Press Release

RedHill Biopharma Reports Third Quarter 2018 Financial Results and Business Highlights

Key Highlights:

- **Top-line results from the confirmatory Phase III study with TALICIA® for *H. pylori* infection are on track to be announced by year-end 2018, with potential NDA filing in early 2019**
- **Positive top-line results from the 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 $43 million in cash as of September 30, 2018**
- **Net revenues of $2.2 million and gross profit of $1.6 million for Q3/2018, compared to $1.5 million and $0.6 million for Q3/2017**
- **Management to host conference call today, November 13th at 8:30 a.m. EST**

TEL-AVIV, Israel and RALEIGH, N.C., USA, November 13, 2018 -- RedHill Biopharma 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 and business highlights for the quarter ended September 30, 2018.

Micha Ben Chorin, RedHill's CFO, said: "Our cash burn continued to steadily decline in the third quarter of 2018. We are approaching the TALICIA® confirmatory Phase III study read-out, expected by year-end 2018, with a solid and debt-free balance sheet of $43 million, allowing us to execute our plans for the next year. Subject to a successful outcome of the

TALICIA® study, we remain on track to file a U.S. NDA in early 2019, with Fast-Track designation. We also continue to strengthen our U.S. commercial operations ahead of the potential commercial launch of TALICIA® in the second half of 2019. Following our announcement of positive top-line results from the Phase III study with RHB-104 for Crohn's disease, we continue to analyze the robust data from the successful study and are holding discussions with KOLs towards the planned FDA meeting and in support of pharma partnership discussions."

Financial highlights for the quarter ended September 30, 2018[1]:

Net Revenues for the third quarter of 2018 were $2.2 million, an increase of 47% from the third quarter of 2017. The growth was attributable to an increase in promotional activities.

Gross Profit for the third quarter of 2018 was $1.6 million, compared to $0.6 million from the third quarter of 2017. Gross margin increased from 39% to 73%.

Research and Development Expenses for the third quarter of 2018 were $6.6 million, a decrease of 18% from the third quarter of 2017. The decrease was mainly due to the finalization of the Phase III study with RHB-104 and completion of the clinical studies with BEKINDA® (RHB-102)[2].

Selling, Marketing and Business Development Expenses for the third quarter of 2018 were $3.0 million, a decrease of 28% from the third quarter of 2017. The decrease was mainly due to the cost cutting plan in place, including a decrease in marketing expenses related to the Company's U.S. commercial operations.

General and Administrative Expenses for the third quarter of 2018 were $1.7 million, a decrease of 26% from the third quarter of 2017, reflecting the continued implementation of the Company's cost reduction plan and optimization measures.

Operating Loss for the third quarter of 2018 was $9.7 million, a decrease of 31% from the third quarter of 2017 due to the increase in gross margin and to a decrease in operating expenses.

Net Cash Used in Operating Activities for the third quarter of 2018 was $8.4 million, a decrease of 21% from the third quarter of 2017. The decrease was due to the decrease in Operating Loss, as described above.

Net Cash Provided by Financing Activities for the third quarter of 2018 was $23.6 million, an increase of $23.5 million resulting from an underwritten offering closed in August 2018.

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

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

Cash Balance[3] as of September 30, 2018 was $43.0 million, an increase of $15.1 million compared to June 30, 2018. The increase was due to the underwritten offering, offset by Net Cash Used in Operating Activities, as described above.

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 the treatment of Crohn's disease (MAP US study). The study successfully met both its primary endpoint and key secondary endpoints.

The top-line results from the MAP US study demonstrate 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= 0.007). 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.

On October 22, 2018, RedHill presented in an oral presentation, additional positive data from the MAP US study as a late-breaking abstract at the United European Gastroenterology Week (UEG Week 2018). The presentation highlighted data from the MAP US Phase III study with RHB-104, including subgroup analysis of treatment with and without anti-TNF agents and enhanced p-values for previously reported outcomes, including the primary endpoint.

The presentation included new positive week 26 remission data demonstrating consistent treatment effects and meaningful clinical benefits, strongly favoring RHB-104 as compared to placebo in subgroups of patients receiving baseline standard-of-care (SoC) therapies, including immunomodulators (39% vs. 20%), corticosteroids (36% vs. 20%) and anti-TNF agents (36% vs. 17%). Additionally, in a small subset of patients in whom endoscopy was performed, the study also showed statistical significant improvement in endoscopic healing at week 26 (36% vs. 10%, p=0.048) (total patients analyzed=35). This data confirms the broad benefit of RHB-104 as an add-on therapy to SoC in Crohn's disease. RedHill continues to assess additional data as it becomes available.

