



## Press Release

### **RedHill Biopharma Reports Results for the Third Quarter of 2014**

#### **Highlights include:**

- **A strong cash position of approximately \$29 million at the end of the third quarter of 2014, enabling the Company to continue to execute its R&D programs including the three ongoing Phase III studies in gastrointestinal indications: RHB-104 for Crohn’s disease, RHB-105 for *H. pylori* infection and RHB-102 for acute gastroenteritis and gastritis**
- **Key milestones achieved in the third quarter of 2014 include the submission of a Marketing Authorization Application (MAA) seeking marketing approval in Europe for RIZAPORT<sup>®</sup> (formerly RHB-103) and the initiation of the U.S. Phase III clinical study of RHB-102 for gastroenteritis and gastritis, with top-line data expected during the second half of 2015**
- **Potential milestones expected in the fourth quarter of 2014 include the planned submission of a European marketing application for RHB-102 for the indications of chemotherapy and radiotherapy-induced nausea and vomiting**

**TEL-AVIV, Israel, November 10, 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 gastrointestinal cancers, today reported financial results for the quarter ended September 30, 2014.

#### **Financial highlights for the third quarter of 2014 and for the nine months ended September 30, 2014:**

**Revenues** for the quarter ended September 30, 2014 and for the quarter ended June 30, 2014 were immaterial. Revenues for the nine months ended September 30, 2014 were approximately \$7.0 million, compared to immaterial Revenues in the nine months ended September 30, 2013. The

increase resulted from an upfront payment of \$7.0 million received from Salix Pharmaceuticals, Inc. ("Salix") in the first quarter of 2014 for the out-licensing of RedHill's RHB-106 encapsulated bowel preparation and related rights.

**Cost of Revenues** for the nine months ended September 30, 2014 was \$1.0 million compared to immaterial Cost of Revenues in the nine months ended September 30, 2013. The increase resulted from a payment of \$1.0 million to Giaconda Limited, under the 2010 agreement with Giaconda, which was triggered by the first payment received from Salix as part of the RHB-106 licensing transaction described above.

**Research and Development Expenses, net** for the quarter ended September 30, 2014 were approximately \$4.1 million, an increase of \$1.0 million, or approximately 30%, compared to \$3.2 million in the second quarter of 2014. Research and Development Expenses, net for the nine months ended September 30, 2014 were approximately \$9.0 million, an increase of \$3.5 million, or approximately 64%, compared to \$5.5 million in the nine months ended September 30, 2013. The increase was mainly attributable to expenses related to the ongoing Phase III studies with RHB-104 and RHB-105.

**General and Administrative Expenses** for the quarter ended September 30, 2014 were approximately \$0.9 million, a decrease of 0.1 million, or approximately 10%, compared to \$1.0 million in the second quarter of 2014. General and Administrative Expenses for the nine months ended September 30, 2014 were approximately \$2.9 million, an increase of \$1.1 million, or approximately 64%, compared to \$1.8 million in the nine months ended September 30, 2013. The increase was mainly attributable to an increase in payroll and share-based compensation and an increase in professional fees, mainly due to an increase in financing and legal consultant fees and costs associated with the January 2014 financing.

**Operating Loss** for the quarter ended September 30, 2014 was approximately \$5.0 million, an increase of \$0.9 million, or approximately 22%, compared to an Operating Loss of approximately \$4.1 million in the second quarter of 2014. The increase was mainly attributable to an increase in research and development expenses. Operating Loss for the nine months ended September 30, 2014 was approximately \$5.8 million, a decrease of \$1.4 million, or approximately 20%, compared to \$7.3 million in the nine months ended September 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 September 30, 2014 was approximately \$3.8 million, a decrease of \$0.4 million, or approximately 9%, compared to \$4.2 million in the second quarter of 2014. The decrease was mainly attributable to advanced payments made to service providers for the Phase III study with RHB-104 in the second quarter of 2014. Net Cash Used in Operating Activities for the nine months ended September 30, 2014 was approximately \$6.3 million, an increase of \$0.3 million, or approximately 5%, compared to \$6.0 million in the nine months ended September 30, 2013. The increase resulted mainly from an increase in research and development expenses.

