



April 30, 2014

## RedHill Biopharma Reports Results for the First Quarter of 2014

### Key financial highlights include:

- **A first profitable quarter, with net income of \$3.4 million, primarily attributed to the \$7 million upfront payment received from Salix Pharmaceuticals as part of the licensing transaction for the rights to RedHill's RHB-106 encapsulated bowel preparation and related rights**
- **RedHill raised \$20 million in two private placements resulting in a strong cash position of approximately \$38 million at the end of the first quarter of 2014**

TEL-AVIV, Israel, April 30, 2014 (GLOBE NEWSWIRE) -- 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 drugs for the treatment of inflammatory and gastrointestinal diseases including cancer and related conditions, today reported financial results for the quarter ended March 31, 2014.

### Financial highlights for the first quarter of 2014:

**Revenues** for the quarter ended March 31, 2014 were approximately \$7 million, compared to immaterial revenues in the first quarter of 2013. The increase resulted from an upfront payment of \$7 million from Salix Pharmaceuticals, Inc. ("Salix") for the out-licensing of RedHill's RHB-106 encapsulated bowel preparation and related rights.

**Cost of Revenues** for the quarter ended March 31, 2014 was approximately \$1 million, primarily due to a payment of \$1 million to Giaconda Limited, under the agreement with Giaconda, which was triggered by the first payment received by RedHill from Salix, as part of the RHB-106 licensing transaction.

**Research and Development Expenses, net** for the quarter ended March 31, 2014 were approximately \$1.7 million, an increase of \$0.4 million, or approximately 31%, compared to \$1.3 million in the first quarter of 2013. The increase was mainly due to expenses related to the ongoing Phase III studies with RHB-104 and RHB-105, to other supportive studies, and a larger R&D discount recorded in the first quarter of 2013.

**General and Administrative Expenses** for the quarter ended March 31, 2014 were approximately \$1 million, an increase of \$0.3 million, or approximately 43%, compared to \$0.7 million in the first quarter of 2013. The increase was mainly due to financing liability-related expenses resulting from a private placement in January 2014.

**Operating Profit** for the quarter ended March 31, 2014 was approximately \$3.3 million, compared to an Operating Loss of approximately \$2 million in the first quarter of 2013. The transition from Operating Loss to Operating Profit resulted mainly from the Salix licensing transaction revenues.

**Net Cash Resulting from Operating Activities** for the quarter ended March 31, 2014 was approximately \$1.7 million, compared to Net Cash Used in Operating Activities of \$1.8 million in the first quarter of 2013. The Net Cash Resulting from Operating Activities resulted mainly from the Salix licensing transaction revenues.

**Net Cash Provided by Financing Activities** for the quarter ended March 31, 2014 was approximately \$23.8 million, compared to \$0.1 million in the first quarter of 2013. The increase resulted mainly from the January 2014 private placements for a total net amount of \$19.4 million, and to the exercise of warrants for a net amount of \$4.5 million.

**Cash Balance**<sup>1</sup> as of March 31, 2014 was approximately \$37.7 million, compared to \$12.1 million at the end of the first quarter of 2013. The increase resulted mainly from the closing of the above-mentioned private placements, exercise of warrants and revenues from the Salix licensing transaction.

**Ori Shilo, Deputy CEO, Finance and Operations said:** "We are very pleased to report the Company's first quarter with meaningful revenues, an important achievement for RedHill and another validation of our business model. The licensing of RHB-106 to Salix Pharmaceuticals generated revenues of \$7 million and could potentially generate another \$5 million in milestone payments, as well as royalties from sales. The additional \$20 million raised in early 2014 from prominent U.S. and Israeli

investors, allows us to continue advancing two Phase III studies currently underway in the U.S., with RHB-104 for Crohn's disease and RHB-105 for *H. pylori* infection, as well as other late clinical-stage programs that are underway."

