# Press Release

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

### Key highlights include:

- **Commencement of the MAP US study – a Phase III clinical study in North America and Israel with RHB-104 for the treatment of Crohn's disease**

- **Commencement of the ERADICATE Hp study – a Phase III clinical study in the U.S. with RHB-105 for the treatment of *H. pylori* bacterial infection**

- **Positive results in two supplementary studies conducted with RHB-102, once daily oncology support anti-emetic, with NDA submission planned for the first quarter of 2014**

- **Company shareholders, board members and officers exercised warrants and options for a total amount of approximately $2.2 million since the beginning of the year**

**TEL-AVIV, Israel, November 12, 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 financial results for the third quarter ended September 30, 2013.

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

(i) Commencement of the MAP US study – a Phase III clinical study in North America and Israel, designed to evaluate the safety and efficacy of fixed-dose RHB-104 in patients with moderately to severely active Crohn's disease.

(ii) Commencement of the ERADICATE Hp study – a Phase III clinical study in the U.S. designed to evaluate the safety and efficacy of RHB-105, proprietary fixed-dose combination therapy as a first-line treatment for confirmed *Helicobacter pylori* (*H. pylori*) bacterial infection.

(iii) Positive results in two supplementary pharmacokinetic (PK) studies conducted with RHB-102, once daily oncology support anti-emetic, with NDA submission planned for the first quarter of 2014.

(iv) Positive results in a pre-clinical study with RHB-104 for the treatment of rheumatoid arthritis (RA) and plans to conduct a Phase IIa proof of concept clinical trial to assess the efficacy and safety of RHB-104 in patients suffering from RA.

**Financial highlights for the third quarter of 2013:**

***Research and Development Expenses, net*** for the quarter ended September 30, 2013 were approximately $2.2 million, an increase of $0.2 million (approximately 10%) compared to $2.0 million for the quarter ended June 30, 2013. Research and Development Expenses, net for the nine months ended September 30, 2013 were approximately $5.5 million, an increase of $0.3 million (approximately 6%) compared to $5.2 million in the nine months ended September 30, 2012. The increase in both periods was mainly due to expenses related to preparations for the Phase III clinical trials with RHB-104 (Crohn's) and RHB-105 (*H. pylori*).

***General and Administrative Expenses*** for each of the quarters ended September 30, 2013 and June 30, 2013 were approximately $0.5 million. General and Administrative Expenses for the nine months ended September 30, 2013 were approximately $1.8 million, an increase of $0.1 million (approximately 6%) compared to $1.7 million for the nine months ended September 30, 2012. The increase was mainly attributed to expenses associated with the requirements of being a dual-listed company on both TASE and NASDAQ.

***Operating Loss*** for the quarter ended September 30, 2013 was approximately $2.7 million, an increase of $0.2 million (approximately 8%) compared to $2.5 million for the quarter ended June 30, 2013. Operating loss for the nine months ended September 30, 2013 was approximately $7.3 million, an increase of $0.4 million (approximately 6%) compared to $6.9 million in the nine months ended September 30, 2012. The increase in both periods was mainly due to an increase in Research and Development Expenses, net.

***Net Cash Used in Operating Activities*** for each of the quarters ended September 30, 2013 and June 30, 2013 was approximately $2.1 million. Net cash used in operating activities for the nine months ended September 30, 2013 was $6.0 million, an increase of $0.8 million (approximately 15%) compared to $5.2 million in the nine months ended September 30, 2012. The increase was mainly due to an increase in Research and Development Expenses, net.

***Net Cash Used from Investment Activities*** for the quarter ended September 30, 2013 was approximately $0.2 million, compared to net cash resulting from investment activities of $0.5 million for the quarter ended June 30, 2013, a decrease of $0.7 million (approximately 140%). The decrease was mainly due to a $0.2 million development milestone payment for RHB-103 in the quarter ended September 30, 2013 and due to proceeds from the sale of tradable securities in the quarter ended June 30, 2013. Net cash resulting from investment activities in the nine months ended September 30, 2013 was $0.9 million, an increase of $0.5 million (approximately 125%) compared to net cash of $0.4 million resulting from investment activities in the nine months ended September 30, 2012. The increase was mainly due to the conversion of short-term deposits into cash and cash equivalents.

