Filed Pursuant to Rule 424(b)(5)
Registration Nos. 333-209702 and 333-226278

PROSPECTUS SUPPLEMENT
(To Prospectus dated July 31, 2018)

2,857,143 American Depositary Shares Representing 28,571,430 Ordinary Shares

RedHill Biopharma Ltd.

We are offering 2,857,143 American Depositary Shares ("ADSs"). Each ADS represents 10 of our ordinary shares, par value NIS 0.01 per share ("Ordinary Shares").

Our ADSs are listed on The NASDAQ Global Market ("The NASDAQ") under the symbol "RDHL." On December 4, 2018, the last reported sale price of our ADSs on The NASDAQ was $7.27 per ADS. Our Ordinary Shares are also listed on the Tel Aviv Stock Exchange (the "TASE") under the symbol "RDHL." On December 4, 2018, the last reported sale price of our Ordinary Shares on the TASE was NIS 2.98, or $0.80 per Ordinary Share (based on the exchange rate reported by the Bank of Israel on such date).

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our securities involves a high degree of risk. Please read "Risk Factors" beginning on page S-14 of this prospectus supplement, on page 3 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement.

None of the United States Securities and Exchange Commission, the Israeli Securities Authority, any state securities commission or any other regulatory body, has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

	PER ADS	TOTAL
Public Offering Price	$ 7.0000	$ 20,000,001
Underwriting Discounts and Commissions (1)	$ 0.4200	$ 1,200,000
Proceeds to Us, before Expenses	$ 6.5800	$ 18,800,001

(1) We have agreed to reimburse the underwriters for certain offering-related expenses. See "Underwriting."

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 428,571 ADSs representing 4,285,710 Ordinary Shares at a price of $7.00 per ADS less underwriting discounts and commissions. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $1.38 million, before reimbursement of expenses and payment of any discretionary fee, and the total proceeds to us, before expenses, will be $21.6 million. In addition, we will pay Ladenburg Thalmann an additional fee based on its efforts and results of the offering of 1% of the aggregate gross proceeds we receive from this offering (excluding proceeds from Israeli investors).

Delivery of the ADSs is expected to be made on or about December 11, 2018.

Joint Book-Running Managers

Ladenburg Thalmann **Nomura**

Lead Manager

H.C. Wainwright & Co.

Co-Managers

LifeSci Capital LLC **Ascendiant Capital Markets**

SMBC **WBB Securities**

Prospectus Supplement dated December 6, 2018.

Table Of Contents

ABOUT THIS PROSPECTUS SUPPLEMENT

You should rely only on the information provided in this prospectus supplement and the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under "Incorporation of Information by Reference" on page S-74 of this prospectus supplement. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell, or a solicitation of an offer to purchase, the securities offered by this prospectus supplement and the accompanying prospectus in any jurisdiction where it is unlawful to make such offer or solicitation. You should not assume that the information contained in this prospectus supplement or the accompanying prospectus, or any document incorporated by reference in this prospectus supplement or the accompanying prospectus, is accurate as of any date other than the date on the front cover of the applicable document. Neither the delivery of this prospectus supplement nor any distribution of securities pursuant to this prospectus supplement shall, under any circumstances, create any implication that there has been no change in the information set forth or incorporated by reference into this prospectus supplement or in our affairs since the date of this prospectus supplement. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus supplement and the accompanying prospectus form part of the registration statements (Nos. 333-226278 and 333-209702) that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. This document comprises two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, gives more general information, some of which may not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. If the description of the offering varies between this prospectus supplement and the accompanying prospectus or the documents incorporated herein by reference filed prior to the date of this prospectus supplement, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

Before purchasing any securities, you should carefully read both this prospectus supplement and the accompanying prospectus, together with the additional information described under the headings, "Where You Can Find More Information" and "Incorporation of Information by Reference," on page S-74 of this prospectus supplement.

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

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

We are offering to sell, and seeking offers to buy, ADSs representing our ordinary shares only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the ADSs in certain jurisdictions may be restricted by law. Persons outside the U.S. who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the ADSs and the distribution of this prospectus supplement and the accompanying prospectus outside the U.S. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein and therein 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, certain sections of this prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein contain information obtained from independent industry and other sources that we have not independently verified. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Our ability to predict our operating results or the effects of various events on our operating results is inherently uncertain. Therefore, we caution you to consider carefully the matters described under the caption "Risk Factors" on page S-14 of this prospectus supplement, and certain other matters discussed in this prospectus supplement, the accompanying prospectus, and the information incorporated by reference herein and therein, and other publicly available sources. Such factors and many other factors beyond our control could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements that may be expressed or implied by the 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 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 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;
- 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.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information about us, this offering and information contained in greater detail elsewhere in this prospectus supplement, the accompanying prospectus, any free writing prospectus that we have authorized for use, and in the documents incorporated by reference. This summary is not complete and does not contain all of the information that you should consider before investing in our ADSs. You should carefully read and consider this entire prospectus supplement, the accompanying prospectus and the documents, including financial statements and related notes, and information incorporated by reference into this prospectus supplement, including the financial statements and "Risk Factors" starting on page S-14 of this prospectus supplement, before making an investment decision. If you invest in our securities, you are assuming a high degree of risk.

Our Business

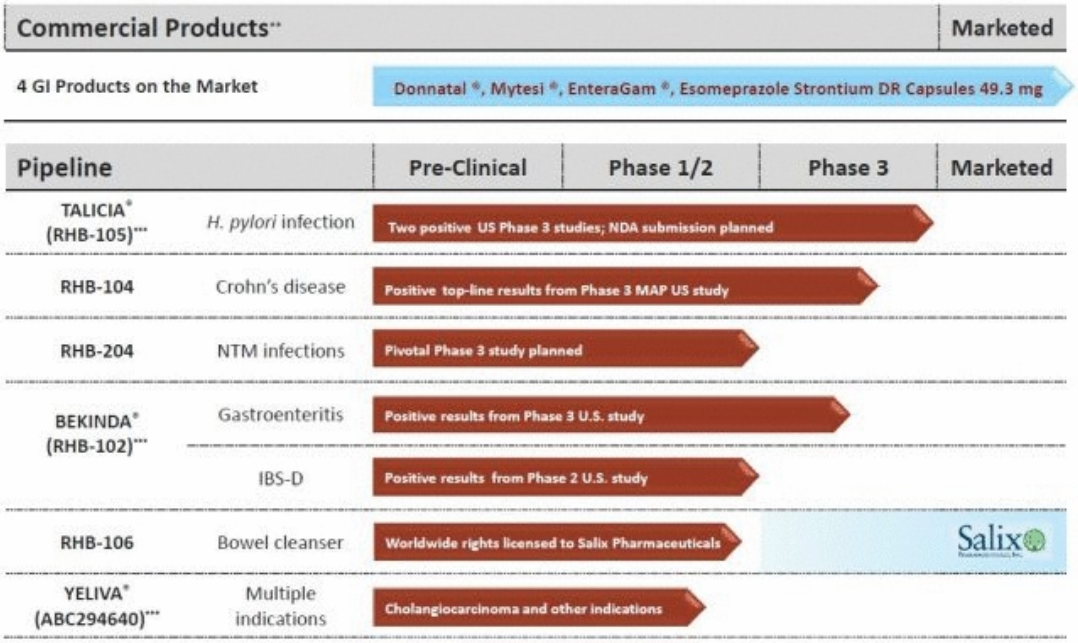
We are a specialty biopharmaceutical company primarily focused on late-clinical stage development, promotion and commercialization of proprietary drugs for gastrointestinal ("GI") diseases.

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.

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. Under agreements with third parties, 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 49.3mg and commercializes EnteraGam® (serum-derived bovine immunoglobulin/protein isolate ("SBI")).

Product Pipeline*

The table below summarizes our current pipeline of products and product candidates, as well as the target indication.



** Estimated timeline/indication in the pipeline is subject to changes in development plans and regulatory requirements/clarifications, including complementary /additional studies*

*** For full prescribing information see: Donnatal: www.Donnatal.com; Mytesi: www.Mytesi.com; Esomeprazole Strontium DR Capsules 49.3 mg: http://www.esostrontium.com; EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI), which is a medical food that must be administered under medical supervision: https://bit.ly/2N3q7DW*

**** BEKINDA®, YELIVA® and TALICIA® are proposed tradenames which are subject to FDA review and approval*

Our Product Candidates

TALICIA® (RHB-105)

In June 2017, we initiated a confirmatory Phase III study with TALICIA® (RHB-105) for the treatment of *Helicobacter pylori* ("*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 (43% 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, preliminary results from the open-label part of the ERADICATE Hp2 Phase 3 study showed 64% 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.

RedHill will continue to analyze the top-line data from the ERADICATE Hp2 study, including antibiotic susceptibility and resistance, and plans 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 a U.S. New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for TALICIA® in the first half of 2019.

In November 2014, TALICIA® was granted Qualified Infectious Disease Product ("QIDP") designation and Fast-Track development designation by the FDA, including eligibility for six-month priority review and a total of eight years of U.S. market exclusivity. The QIDP designation was granted under the Generating Antibiotic Incentives Now (GAIN) Act, which was passed as part of the FDA Safety and Innovation Act, and 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.

RHB-104

In July 2018, we announced positive top-line safety and efficacy results from the first Phase III study with RHB-104 for Crohn's disease (the "MAP US study"). The study successfully met its primary endpoint and key secondary endpoints. In October 2018, we reported additional positive data from the MAP US study, including endoscopic healing and subgroup analysis of treatment with and without anti-TNF agents and new positive week 26 remission data, presented at United European Gastroenterology Week 2018.

The randomized, double-blind, placebo-controlled first Phase III 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.

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 (37% vs. 23%, $p= 0.007$).

The study also successfully met key secondary endpoints, demonstrating consistent benefit to Crohn's disease patients treated with RHB-104. RHB-104 was found to be generally safe and well tolerated.

We will continue to assess additional exploratory endpoints as data becomes available.

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 III 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 III 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 population pharmacokinetic study is ongoing as part of the Phase III MAP US study. We also continue to advance the development program for a companion diagnostic for the detection of *Mycobacterium avium paratuberculosis* ("MAP") bacteria in Crohn's disease patients in collaboration with several U.S. universities and with Q^2 Solutions, although we do not know if and when such a diagnostic test would become available.

RHB-204

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

BEKINDA® (RHB-102)

Acute Gastroenteritis and Gastritis

In June 2017, we announced positive top-line results from the randomized, double-blind, placebo-controlled Phase III study (the "GUARD study") with BEKINDA® (RHB-102) 24 mg for 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 efficacy and safety 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 III study to support a potential NDA with BEKINDA® 24 mg for acute gastroenteritis and gastritis.

Diarrhea-predominant Irritable Bowel Syndrome ("IBS-D")

In January 2018, we announced positive final results from the Phase II clinical study of BEKINDA® (RHB-102) 12 mg for the treatment of IBS-D. The randomized, double-blind, placebo-controlled Phase II study evaluated the efficacy and safety of BEKINDA® 12 mg in 126 subjects over 18 years old at 16 clinical sites in the U.S. The BEKINDA® 12 mg Phase II 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. In September 2018, we announced that we concluded a positive End-of-Phase II/Pre-Phase III (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 III studies with BEKINDA® 12 mg for the treatment of IBS-D.

