



Press Release

RedHill Biopharma Provides 2017 Semi-Annual Business Update

- **RedHill's U.S. gastrointestinal (GI)-focused sales force is promoting two specialty products, setting the stage for the potential launch of RedHill's late clinical-stage GI products, if approved, and for the acquisition of additional commercial GI products**
- **The ERADICATE Hp2 confirmatory Phase III study with TALICIA™ (RHB-105) for *H. pylori* bacterial infection is ongoing; TALICIA™ was granted QIDP designation by the FDA**
- **Following a unanimous positive DSMB recommendation, the Phase III MAP US study with RHB-104 for Crohn's disease is continuing as planned; An open-label extension Phase III study (the MAP US2 study) is ongoing in parallel**
- **Following positive top-line results from the Phase III study with BEKINDA® 24 mg for acute gastroenteritis, the outcome of the planned FDA Type B meeting to discuss the potential path to marketing approval is expected to be announced in October 2017**
- **Top-line results from the Phase II study with BEKINDA® 12 mg for diarrhea-predominant irritable bowel syndrome (IBS-D) are expected in September 2017**
- **In light of recent FDA guidance on the potential path to marketing approval of RHB-104 as first-line therapy for nontuberculous mycobacteria (NTM) infections, RedHill plans, subject to regulatory approvals, to initiate a pivotal Phase III study in the U.S. with RHB-104 for NTM infections in the first quarter of 2018; RHB-104 was granted QIDP designation by the FDA for the treatment of NTM infections**
- **In light of encouraging results from prior non-clinical studies, an NIAID Safety Committee recently approved a planned proof-of-concept study to evaluate RedHill's proprietary experimental therapy for the treatment of**

Ebola virus disease; The study is expected to be initiated in the fourth quarter of 2017

- **Re-submission of the NDA for RIZAPORT[®] for acute migraines is expected in October 2017**

TEL-AVIV, Israel / RALEIGH, NC, August 10, 2017 RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) (“RedHill” or the “Company”), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today provided an update on key programs, potential milestones and estimated timelines.

Dror Ben-Asher, Chief Executive Officer of RedHill, said: “RedHill has transitioned into a revenue-generating, gastrointestinal-focused, specialty pharmaceutical company, as we continue to pursue important clinical development milestones in the near future. I would like to thank the RedHill team for their meaningful achievements on the R&D and commercial fronts thus far in 2017.”

TALICIA[™] (RHB-105)¹ - *H. pylori* bacterial infection (confirmatory Phase III) (QIDP status)

- A confirmatory Phase III study with TALICIA[™] (RHB-105) for the treatment of *H. pylori* infection (the ERADICATE Hp2 study) is ongoing. The two-arm, randomized, double-blind, active comparator, confirmatory Phase III study is planned to enroll 444 non-investigated dyspepsia patients with confirmed *H. pylori* infection in up to 65 clinical sites in the U.S., with a primary endpoint of eradication of *H. pylori* infection at 42 through 70 days after initiation of treatment. Subject to a successful outcome and any additional regulatory feedback, the confirmatory Phase III study is expected to complete the package required for a potential U.S. NDA for TALICIA[™]. RHB-105 was granted QIDP (Qualified Infectious Disease Product) designation by the FDA, allowing for Fast-Track status and Priority Review, potentially leading to a shorter NDA review time by the FDA, and, if approved, an additional five years of U.S. market exclusivity on top of the standard exclusivity period.

RHB-104 - Crohn’s disease (Phase III)

- To date, over 300 of the planned 410 subjects have been enrolled in the ongoing randomized, double-blind, placebo-controlled first Phase III study in the U.S. and additional countries with RHB-104 for Crohn’s disease (the MAP US study).
- A second pre-planned independent data and safety monitoring board (DSMB) meeting reviewed safety and efficacy data of the Phase III MAP US study from the first 222 subjects who have completed week 26 assessments in the MAP US study, to which RedHill remains blinded. The independent DSMB provided RedHill with a unanimous positive recommendation to continue the study as planned.

¹ TALICIA[®] is an investigational new drug, not available for commercial distribution.

- An open-label extension Phase III study (the MAP US2 study) is ongoing to further assess the safety and efficacy of RHB-104 in patients who remain out of remission (CDAI \geq 150) after 26 weeks of blinded study therapy in the ongoing Phase III MAP US study; these patients have the opportunity to receive treatment with RHB-104 for a 52-week period in the open-label extension study. To date, 12 patients have been enrolled in the MAP US2 study.