The Company continues to meet with key opinion leaders and will meet with the U.S. Food and Drug Administration (FDA) to present the data package and discuss the development path to potential FDA approval and continues discussions with potential pharma partners for RHB-104.

RedHill announced in July and August 2018 that it had received two Notices of Allowance from the United States Patent and Trademark Office (USPTO) and an Intention to Grant from

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

the European Patent Office (EPO) for two new patents covering RHB-104, expected to provide coverage until at least 2029, once granted.

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

On October 24, 2018, RedHill announced that the last patient was assessed for primary endpoint in the confirmatory Phase III study with TALICIA® (RHB-105) for the treatment of *H. pylori* infection (ERADICATE Hp2 study). The study is 90% powered to detect a 13% treatment effect (active arm 83% vs. control arm 70%). Top-line results from the ERADICATE Hp2 study are expected to be announced by year-end 2018.

Subject to a successful outcome and additional regulatory feedback, RedHill plans to file a U.S. New Drug Application (NDA) for TALICIA® in early 2019, with an expected six-month priority review period.

On October 30, 2018, RedHill held an analyst and investor webcast on TALICIA® for *H. pylori* infection. Members of RedHill's executive team were joined by the study's lead investigator and key opinion leader, Professor David Y. Graham, M.D., M.A.C.G., and discussed TALICIA®, the ERADICATE Hp2 study, *H. pylori* infection, the current treatment landscape and potential market. A question and answer session was held following the presentations.

The webcast, including a slide presentation, is available for replay on the Company's website, http://ir.redhillbio.com/events.

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

RedHill announced in August 2018 that it had received a Notice of Allowance from the USPTO for a new formulation patent covering RHB-204 for NTM infections, expected to provide coverage until at least 2029, once granted.

BEKINDA® (RHB-102) - gastroenteritis and gastritis (positive first Phase III study)

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

BEKINDA® (RHB-102) - IBS-D (positive Phase II study)

On September 12, 2018, RedHill announced that it recently concluded a positive end-of-Phase II/pre-Phase III (Type B) meeting with the FDA discussing the clinical and regulatory pathway towards potential U.S. approval of BEKINDA® for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D).

YELIVA® (opaganib, ABC294640) - cholangiocarcinoma (Phase IIa study ongoing) (Orphan Drug designation)

On September 6, 2018, RedHill announced that the ongoing single-arm Phase IIa study with orally-administered YELIVA® (opaganib, ABC294640) for the treatment of advanced cholangiocarcinoma (bile duct cancer) achieved its pre-specified efficacy goal for the first stage of the two-stage study design. As a result, the study is advancing to its second stage, enrolling the full cohort of 39 evaluable patients. Enrollment of all subjects is expected to be completed by mid-2019.

Additionally, a patient in the U.S. with advanced gallbladder carcinoma, a condition closely related to cholangiocarcinoma, who had progressed following SoC chemotherapy, received treatment with YELIVA® as part of RedHill's Expanded Access Program, which allows compassionate use for eligible patients. The patient achieved a confirmed complete response, as measured by RECIST criteria (i.e. disappearance of all target lesions and all non-target lesions).

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, once granted.

U.S. Commercial Highlights:

On July 25, 2018, RedHill announced that it had initiated the promotion of its fourth product, Mytesi®, 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). RedHill previously 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)[4] in the U.S. to certain gastroenterologists and primary care physicians for the approved indication in people living with HIV/AIDS. Mytesi® is the fourth product

[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.

being promoted by RedHill's gastrointestinal-focused U.S. sales force, in preparation for the potential U.S. commercial launch of RedHill's late clinical-stage products.

Conference Call and Webcast Information:

The Company will host a conference call **today, Tuesday, November 13, 2018 at 8:30 a.m. EST** 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: +1-866-575-6539; International: +1-929-477-0402; and Israel: +972-3-376-1315. The access code for the call is: 2166581.**

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. (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.

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 risk that top-line results of the confirmatory Phase III study with TALICIA® for H. pylori infection will be later than expected and the risk that the potential filing of a U.S. NDA for TALICIA® and potential FDA approval of TALICIA® will be later than expected or will not occur at all and other 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® 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.

