Press Release

RedHill Biopharma Provides 2016 Semi-Annual R&D Update

TEL-AVIV, Israel, August 11, 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 provided an update on select research and development potential milestones and estimated timelines.

"RedHill continues to pursue its multiple-shots-on-goal strategy with a focus on advancing its three ongoing gastroenterology Phase III programs in the U.S., RHB-105 for *H. pylori* infection, RHB-104 for Crohn's disease and BEKINDA® for gastroenteritis, as well as additional Phase II programs, supported by a strong and debt-free balance sheet," **stated Mr. Dror Ben-Asher, RedHill's Chief Executive Officer**. "We continue to further enhance the overall robustness of our flagship Phase III programs and increase data collection in support of future potential new drug applications, while maintaining a substantially consistent cash burn through the end of 2017." **Mr. Ben-Asher added,** "In light of strong recruitment rates in the ongoing Phase II study with BEKINDA® for IBS-D, we are pleased to provide guidance, for the first time, on the estimated timing for top-line results, which are anticipated in mid-2017. RedHill is well-positioned for continued solid growth and we look forward to several Phase III and Phase II data points and other important milestones and potential catalysts expected in the coming months."

RHB-105 - *H. pylori* bacterial infection (confirmatory Phase III)

- Following the positive FDA meeting in April 2016, and in light of guidance received on the potential path for marketing approval, preparations continue for the confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection. The two-arm, randomized, double-blind, active comparator confirmatory Phase III study is planned to be initiated in the fourth quarter of 2016 or in the first quarter of 2017, following completion of a supportive pharmacokinetic (PK) program. The study is planned to enroll approximately 440 patients in up to 50 clinical sites in the U.S.

  The planned confirmatory Phase III study, along with the results from the successfully completed first Phase III study (the ERADICATE Hp study) and data to be obtained from a supportive PK program, are expected to support a U.S. New Drug Application (NDA) for RHB-105. The first Phase III clinical study with RHB-105 successfully met its primary endpoint of superiority over historical standard-of-care (SoC) eradication rate of 70%, with high statistical significance ($p<0.001$). The Phase III

ERADICATE Hp study results demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105. Notably, subsequent open-label treatment with SoC therapies of patients in the placebo arm of the Phase III ERADICATE Hp study demonstrated only 63% eradication rate, further supporting the potential superior efficacy of RHB-105 over SoC.

RHB-104 - Crohn's disease (Phase III) and multiple sclerosis (Phase IIa)

Crohn's disease - first Phase III study ongoing

- Approximately 200 subjects out of the planned total of 270 have been enrolled to date in the randomized, double-blind, placebo-controlled first Phase III study with RHB-104 for Crohn's disease (the MAP US study).

  Interim data and safety monitoring board (DSMB) analysis is on track to take place in the fourth quarter of 2016 and RedHill remains blinded to the interim and ongoing results.

  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. No changes are planned to the primary endpoint of remission at week 26 or the study's 90% power. Taking into account a potential protocol amendment, completion of recruitment is expected in 2017 with no anticipated material impact on the Company's overall cash burn rate through the end of 2017. The Company expects to provide further details in the coming weeks, once plans are finalized.

Multiple sclerosis – Phase IIa study ongoing

- Top-line final results from the Phase IIa CEASE-MS study with RHB-104 for relapsing-remitting multiple sclerosis (RRMS) are expected in the fourth quarter of 2016, following the recently announced last patient follow-up visit in the study. In the first 24 weeks, patients enrolled in the CEASE-MS study received 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.

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

Acute gastroenteritis and gastritis - Phase III study ongoing

- RedHill has implemented a protocol amendment to the ongoing Phase III study with BEKINDA® 24 mg for acute gastroenteritis (the GUARD study) to increase the safety data collected, so that the study results may support a potential NDA filing, as per FDA's recommendation. The study protocol now requires patients to remain in the emergency room for a longer follow-up period and perform an ECG (electrocardiogram) at the end of follow-up and prior to discharge. In light of this

amendment, completion of patient enrollment in the randomized, double-blind, placebo-controlled Phase III GUARD study is currently expected in early 2017.

