



RedHill Biopharma Reports Second Quarter 2018 Financial Results and Provides Update on Operations

August 30, 2018

Key Highlights:

- **Top-line results from confirmatory Phase III study with TALICIA[®] for *H. pylori* infection on track to be announced in the fourth quarter of 2018**
- **Positive top-line results from Phase III study with RHB-104 for Crohn's disease - the study successfully met both its primary endpoint and key secondary endpoints**
- **Debt-free balance sheet with \$27.9 million in cash on June 30, 2018 and current cash on hand of approximately \$43 million**
- **Steady decrease in operating expenses, operating loss and net cash used in operating activities**
- **Net revenue of \$2.4 million and gross profit of \$1.6 million for the second quarter of 2018, compared to \$0.5 million and \$0.2 million, respectively, in the second quarter of 2017**
- **Management to host conference call today, August 30th at 8:30 a.m. EDT**

TEL-AVIV, Israel and RALEIGH, N.C., Aug. 30, 2018 (GLOBE NEWSWIRE) -- [RedHill Biopharma Ltd.](http://RedHillBiopharma.Ltd) (NASDAQ: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on proprietary drugs for gastrointestinal diseases, today reported its financial results for the quarter ended June 30, 2018 and provided an update on its operations.

"There is a tremendous amount of enthusiasm among the RedHill team which remains focused on the successful execution of our development plans and commercial operations. With enrollment nearly completed, we are on track to generate top-line results from the confirmatory Phase III study with TALICIA[®] for *H. pylori* infection in the fourth quarter of this year," said **Dror Ben-Asher, Redhill's CEO**. "We are also excited by the robust top-line results from the ground-breaking MAP US Phase III study with RHB-104 for Crohn's disease which met both its primary and key secondary endpoints. We will provide an update on next steps after we speak with the FDA about the results and the development path to potential approval. Our financial standing is solid, as we remain debt-free with approximately \$43 million total cash on hand as of today, with steadily declining cash burn."

Financial highlights for the quarter ended June 30, 2018¹:

Net Revenue for the second quarter of 2018 was \$2.4 million, compared to \$0.5 million in the second quarter of 2017. The increase was due to the advancement of promotional activities for Donnatal[®], and EnteraGam[®] and the initial promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in late 2017.

Gross Profit for the second quarter of 2018 was \$1.6 million, compared to \$0.2 million in the second quarter of 2017. Gross margin increased to 69% for the second quarter of 2018 from 44% in the second quarter of 2017.

Research and Development Expenses for the second quarter of 2018 were \$6.0 million, a decrease of 28% from \$8.4 million for the second quarter of 2017. The decrease was mainly due to the initiation of the Company's cost reduction plan, the completion of patient treatment for primary endpoint assessment in the Phase III study with RHB-104 and completion of the Phase III and Phase II studies with BEKINDA[®] (RHB-102) for gastroenteritis and IBS-D, respectively.

Selling, Marketing and Business Development Expenses for the second quarter of 2018 were \$3.1 million, a decrease of 7% from \$3.4 million for the second quarter of 2017. The decrease was due to the continued implementation of the Company's cost reduction plan and optimization measures.

General and Administrative Expenses for the second quarter of 2018 were relatively flat year-over-year at \$2.0 million.

Operating Loss for the second quarter of 2018 was \$9.6 million, a decrease of 29% from \$13.5 million for the second quarter of 2017. The decrease was due to the increase in net revenue and gross profit, and a decrease in operating expenses by 19%.

Net Cash Used in Operating Activities for the second quarter of 2018 was \$8.4 million, a decrease of 14% from \$9.7 million for the second quarter of 2017. The decrease was mainly due to the advancement of the Company's clinical development programs, including completion of patient treatment for primary endpoint assessment in the positive Phase III study of RHB-104 in Crohn's disease, completion of the Phase III and Phase II studies with BEKINDA[®] in gastroenteritis and IBS-D, respectively, and overall optimization of the Company's operations.

Cash Balance² as of June 30, 2018 was \$27.9 million. Subsequent to the end of the quarter, on August 14, 2018, RedHill announced the closing of an underwritten offering for gross proceeds of approximately \$25 million, before commissions and other offering expenses. RedHill's cash balance as of August 30, 2018 is approximately \$43 million.

NASDAQ Uplisting

On July 20, 2018, RedHill's American Depositary Shares (ADSs) started trading on the Nasdaq Global Market after being uplisted from the Nasdaq Capital Market. The Company's ADSs continue to trade under the symbol "RDHL".

Select R&D Highlights:

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

On July 30, 2018, RedHill announced positive top-line safety and efficacy results from the first Phase III study with orally-administered RHB-104 for Crohn's disease (MAP US study). The study successfully met both its primary endpoint and key secondary endpoints. The randomized, double-blind, placebo-controlled first Phase III study enrolled 331 subjects with moderately to severely active Crohn's disease (defined as Crohn's Disease Active Index (CDAI) between 220 and 450) in the U.S., Canada, Europe, Australia, New Zealand and Israel. Subjects were randomized 1:1 to receive RHB-104 or placebo, on-top of baseline background medication, including 5-ASAs, corticosteroids, immunomodulators or anti-TNF α agents.

