Press Release

RedHill Biopharma Reports Second Quarter 2019 Financial Results and Operational Highlights

Key Highlights and Upcoming Milestones:

- **U.S. FDA acceptance of the New Drug Application (NDA) for Talicia® for *H. pylori* for priority review and assignment of a target PDUFA action date of November 2, 2019**

- **Preparations ongoing for the potential U.S. commercial launch of Talicia in Q4/2019, subject to FDA approval, with RedHill's established sales force, led by the Company's experienced commercial management team**

- **FDA meetings planned to take place in H2/2019 to discuss the path to potential approval of RHB-104 for Crohn's disease**

- **Initiation of pivotal Phase 3 study activities with RHB-204 for first-line treatment of pulmonary nontuberculous mycobacteria (NTM) infections expected in Q4/2019**

- **Debt-free balance sheet with $34.9 million cash balance as of June 30, 2019**

TEL-AVIV, Israel and RALEIGH, N.C., July 23, 2019 RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on the development and commercialization of clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases, today reported its financial results and operational highlights for the quarter ended June 30, 2019.

"We continue to maintain strong financial discipline while implementing our strategic commercial and development plans. We achieved a significant milestone with the FDA acceptance of the Talicia NDA for priority review earlier this month**.** With a PDUFA date of November 2, 2019, we continue

our focus on preparations for the potential U.S. commercial launch of Talicia in the fourth quarter of this year, subject to FDA approval" **said Micha Ben Chorin, RedHill's Chief Financial Officer.**

Financial highlights for the quarter ended June 30, 2019[1]

- ***Net Revenues*** of $1.6 million in the second quarter of 2019, compared to $1.7 million in the first quarter of 2019.

- ***Gross Profit*** of $1.1 million in the second quarter of 2019, compared to $1.3 million in the first quarter of 2019.

- ***Research and Development Expenses*** of $7.0 million in the second quarter of 2019, compared to $5.4 million in the first quarter of 2019. The increase is attributable primarily to the one-time PDUFA payment of $2.6 million for the Talicia NDA submission.

- ***Selling, Marketing and Business Development Expenses*** of $4.1 million in the second quarter of 2019, compared to $3.1 million in the first quarter of 2019. The increase is attributable to the expansion of the commercial operations team with several key executive hires, as well as preparations for the potential commercial launch of Talicia in the U.S.

- ***General and Administrative Expenses*** of $2.4 million in the second quarter of 2019, compared to $2.0 million in the first quarter of 2019. The increase is attributable primarily to preparations for the potential U.S. launch of Talicia.

- ***Operating Loss*** of $12.4 million in the second quarter of 2019, compared to $9.2 million in the first quarter of 2019. The increase is primarily due to the PDUFA payment of $2.6 million and the increase in Selling, Marketing and Business Development Expenses, as described above.

- ***Net Cash Used in Operating Activities*** of $10.4 million in the second quarter of 2019, compared to $7.5 million in the first quarter of 2019. The increase is attributable primarily to the one-time PDUFA fee of $2.6 million for the Talicia NDA submission.

- ***Cash Balance***[2] as of June 30, 2019 was $34.9 million, compared to $45.5 million as of March 31, 2019.

Operational Highlights:

[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).

Talicia (RHB-105)[3] **-** ***H. pylori*** **Infection**

The U.S. Food and Drug Administration (FDA) has accepted for priority review the NDA for Talicia for *H. pylori* infection. The NDA for Talicia was assigned a target Prescription Drug User Act (PDUFA) action date of November 2, 2019. If approved, Talicia would be eligible for a total of eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation, in addition to patent protection extending until at least 2034. Assuming FDA approval, RedHill plans to launch Talicia in the U.S. in the fourth quarter of 2019 with the Company's established sales force, led by RedHill's highly experienced commercial management team. The Company further strengthened its commercial management team in the second quarter of 2019 including several key executive hires.

RHB-104 - Crohn's Disease

FDA meetings are planned to take place 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. The MAP US randomized, double-blind, placebo-controlled first Phase 3 study with RHB-104 for Crohn's disease successfully met both its primary endpoint and key secondary endpoints and presented the benefit of RHB-104, including as an add-on therapy to standard-of-care treatments for Crohn's disease, such as anti-TNFs.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

RedHill plans to initiate pivotal Phase 3 study activities with RHB-204 for the treatment of pulmonary NTM infections in the fourth quarter 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 *Mycobacterium avium complex* (MAC) disease, the most common cause of pulmonary NTM infections[4].

BEKINDA® (RHB-102) - Gastroenteritis & 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 will follow the successful completion of a first Phase 3 study with BEKINDA for acute gastroenteritis and gastritis, as well as guidance provided by the FDA.

YELIVA® (opaganib, ABC294640) - 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.

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

[4] Wassilew N et al. Pulmonary disease caused by non-tuberculous mycobacteria. Respiration 91.5 (2016): 386-402.

Conference Call and Webcast Information:

The Company will host a conference call on **Tuesday, July 23, 2019 at 8:30 a.m. EDT** to review the second quarter 2019 financial results and operational 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: +1-866-966-1396; International: +1-631-510-7495; and Israel: +972-3-721-7998; The access code for the call is: 5754875**.

