Press Release

Date: September 10, 2013

RedHill Biopharma Announces Positive Pre-Clinical Results for Lupus with RHB-104

- **The Company is assessing the possibility of a Phase IIa proof of concept study in systemic lupus erythematosus as a next step**

- **RedHill expects to commence a Phase III study with RHB-104 for Crohn's disease in the U.S. during the third quarter of 2013 (the MAP US study), and plans a second Phase III study for Crohn's in Europe (the MAP Europe study)**

- **Patients recruitment is underway in a Phase IIa study with RHB-104 for multiple sclerosis (MS)**

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, proprietary formulations and combinations of existing drugs, today announced positive results from a pre-clinical study with RHB-104 for the treatment of systemic lupus erythematosus (SLE), a systemic autoimmune disease causing inflammation and damage to tissues in various parts of the body. In light of the positive results, the Company is currently assessing the next steps in the clinical development program, including a possible Phase IIa clinical study.

The pre-clinical study was designed to evaluate the potential therapeutic effects of RHB-104 on disease development in an experimental SLE model when administered orally.

The results from the pre-clinical study demonstrated that disease severity and overall disease development were reduced in the RHB-104 arm, indicating that RHB-104 was efficacious in reducing the development of SLE in this study.

SLE is an autoimmune disease in which the body's immune system attacks healthy cells and tissues resulting in inflammation and possible harm to multiple organs and organ systems including joints, skin, kidneys, blood, brain, heart and lungs. Symptoms of SLE may vary accordingly. The underlying cause of SLE is unknown and there is no cure for the disease, thus available therapies are aimed at controlling the symptoms. Worldwide sales of SLE therapies are estimated to have exceeded $370 million in 2012[1].

RHB-104 is a patent protected combination therapy of three antibiotics in a single oral capsule. It is a multifaceted drug with potentially distinct anti-inflammatory and neuroprotective properties, in addition to its antibacterial activity against intracellular infections. RHB-104 is being evaluated for the treatment of Crohn's disease - with a phase III clinical study planned to commence in the third quarter of 2013 in the U.S., Canada and Israel (the MAP US study) and a planned Phase III study in Europe (the MAP Europe study), the treatment of multiple sclerosis - with an ongoing phase IIa proof of concept study, and the treatment of rheumatoid arthritis - with a planned Phase IIa proof of concept study**.**

Dr. Reza Fathi, RedHill's Senior VP R&D, commented: "We are very pleased with the results of the pre-clinical study conducted with RHB-104 in the treatment of systemic lupus erythematosus. The results of this study are consistent with the hypothesis that a dysregulated immune system response to bacterial origin in genetically predisposed individuals plays a role in the pathogenesis of various autoimmune diseases for which there is no available cure, such as Crohn's disease, multiple sclerosis, rheumatoid arthritis and lupus. We are currently assessing next steps in the development program, including the possibility of a Phase IIa proof of concept clinical study with RHB-104 for the treatment of systemic lupus erythematosus."

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, proprietary 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 a planned NDA submission in the U.S. subject to further CMC and PK work, and a planned Marketing Authorization Application (MAA) in Europe 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 quarter of 2014; (iii) **RHB-103** - an oral thin film formulation of a leading drug for the treatment of acute migraine, with a U.S. NDA accepted for review by the FDA in June 2013 and a PDUFA date of February 3, 2014; (iv) **RHB-104** - a combination therapy for the treatment of Crohn's disease, planned to commence a first Phase III trial in the third quarter of 2013, multiple sclerosis (MS), with a Phase IIa proof of concept trial currently underway, rheumatoid arthritis (RA), with plans for a Phase IIa proof of concept trial, and systemic lupus erythematosus; (v) **RHB-105** - a combination

[1] EvaluatePharma - 2013 worldwide sales by indication

therapy for *Helicobacter pylori* infection, planned to commence a phase II/III trial in the third quarter of 2013, and (vi) **RHB-106** - an encapsulated formulation for bowel preparation (laxative) ahead of colonoscopy and other GI procedures. 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 and technologies within the Company's industry; and (xii) 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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