Press Release

RedHill Biopharma Reports 2016 Third Quarter Financial Results

- **RedHill maintains a debt-free balance sheet with $40.5 million in cash at the end of the third quarter, allowing the Company to continue to diligently execute its three ongoing Phase III gastrointestinal disease programs and other clinical-stage programs**

- **Recent key milestones include:**

    - **Enhancement of the RHB-104 Phase III Crohn's disease program, including the introduction of an option for early stop for success for overwhelming efficacy, expected in Q2/2017**
    - **Initiation of Phase II studies with YELIVA™ for multiple myeloma and hepatocellular carcinoma**
    - **Signing of an exclusive license agreement with Grupo JUSTE for the commercialization in Spain of RIZAPORT® oral thin-film migraine drug and filing of a national Marketing Authorization Application in Spain by Grupo JUSTE**
    - **Signing of a binding term sheet with Pharmatronic Co. for the commercialization of RIZAPORT® in South Korea**

- **Potential milestones expected in the coming year include:**

    - **Q4/2016 - Safety-focused independent data and safety monitoring board (DSMB) meeting for the MAP US Phase III study with RHB-104 for Crohn's disease**
    - **Q4/2016 - Top-line final results from the ongoing Phase IIa CEASE-MS study with RHB-104 for multiple sclerosis**
    - **Q2/2017 - Independent DSMB evaluation of the MAP US Phase III study with RHB-104 for Crohn's disease, including option for early stop for success for overwhelming efficacy**
    - **H1/2017 - Initiation of a confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection**

- **Mid-2017 - Top-line results from the ongoing Phase III study with BEKINDA® for gastroenteritis and gastritis in the U.S. (the GUARD study)**
- **Mid-2017 - Top-line results from the ongoing Phase II study with BEKINDA® for diarrhea-predominant irritable bowel syndrome (IBS-D) in the U.S.**
- **H1/ 2017 - Re-submission of the RIZAPORT® U.S. NDA to the FDA**

TEL-AVIV, Israel, November 14, 2016 RedHill Biopharma Ltd. (NASDAQ: RDHL) (TASE: RDHL) ("RedHill" or the "Company"), a biopharmaceutical company primarily focused on development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today reported its financial results for the quarter ended September 30, 2016.

The Company will host a conference call on **Monday, November 14, 2016, at 9:00 am EST** to review the financial results and business highlights, dial-in details are included below.

Financial highlights for the quarter ended September 30, 2016[1]

Research and Development Expenses for the third quarter of 2016 were $7.0 million, an increase of $3.1 million, compared to $3.9 million in the third quarter of 2015 and an increase of $1.0 million, compared to $6.0 million in the second quarter of 2016. Research and Development Expenses for the nine months ended September 30, 2016 were $17.7 million, an increase of $4.9 million, compared to $12.8 million in the comparable period of 2015. The increase in 2016 resulted primarily from the ongoing Phase III MAP US study with RHB-104 (Crohn's disease), the ongoing Phase II and Phase III studies with BEKINDA® (IBS-D and gastroenteritis, respectively) and from preparations for several Phase I/II studies with YELIVA™ for multiple indications.

General, Administrative and Business Development Expenses in the third quarter of 2016 were $1.4 million, an increase of $0.7 million, compared to $0.7 million in the third quarter of 2015 and an increase of $0.2 million, compared to $1.2 million in the second quarter of 2016. General, Administrative and Business Development Expenses for the nine months ended September 30, 2016 were $3.8 million, an increase of $1.4 million, compared to $2.4 million in the comparable period of 2015. The increase was mainly due to enhanced business development and investor relations activities.

Operating Loss in the third quarter of 2016 was $8.5 million, an increase of $3.9 million, compared to $4.6 million in the third quarter of 2015 and an increase of $1.3 million, compared to $7.2 million in the second quarter of 2016. Operating Loss for the nine months ended September 30, 2016 were $21.6 million, an increase of $6.4 million, compared to $15.2 million in the comparable period of 2015. The increase was mainly due to increases in Research and Development Expenses, as detailed above.

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

Net Cash Used in Operating Activities in the third quarter of 2016 was $7.4 million, an increase of $3.7 million, compared to $3.7 million in the third quarter of 2015 and an increase of $1.7 million, compared to $5.7 million in the second quarter of 2016. Net Cash Used in Operating Activities for the nine months ended September 30, 2016 was $18.1 million, an increase of $6.3 million, compared to $11.8 million in the comparable period of 2015. The increase mainly reflects the increase in Operating Loss, as detailed above.

Net Cash Used in Investment Activities in the third quarter of 2016 was $10.7 million, compared to Net Cash Used in Investment Activities of $2.4 million in the third quarter of 2015. Net Cash Used in Investment Activities for the nine months ended September 30, 2016 was $3.2 million, an increase of $4.3 million, compared to Net Cash Provided by Investment Activities of $1.1 million in the comparable period of 2015. The increase in Net Cash Used in Investment Activities was due to an increase in bank deposits and marketable securities in 2016.