#### **Key highlights for the first quarter ended March 31, 2014:**

1. In January 2014, the Company closed two private placement transactions for total gross proceeds of approximately \$20 million. This included \$8.5 million raised from OrbiMed Israel Partners Limited Partnership and Broadfin Healthcare Master Fund, LTD and \$11.7 million raised from prominent Israeli investors, including Migdal Insurance Company, Yelin Lapidot, Excellence Nessuah, and Sphera Global Healthcare Master Fund.
2. In February 2014, the Company, together with Salix Pharmaceuticals, announced that they had entered into an exclusive agreement under which Salix licensed the worldwide exclusive rights to RedHill's RHB-106 encapsulated bowel preparation and rights to other purgative developments. Financial terms of the transaction included an upfront payment of \$7 million and an additional \$5 million (gross) in subsequent potential milestone payments to RedHill. Salix also agreed to pay RedHill tiered royalties on net sales, ranging from low single-digit up to low double-digits.
3. In February 2014, the Company and its co-development partner for RHB-103, IntelGenx Corp. ("IntelGenx"), reported that they had received a Complete Response Letter ("CRL") from the Food and Drug Administration ("FDA") regarding the NDA for RHB-103, an oral thin film migraine drug. The CRL raised questions primarily related to third party Chemistry, Manufacturing and Controls ("CMC") and to the packaging and labeling of RHB-103, but did not raise any questions or deficiencies relating to RHB-103's safety, nor any requirement for additional clinical studies. RedHill and IntelGenx recently reported that they believe that FDA approval of the RHB-103 NDA is subject to the satisfactory resolution of the remaining CMC questions, as well as securing a compliant source of the raw material. RedHill and IntelGenx continue to work with the FDA in order to address and resolve all remaining CMC questions in addition to securing a compliant source of the raw material.
4. In April 2014, the Company and IntelGenx reported that they had commenced a comparative bioavailability clinical study comparing RHB-103 to a European reference drug. The study is intended to support the planned submission of a European Marketing Authorization Application ("MAA") for RHB-103. The comparative bioavailability study follows a positive scientific advice meeting with the German Federal Institute for Drugs and Medical Devices ("BfArM") announced by RedHill in November 2013. Results of the bioavailability study are anticipated by June 2014. Subject to the results of the study and to the required regulatory process, and in light of the data from prior successful studies conducted with RHB-103, RedHill and IntelGenx plan to submit a European MAA in the third quarter of 2014.
5. In March 2014, the Company reported that it had secured direct rights from Temple University to the original RHB-102 patents after SCOLR Pharma Inc., which had originally licensed certain patents to RedHill for RHB-102, ceased business operations. The Company further reported that a pre-New Drug Application (pre-NDA) meeting was held with the FDA regarding the development of RHB-102, a once-daily oral pill formulation of ondansetron, for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting ("CINV" and "RINV" respectively). Following the pre-NDA meeting, RedHill provided the FDA with additional information and is currently awaiting the FDA's response. RedHill also reported that, in parallel to pursuing the CINV and RINV indications, it is pursuing a new undisclosed indication for RHB-102. To support the submission of marketing applications for this additional new indication in the U.S. and Europe, RedHill is planning to commence a Phase III clinical study later this year.
6. In April 2014, the Company announced that it had concluded a positive European scientific advice meeting with the UK Medicines and Healthcare Products Regulatory Agency ("MHRA") regarding RHB-102. Following the meeting, the Company conducted a comparative bioavailability study comparing RHB-102 to a European reference drug in order to support a Marketing Authorization Application ("MAA") in Europe for RHB-102 for the indications of CINV and RINV. On April 30, 2014, the Company reported that it had received positive results from the bioavailability study with RHB-102, and that in light of these results, data generated in previous studies and the positive feedback from the MHRA, the Company intends to submit, during the third quarter of 2014, an MAA in Europe for RHB-102 for the CINV and RINV indications.

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

The Company will host a conference call and an audio webcast on **Thursday, May 1, 2014, at 9:00 a.m. ET (16:00 Israel time)** to review the first quarter 2014 financial results and business highlights.

In order to participate in the conference call, please dial the following numbers five to ten minutes prior to the start of the call: **United States: +1-646-254-3365; International +1-877-280-2342; Israel: +972-3-763-0147. The access code for the call is 1259330.**

The conference call will also be broadcasted simultaneously and available for replay on the Company's website, <http://ir.redhillbio.com/events.cfm>, for 30 days. To participate, 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 formulations and combinations of existing drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer 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-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals Ltd.; (iv) **RHB-103** - an oral thin film formulation of rizatriptan for acute migraines with a U.S. NDA under FDA review; (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 and, (vi) **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).