***Cash Resulting from Financing Activities*** for the quarter ended September 30, 2013 was approximately $1.3 million, an increase of $1.2 million (approximately 1,200%) compared to $0.1 million for the quarter ended June 30, 2013. The increase was mainly due to the exercise of warrants by investors from the 2010 financing. Cash resulting from financing activities for the nine months ended September 30, 2013 was $1.4 million, an increase of $1.1 million (approximately 370%) compared to net cash of $0.3 million in the nine months ended September 30, 2012. The increase was mainly due to exercise of warrants by investors from the 2010 financing.

***Cash Balance***[1] as of September 30, 2013 was approximately $13.7 million, a decrease of $1.0 million (approximately 7%) compared to $14.7 million at the end of the previous quarter ended June 30, 2013 and a decrease of $4.7 million (approximately 25%) compared to $18.5 million as of December 31, 2012.

**Ori Shilo, Deputy CEO Finance and Operations said:** "Activities in the third quarter of 2013 were mainly focused on preparations for the Phase III clinical trials with RHB-104 for Crohn's and RHB-105 for *H. pylori* infection which commenced in September and October 2013 respectively. Our cash position remains strong with approximately $14 million in cash at the end of the quarter and no financial debt. We are very pleased with the vote of confidence by our shareholders, including board members and officers, who elected to exercise warrants and options since the beginning of the year for a total amount of approximately $2.2 million." **Mr. Shilo added**: "Looking ahead, we are excited by the prospective milestones for 2014, including the PDUFA date for our migraine drug RHB-103, expected in February 3, 2013, results from the Phase III study with RHB-105 for *H. pylori* bacterial infection, the planned NDA submission with RHB-102 for prevention of nausea and vomiting in cancer patients and results from the Phase IIa study with RHB-104 for multiple sclerosis."

**Key operational highlights for the third quarter ended September 30, 2013:**

1. On October 30, 2013, the Company announced that it had commenced the patient screening process for the ERADICATE Hp study – a Phase III clinical study in the U.S. designed to evaluate the safety and efficacy of RHB-105, a proprietary fixed-dose combination therapy of two antibiotics and a proton pump inhibitor (PPI), as a first-line treatment for confirmed

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

*H. pylori* bacterial infection. The randomized, double-blind, placebo-controlled Phase III study is expected to enroll 90 subjects in up to ten clinical sites in the U.S. The primary endpoint of the study will be eradication of *H. pylori* infection 28 to 56 days after completion of treatment and data is expected by the second half of 2014.

2. On October 15, 2013, the Company announced the presentation of a poster at the ACG (American College of Gastroenterology) 2013 Annual Scientific Meeting and the pending publication in the American Journal of Gastroenterology on positive results from an independent, single-center, retrospective study with pediatric patients suffering from Crohn's disease. The study was conducted by Professor Thomas Borody, a member of RedHill's advisory board, with an earlier formulation of RedHill's RHB-104 anti-MAP (*Mycobacterium avium subspecies paratuberculosis*) combination therapy, using the same active ingredients in doses adjusted for pediatric usage. The results of the study demonstrated a clinical remission rate of 80% in 10 pediatric Crohn's disease patients, with a median duration of remission of 16 months.

3. On October 8, 2013, the Company announced positive results in two supplementary pharmacokinetic (PK) studies conducted with RHB-102, 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 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, the Company is seeking a pre-NDA meeting with the U.S. Food and Drug Administration (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.