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	U.S. dollars in thousands			
NET REVENUES	2,206	1,523	7,001	2,006
COST OF REVENUES	598	935	2,253	1,207
GROSS PROFIT	1,608	588	4,748	799
RESEARCH AND DEVELOPMENT EXPENSES, net	6,624	8,106	19,084	24,677
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,040	4,189	9,333	8,170
GENERAL AND ADMINISTRATIVE EXPENSES	1,680	2,258	5,619	5,513
OTHER EXPENSES	—	—	—	45
OPERATING LOSS	9,736	13,965	29,288	37,606
FINANCIAL INCOME	133	150	364	2,541
FINANCIAL EXPENSES	480	1,697	2,212	66
FINANCIAL INCOME (EXPENSES), net	(347)	(1,547)	(1,848)	2,475
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	10,083	15,512	31,136	35,131
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.04	0.09	0.14	0.21
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	234,960	171,678	220,560	170,990

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	September 30, 2018	December 31, 2017
	Unaudited	Audited
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	18,684	16,455
Bank deposits	8,221	13,163
Financial assets at fair value through profit or loss	16,121	16,587
Trade receivables	1,920	1,528
Prepaid expenses and other receivables	2,350	3,290
Inventory	469	653
	47,765	51,676
NON-CURRENT ASSETS:		
Bank deposits	145	152
Fixed assets	181	230
Intangible assets	5,285	5,285
	5,611	5,667
TOTAL ASSETS	53,376	57,343
CURRENT LIABILITIES:		
Accounts payable	3,867	4,805
Accrued expenses and other current liabilities	6,630	6,025
Payable in respect of intangible asset purchase	500	1,000
	10,997	11,830
NON-CURRENT LIABILITIES:		
Derivative financial instruments	2,536	448
TOTAL LIABILITIES	13,533	12,278
EQUITY:		
Ordinary shares	690	575
Additional paid-in capital	201,226	177,434
Accumulated deficit	(162,073)	(132,944)
TOTAL EQUITY	39,843	45,065
TOTAL LIABILITIES AND EQUITY	53,376	57,343

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
	U.S. dollars in thousands			
OPERATING ACTIVITIES:				
Comprehensive loss	(10,083)	(15,512)	(31,136)	(35,131)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	468	640	2,007	1,652
Depreciation	22	26	67	58
Write-off of intangible assets	—	—	—	45
Fair value adjustments on derivative financial instruments	471	1,685	2,088	(1,828)
Fair value losses (gains) on financial assets at fair value through profit or loss	28	(12)	140	67
Revaluation of bank deposits	3	(3)	80	(108)
Exchange differences in respect of cash and cash equivalents	21	46	87	(315)
	1,013	2,382	4,469	(429)
Changes in assets and liability items:				
Increase in trade receivables	(124)	(621)	(392)	(1,300)
Decrease (increase) in prepaid expenses and other receivables	(519)	336	940	(1,198)
Decrease (increase) in inventory	221	389	184	(221)
Increase (decrease) in accounts payable	(156)	737	(938)	1,822
Increase in accrued expenses and other current liabilities	1,276	1,734	605	5,853
	698	2,575	399	4,956
Net cash used in operating activities	**(8,372)**	**(10,555)**	**(26,268)**	**(30,604)**
INVESTING ACTIVITIES:				
Purchase of fixed assets	(3)	(41)	(18)	(143)
Purchase of intangible assets	—	(1,035)	(500)	(1,035)
Change in investment in current bank deposits	—	7,284	4,869	(7,976)
Purchase of financial assets at fair value through profit or loss	(3,987)	(978)	(5,075)	(14,931)
Proceeds from sale of financial assets at fair value through profit or loss	1,951	8,685	5,401	14,532
Net cash provided by (used in) investing activities	**(2,039)**	**13,915**	**4,677**	**(9,553)**
FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares, net of expenses	23,552	—	23,552	1,282
Exercise of warrants and options into ordinary shares, net of expenses	—	30	355	3,437
Net cash provided by financing activities	**23,552**	**30**	**23,907**	**4,719**
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	13,141	3,390	2,316	(35,438)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(21)	(46)	(87)	315
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	5,564	15,319	16,455	53,786
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	18,684	18,663	18,684	18,663
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	156	153	571	354