YELIVA® (Opaganib, ABC294640)

A Phase IIa clinical study with YELIVA ® in patients with advanced, unresectable, intrahepatic, perihilar and extrahepatic cholangiocarcinoma is ongoing at Mayo Clinic's major campuses in Arizona and Minnesota, University of Texas MD Anderson Cancer Center, the Huntsman Cancer Institute, University of Utah Health and at Emory University. In September 2018, we announced that the study achieved its pre-specified efficacy goal 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 39 evaluable patients, with enrollment expected to be completed by mid-2019. 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 upon submission of a potential NDA and, if approved, a seven-year marketing exclusivity period (subject to certain exceptions) for the treatment of cholangiocarcinoma.

A Phase Ib/II study with YELIVA® for the treatment of refractory or relapsed multiple myeloma is ongoing at Duke University Medical Center. Enrollment for the Phase Ib portion of the study has been completed with a total of 11 patients enrolled and treated in three dose cohorts. Results from the Phase Ib portion of the study did not show any dose-limiting toxicities. Additionally, while efficacy was not the primary endpoint of the Phase I 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.

An investigator sponsored Phase II study with YELIVA ® for the treatment of advanced hepatocellular carcinoma 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 sponsored by Dr. Carolyn D. Britten, MD and 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.

RHB-107 (formerly MESUPRON)

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

We are also working on several oncology projects, evaluating multiple clinical candidates including RHB-107 as a component spanning oncology and inflammatory digestive disease indications where a strong unmet medical need exists.

In October 2017, the FDA granted RHB-107 orphan drug designation for the adjuvant treatment of pancreatic cancer, allowing us to benefit from various incentives to develop RHB-107 for this indication and, if approved, a seven-year marketing exclusivity period (subject to certain exceptions) for the adjuvant treatment of pancreatic cancer.

RHB-106

In April 2018, we and Salix Pharmaceuticals ("Salix"), which has been acquired by Valeant Pharmaceuticals International, Inc. and renamed as Bausch Health Companies Inc. ("Bausch Health"), amended our 2014 worldwide license agreement relating to the RHB-106 encapsulated bowel cleanser, as well as additional related rights. The amendment clarifies the development efforts to be used by Salix and provides for enhanced involvement by us 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 continue to assist Salix in the development of RHB-106, as needed. We have agreed to pay a percentage of the amounts received by us from Salix to the third party from which we acquired the rights to RHB-106.

Our Commercial Products in the U.S.

We have established the headquarters of our U.S. commercial operations in Raleigh, North Carolina. Our U.S. operations are intended to set the stage for the potential launch of our proprietary, late-clinical stage GI products, if approved by the FDA.

In December 2016, we entered into a co-promotion agreement (the "Concordia Co-Promotion Agreement") with a subsidiary of Concordia International Corp ("Concordia"), recently renamed as ADVANZ PHARMA, for the promotion of Donnatal® (Phenobarbital, Hyoscyamine 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 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. We commenced promotional activities for Donnatal® in June 2017.

In April 2017, we entered into a license agreement with Entera Health Inc. ("Entera Health") pursuant to which we were granted exclusive commercialization U.S. rights to EnteraGam®. EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is promoted as a 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.

In August 2017, we entered into a commercialization agreement with ParaPRO LLC ("ParaPRO"), an Indiana-based specialty pharmaceutical company, granting us the exclusive rights to promote Esomeprazole Strontium Delayed-Release Capsules 49.3mg to gastroenterologists in certain U.S. territories. Esomeprazole Strontium Delayed-Release Capsules 49.3mg is a FDA-approved prescription proton pump inhibitor (PPI) drug product indicated for adults for the treatment of gastroesophageal reflux disease ("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 49.3mg in selected U.S. territories.

In June 2018, we entered into a co-promotion agreement with Napo Pharmaceuticals, Inc. ("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 primary care physicians. 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, for a one-month period for a total of seven months, ending in January 2019. In July 2018, we initiated the promotion of Mytesi® in the U.S.

Our GI-focused sales force consists of approximately 40 sales representatives. The net revenues for the nine months ended September 30, 2018 from the commercial products were approximately $7.0 million. We continue to pursue the acquisition of additional commercial GI products in the U.S., including, without limitation, through a 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 products in the U.S.

Expanded Access Program (EAP)

We have adopted an Expanded Access Program ("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.

Corporate Information

We were incorporated as a limited liability company under the laws of the State of Israel on August 3, 2009. Our principal executive offices are located at 21 Ha'arba'a Street, Tel Aviv, Israel and our telephone number is +972 (3) 541-3131. Our web site address is http://www.redhillbio.com. The information on, or that can be accessed through, our web site does not constitute part of this prospectus. Our registered agent in the U.S. is RedHill Biopharma Inc. The address of RedHill Biopharma Inc. is 8045 Arco Corporate Drive, Raleigh, NC 27617.

THE OFFERING

ADSs offered by us in the offering	2,857,143 ADSs representing 28,571,430 Ordinary Shares (3,285,714 ADSs representing 32,857,140 Ordinary Shares if the underwriters exercise their option to purchase additional ADSs in full).
Total Ordinary Shares outstanding immediately after this offering	283,686,908 Ordinary Shares. If the underwriters exercise their option in full, the total Ordinary Shares outstanding immediately after this offering will be 287,972,618 Ordinary Shares.
The ADSs	Each ADS represents 10 Ordinary Shares. The ADSs initially will be evidenced by American Depositary Receipts ("ADRs"), issued and delivered by The Bank of New York Mellon, as depositary (the "Depositary"). The Depositary, as depositary, or its nominee, will be the holder of the Ordinary Shares underlying your ADSs and you will have rights as provided in the Deposit Agreement dated as of December 26, 2012, among us, The Bank of New York Mellon, as Depositary, and all owners and holders from time to time of ADSs issued thereunder (the "Deposit Agreement"), a form of which has been filed as Exhibit 1 to the Registration Statement on Form F-6 filed by the Depositary with the SEC on December 6, 2012. Subject to the terms of the Deposit Agreement and compliance with the relevant requirements set out in the prospectus, you may turn in your ADSs to the Depositary for cancellation and withdrawal of the Ordinary Shares underlying your ADSs. The Depositary will charge you fees for such cancellations pursuant to the Deposit Agreement. You should carefully read the "Description of American Depositary Shares" section of the accompanying prospectus and the Deposit Agreement to better understand the terms of the ADSs.
Offering Price	The public offering price is $7.00 per one ADS.
Option to purchase additional ADSs	We have granted the underwriters an option to purchase up to an additional 428,571 ADSs representing 4,285,710 Ordinary Shares.

Use of Proceeds	We intend to use the net proceeds from the offering, together with our existing cash and cash equivalents, to fund preparations for TALICIA® (*H. pylori*) commercial launch and commercialization activities, clinical development programs, including initiation of a pivotal Phase III study with RHB-204 for NTM, preparations for a second Phase III study with RHB-104 for Crohn's disease and for acquisitions and general corporate purposes. See "Use of Proceeds" for additional information.
Listing	Our ADSs are listed on The NASDAQ under the symbol "RDHL" and our Ordinary Shares currently trade on the TASE in Israel under the symbol "RDHL".
Risk Factors	Before deciding to invest in our ADSs, you should carefully consider the risks related to our business, the offering and our securities, and our location in Israel. See "Risk Factors" on page S-14 of this prospectus supplement.
Dividend Policy	We have never declared or paid any cash dividends to our shareholders, and we currently do not expect to declare or pay any cash dividends in the foreseeable future. See "Dividend Policy."
Depositary	The Bank of New York Mellon

The number of Ordinary Shares to be outstanding immediately after the offering as shown above is based on 255,115,478 Ordinary Shares outstanding as of November 30, 2018, and excludes, as of such date (i) 29,985,863 Ordinary Shares issuable upon the exercise of outstanding options to purchase 29,985,863 Ordinary Shares at a weighted average exercise price of $1.032 per share (equivalent to 2,998,586 ADSs at a weighted average exercise price of $10.32 per ADS), and (ii) 20,254,580 Ordinary Shares issuable upon the exercise of outstanding non-tradable warrants to purchase 20,254,580 Ordinary Shares at an exercise price of $1.333 per share (equivalent to 2,025,458 ADSs at an exercise price of $13.33 per ADS).

Unless otherwise stated, outstanding share information throughout this prospectus supplement excludes such outstanding securities. Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their option to purchase an additional 428,571 ADSs.

SUMMARY FINANCIAL DATA

We derived the summary financial statement data for the years ended December 31, 2015, 2016 and 2017 set forth below from our audited financial statements and related notes incorporated by reference in this prospectus supplement and the accompanying prospectus. We derived the summary financial statement data as of September 30, 2018 and for the nine months ended September 30, 2017 and 2018 from our unaudited condensed interim financial statements and related notes incorporated by reference in this prospectus supplement and the accompanying prospectus. Our results for interim periods are not necessarily indicative of the results that may be expected for the entire year. You should read the information presented below together with our financial statements, the notes to those statements and the other financial information incorporated by reference in this prospectus supplement and the accompanying prospectus.

	Year Ended December 31,		
	2015	**2016**	**2017**
	(U.S. Dollars, in thousands, except per share and weighted average shares data)		
Statement of Comprehensive Loss			
Net Revenues	3	101	4,007
Cost of Revenues	-	-	2,126
Gross profit	3	101	1,881
Research and development expenses, net	17,771	25,241	32,969
Selling, marketing and business development expenses	1,386	1,555	12,014
General and administrative expenses	2,748	3,848	8,025
Other expenses	100	-	845
Operating loss	22,002	30,543	51,972
Financial income	1,124	1,548	6,505
Financial expenses	212	375	77
Financial income, net	(912)	(1,173)	(6,428)
Loss and comprehensive loss	21,090	29,370	45,544
Loss per ordinary share (in U.S. dollars) (1):			
Basic	0.19	0.23	0.26
Diluted	0.19	0.24	0.26
Number of Ordinary Shares used in computing Loss per ordinary share (in thousands):			
Basic	110,814	128,514	176,579
Diluted	111,715	128,809	176,579

	Nine Months ended September 30,	
	2017	2018
	(unaudited) (U.S. Dollars, in thousands, except per share and weighted average shares data)	
Statement of Comprehensive Loss		
Net Revenues	2,006	7,701
Cost of Revenues	1,207	2,253
Gross Profit	799	4,748
Research and development expenses, net	24,677	19,084
Selling, Marketing and Business Development Expenses	8,170	9,333
General and administrative expenses	5,513	5,619
Other expenses	45	-
Operating loss	37,606	29,288
Financial income	2,541	364
Financial expenses	66	2,212
Financial income (expenses), net	2,475	(1,848)
Loss and comprehensive loss	35,131	31,136
Loss per ordinary share (in U.S. dollars):		
Basic and Diluted	0.21	0.14
Number of Ordinary Shares used in computing Loss per ordinary share (in thousands):		
Basic and Diluted	170,990	220,560

	As of September 30, 2018	
	Actual	As Adjusted
	(unaudited) (U.S. Dollars, in thousands)	
Balance Sheet Data		
Cash and short-term investments	43,026	61,405
Working capital	36,768	55,148
Total assets	53,376	71,755
Total liabilities	13,533	13,533
Accumulated deficit	162,073	162,073
Equity	39,843	58,222

_____

(1) See Note 23 of the notes to the audited financial statements incorporated by reference in this prospectus supplement and the accompanying prospectus for an explanation of the determination of the number of shares used to compute basic and dilutive per share amounts for the years ended December 31, 2015, 2016 and 2017.