Cash Balance[2] as of September 30, 2016 was $40.5 million, a decrease of $17.6 million, compared to $58.1 million as of December 31, 2015. The decrease was a result of the ongoing operations, mainly related to research and development activities.

"We are very pleased with the important operational milestones achieved during this quarter, including the significant enhancements to the RHB-104 Phase III development program for Crohn's disease and the initiation of several clinical studies with our novel Phase II oncology drug YELIVA™," **said Mr. Micha Ben Chorin, RedHill's CFO**. "We maintained a debt-free balance sheet and a cash position of $40.5 million at the end of the third quarter of 2016 as we continue to advance several Phase III and Phase II gastrointestinal programs toward important data points in the coming months. We also continue to advance our strategic plan to build a U.S. specialty GI pharmaceutical company."

Conference Call and Webcast Information:

The Company will host a conference call on Monday**, November 14, 2016, at 9:00 am EST** to review the financial results and business highlights.

To participate in the conference call, please dial the following numbers 5-10 minutes prior to the start of the call: **United States: +1-877-280-2342; International: +1-646-254-3367; and Israel: +972-3-721-9510. The access code for the call is 2341628.**

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

Recent operational highlights:

[2] Including cash and short-term investments

1. On July 5, 2016, RedHill and its co-development partner, IntelGenx Corp. (IntelGenx), announced the signing of an exclusive license agreement with Grupo JUSTE S.A.Q.F (Grupo JUSTE), for the commercialization of RIZAPORT® oral thin-film for acute migraines. Under the terms of the agreement, RedHill granted Grupo JUSTE the exclusive rights to register and commercialize RIZAPORT® in Spain and a right of first refusal for a predefined term for additional territories. RedHill and IntelGenx received an upfront payment and are entitled to receive additional milestone payments upon the achievement of certain predefined regulatory and commercial targets, as well as tiered royalties. Further financial terms of the agreement were not disclosed. Grupo JUSTE recently filed a national Marketing Authorization Application for RIZAPORT® in Spain and commercial launch in Spain is expected to take place in the second half of 2017.

2. On July 13, 2016, RedHill announced the signing of a research collaboration agreement with the U.S. National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), intended to evaluate RedHill's proprietary experimental therapy for the treatment of Ebola virus disease. The new research collaboration follows encouraging results from preliminary non-clinical studies conducted in conjunction with the NIAID using RedHill's proprietary experimental therapy. If successful, this study is intended to provide supportive data for discussions with the FDA for potential use of the Animal Rule pathway for approval. Ebola virus disease is a severe and often fatal illness, which can cause severe hemorrhagic fever in humans and has a mortality rate ranging from 25% to 90%[3]. There is currently no FDA-approved treatment for Ebola virus disease.

3. On July 21, 2016, RedHill announced that it had received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a new patent covering RHB-105. The patent application, entitled *"Pharmaceutical Compositions For The Treatment Of Helicobacter Pylori"* expands RedHill's patent portfolio covering RHB-105 and is expected to be valid until 2034, once granted.

4. On August 1, 2016, RedHill announced that the last patient completed the final scheduled follow-up visit in the Phase IIa proof-of-concept clinical study evaluating RHB-104 in patients treated for relapsing-remitting multiple sclerosis (the CEASE-MS study). The analysis of the study is ongoing, with top-line final results expected in Q4/2016. Previously announced interim results after completion of the 24-week RHB-104 treatment period of the study demonstrated positive safety and efficacy signals and support further clinical development.

5. On August 29, 2016, RedHill announced that it had received from the European Patent Office a Notice of Intention to Grant for a new patent covering the use of RHB-104 in the treatment of multiple sclerosis. Upon grant by the European Patent Office, the patent is expected to be valid until 2032 and can be officially validated in up to 38 European countries.

[3] World Health Organization (WHO), Fact sheet No° 103, January 2016.

6. On September 8, 2016, RedHill announced that a Phase Ib/II clinical study evaluating YELIVA™ in patients with refractory or relapsed multiple myeloma was initiated. The open-label, dose escalation Phase Ib/II study is being conducted at Duke University Medical Center and will enroll up to 77 patients with refractory or relapsed multiple myeloma who have previously been treated with proteasome inhibitors and immunomodulatory drugs. The study is supported by a $2 million grant from the National Cancer Institute Small Business Innovation Research Program awarded to Apogee Biotechnology Corp., in conjunction with Duke University, with additional support from RedHill.

7. On September 12, 2016, RedHill announced a research collaboration with Stanford University School of Medicine for the evaluation of YELIVA™. The research collaboration is intended to complement RedHill's planned Phase Ib clinical study to evaluate YELIVA™ as a radioprotectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy. Results from the research collaboration are expected in mid-2017.

8. On September 21, 2016, RedHill and IntelGenx, announced that they had entered into a binding term sheet with Pharmatronic Co., granting Pharmatronic Co. the exclusive license to commercialize RIZAPORT® in the Republic of Korea (South Korea). Under the term sheet, RedHill and IntelGenx are to receive an upfront payment and will be eligible to receive additional milestone payments upon achievement of certain predefined regulatory and commercial targets, as well as tiered royalties. Subject to the satisfaction of the remaining conditions, the parties will endeavor to enter into a definitive agreement within 60 days of the execution of the term sheet. Further financial terms of the term sheet were not disclosed.

