Press Release

RedHill Biopharma Provides Update on Planned NDA Filing for RHB-102 (Once Daily Anti-Emetic) in Q1 2014 and Commences PK Program

- **Following a Type B meeting with the FDA in February 2013, the Company commenced the first of two supplementary pharmacokinetic studies with RHB-102, with a second comparative bioavailability study planned to commence next month**
- **The Company expects to receive results from both studies by October 2013, and plans to file a New Drug Application (NDA) for RHB-102 in the first quarter of 2014, earlier than previously planned**
- **RHB-102 is a proprietary, extended release, once-daily oral formulation of ondansetron, a leading drug for the prevention of nausea and vomiting in cancer patients**

Tel-Aviv, Israel, July 11, 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 had

commenced dosing in the first of two supplementary pharmacokinetic studies with RHB-102, a patent protected, oral, extended-release (24 hours) formulation of ondansetron. Ondansetron is the active ingredient in GlaxoSmithKline's Zofran® immediate release tablets for the prevention of radiotherapy induced nausea and vomiting (RINV) and chemotherapy induced nausea and vomiting (CINV).

The supplementary pharmacokinetic studies follow a Type B meeting held with the FDA in February 2013. The first pharmacokinetic study, conducted in Canada, includes 14 healthy volunteers and is intended to assess the effect of food on the absorption of RHB-102. The Company also plans to initiate, in August 2013, a supplementary comparative bioavailability clinical study with RHB-102, with Zofran® immediate release tablets as the reference drug.

Based on the planned dosing schedule for the pharmacokinetic studies, the Company anticipates that the results of the studies will be available by October 2013. Subject to the results from the two studies and the required regulatory process, and in light of the data from prior successful studies with RHB-102, the Company plans to submit a New Drug Application (NDA) seeking U.S. marketing approval of RHB-102 in the first quarter of 2014, earlier than previously planned.

With significant potential advantages to cancer patients over the immediate release oral ondansetron tablets, including increased convenience of use, potential prevention of breakthrough emesis and the potential to enhance patient compliance and adherence, RHB-102 is targeting a considerable segment of the 5-HT3 anti-emetic oncology support drug products' market, which was estimated to have sales exceeding $900 million in 2012[1].

Gilead Raday, RedHill Biopharma's Senior VP Corporate and Product Development, commented: "We are very pleased with the initiation of this pharmacokinetic study with RHB-102 and the planned initiation of the supplemental comparative bioavailability study next month. We hope that these studies will establish the necessary equivalence criteria that will allow us to proceed, earlier than previously planned, to a submission of a New Drug Application (NDA) for RHB-102, as a once daily alternative for the benefit of cancer patients suffering from nausea and vomiting."

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] EvaluatePharma 2013, 5-HT3 (serotonin) antagonist, Worldwide sales by pharmacological class

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 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, as well as Multiple Sclerosis (MS), with 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 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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