4. On October 1, 2013, the Company announced that it had commenced the patient screening process in the MAP US study, a Phase III clinical study designed to evaluate the safety and efficacy of fixed-dose RHB-104 in patients with moderately to severely active Crohn's disease. The randomized, double-blind, placebo-controlled Phase III clinical study is expected to enroll 240 subjects with moderately to severely active Crohn's disease in approximately 50 clinical sites in the U.S., Canada and Israel. Subjects will be treated for a period of 52 weeks and will be assessed for remission at 26 weeks. The primary endpoint for the study will be the state of remission at week 26 in subjects randomized to receive RHB-104, compared to subjects randomized to receive placebo. An independent data and safety monitoring board (DSMB) will review safety intermittently throughout the study and will perform a futility analysis when half the subjects complete the first 26 weeks of blinded treatment.

5. On September 10, 2013, the Company announced positive results from a pre-clinical study with RHB-104 for the treatment of systemic lupus erythematosus (SLE), a systemic autoimmune disease causing inflammation and damage to tissues in various parts of the body. The pre-

clinical study was designed to evaluate the potential therapeutic effects of RHB-104 on disease development in an experimental SLE model when administered orally. The results from the pre-clinical study demonstrated that disease severity and overall disease development were reduced in the RHB-104 arm, indicating that RHB-104 was efficacious in reducing the development of SLE in this study. In light of the positive results, the Company is currently assessing the next steps in the clinical development program, including a possible Phase IIa clinical study.

6. On August 20, 2013, the Company announced that it had recently concluded Scientific Advice Meetings with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and the Swedish Medical Products Agency (MPA) regarding the regulatory path towards a Phase III clinical study in Europe with RHB-104. In light of the positive feedback received from the UK MHRA and the Swedish MPA, the Company believes there is a clear regulatory path towards a Phase III clinical study in Europe with RHB-104 for the treatment of Crohn's disease (the "MAP Europe" study). The Phase III double-blind placebo-controlled MAP Europe study is expected to enroll 360 subjects with moderately active Crohn's disease randomized in up to 60 sites in six European countries and is planned to commence in the first half of 2014, subject to regulatory approvals.

7. On July 30, 2013, the Company announced positive results from a pre-clinical study with RHB-104 for the treatment of rheumatoid arthritis (RA), a systemic chronic inflammatory disease considered to be one of the most prevalent immune-mediated inflammatory diseases. The pre-clinical study was designed to evaluate the potential therapeutic effects of RHB-104 using the Collagen-Induced Arthritis (CIA) pre-clinical model, the most commonly studied autoimmune model of RA. The results from the pre-clinical study demonstrated that disease severity was significantly reduced in the RHB-104 arm, indicating that RHB-104 was effective in treating CIA in the study. In light of these positive results, the Company plans to conduct a phase IIa, proof of concept, clinical study to assess the efficacy and safety of RHB-104 in patients suffering from RA.

**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 migraines, 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, currently underway, 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 September 30 | | Nine months ended September 30 | |
|---|---|---|---|---|
| | **2013** | **2012** | **2013** | **2012** |
| | **U.S. dollars in thousands** | | | |
| **REVENUE** | 3 | 3 | 11 | 12 |
| **RESEARCH AND DEVELOPMENT EXPENSES,** NET, see note 6 | (2,207) | (1,379) | (5,535) | (5,207) |
| **GENERAL AND ADMINISTRATIVE EXPENSES** | (545) | (550) | (1,768) | (1,730) |
| **OPERATING LOSS** | (2,749) | (1,926) | (7,292) | (6,925) |
| **FINANCIAL INCOME** | 53 | 57 | 113 | 145 |
| **FINANCIAL EXPENSES** | (3) | (98) | (9) | (194) |
| **FINANCIAL INCOME (EXPENSES),** NET | 50 | (41) | 104 | (49) |
| **LOSS AND COMPREHENSIVE LOSS** | (2,699) | (1,967) | (7,188) | (6,974) |
| **LOSS PER ORDINARY SHARE,** basic and diluted (U.S. dollars) | 0.04 | 0.04 | 0.12 | 0.13 |
| **WEIGHTED AVERAGE OF ORDINARY SHARES** (in thousands) | 62,637 | 52,745 | 61,800 | 52,462 |

