



Press Release

RedHill Biopharma Reports 2013 Fourth Quarter and Year-End Financial Results

2013 key highlights include:

- **Strong cash position of over \$34 million, as of February 2014, following two private placements in early 2014 and the exercise of warrants, including by directors and management**
- **Net R&D expenses of \$8.1 million during 2013, compared to \$6.5 million in 2012**
- **Substantial progress in clinical development, including the commencement of Phase III clinical studies in the U.S. with RHB-104 for the treatment of Crohn's disease and RHB-105 for the treatment of *H. pylori* bacterial infection**

TEL-AVIV, Israel, February 25, 2014 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 for the treatment of inflammatory and gastrointestinal diseases including cancers and related conditions, today reported financial results for the year ended December 31, 2013.

Financial highlights for the year ended December 31, 2013 and for the Fourth Quarter of 2013:

Research and Development Expenses, net for the year ended December 31, 2013 were approximately \$8.1 million (\$9.1 million gross), an increase of \$1.6 million, or approximately 25%, compared to \$6.5 million for the year ended December 31, 2012. Research and Development Expenses, net for the quarter ended December 31, 2013 were approximately \$2.6 million, compared

to \$1.2 million in the comparable quarter of 2012 and \$2.2 million in the third quarter of 2013. The increase was mainly due to the commencement of the Phase III clinical studies with RHB-104 (Crohn's disease) and RHB-105 (*H. pylori*) and the ongoing Phase IIa study with RHB-104 in multiple sclerosis (MS)).

General and Administrative Expenses for the year ended December 31, 2013 were approximately \$2.7 million, an increase of \$0.1 million, or approximately 4%, compared to \$2.6 million for the year ended December 31, 2012. The increase was mainly due to the recruitments of new employees, and was partially offset by a decrease in share-based payments. General and Administrative Expenses for the quarter ended December 31, 2013 as well as the comparable quarter of 2012 were approximately \$0.9 million, compared to 0.5 million in the third quarter of 2013. The increase in the fourth quarter of 2013 was mainly due to costs related to payroll expenses, professional services and travel expenses.

Operating Loss for the year ended December 31, 2013 was approximately \$10.8 million, an increase of \$1.8 million, or approximately 20%, compared to \$9 million for the year ended December 31, 2012. Operating loss for the quarter ended December 31, 2013 was \$3.4 million, compared to \$2.4 million in the comparable quarter of 2012 and \$2.7 million in the third quarter of 2013. The increase was mainly due to Research and Development Expenses.

Net Cash Used in Operating Activities for the year ended December 31, 2013 was approximately \$8.4 million, an increase of \$1.4 million compared to the year ended December 31, 2012. The increase was mainly due to research and development activities. Net Cash Used in Operating Activities for the quarter ended December 31, 2013 was \$2.5 million, compared to \$1.5 million in the comparable quarter of 2012 and \$2.1 million in the third quarter of 2013. The increase was mainly due Research and Development Expenses, net.

Cash Resulting from Financing Activities for the year ended December 31, 2013 was approximately \$2.3 million, a decrease of \$4.3 million, or approximately 65%, compared to \$6.6 million for the year ended December 31, 2012. The Cash Resulting from Financing Activities in 2013 resulted primarily from the exercise of warrants, whereas in 2012 it resulted primarily from the private financing transaction that closed in January 2013.

Cash Balance¹ as of December 31, 2013 was approximately \$12.1 million, a decrease of \$6.3 million, or approximately 34%, compared to \$18.4 million as of December 31, 2012 and a decrease of \$1.6 million, approximately 12%, compared to \$13.7 million as of September 30, 2013.

Ori Shilo, Deputy CEO, Finance and Operations said: "RedHill achieved important milestones in 2013. We recently closed two private placements with leading global healthcare investment firms and Israeli institutional investors, for a total of approximately \$20 million. In addition, during 2013 and up to February 2014 we received approximately \$6.7 million from the exercise of warrants and options, including exercise of warrants by directors and management. As of February 2014, RedHill has over \$34 million in cash. This strong cash position, together with the continuing support from

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

our shareholders, allow us to continue advancing our strategic plans and we look forward to achieving additional important milestones in 2014."

Key operational highlights for the year ended December 31, 2013:

1. In June 2013, the Company initiated the CEASE-MS study - a Phase IIa, proof of concept, clinical study, to assess the efficacy and safety of RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing remitting multiple sclerosis (RRMS).
2. In June 2013, the Company reported that the NDA for RHB-103 oral thin film for migraines had been accepted for substantive review by the FDA. On February 4, 2014, the Company reported receipt of a Complete Response Letter (CRL) from the FDA with questions primarily relating to third party manufacturing, packaging and labeling. The CRL accepted the bioequivalence study and safety information submitted and required no additional clinical studies.
3. In August 2013, the Company announced that it had 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 for the treatment of Crohn's disease (the "MAP Europe" study). The Phase III MAP Europe study is planned to commence during the first half of 2014, subject to regulatory approvals.
4. In November 2013, the Company announced that the first patient had been dosed in 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.
5. In December 2013, the Company announced that the first patients had been dosed in the ERADICATE Hp study - a Phase III clinical study in the U.S. designed to evaluate the safety and efficacy of RHB-105 as a first-line treatment for confirmed *H. pylori* bacterial infection.
6. In November 2013, the Company reported that it had concluded a European Scientific Advice meeting with the German Federal Institute for Drugs and Medical Devices (BfArM) regarding RHB-103 for migraines, following which RedHill plans to complete a small bioavailability study and submit a Marketing Authorization Application (MAA) for marketing approval of RHB-103 in Europe during the first half 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 for the treatment of inflammatory and gastrointestinal diseases including cancers and related conditions. The Company's current pipeline of proprietary products includes: (i) **RHB-104** - an oral combination therapy for the

