Press Release

RedHill Biopharma Commences Patient Screening in a Phase IIa Clinical Trial with RHB-104 for Multiple Sclerosis

- **The open label Phase IIa study is designed to assess the efficacy and safety of RHB-104 in Multiple Sclerosis (MS) patients. The study follows successful completion of 4 pre-clinical studies**

- **A first Phase III clinical trial with RHB-104 for Crohn's disease (the "MAP US Study") is planned to commence by the third quarter of 2013. Recruitment of sites in the U.S., Canada and Israel is underway**

Tel-Aviv, Israel, June 5, 2013 - RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill"), an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, patent-protected, new formulations and combinations of existing drugs, announced that patient screening has commenced in the Phase IIa, proof of concept, clinical study (the "CEASE-MS Study"), to assess the efficacy and safety of fixed dose combination RHB-104, a patent protected combination therapy of three antibiotics in a single capsule, as an add-on therapy to interferon beta-1a in patients treated for Relapsing Remitting Multiple Sclerosis ("RRMS").

The phase IIa CEASE-MS Study follows the successful completion of four pre-clinical studies with RHB-104.

Sixteen patients with RRMS are expected to participate in the open label Phase IIa CEASE-MS Study, which will be conducted at two medical centers in Israel. The study is designed to assess the efficacy and safety of RHB-104 in RRMS patients after 24 weeks of treatment, with the primary endpoint being the number of combined unique active lesions after treatment as compared to baseline. Patients will be followed-up for an additional term of 24 weeks after completing treatment with RHB-104. Secondary endpoints will include changes in pro-inflammatory cytokine markers, *Mycobacterium avium subsp. paratuberculosis* (MAP) status, relapse rate, Expanded Disability Status Scale (EDSS) and safety and tolerability of RHB-104.

"We are very pleased that this important Phase IIa Multiple Sclerosis study is now underway," **said Clara Fehrmann, RedHill's RHB-104 MS Product Manager**. "There is an increasing awareness in the medical community to the possibility that a bacterial induced dysregulated immune system plays a critical role in the pathogenesis of MS. It is RedHill's hope that the CEASE-MS Study will demonstrate RHB-104's potential to become an effective treatment option for patients with MS."

Dr. Radi Shahien of Ziv Medical Center, Principal Investigator of the CEASE-MS Study added: "The MAP bacterium has been identified as a pathogen that may contribute to the development of MS. The CEASE-MS Study with RHB-104 aims to test this new hypothesis to the etiology of MS. RHB-104 has the potential to improve the lives of people with MS, and I am excited to be leading this important study."

Multiple Sclerosis is an inflammatory, demyelinating, and neurodegenerative disease of the central nervous system of uncertain etiology that exhibits characteristics of both infectious and autoimmune pathology. 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. The worldwide sales of MS therapies are estimated to have exceeded $14 billion USD in 2012[1].

RHB-104 is also being evaluated for the treatment of Crohn's disease. The Company is planning to commence a first Phase III clinical trial (named "MAP US Study") for this indication by the third quarter of 2013, with recruitment of sites in the U.S., Canada and Israel underway.

The Company also plans to commence a Phase II/III clinical trial with RHB-105 (*H. Pylori*) in the third quarter of 2013.

[1] EvaluatePharma - 2013 worldwide sales by indication

RedHill has recently submitted its first U.S. New Drug Application ("NDA") for RHB-103 (migraine), and plans to submit a second U.S. NDA, for RHB-102 (oncology support anti-emetic), by the first half of 2014.

About RedHill Biopharma Ltd.:
RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) is an emerging Israeli biopharmaceutical company focused primarily on the development and acquisition of late clinical-stage, patent protected, new formulations and combinations of existing drugs. The Company's current product pipeline includes: (i) RHB-101 - a once-daily formulation of a leading congestive heart failure and high blood pressure drug, with NDA planned to be submitted subject to further CMC and PK work, and Marketing Authorization Application (MAA) in Europe planned to be submitted subject to further CMC work, (ii) RHB-102 - a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, planned for U.S. NDA submission in the first half of 2014, (iii) RHB-103 - an oral thin film formulation drug for the treatment of acute migraine, with a U.S. NDA submitted March 2013, (iv) RHB-104 - a combination therapy for the treatment of Crohn's disease, planned to commence a first Phase III trial by the third quarter of 2013, as well as Multiple Sclerosis (MS) Phase IIa proof of concept trial currently underway, (v) RHB-105 - a combination therapy for the treatment of ulcer causing *Helicobacter pylori* infection, planned to commence a phase II/III trial by the third quarter of 2013, and (vi) RHB-106 - an encapsulated formulation for bowel preparation (laxative) ahead of colonoscopy. For more information please visit: 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 not guarantees of future performance, are based on certain assumptions and the Company's current and best understanding of the regulatory status 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 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 and approvals; (iv) the 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 interpretation of the properties and characteristics of the Company's

therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; (vii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (viii) 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; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company under their respective licensing agreements; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xi) competitive companies, technologies and the Company's industry; and (xii) statements as to 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 From 20-F filed with the SEC on February 19, 2013, and its Reports on Form 6-K. Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. 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 made by us or on our behalf as a result of new information, future events or other factors.

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