



Press Release

RedHill Biopharma Reports Results for the Second Quarter of 2014

Highlights include:

- **A strong cash position of approximately \$34 million at the end of the second quarter of 2014, following the acquisition of rights to MESUPRON[®], a Phase II drug targeting gastrointestinal cancers**
- **Top-line data from the Phase III study of RHB-105 for *H. pylori* infection expected in Q4/2014**
- **Potential milestones during Q3/2014 include the planned submission of European marketing applications for RHB-102 (chemotherapy and radiotherapy-induced nausea and vomiting) and RHB-103 (acute migraines) and the planned initiation of a Phase III clinical study of RHB-102 for a new undisclosed indication**

TEL-AVIV, Israel, July 23, 2014, RedHill Biopharma Ltd. (NASDAQ: RDHL; TASE: RDHL) (the "Company" or "RedHill"), an Israeli biopharmaceutical company focused on late clinical-stage drugs for inflammatory and gastrointestinal diseases, including cancer, today reported financial results for the quarter ended June 30, 2014.

Financial highlights for the second quarter of 2014 and six months ended June 30, 2014:

Revenues for the quarter ended June 30, 2014 were immaterial compared to approximately \$7.0 million in the first quarter of 2014. Revenues for the six months ended June 30, 2014 were approximately \$7.0 compared to immaterial Revenues in the six months ended June 30, 2013. The differences in both periods resulted from an upfront payment of \$7.0 million from Salix Pharmaceuticals, Inc. ("Salix") for the out-licensing of RedHill's RHB-106 encapsulated bowel preparation and related rights in the first quarter of 2014.

Cost of Revenues for the quarter ended June 30, 2014 was immaterial compared to approximately \$1.0 million in the first quarter of 2014. Cost of Revenues for the six months ended June 30, 2014

was approximately \$1.0 compared to immaterial Cost of Revenues in the six months ended June 30, 2013. The differences in both periods were primarily due to a payment of \$1.0 million to Giaconda Limited, under the 2010 agreement with Giaconda, which was triggered by the first payment received by RedHill from Salix, as part of Salix licensing transaction.

Research and Development Expenses, net for the quarter ended June 30, 2014 were approximately \$3.2 million, an increase of \$1.5 million, or approximately 88%, compared to \$1.7 million in the first quarter of 2014. The increase was mainly attributable to expenses related to the ongoing Phase III studies of RHB-104 and RHB-105, in addition to advanced preparations for a Phase III study of RHB-102. Research and Development Expenses, net for the six months ended June 30, 2014 were approximately \$4.9 million, an increase of \$1.6 million, or approximately 48%, compared to \$3.3 million in the six months ended June 30, 2013. The increase was mainly attributable to expenses related to the ongoing Phase III studies of RHB-104 and RHB-105 and due to a larger R&D discount from a main supplier recorded in the first quarter of 2013.

General and Administrative Expenses for the quarter ended June 30, 2014 were approximately \$1.0 million, similar to the General and Administrative expenses for the first quarter of 2014. General and Administrative Expenses for the six months ended June 30, 2014 were approximately \$2.0 million, an increase of \$0.8 million, or approximately 66%, compared to \$1.2 million in the six months ended June 30, 2013. The increase was mainly attributable to an increase in payroll and professional fees.

Operating Loss for the quarter ended June 30, 2014 was approximately \$4.1 million, compared to an Operating Profit of approximately \$3.3 million in the first quarter of 2014. The transition from Operating Profit to Operating Loss resulted from the \$7.0 million upfront payment from the Salix licensing transaction received in the first quarter of 2014. Operating Loss for the six months ended June 30, 2014 was approximately \$0.8 million, a decrease of \$3.7 million, or approximately 82%, compared to \$4.5 million in the six months ended June 30, 2013. The decrease was mainly due to revenues from the Salix licensing transaction received in the first quarter of 2014.