The as adjusted balance sheet data above reflects the application of the net proceeds from the sale of 2,857,143 ADSs representing 28,571,430 Ordinary Shares from this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering.

RISK FACTORS

You should carefully consider the risks described below and in our annual report on Form 20-F for the year ended December 31, 2017, as well as the other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, including our financial statements and the related notes, before you decide to buy our securities. The risks and uncertainties described below and incorporated by reference in this prospectus supplement 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 prospectus supplement, and any such additional risks, could materially adversely affect our business, financial condition or results of operations. In such case, you may lose all or part of your original investment.

Risks Related to Our Financial Condition and Capital Requirements

Since our incorporation in 2009, we have focused primarily on the development and acquisition of late-clinical development stage 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-clinical development stage therapeutic candidates. Most of our therapeutic candidates are in the late-clinical development stage and none of our therapeutic candidates are 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 Concordia. 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 primary care physicians

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 $31.1 million in the nine months ended September 30, 2018, and annual net losses of approximately $45.5 million in 2017, $29.4 million in 2016 and $21.1 million in 2015. As of September 30, 2018, we had an accumulated deficit of approximately $162.1 million. We will incur 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® and 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, 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®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and Mytesi®, 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®, Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, Mytesi® 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 EnteraGam®, and including the promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg. 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, or commercialize EnteraGam® or the products we may commercialize in the future, or 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, attract development or commercial partners and retain key personnel.

As of September 30, 2018, we had cash and short-term investments of approximately $43.0 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 may also need to raise additional capital in the future through equity or debt financing or a 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. Accordingly, we may need to raise additional capital in the future.

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 commercialize EnteraGam®, and promote Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, and to 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 a material adverse effect on our business, financial condition and results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

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

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

- the number of therapeutic candidates in development;
- the regulatory clarity and path of each of our therapeutic candidates;
- the progress, success and cost of our clinical trials and research and development programs including manufacturing;
- 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 II 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 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. Most of the products that we 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 gain an NDA approval. 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, *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 development stage: TALICIA® (RHB-105) for the treatment of *H. pylori* infection with two positive Phase III studies; RHB-104 for the treatment of Crohn's disease with positive top-line results from a first Phase III study and a completed proof-of-concept Phase IIa study for multiple sclerosis; RHB-204, with a planned pivotal Phase III study for pulmonary NTM infections; RHB-106 (out-licensed to Bausch Health) for bowel preparation; BEKINDA® (RHB-102) with positive results from a first Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; YELIVA® (ABC294640) with an ongoing Phase IIa study for cholangiocarcinoma and other ongoing studies; and RHB-107 (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 and commercialization of drugs. We may not be able to obtain marketing approval for any of our therapeutic candidates in a timely manner or at all.

Any material delay in obtaining or 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, commercialize EnteraGam®, promote Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and products that we may promote or commercialize in the future.

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 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 is cleared to be marketed and sold until a final determination regarding efficacy is made. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®.

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

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

We have limited experience in conducting and managing the clinical trials that are required to 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 does not produce favorable results, 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 business, financial condition and results of operations.

If we are unable to develop a diagnostic test for 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 business, financial condition and results of operations.

Any collaborative arrangements that we have established or may establish may not be successful, or we may otherwise not realize the anticipated benefits from these collaborations, including our out-licensing of RHB-106, commercialization of EnteraGam® as well as our promotion of Donnatal®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg. 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 commercialize RHB-106 and related rights. In addition, with respect to Donnatal®, Mytesi®, EnteraGam®, and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg, we rely on Concordia, Napo, Entera Health and ParaPRO, 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, 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;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may experience financial difficulties, making it difficult for them to fulfill their obligations to us, including payment obligations, or they may experience changes in business focus;

- our collaborators' partners may fail to secure adequate commercial supplies of our therapeutic candidates upon or after obtaining marketing approval, if at all, 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;
- 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 illegal 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 business, financial condition or results of operations.

As a result of Concordia's debt obligations, its recapitalization and its delisting from The Nasdaq Stock Market in July 2018, we are subject to the additional risks that Concordia may delay, reduce or cease payments to us under the Concordia Co-Promotion Agreement or otherwise be unable or unwilling to meet its obligations to us under the Concordia 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 business, financial condition or results of operations.

Our co-promotion agreement with Napo for the promotion of Mytesi® may be 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 extended in November 2018, has a term of seven months and will expire, without renewal or a follow-on agreement, on January 28, 2019, 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 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.

Our current commercial products 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 due to their classification as a DESI product, which the FDA has the right to determine as ineffective and impose limitations or request withdrawal of the product from the market. Donnatal® is currently subject to the FDA's DESI proceedings to determine its effectiveness and the right to continue to be marketed in the U.S., and there is no assurance as to the outcome of such proceedings. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®. In addition, the process and timing of any FDA DESI proceedings with respect to Donnatal® are unclear. Historically, the FDA has generally permitted products to stay on the market during these proceedings, although there is no assurance as to the time of commencement of such proceedings or whether the FDA will in fact grant such permission to any future DESI-related proceedings, 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 Concordia 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 the U.S. to certain gastroenterologists and primary care physicians 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 business, financial condition and 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 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.

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 have only begun 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 promote and 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 and 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.

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 no prior experience in commercializing therapeutic candidates or marketed products on our own, which may materially increase marketing and sales expenses or cause us to be ineffective in these efforts. 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 gastroenterologists and primary care physicians 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 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. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices ("GCP"), for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected, and regulatory authorities in other jurisdictions may have similar responsibilities and requirements. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them or perform such functions independently. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial and additional costs. Accordingly, we may be materially delayed in obtaining regulatory approvals 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.

We rely on contract research organizations for the management of clinical data generated from our studies, including the MAP US study, 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 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 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 the MAP US study 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 the MAP US study. Replacing a contract research organization may result in a delay of the MAP US study. 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 regarding RHB-104.

If third parties do not manufacture our 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 our 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, and expect to continue to rely, on third parties to manufacture clinical and commercial quantities of our therapeutic candidates and products that we may promote or commercialize. For Donnatal®, we rely on Concordia, which has a manufacturing agreement with a third party to provide sufficient quantities of Donnatal® in the required timeframe. 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, we or our partners may be required to replace them, in which event we may incur added costs and delays in identifying, engaging, qualifying and training any such replacements, and such additional costs and delays may adversely impact our ability to obtain regulatory clearances and approvals to commercialize our therapeutic candidates or any product we may 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 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 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 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.

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 and 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, if required at all, and our reputation, business, financial condition and 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 but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate or any product we may promote or commercialize, including our current commercial products.

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, 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 November 2014, the FDA granted TALICIA® QIDP designation. In January 2017, we announced that RHB-204 had been granted QIDP designation by the FDA for the treatment of NTM infections. If TALICIA® and/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.

In addition, third-party manufacturers and the manufacturing facilities that we and our development or commercialization partners use to manufacture any therapeutic candidate and any 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 and 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 development stage 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 business, financial condition and 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 business, financial condition and 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 primary care physicians in the U.S. 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 business, financial condition and 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 business, financial condition and results of operations. We manage a large portfolio of patents and may decide to discontinue maintaining certain patents in certain territories for various reasons, 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 business, financial condition and 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 recent 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 business, financial condition and results of operation. 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 business, financial condition and 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.

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, illegal 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 Concordia is pursuing legal remedies in an attempt to stop the sale of illegal 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, he 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 business, financial condition and 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 business, financial condition and results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, the states have a choice as to whether they will expand the number of individuals covered by their respective state Medicaid programs. Some states have 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 business, financial condition and results of operations.

Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, 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 enacted legislation that repeals certain portions of the Healthcare Reform Law, including 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 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 and/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, imposed. Commercial coverage for Mytesi® has been limited and Mytesi® reimbursement currently relies mostly on government reimbursement programs, which vary on a state-by-state basis. 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 business, financial condition and 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 business, financial condition and 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 business, financial condition and results of operations.

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

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 and results of operations.

The Healthcare Reform Law also imposes reporting requirements on certain medical device and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members. Failure to submit required information may result in civil monetary penalties 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 business, financial condition and results of operations by promoting a reduction in drug prices. As such, patients may choose to use other low-cost, established drugs or therapies.

The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and guidance. We cannot predict the impact that new legislation or any changes in existing legislation will have on our 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 and 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 and 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 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. Further, all of our marketing and promotional materials must comply with the FDA's extensive regulations pertaining to advertising and promotions, including, but not limited to, restrictions on pre-approval marketing, "fair balance" requirements, and inclusion of adequate instructions for use based on the uses for which our products were approved. If the FDA investigates our marketing and promotional materials and finds that any of our current or future commercial products are being marketed or promoted in a manner that is not in compliance with the applicable regulatory restrictions, we could be subject to enforcement action and/or false advertising consumer lawsuits. For example, 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, any such lawsuit or 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 and 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.

If serious adverse events or other undesirable side effects are identified during the use of our investigational new drugs that have not yet received regulatory marketing approval under the EAP, it may adversely affect our development of such therapeutic candidates.

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 method 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 a 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.

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 business, financial condition and results of operations.

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

In addition to infringement claims against us, we may become a party to other patent litigation or proceedings before regulatory agencies, including 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

Although we do not anticipate being a "passive foreign investment company" for U.S. federal income tax purposes, it is possible that we may be a "passive foreign investment company", which could result in adverse U.S. federal income tax consequences to U.S. investors.

Although we do not anticipate being a passive foreign investment company, or PFIC for 2018, the determination of PFIC status is fact-specific and generally cannot be made until the close of the taxable year in question, based on the value and composition of our assets, and it is possible that we may be a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. Because the value of our assets for purposes of this determination will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies") holds Ordinary Shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Each U.S. Holder is 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 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, geo-political 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 November 30, 2018, we had options to purchase 29,955,863 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 November 30, 2018, there were 8,562,512 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 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 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.

Since we are an "emerging growth company," as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act (and the rules and regulations of the SEC thereunder). We will no longer qualify as an emerging growth company commencing December 31, 2018, and as these exemptions will soon cease to apply, we have begun to incur and expect to incur additional expenses and devote increased management effort toward ensuring compliance with such reporting requirements, which may be 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 home country practice in Israel with regard to, among other things, director nomination procedures and quorum at shareholders' meetings. In addition, we follow our home country law, instead of The NASDAQ Listing Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans, an issuance that will result in a change of control, 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, commencing with our annual report for the year ending December 31, 2018, 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 and time-consuming. While our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2017, 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. Failure to maintain effective internal control over financial reporting could result in investigation or sanctions by regulatory authorities and could have a material adverse effect on our reputation, business, financial condition, results of operations, and investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our Ordinary Shares and ADSs to decline.

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

We currently anticipate that we will retain future earnings, 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, which could adversely affect their interests.

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

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

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

Risks Related to our Operations in Israel

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

We are incorporated under the laws of the State of Israel, 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 and 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 on 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 the currency fluctuation risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

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

Our 2010 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 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.

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 and 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.

Risks Related to this Offering

We will have broad discretion in how to use the net proceeds of this offering, and we may not use these proceeds in a manner desired by our investors.

