



## Press Release

### **RedHill Biopharma Reports Results for the First Quarter of 2015**

#### **Key Highlights Include:**

- **Strong cash position of approximately \$32.5 million at the end of the first quarter of 2015, following the closing of the Company's first public offering in the U.S. including participation by leading institutional healthcare investors**
- **Key milestones achieved in the first quarter of 2015 included the acquisition of the exclusive worldwide license to ABC294640, a Phase II-stage, proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) inhibitor from Apogee Biotechnology Corp., targeting multiple oncology and inflammatory-GI diseases**
- **Milestones expected in the second quarter of 2015 include top-line results from the first Phase III study with RHB-105 for the treatment of *H. pylori* bacterial infection, expected in mid-end June 2015, and the initiation of a Phase Ib/II study with ABC294620 for refractory/relapsed diffuse large B cell lymphoma**

**TEL-AVIV, Israel, April 30, 2015** RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) (“RedHill” or the “Company”), an Israeli biopharmaceutical company primarily focused on late clinical-stage, proprietary, orally-administered drugs for inflammatory and gastrointestinal diseases, including gastrointestinal cancers, today reported its financial results for the quarter ended March 31, 2015.

#### **Financial highlights for the three months ended March 31, 2015:**

**Revenues** for the quarter ended March 31, 2015 were immaterial compared to revenues of approximately \$7.0 million for the quarter ended March 31, 2014. Revenues for the first quarter of 2014 resulted mainly from an upfront payment of \$7.0 million received from Salix Pharmaceuticals,

Inc. ("Salix") for the out-licensing of RedHill's RHB-106 encapsulated bowel preparation and related rights.

**Research and Development Expenses, net** for the quarter ended March 31, 2015 were approximately \$3.8 million, an increase of \$2.1 million, or approximately 121%, compared to \$1.7 million in the first quarter of 2014. The increase was mainly due to expenses related to the ongoing Phase III studies with RHB-104 (Crohn's disease) and BEKINDA™ (gastroenteritis and gastritis).

**General and Administrative Expenses** for the quarter ended March 31, 2015 were approximately \$0.9 million, a decrease of \$0.1 million, or approximately 10%, compared to \$1.0 million in the first quarter of 2014. The decrease was mainly due to professional fees incurred during the first quarter of 2014 in connection with the January 2014 financing.

**Operating Loss** for the quarter ended March 31, 2015 was approximately \$4.8 million, a change of \$8.1 million, compared to an Operating Income of approximately \$3.3 million in the first quarter of 2014. The change resulted mainly from revenues of \$7.0 million from the Salix licensing transaction received in the first quarter of 2014.

**Net Cash Used in Operating Activities** for the quarter ended March 31, 2015 was approximately \$3.3 million, compared to Net Cash Provided by Operating Activities of \$1.7 million in the first quarter of 2014. The shift resulted mainly from revenues received from the Salix licensing transaction in the first quarter of 2014.

**Net Cash Used in Investment Activities** for the quarter ended March 31, 2015 was approximately \$7.0 million compared to immaterial Net Cash Used in Investment Activities in the first quarter of 2014. The increase was mainly due to investment of cash in short-term bank deposits during the first quarter of 2015.

**Net Cash Provided by Financing Activities** for the quarter ended March 31, 2015 was \$13.2 million, compared to \$23.8 million in the first quarter of 2014. The decrease 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, partially offset by the public offering of approximately \$14.4 million in the first quarter of 2015.

**Cash Balance**<sup>1</sup> as of March 31, 2015 was approximately \$32.5 million, compared to \$22.9 million for the year ended December 31, 2014. The increase resulted mainly from the closing of the underwritten public offering of approximately \$14.4 million in February 2015.

**Ori Shilo, Deputy CEO, Finance and Operations said:** "We are very pleased with the first quarter 2015 results. During this quarter we strengthened our cash position following the Company's first underwritten public offering in the U.S., supported by reputable investors such as OrbiMed and Broadfin Capital, further validating our promising pipeline of late clinical-stage drugs. We completed an important the acquisition of an exclusive worldwide license to ABC294640, a Phase II-stage, first-in-class, orally-administered SK2 inhibitor targeting multiple

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

oncology and inflammatory-GI diseases. We also made substantial progress in our clinical programs in recent months, including the completion of patient enrollment in the first phase III study with RHB-105 for eradication of *H. pylori* bacterial infection, and we are very excited about the top-line results from this study which are expected in mid-end June 2015. Our operational expenses during the first quarter of 2015 were in line with expectations, and our cash balance at the end of the quarter remains solid, exceeding \$32 million, with no debt, and we are well positioned to execute our plans for the coming year."

