Press Release

RedHill Biopharma Reports First Quarter 2019 Financial Results and Operational Highlights

Key Highlights and Upcoming Milestones:

- **NDA submitted to the FDA for Talicia® for *H. pylori* infection, with potential U.S. commercial launch in Q4/2019, assuming FDA approval**
- **FDA meeting planned for H2/2019 to discuss design of confirmatory Phase 3 study and path to potential approval for RHB-104 for Crohn's disease**
- **Initiation of pivotal Phase 3 study expected in H2/2019 with RHB-204 for first-line treatment of pulmonary nontuberculous mycobacteria (NTM) infections**
- **Net revenues of $1.7 million, an increase of 28% over previous quarter**
- **Debt-free balance sheet with $45.5 million in cash as of March 31, 2019, with quarterly cash burn at its lowest in two years**

TEL-AVIV, Israel and RALEIGH, N.C., May 7, 2019 -- RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on gastrointestinal (GI) diseases, today reported its financial results and operational highlights for the quarter ended March 31, 2019.

"We had a productive quarter with Talicia leading up to the NDA submission to the FDA, announced earlier today. With potential NDA approval as early as the fourth quarter of this year, we have expanded our highly experienced commercial management team and are advancing the preparations for the potential U.S. launch of Talicia with our established sales-force," **said Micha Ben Chorin, RedHill's chief financial officer.** "As of March 31, 2019, we have maintained a cash position of $45.5 million with a debt-free balance sheet and continued decrease of our quarterly cash burn to its lowest level in two years."

Operational Highlights:

Talicia (RHB-105)[1] - Eradication of *H. pylori* Infection

RedHill submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Talicia for the treatment of *H. pylori* infection following positive results from two Phase 3 studies and a positive pre-NDA meeting with the FDA earlier this year. Talicia was granted Qualified Infectious Disease Product (QIDP) designation by the FDA, including eligibility for six-month priority review and an additional three years of market exclusivity on top of the standard five years, for a total of eight years of U.S. market exclusivity. Assuming FDA approval, RedHill plans to launch Talicia in the U.S. in the fourth quarter of 2019 with the Company's dedicated sales force.

RedHill announced in January 2019 that it had received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for an additional new patent covering Talicia. The patent was subsequently granted and is valid until at least 2034. This is the fifth patent covering Talicia in the U.S. RedHill also announced in March 2019 that the European Patent Office (EPO) and the Japan Patent Office (JPO) accepted pending patent applications covering Talicia for *H. pylori* infection. The Japanese patent was subsequently granted and is valid until 2034.

RHB-104 - Crohn's Disease

RedHill plans to meet with the FDA in the second half of 2019 to discuss the development path toward potential approval of RHB-104**,** including the design of a confirmatory Phase 3 study**.** This meeting follows the positive results from the first Phase 3 study with orally-administered RHB-104 for the treatment of Crohn's disease (MAP US study). The MAP US study successfully met both its primary endpoint and its key secondary endpoints and presented the broad benefit of RHB-104 as an add-on therapy to standard-of-care treatments for Crohn's disease, including anti-TNFs. RedHill continues to assess additional data from the positive study as it becomes available.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

RedHill plans to initiate a pivotal Phase 3 study with RHB-204 for the treatment of pulmonary NTM infections in the second half of 2019, subject to completion of the ongoing supportive non-clinical program and additional input from the FDA. The study is intended to assess the efficacy and safety of RHB-204 and potentially support its approval as a stand-alone, first-line treatment for pulmonary NTM infections caused by Mycobacterium avium complex (MAC).

BEKINDA® (RHB-102)[1] - Gastroenteritis and Gastritis and Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

RedHill is currently working toward a confirmatory Phase 3 study to support a potential NDA for BEKINDA® for acute gastroenteritis and gastritis. This study follows the successful completion of a first Phase 3 study with BEKINDA for acute gastroenteritis and gastritis and guidance provided by the FDA.