**REDHILL BIOPHARMA LTD.**

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

| | September 30 2013 | December 31 2012 |
|---|---|---|
| | U.S. dollars in thousands | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | 13,165 | 16,814 |
| Bank deposits | 302 | 486 |
| Financial assets at fair value through profit or loss | 239 | 1,065 |
| Prepaid expenses and receivables | 778 | 198 |
| | 14,484 | 18,563 |
| **NON-CURRENT ASSETS:** | | |
| Restricted bank deposit | 79 | 75 |
| Fixed assets | 107 | 113 |
| Intangible assets | 1,545 | 1,345 |
| | 1,731 | 1,533 |
| Total assets | 16,215 | 20,096 |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accrued expenses | 1,924 | 1,078 |
| **EQUITY:** | | |
| Ordinary shares | 171 | 143 |
| Ordinary shares to be issued | - | 8,020 |
| Additional paid-in capital | 41,679 | 31,469 |
| Warrants | 2,499 | 3,273 |
| Accumulated deficit | (30,058) | (23,887) |
| Total equity | 14,291 | 19,018 |
| Total liabilities and equity | 16,215 | 20,096 |

**REDHILL BIOPHARMA LTD.**

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

| | Nine months ended September 30 | | Three months ended September 30 | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| | U.S. dollars in thousands | | | |
| **CASH FLOW FROM OPERATING ACTIVITIES:** | | | | |
| Loss | (7,188) | (6,974) | (2,699) | (1,967) |
| Adjustments in respect of income and expenses notinvolving cash flow: | | | | |
| Share-based compensation to employees and service providers | 1,017 | 1,363 | 463 | 344 |
| Depreciation | 18 | 15 | 7 | 4 |
| Fair value gains on financial assets at fair value through profit or loss | (50) | 2 | (6) | (18) |
| Revaluation of bank deposits | (13) | (31) | (15) | 3 |
| Accretion of royalty obligations to investors | - | 129 | - | 67 |
| Exchange differences relating to cash and cash equivalents | (32) | (28) | (27) | (18) |
| | 940 | 1,450 | 422 | 382 |
| Changes in assets and liability items: | | | | |
| Decrease (increase) in prepaid expenses and receivables | (580) | (31) | (192) | 115 |
| Increase in accounts payable and accrued expenses | 846 | 306 | 363 | 7 |
| | 266 | 275 | 171 | 122 |
| Net cash used in operating activities | (5,982) | (5,249) | (2,106) | (1,463) |
| **CASH FLOW FROM INVESTING ACTIVITIES:** | | | | |
| Purchase of fixed assets | (12) | (5) | (3) | - |
| Purchase of intangible assets | (200) | (100) | (200) | - |
| Change in investment in bank deposits | 193 | 529 | - | 5,996 |
| Purchase of financial assets at fair value through profit or loss | - | (1,032) | - | (927) |
| Proceeds from sale of financial assets at fair value through profit or loss | 876 | 1,030 | - | 925 |
| Net cash resulting in investing activities | 857 | 422 | (203) | 5,994 |

| | | | | |
|---|---|---|---|---|
| **CASH FLOW FROM FINANCING ACTIVITIES:** | | | | |
| Proceeds from issuance of ordinary shares and warrants | 100 | - | - | - |
| Exercise of warrants and options into ordinary shares | 1,344 | 302 | 1,271 | 275 |
| Net cash provided by financing activities | 1,444 | 302 | 1,271 | 275 |
| **INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | (3,681) | (4,525) | (1,038) | 4,806 |
| **EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS** | 32 | 28 | 27 | 18 |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD** | 16,814 | 14,070 | 14,176 | 4,749 |
| **BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD** | 13,165 | 9,573 | 13,165 | 9,573 |
| **Supplementary information on interest received in cash** | 25 | 50 | 10 | 4 |

**The accompanying notes are an integral part of these condensed financial statements.**