parties to, that certain Agreement, dated as of 11 August 2010 (the "**ROFR Agreement**"), which in Section 4.2 thereof contains provisions that impose certain restraints on the ability of Borody and his affiliates to supply or grant certain goods, services or rights;

WHEREAS, Borody, together with Dr. Sanjay Ramrakha, Dr. John Saxon, and Dr. Antony Wettstein (collectively, including Borody, the "**Inventors**"), has conducted work in the field of colonic purgatives, laxatives, and gastrointestinal cleansers and has in connection therewith developed certain know-how and intellectual property with respect thereto;

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

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

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

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

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

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

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

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

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

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

"**Purgative Product**" means any substance or product, including the Picoconda product, intended for use as a colonic purgative, laxative or gastrointestinal cleanser (including in, or for the purpose of, the prevention, diagnosis, staging, monitoring, treatment or maintenance of any disease or condition) in humans or non-human animals, but not, for the avoidance of doubt, any of RedHill's RHB-102 (extended release anti-emetic ondansetron), Myoconda (RedHill's RHB-104 - a product containing a combination of clarithromycin, clofazamine and rifabutin) and Heliconda (RedHill's RHB-105 - a product containing a combination of rifabutin, amoxicillin and pantoprazole or omeprazole).

SECTION 2. Non-Competition.

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

> "Restraint. Seller agrees and undertakes that neither Seller or its Affiliates (excluding Borody and the Centre for Digestive Diseases Pty Limited (ACN 097 085 884)) (CDD) , will, without the prior written consent of Buyer directly or indirectly, as owner, part-owner, financier, partner, joint venturer, stockholder, employee, broker, agent, principal, corporate officer, director, licensor or in any other capacity whatever (a) supply or grant services or rights similar to or competing with the Designated Products or the Designated Technology; or (b) supply goods or services that assist any other person, entity, or organization in competing or in preparing to compete with the Designated Products or the Designated Technology. The foregoing restrictions do not prevent Seller from selling, licensing, or dealing with Hepaconda or Ibaconda provided that those patents and associated intellectual property are not the subject of the Charges. The foregoing

restrictions do not apply if Seller proposes to exercise or exercises its Buy Back Option. ”

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

This Section 13.2.1 does not restrict:

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

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

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

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

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

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

> “Notwithstanding any clause in this agreement, nothing in this agreement restricts Borody or his Affiliates from taking any action or conducting any activities with respect to Purgative Products or otherwise in the Purgative Field.”

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

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

> “Notwithstanding anything in this Article 14 to the contrary, nothing in this Article 14 shall operate to limit or qualify the right and ability of Seller, Borody, CDD and their respective Affiliates to use and to disclose to Salix Pharmaceuticals, Inc. information, including information that would otherwise constitute Confidential

Information subject to the restrictions and limitations set forth in this Article 14, to the extent (but only to the extent) the same relates to Purgative Products or the Purgative Field."

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

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

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

[*Remainder of page intentionally left blank*]

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

RedHill Biopharma Ltd.

By: /s/ Dror Ben-Asher
Name: Dror Ben-Asher

Title: CEO
February 26, 2014

/s/ Ori Shilo
Ori Shilo

Deputy CEO
February 26, 2014

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

/s/ Thomas Borody
Signature of director

Name of director: Thomas Borody

/s/ Christopher Robert Bilkey
Signature of director/company secretary

Name of director/company secretary:
Christopher Robert Bilkey

ANNEX 1

Interdependent Documents

Core Transactional Documents

1. Assignment and License Agreement by and among Professor Thomas J. Borody, Dr Sanjay Ramrakha, Dr John Saxon, and Dr Antony Wettstein and Salix Pharmaceuticals, Inc.

2. Agreement between RedHill Biopharma Ltd. and Salix Pharmaceuticals, Inc.

Giaconda / Redhill Arrangements

3. This Amendment to Asset Purchase Agreement by and between RedHill Biopharma Ltd. and Giaconda Limited ACN 108 088 517

4. Deed of Waiver, Confirmation, Termination, and Amendment by and between Giaconda Limited ACN 108 088 517, Centre for Digestive Diseases Pty Limited ACN 097 085 884, Professor Thomas Julius Borody, RedHill Biopharma Ltd., and Salix Pharmaceuticals, Inc.

Borody / RedHill Arrangements

5. Deed of Variation by and between RedHill Biopharma Ltd. and Professor Thomas J. Borody

6. Deed of Termination by and between RedHill Biopharma Ltd and Centre for Digestive Diseases Pty Limited ACN 097 085 884

7. Deed of Termination by and between RedHill Biopharma Ltd and Professor Thomas J. Borody

General Facilitating Documents

8. Deed of Waiver and Confirmation by and among Centre for Digestive Diseases Pty Limited ACN 097 085 884, Professor Thomas Julius Borody, and Salix Pharmaceuticals, Inc.