RHB-104 - nontuberculous mycobacteria (NTM) infections (Phase III) (QIDP status)

- Following a positive meeting with the FDA, and in light of their recent guidance on the potential path toward marketing approval of RHB-104 as first-line therapy for nontuberculous mycobacteria (NTM) infections, RedHill plans, subject to approval of the study protocol by the FDA, to initiate a pivotal Phase III study with RHB-104 for the treatment of NTM infections in the first quarter of 2018.
- RHB-104 was granted QIDP designation by the FDA for the treatment of NTM infections. The QIDP designation was granted under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, which is intended to encourage development of new antibiotic drugs for the treatment of serious or life-threatening infections. Under the FDA's GAIN Act, QIDP designation allows for Fast-Track status and Priority Review, potentially leading to a shorter NDA review time by the FDA, and, if approved, an additional five years of U.S. market exclusivity on top of the standard exclusivity period.

BEKINDA[®] (RHB-102)² - acute gastroenteritis (Phase III) and IBS-D (Phase II)

- Positive top-line results from the Phase III GUARD study with BEKINDA[®] (RHB-102) 24 mg for acute gastroenteritis and gastritis were announced in June 2017. 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 randomized, double-blind, placebo-controlled Phase III 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. RedHill plans to meet with the FDA for a Type B meeting to discuss the study results and the potential path to NDA filing. The outcome of this meeting is expected to be announced in October 2017.
- The last patient has completed the treatment course and the last follow-up visit in the Phase II study with BEKINDA[®] 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The randomized, double-blind, placebo-controlled Phase II study is evaluating the efficacy and safety of BEKINDA[®] 12 mg in adults 18 years and older who suffer from IBS-D. The study enrolled 127 subjects at 16 clinical sites in the U.S. Top-line results are expected in September 2017.

YELIVA[®] (ABC294640)³ - Phase I/II studies for multiple oncology, inflammatory and GI indications

² BEKINDA[®] is an investigational new drug, not available for commercial distribution.

³ YELIVA[®] is an investigational new drug, not available for commercial distribution.

- RedHill is currently pursuing several Phase I/II clinical studies with YELIVA[®] (ABC294640) in the U.S., with support from National Cancer Institute (NCI) grants awarded to Apogee Biotechnology and U.S. universities, including ongoing studies for advanced hepatocellular carcinoma (Phase II, Medical University of South Carolina), refractory or relapsed multiple myeloma (Phase Ib/II, Duke University Medical Center) and refractory/relapsed diffuse large B-cell lymphoma and Kaposi sarcoma (Phase I/IIa, Louisiana State University Health Sciences Center).
- A Phase IIa clinical study with YELIVA[®] in patients with advanced, unresectable, intrahepatic and extrahepatic cholangiocarcinoma is planned to be initiated in the fourth quarter of 2017. YELIVA[®] was granted Orphan Drug designation by the FDA for the treatment of cholangiocarcinoma. Orphan Drug designation would allow RedHill to benefit from a seven-year marketing exclusivity period for the indication, if approved, as well as other development incentives to develop YELIVA[®] for cholangiocarcinoma.
- A Phase Ib study to evaluate YELIVA[®] as a radioprotectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy is planned to be initiated in the fourth quarter of 2017.
- A Phase II study for ulcerative colitis is expected to be initiated in the fourth quarter of 2017.

RHB-106 - encapsulated bowel preparation, exclusive worldwide rights licensed to Salix Pharmaceuticals (now Valeant Pharmaceuticals International)

- The exclusive worldwide rights to RedHill's RHB-106 encapsulated bowel cleanser, as well as additional related rights (RHB-106 Program), were licensed to Salix Pharmaceuticals Ltd. in 2014, which was acquired by Valeant Pharmaceuticals International Inc. (Valeant) in 2015. Valeant remains fully responsible for the development of the RHB-106 Program and for future potential commercialization. RedHill continues its discussion with Valeant regarding the RHB-106 Program.

