Press Release

RedHill Biopharma Provides Full-Year 2018 Financial Results and Operational Highlights

TEL-AVIV, Israel and RALEIGH, N.C., February 26, 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 full-year 2018 financial results and operational highlights.

Key Highlights:

- Positive top-line results from the confirmatory Phase 3 study with TALICIA® for eradication of *H. pylori* infection; NDA filing expected in H1/19 with potential U.S. commercial launch in Q4/19
- Positive top-line results from a first Phase 3 study with RHB-104 for Crohn's disease; FDA meeting planned mid-2019
- Initiation of pivotal Phase 3 study with RHB-204 for first-line treatment of pulmonary nontuberculous mycobacteria (NTM) infections expected in H2/19
- Strengthening of commercial management team with appointment of Rick D. Scruggs, former executive VP at Salix Pharmaceuticals, as RedHill's chief operating officer, U.S. operations
- Debt-free balance sheet with approximately $53 million in cash as of December 31, 2018
- Net revenues of $8.4 million and gross margin of 66% in 2018, compared to net revenues of $4.0 million and gross margin of 47% in 2017[1]

Micha Ben Chorin, RedHill's chief financial officer, said: "We had a successful 2018 with positive data reported from our two key Phase 3 studies: the confirmatory Phase 3 study with

[1] Promotional activities initiated mid-2017.

TALICIA® for eradication of *H. pylori* infection and the first Phase 3 study with RHB-104 for Crohn's disease."

Mr. Ben Chorin added: "We enter 2019 with a solid cash position of $53.2 million and a debt-free balance sheet. One of our potential key upcoming milestones this year is the planned filing of a U.S. NDA for TALICIA® in the first half of 2019, which is expected to support a potential commercial launch in the fourth quarter of 2019, subject to FDA approval. Additionally, we expect to meet with the FDA to discuss the development path to potential approval of RHB-104 for Crohn's disease following the positive Phase 3 study results. We also plan to initiate a pivotal Phase 3 study with RHB-204 for potential first-line treatment of pulmonary nontuberculous mycobacteria (NTM) infections, an orphan disease with a strong unmet medical need, in the second half of 2019."

"We continue to strengthen our commercial management team with senior industry executives and are pleased to have Rick D. Scruggs, a former senior executive at Salix Pharmaceuticals, expand his role as chief operating officer, U.S. operations to lead our growing U.S. commercial operations. For 2019, our established sales team is positioned to drive revenue growth with a lineup of four commercial products. In an effort to drive additional revenue growth and further leverage our existing U.S. commercial operations, we continue to evaluate opportunities to in-license and acquire additional U.S commercial products," **concluded Mr. Ben Chorin.**

Select 2018 operational highlights:

TALICIA® (RHB-105)[2] - Eradication of *H. pylori* Infection

Following the positive results from the confirmatory Phase 3 study with TALICIA® for eradication of *H. pylori* infection (ERADICATE Hp2 study), RedHill plans to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) in the first half of 2019, with eligibility for six-month priority review and potential U.S. commercial launch in the fourth quarter of 2019, subject to FDA approval.

RHB-104 - Crohn's Disease

The first Phase 3 study with orally-administered RHB-104 for the treatment of Crohn's disease (MAP US study) successfully met both its primary endpoint and key secondary endpoints and confirmed the broad benefit of RHB-104 as an add-on therapy to standard-of-care treatments for Crohn's disease. RedHill continues to assess additional data from the positive study as it becomes available and plans to meet with the FDA mid-2019 to discuss the development path towards potential approval.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

A pivotal Phase 3 study with RHB-204 for the treatment of pulmonary nontuberculous mycobacteria infections is expected to be initiated 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

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

approval as a first-line treatment for pulmonary NTM infections caused by *Mycobacterium avium complex* (MAC).