We will have broad discretion as to the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity as part of your investment decision to assess whether the proceeds are being used appropriately. Our needs may change as the business and the industry that we address evolves. As a result, the proceeds to be received in this offering may be used in a manner significantly different from our current expectations. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

You will experience immediate dilution in book value of any ADSs you purchase.

Because the price per ADS being offered is substantially higher than our net tangible book value per ADS, you will suffer substantial dilution in the net tangible book value of any ADSs you purchase in this offering. After giving effect to the sale by us of 2,857,143 ADSs in this offering, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering, our as adjusted net tangible book value would be $52.9 million, or approximately $1.87 per ADS, as of September 30, 2018. If you purchase ADSs in this offering, you will suffer immediate and substantial dilution of approximately $5.13 per ADS. If the underwriters exercise their option to purchase additional ADSs, you will experience additional dilution. See "Dilution" on page S-53 for a more detailed discussion of the dilution you will incur in connection with this offering.

***ADSs representing a substantial percentage of our outstanding shares may be sold in this offering, which could cause the price of our ADSs and Ordinary Shares* to *decline*.**

Pursuant to this offering, we will sell 2,857,143 ADSs representing 28,571,430 Ordinary Shares, or approximately 11% of our outstanding Ordinary Shares as of November 30, 2018. These sales and any future sales of a substantial number of ADSs in the public market, or the perception that such sales may occur, could materially adversely affect the price of our ADSs and Ordinary Shares. We cannot predict the effect, if any, that market sales of those ADSs or the availability of those ADSs for sale will have on the market price of our ADSs and Ordinary Shares.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of 2,857,143 of our ADSs representing 28,571,430 Ordinary Shares in this offering will be approximately $18.4 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering. If the underwriters' option to purchase additional ADSs is exercised in full, we estimate that we will receive net proceeds of approximately $21.2 million, after deducting underwriter discounts and commissions and estimated offering expenses payable by us in connection with this offering.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund preparations for TALICIA® (*H. pylori*) commercial launch and commercialization activities, clinical development programs, including initiation of a pivotal Phase III study with RHB-204 for NTM, preparations for a second Phase III study with RHB-104 for Crohn's disease and for acquisitions and general corporate purposes.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the progress of our development and commercialization efforts, the status of and results from our clinical trials, whether or not we enter into strategic collaborations or partnerships, and our operating costs and expenditures. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering. In addition, while we have not entered into any binding agreements or commitments relating to any significant transaction as of the date of this prospectus supplement, we may use a portion of the net proceeds to pursue acquisitions, joint ventures and other strategic transactions.

DILUTION

If you invest in our ADSs, your interest will be diluted immediately to the extent of the difference between the public offering price per ADS and our as-adjusted net tangible book value per ADS after this offering.

Our net tangible book value as of September 30, 2018 was approximately $34.6 million, or approximately $1.35 per ADS. Net tangible book value per ADS represents the amount of our total tangible assets less total liabilities divided by the total number of our Ordinary Shares outstanding as of September 30, 2018 and multiplying such amount by 10 (one ADS represents 10 Ordinary Shares).

After giving effect to the sale of our ADSs offered by this prospectus supplement at the public offering price of $7.00 per ADS, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering, our as adjusted net tangible book value as of September 30, 2018 would have been approximately $52.9 million, or approximately $1.87 per ADS. This represents an immediate increase in net tangible book value of approximately $0.52 per ADS to our existing security holders and an immediate dilution of approximately $5.13 per ADS to purchasers of our ADSs in this offering, as illustrated by the following table:

Public offering price per ADS		$ 7.00
Net tangible book value per ADS as of September 30, 2018	$ 1.35	
Increase in net tangible book value per ADS attributable to this offering	$ 0.52	
As-adjusted net tangible book value per ADS as of September 30, 2018 after giving effect to this offering		$ 1.87
Dilution per ADS to new investors purchasing our ADSs in this offering		$ 5.13

If the underwriters exercise in full their option to purchase 428,571 additional ADSs at the public offering price of $7.00 per ADS, the as-adjusted net tangible book value after this offering would be approximately $1.94 per ADS, representing an increase in net tangible book value of approximately $0.59 per ADS to existing security holders and immediate dilution in net tangible book value of approximately $5.06 per ADS to new investors purchasing our ADSs in this offering at the public offering price.

The number of Ordinary Shares to be outstanding after this offering is based on 255,106,104 Ordinary Shares outstanding as of September 30, 2018, and excludes as of such date (i) 29,790,237 Ordinary Shares issuable upon the exercise of outstanding options to purchase 29,790,237 Ordinary Shares at a weighted average exercise price of $1.033 per share (equivalent to 2,979,023 ADSs at a weighted average exercise price of $10.33 per ADS), and (ii) 20,254,580 Ordinary Shares issuable upon the exercise of outstanding non-tradable warrants to purchase 20,254,580 Ordinary Shares at an exercise price of $1.33 per share (equivalent to 2,025,458 ADSs at a weighted average exercise price of $13.33 per ADS).

The as-adjusted information discussed above is illustrative only. Our net tangible book value following the completion of the offering is subject to further adjustment based on the actual offering price of our ADSs and other terms of this offering determined at pricing.

CAPITALIZATION AND INDEBTEDNESS

The following table sets forth our total capitalization as of September 30, 2018:

- on an actual basis; and
- on an as-adjusted basis to reflect the sale of 2,857,143 ADSs representing 28,571,430 Ordinary Shares in this offering, and the receipt by us of net proceeds of approximately $18.4 million, after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us in connection with this offering.

The information set forth in the following table should be read in conjunction with and is qualified in its entirety by reference to the audited and unaudited financial statements and notes thereto incorporated by reference in this prospectus supplement and the accompanying prospectus.

	As of September 30, 2018	
(In thousands, except share data)	*Actual*	*As Adjusted*
	(unaudited)	
Total debt (1)	$ 13,533	$ 13,533
Ordinary shares, par value NIS 0.01 per share	690	767
Additional paid-in capital	201,226	219,528
Accumulated deficit	162,073	162,073
Total shareholders' equity	$ 39,843	$ 58,222
Total capitalization	$ 53,376	$ 71,755

(1) Represents $10,997 thousand reported as current liabilities, which mainly consists of accounts payable and accrued expenses, and $2,536 thousand of derivative financial instrument reported as non-current liabilities, which represents non-tradable warrants.

The number of shares in the above table is based on 255,106,104 Ordinary Shares outstanding as of September 30, 2018, and excludes as of such date (i) 29,790,237 Ordinary Shares issuable upon the exercise of outstanding options to purchase 29,790,237 Ordinary Shares at a weighted average exercise price of $1.033 per share (equivalent to 2,979,023 ADSs at a weighted average exercise price of $10.33 per ADS), and (ii) 20,254,580 Ordinary Shares issuable upon the exercise of outstanding non-tradable warrants to purchase 20,254,580 Ordinary Shares at an exercise price of $1.33 per share (equivalent to 2,025,458 ADSs at a weighted average exercise price of $13.33 per ADS).

DIVIDEND POLICY

We have never declared or paid any cash dividends to our shareholders. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

MATERIAL TAX CONSIDERATIONS

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 Ordinary Shares and ADSs of our company.

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of Ordinary Shares and ADSs of our company. 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 Ordinary Shares or ADSs being offered hereby, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

The Israeli corporate tax rate applicable to Israeli resident companies is 23% in 2018.

Taxation of Shareholders

Capital Gains

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

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

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income which is 23% in 2018, and a marginal tax rate of up to 47% in 2018 for individuals, not including excess tax (as discussed below).

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

In addition, the sale of the Ordinary Shares or ADSs may be exempt from Israeli capital gains tax under the provisions of an applicable double tax treaty. For example, the Convention between the Government of the U.S. and the Government of the State of Israel with respect to Taxes on Income (the "U.S.-Israel Double Tax Treaty") exempts a U.S. resident (for purposes of the treaty) from Israeli capital gains tax in connection with the sale of the Ordinary Shares or ADSs, 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, 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 Ordinary Shares or ADSs, including the purchaser, the Israeli stockbroker or the financial institution through which the Ordinary Shares or ADSs are held, are obligated, subject to certain exemptions, to withhold tax upon the sale of Ordinary Shares or ADSs.

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

Dividends

Dividends distributed by a company to a shareholder who is an Israeli resident individual will be generally subject to income tax at a rate of 25%. However, a 30% tax rate will generally 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 not be subject to 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 Israeli 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 641,880 for 2018, 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.

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 U.S. federal income 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; and
- persons whose functional currency is not the U.S. dollar.

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 address any 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 our Ordinary Shares or ADSs.

For purposes of this summary, a "U.S. Holder" means a beneficial owner of an Ordinary Share or ADSs 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.

Taxation of ADSs

Exchange of ADSs for Ordinary Shares

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

Distributions

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

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

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

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

Sale or Other Disposition of Ordinary Shares or ADSs

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

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

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

Medicare Tax on Unearned Income

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

Passive Foreign Investment Companies

Although we do not anticipate being classified as a PFIC for U.S. federal income tax purposes for our current taxable year, because the PFIC determination is not made until the close of the year, it is possible that we may be classified as a PFIC for the current and future taxable years. A non-U.S. corporation is considered a PFIC for any taxable year if either:

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

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

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of our Ordinary Shares, our PFIC status will depend in large part on the market price of the Ordinary Shares, which may fluctuate significantly. Based on our retention of a significant amount of cash and cash equivalents, and depending on the market price of our Ordinary Shares, 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 or Ordinary Shares, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold the ADSs or Ordinary Shares, unless we cease to be a PFIC and you make a "deemed sale" election with respect to the ADSs or Ordinary Shares you hold. If such election is made, you will be deemed to have sold the ADSs or Ordinary Shares 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 or Ordinary Shares 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 for which 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 or Ordinary Shares, 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 or Ordinary Shares 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 or Ordinary Shares:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs or Ordinary Shares,
- 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, will 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 thereto

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

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

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

Unless otherwise provided by the 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 "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.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated December 6, 2018, among us and Ladenburg Thalmann and Nomura Securities International, Inc., as representatives of the several underwriters named below (the "Representatives"), we have agreed to sell to the underwriters, and each of the underwriters have agreed to purchase from us, severally and not jointly, the ADSs shown opposite its name below:

Underwriter	Number of ADSs
Ladenburg Thalmann & Co. Inc.	1,571,430
Nomura Securities International, Inc.	714,286
H.C. Wainwright & Co.	428,571
LifeSci Capital LLC	57,143
Ascendiant Capital Markets	28,571
SMBC Nikko Securities America, Inc.	28,571
WBB Securities LLC	28,571
Total	2,857,143

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the ADSs if any of them are purchased. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the ADSs subject to their acceptance of the ADSs from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority. The underwriters may offer and sell the ADSs through certain of their affiliates or selling agents.

Settlement

We expect to deliver the ADSs against payment for the ADSs on or about December 11, 2018, which will be the third business day following the date of the pricing of the ADSs (such settlement cycle being referred to as T+3). Under Rule 15c6-1 of the Exchange Act, trades in secondary market generally are required to settle in two business days, unless the parties to any such trade expressly agree otherwise. Accordingly, purchasers who wish to trade ADSs prior to the second business day before the settlement date will be required, by virtue of the fact that the ADSs initially will settle in T+3, to specify alternative settlement arrangements to prevent a failed settlement. Purchasers of the ADSs who wish to trade the ADSs prior to the date of delivery hereunder should consult their own advisors.