RIZAPORT[®] (RHB-103) - acute migraines (approved for marketing in Germany and Luxembourg)

- Re-submission of the RIZAPORT[®] NDA to the FDA is expected in October 2017.
- The Ministry of Health of Luxembourg granted national marketing authorization for RIZAPORT[®] (5 mg and 10 mg) in April 2017. The national marketing authorization was granted in Luxembourg on the basis of the European Decentralized Procedure (DCP), in which Luxembourg served as the Concerned Member State. The approval in Luxembourg marked the completion of the current marketing approval process for RIZAPORT[®] under the European DCP. RIZAPORT[®] is also approved for marketing in Germany, which served as the Reference Member State, and a national Marketing Authorization Application (MAA) has been submitted in Spain.
- RedHill continues discussions with additional potential commercialization partners for RIZAPORT[®] in the U.S., Europe and other territories.

MESUPRON - pancreatic cancer (Phase I/II)

- A Phase I/II study with MESUPRON in unresectable pancreatic cancer is planned to be initiated in the first half of 2018 in Germany.

Ebola virus disease therapy (RedHill's proprietary experimental therapy) - NIH collaboration

- Following approval by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) Safety Committee, a non-clinical study to evaluate RedHill's proprietary experimental therapy for the treatment of Ebola virus disease is planned to be initiated in the fourth quarter of 2017. RedHill's research collaboration with the NIAID, part of the National Institutes of Health (NIH), is intended to evaluate survival outcome and assess disease severity through comparison of viral loads and cytokine levels in active treatment arms and placebo. The study follows encouraging results from preliminary non-clinical studies conducted in conjunction with NIAID using RedHill's proprietary experimental therapy.

U.S. Commercial Operations

- RedHill has established its U.S. commercial operations in Raleigh, NC, and initiated the promotion of two gastrointestinal products in June 2017. RedHill's U.S. operations are intended to set the stage for the potential launch of RedHill's proprietary, late-clinical stage GI products, if approved by the FDA.
- RedHill's GI-focused sales force, promotes two GI-specialty products, Donnatal[®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)⁴ and EnteraGam[®] (serum-derived bovine immunoglobulin/protein isolate, SBI)⁵ in select U.S. territories. The sales force consists of approximately 40 sales representatives. Initial net revenues for June 12-30, 2017 were approximately \$0.5 million. RedHill continues to pursue the acquisition of additional commercial GI products in the U.S.

Expanded Access Program (EAP)

- RedHill has adopted an Expanded Access Program (EAP), allowing patients with life-threatening diseases potential access to RedHill's investigational new drugs that have not yet received regulatory marketing approval. Expanded access (sometimes referred to as "compassionate use") is possible outside RedHill's clinical trials, under certain eligibility criteria, when a certain investigational new drug is needed to treat life-threatening condition and there is some clinical evidence suggesting that the drug might be effective in that condition. Following the adoption of the program, RedHill continues to

⁴ Donnatal[®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription drug, classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. For more information, please see the prescribing information: <http://www.donnatal.com/wp-content/uploads/2015/02/2015-02-18-Risk-Benefit-information-DTC-REV.-SE.pdf>.

⁵ EnteraGam[®] (serum-derived bovine immunoglobulin/protein isolate, SBI) is a commercially-available medical food, intended for the dietary management of chronic diarrhea and loose stools due to specific intestinal disorders, which must be administered under medical supervision.

receive patient requests to obtain access to investigational drugs. Therefore, subject to evaluation of eligibility and all the necessary regulatory and other approvals, RedHill is likely to provide certain patients with an investigational new drug under the EAP. Further information about RedHill's EAP can be found on the Company's website at: <http://www.redhillbio.com/expandedaccess>.

About Donnatal[®]:

Donnatal[®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide), a prescription drug, is classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. Donnatal[®] slows the natural movements of the gut by relaxing the muscles in the stomach and intestines. Donnatal[®] comes in two formulations: immediate release Donnatal[®] Tablets and immediate release Donnatal[®] Elixir, a fast-acting liquid.

Important Safety Information about Donnatal[®]:

Donnatal[®] is contraindicated in patients who have glaucoma, obstructive uropathy, obstructive disease of the gastrointestinal tract, paralytic ileus, unstable cardiovascular status, severe ulcerative colitis, myasthenia gravis, hiatal hernia with reflux esophagitis, or known hypersensitivity to any of the ingredients. Patients who are pregnant or breast-feeding or who have autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia or hypertension should notify their doctor before taking Donnatal[®]. Side effects may include: dryness of the mouth, urinary retention, blurred vision, dilation of pupils, rapid heartbeat, loss of sense of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia, nausea, vomiting and allergic reactions which may be severe.

Further information, including prescribing information, can be found on www.donnatal.com.