The top-line results from the MAP US study demonstrated the superiority of RHB-104 over placebo in achieving remission at week 26, defined as CDAI value of less than 150, the primary endpoint of the study. The proportion of patients meeting the primary endpoint was significantly greater in the RHB-104 group compared to placebo (37% vs. 23%, $p=0.013$). The study also successfully met key secondary endpoints, demonstrating a consistent benefit to Crohn's disease patients treated with RHB-104. RHB-104 was found to be generally safe and well tolerated. RedHill will continue to assess additional data as it becomes available. The Company will meet with key opinion leaders and the U.S. Food and Drug Administration (FDA) to present the data package and discuss the development path to potential FDA approval and will continue discussions with potential partners for RHB-104.

On July 2, 2018, RedHill announced that it had received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) and an Intention to Grant from the European Patent Office (EPO) for two new patents covering RHB-104, expected to be valid until at least February 5, 2029, once granted. On August 13, 2018, the Company announced that it has received a Notice of Allowance from the USPTO for a new formulation patent, expected to be valid until at least 2029, that further expands the Company's intellectual property portfolio covering RHB-104 for Crohn's disease and RHB-204 for pulmonary nontuberculous mycobacteria (NTM) infections.

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

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

Subject to a successful outcome of the study and additional regulatory feedback, the ERADICATE Hp2 study is expected to complete the clinical package required for a potential submission of a U.S. New Drug Application (NDA) for TALICIA[®] in early 2019, which is eligible to benefit from priority review of six months.

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 pulmonary nontuberculous mycobacteria (NTM) infections is expected to be initiated in the first quarter of 2019, subject to completion of a supportive non-clinical program and additional input from the FDA. The study is intended to assess the efficacy and safety of RHB-204 as a first-line treatment for pulmonary NTM infections caused by *Mycobacterium avium complex* (MAC).

BEKINDA[®](RHB-102) 24 mg - Gastroenteritis (Phase III)

Following the positive results of the Phase III study with BEKINDA[®] 24 mg for acute gastroenteritis (GUARD study) and guidance provided by the FDA, RedHill is currently in discussions with the FDA on the design of a confirmatory Phase III study to support a potential NDA.

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

Following positive results of the Phase II study with BEKINDA[®] 12 mg for diarrhea-predominant irritable bowel syndrome (IBS-D), RedHill is in discussions with the FDA on the design of pivotal Phase III studies and path to potential NDA approval.

An abstract⁴ (number: 2908495), describing the results of the Phase II study with BEKINDA[®] 12 mg for the treatment of IBS-D, was presented as a Poster of Distinction at Digestive Disease Week[®] (DDW) in June 2018.

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

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

RHB-106 - encapsulated bowel cleanser licensed to Salix Pharmaceuticals

On August 20, 2018, RedHill announced that it had received a Notice of Allowance from the USPTO for a new formulation patent covering RHB-106, which is expected to be valid until at least 2033.

RedHill recently amended its 2014 worldwide license agreement with Salix Pharmaceuticals ("Salix"), a wholly-owned subsidiary of Bausch Health Companies Inc., relating to RHB-106, as well as additional related rights. The amendment clarified Salix's future development efforts and provides for enhanced involvement by RedHill in certain intellectual property matters and increased 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. Milestone payments remain unchanged. RedHill continues to assist Salix in the

development of RHB-106, as needed.

U.S. Commercial Highlights:

On June 28, 2018, RedHill announced that it had entered into a co-promotion agreement with Napo Pharmaceuticals, a human health company developing and commercializing novel gastrointestinal prescription products, granting RedHill the exclusive right to co-promote Mytesi[®] (crofelemer 125 mg delayed-release tablets)⁵ in the U.S. to certain gastroenterologists and primary care physicians for the approved indication in people living with HIV/AIDS. Mytesi[®] is an FDA-approved anti-diarrheal prescription drug indicated for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy (ART). On July 25, 2018, RedHill announced that it had initiated the promotion of Mytesi[®]. Mytesi[®] is the fourth product being promoted by RedHill's gastrointestinal-focused U.S. salesforce, in preparation for potential U.S. launch of RedHill's late clinical-stage products.

Conference Call and Webcast Information:

The Company will host a conference call **today, August 30, 2018 at 8:30 a.m. 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: +1-800-263-0877; International: +1-646-828-8143; and Israel: +972-3-721-9463. The access code for the call is: 9460445.**

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.

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 four gastrointestinal products in the U.S.: **Donnatal[®]**- a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Mytesi[®]**- an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy; **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 positive top-line results from a 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[®], Mytesi[®], 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 investigational 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.