Net Cash Used in Operating Activities for the quarter ended June 30, 2014 was approximately \$4.2 million, compared to Net Cash Resulting from Operating Activities of \$1.7 million in the first quarter of 2014. The decrease was mainly due to revenues from the Salix licensing transaction received in the first quarter of 2014. Net Cash Used in Operating Activities for the six months ended June 30, 2014 was approximately \$2.5 million, a decrease of \$1.4 million, or approximately 36%, compared to \$3.9 million in the six months ended June 30, 2013. The decrease was mainly due to revenues from the Salix transaction received in the first quarter of 2014 and an increase in prepaid expenses paid mainly to research and development service providers.

Net Cash Used for Investment Activities for the quarter ended June 30, 2014 was \$16.8 million compared to immaterial Net Cash Resulting from Investment Activities in the first quarter of 2014. The transition was mainly due to investment of cash in short and long-term bank deposits during the quarter ended June 30, 2014.

Net Cash Resulting from Financing Activities for the quarter ended June 30, 2014 was \$0.5 million, compared to \$23.8 million in the first quarter of 2014. The difference resulted mainly from two private placements, for a total of \$20 million and the exercise of warrants, during the first quarter of 2014.

Cash Balance¹ as of June 30, 2014 was approximately \$34.2 million, partially held in short and long-term bank deposits, compared to \$37.7 million at the end of the first quarter of 2014. The decrease resulted mainly from the Company's research and development activities.

Ori Shilo, Deputy CEO, Finance and Operations said: "This was another successful quarter for RedHill. The ongoing Phase III studies for our lead programs, RHB-104 for Crohn's disease and RHB-105 for *H. pylori* infection are advancing satisfactorily, with top-line data from the RHB-105 study expected in the fourth quarter of 2014, and new sites being added to the RHB-104 study to expedite recruitment. Our cash position remains strong with over \$34 million and no debt. Major milestones planned for the third quarter of 2014 include the submission of European marketing applications for our antiemetic drug RHB-102 and RHB-103 for acute migraines, as well as the initiation of a Phase III clinical study of RHB-102 in the U.S. for a new indication. The recent acquisition of MESUPRON[®], a Phase II oncology drug targeting gastrointestinal cancers, is a substantial addition to our late clinical-stage pipeline, as we continue to grow and advance new and innovative therapeutic options for inflammatory and gastrointestinal diseases."

Operational highlights for the second quarter ended June 30, 2014:

1. On June 30, 2014, the Company and WILEX AG, a German biopharmaceutical company focused on oncology, announced that RedHill acquired the exclusive development and commercialization rights to MESUPRON[®], a proprietary, first-in-class, urokinase-type plasminogen activator (uPA) inhibitor administered by oral capsule, throughout the world for all indications, other than in China, Hong Kong, Taiwan and Macao. The agreement included an upfront payment of \$1.0 million and potential tiered royalties on net revenues, ranging from mid-teens up to 30%. RedHill will be responsible for all development, regulatory and commercialization aspects of MESUPRON[®].
2. On June 26, 2014, the Company announced preliminary positive data from a pre-clinical study of RHB-104 for the treatment of type 1 diabetes, a chronic autoimmune disease with an unknown cause. RHB-104 is a proprietary and potentially groundbreaking antibiotic combination therapy administered by oral capsule, with potent intracellular, anti-mycobacterial and anti-inflammatory properties.
3. On June 5, 2014, the Company reported that the Japan Patent Office (JPO) issued a Decision to Grant a Patent for a new patent covering RHB-104. The patent is expected to be issued during 2014 and will have a 2029 expiry date. RedHill further reported that it has initiated a long-term population pharmacokinetic (Pop PK) study as part of the ongoing RHB-104 Phase III MAP US study for the treatment of Crohn's disease. The Pop PK study, together with other supportive studies, including a recently completed food effect study, a drug-drug interaction (DDI) study currently being reviewed and additional clinical and other studies are designed to satisfy various regulatory requirements for future potential marketing applications of RHB-104. The Company also reported that there are 44 clinical sites in the U.S., Canada and Israel actively enrolling patients for the RHB-104 Phase III MAP US study, and that it has increased the total number of

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

planned clinical sites to up to approximately 90 sites in the U.S., Canada and Israel, and is planning additional clinical sites in other countries.

