Press Release

RedHill Biopharma Announces FDA Acceptance for Review of RHB-103 NDA for Acute Migraine and PDUFA Goal Date of February 3, 2014

- **The RHB-103 New Drug Application (NDA) for marketing approval in the U.S. is subject to a standard 10-month review period and will have a Prescription Drug User Fee Act (PDUFA) action date (targeted date for completion of FDA review) of February 3, 2014**

- **The Company recently received from FDA a PDUFA fee waiver and a subsequent refund of $979,400**

- **RHB-103 is a proprietary, oral thin film formulation of rizatriptan, a leading drug for the treatment of acute migraine**

Tel-Aviv, Israel, June 18, 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 the New Drug Application ("NDA") for marketing approval in the U.S. of RHB-103 of the Company and its co-development partner, IntelGenx Corp. ("IntelGenx"), has been accepted for substantive review by the U.S. Food and Drug Administration ("FDA").

RHB-103 is a proprietary, oral thin film formulation of rizatriptan, a leading drug for the treatment of acute migraine.

The acceptance of the NDA for review reflects FDA's determination that the application is sufficiently complete to permit a substantive review of RedHill's RHB-103 marketing application. FDA indicated that the NDA is subject to a standard 10-month review period and will have a Prescription Drug User Fee Act ("PDUFA") goal date of February 3, 2014. The PDUFA action goal date is the targeted date for FDA to complete its review of the NDA.

The Company has recently been granted a waiver of the PDUFA fee under the small business waiver provision of the Federal Food, Drug and Cosmetic Act and subsequently has received from FDA a refund in the amount of $979,400, which represents the PDUFA fee previously paid by the Company.

RHB-103 is a proprietary oral thin film formulation of rizatriptan benzoate, a 5-HT1 agonist and the active drug in Merck & Co.'s Maxalt®. Rizatriptan is considered one of the most effective oral triptans, a class of molecules that constrict blood vessels in the brain to relieve swelling and other migraine symptoms. The worldwide market of triptans was estimated at approximately $2.1 billion in 2011[1], and the worldwide direct sales of Merck & Co.'s rizatriptan-based drugs exceeded $600 million in 2012[2].

RHB-103 is based on IntelGenx' proprietary "VersaFilm™" technology. The RHB-103 thin film strip dissolves rapidly in the mouth, leading to the absorption of the drug through the gastro intestinal track and into the bloodstream.

"Acceptance of the NDA for review and setting a Prescription Drug User Fee Act (PDUFA) goal date for RHB-103 are important milestones for RedHill and IntelGenx." said **Dr. Elkan Gamzu Ph.D., RedHill's RHB-103 Product Manager**. "We are excited about the possibility of bringing RHB-103 to the market as an attractive new treatment option for physicians and for migraine sufferers who may benefit from the significant potential advantages of RHB-103, such as rapid dissolution, ease of use, pleasant flavoring, and the ability to administer without water."

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.

[1] 2011 report by Business Insights
[2] 2012 annual report of Merck & Co., Inc

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 during the first half 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, as well as a Multiple Sclerosis (MS) Phase IIa proof of concept trial currently underway, (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 Amendment No. 1 to the Company's Annual Report on Form 20-F/A filed with the SEC on March 4, 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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