Please see the following website for complete important safety information about Donnatal[®]:
<http://www.donnatal.com/professionals/important-safety-information/>

To report suspected adverse reactions, contact Concordia Pharmaceuticals Inc. at 1-877-370-1142 or email: medicalinformation@concordiarx.com, or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

About EnteraGam[®]:

EnteraGam[®] (serum-derived bovine immunoglobulin/protein isolate, SBI) is a medical food product intended for the dietary management of chronic diarrhea and loose stools. EnteraGam[®] must be administered under medical supervision. EnteraGam[®] binds microbial components⁶, such as toxic substances released by bacteria, that upset the intestinal environment. This helps prevent them from

⁶ Horgan A, Maas K, Henderson A, Detzel C, Weaver E. Serum-derived bovine immunoglobulin/protein isolate binds to pathogen-associated molecular patterns. Poster presented at: Federation of American Societies for Experimental Biology; April 26-30, 2014; San Diego, CA.

penetrating the lining of the intestine, which may contribute to chronic diarrhea and loose stools in people who have specific intestinal disorders⁷.

Safety Information about EnteraGam®:

EnteraGam® contains beef protein; therefore, patients who have an allergy to beef or any other component of EnteraGam® should not take this product. EnteraGam® has not been studied in pregnant women, in women during labor and delivery, or in nursing mothers. The choice to administer EnteraGam® during pregnancy, labor and delivery, or to nursing mothers is at the clinical discretion of the prescribing physician.

EnteraGam® does not contain any milk-derived ingredients such as lactose, casein or whey. EnteraGam® is gluten-free, dye-free and soy-free.

Please see full [Product Information](#).

To report suspected adverse reactions, contact Entera Health, Inc. at 1-855-4ENTERA (1-855-436-8372), or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. RedHill promotes two gastrointestinal products in the U.S. - **Donnatal®**, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, and **EnteraGam®**, a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's clinical-stage pipeline includes: (i) **TALICIA™ (RHB-105)** - an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study and an ongoing confirmatory Phase III study; (ii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study, a completed proof-of-concept Phase IIa study for multiple sclerosis, and a planned Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102)** - a once-daily oral pill formulation of ondansetron with successful top-line results in a Phase III study for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106** - an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA® (ABC294640)** - a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON** - a Phase II-stage first-in-class, orally-administered protease inhibitor, targeting pancreatic cancer and other solid tumors and (vii) **RIZAPORT® (RHB-103)** - an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in two EU member states under the European Decentralized Procedure (DCP). More information about the Company is available at: www.redhillbio.com.

⁷ Petschow BW, Burnett B, Shaw AL, Weaver EM, Klein GL. Serum-derived bovine immunoglobulin/protein isolate: postulated mechanism of action for management of enteropathy. Clin Exp Gastroenterol. 2014;7:181-190.

Gasbarrini A, Lauritano EC, Garcovich M, Sparano L, Gasbarrini G. New insights into the pathophysiology of IBS: intestinal microflora, gas production and gut motility. Eur Rev Med Pharmacol Sci. 2008;12 Suppl 1:111-117.

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential” or similar words. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company’s control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company’s research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts; (ii) the Company’s ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number of additional studies that the Company may be required to conduct and the Company’s receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings, approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Company’s therapeutic candidates; (v) the Company’s ability to successfully market Donnatal[®] and EnteraGam[®], (vi) the Company’s ability to establish and maintain corporate collaborations; (vii) the Company’s ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (viii) the interpretation of the properties and characteristics of the Company’s therapeutic candidates and of the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (ix) the implementation of the Company’s business model, strategic plans for its business and therapeutic candidates; (x) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; and (xii) estimates of the Company’s expenses, future revenues capital requirements and the Company’s needs for additional financing; (xiii) the Company’s Expanded Access Program, which allows patients with life-threatening diseases potential access, subject to regulatory and other approvals, to RedHill’s investigational new drugs that have not yet received regulatory marketing approval, if a patient suffers an adverse experience using such investigative drug, potentially adversely affecting the clinical development program of that investigational product or the Company generally; (xiv) competitive companies and technologies within the Company’s industry. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company’s filings with the Securities and Exchange Commission (SEC), including the Company’s Annual Report on Form 20-F filed with the SEC on February 23, 2017. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.

Company contact:

Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):

Marcy Nanus
Senior Vice President
The Trout Group
+1-646-378-2927
Mnanus@troutgroup.com