4. On May 22, 2014, the Company announced that the U.S. Food and Drug Administration ("FDA") has allowed the initiation of the Company's planned Phase III clinical study for the treatment of a new, undisclosed indication for RHB-102, an extended release oral pill formulation of the antiemetic drug ondansetron. RedHill plans to begin enrolling patients for the Phase III study during the third quarter of 2014. The double-blind placebo-controlled Phase III study is planned to be conducted in eight clinical sites in the U.S. and is expected to include 320 subjects. Based on prior discussions with the FDA and the UK Medicines and Healthcare Products Regulatory Agency ("MHRA"), the study is intended to support potential future submissions of marketing applications for a new undisclosed indication in both the U.S. and Europe.
5. On May 21, 2014, the Company and its co-development partner for RHB-103, IntelGenx Corp. ("IntelGenx") reported positive results from a comparative bioavailability study for RHB-103, an oral thin film formulation of rizatriptan for acute migraines. The study followed a positive scientific advice meeting with the German Federal Institute for Drugs and Medical Devices (BfArM), previously announced by RedHill in November 2013. In light of the positive results from the bioavailability study and data from prior clinical studies conducted for RHB-103, and subject to various regulatory requirements, RedHill and IntelGenx plan to submit a European Marketing Authorization Application ("MAA") during the third quarter of 2014.
6. On April 30, 2014, the Company reported positive results from a comparative bioavailability study for RHB-102, a proprietary, extended-release, once-daily oral pill formulation of the antiemetic oncology support drug ondansetron for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively). The study followed a positive European scientific advice meeting with the UK MHRA, announced on April 7, 2014. In light of the positive results from the bioavailability study and data from prior successful clinical studies conducted for RHB-102, and subject to various regulatory requirements, RedHill plans to submit, during the third quarter of 2014, a European MAA for RHB-102.
7. On April 24, 2014, the Company and IntelGenx reported that the U.S. FDA acknowledged receipt of their response to the Complete Response Letter ("CRL") for the RHB-103 New Drug Application ("NDA") and has requested further clarifications. RedHill and IntelGenx reported on March 3, 2014 that they had submitted their response to the FDA's CRL for the RHB-103 NDA, which had raised questions primarily related to Chemistry, Manufacturing and Controls (CMC). The companies further reported that a supplier of raw material for RHB-103 is currently holding compliance discussions with the FDA, which are independent of RedHill and IntelGenx and are not specific to RHB-103. The companies are diligently working on a variety of options to ensure continued supply of the raw material regardless of the result of these compliance discussions.

Conference Call and Webcast Information:

The Company will host a conference call and an audio webcast on **Thursday, July 24, 2014, at 9:00 a.m. ET (16:00 Israel time)** to review the second quarter 2014 financial results and business highlights.

To participate in the conference call, please dial the following numbers five to ten minutes prior to the start of the call: **United States: +1-646-254-3388; International: +1-877-280-2342; and Israel: +972-3-763-0146. The access code for the call is 9222805.**

The conference call will be broadcasted simultaneously and available for replay on the Company's website, <http://ir.redhillbio.com/events.cfm>, for 30 days. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

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 drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill'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-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (iv) **MESUPRON**[®] - a Phase II uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (v) **RHB-102** - a once-daily oral pill formulation of ondansetron for the prevention of nausea and vomiting, in advanced development stages for multiple indications, including a European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting planned for the third quarter of 2014 and a Phase III study for an undisclosed indication planned to commence in 2014, (vi) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review and a European marketing application planned for the third quarter of 2014; and (vii) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit www.redhillbio.com

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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, including any independent reports relating thereto; (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 filed with the SEC on February 25, 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.

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended		Six months ended	
	June 30		June 30	
	2014	2013	2014	2013
U.S. dollars in thousands				
REVENUES:				
Licensing revenue	-	-	7,000	-
Other revenue	4	4	9	8
TOTAL REVENUES	4	4	7,009	8
COST OF REVENUE	-	-	(1,050)	-
RESEARCH AND DEVELOPMENT EXPENSES, net	(3,157)	(1,982)	(4,893)	(3,328)
GENERAL AND ADMINISTRATIVE EXPENSES	(961)	(548)	(1,988)	(1,223)
OTHER INCOME	-	-	100	-
OPERATING LOSS	(4,114)	(2,526)	(822)	(4,543)
FINANCIAL INCOME	133	17	222	60
FINANCIAL EXPENSES	(543)	(3)	(547)	(6)
FINANCIAL INCOME (EXPENSES), net	(410)	14	(325)	54
COMPREHENSIVE LOSS	(4,524)	(2,512)	(1,147)	(4,489)
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.05	0.04	0.01	0.07
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	87,559	61,842	85,354	61,376

