



Press Release

Date: May 2, 2013

RedHill Biopharma Reports Financial Results for the First Quarter of 2013

The Company maintains a strong balance sheet following submission to the FDA of its first New Drug Application (NDA) for RHB-103 (migraine)

RedHill plans to submit a second NDA, for RHB-102 (oncology support anti emetic), by the first or second quarter of 2014 and continues to advance the planned Phase III and Phase II/III studies with RHB-104 (Crohn's) and RHB-105 (*H. pylori*), respectively

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, today reported financial results for the first quarter ended March 31, 2013.

The Company completed significant milestones in the first quarter of 2013, including:

- (i) Submission of the Company’s first New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the marketing approval of RHB-103, an oral thin film formulation of rizatriptan for the treatment of acute migraine.
- (ii) A positive Type B meeting with the FDA regarding the submission of RHB-102 (oncology support anti emetic) for a U.S. NDA, planned by the first or second quarter of 2014; and,
- (iii) A successful Scientific Advice Meeting held with the Danish Health and Medicines Authority (DKMA) regarding the planned submission of RHB-101(cardio) for a Marketing

Authorization Application (MAA) in Europe, with Denmark as the reference member state for the European Mutual Recognition Procedure (MRP).

- (iv) Issuance of a new patent by the United States Patent and Trademark Office (USPTO) covering RHB-104 (Crohn's). The new patent (No.: 8,343,511), entitled "*Methods and Compositions for Treating Inflammatory Bowel Disease*", will expire no earlier than 2029, and forms a substantial addition to the already issued and pending patents that support the intellectual property estate of RHB-104.

Financial highlights for the first quarter ended March 31, 2013:

Research and Development Expenses, net for the quarter ended March 31, 2013 were approximately \$1.3 million, a decrease of \$1.1 million (approximately 48%) compared to \$2.3 million in the first quarter of 2012. This decrease was mainly attributed to two clinical studies conducted during the first quarter of 2012, a discount from a Canadian service provider recognized in March 2013 and a reduction in expenses related to options granted to employees and service providers.

General and Administrative Expenses for the quarter ended March 31, 2013 were approximately \$0.7 million, an increase of \$0.1 million (approximately 16%) compared to \$0.6 million in the first quarter of 2012. This increase was mainly due to an increase in professional services fees in connection with the Company's NASDAQ listing, partly offset by a decrease in expenses related to options granted to employees and service providers.

Operating Loss for the quarter ended March 31, 2013 was approximately \$2.0 million, a decrease of \$0.9 million (approximately 31%) compared to \$2.9 million in the first quarter of 2012. This decrease was mainly attributed to a decrease in research and development expenses, net.

Financing Income, net for the quarter ended March 31, 2013 was approximately \$40,000, a decrease of \$0.16 million (approximately 80%) compared to \$0.2 million in the first quarter of 2012. This decrease was mainly due to a decrease in exchange rates and interest income.

Net Cash Used in Operating Activities for the quarter ended March 31, 2013 was \$1.8 million, a decrease of \$0.2 million (approximately 10%) compared to \$2.0 million in the first quarter of 2012. This decrease was mainly due to a reduction in research and development expenses, net.

Net Cash Resulting from Investment Activities for the quarter ended March 31, 2013 was \$0.55 million, a decrease of \$5 million compared to \$5.5 million in the first quarter of 2012. The decrease was mainly due to a change of short term deposits to cash and cash equivalents.

Cash Balance¹ as of March 31, 2013 was approximately \$16.8 million, a decrease of \$1.6 million during the quarter (approximately 9%). This decrease was mainly due to cash used to fund operating activities.

¹ Including cash, bank deposits and short term investments.

Key operational highlights for the first quarter ended March 31, 2013:

1. On March 25, 2013 the Company and its co-development partner for RHB-103, IntelGenx Corp. submitted an NDA to the FDA seeking marketing approval of RHB-103, a proprietary oral thin film formulation of rizatriptan, a leading drug for the treatment of acute migraine. The NDA was submitted under the 505(b)(2) regulatory path, following a positive pre-NDA meeting with the FDA.
2. On March 19, 2013 the Company reported that it had concluded a European Scientific Advice meeting with the Danish Health and Medicines Authority (DKMA) regarding its RHB-101, a controlled release, proprietary, once-daily formulation of carvedilol for the treatment of hypertension. Based on the positive results of the meeting, the Company intends to submit a Marketing Authorization Application (MAA) in Europe, with Denmark as the reference member state for the European Mutual Recognition Procedure (MRP).
3. On February 28, 2013 the Company reported that it had concluded a Type B meeting and additional communications with the FDA regarding its RHB-102 drug, a patent protected, oral, extended release (24 hours) formulation of ondansetron for the prevention of radiotherapy induced nausea and vomiting (RINV) and chemotherapy induced nausea and vomiting (CINV). Based on these communications and subject to additional regulatory and other activities, the Company currently estimates that an NDA for RHB-102 will be filed by the first or second quarter of 2014.
4. On February 19, 2013 the Company reported that the USPTO published a Notice of Allowance for U.S. Patent Application Serial Number 12/076,105 entitled "*Controlled Release Carvedilol Compositions*" for RedHill's RHB-101 drug. 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.
5. On January 7, 2013 the Company reported that a multi-site initiation process is underway in the U.S., Canada and Israel for a first multi-center, randomized, double-blind, placebo-controlled, parallel group initial Phase III study (the "MAP US Study") to assess the efficacy and safety of fixed-dose combination RHB-104 in subjects with moderately to severely active Crohn's disease. Recruitment of patients for the MAP US Study is currently planned to commence in the third quarter of 2013. The MAP US Study will be conducted under an Investigational New Drug (IND) application amended in August, 2012.
6. On January 1, 2013 the USPTO issued a new patent covering RHB-104 (No.: 8,343,511) entitled "*Methods and Compositions for Treating Inflammatory Bowel Disease*", which expires no earlier than 2029.