9. Deed of Waiver and Confirmation by and between Pharmatel Research & Development Pty Ltd as trustee for the Pharmatel Research & Development Trust ACN 104 997 328 and Salix Pharmaceuticals, Inc.

10. Research Services Agreement by and between Centre for Digestive Disease Pty Limited ACN 097 085 884 and Salix Pharmaceuticals, Inc.

11. Deed of Waiver and Confirmation, between Giaconda Limited ABN 108 088 517 and Centre for Digestive Diseases Pty Limited ABN 54 097 085 884

12. Letter agreement, between Giaconda Limited ACN 108 088 517 and Salix Pharmaceuticals, Inc.

Giaconda / Borody/ Salix Arrangements

13. Deed of Waiver and Confirmation by and among Giaconda Limited ACN 108 088 517, Professor Thomas Julius Borody, and Salix Pharmaceuticals, Inc.

14. Ibaconda Assignment Agreement by and between Giaconda Limited ACN 108 088 517 and Salix Pharmaceuticals, Inc.

Rosenhain Arrangements

15. Releases for Salix Deed, dated 23 December 2013, by and between Mrs. Norma Rosenhain, CIPAC Limited, and Salix Pharmaceuticals, Inc.

16. Deed of Assignment and License, dated on or about 25 January 2013, between Professor Thomas Julius Borody and CIPAC Limited

17. Letter agreement, dated 23 December 2013, between Mrs. Norma Rosenhain and CIPAC Limited

18. Termination Deed, dated 23 December 2013, between Professor Thomas Julius Borody, Centre for Digestive Diseases Pty Limited ACN 097 085 884, and Mrs. Norma Rosenhain

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

AMENDMENT NO. 1 TO AGREEMENT

This Amendment No.1 to Agreement is made as of February 26, 2018 (the "**Amendment Effective Date**") by and between RedHill Biopharma Ltd. ("**RedHill**") and Salix Pharmaceuticals, Inc. ("**Salix**").

WITNESETH

WHEREAS, RedHill and Salix have entered into that certain Agreement dated February 27, 2014 (the "**Agreement**"); and

WHEREAS, [****] and the Parties desire to amend the Agreement to reflect certain changes to the Agreement;

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, the Parties hereby agree as follows:

1. All terms not otherwise defined herein shall have the meaning ascribed thereto in the Agreement, unless the context requires otherwise.

2. RedHill hereby [****] of the Agreement pursuant to [****] and the Parties agree that the Agreement shall be [****].

3. In consideration for the covenants, agreements and undertakings made herein, the receipt and sufficiency of which is hereby acknowledged, RedHill (for itself and each of its successors, assigns, parents, subsidiaries, affiliates, attorneys, agents, employees, directors, officers, representatives, or any persons or entities acting on its behalf) hereby releases and discharges Salix from and against any and all claims, liabilities or damages, whether known or unknown, whether present or future, that RedHill had, has or may have against Salix, and hereby waives any right RedHill may have [****], in each case, relating to or arising out of any [****] of the Agreement, from the beginning of time through the Amendment Effective Date.

4. Other than with respect to the releases expressly detailed in Section 3 of this Amendment, nothing herein shall prejudice any rights and remedies conferred [****] in accordance with its terms following the Amendment Effective Date.

5. In accordance with Section 13.7 of the Agreement, the Agreement is hereby amended as follows:

   5.1. Article 1 is hereby amended to include the following definitions:

*"**Commercially Reasonable Efforts**" shall mean, with respect to the efforts and resources to be expended by a Party with respect to any objective or activity under this Agreement,* [****].

*"**Development Plan**" shall mean the development plan prepared by Salix setting out Salix's plan to Develop* [****]*, as such plan may be amended from time to time by Salix* [****]*, which development plan (and any amendments thereto) shall be provided to RedHill promptly upon completion and, in the case of the initial Development Plan, no later than* [****] *following the Amendment Effective Date."*

5.2. Article 3.7.2 is hereby deleted in its entirety and replaced with the following:

"3.7.2 Without limiting the provisions of Section 3.7.1, the Parties acknowledge and agree that, other than as set out in Sections 5.4 and 12.3, Salix has no obligation to Develop or Commercialize any Licensed Product or any obligation to satisfy the conditions to the milestone payments set forth in Section 6.2 or to achieve any particular level of additional consideration or other payments (or additional consideration or other payments payable to Redhill under Section 6.3)."