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

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

RedHill held a positive end-of-Phase 2/pre-Phase 3 (Type B) meeting with the FDA discussing the clinical and regulatory pathway towards potential U.S. approval of BEKINDA® for the treatment of IBS-D. RedHill is currently finalizing the design of two pivotal Phase 3 studies with BEKINDA® for IBS-D.

YELIVA® (opaganib, ABC294640) - Cholangiocarcinoma

The ongoing Phase 2a study evaluating the activity of orally-administered YELIVA® in advanced cholangiocarcinoma (bile duct cancer) achieved its pre-specified efficacy goal for the first stage of the two-stage study design and advanced to its second stage. Enrollment of the full cohort of 39 evaluable patients is expected to be completed in the second half of 2019.

U.S. Commercial Highlights:

RedHill currently commercializes and promotes four GI-specialty products in select U.S. territories, Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)[3], EnteraGam® (serum-derived bovine immunoglobulin/protein isolate SBI)[4], Mytesi® (crofelemer 125 mg delayed-release tablets)[5] and Esomeprazole Strontium DR Capsules 49.3 mg[6].

[3] 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.

[4] 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.

[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.

[6] Esomeprazole Strontium Delayed-Release (DR) Capsules 49.3 mg is an FDA-approved, proprietary, prescription proton pump inhibitor, indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions. For more information, please see the prescribing information: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=53240ab5-98e7-4050-b640-e09c1271899a&type=display

RedHill expanded its leadership team with the appointment of Rick D. Scruggs as chief operating officer, U.S. operations. With more than 25 years of experience in the pharmaceutical industry, Rick has extensive experience in commercial operations and business development, having served as executive vice president of business development at Salix Pharmaceuticals, Inc., up to its acquisition by Valeant Pharmaceuticals International, Inc. (now Bausch Health Companies Inc.).

Full-Year 2018 Results[7]

- ***Net Revenues*** of $8.4 million for 2018, compared to $4.0 million for 2017[8].
- ***Cost of Revenues*** of $2.8 million for 2018, compared to $2.1 million for 2017.
- ***Gross Profit*** of $5.5 million for 2018, compared to $1.9 million for 2017; with gross margin increased from 47% to 66%.
- ***Research and Development Expenses*** of $24.9 million for 2018, compared to $33.0 million for 2017. The decrease was mainly due to the finalization of the Phase 3 study with RHB-104 and completion of the clinical studies with BEKINDA®.
- ***Selling, Marketing and Business Development Expenses*** were $12.5 million for 2018, compared to $12.0 million for 2017.
- ***General and Administrative Expenses*** were approximately $7.5 million for 2018, compared to $8.0 million for 2017.
- ***Operating Loss*** of $39.3 million for 2018, compared to $52.0 million for 2017.
- ***Net Cash Used in Operating Activities*** was $34.5 million for 2018, compared to $44.8 million for 2017.
- ***Net Cash Provided by Financing Activities*** was $41.8 million for 2018, compared to $25.7 million for 2017. The increase was mainly due to higher gross proceeds raised in underwritten public offerings.
- ***Cash Balance***[9] as of December 31, 2018, was $53.2 million, compared to $46.2 million as of December 31, 2017.

Conference Call and Webcast Information:

The Company will host a conference call **today, February 26, 2019, at 8:30 a.m. EST** to review the financial results and operational highlights.

[7] All financial highlights are approximate and are rounded to the nearest hundreds of thousands.
[8] Promotional activities initiated mid-2017.
[9] Including cash and short-term investments (bank deposits and financial assets at fair value).

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: 3459887.**

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.

Availability of RedHill's Annual Report on Form 20-F Through its Website

RedHill's Annual Report on Form 20-F, containing audited financial statements for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on February 26, 2019, is available on its website (http://www.redhillbio.com). Shareholders may receive a hard copy of the annual report free of charge upon request.