**Net Cash Used in Investment Activities** for the quarter ended September 30, 2014 was \$1.0 million compared to \$16.8 million in the second quarter of 2014. The decrease was mainly due to investment of cash in short and long-term bank deposits during the second quarter of 2014.

*Net Cash Provided by Financing Activities* for the quarter ended September 30, 2014 was immaterial, compared to \$0.5 million in the second quarter of 2014. The decrease was mainly due to the exercise of warrants during the second quarter of 2014. Net Cash Resulting from Financing Activities for the nine months ended September 30, 2014 was \$24.4 million, an increase of \$23.0 million compared to \$1.4 million in the nine months ended September 30, 2013. The increase was mainly due to two private placements, for a total of approximately \$20 million, and the exercise of warrants, during the first quarter of 2014.

*Cash Balance*<sup>1</sup> as of September 30, 2014 was approximately \$29 million, compared to \$34.2 million at the end of the second quarter of 2014. The decrease resulted mainly from the Company's research and development activities.

**Ori Shilo, Deputy CEO, Finance and Operations said:** "During the third quarter of 2014 we continued to execute our R&D programs as planned. We recently submitted a first European marketing application for RIZAPORT<sup>®</sup> (formerly RHB-103), an oral thin film for acute migraines. We also plan to submit in the next few weeks a European marketing application, with our oral once-daily antiemetic drug RHB-102 for oncology support. During the third quarter of 2014, we initiated a Phase III study for RHB-102 in acute gastroenteritis and gastritis, a major potential expansion to the potential market for this drug. This is the third gastrointestinal-focused Phase III study that RedHill is currently conducting in the U.S., along with the ongoing first Phase III studies for our lead programs RHB-104 for Crohn's disease and RHB-105 for *H. pylori* infection. Our cash position remains strong, with over \$29 million and no debt, as we continue to advance our gastrointestinal and inflammation-focused late clinical-stage pipeline."

**Operational highlights for the third quarter ended September 30, 2014:**

1. On October 1, 2014, the Company and its co-development partner for RIZAPORT<sup>®</sup> (formerly RHB-103), IntelGenx Corp., announced that they had submitted a Marketing Authorization Application (MAA) to the German Federal Institute for Drugs and Medical Devices (BfArM) and to the Luxemburg Ministry of Health seeking European marketing approval for RIZAPORT<sup>®</sup>, an oral thin film formulation of rizatriptan for acute migraines. The MAA was submitted under the European Mutual Recognition Procedure with Germany as the reference member state. The submission is supported by several studies, including a comparative bioavailability study which successfully established the bioequivalence between RIZAPORT<sup>®</sup> and the European reference drug Maxalt<sup>®</sup> Lingua, and follows a positive scientific advice meeting with BfArM.
2. On September 3, 2014, the Company announced that it had initiated a Phase III clinical study designed to evaluate the safety and efficacy of RHB-102, a proprietary, oral, extended-release, once-daily formulation of the antiemetic drug ondansetron, in patients suffering from acute gastroenteritis and gastritis, inflammations of the gastrointestinal tract which cause, among other symptoms, nausea and vomiting (the GUARD study). The randomized, double-blind, placebo-controlled, parallel group Phase III study will be conducted in up to 10 clinical sites in

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<sup>1</sup> Including cash, bank deposits and short-term investments

the U.S. and is expected to enroll 320 adults and children over the age of 12 who suffer from acute gastroenteritis or gastritis. Patients are randomized to receive either RHB-102 or a placebo. Top-line results from the RHB-102 Phase III GUARD study are expected during the second half of 2015.

