Press Release

RedHill Biopharma Reports Positive PK Clinical Studies Towards Planned NDA with RHB-102 (Anti-Emetic)

- **Following the positive results from two supportive pharmacokinetic (PK) studies, the Company plans to file a new drug application (NDA) in the first quarter of 2014 and is seeking a pre-NDA meeting with the FDA**

- **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**

- **RHB-102 is one of RedHill's most advanced programs, along with RHB-103 (migraine) which has a PDUFA date of February 3, 2014, and RHB-104 (Crohn's) which recently commenced a Phase III study**

Tel-Aviv, Israel, October 8, 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, proprietary formulations and combinations of existing drugs, today reported positive results from two supplementary pharmacokinetic (PK) studies with RHB-102, an anti-emetic oncology-support drug.

The results of these studies are subject to final QA and an independent study report by the Canadian clinical research organization (CRO) which conducted the studies. The final independent report from the CRO is expected in the coming weeks.

RHB-102 is a patent protected, extended-release (24 hours) oral formulation of ondansetron, 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 Company believes that, if approved for marketing, RHB-102 will be the first and only once-daily oral ondansetron on the U.S. market at the time of approval. With clear potential advantages to cancer patients over the immediate release oral ondansetron tablets currently on the market, including the potential to enhance patient compliance and adherence thanks to increased convenience of use, RHB-102 is targeting a considerable segment of the 5-HT3 anti-emetic market, which was estimated to have worldwide sales of approximately $900 million in 2012[1].

The supplementary PK program was initiated by the Company in July 2013 to support the planned submission of a New Drug Application (NDA). Following the successful PK program, positive data generated from previous studies with RHB-102 and the Type B meeting held with the U.S. Food and Drug Administration (FDA) in February 2013, the Company is seeking a pre-NDA meeting with the FDA to discuss the clinical aspects of the planned NDA. Subject to the results of the pre-NDA meeting, completion of CMC (Chemistry, Manufacturing and Control) modules, and the required regulatory process, the Company plans to submit an NDA for RHB-102 in the first quarter of 2014, seeking U.S. marketing approval.

The supplementary PK program recently conducted with RHB-102 included two studies. The first study assessed the effect of food on the bioavailability of RHB-102. Results from this study showed that the increase in bioavailability for the extended-release formulation after administration in the fed state is consistent with the pharmacokinetics of Zofran® (ondansetron) immediate release formulation. The second study was a multiple day dosing comparative bioavailability study with Zofran® immediate release tablets as the reference drug. Results from this study demonstrated that the exposure provided by RHB-102 meets the targeted pharmacokinetic parameters and supports once-daily dosage.

Gilead Raday, RedHill Biopharma's Senior VP Corporate and Product Development, commented: "We are very pleased with the results from the two supportive pharmacokinetic studies. We are on schedule with the regulatory plan for RHB-102 and are looking forward to a pre-NDA meeting with the FDA, followed by the planned submission of a New Drug Application for RHB-102 in the first quarter of 2014."

[1] EvaluatePharma 2013, 5-HT3 (serotonin) antagonist, worldwide sales by pharmacological class

RHB-102 is one of RedHill's most advanced programs, along with RHB-103 oral thin film formulation of rizatriptan, a leading drug for the treatment of acute migraine. The NDA for RHB-103 was submitted in June 2013 and was accepted for substantive review by the FDA with a PDUFA date of February 3, 2014. The Company recently initiated a Phase III study with RHB-104 for the treatment of Crohn's disease and plans to commence a Phase II/III study with RHB-105 (*H. pylori*) later this month.

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 antibiotic therapy for the treatment of (a) Crohn's disease, with a first Phase III trial currently underway, (b) multiple sclerosis (MS), with a Phase IIa proof of concept trial currently underway, (c) rheumatoid arthritis (RA), with plans for a Phase IIa proof of concept trial, and (d) systemic lupus erythematosus; (v) **RHB-105** - a combination therapy for *Helicobacter pylori* infection, planned to commence a phase II/III trial shortly, 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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