5.3. Article 5 is hereby amended by the addition of the following after Section 5.3:

*"5.4 **Development Diligence**. Salix shall use Commercially Reasonable Efforts to pursue the Development of* [****] *in accordance with the Development Plan."*

5.4. Section 6.3.1(c) is hereby amended by replacing [****].

5.5. Section 7.1.1(c) is hereby deleted in its entirety and replaced with the following:

"(c) RedHill shall have the right to be actively involved in the maintenance of Licensed RedHill Patents and License RedHill Know-how. Salix shall provide RedHill with copies of all relevant documentation so that RedHill will be informed of the continuing preparation, filing, prosecution and maintenance of the Licensed RedHill Patents and may comment upon such documentation sufficiently in advance of any filing deadline. Salix shall consider in good faith any comments received from RedHill; provided, however, that if RedHill has not commented upon such documentation in a reasonable time for Salix to sufficiently consider RedHill's comments prior to a deadline with the relevant government patent office, or Salix must act to preserve the Licensed RedHill Patents, Salix will be free to act without consideration of RedHill's comments, if any. Salix shall keep RedHill fully informed with respect to any communications with any relevant governmental offices and (i) within [****] *of Salix's receipt thereof, provide to RedHill any written correspondence from any governmental office, and (ii) no later than* [****] *prior to the submission thereof provide to RedHill any proposed written correspondence to any governmental office, including copies of any and all underlying data to accompany any such correspondence. Salix shall consider in good faith any written comments received from RedHill with respect to such*

correspondence prior to its submission; provided, however, that if RedHill has not commented upon such correspondence in a reasonable time for Salix to sufficiently consider RedHill's comments prior to a deadline with respect to such correspondence, Salix will be free to act without consideration of RedHill's comments, if any. Without derogating from the foregoing, at any time that Salix is not Developing [****] *or the Development Plan does not contemplate the Development of* [****]*, Salix shall act in accordance with all comments provided by RedHill in connection with preparation, filing, prosecution and maintenance of the Licensed RedHill Patents, including in preparing any proposed written correspondence to any governmental office and otherwise act in accordance with RedHill's patent and regulatory strategy as notified timely to Salix's patent counsel in writing, in each case, unless Salix has a documented and compelling reason not to do so. All of the obligations of Salix set out in this Section 7.1.1(c) shall be subject to (and limited by) its obligations under Applicable Law and under its contractual commitments with any Third Party, including, but not limited to, its obligations of confidentiality and non-disclosure existing as of the Amendment Effective Date."*

5.6. Section 12.3 is hereby deleted in its entirety and replaced with the following:

"12.3 Additional Termination Rights by RedHill.

12.3.1 In the event that Salix should, at any time during the period beginning [****] *following the Effective Date and ending on the date* [****]*, not then be using Commercially Reasonable Efforts to pursue the Development of* [****] *in accordance with the Development Plan, then RedHill shall be entitled to give Salix notice requiring Salix to commence or resume using Commercially Reasonable Efforts to Develop* [****] *in accordance with the Development Plan and stating RedHill's intention to terminate this Agreement if Salix fails to do so. For the avoidance of doubt, RedHill shall be entitled to give such notice more than once, but any such notice may be given only during the period beginning* [****] *and ending on the date on which* [****]*. If Salix fails to commence or resume using Commercially Reasonable Efforts to Develop* [****]*, and give notice of such commencement or resumption to RedHill, within* [****] *after its receipt of such notice (or, if relevant Development activities cannot reasonably be commenced or resumed within such* [****] *period, if Salix does not commence actions to commence or resume relevant Development activities, and give notice of such commencement to RedHill, within* [****] *period and thereafter diligently continue such actions or if in any event Salix has not commenced or resumed relevant Development activities, and given notice of such commencement or resumption to RedHill, within* [****] *after its receipt of such notice), then RedHill shall be entitled, by notice to Salix and without prejudice to any other rights conferred on RedHill by this Agreement and in addition to any other remedies available to RedHill at law or in equity, to terminate this Agreement forthwith.*

12.3.2 Without derogating from the foregoing, in the event that Salix shall fail, for any reason, and even if having used Commercially Reasonable Efforts to do so, to (i) [****] *(ii)* [****] *(as may be extended on mutual agreement of the Parties), then RedHill shall be entitled to give Salix notice requiring Salix to* [****] *and stating RedHill's intention to terminate this Agreement if Salix fails to do so. For the avoidance of doubt, RedHill shall be entitled to give such notice more than once (but not for the same event resulting in Salix' failure to comply with such matters), but any such notice may be given only during (and with respect to events occurring during) the period beginning on the Amendment Effective Date and ending on the date on which* [****]. *If Salix fails to* [****], *in each case, within* [****] *after its receipt of such notice, then this Agreement shall terminate forthwith. Such right of termination shall be RedHill's sole remedy with respect to the breaches described in this Section 12.3.2.*

6. Except as specifically amended herein, the provisions of the Agreement shall continue in full force and effect.

[***signature page follows***]

IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date first above written.