Option to Purchase Additional ADSs

We have granted to the underwriters an option, exercisable 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of 428,571 ADSs from us at the public offering price set forth on the cover page of this prospectus supplement, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to certain conditions, to purchase a number of additional ADSs approximately proportionate to that underwriter's initial purchase commitment as indicated in the table above.

Commission and Expenses

The underwriters have advised us that they propose to offer the ADSs to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $0.252 per ADS. After the initial offering, the underwriters may change the offering price and other selling terms.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering.

	Per ADS		Total	
	Without Option to Purchase Additional ADSs	With Option to Purchase Additional ADSs	Without Option to Purchase Additional ADSs	With Option to Purchase Additional ADSs
Public offering price	$ 7.0000	$ 7.0000	$ 20,000,001	$ 22,999,998
Underwriting discounts and commissions	$ 0.4200	$ 0.4200	$ 1,200,000	$ 1,380,000
Proceeds to us, before expenses	$ 6.5800	$ 6.5800	$ 18,800,001	$ 21,619,998

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $420,000. This amount includes an additional fee that we have elected to pay to Ladenburg Thalmann based on its efforts and results of the offering of 1% of the aggregate gross proceeds we receive from this offering (excluding proceeds from Israeli investors). Banks and brokers and certain other parties in non-U.S. jurisdictions who raise capital in connection with this offering in such non-U.S. jurisdictions may be paid up to 2% from amounts received due to their efforts. Such amounts will be deducted from the above total underwriting discounts and commissions. We also have agreed to reimburse the underwriters for up to $40,000 for their legal counsel and FINRA fees. We have paid an aggregate of $75,000 in advisory fees to Nomura Securities International, Inc., an underwriter of this offering. In accordance with Financial Industry Regulatory Authority, Inc. Rule 5110, such expense reimbursements and advisory fees are deemed underwriting compensation for this offering. In no event shall the total underwriter compensation, including such discretionary additional fees and expense reimbursements, together with the underwriting discounts and commissions, exceed 8% of the offering proceeds.

Listing

Our ADSs are listed on The NASDAQ under the trading symbol “RDHL” and our Ordinary Shares currently trade on the TASE in Israel under the symbol “RDHL”.

No Sales of Similar Securities

We, our officers and our directors have agreed, subject to certain specified exceptions, not to directly or indirectly, for a period of 90 days after the date of the underwriting agreement:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open “put equivalent position” within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or otherwise dispose of, any Ordinary Shares or ADSs, options or warrants to acquire Ordinary Shares or ADSs, or securities exchangeable or exercisable for or convertible into Ordinary Shares or ADSs currently or hereafter owned either of record or beneficially,

- enter into any swap, hedge or other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of Ordinary Shares or ADSs, or securities exchangeable or exercisable for or convertible into Ordinary Shares or ADSs, or

- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus supplement without the prior written consent of the underwriters.

In addition, we and each such person agree that, without the prior written consent of the Representatives, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any Ordinary Shares or ADSs or any security convertible into or exercisable or exchangeable for Ordinary Shares or ADSs.

The restrictions in the immediately preceding paragraph do not apply in certain circumstances, including, with respect to directors and officers:

- dispositions solely in connection with the "cashless" exercise of stock options,
- transfers of Ordinary Shares or ADSs or any security convertible into or exercisable or exchangeable for Ordinary Shares or ADSs acquired in open market transactions after the completion of this offering,
- transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of our capital stock involving a change of control,
- transfers to certain affiliates,
- transfers by gift, will or intestate, or
- transfers pursuant to a so-called "living trust" or other revocable trust.

In our case, the restrictions described above do not apply in certain circumstances, including:

- certain issuances pursuant to stock option plans, stock purchase or other equity incentive plans,
- issuances upon exercise of stock options issued under such stock option or other equity incentive plans,
- issuances upon the exercise of outstanding warrants, convertible debentures and other outstanding instruments convertible into or exercisable or exchangeable for Ordinary Shares or ADSs, or
- issuances connection with strategic partnering transactions in an amount not to exceed 10% of our outstanding Ordinary Shares or ADSs.

The Representatives may, in their sole discretion and at any time or from time to time before the termination of the 90-day period release all or any portion of the securities subject to lock-up agreements.

Market Making, Stabilization and Other Transactions

The underwriters may make a market in the ADSs as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the ADSs, that you will be able to sell any of the ADSs held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the ADSs at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

A stabilizing bid is a bid for the purchase of ADSs on behalf of the underwriters for the purpose of fixing or maintaining the price of the ADSs. A syndicate covering transaction is the bid for or the purchase of ADSs on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our ADSs or preventing or retarding a decline in the market price of our ADSs. As a result, the price of our ADSs may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the ADSs originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ADSs. The underwriters are not obligated to engage in these activities and, if commenced, may end any of these activities at any time.

Passive Market Making

The underwriters may also engage in passive market making transactions in our ADSs on The NASDAQ in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of our ADSs in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our ADSs to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and, if commenced, may end passive market making activities at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by the underwriters, selling group members (if any) or their affiliates. The underwriters may agree with us to allocate a specific number of ADSs for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus supplement, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in a wide range of activities for their own accounts and the accounts of customers, which may include, among other things, corporate finance, mergers and acquisitions, merchant banking, equity and fixed income sales, trading and research, derivatives, foreign exchange, futures, asset management, custody, clearance and securities lending. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their business, the underwriters and their affiliates may, directly or indirectly, hold long or short positions, trade and otherwise conduct such activities in or with respect to debt or equity securities and/or bank debt of, and/or derivative products. Such investment and securities activities may involve our securities and instruments. The underwriters and their affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Stamp Taxes

If you purchase ADSs offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

NOTICE TO INVESTORS

Canada

This prospectus supplement constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the ADSs. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus supplement or on the merits of the ADSs and any representation to the contrary is an offence.

Canadian investors are advised that this prospectus supplement has been prepared in reliance on section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this prospectus supplement is exempt from the requirement that the Company and the underwriter(s) provide Canadian investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships that may exist between the Company and the underwriter(s) as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the ADSs in Canada is being made on a private placement basis only and is exempt from the requirement that the Company prepares and files a prospectus under applicable Canadian securities laws. Any resale of the ADSs acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the ADSs outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the ADSs will be deemed to have represented to the Company and the underwriter(s) that the investor (i) is purchasing the ADSs as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* ("NI 45-106") or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this prospectus supplement does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the ADSs and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the ADSs or with respect to the eligibility of the ADSs for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus supplement), including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defenses under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur Canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the ADSs issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area

Our shares are not intended to be offered, sold or otherwise made available to and should not be offered, sold or otherwise made available to any retail investor in the European Economic Area ("EEA"). For these purposes, a retail investor means a person who is one (or more) of: (i) a retail client as defined in point (11) of Article 4(1) of Directive 2014/65/EU (or as amended, "MiFID "II), or (ii) a customer within the meaning of Directive 2002/92/EC, where that customer would not qualify as a professional client as defined in point (10) of Article 4(1) of MiFID II, or (iii) not a qualified investor as defined in Directive 2003/71/EC (as amended, the "Prospectus Directive"). Consequently, no key information document required by Regulation (EU) No 1286/2014 (as amended, the "PRIIPs Regulation") for offering or selling the shares or otherwise making them available to retail investors in the EEA has been prepared and therefore offering or selling the shares or otherwise making them available to any retail investor in the EEA may be unlawful under the PRIIPs Regulation. This prospectus has been prepared on the basis that any offer of the shares in any Member State of the EEA will be made pursuant to an exemption under the PRIIPs Regulation. This prospectus has been prepared on the basis that any offer of the shares in any Member State of the EEA will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of the shares. This prospectus is not a prospectus for the purposes of the Prospectus Directive.

MiFID II Product Governance

Any person offering, selling or recommending the shares (a "distributor") should take into consideration the manufacturers' target market assessment; however, a distributor subject to MiFID II is responsible for undertaking its own target market assessment in respect of the shares (by either adopting or refining the manufacturers' target market assessment) and determining appropriate distribution channels.

France

Neither this prospectus nor any other offering material relating to the securities described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the securities has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the securities to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1° -or-2° -or 3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l'épargne*).
- The securities may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32) of Hong Kong. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations, and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The common stock has not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Italy

The offering of the common stock in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa), the "CONSOB," pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree No. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation No. 1197l") as amended ("Qualified Investors"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the common stock in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta púbica de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the common stock has not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of common stock in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Singapore

This prospectus has not been and will not be lodged or registered with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase of the securities may not be issued, circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to the public or any member of the public in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person as defined under Section 275(2), or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor as defined under Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for six months after that corporation or that trust has acquired the Offer Shares under Section 275 of the SFA except:

- to an institutional investor under Section 274 of the SFA or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than $200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions, specified in Section 275 of the SFA;
- where no consideration is given for the transfer; or
- where the transfer is by operation of law.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the "Swedish Financial Supervisory Authority"). Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of common stock in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for an issuance prospectus under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for a listing prospectus under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the ADSs is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors (as defined in the Prospectus Directive) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, referred to herein as the Order, and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated. Each such person is referred to herein as a Relevant Person.

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a Relevant Person should not act or rely on this document or any of its contents.

LEGAL MATTERS

Certain matters concerning this offering will be passed upon for us by Haynes and Boone, LLP, New York, New York. The validity of the securities being offered by this prospectus will be passed upon for us by Gross, Kleinhendler, Hodak, Halevy, Greenberg, Shenhav & Co., Tel Aviv, Israel. Legal counsel to the underwriters are Covington & Burling LLP, New York, New York, with respect to the U.S. law, and Gornitzky & Co., Tel Aviv, Israel, with respect to Israeli law. Members of Covington & Burling LLP are the beneficial owners of an aggregate of less than 1% of our ordinary shares.

EXPERTS

The financial statements of RedHill Biopharma Ltd. incorporated in this prospectus supplement by reference to the Annual Report on Form 20-F for the year ended December 31, 2017 have been so incorporated in reliance on the report of Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, and in accordance therewith file annual and special reports with, and furnish other information to, the SEC. The SEC maintains a web site that contains reports and other information regarding issuers that file electronically with the SEC. You may access the SEC's website at http://www.sec.gov. These SEC filings are also available to the public on the Israel Securities Authority's Magna website at www.magna.isa.gov.il and from commercial document retrieval services.

This prospectus supplement is part of the registration statements on Form F-3 filed with the SEC in connection with this offering and does not contain all of the information included in the registration statements. Whenever a reference is made in this prospectus supplement to any of our contracts or other documents, the reference may not be complete and, for a copy of the contract or document, you should refer to the exhibits that are a part of the registration statements.