Company contact:

Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):

Timothy McCarthy, CFA, MBA
Managing Director, Relationship Manager
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
	U.S. dollars in thousands			
NET REVENUES	2,350	483	4,795	483
COST OF REVENUES	725	272	1,655	272
GROSS PROFIT	1,625	211	3,140	211
RESEARCH AND DEVELOPMENT EXPENSES, net	6,044	8,434	12,460	16,571
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,123	3,376	6,293	3,981
GENERAL AND ADMINISTRATIVE EXPENSES	2,015	1,940	3,939	3,255
OTHER EXPENSES	—	—	—	45
OPERATING LOSS	9,557	13,539	19,552	23,641
FINANCIAL INCOME	156	2,523	239	4,078
FINANCIAL EXPENSES	1,717	7	1,740	56
FINANCIAL INCOME (EXPENSES), net	(1,561)	2,516	(1,501)	4,022
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	11,118	11,023	21,053	19,619
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.05	0.06	0.10	0.11
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	213,439	171,640	213,316	170,640

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	June 30,	December 31,
	2018	2017
	Unaudited	Audited
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	5,564	16,455
Bank deposits	8,225	13,163
Financial assets at fair value through profit or loss	14,113	16,587
Trade receivables	1,796	1,528
Prepaid expenses and other receivables	1,831	3,290
Inventory	690	653
	32,219	51,676
NON-CURRENT ASSETS:		
Bank deposits	144	152
Fixed assets	200	230
Intangible assets	5,285	5,285
	5,629	5,667
TOTAL ASSETS	37,848	57,343
CURRENT LIABILITIES:		
Accounts payable	4,023	4,805
Accrued expenses and other current liabilities	5,354	6,025
Payable in respect of intangible asset purchase	500	1,000
	9,877	11,830
NON-CURRENT LIABILITIES:		
Derivative financial instruments	2,065	448

TOTAL LIABILITIES	11,942	12,278
EQUITY:		
Ordinary shares	577	575
Additional paid-in capital	177,787	177,434
Accumulated deficit	(152,458)	(132,944)
TOTAL EQUITY	25,906	45,065
TOTAL LIABILITIES AND EQUITY	37,848	57,343

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(Unaudited)

Three Months Ended		Six Months Ended	
June 30,		June 30,	
2018	2017	2018	2017

U.S. dollars in thousands

OPERATING ACTIVITIES:			
Comprehensive loss	(11,118)	(11,023)	(21,053) (19,619)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	733	705	1,539 1,012
Depreciation	23	18	45 32
Write-off of intangible assets	—	—	— 45
Fair value adjustments on derivative financial instruments	1,667	(2,251)	1,617 (3,513)
Fair value losses on financial assets at fair value through profit or loss	13	64	112 79
Revaluation of bank deposits	(13)	(87)	77 (105)
Exchange differences in respect of cash and cash equivalents	53	(119)	67 (361)
	2,476	(1,670)	3,457 (2,811)
Changes in assets and liability items:			
Decrease (increase) in trade receivables	13	(778)	(268) (679)
Decrease (increase) in prepaid expenses and other receivables	188	(421)	1,459 (1,534)
Increase in inventory	(130)	(610)	(37) (610)
Increase (decrease) in accounts payable	1,299	1,124	(782) 1,085
Increase (decrease) in accrued expenses and other current liabilities	(1,127)	3,650	(671) 4,119
	243	2,965	(299) 2,381
Net cash used in operating activities	(8,399)	(9,728)	(17,895) (20,049)
INVESTING ACTIVITIES:			
Purchase of fixed assets	(2)	(102)	(15) (102)
Purchase of intangible assets	—	—	(500) —
Change in investment in current bank deposits	5,000	284	4,869 (15,260)
Purchase of financial assets at fair value through profit or loss	(42)	(10,500)	(1,088) (13,953)
Proceeds from sale of financial assets at fair value through profit or loss	1,500	5,447	3,450 5,847
Net cash provided by (used in) investing activities	6,456	(4,871)	6,716 (23,468)
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, net of expenses	—	—	— 1,282
Exercise of warrants and options into ordinary shares, net of expenses	—	175	355 3,407
Net cash provided by financing activities	—	175	355 4,689
DECREASE IN CASH AND CASH EQUIVALENTS	(1,943)	(14,424)	(10,824) (38,828)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(53)	119	(67) 361
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	7,560	29,624	16,455 53,786
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	5,564	15,319	5,564 15,319
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	148	130	415 201

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 investigational new drugs, not available for commercial distribution.

⁴ 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.

⁵ Mytesi[®] (crofelemer 125 mg delayed-release tablets) is a first-in-class anti-secretory prescription drug approved by the U.S. FDA for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy. For more information, see the prescribing information http://mytesi.com/assets/mytesi_package_insert_june_2016.pdf.

 red.jpg

Source: RedHill Biopharma Ltd.