



RedHill Biopharma Reports First Quarter 2018 Financial Results

May 8, 2018

Key Highlights:

- **Top-line results from Phase III study with RHB-104 for Crohn's disease (MAP US study) expected in approximately 3 months**
- **Top-line results from confirmatory Phase III study with TALICIA® for *H. pylori* infection (ERADICATE Hp2 study) expected Q4/2018**
- **Net revenues of \$2.4 million and gross profit of \$1.5 million in Q1/2018, up 22% and 40%, respectively, sequentially over the previous quarter**
- **Operating loss of \$9.9 million in Q1/2018, reduced 30% over the previous quarter and expected to continue to decrease over the coming quarters**
- **Debt-free balance sheet with \$36.4 million in cash at the end of Q1/2018**
- **RedHill does not have plans to raise additional capital ahead of the MAP US Phase III study top-line results with RHB-104 for Crohn's disease**
- **Conference call today, Tuesday, May 8 at 8:30 am EDT to review the financial results and business highlights; Dial-in details are included below**

TEL-AVIV, Israel and RALEIGH, N.C., May 08, 2018 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal diseases, today reported its financial results for the quarter ended March 31, 2018.

Dror Ben-Asher, RedHill's CEO, said: "There is tremendous energy and enthusiasm within RedHill currently as we approach two planned Phase III readouts, with RHB-104 for Crohn's disease in approximately three months and with TALICIA® for *H. pylori* infection in the fourth quarter. We are attentive to our shareholders and do not have plans to raise additional capital ahead of the MAP US Phase III study top-line results with RHB-104 for Crohn's disease. Rapid quarter-on-quarter revenue growth from our commercial activities in the U.S. and decreased operational costs in the first quarter of 2018 underscore our continued commitment to reducing cash burn rate and building shareholder value."

Financial highlights for the quarter ended March 31, 2018¹

Net Revenues for the first quarter of 2018 were \$2.4 million, an increase of 22% from the fourth quarter of 2017.

Gross Profit for the first quarter of 2018 was \$1.5 million, an increase of 40% from the fourth quarter of 2017. Gross margin increased from 54% for the fourth quarter of 2017 to 62% for the first quarter of 2018.

Research and Development Expenses for the first quarter of 2018 were \$6.4 million, a decrease of 23% from the fourth quarter of 2017. The decrease from the fourth quarter of 2017 was mainly due to the completion of patient enrollment in the RHB-104 Phase III study for Crohn's disease (MAP US study).

Selling, Marketing and Business Development Expenses for the first quarter of 2018 were \$3.2 million, a decrease of 18% from the fourth quarter of 2017. The decrease was due to the Company's cost reduction plan.

General and Administrative Expenses for the first quarter of 2018 were \$1.9 million, a decrease of 23% from the fourth quarter of 2017. The decrease was due to the Company's cost reduction plan.

Operating Loss for the first quarter of 2018 was \$9.9 million, a decrease of 30% from fourth quarter of 2017. The decrease was due to the increase in net revenues and gross profit, and the decrease in operating expenses, as detailed above.

Net Cash Used in Operating Activities for the first quarter of 2018 was \$9.5 million, compared to \$14.2 million in the fourth quarter of 2017. The decrease was due to the Company's progress with the RHB-104 Phase III study for Crohn's disease (MAP US study) and the overall reduction in operating loss.

Cash Balance² as of March 31, 2018 was \$36.4 million, compared to \$46.2 million as of December 31, 2017. The decrease was a result of the

Company's ongoing operational activities.

Conference Call and Webcast Information:

The Company will host a conference call **today, Tuesday, May 8, 2018 at 8:30 am EDT** to review the financial results and business highlights.

To participate in the conference call, please dial one of the following numbers 15 minutes prior to the start of the call: **United States: +1-800-289-0438; International: +1-929-477-0353; and Israel: +972-3-376-1315. The access code for the call is: 6285484.**

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

Select R&D highlights:

RHB-104 - Crohn's disease (first Phase III)

The last patient enrolled in the first Phase III study with RHB-104 for Crohn's disease (MAP US study) has completed 26 weeks of treatment for primary endpoint evaluation. Top-line results from the MAP US study are expected to be announced in approximately 3 months.