INCORPORATION OF INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus supplement, which means that we can disclose important information to you by referring you to other documents which we have filed or will file with the SEC. We are incorporating by reference in this prospectus supplement the documents listed below and all amendments or supplements we may file to such documents, as well as any future filings we may make with the SEC on Form 20-F under the Securities Exchange Act of 1934, as amended before the time that all of the securities offered by this prospectus have been sold or de-registered:

- the description of our Ordinary Shares contained in our Registration Statement on Form 20-F filed with the SEC on December 26, 2012;
- our Annual Report on Form 20-F for the fiscal year ended December 31, 2017, filed with the SEC on February 22, 2018; and
- Reports on Form 6-K filed on February 22, 2018, March 19, 2018, March 20, 2018, March 26, 2018 (relating to notice and proxy statement for annual general meeting), March 27, 2018, April 9, 2018, May 1, 2018, May 2, 2018, May 4, 2018, May 7, 2018, May 8, 2018, May 14, 2018, May 29, 2018, May 30, 2018, June 28, 2018, and July 2, 2018, July 23, 2018, July 24, 2018, July 25, 2018, July 30, 2018, August 1, 2018, August 9, 2018, August 13, 2018 (two filings), August 14, 2018, August 20, 2018, August 30, 2018, September 4, 2018, September 6, 2018, September 12, 2018, October 10, 2018, October 22, 2018, October 24, 2018, October 29, 2018, November 13, 2018, November 14, 2018, December 3, 2018, December 4, 2018, and December 6, 2018.

In addition, any reports on Form 6-K submitted to the SEC prior to the termination of the offering that we specifically identify in such forms as being incorporated by reference into the registration statement of which this prospectus supplement forms a part.

Certain statements in and portions of this prospectus supplement update and replace information in the above listed documents incorporated by reference. Likewise, statements in or portions of a future document incorporated by reference in this prospectus supplement may update and replace statements in and portions of this prospectus supplement or the above listed documents.

We will provide you without charge, upon your written or oral request, a copy of any of the documents incorporated by reference in this prospectus supplement, other than exhibits to such documents which are not specifically incorporated by reference into such documents. Please direct your written or telephone requests to RedHill Biopharma Ltd., 21 Ha'arba'a Street, Tel Aviv 6473921, Israel, Attn: Micha Ben Chorin, telephone number +972 (3) 541-3131. You may also obtain information about us by visiting our website at *www.redhillbio.com*. Information contained in our website is not part of this prospectus supplement.

PROSPECTUS

$175,000,000 of
American Depositary Shares representing Ordinary Shares,
Ordinary Shares,
Warrants to Purchase American Depositary Shares,
Subscription Rights and/or Units
Offered by the Company

REDHILL BIOPHARMA LTD.

We may offer to the public from time to time in one or more series or issuances American Depositary Shares ("ADSs"), ordinary shares, warrants, subscription rights and/or units, including the securities carried forward from the Prior Shelf Registration Statement, consisting of two or more of these classes or series of securities. Each ADS represents 10 ordinary shares.

We refer to the ADSs, ordinary shares, warrants, subscription rights and units collectively as “securities” in this prospectus.

This prospectus also may be used in connection with the issuance of up to 2,025,458 ADSs issuable upon the exercise of outstanding warrants.

Each time we sell securities pursuant to this prospectus, we will provide a supplement to this prospectus that contains specific information about the offeror, the offering and the specific terms of the securities offered. This prospectus may not be used to consummate a sale of securities by us unless accompanied by the applicable prospectus supplement. You should read this prospectus and the applicable prospectus supplement carefully before you invest in our securities.

We may, from time to time, offer to sell the securities, through public or private transactions, directly or through underwriters, agents or dealers, on or off the Nasdaq Global Market or Tel Aviv Stock Exchange (the "TASE"), as applicable, at prevailing market prices or at privately negotiated prices. If any underwriters, agents or dealers are involved in the sale of any of these securities, the applicable prospectus supplement will set forth the names of the underwriter, agent or dealer and any applicable fees, commissions or discounts.

Our ordinary shares are traded on the TASE, and our ADSs are traded on the Nasdaq Global Market under the symbol “RDHL.” The last reported sale price for our ADSs on July 20, 2018 as quoted on the Nasdaq Global Market was $9.96 per ADS, and the last reported sale price for our ordinary shares on July 19, 2018 as quoted on the TASE was NIS3.93 per share, or $1.08 per share (based on the exchange rate reported by the Bank of Israel for such date).

Investing in these securities involves a high degree of risk. Please carefully consider the risks discussed in this prospectus under “Risk Factors” beginning on page 3 and the “Risk Factors” in “Item 3: Key Information- Risk Factors” of our most recent Annual Report on Form 20-F incorporated by reference in this prospectus and in any applicable prospectus supplement for a discussion of the factors you should consider carefully before deciding to purchase these securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities being offered by this prospectus, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 31, 2018

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a "shelf" registration process. Under this process, we may offer and sell our securities under this prospectus.

Under this shelf process, we may sell the securities described in this prospectus, including the securities carried forward from the Prior Shelf Registration Statement, in one or more offerings up to a total price to the public of $175,000,000. The offer and sale of securities under this prospectus may be made from time to time, in one or more offerings, in any manner described under the section in this prospectus entitled "Plan of Distribution."

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus, and may also contain information about any material federal income tax considerations relating to the securities covered by the prospectus supplement. You should read both this prospectus and any prospectus supplement together with additional information under the headings "Where You Can Find More Information" and "Incorporation of Certain Documents by Reference."

This summary may not contain all of the information that may be important to you. You should read this entire prospectus, including the financial statements and related notes and other financial data incorporated by reference in this prospectus, before making an investment decision. This summary contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause or contribute to such differences include those discussed in "Risk Factors" and "Forward-Looking Statements."

REDHILL BIOPHARMA LTD.

Overview

Our legal and commercial name is RedHill Biopharma Ltd. We were incorporated on August 3, 2009 and were registered as a private company limited by shares under the laws of the State of Israel. Our ordinary shares are traded on TASE under the symbol "RDHL" and our ADSs are traded on the Nasdaq Global Market under the symbol "RDHL". Each ADS represents 10 ordinary shares.

We are a specialty biopharmaceutical company primarily focused on late-clinical stage development and commercialization of proprietary drugs for gastrointestinal ("GI") diseases. 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.

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. Under agreements with third parties, our GI-focused sales force in the U.S. currently promotes Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) and Esomeprazole Strontium Delayed-Release Capsules 49.3mg and commercialize EnteraGam® (serum-derived bovine immunoglobulin/protein isolate ("SBI"), and we have the exclusive U.S. rights to co-promote Mytesi® (crofelemer 125 mg delayed-release tablets) to certain gastroenterologists and primary care physicians.

Our key clinical-stage development programs include: (i) TALICIA® (RHB-105) for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) RHB-104 with an ongoing first Phase III study for Crohn's disease; (iii) RHB-204**,** with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) BEKINDA® (RHB-102) with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (v) YELIVA® (ABC294640), a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (vi) RHB-106, an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) RHB-107 (formerly MESUPRON), a Phase II-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases.

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

Corporate Information

Our principal executive offices are located at 21 Ha'arba'a Street, Tel Aviv, Israel and our telephone number is +972 (3) 541-3131. Our web site address is http://www.redhillbio.com. The information on our web site does not constitute part of this prospectus. Our registered agent in the United States is RedHill Biopharma Inc. The address of RedHill Biopharma Inc. is 8045 Arco Corporate Drive, Suite 130 Raleigh, NC 27617.

RISK FACTORS

An investment in our securities involves a high degree of risk. Our business, financial condition or results of operations could be adversely affected by any of these risks. You should carefully consider the risk factors discussed under the caption "Item 3: Key Information - Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2017, and in any other filing we make with the SEC subsequent to the date of this prospectus, each of which are incorporated herein by reference, and in any supplement to this prospectus, before making your investment decision. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our ordinary shares (directly or in the form of ADSs) to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled "Forward-Looking Statements."

FORWARD-LOOKING STATEMENTS

This prospectus, including the information incorporated by reference into this prospectus, contains, and any prospectus supplement may include forward-looking statements within the meaning of Private Securities Litigation Reform Act of 1995. 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. 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 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 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 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;
- 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.

We caution you to carefully consider these risks and not to place undue reliance on our forward-looking statements. Except as required by law, we assume no responsibility for updating any forward-looking statements.

CAPITALIZATION

The table below sets forth our total capitalization as of March 31, 2018. The financial data in the following table should be read in conjunction with our financial statements and notes thereto incorporated by reference herein.

	As of March 31, 2018 Actual (in thousands)
Total debt (1) (1)	$ 10,103
Ordinary shares, par value NIS 0.01 per share	577
Additional paid-in capital	177,787
Warrants	–
Accumulated deficit	(142,073)
Total shareholders' equity	36,291
Total capitalization	$ 46,394

(1) Represents $9,705 thousand under current liabilities, mainly accounts payable and accrued expenses.

PRICE RANGE OF OUR ORDINARY SHARES

Our ordinary shares have been trading on the TASE under the symbol "RDHL" since February 3, 2011. Prior to that date, there was no public market for our ordinary shares. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date to which the high or low market price is applicable, as reported by the Bank of Israel. The following table lists the high and low closing prices for our ordinary shares for the periods indicated as reported by the TASE.

	NIS		$U.S.	
	Price per Ordinary Share		Price per Ordinary Share	
Annual Data	High	Low	High	Low
2018 (through July 19, 2018)	4.08	1.72	1.12	0.47
2017	4.16	1.59	1.08	0.45
2016	6.05	3.32	1.58	0.86
2015	7.80	4.34	2.03	1.12
2014	6.80	3.00	1.96	0.78
2013	4.29	3.23	1.15	0.92
Quarterly Data				
2018				
Third quarter (through July 19, 2018)	4.08	3.04	1.12	0.83
Second quarter	2.97	1.72	0.82	0.47
First quarter	2.27	1.76	0.66	0.50
2017				
Fourth quarter	3.80	1.59	1.07	0.45
Third quarter	3.75	2.85	1.05	0.81
Second quarter	3.79	3.00	1.04	0.86
First quarter	4.16	3.38	1.08	0.92
2016				
Fourth quarter	5.51	3.73	1.45	0.98
Third quarter	6.05	4.21	1.58	1.09
Second quarter	5.30	3.90	1.41	1.41
First quarter	5.14	3.32	1.31	0.86
Most Recent Six Months				
July 2018 (through July 19, 2018)	4.08	3.04	1.12	0.83
June 2018	2.97	2.53	0.82	0.71
May 2018	2.57	1.72	0.71	0.47
April 2018	1.83	1.72	0.52	0.48
March 2018	2.11	1.77	0.60	0.50
February 2018	2.16	1.94	0.61	0.58
January 2018	2.27	1.76	0.66	0.51

On July 19, 2018, the last reported sales price of our ordinary shares on the TASE was NIS 3.93 per share, or $1.08 per share (based on the exchange rate reported by the Bank of Israel for such date). On July 19, 2018 the exchange rate of the NIS to the U.S. dollar was $1.00 = NIS 3.65, as reported by the Bank of Israel.

PRICE RANGE OF OUR ADSs

Our ADSs were traded under the symbol “RDHL” on the Nasdaq Capital Market from December 27, 2012 through July 19, 2018, and commenced trading on the Nasdaq Global Market on July 20, 2018.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Capital Market and the Nasdaq Global Market (commencing on July 20, 2018) in U.S. dollars.