RedHill held a positive end-of-Phase 2 Type B meeting with the FDA to discuss the clinical and regulatory pathway toward potential U.S. approval of BEKINDA for the treatment of IBS-

[1] Talicia® (RHB-105), BEKINDA® (RHB-102) and YELIVA® (opaganib, ABC294640) are investigational new drugs, not available for commercial distribution.

D. RedHill is currently finalizing the design of two pivotal Phase 3 studies with BEKINDA for IBS-D.

YELIVA® (opaganib, ABC294640)[1] - Cholangiocarcinoma

The ongoing Phase 2a study evaluating the activity of orally-administered YELIVA in advanced cholangiocarcinoma (bile duct cancer) continues to enroll patients in the second stage of the two-stage study design. Enrollment of the full cohort of 39 evaluable patients is expected to be completed by the end of 2019.

Commercial Highlights:

RedHill is continuing its preparations for the potential U.S. launch of Talicia in the fourth quarter of 2019 with its dedicated sales force. RedHill currently commercializes and promotes several GI-specialty products in select U.S. territories, including Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)[2], EnteraGam® (serum-derived bovine immunoglobulin/protein isolate SBI)[3] and Mytesi® (crofelemer 125 mg delayed-release tablets)[4].

Financial highlights for the quarter ended March 31, 2019[5]

- ***Net Revenues*** of $1.7 million in the first quarter of 2019, an increase of 28% compared to the fourth quarter of 2018. The growth was attributable to an increase in revenues from promoted products.

- ***Gross Profit*** of $1.3 million in the first quarter of 2019, compared to $0.8 million in the fourth quarter of 2018, with gross margin increased from 57% to 76%. The growth was attributable to an increase in revenues from promoted products.

[2] Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription drug, classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. For more information, please see the prescribing information: http://www.donnatal.com/wp-content/uploads/2015/02/2015-02-18-Risk-Benefit-information-DTC-REV.-SE.pdf.

[3] EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is a commercially-available medical food, intended for the dietary management of chronic diarrhea and loose stools due to specific intestinal disorders, which must be administered under medical supervision.

[4] 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.

[5] All financial highlights are approximate and are rounded to the nearest hundreds of thousands.

- ***Research and Development Expenses*** of $5.4 million in the first quarter of 2019, compared to $5.8 million in the fourth quarter of 2018, resulting from the successful finalization of the confirmatory Phase 3 study with Talicia.

- ***Selling, Marketing and Business Development Expenses*** of $3.1 million in the first quarter of 2019, compared to $3.2 million in the fourth quarter of 2018.

- ***General and Administrative Expenses*** of $2.0 million in the first quarter of 2019, compared to $1.9 million in the fourth quarter of 2018.

- ***Operating Loss*** of $9.2 million in the first quarter of 2019, compared to $10 million in the fourth quarter of 2018. The decrease in Operating Loss was primarily due to the increase in Gross Profit and the decrease in Research and Development Expenses, as described above.

- ***Net Cash Used in Operating Activities*** of $7.5 million in the first quarter of 2019, compared to $8.2 million in the fourth quarter of 2018.

- ***Cash Balance***[6] as of March 31, 2019, was $45.5 million, compared to $53.2 million as of December 31, 2018.

Conference Call and Webcast Information:

The Company will host a conference call today, May 7, 2019, at 8:30 a.m. EDT to review the financial results and operational highlights. The conference call will be broadcast live on the Company's website, http://ir.redhillbio.com/events.

To participate in the conference call, please dial one of the following numbers 15 minutes prior to the start of the call: United States: +1-866-966-1396, International: +1-631-510-7495 and Israel: +972-3-721-7998. The access code for the call is: 1777567. A replay of the webcast will be available for 30 days on the Company's website, http://ir.redhillbio.com/events.

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 clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S.: **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi®** - an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. RedHill's key clinical late-stage development programs include: (i) **Talicia® (RHB-105)** for the treatment of *Helicobacter pylori* infection with a U.S. NDA submitted; (ii) **RHB-104,** with positive top-line results from a first Phase 3 study for Crohn's disease; (iii)

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

RHB-204, with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (RHB-102),** with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 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 2a study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107,** a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases.

