Press Release

RedHill Biopharma Announces Positive FDA Meeting Regarding the Regulatory Path towards NDA Submission of RHB-101 for the Treatment of Congestive Heart Failure and Hypertension

- **Following the prior successful completion of four pharmacokinetic (PK) clinical studies, the Company held a Type B meeting regarding RHB-101 with the U.S. Food and Drug Administration (FDA)**

- **Based on the FDA's positive feedback, the Company plans to conduct additional Chemistry, Manufacturing, and Controls (CMC) and PK work prior to submission of a New Drug Application (NDA) of RHB-101**

- **The Company also plans to conduct CMC work prior to submission of a Marketing Authorization Application (MAA) to market RHB-101 in Europe, with Denmark as the reference member state for the European Mutual Recognition Procedure (MRP)**

- **On May 28, 2013, the United States Patent and Trademark Office (USPTO) issued a new patent covering RHB-101 entitled *"Controlled release carvedilol compositions"*, which expires no earlier than 2024**

Tel-Aviv, Israel, May 29, 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, reported that it recently concluded a positive Type B meeting with the U.S. Food and Drug Administration (FDA) regarding its cardio drug RHB-101, a controlled release, proprietary, once-daily formulation of carvedilol, for the treatment of congestive heart failure and hypertension.

Following the positive FDA meeting, the Company plans to submit a New Drug Application (NDA) seeking marketing approval of RHB-101 in the U.S. Based on the FDA's feedback, prior to the NDA submission, the Company plans to conduct additional Chemistry, Manufacturing, and Controls (CMC) work and to conduct a comparative bioavailability study and a dose linearity study.

The planned single dose comparative bioavailability study versus Coreg CR® (the branded controlled release carvedilol marketed by GSK in the U.S.) is intended to assess the comparability of RHB-101 pharmacokinetics to Coreg CR® and follows the prior successful completion of four pharmacokinetic (PK) clinical trials comparing RHB-101 to Eucardic® (the branded immediate release carvedilol marketed by Roche in Europe, equivalent to Coreg®).

Following positive results in a recent meeting held with the Danish Health and Medicines Authority (DKMA), the Company plans to submit a Marketing Authorization Application (MAA) in Europe for RHB-101, with Denmark as the reference member state for the European Mutual Recognition Procedure (MRP). Based on the response in the official minutes of the meeting with the DKMA, RedHill believes that, while additional CMC work is required, no further clinical studies will be required prior to submission of the MAA.

Based on the feedback from the recent meetings with the FDA and the DKMA, RedHill is currently planning its next steps and will provide, in due course, additional updates regarding the estimated timeline for a possible submission of an NDA in the U.S. and an MAA in Europe, currently expected no earlier than the second half of 2014.

The Company is currently seeking suitable pharma partners to commercialize RHB-101 in the relevant territories, if and when RHB-101 is approved.

"We are very encouraged by the positive feedback received from the FDA, and appreciate the informative interactions and clarity provided. We intend to advance the preparations for the planned pharmacokinetic studies with RHB-101 toward the submission of a New Drug Application in the U.S.", **said Dr. Reza Fathi, RedHill's Senior VP R&D.** "The FDA meeting and the recent Scientific Advice meeting held with the Danish Health and Medicines Authority (DKMA) have provided a clear regulatory path towards a submission of RHB-101 for marketing approval both in the U.S. and Europe".

On May 28, 2013, the United States Patent and Trademark Office (USPTO) issued a new patent covering RHB-101 (No.: 8,449,914) entitled *"Controlled release carvedilol compositions"*, which expires no earlier than June, 2024.

RHB-101 is a once-daily controlled release formulation of carvedilol, a non-selective β-adrenergic blocking agent with α1-blocking activity. RHB-101 is based on a patented technology for the controlled release of drugs administered orally.

RHB-101 presents two main advantages over Coreg CR®. RHB-101 is absorbed effectively with and without food, allowing it to be taken at any time during the day instead of only with food. Additionally, RHB-101 provides a reduced drug dose (less API), potentially improving the safety profile of the drug. With clear potential advantages over both the generic immediate release carvedilol and Coreg CR®, RHB-101 is targeting the European carvedilol market of approximately $220 million (2011)[1], as well as the $210 million U.S. Coreg CR® market (2012)[2] and the $273 million U.S. generic immediate release carvedilol market (2010)[3].

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

[1] IMS Health
[2] EvaluatePharma, 2012, Annual U.S. Product Sales, Coreg CR®
[3] IMS Health

submission by the first or second 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 submitted in March 2013, (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, as well as a Multiple Sclerosis (MS) Phase IIa proof of concept trial, (v) RHB-105 - a combination 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, 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.

PR contact (US):
Lauren Glaser
Vice President
The Trout Group
+1-646-378-2972
lglaser@troutgroup.com

Company contact:
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com