Press Release

RedHill Biopharma Receives Notice of Allowance for a New U.S. Patent Covering RHB-104

- **The new patent, covering RHB-104 for relapsing-remitting multiple sclerosis (MS), is expected to be valid until 2032, once granted**
- **Enrollment in the Phase III study with RHB-104 for Crohn's disease to be completed in November 2017 and top-line results expected in Q3/2018**
- **A pivotal Phase III study with RHB-104 for Nontuberculous Mycobacteria (NTM) infections, with Fast-Track development status, is planned to be initiated in H1/2018**
- **RedHill's robust RHB-104 patent portfolio is comprised of more than 60 patents in many countries, including the U.S., Australia, Canada, Japan and multiple European countries, with additional patent claims being pursued**

TEL-AVIV, Israel / RALEIGH, NC, October 23, 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 announced that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a new patent covering RHB-104 for relapsing-remitting multiple sclerosis (MS), which is expected to be valid until 2032, once granted.

RHB-104 is a proprietary, orally-administered, potentially ground-breaking, antibiotic combination therapy with potent intracellular, antimycobacterial and anti-inflammatory properties.

A randomized, double-blind, placebo-controlled first Phase III study with RHB-104 for the treatment of Crohn's disease is currently ongoing (the MAP US study). RedHill expects to complete enrollment in November 2017 and to announce top-line results in the third quarter of 2018.

RedHill plans, subject to regulatory approvals, to initiate a pivotal Phase III study with RHB-104 for the treatment of nontuberculous mycobacteria (NTM) infections in the U.S. in the first half of 2018. RHB-104 was granted Qualified Infectious Disease Product (QIDP) status by the U.S. FDA for the treatment of NTM infections. QIDP designation allows for Fast-Track development status, Priority Review of a New Drug Application (NDA), if filed, and an additional five years of U.S. market exclusivity on top of the standard exclusivity period or Orphan Designation exclusivity period, as applicable, for a total U.S. market exclusivity of 8-12 years.

RedHill's robust RHB-104 patent portfolio covering its oral antibiotic combination therapy is comprised of more than 60 patents in many countries, including the U.S., Australia, Canada, Japan and multiple European countries with additional patent claims being pursued.

Results from a Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in subjects treated for relapsing-remitting multiple sclerosis (the CEASE MS study), announced in December 2016, demonstrate safety data and clinical signals, supporting additional studies to better investigate the therapeutic potential of RHB-104 in relapsing-remitting multiple sclerosis.

The MAP US Phase III study and the CEASE-MS Phase IIa study are registered on www.ClinicalTrials.gov, a web-based service of the U.S. National Institute of Health, which provides access to information on publicly and privately supported clinical studies.

About RHB-104:
Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study), RHB-104 is a proprietary, orally-administered, potentially ground-breaking oral antibiotic combination therapy, with potent intracellular, antimycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is related to *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. The development of RHB-104 is consistent with the growing awareness of the possibility that a bacterially-induced dysregulated immune system may contribute to the pathogenesis of various autoimmune diseases of unknown etiology. Clinical trials conducted with earlier formulations of RHB-104 include an Australian Phase III study conducted by Pharmacia/Pfizer. RedHill has conducted several supportive studies with the current formulation of RHB-104 and a long-term population pharmacokinetic (pop-PK) study is ongoing as part of the Phase III MAP US study. Additionally, an open-label extension Phase III study (the MAP US2 study) is ongoing to assess the safety and efficacy of RHB-104 in subjects who have completed week 26 assessments in the ongoing Phase III MAP US study and remain with active Crohn's disease (CDAI $\geq$ 150) at week 26. RHB-104 is covered by several issued and pending patents. RHB-104 was granted Qualified Infectious

Disease Product (QIDP) designation by the U.S. FDA for the treatment of nontuberculous mycobacteria (NTM) infections, providing a Fast-Track development pathway, as well as NDA Priority Review and an additional five years of U.S. market exclusivity, if approved. A pivotal Phase III study with RHB-104 for NTM infections is planned to be initiated. RedHill also completed a Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in subjects treated for relapsing-remitting multiple sclerosis (the CEASE MS study), supporting additional studies.

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 three gastrointestinal products in the U.S. - **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg -** a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions; 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 pivotal 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 from a Phase III study in acute gastroenteritis and gastritis and successful top-line results from a Phase II study in 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 inflammatory gastrointestinal diseases 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.

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