Press Release

RedHill Biopharma Announces Notice of Allowance from the United States Patent and Trademark Office for its Cardio Drug RHB-101

- **RHB-101 is a proprietary, controlled release, once-daily formulation of carvedilol for the treatment of hypertension, congestive heart failure and left ventricular dysfunction**

- **The expected expiration date of the US patent is 2024**

Tel-Aviv, Israel, February 19, 2013 - RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill Biopharma"), 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 today that the United States Patent and Trademark Office ("USPTO") published a Notice of Allowance for RHB-101.

The USPTO has published the notification of a Notice of Allowance for U.S. Patent Application Serial Number 12/076,105 entitled *"Controlled Release Carvedilol Compositions*". This patent family has a priority date of November 8, 2002, and the U.S. patent, once granted, is not expected to expire until 2024.

RHB-101 is a once-daily, controlled release, proprietary formulation of carvedilol. Carvedilol is marketed under various trade names including GlaxoSmithKline's ("GSK") Coreg®. RHB-101 was licensed from the Danish company Egalet a/s in 2009. As carvedilol, RHB-101 is a β-adrenergic blocking agent with α1-blocking activity and is planned to be indicated for the treatment of hypertension, heart failure and left ventricular

dysfunction. The Company is assessing RHB-101's development strategy, including its regulatory path, for marketing approvals in the U.S. pursuant to the 505(b)(2) regulatory path, and in Europe, based on clinical data generated in several pharmacokinetic (PK) trials.

RHB-101 entails several potential advantages over existing drugs on the market. One of the key advantages of RHB-101 is a once-daily administration regime, as oppose to generic drugs (such as GSK's Coreg®) which are administered to patients twice a day due to their relatively short active span. Administration once per day instead of several times per day has the potential to be a significant advantage, including improved compliance, especially for the elderly who commonly take a relatively large number of drugs over long periods of time. RHB-101 has also potential advantages over GSK's Coreg CR® - an improvement over the generic Coreg® drug, having a longer duration of action and being administered once per day. One of the potential advantages of RHB-101 over Coreg CR® is that RHB-101 is expected to be priced below the current price of Coreg CR®. Further potential advantages indicated by studies conducted to date consist of: (i) a reduced food effect on bioavailability, expected to allow patients to take RHB-101 with or without food while Coreg CR® is indicated to be taken with food and (ii) a markedly reduced dose.

The worldwide target market of RHB-101 was estimated to be in excess of $500 million in 2011[1].

"We are very pleased with this Notice of Allowance which serves as an indication of yet another important layer of intellectual property protection for RHB-101, our controlled release formulation of carvedilol", said **Guy Goldberg, RedHill's Chief Business Officer. "**We continue to move ahead with the development plan for RHB-101, which is aimed at improving existing treatments for patients suffering from hypertension, heart failure and left ventricular dysfunction, while exploring potential paths for obtaining marketing approvals in the U.S and Europe".

About RedHill Biopharma Ltd.:

RedHill Biopharma 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 a once-daily formulation of a leading congestive heart failure and high blood pressure drug, a once-daily formulation of a leading chemotherapy and radiotherapy-induced nausea and vomiting prevention drug, an oral thin film formulation

[1] Based on sales market data integrated from a 2012 report by Scrip Intelligence, the 2011 annual report of GlaxoSmithKline and European 2011 sales data for carvedilol from IMS Health.

drug for the treatment of acute migraines, a combination therapy for the treatment of Crohn's disease as well as Multiple Sclerosis (MS), a combination therapy for the treatment of *Helicobacter pylori* bacteria causing ulcers, and an encapsulated formulation for bowel preparation ahead of certain gastro procedures. For more information please visit: www.redhillbio.com.

Statements in this Press Release that are not historical facts, including the regulatory status of the programs and the expected timing and description of the clinical trials, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the Company's current understanding of the regulatory status and expectations of future events and are subject to significant regulatory and development risks and uncertainties that could cause actual results and development and regulatory progress to differ materially from those expressed or implied by such statements, including (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) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (x) competitive companies, technologies and the Company's industry; and (xi) 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 Registration Statement on From 20-F filed with the SEC on December 26, 2012, 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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