IBS-D - Phase II study ongoing

- Completion of patient enrollment in the ongoing randomized, double-blind, placebo-controlled Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) is expected in the first half of 2017, with top-line results expected mid-2017.

YELIVA™ - Phase I/II studies for multiple oncology and inflammatory indications

- A Phase I/II study with YELIVA™, a first-in-class SK2 selective inhibitor, for the treatment of refractory or relapsed multiple myeloma is planned to be initiated later this year at Duke University Medical Center. The study is supported by a $2 million grant from the National Cancer Institute (NCI) awarded to Apogee Biotechnology Corp. (Apogee) in conjunction with Duke University, with additional support from RedHill.

- A Phase II study with YELIVA™ for the treatment of advanced hepatocellular carcinoma is planned to be initiated later this year. The study will be conducted at the Medical University of South Carolina (MUSC) Hollings Cancer Center and additional clinical centers in the U.S. It is supported by a $1.8 million grant from the NCI awarded to MUSC, 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, including the Phase II study with YELIVA™, and will be further supported by additional funding from RedHill.

- A Phase I/II clinical study to evaluate YELIVA™ as a radioprotectant to prevent mucositis in cancer patients undergoing therapeutic radiotherapy is planned to be initiated later this year.

- A Phase I/II clinical study evaluating YELIVA™ in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) was initiated at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans in June 2015 and was recently put on administrative hold, pending a protocol amendment aimed at improving overall recruitment prospects. The study is supported by a grant awarded to Apogee from the NCI, as well as additional support from RedHill.

- Following the successful Phase I study with YELIVA™ in patients with advanced solid tumors, and in light of the drug's novel mechanism of action, RedHill is evaluating potential clinical studies for additional oncology and inflammatory indications, as well as potential collaboration opportunities to evaluate YELIVA™ as an add-on therapy.

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 has recently been informed by Valeant that, as a result of Valeant's greater focus on R&D investment, the development of the RHB-106 Program continues to be explored.

- Earlier this week, Valeant highlighted their commitment to bolstering their R&D and commercial offering and enhance their gastrointestinal business with the acquisition of the North American rights to a powder for oral solution bowel cleanser (NER1006) from Norgine B.V.

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

- Initiation of the research collaboration with the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), is expected in the fourth quarter of 2016. The new study is intended to evaluate RedHill's proprietary experimental therapy for the treatment of Ebola virus disease and follows encouraging results from preliminary non-clinical studies conducted in conjunction with NIAID. Top-line results from the study are expected in 2017.

RIZAPORT® (RHB-103) - acute migraines (approved for marketing in Germany)

- Re-submission of the RIZAPORT® U.S. NDA to the FDA is expected in the first half of 2017. RIZAPORT® was approved for marketing in Germany under the European Decentralized Procedure (DCP) in October 2015 and a first commercialization agreement was recently signed with Grupo JUSTE S.A.Q.F for Spain and additional potential territories.

  RedHill continues discussions with additional potential commercialization partners for RIZAPORT® in the U.S., Europe and other territories.

MESUPRON – First-in-class small molecule for oncology indications (Phase II-stage)

- RedHill's current development program for MESUPRON includes nonclinical studies as well as re-analysis of certain prior clinical data. MESUPRON is a first-in-class, orally-administered uPA inhibitor targeting gastrointestinal and other solid tumors. MESUPRON completed a total of ten Phase I and Phase II clinical studies, and the ongoing development program is intended to better define the molecular markers and patient population for future clinical studies. RedHill plans to initiate a Phase II development program with MESUPRON in 2017, subject to a successful outcome in the ongoing nonclinical studies.

RP101 – First-in-class small molecule for oncology indications (Phase II-stage)

- RedHill has extended the term of the August 2014 exclusive option agreement with RESprotect GmbH for RP101, a first-in-class, orally-administered Hsp27 inhibitor, for an additional nine months period until May 2017. The Company intends to conduct additional nonclinical studies with RP101 before concluding whether to advance its development or terminate the option agreement with RESprotect GmbH.

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 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.

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