# Press Release

**Date: July 22, 2013**

## RedHill Biopharma Reports Results for the Second Quarter of 2013

### RedHill continues advanced preparations for the Phase III study with RHB-104 (Crohn's) and Phase II/III study with RHB-105 (*H. pylori*)

### Key Highlights include:

- **FDA acceptance of RHB-103 (migraine) NDA for substantive review, with a PDUFA goal date of February 3, 2014**
- **Commencement of supplementary PK program with RHB-102 (once daily anti-emetic) to support an NDA submission planned for the first quarter of 2014**
- **Commencement of patient screening in a phase IIa study with RHB-104 for Multiple Sclerosis in June 2013**
- **Receipt of warrants exercise notice from directors for a total consideration of approximately $400,000**

**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 financial results for the second quarter ended June 30, 2013.

The Company achieved significant milestones in the second quarter of 2013, including:

(i) Acceptance of the RHB-103 (a proprietary oral thin film formulation of rizatriptan for the treatment of acute migraine) New Drug Application (NDA) for substantive review by the

U.S. Food and Drug Administration (FDA) and assignment of a Prescription Drug User Fee Act (PDUFA) goal date of February 3, 2014.

(ii) Commencement of the first of two pharmacokinetic (PK) studies with RHB-102 (a once daily oncology support anti-emetic), with the results from both trials expected by October 2013 and an NDA submission planned for the first quarter of 2014.

(iii) Commencement of patient screening in a Phase IIa, proof of concept, clinical study with RHB-104 for Multiple Sclerosis (MS).

**Financial highlights for the first half of 2013:**

***Research and Development Expenses, net*** for the quarter ended June 30, 2013 were approximately $2.0 million, an increase of $0.7 million (approximately 54%) compared to $1.3 million for the quarter ended March 31, 2013. The increase was mainly due to expenses related to preparations for the Phase III clinical trial with RHB-104 (Crohn's). Research and Development Expenses, net for the six months ended June 30, 2013 were approximately $3.3 million, a decrease of $0.5 million (approximately 13%) compared to $3.8 million in the six months ended June 30, 2012. The decrease was mainly attributed to a discount from a Canadian service provider in the amount of $0.6 million.

***General and Administrative Expenses*** for the quarter ended June 30, 2013 were approximately $0.5 million, a decrease of $0.2 million (approximately 28%) compared to $0.7 million for the quarter ended March 31, 2013. The decrease was mainly due to expenses associated with the Company's listing on NASDAQ. General and Administrative Expenses for the six months ended June 30, 2013 were approximately $1.2 million, similar to the six months ended June 30, 2012.

***Operating Loss*** for the quarter ended June 30, 2013 was approximately $2.5 million, an increase of $0.5 million (approximately 25%) compared to $2.0 million for the quarter ended March 31, 2013. The increase was mainly due to increase in Research and Development Expenses, net. Operating Loss for the six months ended June 30, 2013 was approximately $4.5 million, a decrease of $0.5 million (approximately 10%) compared to $5 million in the six months ended June 30, 2012. The decrease was mainly due to a decrease in research and development expenses, net.

***Net Cash Used in Operating Activities*** for the six months ended June 30, 2013 was $3.9 million, an increase of $0.1 million compared to $3.8 million in the six months ended June 30, 2012.

***Net Cash Resulting from Investment Activities*** for the six months ended June 30, 2013 was $1.1 million compared to net cash of $5.6 million used for investment activities in the six months ended June 30, 2012. The decrease was mainly due to the conversion of short term deposits into cash and cash equivalents and to proceeds the Company received from the sale of marketable securities during the six months ended June 30, 2013.

***Cash Balance***[1] as of June 30, 2013 was approximately $14.7 million compared to $18.4 million as of December 31, 2012. The decrease of $3.7 million was mainly due to cash used to fund operating activities during the six months ended June 30, 2013.