TALICIA® (RHB-105)- *H. pylori* infection (confirmatory Phase III) (FDA Fast-Track QIDP status)

To date, over 300 of the planned total of 444 patients have been enrolled in the ongoing confirmatory Phase III study with TALICIA® (RHB-105)³ for *H. pylori* infection (ERADICATE Hp2). RedHill expects to complete enrollment of the ERADICATE Hp2 study in the third quarter of 2018 and announce top-line results in the fourth quarter of 2018.

Subject to a successful outcome and additional regulatory feedback, the ERADICATE Hp2 study is expected to complete the package required for a potential U.S. NDA for TALICIA®. The filing is planned for early 2019 and, if accepted for review, the FDA could potentially approve TALICIA® in the second half of 2019 following a priority NDA review.

BEKINDA®(RHB-102) 12 mg - IBS-D (Phase II)

On January 16, 2018, RedHill announced positive final results⁴ from the Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The randomized, double-blind, placebo-controlled Phase II study successfully met its primary endpoint, improving stool consistency (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo (p-value=0.036). RedHill plans to meet with the FDA in the second quarter of 2018 to discuss the design for one or two pivotal Phase III studies.

An abstract⁵ (number: 2908495), describing the results of the study, will be presented as a Poster of Distinction, at Digestive Disease Week® (DDW) 2018 on Sunday, June 3, 2018, from 12:00 PM to 2:00 PM EDT, at the Walter E. Washington Convention Center, Washington, DC.

YELIVA® (ABC294640) - cholangiocarcinoma (Phase IIa) (FDA Orphan Drug designation)

To date, nine patients have been enrolled in the single-arm Phase IIa study with YELIVA® (ABC294640) for the treatment of cholangiocarcinoma (bile duct cancer). Enrollment is expected to be completed by the end of 2018. The study is being conducted at Mayo Clinic major campuses in Arizona and Minnesota, University of Texas MD Anderson Cancer Center and the Huntsman Cancer Institute, University of Utah Health, and is designed to enroll up to 39 patients.

RHB-106 - encapsulated bowel cleanser licensed to Salix Pharmaceuticals

RedHill recently amended its 2014 worldwide license agreement with Salix Pharmaceuticals related to RHB-106 encapsulated bowel cleanser, as well as additional related rights. The amendment clarifies the development efforts to be used by Salix, as well as provides for enhanced involvement by RedHill in certain intellectual property matters. In addition, the parties have agreed to increase the lower end of the range of royalty payments to be paid to RedHill on net sales from low single digits to high single digits, such that the potential royalties now range from high single digits up to low double digits. Milestone payments remain unchanged.

RHB-204 - nontuberculous mycobacteria (NTM) infections (planned pivotal Phase III) (FDA Fast-Track QIDP status)

A pivotal Phase III study with RHB-204 for the treatment of nontuberculous mycobacteria (NTM) infections is expected to be initiated in the second half of 2018, subject to completion of a supportive non-clinical program and additional input from the FDA. RHB-204 is planned to be assessed as a first-line treatment of NTM disease caused by *Mycobacterium avium complex* (MAC) infection.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes three gastrointestinal products in the U.S.: **Donnatal®**- a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg** - a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions; and **EnteraGam®**- a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104** with an ongoing first Phase III study for Crohn's disease; (iii) **RHB-204** with a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (RHB-102)** with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (v) **YELIVA® (ABC294640)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (vi) **RHB-106**, an encapsulated

bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107 (formerly MESUPRON)**, a Phase II-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at: 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 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 successfully promote Donnatal® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam®; (vi) the Company’s ability to establish and maintain corporate collaborations; (vii) the Company’s ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (viii) the interpretation of the properties and characteristics of the Company’s therapeutic candidates and the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (ix) the implementation of the Company’s business model, strategic plans for its business and therapeutic candidates; (x) 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; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company’s expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company’s Expanded Access Program; and (xiv) competition from other companies and technologies within 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 22, 2018. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise, unless required by law.

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¹ All financial highlights are approximate and are rounded to the nearest hundreds of thousands.

² Including cash and short-term investments (bank deposits and financial assets at fair value).