**Operational highlights for the first quarter ended March 31, 2015:**

1. In January 2015, the Company concluded, together with Quest Diagnostics, a pre-submission meeting with the FDA regarding the development path of a commercial companion diagnostic test for the detection of *Mycobacterium avium subspecies paratuberculosis* (MAP) in Crohn's disease patients. RedHill also announced its intention to initiate a study of approximately 40 Crohn's disease patients to assess the clinical utility of the companion diagnostic test during the second or third quarter of 2015. This study has commenced and is currently underway in the U.S. RedHill further announced that a protocol amendment had been made to the approved IND in relation to the ongoing Phase III MAP US study with RHB-104 for the treatment of Crohn's disease. The protocol amendment significantly increases the number of Crohn's disease patients potentially eligible to enroll in the ongoing Phase III MAP US study. As part of the amendment, the number of subjects planned to be enrolled in the study was increased from 240 to 270. RedHill also reported that it plans to increase the number of clinical sites in the study from 100 to 120 to include new sites in Australia, New Zealand and Europe, along with currently active sites in the U.S., Canada, and Israel.
2. In February 2015, the Company closed its underwritten public offering, which included an over-allotment option exercised in full by the underwriters, for a total of 1,150,000 American Depository Shares ("ADSs"), each representing ten Company ordinary shares, at an offering price of \$12.50 per ADS. Gross proceeds from the public offering were approximately \$14.4 million, before underwriting discounts and commissions and other offering expenses. Investors in the offering included Broadfin Capital LLC, OrbiMed, Sabby Capital, LLC, Rosalind Advisors, Inc. and others. Wells Fargo Securities acted as lead book-running manager and Roth Capital Partners acted as joint book-running manager. MLV & Co acted as co-manager of the offering.
3. In March 2015, the Company and Apogee Biotechnology Corporation ("Apogee"), a privately-held biotech company located in Hummelstown, Pennsylvania, U.S., entered into an exclusive worldwide license agreement under which RedHill acquired the rights to the Phase II drug candidate ABC294640 and additional intellectual property rights. ABC294640 is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple oncology and inflammatory-GI diseases. Under the terms of the agreement, RedHill acquired the exclusive worldwide development and commercialization rights to ABC294640 and additional intellectual property for all indications. RedHill undertook to pay Apogee an upfront payment of \$1.5 million, and an additional amount of \$2 million which will be paid on the earlier of (i) a specific date and (ii) reaching a specific development milestone. In addition, the Company undertook to pay up to \$2 million in potential

development milestone payments, and potential tiered royalties starting in the low double-digits. A Phase Ib/II clinical study with ABC294640 for refractory/relapsed diffuse large B cell lymphoma (DLBCL) is planned to commence in the second quarter of 2015 and will be funded by a \$1.5 million grant awarded by the National Cancer Institute under the NIH SBIR/STTR program to Apogee in conjunction with the Louisiana State University Health Science Center. A second Phase II clinical study of ABC294640 for the treatment of multiple myeloma is planned, subject to funding by a pending grant from the National Cancer Institute. A third Phase II clinical study is being planned by RedHill in order to evaluate ABC294640 as a radio-protectant and radiation enhancer in cancer patients undergoing radiotherapy.

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

The Company will host a conference call and an audio webcast on **Thursday, April 30, 2015, at 9:00 a.m. ET (16:00 Israel time)** to review the first quarter 2015 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: +1-718-354-1357; International: +1-877-280-2342; and Israel: +972-3-763-0146. The access code for the call is 5605589.**

**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/TASE: RDHL) is an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. RedHill's current pipeline of proprietary products includes: (i) **RHB-105** - an oral combination therapy for the treatment of *Helicobacter pylori* infection, with an ongoing first Phase III study; (ii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease, with an ongoing first Phase III study; (iii) **BEKINDA™ (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 European marketing application for chemotherapy and radiotherapy-induced nausea and vomiting submitted in December 2014; (iv) **RHB-106** - an encapsulated formulation for bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **ABC294640** - a Phase II-stage orally-administered SK2 inhibitor targeting multiple oncology and inflammatory-GI diseases; (vi) **MESUPRON®** - a Phase II-stage uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers; (vii) **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; (viii) **RIZAPORT™ (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 (ix) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol.