The conference call will be broadcast live and will be available for replay for 30 days on the Company's website, http://ir.redhillbio.com/events. Please access the Company's website at least 15 minutes ahead of the conference call to register.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. 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 and eradication of *Helicobacter pylori* infection with a U.S. NDA submitted and accepted for priority review; (ii) **RHB-104,** with positive top-line results from a first Phase 3 study for Crohn's disease; (iii) **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, the approval of the NDA for Talicia® by the FDA and such

approval's timing, the initiation and timing of the commercial launch of Talicia®, the timing of meetings scheduled with the FDA, including in regards with RHB-104 for Crohn's disease, as well as 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® and Mytesi®; (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; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. 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, as amended on May 15, 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	U.S. dollars in thousands			
NET REVENUES	1,563	2,350	3,300	4,795
COST OF REVENUES	425	725	842	1,655
GROSS PROFIT	1,138	1,625	2,458	3,140
RESEARCH AND DEVELOPMENT EXPENSES, net	6,972	6,044	12,344	12,460
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	4,147	3,123	7,283	6,293
GENERAL AND ADMINISTRATIVE EXPENSES	2,399	2,015	4,424	3,939
OPERATING LOSS	12,380	9,557	21,593	19,552
FINANCIAL INCOME	1,546	156	948	239
FINANCIAL EXPENSES	74	1,717	133	1,740
FINANCIAL EXPENSES (INCOME), net	(1,472)	1,561	(815)	1,501
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	10,908	11,118	20,778	21,053
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)**:**	0.04	0.05	0.07	0.10
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	283,687	213,439	283,687	213,316

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	June 30, 2019	December 31, 2018
	Unaudited	Audited
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	8,995	29,005
Bank deposits	9,403	8,271
Financial assets at fair value through profit or loss	16,471	15,909
Trade receivables	963	958
Prepaid expenses and other receivables	2,315	1,876
Inventory	1,826	769
	39,973	56,788
NON-CURRENT ASSETS:		
Bank deposits	147	140
Fixed assets	250	163
Right-of-use assets	4,005	—
Intangible assets	5,320	5,320
	9,722	5,623
TOTAL ASSETS	49,695	62,411
CURRENT LIABILITIES:		
Accounts payable	4,743	3,324
Lease liabilities	845	—
Accrued expenses and other current liabilities	8,465	7,057
	14,053	10,381
NON-CURRENT LIABILITIES:		
Derivative financial instruments	13	344
Lease liabilities	3,225	—
Royalty obligation	500	500
	3,738	844
TOTAL LIABILITIES	17,791	11,225
EQUITY:		
Ordinary shares	767	767
Additional paid-in capital	219,505	219,505
Accumulated deficit	(188,368)	(169,086)
TOTAL EQUITY	31,904	51,186
TOTAL LIABILITIES AND EQUITY	49,695	62,411

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	U.S. dollars in thousands			
OPERATING ACTIVITIES:				
Comprehensive loss	(10,908)	(11,118)	(20,778)	(21,053)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	937	733	1,496	1,539
Depreciation	226	23	456	45
Fair value adjustments on derivative financial instruments	(1,304)	1,667	(331)	1,617
Fair value losses (gains) on financial assets at fair value through profit or loss	(35)	13	(87)	112
Revaluation of bank deposits	(60)	(13)	(70)	77
Exchange differences in respect of lease liabilities	35	—	41	—
Exchange differences in respect of cash and cash equivalents	(23)	53	(39)	67
	(224)	2,476	1,466	3,457
Changes in assets and liability items:				
Decrease (Increase) in trade receivables	457	13	(5)	(268)
Decrease (Increase) in prepaid expenses and other receivables	(1,072)	188	(439)	1,459
Increase in inventory	(538)	(130)	(1,057)	(37)
Increase (decrease) in accounts payable	330	1,299	1,419	(782)
Increase (decrease) in accrued expenses and other current liabilities	1,502	(1,127)	1,408	(671)
	679	243	1,326	(299)
Net cash used in operating activities	**(10,453)**	**(8,399)**	**(17,986)**	**(17,895)**
INVESTING ACTIVITIES:				
Purchase of fixed assets	(128)	(2)	(134)	(15)
Change in investment in current bank deposits	(3,200)	5,000	(1,069)	4,869
Purchase of financial assets at fair value through profit or loss	(1,942)	(42)	(2,575)	(1,088)
Proceeds from sale of financial assets at fair value through profit or loss	1,880	1,500	2,100	3,450
Net cash provided by investing activities	**(3,390)**	**6,456**	**(1,678)**	**7,216**
FINANCING ACTIVITIES:				
Exercise of options into ordinary shares	—	—	—	355
Principal elements of lease payments	(199)	—	(385)	—
Repayment of payable in respect of intangible asset purchase	—	—	—	(500)
Net cash used in financing activities	**(199)**	**—**	**(385)**	**(145)**
DECREASE IN CASH AND CASH EQUIVALENTS	(14,042)	(1,943)	(20,049)	(10,824)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	23	(53)	39	(67)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	23,014	7,560	29,005	16,455
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	8,995	5,564	8,995	5,564
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	162	148	325	415
SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING ACTIVITIES				
Acquisition of right-of-use assets by means of lease liabilities	1,101	—	2,681	—