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, and the timing of the commercial launch of its therapeutic candidates; (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 commercialize and promote Donnatal®, EnteraGam®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg; (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 26, 2019. 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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REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
	U.S. dollars in thousands	
NET REVENUES	1,737	2,445
COST OF REVENUES	417	930
GROSS PROFIT	1,320	1,515
RESEARCH AND DEVELOPMENT EXPENSES, net	5,372	6,416
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,136	3,170
GENERAL AND ADMINISTRATIVE EXPENSES	2,025	1,924
OPERATING LOSS	9,213	9,995
FINANCIAL INCOME	374	134
FINANCIAL EXPENSES	1,031	74
FINANCIAL EXPENSES (INCOME), net	657	(60)
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	9,870	9,935
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.03	0.05
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	283,687	213,192

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	March 31, 2019	December 31, 2018
	Unaudited	Audited
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	23,014	29,005
Bank deposits	6,145	8,271
Financial assets at fair value through profit or loss	16,374	15,909
Trade receivables	1,419	958
Prepaid expenses and other receivables	1,243	1,876
Inventory	1,288	769
	49,483	56,788
NON-CURRENT ASSETS:		
Bank deposits	145	140
Fixed assets	146	163
Right-of-use assets	3,040	—
Intangible assets	5,320	5,320
	8,651	5,623
TOTAL ASSETS	58,134	62,411
CURRENT LIABILITIES:		
Accounts payable	4,413	3,324
Lease liabilities	713	—
Accrued expenses and other current liabilities	6,962	7,057
	12,088	10,381
NON-CURRENT LIABILITIES:		
Derivative financial instruments	1,317	344
Lease liabilities	2,354	—
Royalty obligation	500	500
	4,171	844
TOTAL LIABILITIES	16,259	11,225
EQUITY:		
Ordinary shares	767	767
Additional paid-in capital	219,505	219,505
Accumulated deficit	(178,397)	(169,086)
TOTAL EQUITY	41,875	51,186
TOTAL LIABILITIES AND EQUITY	58,134	62,411

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2019	2018
	U.S. dollars in thousands	
OPERATING ACTIVITIES:		
Comprehensive loss	(9,870)	(9,935)
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	559	806
Depreciation	231	22
Fair value adjustments on derivative financial instruments	973	(50)
Fair value losses (gains) on financial assets at fair value through profit or loss	(52)	99
Revaluation of bank deposits	(10)	90
Exchange differences in respect of lease liabilities	5	—
Exchange differences in respect of cash and cash equivalents	(16)	14
	1,690	981
Changes in assets and liability items:		
Increase in trade receivables	(461)	(281)
Decrease in prepaid expenses and other receivables	633	1,271
Decrease (increase) in inventory	(519)	93
Increase (decrease) in accounts payable	1,089	(2,081)
Increase (decrease) in accrued expenses and other current liabilities	(95)	456
	647	(542)
Net cash used in operating activities	**(7,533)**	**(9,496)**
INVESTING ACTIVITIES:		
Purchase of fixed assets	(6)	(13)
Change in investment in current bank deposits	2,131	(131)
Purchase of financial assets at fair value through profit or loss	(633)	(1,046)
Proceeds from sale of financial assets at fair value through profit or loss	220	1,950
Net cash provided by investing activities	**1,712**	**760**
FINANCING ACTIVITIES:		
Exercise of options into ordinary shares	—	355
Principal elements of lease payments	(186)	—
Repayment of payable in respect of intangible asset purchase	—	(500)
Net cash used in financing activities	**(186)**	**(145)**
DECREASE IN CASH AND CASH EQUIVALENTS	(6,007)	(8,881)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	16	(14)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,005	16,455
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	23,014	7,560
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	163	267
SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING ACTIVITIES		
Acquisition of right-of-use assets by means of lease liabilities	1,580	-