	$U.S. Price per ADS	
	High	**Low**
Annual		
2018 (through July 20, 2018)	11.35	4.82
2017	10.88	4.58
2016	16.29	8.21
2015	19.79	11.05
2014	19.20	8.03
2013	13.60	8.31
Quarter		
2018		
Third quarter (through July 20, 2018)	11.35	9.08
Second quarter	8.53	4.82
First quarter	6.84	4.96
2017		
Fourth quarter	10.81	4.58
Third quarter	10.81	8.18
Second quarter	10.38	8.44
First quarter	10.88	9.30
2016		
Fourth quarter	14.47	9.65
Third quarter	16.29	10.80
Second quarter	13.79	10.00
First quarter	12.61	8.21
Most Recent Six Months		
July 2018 (through July 20, 2018)	11.35	9.08
June 2018	8.53	7.00
May 2018	7.24	4.89
April 2018	5.21	4.82
March 2018	6.42	4.96
February 2018	6.44	5.57
January 2018	6.84	5.13

On July 20, 2018, the last reported sales price of our ADSs on the Nasdaq Global Market was $9.96 per ADS.

USE OF PROCEEDS

Unless otherwise indicated in an accompanying prospectus supplement, the net proceeds from the sale of securities will be used for general corporate purposes, including research and development related purposes in connection with our therapeutic candidates, for potential acquisitions and to support commercial operations.

DESCRIPTION OF ORDINARY SHARES

A description of our ordinary shares, par value NIS 0.01 per share, can be found in Item 10B of the Registration Statement on Form 20-F filed with the SEC on December 26, 2012.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

A description of our ADSs, each of which represents 10 of our ordinary shares, can be found in Item 12 of the Registration Statement on Form 20-F filed with the SEC on December 26, 2012.

DESCRIPTION OF WARRANTS

We may issue warrants to purchase ADS and/or ordinary shares. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. We will evidence each series of warrants by warrant certificates that we may issue under a separate agreement. We may enter into a warrant agreement with a warrant agent. We may also choose to act as our own warrant agent. We will indicate the name and address of any such warrant agent in the applicable prospectus supplement relating to a particular series of warrants. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in the applicable prospectus supplement.

The applicable prospectus supplement will describe the following terms of any warrants in respect of which this prospectus is being delivered:

- the title of such warrants;
- the aggregate number of such warrants;
- the price or prices at which such warrants will be issued and exercised;
- the currency or currencies in which the price of such warrants will be payable;
- the securities purchasable upon exercise of such warrants;
- the date on which the right to exercise such warrants shall commence and the date on which such right shall expire;
- if applicable, the minimum or maximum amount of such warrants which may be exercised at any one time;
- if applicable, the designation and terms of the securities with which such warrants are issued and the number of such warrants issued with each such security;
- if applicable, the date on and after which such warrants and the related securities will be separately transferable;
- information with respect to book-entry procedures, if any;
- any material Israeli and United States federal income tax consequences;
- the anti-dilution provisions of the warrants, if any; and
- any other terms of such warrants, including terms, procedures and limitations relating to the exchange and exercise of such warrants.

Amendments and Supplements to Warrant Agreement

We and the warrant agent may amend or supplement the warrant agreement for a series of warrants without the consent of the holders of the warrants issued thereunder to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants.

Outstanding Warrants

On December 27, 2016, in connection with an underwritten public offering and concurrent registered direct offering of our ADSs and warrants, we issued three-year warrants to purchase 2,025,458 (representing 20,254,580 ordinary shares) of our ADSs at an exercise price of $13.33 per ADS.

Exercisability. The warrants were exercisable immediately upon issuance and at any time during the following 36 months. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of ADSs purchased upon such exercise, together with applicable charges and taxes. Unless otherwise specified in the form of warrant, the holder (together with its affiliates) do not have the right to exercise any portion of the warrant, to the extent that after giving effect to the issuance after exercise, the holder would beneficially own in excess of 4.99% (which may be increased by the holder to up to 9.99%) of the number of our ordinary shares outstanding immediately after giving effect to the exercise, as such percentage is determined in accordance with the terms of the warrants. If at any time after the 6th month anniversary of the issuance date, a registration statement registering the issuance of the ADSs underlying the warrants under the Securities Act of 1933, as amended (the "Securities Act"), is not then effective or available, the holder may exercise the warrant through a cashless exercise, in whole or in part, in which case the holder would receive upon such exercise the net number of ADSs determined according to the formula set forth in the warrant. No fractional ADSs are to be issued upon the exercise of the warrants. If any fractional share of an ADS would be deliverable upon the exercise of the warrants, we, in lieu of delivering such fractional ADS, shall pay to the exercising holder an amount in cash equal to the closing sale price on the principal market of such fractional ADS on the date of exercise.

Exercise Price. The initial exercise price per ADS purchasable upon exercise of the warrants is equal to $13.33 per full ADS (which may be adjusted as set forth below). In addition to the exercise price per ADS, other applicable charges and taxes are due and payable upon exercise.

Adjustment Provisions. The exercise price and the number of ADSs issuable upon exercise are subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock subdivisions and combinations, reclassifications or similar events affecting our ADSs or ordinary shares.

Transferability. Subject to applicable laws, the warrants may be transferred at the option of the holders upon surrender of the warrants to the warrant agent, together with the appropriate instruments of transfer.

Exchange Listing. There is no established public trading market for the warrants, and we do not intend to apply to list the warrants on any securities exchange or automated quotation system.

Fundamental Transaction. If, at any time while the warrants are outstanding, (1) we consolidate or merge with or into another corporation and we are not the surviving corporation, (2) we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets, (3) any purchase offer, tender offer or exchange offer (whether by us or another individual or entity) is completed pursuant to which holders of our shares of common stock are permitted to sell, tender or exchange their shares of common stock for other securities, cash or property and has been accepted by the holders of 50% or more of our outstanding shares of common stock, (4) we effect any reclassification or recapitalization of our shares of common stock or any compulsory share exchange pursuant to which our shares of common stock are converted into or exchanged for other securities, cash or property, or (5) we consummate a stock or share purchase agreement or other business combination with another person or entity whereby such other person or entity acquires more than 50% of our outstanding shares of common stock, each, a Fundamental Transaction, then upon any subsequent exercise of the Warrants, the holders thereof will have the right to receive the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant shares then issuable upon exercise of the Warrant, and any additional consideration payable as part of the Fundamental Transaction.

Rights as a Stockholder. Except as otherwise provided in the Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrants.

DESCRIPTION OF SUBSCRIPTION RIGHTS

We may issue subscription rights to purchase our ordinary shares and/or our ADSs. These subscription rights may be issued independently or together with any other security offered hereby and may or may not be transferable by the shareholder receiving the subscription rights in such offering. In connection with any offering of subscription rights, we may enter into a standby arrangement with one or more underwriters or other purchasers pursuant to which the underwriters or other purchasers may be required to purchase any securities remaining unsubscribed for after such offering.

The prospectus supplement relating to any subscription rights we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the price, if any, for the subscription rights;
- the exercise price payable for each ordinary share and/or ADS upon the exercise of the subscription rights;
- the number of subscription rights to be issued to each shareholder;
- the number and terms of the ordinary shares and/or ADSs which may be purchased per each subscription right;
- the extent to which the subscription rights are transferable;
- any other terms of the subscription rights, including the terms, procedures and limitations relating to the exchange and exercise of the subscription rights;
- the date on which the right to exercise the subscription rights shall commence, and the date on which the subscription rights shall expire;
- the extent to which the subscription rights may include an over-subscription privilege with respect to unsubscribed securities; and
- if applicable, the material terms of any standby underwriting or purchase arrangement which may be entered into by us in connection with the offering of subscription rights.

The description in the applicable prospectus supplement of any subscription rights we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable subscription right agreement, which will be filed with the SEC if we offer subscription rights. For more information on how you can obtain copies of the applicable subscription right agreement if we offer subscription rights, see "Where You Can Find More Information" beginning on page 12. We urge you to read the applicable subscription right agreement and any applicable prospectus supplement in their entirety.

DESCRIPTION OF UNITS

We may issue units comprised of one or more of the other securities that may be offered under this prospectus, in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately at any time, or at any time before a specified date.

The prospectus supplement relating to any units we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the material terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any material provisions relating to the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- any material provisions of the governing unit agreement that differ from those described above.

The description in the applicable prospectus supplement of any units we offer will not necessarily be complete and will be qualified in its entirety by reference to the applicable unit agreement, which will be filed with the SEC if we offer units. For more information on how you can obtain copies of the applicable unit agreement if we offer units, see "Where You Can Find More Information" beginning on page 12. We urge you to read the applicable unit agreement and any applicable prospectus supplement in their entirety.

PLAN OF DISTRIBUTION

The securities being offered by this prospectus may be sold:

- through agents;
- to or through one or more underwriters on a firm commitment or agency basis;
- through put or call option transactions relating to the securities;
- in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) of the Securities Act;
- through broker-dealers;
- directly to purchasers, through a specific bidding or auction process, on a negotiated basis or otherwise;
- through any other method permitted pursuant to applicable law; or
- through a combination of any such methods of sale.

At any time a particular offer of the securities covered by this prospectus is made, a revised prospectus or prospectus supplement, if required, will be distributed which will set forth the aggregate amount of securities covered by this prospectus being offered and the terms of the offering, including the name or names of any underwriters, dealers, brokers or agents, any discounts, commissions, concessions and other items constituting compensation from us and any discounts, commissions or concessions allowed or reallowed or paid to dealers. Such prospectus supplement, and, if necessary, a post-effective amendment to the registration statement of which this prospectus is a part, will be filed with the SEC to reflect the disclosure of additional information with respect to the distribution of the securities covered by this prospectus. In order to comply with the securities laws of certain states, if applicable, the securities sold under this prospectus may only be sold through registered or licensed broker-dealers. In addition, in some states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from registration or qualification requirements is available and is complied with.

The distribution of securities may be effected from time to time in one or more transactions, including block transactions and transactions on the Nasdaq Global Market or any other organized market where the securities may be traded. The securities may be sold at a fixed price or prices, which may be changed, or at market prices prevailing at the time of sale, at prices relating to the prevailing market prices or at negotiated prices. The consideration may be cash or another form negotiated by the parties. Agents, underwriters or broker-dealers may be paid compensation for offering and selling the securities. That compensation may be in the form of discounts, concessions or commissions to be received from us or from the purchasers of the securities. Any dealers and agents participating in the distribution of the securities may be deemed to be underwriters, and compensation received by them on resale of the securities may be deemed to be underwriting discounts. If any such dealers or agents were deemed to be underwriters, they may be subject to statutory liabilities under the Securities Act.

Agents may from time to time solicit offers to purchase the securities. If required, we will name in the applicable prospectus supplement any agent involved in the offer or sale of the securities and set forth any compensation payable to the agent. Unless otherwise indicated in the prospectus supplement, any agent will be acting on a best efforts basis for the period of its appointment. Any agent selling the securities covered by this prospectus may be deemed to be an underwriter, as that term is defined in the Securities Act, of the securities.

If underwriters are used in a sale, securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale, or under delayed delivery contracts or other contractual commitments. Securities may be offered to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. If an underwriter or underwriters are used in the sale of securities, an underwriting agreement will be executed with the underwriter or underwriters, as well as any other underwriter or underwriters, with respect to a particular underwritten offering of securities, and will set forth the terms of the transactions, including compensation of the underwriters and dealers and the public offering price, if applicable. The prospectus and prospectus supplement will be used by the underwriters to resell the securities.

If a dealer is used in the sale of the securities, we or an underwriter will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. To the extent required, we will set forth in the prospectus supplement the name of the dealer and the terms of the transactions.