³ TALICIA® (RHB-105), BEKINDA® (RHB-102) and YELIVA® (ABC294640) are an investigational new drugs, not available for commercial distribution.

⁴ Final results remain subject to the Clinical Study Report (CSR).

⁵ The abstract was authored by Terry Plasse, MD, Danielle Abramson, PhD, Gilead Raday, Reza Fathi, PhD and Ira Kalfus, MD from RedHill Biopharma; Gary Barton, MD from Arkansas Gastroenterology; Evelyne Davidson, MD from New Phase Research & Development and Louis Velez, MD from Applied Research Center of Arkansas.

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended	
	March 31,	
	2018	2017
	U.S. dollars in thousands	
NET REVENUES	2,445	—
COST OF REVENUES	930	—
GROSS PROFIT	1,515	—
RESEARCH AND DEVELOPMENT EXPENSES, net	6,416	8,137
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,170	605
GENERAL AND ADMINISTRATIVE EXPENSES	1,924	1,315
OTHER EXPENSES	—	45
OPERATING LOSS	9,995	10,102
FINANCIAL INCOME	134	1,556
FINANCIAL EXPENSES	74	50
FINANCIAL INCOME, net	60	1,506
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	9,935	8,596

LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)

0.05

0.05

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	March 31, 2018	December 31, 2017
	Unaudited	Audited
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	7,560	16,455
Bank deposits	13,206	13,163
Financial assets at fair value through profit or loss	15,584	16,587
Trade receivables	1,809	1,528
Prepaid expenses and other receivables	2,019	3,290
Inventory	560	653
	40,738	51,676
NON-CURRENT ASSETS:		
Bank deposits	150	152
Fixed assets	221	230
Intangible assets	5,285	5,285
	5,656	5,667
TOTAL ASSETS	46,394	57,343
CURRENT LIABILITIES:		
Accounts payable	2,724	4,805
Accrued expenses and other current liabilities	6,481	6,025
Payable in respect of intangible asset purchase	500	1,000
	9,705	11,830
NON-CURRENT LIABILITIES:		
Derivative financial instruments	398	448
TOTAL LIABILITIES	10,103	12,278
COMMITMENTS		
EQUITY:		
Ordinary shares	577	575
Additional paid-in capital	177,787	177,434
Warrants	—	—
Accumulated deficit	(142,073)	(132,944)
TOTAL EQUITY	36,291	45,065
TOTAL LIABILITIES AND EQUITY	46,394	57,343

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31,	
	2018	2017
	U.S. dollars in thousands	
OPERATING ACTIVITIES:		
Comprehensive loss	(9,935)	(8,596)
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	806	307
Depreciation	22	14

Write-off of intangible assets	—	45	
Fair value adjustments on derivative financial instruments	(50)	(1,262)
Fair value losses on financial assets at fair value through profit or loss	99		15
Revaluation of bank deposits	90		(18)
Exchange differences in respect of cash and cash equivalents	14		(242)
	981		(1,141)
Changes in assets and liability items:			
Decrease (increase) in trade receivables	(281)	99
Decrease (increase) in prepaid expenses and other receivables	1,271		(1,113)
Decrease in inventory	93		—
Decrease in accounts payable	(2,081)	(39)
Increase in accrued expenses and other current liabilities	456		470
	(542)	(584)
Net cash used in operating activities	(9,496)	(10,322)
INVESTING ACTIVITIES:			
Purchase of fixed assets	(13)	—
Purchase of intangible assets	(500)	—
Change in investment in current bank deposits	(131)	(15,544)
Purchase of financial assets at fair value through profit or loss	(1,046)	(3,453)
Proceeds from sale of financial assets at fair value through profit or loss	1,950		400
Net cash provided by (used in) investing activities	260		(18,597)
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares and warrants, net of expenses	—		1,282
Exercise of warrants and options into ordinary shares, net of expenses	355		3,232
Net cash provided by financing activities	355		4,514
DECREASE IN CASH AND CASH EQUIVALENTS	(8,881)	(24,404)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(14)	242
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	16,455		53,786
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	7,560		29,624
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	267		71

 [Primary Logo](#)

Source: RedHill Biopharma Ltd.