**Key operational highlights for the second quarter ended June 30, 2013:**

1. On June 18, 2013, the Company and its co-development partner for RHB-103, IntelGenx Corp., reported that the NDA submitted for RHB-103, a proprietary oral thin film formulation of rizatriptan, a leading drug for the treatment of acute migraine, had been accepted for substantive review by the FDA. The RHB-103 NDA is subject to a standard 10-month review period and has been assigned a PDUFA goal date of February 3, 2014.

2. On July 11, 2013, the Company 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, indicated for the prevention of radiotherapy induced nausea and vomiting (RINV) and chemotherapy induced nausea and vomiting (CINV). Subject to the results from the two studies, expected by October 2013, and the required regulatory process, and in light of the data from prior successful studies with RHB-102, the Company plans to submit an NDA seeking U.S. marketing approval of RHB-102 in the first quarter of 2014, earlier than previously planned.

3. On June 5, 2013, the Company reported that it had commenced patient screening in the Phase IIa, proof of concept, clinical study (the "CEASE-MS Study"), to assess the efficacy and safety of fixed dose combination RHB-104, a patent protected combination therapy of three antibiotics in a single capsule, as an add-on therapy to interferon beta-1a in patients treated for Relapsing Remitting Multiple Sclerosis (RRMS). The study follows the successful completion of four pre-clinical studies with RHB-104.

4. On May 29, 2013, the Company reported that it had concluded a Type B meeting with the 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. Based on the FDA's feedback, prior to 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.

5. 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 will expire no earlier than June, 2024.

6. SCOLR Pharma, Inc. a U.S.- publicly traded company from whom the Company licenses its rights to its RHB-102 anti-emetic drug, recently announced that it ceased business operations. It should be noted that under the terms of the license agreement between RedHill and SCOLR, should SCOLR file for bankruptcy, RedHill has the protection afforded to the licensee under the

[1] Including cash, bank deposits and short term investments.

United States Bankruptcy Code. Moreover, RedHill independently filed with the USPTO, on March 14, 2013, a provisional patent application, owned by RedHill, covering the formulation of RHB-102. The Company is currently assessing the possible implications of SCOLR's decision to cease its operations and is taking active steps to further safeguard its rights under the RHB-102 license agreement. The Company continues the development program of RHB-102 as planned, and is not expecting any delays in such program resulting from SCOLR's decision to cease its operations.

7. On July 2013, the Company received a notice of exercise from two of its directors, Dr. Shmuel Cabilly and Mr. Eric Swenden, with respect to non-tradable warrants that had been granted to them as part of their investment in the Company during the 2010 pre-IPO bridge financing. Accordingly, the Company will issue to the directors 471,962 ordinary shares for a total consideration to the Company of $405,000.

***Ori Shilo, Deputy CEO Finance and Operations said:*** "We are very pleased with our second quarter results. We continued to advance our late clinical stage development programs and achieved another significant milestone with the acceptance of our first New Drug Application (NDA) of RHB-103 for substantive review by the FDA and the assignment of a Prescription Drug User Fee Act (PDUFA) goal date of February 3, 2014. The Company maintains a strong cash balance, with approximately $14.7 million in cash at the end of the second quarter, and no financial debt. We are also very pleased with the vote of confidence by two of our directors who elected to invest another $400,000 in the Company through the exercise of warrants. Looking ahead, we expect significant milestones in the second half of 2013, including the planned commencement of a Phase III study with RHB-104 for Crohn's disease and a Phase II/III study with RHB-105 for *H. pylori* bacterial infection, and completion of the PK program with the anti-emetic drug RHB-102 supporting planned NDA submission in the first quarter of 2014."

**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 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 a 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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**REDHILL BIOPHARMA LTD.**
CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