We may directly solicit offers to purchase the securities and may make sales of securities directly to institutional investors or others. These persons may be deemed to be underwriters within the meaning of the Securities Act with respect to any resale of the securities. To the extent required, the prospectus supplement will describe the terms of any such sales, including the terms of any bidding or auction process, if used.

Agents, underwriters and dealers may be entitled under agreements which may be entered into with us to indemnification by us against specified liabilities, including liabilities incurred under the Securities Act, or to contribution by us to payments they may be required to make in respect of such liabilities. If required, the prospectus supplement will describe the terms and conditions of the indemnification or contribution. Some of the agents, underwriters or dealers, or their affiliates may be customers of, engage in transactions with or perform services for us or our subsidiaries.

Any person participating in the distribution of securities registered under the registration statement that includes this prospectus will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the applicable SEC rules and regulations, including, among others, Regulation M, which may limit the timing of purchases and sales of any of our securities by that person. Furthermore, Regulation M may restrict the ability of any person engaged in the distribution of our securities to engage in market-making activities with respect to our securities. These restrictions may affect the marketability of our securities and the ability of any person or entity to engage in market-making activities with respect to our securities.

Certain persons participating in an offering may engage in over-allotment, stabilizing transactions, short-covering transactions, penalty bids and other transactions that stabilize, maintain or otherwise affect the price of the offered securities. These activities may maintain the price of the offered securities at levels above those that might otherwise prevail in the open market, including by entering stabilizing bids, effecting syndicate covering transactions or imposing penalty bids, each of which is described below.

- A stabilizing bid means the placing of any bid, or the effecting of any purchase, for the purpose of pegging, fixing or maintaining the price of a security.
- A syndicate covering transaction means the placing of any bid on behalf of the underwriting syndicate or the effecting of any purchase to reduce a short position created in connection with the offering.
- A penalty bid means an arrangement that permits the managing underwriter to reclaim a selling concession from a syndicate member in connection with the offering when offered securities originally sold by the syndicate member are purchased in syndicate covering transactions.

These transactions may be effected on an exchange or automated quotation system, if the securities are listed on that exchange or admitted for trading on that automated quotation system, or in the over-the-counter market or otherwise.

If so indicated in the applicable prospectus supplement, we will authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase offered securities from us at the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. Such contracts will be subject only to those conditions set forth in the prospectus supplement and the prospectus supplement will set forth the commission payable for solicitation of such contracts.

In addition, ordinary shares or ADSs may be issued upon conversion of or in exchange for debt securities or other securities.

Any underwriters to whom offered securities are sold for public offering and sale may make a market in such offered securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. The offered securities may or may not be listed on a national securities exchange. No assurance can be given that there will be a market for the offered securities.

Any securities that qualify for sale pursuant to Rule 144 or Regulation S under the Securities Act, may be sold under Rule 144 or Regulation S rather than pursuant to this prospectus.

To the extent that we make sales to or through one or more underwriters or agents in at-the-market offerings, we will do so pursuant to the terms of a distribution agreement between us and the underwriters or agents. If we engage in at-the-market sales pursuant to a distribution agreement, we will sell our ordinary shares or ADSs to or through one or more underwriters or agents, which may act on an agency basis or on a principal basis. During the term of any such agreement, we may sell ordinary shares or ADSs on a daily basis in exchange transactions or otherwise as we agree with the underwriters or agents. The distribution agreement will provide that any ordinary shares or ADSs sold will be sold at prices related to the then prevailing market prices for our ordinary shares or ADSs. Therefore, exact figures regarding proceeds that will be raised or commissions to be paid cannot be determined at this time and will be described in a prospectus supplement. Pursuant to the terms of the distribution agreement, we also may agree to sell, and the relevant underwriters or agents may agree to solicit offers to purchase, blocks of our ordinary shares, ADSs or warrants. The terms of each such distribution agreement will be set forth in more detail in a prospectus supplement to this prospectus.

In connection with offerings made through underwriters or agents, we may enter into agreements with such underwriters or agents pursuant to which we receive our outstanding securities in consideration for the securities being offered to the public for cash. In connection with these arrangements, the underwriters or agents may also sell securities covered by this prospectus to hedge their positions in these outstanding securities, including in short sale transactions. If so, the underwriters or agents may use the securities received from us under these arrangements to close out any related open borrowings of securities.

We may enter into derivative transactions with third parties or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, such third parties (or affiliates of such third parties) may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, such third parties (or affiliates of such third parties) may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of shares, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of shares. The third parties (or affiliates of such third parties) in such sale transactions will be underwriters and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).

We may loan or pledge securities to a financial institution or other third party that in turn may sell the securities using this prospectus. Such financial institution or third party may transfer its short position to investors in our securities or in connection with a simultaneous offering of other securities offered by this prospectus or in connection with a simultaneous offering of other securities offered by this prospectus.

LEGAL MATTERS

Certain legal matters with respect to Israeli law and with respect to the validity of the offered securities under Israeli law will be passed upon for us by Gross, Kleinhendler, Hodak, Halevy, Greenberg, Shenhav & Co. Certain legal matters with respect to U.S. federal securities law and New York law will be passed upon for us by Haynes and Boone, LLP.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 20-F for the year ended December 31, 2017 have been so incorporated in reliance on the report of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-3 under the Securities Act, with respect to the securities offered by this prospectus. However, as is permitted by the rules and regulations of the SEC, this prospectus, which is part of our registration statement on Form F-3, omits certain non-material information, exhibits, schedules and undertakings set forth in the registration statement. For further information about us, and the securities offered by this prospectus, please refer to the registration statement.

We are subject to the reporting requirements of the Exchange Act that are applicable to a foreign private issuer. In accordance with the Exchange Act, we file reports, including annual reports on Form 20-F by April 30 of each year. We also furnish to the SEC under cover of Form 6-K material information required to be made public in Israel, filed with and made public by any stock exchange or distributed by us to our shareholders.

The registration statement on Form F-3 of which this prospectus forms a part, including the exhibits and schedules thereto, and reports and other information filed by us with the SEC may be inspected without charge and copied at prescribed rates at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Copies of this material are also available by mail from the Public Reference Section of the SEC, at 100 F. Street, N.E., Washington D.C. 20549, at prescribed rates. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as us, that file electronically with the SEC (*http://www.sec.gov*).

As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of proxy statements to shareholders and our officers, directors and principal shareholders are exempt from the "short-swing profits" reporting and liability provisions contained in Section 16 of the Exchange Act and related Exchange Act rules.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We file annual and special reports and other information with the SEC. These filings contain important information which does not appear in this prospectus. The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to other documents which we have filed or will file with the SEC. We are incorporating by reference in this prospectus the documents listed below and all amendments or supplements we may file to such documents, as well as any future filings we may make with the SEC on Form 20-F under the Exchange Act before the time that all of the securities offered by this prospectus have been sold or de-registered:

- the description of our ordinary shares contained in our Registration Statement on Form 20-F filed with the SEC on December 26, 2012;
- our Annual Report on Form 20-F for the fiscal year ended on December 31, 2017, filed with the SEC on February 22, 2018; and
- Reports on Form 6-K filed on March 19, 2018, March 20, 2018, March 26, 2018 (relating to notice and proxy statement for annual general meeting), March 27, 2018, April 9, 2018, May 1, 2018, May 2, 2018, May 4, 2018, May 7, 2018, May 8, 2018, May 14, 2018, May 29, 2018, May 30, 2018, June 28, 2018, and July 2, 2018.

In addition, any reports on Form 6-K submitted to the SEC by the registrant pursuant to the Exchange Act after the date of the initial registration statement and prior to effectiveness of the registration statement that we specifically identify in such forms as being incorporated by reference into the registration statement of which this prospectus forms a part and all subsequent annual reports on Form 20-F filed after the effective date of this registration statement and prior to the termination of this offering and any reports on Form 6-K subsequently submitted to the SEC or portions thereof that we specifically identify in such forms as being incorporated by reference into the registration statement of which this prospectus forms a part, shall be considered to be incorporated into this prospectus by reference and shall be considered a part of this prospectus from the date of filing or submission of such documents.

Certain statements in and portions of this prospectus update and replace information in the above listed documents incorporated by reference. Likewise, statements in or portions of a future document incorporated by reference in this prospectus may update and replace statements in and portions of this prospectus or the above listed documents.

We will provide you without charge, upon your written or oral request, a copy of any of the documents incorporated by reference in this prospectus, other than exhibits to such documents which are not specifically incorporated by reference into such documents. Please direct your written or telephone requests to RedHill Biopharma Ltd., 21 Ha'arba'a Street, Tel Aviv 64739, Israel, Attn: Dror Ben-Asher, telephone number +972 (3) 541-3131. You may also obtain information about us by visiting our website at *www.redhillbio.com*. Information contained in our website is not part of this prospectus.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the State of Israel. Service of process upon us and upon our directors and officers and the Israeli experts named in this prospectus, substantially all of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because substantially all of our assets and substantially all of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of our directors and officers may not be collectible within the United States.

It may be difficult to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

Subject to specified time limitations and legal procedures, Israeli courts may enforce a United States judgment in a civil matter which, subject to certain exceptions, is non-appealable, including judgments based upon the civil liability provisions of the Securities Act and the Exchange Act and including a monetary or compensatory judgment in a non-civil matter, provided that:

- the judgments are obtained after due process before a court of competent jurisdiction, according to the laws of the state in which the judgment is given and the rules of private international law currently prevailing in Israel;
- the prevailing law of the foreign state in which the judgments were rendered allows the enforcement of judgments of Israeli courts (however, the Israeli courts may waive this requirement following a request by the attorney general);
- adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard and to present his or her evidence;
- the judgments are not contrary to public policy, and the enforcement of the civil liabilities set forth in the judgment does not impair the security or sovereignty of the State of Israel;
- the judgments were not obtained by fraud and do not conflict with any other valid judgment in the same matter between the same parties;
- an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court; and
- the obligations under the judgment are enforceable according to the laws of the State of Israel and according to the law of the foreign state in which the relief was granted.

We have irrevocably appointed RedHill Biopharma Inc. as our agent to receive service of process in any action against us in any United States federal or state court arising out of this offering or any purchase or sale of securities in connection with this offering.

If a foreign judgment is enforced by an Israeli court, it generally will be payable in Israeli currency, which can then be converted into non-Israeli currency and transferred out of Israel. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to issue a judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment, but the judgment debtor may make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily will be linked to the Israeli consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at the time. Judgment creditors must bear the risk of unfavorable exchange rates.

OFFERING EXPENSES

The following is a statement of expenses in connection with the distribution of the securities registered. All amounts shown are estimates except the SEC registration fee. The estimates do not include expenses related to offerings of particular securities. Each prospectus supplement describing an offering of securities will reflect the estimated expenses related to the offering of securities under that prospectus supplement.

SEC registration fees	$	14,557.50
FINRA fees		18,039.15
Legal fees and expenses		10,000.00
Accountants fees and expenses		5,000.00
Miscellaneous		5,000.00
Total	$	52,596.65

2,857,143 American Depositary Shares Representing 28,571,430 Ordinary Shares

RedHill Biopharma Ltd.

PROSPECTUS SUPPLEMENT

Joint Book-Running Managers

Ladenburg Thalmann **Nomura**

Lead Manager

H.C. Wainwright & Co.

Co-Managers

LifeSci Capital LLC **Ascendiant Capital Markets**

SMBC **WBB Securities**

December 6, 2018