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-stage clinical, 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; **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools; **Mytesi®** - an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy, and **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. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with two positive Phase 3 studies; (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 (formerly MESUPRON),** 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.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2018	2017
	U.S. dollars in thousands	
NET REVENUES	8,360	4,007
COST OF REVENUES	2,837	2,126
GROSS PROFIT	5,523	1,881
RESEARCH AND DEVELOPMENT EXPENSES, net	24,862	32,969
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	12,486	12,014
GENERAL AND ADMINISTRATIVE EXPENSES	7,506	8,025
OTHER EXPENSES	—	845
OPERATING LOSS	39,331	51,972
FINANCIAL INCOME	678	6,505
FINANCIAL EXPENSES	167	77
FINANCIAL INCOME, net	(511)	(6,428)
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR	38,820	45,544
LOSS PER ORDINARY SHARE (U.S. dollars)		
Basic	0.17	0.26
Diluted	0.17	0.26

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2018	2017
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	29,005	16,455
Bank deposits	8,271	13,163
Financial assets at fair value through profit or loss	15,909	16,587
Trade receivables	958	1,528
Prepaid expenses and other receivables	1,876	3,290
Inventory	769	653
	56,788	51,676
NON-CURRENT ASSETS:		
Bank deposits	140	152
Fixed assets	163	230
Intangible assets	5,320	5,285
	5,623	5,667
TOTAL ASSETS	62,411	57,343
CURRENT LIABILITIES:		
Accounts payable	3,324	4,805
Accrued expenses and other current liabilities	7,057	6,025
Payable in respect of intangible asset purchase	—	1,000
	10,381	11,830
NON-CURRENT LIABILITIES:		
Derivative financial instruments	344	448
Royalty obligation	500	—
	844	448
TOTAL LIABILITIES	11,225	12,278
EQUITY:		
Ordinary shares	767	575
Additional paid-in capital	219,505	177,434
Accumulated deficit	(169,086)	(132,944)
TOTAL EQUITY	51,186	45,065
TOTAL LIABILITIES AND EQUITY	62,411	57,343

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2018	**2017**	**2016**
	U.S. dollars in thousands		
OPERATING ACTIVITIES:			
Comprehensive loss	(38,820)	(45,544)	(29,370)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	2,678	2,235	1,679
Depreciation	90	81	44
Write-off of intangible assets	—	845	—
Fair value adjustments on derivative financial instruments	(104)	(5,687)	(1,152)
Fair value losses (gains) on financial assets at fair value through profit or loss	137	127	(67)
Revaluation of bank deposits	35	(123)	(274)
Issuance costs in respect of warrants	—	—	368
Exchange differences in respect of cash and cash equivalents	103	(367)	(39)
	2,939	(2,889)	559
Changes in assets and liability items:			
Decrease (increase) in trade receivables	570	(1,429)	99
Decrease (increase) in prepaid expenses and other receivables	1,414	(1,728)	612
Decrease (increase) in inventory	(116)	(653)	—
Increase (decrease) in accounts payable	(1,481)	4,745	(60)
Increase (decrease) in accrued expenses and other current liabilities	1,032	2,729	(98)
	1,419	3,664	553
Net cash used in operating activities	**(34,462)**	**(44,769)**	**(28,258)**
INVESTING ACTIVITIES:			
Purchase of fixed assets	(23)	(146)	(85)
Purchase of intangible assets	(35)	(1,035)	(35)
Change in investment in current bank deposits	4,869	(13,000)	36,838
Purchase of financial assets at fair value through profit or loss	(6,976)	(21,923)	(12,246)
Proceeds from sale of financial assets at fair value through profit or loss	7,517	17,522	—
Net cash provided by (used in) investing activities	**5,352**	**(18,582)**	**24,472**
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, net of expenses	41,902	22,216	35,754
Exercise of warrants and options into ordinary shares, net of expenses	361	3,437	263
Repayment of payable in respect of intangible asset purchase	(500)	—	—
Net cash provided by financing activities	**41,763**	**25,653**	**36,017**
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,653	(37,698)	32,231
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(103)	367	39
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	16,455	53,786	21,516
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	29,005	16,455	53,786
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	728	469	408