*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.*

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

#### REDHILL BIOPHARMA LTD.

##### CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Three months ended	
	March 31	
	2014	2013
	U.S. dollars	
	in thousands	
<b>REVENUES:</b>		
Licensing revenue	7,000	--
Other revenue	5	4
<b>TOTAL REVENUE</b>	7,005	4
<b>COST OF REVENUE</b>	(1,050)	--
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	(1,736)	(1,346)

GENERAL AND ADMINISTRATIVE EXPENSES	(1,027)	(675)
OTHER INCOME	100	--
OPERATING INCOME (LOSS)	3,292	(2,017)
FINANCIAL INCOME	89	43
FINANCIAL EXPENSES	(4)	(3)
FINANCIAL INCOME, net	85	40
COMPREHENSIVE INCOME (LOSS)	3,377	(1,977)

EARNINGS (LOSS) PER ORDINARY SHARE, (U.S. dollars):

BASIC	0.041	(0.032)
DILUTED	0.039	(0.032)

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

	<u>March 31</u>	<u>December 31</u>
	<u>2014</u>	<u>2013</u>
	<u>U.S. dollars in thousands</u>	
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	37,414	11,851
Bank deposits	18	19
Financial assets at fair value through profit or loss	242	243
Prepaid expenses and receivables	1,204	488
	<u>38,878</u>	<u>12,601</u>
<b>NON-CURRENT ASSETS</b>		
Restricted bank deposit	80	81
Fixed assets	121	103
Intangible assets	1,505	1,555
	<u>1,706</u>	<u>1,739</u>
<b>TOTAL ASSETS</b>	<u>40,584</u>	<u>14,340</u>
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	1,225	2,415
<b>NON-CURRENT LIABILITIES</b>		
Derivative financial instruments, see note 5	2,309	--
<b>TOTAL LIABILITIES</b>	<u>3,534</u>	<u>2,415</u>
<b>EQUITY</b>		
Ordinary shares	239	174
Additional paid-in capital	64,858	43,144
Warrants	1,591	1,867
Accumulated deficit	(29,638)	(33,260)
<b>TOTAL EQUITY</b>	<u>37,050</u>	<u>11,925</u>
<b>TOTAL LIABILITIES AND EQUITY</b>	<u>40,584</u>	<u>14,340</u>

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

Three months ended  
March 31

	<u>2014</u>	<u>2013</u>
	<u>U.S. dollars</u>	
	<u>in thousands</u>	
<b>OPERATING ACTIVITIES:</b>		
Profit (Loss)	<u>3,377</u>	<u>(1,977)</u>
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	245	207
Depreciation and amortization	57	6
Fair value gains on derivative financial instruments	(16)	--
Fair value (gains) loss on financial assets at fair value through profit or loss	1	(30)
Revaluation of bank deposits	2	(3)
Exchange differences relating to cash and cash equivalents	<u>(84)</u>	<u>(8)</u>
	<u>205</u>	<u>172</u>
Changes in assets and liability items:		
Increase in prepaid expenses and receivables	(716)	(206)
Increase (decrease) in accounts payable and accrued expenses	<u>(1,190)</u>	<u>253</u>
	<u>(1,906)</u>	<u>47</u>
Net cash provided by (used in) operating activities	<u>1,676</u>	<u>(1,758)</u>
<b>INVESTING ACTIVITIES:</b>		
Purchase of fixed assets	(25)	(2)
Change in investment in bank deposits	--	473
Proceeds from sale of financial assets at fair value through profit or loss	<u>--</u>	<u>79</u>
Net cash provided by investing activities	<u>(25)</u>	<u>550</u>
<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	<u>4,464</u>	<u>15</u>
Net cash provided by financing activities	<u>23,828</u>	<u>115</u>
<b>INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	25,479	(1,093)
<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	84	8
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>11,851</u>	<u>16,814</u>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u>37,414</u>	<u>15,729</u>
<b>Supplementary information on interest received in cash</b>	<u>6</u>	<u>2</u>

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

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