3. On August 27, 2014, the Company updated that in order to enhance statistical powering and expedite recruitment in its ongoing RHB-105 first Phase III ERADICATE Hp study, the Company was expanding the study to include, respectively, additional subjects and clinical sites. The Company also announced that, based on prior discussions, the U.S. Food and Drug Administration (FDA) had authorized RedHill to pursue a new, distinct and broader indication with RHB-105, a proprietary fixed-dose combination therapy of two antibiotics and a proton pump inhibitor (PPI) in an all-in-one oral capsule, for the first line treatment of *Helicobacter pylori* (*H. pylori*) infection. While current standard treatments for *H. pylori* are typically indicated to treat patients with active or recent history of ulcers, RedHill's RHB-105 new intended indication will target *H. pylori* infection as a first line treatment regardless of ulcer status. In light of the changes to the study protocol, top-line data from the study is currently expected in the second quarter of 2015.
4. On August 13, 2014, the Company and RESprotect GmbH, a privately-held biotech company located in Dresden, Germany, announced that they had entered into a binding exclusive option agreement for the acquisition of the oncology drug candidate RP101 and next generation compounds. RP101 is a proprietary, first-in-class, heat shock protein 27 (Hsp27) inhibitor, administered orally, which may prevent the induction of resistance to chemotherapy (chemoresistance), thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival. Under the terms of the agreement, RedHill has the option to acquire the worldwide exclusive rights to RP101 for all indications, other than for pancreatic cancer indication in South Korea. RedHill paid RESprotect for a one year option, which may be extended by RedHill under certain agreed terms. During the option period, RedHill may, at its discretion, conduct development activities on RP101. If RedHill elects to exercise the option, it will acquire the exclusive rights to RP101 for a total payment of \$100,000, covering both the option and the acquisition of the rights, as well as potential milestone payments and tiered royalties on net revenues, ranging from single-digit to mid-teens.
5. On June 26, 2014, the Company reported that it had received preliminary positive data from a pre-clinical study for RHB-104 for the treatment of type 1 diabetes, a chronic autoimmune disease with an unknown cause. During the third quarter of 2014 the Company received the final results and an independent report which confirmed the preliminary positive data. The Company also completed, during the third quarter of 2014, a pre-clinical study for RHB-104 for the treatment of psoriasis, a chronic autoimmune skin disease with an unknown cause. The Company has recently received positive final data from the study which was designed to evaluate the potential therapeutic effect of RHB-104 using a pre-clinical psoriasis model.

#### **Conference Call and Webcast Information:**

The Company will host a conference call and an audio webcast on **Monday, November 10, 2014, at 9:00 a.m. ET (16:00 Israel time)** to review the third 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: +1-212-444-0412; International: +1-877-280-2342; and Israel: +972-3-763-0145. The access code for the call is 2589183.**

**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 on the development and acquisition of late clinical-stage, proprietary drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. 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 first Phase III study; (ii) **RHB-105** - an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing first Phase III study; (iii) **RHB-102** - a once-daily oral pill formulation of ondansetron with a Phase III study in the U.S. for acute gastroenteritis and gastritis and a planned European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting (iv) **RHB-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **MESUPRON**<sup>®</sup> - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vi) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (vii) **RIZAPORT**<sup>®</sup> (formerly **RHB-103**) - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA currently under discussions with the FDA and a European marketing application submitted in October 2014; and (viii) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol. For more information please visit [www.redhillbio.com](http://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; (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		Nine months ended	
	September 30		September 30	
	2014	2013	2014	2013
	U.S. dollars in thousands			
<b>REVENUES:</b>				
Licensing revenue	-	-	7,000	-
Other revenue	4	3	13	11
<b>TOTAL REVENUES</b>	4	3	7,013	11
<b>COST OF REVENUE</b>	-	-	(1,050)	-
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	(4,103)	(2,207)	(8,996)	(5,535)
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	(912)	(545)	(2,900)	(1,768)
<b>OTHER INCOME</b>	-	-	100	-
<b>OPERATING LOSS</b>	(5,011)	(2,749)	(5,833)	(7,292)
<b>FINANCIAL INCOME</b>	1,146	53	637	113
<b>FINANCIAL EXPENSES</b>	(371)	(3)	(187)	(9)
<b>FINANCIAL INCOME, net</b>	775	50	450	104
<b>COMPREHENSIVE LOSS</b>	(4,236)	(2,699)	(5,383)	(7,188)
<b>LOSS PER ORDINARY SHARE, (U.S. dollars)</b>				
<b>BASIC</b>	0.05	0.04	0.06	0.12
<b>DILUTED</b>	0.06	0.04	0.07	0.12