REDHILL BIOPHARMA LTD.
CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION
(Unaudited)

	June 30, 2014	December 31, 2013
	U.S. dollars in thousands	
CURRENT ASSETS		
Cash and cash equivalents	17,145	11,851
Bank deposits	7,027	19
Financial assets at fair value through profit or loss	-	243
Prepaid expenses and receivables	2,369	488
	26,541	12,601
NON-CURRENT ASSETS		
Bank deposits	10,081	81
Fixed assets	120	103
Intangible assets	2,505	1,555
	12,706	1,739
T O T A L A S S E T S	39,247	14,340
CURRENT LIABILITIES		
Accounts payable and accrued expenses	2,709	2,415
NON-CURRENT LIABILITIES		
Derivative financial instruments, see note 5	2,859	-
T O T A L L I A B I L I T I E S	5,568	2,415
EQUITY		
Ordinary shares	240	174
Additional paid-in capital	65,447	43,144
Warrants	1,528	1,867
Accumulated deficit	(33,536)	(33,260)
T O T A L E Q U I T Y	33,679	11,925
T O T A L L I A B I L I T I E S A N D E Q U I T Y	39,247	14,340

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Six months ended June 30		Three months ended June 30	
	2014	2013	2014	2013
U.S. dollars in thousands				
OPERATING ACTIVITIES:				
Comprehensive loss	(1,147)	(4,489)	(4,524)	(2,512)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	871	554	626	347
Depreciation and amortization	63	11	6	5
Fair value loss on derivative financial instruments	534	-	550	-
Fair value (gains) loss on financial assets at fair value through profit or loss	-	(44)	(1)	(14)
Revaluation of bank deposits	(8)	2	(10)	5
Exchange differences relating to cash and cash equivalents	(214)	(5)	(130)	3
	<u>1,246</u>	<u>518</u>	<u>1,041</u>	<u>346</u>
Changes in assets and liability items:				
Increase in prepaid expenses and receivables	(1,881)	(388)	(1,165)	(182)
Increase (decrease) in accounts payable and accrued expenses	(706)	483	484	230
	<u>(2,587)</u>	<u>95</u>	<u>(681)</u>	<u>48</u>
Net cash provided by (used in) operating activities	<u>(2,488)</u>	<u>(3,876)</u>	<u>(4,164)</u>	<u>(2,118)</u>
INVESTING ACTIVITIES:				
Purchase of fixed assets	(30)	(9)	(5)	(7)
Change in investment in current bank deposits	(7,000)	193	(7,000)	(280)
Purchase of non-current bank deposits	(10,000)	-	(10,000)	-
Proceeds from sale of financial assets at fair value through profit or loss	243	876	243	797
Net cash provided by investing activities	<u>(16,787)</u>	<u>1,060</u>	<u>(16,762)</u>	<u>510</u>
FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares and derivative financial instruments, net	19,364	100	-	-
Exercise of warrants and options into ordinary shares	4,991	73	527	58
Net cash provided by financing activities	<u>24,355</u>	<u>173</u>	<u>527</u>	<u>58</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>5,080</u>	<u>(2,643)</u>	<u>(20,399)</u>	<u>(1,550)</u>

EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	214	5	130	(3)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	<u>11,851</u>	<u>16,814</u>	<u>37,414</u>	<u>15,729</u>
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	<u>17,145</u>	<u>14,176</u>	<u>17,145</u>	<u>14,176</u>
Supplementary information on interest received in cash	<u>15</u>	<u>15</u>	<u>9</u>	<u>13</u>
Supplementary information on investing activities not involving cash flows:				
Purchase of intangible assets	<u>1,000</u>	<u>200</u>	<u>1,000</u>	<u>200</u>

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