treatment of Crohn's disease, with an ongoing Phase III study; (ii) **RHB-105** - an oral combination therapy for *Helicobacter pylori* infection, with an ongoing phase III study; (iii) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines with U.S. NDA under FDA review; (iv) **RHB-102** - a once-daily oral pill formulation of ondansetron for the prevention of chemotherapy and radiotherapy induced nausea and vomiting; (v) **RHB-106** - an encapsulated formulation for bowel preparation and (vi) **RHB-101** - a once-daily formulation of carvedilol. 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 based on certain assumptions 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; (x) estimates of the Company’s expenses, future revenues capital requirements and the Company’s needs for additional financing; and (xi) competitive companies, technologies and the Company’s industry. 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/A filed with the SEC on March 4, 2013, and its prospectus filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the SEC on February 4, 2014. 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 unless required by law.

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REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31		Three months ended December 31	
	2013	2012	2013	2012
	U.S. dollars in thousands			
REVENUE	12	16	1	4
RESEARCH AND DEVELOPMENT EXPENSES, NET	(8,100)	(6,455)	(2,565)	(1,248)
GENERAL AND ADMINISTRATIVE EXPENSES	(2,684)	(2,601)	(916)	(871)
OPERATING LOSS	(10,772)	(9,040)	(3,480)	(2,115)
FINANCIAL INCOME	158	197	45	52
FINANCIAL EXPENSES	(14)	(1,483)	(5)	(1,289)
FINANCIAL INCOME (EXPENSES), NET	144	(1,286)	40	(1,237)
LOSS AND COMPREHENSIVE LOSS	(10,628)	(10,326)	(3,440)	(3,352)
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.17	0.20	0.05	0.07
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	62,379	52,595	64,099	52,990

REDHILL BIOPHARMA LTD.**CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION**

	December 30	December 31
	2013	2012
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	11,851	16,814
Bank deposits	19	486
Financial assets at fair value through profit or loss	243	1,065
Prepaid expenses and receivables	488	198
	<u>12,601</u>	<u>18,563</u>
NON-CURRENT ASSETS:		
Restricted bank deposit	81	75
Fixed assets	103	113
Intangible assets	1,555	1,345
	<u>1,739</u>	<u>1,533</u>
T o t a l assets	<u>14,340</u>	<u>20,096</u>
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	<u>2,415</u>	<u>1,078</u>
EQUITY:		
Ordinary shares	174	143
Ordinary shares to be issued	-	8,020
Additional paid-in capital	43,144	31,469
Warrants	1,867	3,273
Accumulated deficit	(33,260)	(23,887)
T o t a l equity	<u>11,925</u>	<u>19,018</u>
T o t a l liabilities and equity	<u>14,340</u>	<u>20,096</u>

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Year ended December 31		Three months ended December 31	
	2013	2012	2013	2012
U.S. dollars in thousands				
CASH FLOW FROM OPERATING ACTIVITIES:				
Loss	(10,628)	(10,326)	(3,440)	(3,352)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	1,255	1,648	238	285
Depreciation	24	24	6	9
Fair value gains on financial assets at fair value through profit or loss	(54)	(57)	(4)	(59)
Revaluation of bank deposits	(16)	(4)	(3)	27
Accretion of royalty obligations to investors	-	1,473	-	1,344
Exchange differences relating to cash and cash equivalents	(64)	(12)	(32)	16
	<u>1,145</u>	<u>3,072</u>	<u>205</u>	<u>1,622</u>
Changes in assets and liability items:				
Decrease (increase) in prepaid expenses and receivables	(290)	(109)	(290)	(78)
Increase in accounts payable and accrued expenses	1,337	568	491	262
	<u>1,047</u>	<u>459</u>	<u>781</u>	<u>184</u>
Net cash used in operating activities	<u>(8,436)</u>	<u>(6,795)</u>	<u>(2,454)</u>	<u>(1,546)</u>
CASH FLOW FROM INVESTING ACTIVITIES:				
Purchase of fixed assets	(14)	(8)	(2)	(3)
Purchase of intangible assets	(210)	(100)	(10)	-
Change in investment in bank deposits	477	2,529	284	2,000
Purchase of financial assets at fair value through profit or loss	-	-	-	-
Proceeds from sale of financial assets at fair value through profit or loss	876	1,588	-	558
Net cash resulting in investing activities	<u>1,129</u>	<u>2,977</u>	<u>272</u>	<u>2,555</u>

**CASH FLOW FROM FINANCING
ACTIVITIES:**

Proceeds from issuance of ordinary shares and warrants, net	100	6,248	-	6,248
Exercise of warrants and options into ordinary shares, net of expenses	2,180	302	836	-
Net cash provided by financing activities	<u>2,280</u>	<u>6,550</u>	<u>836</u>	<u>6,248</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,027)	2,732	(1,346)	7,257
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	64	12	32	(16)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	<u>16,814</u>	<u>14,070</u>	<u>13,165</u>	<u>9,573</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>11,851</u>	<u>16,814</u>	<u>11,851</u>	<u>16,814</u>
Supplementary information on interest received in cash	<u>30</u>	<u>126</u>	<u>5</u>	<u>76</u>

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