| | Three months ended June 30 | | Six months ended June 30 | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| | U.S. dollars in thousands | | | |
| **REVENUE** | 4 | 5 | 8 | 9 |
| **RESEARCH AND DEVELOPMENT EXPENSES,** NET | 1,982 | 1,493 | 3,328 | 3,821 |
| **GENERAL AND ADMINISTRATIVE EXPENSES:** | 548 | 578 | 1,223 | 1,187 |
| **OPERATING LOSS** | 2,526 | 2,066 | 4,543 | 4,999 |
| **FINANCIAL INCOME** | 17 | 40 | 60 | 123 |
| **FINANCIAL EXPENSES** | 3 | 247 | 6 | 131 |
| **FINANCIAL INCOME (EXPENSES),** NET | 14 | (207) | 54 | (8) |
| **LOSS AND COMPREHENSIVE LOSS** | 2,512 | 2,273 | 4,489 | 5,007 |
| **LOSS PER ORDINARY SHARE,** basic and diluted (U.S. dollars) | 0.04 | 0.04 | 0.07 | 0.10 |
| **WEIGHTED AVERAGE OF ORDINARY SHARES** (in thousands) | 61,842 | 52,398 | 61,376 | 52,359 |

**REDHILL BIOPHARMA LTD.**

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

| | June 30 2013 | December 31 2012 |
|---|---|---|
| | U.S. dollars in thousands | |
| **CURRENT ASSETS** | | |
| Cash and cash equivalents | 14,176 | 16,814 |
| Bank deposits | 293 | 486 |
| Financial assets at fair value through profit or loss | 233 | 1,065 |
| Prepaid expenses and receivables | 586 | 198 |
| | 15,288 | 18,563 |
| **NON-CURRENT ASSETS** | | |
| Restricted bank deposit | 73 | 75 |
| Fixed assets | 111 | 113 |
| Intangible assets | 1,545 | 1,345 |
| | 1,729 | 1,533 |
| Total assets | 17,017 | 20,096 |
| **CURRENT LIABILITIES** | | |
| accounts payable and accrued expenses | 1,761 | 1,078 |
| **EQUITY** | | |
| Ordinary shares | 167 | 143 |
| Ordinary shares to be issued | - | 8,020 |
| Additional paid-in capital | 39,679 | 31,469 |
| Warrants | 3,232 | 3,273 |
| Accumulated deficit | (27,822) | (23,887) |
| Total equity | 15,256 | 19,018 |
| Total liabilities and equity | 17,017 | 20,096 |

**REDHILL BIOPHARMA LTD.**

CONDENSED INTERIM STATEMENTS OF CASH FLOW

(Unaudited)

| | Six months ended June 30 | |
|---|---|---|
| | 2013 | 2012 |
| | U.S. dollars in thousands | |
| **CASH FLOW FROM OPERATING ACTIVITIES** | | |
| Loss | (4,489) | (5,007) |
| Adjustments in respect of income and expenses not involving cash flow | | |
| Share-based compensation to employees and service providers | 554 | 1,019 |
| Depreciation | 11 | 11 |
| Fair value gains on financial assets at fair value through profit or loss | (44) | 20 |
| Revaluation of bank deposits | 2 | (34) |
| Accretion of royalty obligations to investors | - | 62 |
| Exchange differences relating to cash and cash equivalents | (5) | (10) |
| | 518 | 1,068 |
| Changes in assets and liability items | | |
| Increase in prepaid expenses and receivables | (388) | (146) |
| Increase in accounts payable and accrued expenses | 483 | 299 |
| | 95 | 153 |
| Net cash used in operating activities | (3,876) | (3,786) |
| **CASH FLOW FROM INVESTING ACTIVITIES** | | |
| Purchase of fixed assets | (9) | (5) |
| Purchase of intangible assets | - | (100) |
| Change in investment in bank deposits | 193 | (5,467) |
| Purchase of financial assets at fair value through profit or loss | - | (105) |
| Proceeds from sale of financial assets at fair value through profit or loss | 876 | 105 |
| Net cash resulting (used) in investing activities | 1,060 | (5,572) |
| **CASH FLOW FROM FINANCING ACTIVITIES** | | |
| Proceeds from issuance of ordinary shares and warrants | 100 | - |
| Exercise of warrants and options into ordinary shares | 73 | 27 |
| Net cash provided by financing activities | 173 | 27 |
| **DECREASE IN CASH AND CASH EQUIVALENTS** | (2,643) | (9,331) |
| **EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS** | 5 | 10 |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD** | 16,814 | 14,070 |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT** | 14,176 | 4,749 |

**END OF PERIOD**