Press Release

RedHill Biopharma Announces Approval of a European Patent Supporting RHB-104 for Multiple Sclerosis

- **RedHill has received from the European Patent Office a Notice of Intention to Grant a new patent covering RHB-104 for multiple sclerosis (MS), expected to be valid until 2032, once granted**

- **A Phase IIa proof-of-concept study evaluating RHB-104 in patients treated for relapsing-remitting multiple sclerosis is ongoing (the CEASE-MS study), with top-line final results expected in the fourth quarter of 2016**

- **Encouraging interim results from the Phase IIa CEASE-MS study, after completion of the 24-week treatment period with RHB-104 as an add-on therapy to interferon beta-1a, demonstrated positive safety and efficacy signals that support further clinical development**

- **2016 U.S. and worldwide sales of MS therapies are estimated to exceed $12 billion and $18 billion, respectively**

- **RHB-104 is also undergoing a first Phase III clinical study for Crohn's disease (the MAP US study), with over 200 patients enrolled to date and interim DSMB analysis on track for the fourth quarter of 2016**

TEL-AVIV, Israel, August 29, 2016 RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today announced that it has received from the European Patent Office a Notice of Intention to Grant for a new patent covering the use of RHB-104 in the treatment of multiple sclerosis (MS). Upon grant by the European Patent Office, the patent can be officially validated in up to 38 European countries.

RHB-104 is a proprietary and potentially groundbreaking oral antibiotic combination therapy, with potent intracellular, anti-mycobacterial and anti-inflammatory properties. A first Phase III study with RHB-104 for the treatment of Crohn's disease is currently ongoing, as well as a Phase IIa proof-of-concept study for the treatment of MS.

"RHB-104 is a multifaceted drug that, in addition to bactericidal properties against intracellular infections, has potentially distinct mechanisms of action that include both anti-inflammation and neuroprotection. This new European patent is an important addition to RedHill's already robust patent portfolio covering RHB-104 and we continue to pursue additional patent claims for this potentially groundbreaking therapy," **stated Danielle Abramson, Ph.D., RedHill's Director of Intellectual Property & Research.** "We are very pleased with the progress achieved with the RHB-104 development programs for Crohn's disease and multiple sclerosis and look forward to several important upcoming potential milestones. Interim results from the Phase IIa proof-of-concept study with RHB-104 for relapsing-remitting multiple sclerosis were encouraging, demonstrating positive safety and efficacy signals and we are expecting top-line final results from this study during the fourth quarter of 2016. A DSMB analysis in the Phase III study with RHB-104 for Crohn's disease is also expected in the fourth quarter."

Patents covering the antibiotic combination therapy, including the RHB-104 formulation and uses, have been granted in over 25 countries, including the U.S., Australia, Canada, Japan and multiple European countries. This new allowed patent application further expands RedHill's worldwide patent portfolio covering the use of RHB-104 for the treatment of multiple sclerosis and is expected to be valid until 2032, once granted. Additional U.S. and foreign patent applications are pending, covering the use of RHB-104 for the treatment of multiple sclerosis, with recent patent allowances in a number of territories.

RHB-104 is being evaluated as a treatment for relapsing-remitting multiple sclerosis (RRMS), with an open-label Phase IIa proof-of-concept clinical study currently ongoing in Israel (the CEASE-MS study). The Phase IIa CEASE-MS study was initiated following several successful pre-clinical studies conducted by RedHill and is designed to evaluate RHB-104 as an add-on therapy to interferon beta-1a in patients treated for RRMS. Patients enrolled in the study received 24 weeks of treatment with RHB-104 as an add-on therapy to interferon beta-1a and were then evaluated for an additional 24-week follow-up period during which they were treated with interferon beta-1a alone. Top-line interim results announced in March 2016, after completion of the 24-week treatment period, demonstrated positive safety and efficacy signals, including an encouraging relapse-free rate, Expanded Disability Status Scale (EDSS) scores and MRI results, which support further clinical development. Top-line final results from the CEASE-MS study are expected in the fourth quarter of 2016.

RHB-104 is also undergoing a first Phase III study for Crohn's disease in the U.S., Canada, Israel, Australia and Europe (the MAP US study). With over 200 patients of the planned total of 270 enrolled to date in the ongoing randomized, double-blind, placebo-controlled MAP US study, interim data and safety monitoring board (DSMB) analysis is expected in the fourth quarter of 2016.

RedHill is currently reviewing a possible amendment to the Phase III MAP US study protocol intended to further enhance the overall robustness of the study, provide a more precise assessment of RHB-104's treatment effect, collect additional endoscopic mucosal healing

data, further evaluate the Crohn's disease population enrolled and address retention and early terminations. The Company expects to provide further details in the coming weeks, once plans are finalized.

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 Institutes of Health, which provides access to information on publicly and privately supported clinical studies.

About Multiple Sclerosis:
Multiple sclerosis (MS) is a chronic inflammatory, demyelinating disease of the central nervous system with an unknown etiology, believed to be multifactorial. A dysfunctional immune system in MS patients causes recurrent inflammatory attacks on the central nervous system (CNS), leading to neurological disability. Diffuse inflammatory and demyelinating lesions, also known as plaques, are the main pathological finding in MS neural tissue. The lesions are primarily found in the spinal cord, optic nerves, brainstem and periventricular white matter. The symptoms of MS are dictated by the location of the lesions within the CNS. Geographic variation in MS distribution, which cannot be solely explained by population genetics, supports the notion that environmental factors also hold etiological importance. There is currently no known cure for MS and available treatments are mainly intended to manage or prevent relapses or reduce symptoms. In 2015, there were estimated to be over 900,000 diagnosed patients with MS worldwide. Approximately 85% of MS patients initially exhibit relapse-remitting disease (RRMS). The 2016 U.S. and worldwide sales of MS therapies are estimated to exceed $12 billion and $18 billion, respectively[1].

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 and potentially groundbreaking oral antibiotic combination therapy, with potent intracellular, anti-mycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is caused by *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. Clinical trials conducted with earlier formulations of RHB-104 include an Australian Phase III study conducted by 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. RHB-104 is covered by several issued and pending patents. RedHill is also conducting the CEASE-MS Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (RRMS), with encouraging top-line interim results announced in March 2016.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a 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

[1] GlobalData PharmaPoint report, August 2015.

gastrointestinal and inflammatory diseases and cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing 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 uPA inhibitor, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class, orally-administered Hsp27 inhibitor, targeting pancreatic and other gastrointestinal cancers; (viii) **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 Germany in October 2015; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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 establish and maintain corporate collaborations; (vi) 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; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) the impact of the political and security situation in Israel on the Company's business. 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 25, 2016. 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