RedHill Biopharma Ltd.

By: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO
Feb. 26, 2018

By: /s/ Micha Ben Chorin
Name: Micha Ben Chorin
Title: CFO
February 26, 2018

Salix Pharmaceuticals, Inc.

By: /s/ Mark McKenna
Name: Mark McKenna
Title: SVP & GM
3.20.2018

ANNEX A

[****]

Confidential

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

Amendment #1
To
EXCLUSIVE LICENSE AGREEMENT

Apogee Biotechnology Corporation
and
RedHill Biopharma Ltd

This Amendment is entered into effective as of the date of the last signature below (the "Effective Date") by and between RedHill Biopharma Ltd ("RedHill") and Apogee Biotechnology Corporation ("Apogee") to amend the terms of that Exclusive License Agreement entered into by the parties effective March 30, 2015 ("Agreement").

NOW, THEREFORE, the mutual covenants set forth herein, the parties agree to amend the terms of the Agreement as follows:

1. Clause 6.2.1 is hereby modified to: [****] days following the earlier of (i) [****] and (ii) [****]: Two Million US Dollars ($2,000,000).

2. All other terms of the Agreement are unchanged and remain in full force and effect.

WHEREFORE, the parties hereunto have caused this Amendment to be executed by their duly authorized representatives as of the date of the last party to sign to be effective and in agreement.

RedHill Biopharma Ltd	**Apogee Biotechnology Corporation**
By: /s/ Micha Ben Chorin /s/ Dror Ben-Asher	By: /s/ Charles D. Smith
Printed Name: Micha Ben Chorin Dror Ben-Asher	Printed Name: Charles D. Smith
Title: CFO CEO	Title: President and CEO
Date: January 23, 2017	Date: January 21, 2017

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

Amendment #4
To
EXCLUSIVE LICENSE AGREEMENT

Apogee Biotechnology Corporation
and
RedHill Biopharma Ltd

This Amendment is entered into effective as of the date of the last signature below (the "Effective Date") by and between RedHill Biopharma Ltd ("RedHill") and Apogee Biotechnology Corporation ("Apogee") to amend the terms of that Exclusive License Agreement entered into by the parties effective March 30, 2015 ("Agreement").

NOW, THEREFORE, the mutual covenants set forth herein, the parties agree to amend the terms of the Agreement as follows:

1. Clause 6.2.1 is hereby modified to: [****] days following [****]: One Million US Dollars ($1,000,000). Additionally, [****] days following[****]: Five hundred thousand US Dollars ($500,000).

2. Clause 6.3.1.1 is hereby modified to: A Royalty equal to [****].

3. Clause 6.3.1.2 is hereby modified to: A Royalty equal to [****].

4. Clause 6.3.2.1 is hereby modified to: A Royalty equal to [****].

5. Clause 6.3.2.2 is hereby modified to: A Royalty equal to [****].

6. Clause 6.3.3 is hereby modified to: A royalty equal to [****].

All other terms of the Agreement are unchanged and remain in full force and effect.

WHEREFORE, the parties hereunto have caused this Amendment to be executed by their duly authorized representatives as of the date of the last party to sign to be effective and in agreement.

RedHill Biopharma Ltd	**Apogee Biotechnology Corporation**
By: */s/ Micha Ben Chorin* */s/ Dror Ben-Asher*	By: */s/ Charles D. Smith*
Printed Name: Micha Ben Chorin Dror Ben-Asher	Printed Name: Charles D. Smith
Title: CFO CEO	Title: President and CEO
Date: January 3, 2019	Date: January 1, 2019

Exhibit 12.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dror Ben-Asher, certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 25, 2019

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Micha Ben Chorin certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to

adversely affect the company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 25, 2019

/s/ Micha Ben Chorin
Micha Ben Chorin
Chief Financial Officer

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUAN TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RedHill Biopharma Ltd. (the "Company") on Form 20-F for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company

Dated: February 25, 2019

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

/s/ Micha Ben Chorin
Micha Ben Chorin
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form F-3 (file No. 333-209702 and file No. 333-226278) and the Registration Statements on Form S-8 (file No. 333-225122, file No. 333-219441, file No. 333-207654 and file No. 333-188286) of RedHill Biopharma Ltd. of our report dated February 25, 2019 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

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

Tel-Aviv, Israel
February 25, 2019