*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 research, manufacturing, 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, approvals and feedback; (iv) the manufacturing, 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 research, 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 (xi) competitive companies and technologies within the Company’s industry; and (xii) 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 26, 2015. 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 INCOME (LOSS)  
(Unaudited)

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
	<b>U.S. dollars in thousands</b>	
<b>REVENUES:</b>		
Licensing revenue	-	7,000
Other revenue	1	5
<b>TOTAL REVENUES</b>	1	7,005
<b>COST OF REVENUE</b>	-	1,050
<b>RESEARCH AND DEVELOPMENT EXPENSES, net</b>	3,829	1,736
<b>GENERAL AND ADMINISTRATIVE EXPENSES</b>	927	1,027
<b>OTHER INCOME</b>	-	100
<b>OPERATING INCOME (LOSS)</b>	(4,755)	3,292
<b>FINANCIAL INCOME</b>	286	89
<b>FINANCIAL EXPENSES</b>	173	4
<b>FINANCIAL INCOME, net</b>	113	85
<b>INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS) FOR THE PERIOD</b>	(4,642)	3,377
<b>EARNINGS (LOSS) PER ORDINARY SHARE, (U.S. dollars):</b>		
Basic	(0.05)	0.04
Diluted	(0.05)	0.04

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

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
	<b>U.S. dollars in thousands</b>	
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	8,474	5,892
Bank deposits	24,058	17,053
Prepaid expenses and receivables	2,368	3,074
	<u>34,900</u>	<u>26,019</u>
<b>NON-CURRENT ASSETS</b>		
Bank deposits	75	76
Fixed assets	139	146
Intangible assets	6,115	2,615
	<u>6,329</u>	<u>2,837</u>
<b>T O T A L A S S E T S</b>	<u><u>41,229</u></u>	<u><u>28,856</u></u>
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued expenses	1,963	1,720
Intangible assets payable, see note 3	3,500	-
	<u>5,463</u>	<u>1,720</u>
<b>NON-CURRENT LIABILITIES</b>		
Derivative financial instruments	1,877	2,125
<b>T O T A L L I A B I L I T I E S</b>	<u><u>7,340</u></u>	<u><u>3,845</u></u>
<b>EQUITY:</b>		
Ordinary shares	271	240
Additional paid-in capital	79,099	65,461
Warrants	1,057	1,528
Accumulated deficit	(46,538)	(42,218)
<b>T O T A L E Q U I T Y</b>	<u><u>33,889</u></u>	<u><u>25,011</u></u>
<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>	<u><u>41,229</u></u>	<u><u>28,856</u></u>

**REDHILL BIOPHARMA LTD.**

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
	<b>U.S. dollars in</b>	
	<b>thousands</b>	
<b>OPERATING ACTIVITIES:</b>		
Comprehensive income (loss)	(4,642)	3,377
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	322	245
Depreciation	9	7
Cost of out-licensing of intangible assets	-	50
Fair value gains on derivative financial instruments	(248)	(16)
Fair value gains on financial assets at fair value through profit or loss	-	1
Revaluation of bank deposits	(4)	2
Exchange differences relating to cash and cash equivalents	167	(84)
	246	205
Changes in assets and liability items:		
Decrease (increase) in prepaid expenses and receivables	706	(716)
Increase (decrease) in accounts payable and accrued expenses	318	(1,190)
	1,024	(1,906)
Net cash provided by (used in) operating activities	(3,372)	1,676
<b>INVESTING ACTIVITIES:</b>		
Purchase of fixed assets	(2)	(25)
Purchase of intangible assets	(75)	-
Change in investment in current bank deposits	(7,000)	-
Net cash used in investing activities	(7,077)	(25)
<b>FINANCING ACTIVITIES:</b>		
Proceeds from issuance of ordinary shares, warrants and derivative financial instruments, net of expenses	13,198	19,364
Exercise of warrants and options into ordinary shares, net of expenses	-	4,464
Net cash provided by financing activities	13,198	23,828
<b>INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>2,749</b>	<b>25,479</b>

<b>EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS</b>	(167)	84
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>5,892</u>	<u>11,851</u>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u>8,474</u>	<u>37,414</u>
<b>Supplementary information on interest received in cash</b>	<u>26</u>	<u>6</u>
<b>Supplementary information on investing activities not involving cash flows - Purchase of intangible assets</b>	<u>3,500</u>	<u>-</u>