Ori Shilo, Deputy CEO Finance and Operations said: "We had a solid first quarter with substantial progress achieved in our development plans. We achieved a significant milestone with the submission of our first New Drug Application (NDA) for RHB-103, an oral thin film formulation of rizatriptan for the treatment of acute migraine. The Company's cash position remains

strong, with approximately \$17 million in cash at the end of the first quarter, with no financial debt. We continue to advance our operational plans for 2013, including the planned commencement of the Phase III MAP US Study with RHB-104 for Crohn's disease, with recruitment of clinical sites in the U.S., Canada and Israel underway, and the Phase II/III clinical trial with RHB-105 for *H. pylori* bacterial infection".

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. 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, planned to be submitted for a Marketing Authorization Application (MAA) in Europe, (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 by the first or second 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 submitted in March 2013, (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) Phase IIa proof of concept trial, (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 Form 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.

STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended	
	March 31	
	2013	2012
	U.S. dollars in	
	thousands	
REVENUE	4	4
RESEARCH AND DEVELOPMENT EXPENSES, NET	(1,346)	(2,328)
GENERAL AND ADMINISTRATIVE EXPENSES	(675)	(609)
OPERATING LOSS	(2,017)	(2,933)
FINANCIAL INCOME	43	258
FINANCIAL EXPENSES	3	59
FINANCIAL INCOME, NET	40	199
LOSS AND COMPREHENSIVE LOSS	(1,977)	(2,734)
LOSS PER ORDINARY SHARE – basic and diluted (U.S. dollars)	0.03	0.05

REDHILL BIOPHARMA LTD.
STATEMENTS OF FINANCIAL POSITION

	March 31	December 31
	2013	2012
	(Unaudited)	(Audited)
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	15,729	16,814
Bank deposits	14	486
Financial assets at fair value through profit or loss	1,016	1,065
Prepaid expenses and receivables	404	198
	17,163	18,563
NON-CURRENT ASSETS:		
Restricted bank deposit	77	75
Fixed assets	109	113
Intangible assets	1,345	1,345
	1,531	1,533
T o t a l assets	18,694	20,096
CURRENT LIABILITIES -		
Accounts payable and accrued expenses	1,331	1,078
COMMITMENTS		
EQUITY:		
Ordinary shares	167	143
Ordinary shares to be issued	-	8,020
Additional paid-in capital	39,598	31,469
Warrants	3,255	3,273
Accumulated deficit	(25,657)	(23,887)
T o t a l equity	17,363	19,018
T o t a l liabilities and equity	18,694	20,096

REDHILL BIOPHARMA LTD.
STATEMENTS OF CASH FLOWS
(Unaudited)

	Three months ended	
	March 31	
	2013	2012
	US dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss	(1,977)	(2,734)
Adjustments in respect of income and expenses not involving cash flows:		
Share-based compensation to employees and service providers	207	579
Depreciation	6	7
Fair value gains on financial assets at fair value through profit or loss	(30)	(55)
Revaluation of bank deposits	(3)	(34)
Accretion of royalty obligations to investors	-	56
Exchange differences in respect of cash and cash equivalents	(8)	(132)
Changes in asset and liability items:		
Increase in prepaid expenses and receivables	(206)	(90)
Increase in accounts payable and accrued expenses	253	367
Net cash used in operating activities	<u>(1,758)</u>	<u>(2,036)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(2)	(5)
Changes in investment in bank deposits	473	(5,467)
Proceeds from sale of financial assets at fair value through profit or loss	79	-
Net cash used in investing activities	<u>550</u>	<u>(5,472)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares and warrants	100	-
Exercise of warrants into ordinary shares	15	-
Net cash provided by financing activities	<u>115</u>	<u>-</u>
DECREASE IN CASH AND CASH EQUIVALENTS	<u>(1,093)</u>	<u>(7,508)</u>
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	8	132
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	<u>16,814</u>	<u>14,070</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>15,729</u>	<u>6,694</u>
Supplementary information on interest received in cash	<u>2</u>	<u>33</u>