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

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
	<b>U.S. dollars in thousands</b>	
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	12,008	11,851
Bank deposits	17,040	19
Financial assets at fair value through profit or loss	-	243
Prepaid expenses and receivables	2,518	488
	31,566	12,601
<b>NON-CURRENT ASSETS</b>		
Bank deposits	80	81
Fixed assets	118	103
Intangible assets	2,525	1,555
	2,723	1,739
<b>T O T A L A S S E T S</b>	<b>34,289</b>	<b>14,340</b>
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	2,584	2,415
<b>NON-CURRENT LIABILITIES</b>		
Derivative financial instruments	1,766	-
<b>T O T A L L I A B I L I T I E S</b>	<b>4,350</b>	<b>2,415</b>
<b>EQUITY</b>		
Ordinary shares	240	174
Additional paid-in capital	65,461	43,144
Warrants	1,528	1,867
Accumulated deficit	(37,290)	(33,260)
<b>T O T A L E Q U I T Y</b>	<b>29,939</b>	<b>11,925</b>
<b>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</b>	<b>34,289</b>	<b>14,340</b>

**REDHILL BIOPHARMA LTD.**

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended September 30		Nine months ended September 30	
	2014	2013	2014	2013
	U.S. dollars in thousands			
<b>OPERATING ACTIVITIES:</b>				
Comprehensive loss	(4,236)	(2,699)	(5,383)	(7,188)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	482	463	1,353	1,017
Depreciation and amortization	6	7	69	18
Fair value gain on derivative financial instruments	(1,093)	-	(559)	-
Fair value gains on financial assets at fair value through profit or loss	-	(6)	-	(50)
Revaluation of bank deposits	(12)	(15)	(20)	(13)
Exchange differences relating to cash and cash equivalents	323	(27)	109	(32)
	(294)	422	952	940
Changes in assets and liability items:				
Increase in prepaid expenses and receivables	(149)	(192)	(2,030)	(580)
Increase in accounts payable and accrued expenses	875	363	169	846
	726	171	(1,861)	266
Net cash used in operating activities	(3,804)	(2,106)	(6,292)	(5,982)
<b>INVESTING ACTIVITIES:</b>				
Purchase of fixed assets	(4)	(3)	(34)	(12)
Purchase of intangible assets	(1,020)	(200)	(1,020)	(200)
Change in investment in current bank deposits	-	-	(17,000)	193
Purchase of non-current bank deposits	-	-	(10,000)	-
Proceeds from sale of financial assets at fair value through profit or loss	-	-	243	876
Net cash provided by (used in) investing activities	(1,024)	(203)	(17,811)	876
<b>FINANCING ACTIVITIES:</b>				
Proceeds from issuance of ordinary shares and derivative financial instruments, net	-	-	19,364	100
Exercise of warrants and options into ordinary shares, net	14	1,271	5,005	1,344
Net cash provided by financing activities	14	1,271	24,369	1,444
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(4,814)	(1,038)	266	(3,681)

<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	(323)	27	(109)	32
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>17,145</u>	<u>14,176</u>	<u>11,851</u>	<u>16,814</u>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u>12,008</u>	<u>13,165</u>	<u>12,008</u>	<u>13,165</u>
<b>Supplementary information on interest received in cash</b>	<u>62</u>	<u>10</u>	<u>77</u>	<u>25</u>