9. On October 5, 2016, RedHill announced that a Phase II clinical study evaluating YELIVA™ in patients with advanced hepatocellular carcinoma (HCC) was initiated at the Hollings Cancer Center at the Medical University of South Carolina (MUSC), subject to IND clearance by the FDA. The study is supported by a grant from the U.S. National Cancer Institute (NCI) awarded to MUSC, with additional support from RedHill. The HCC study protocol is still under FDA review. Enrolment in the study is expected to begin following successful completion of the FDA's review process, anticipated by end of 2016.

10. On October 6, 2016, RedHill provided an update on the RHB-104 Phase III Crohn's disease development program, planned enhancements to the MAP US first Phase III study and expected milestones, including:

    - An increase in the total number of patients planned to be enrolled in the study from 270 to 410 and the addition of an open-label extension study offering all patients who complete 26 weeks of study participation and remain out of

remission (Crohn's disease active index (CDAI) >150) the opportunity to receive treatment with RHB-104 for a 52-week period.

- A first safety-focused independent DSMB meeting is on track to take place in the fourth quarter of 2016. A second independent DSMB meeting is expected in the second quarter of 2017 and will include safety and interim efficacy analysis, with evaluation of an early stop for success for overwhelming efficacy, under pre-specified efficacy criteria.

- Two small-scale, open-label ex-U.S. clinical studies with RHB-104, each with up to 20 Crohn's disease patients, are planned to be initiated and are intended to provide additional supportive clinical data to potential future marketing applications, as well as to evaluate RHB-104's efficacy in newly diagnosed and treatment-naïve Crohn's disease patients, and as an add-on therapy to current standard-of-care.

- RedHill will remain blinded to the interim and ongoing results from the Phase III study and no changes are planned to the MAP US Phase III study's primary endpoint or 90% power.

- Assuming enrollment of all 410 planned subjects, completion of patient recruitment in the MAP US Phase III study is expected by the end of 2017.

11. On October 18, 2016, RedHill announced that it had received from the Japan Patent Office a Notice of Allowance for a new patent covering RHB-104 for the treatment of multiple sclerosis, which is expected to be valid until 2032, once granted.

12. On November 1, 2016, RedHill announced that it had intended to offer its American Depositary Shares (ADSs), each representing 10 of its ordinary shares, in an underwritten public offering. RedHill subsequently announced, on November 2, 2016, that it had withdrawn the proposed underwritten public offering of its ADSs due to market conditions.

13. On November 1, 2016, RedHill announced that it had entered into a non-binding term sheet with a pharmaceutical company as part of its potential strategic vertical integration plan to build a U.S. specialty pharmaceutical company by establishing a commercial presence and capabilities. Under the term sheet, RedHill would be granted the right to exclusively promote a specialty gastrointestinal product in certain territories in the U.S. The parties would share revenues generated in such territories based on an agreeable split between the parties. RedHill is not required to make any upfront or milestone payments under the term sheet. Although RedHill's goal is to complete the transaction pertaining to the commercial asset in the fourth quarter of 2016, the term sheet is non-binding and there is no certainty as to the execution nor timing of execution of a definitive agreement between RedHill and its potential

partner. There is no assurance that satisfactory due diligence will be completed or that the parties will obtain all necessary corporate approvals.

14. On November 3, 2016, RedHill announced that top-line results from both the ongoing Phase III clinical study with BEKINDA® 24 mg for acute gastroenteritis and gastritis (the GUARD study) and the ongoing Phase II clinical study with BEKINDA® 12 mg for diarrhea-predominant irritable bowel syndrome (IBS-D) are expected in mid-2017. Over two-thirds of the planned total of 320 subjects have been enrolled in the Phase III GUARD study with BEKINDA® 24 mg for acute gastroenteritis and gastritis in the U.S. Approximately half of the planned total of 120 subjects have been enrolled in the Phase II clinical study with BEKINDA® 12 mg for the treatment of IBS-D in the U.S.

15. On November 10, 2016, RedHill announced that it has concluded a positive Type B Meeting with the U.S. Food and Drug Administration (FDA) discussing the chemistry, manufacturing and controls (CMC) aspects of the RHB-105 Phase III development program. The confirmatory Phase III study with RHB-105 for *H. pylori* infection is planned to be initiated in H1/2017, after completion of the ongoing supportive PK program. Subject to a successful outcome, the confirmatory Phase III study and the supportive PK program are expected to complete the package required for a U.S. NDA for RHB-105, including clinical data and CMC.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is a biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. RedHill's pipeline of proprietary products includes: (i) **RHB-105 -** an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study; (ii) **RHB-104 -** an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study and an ongoing proof-of-concept Phase IIa study for multiple sclerosis; (iii) **BEKINDA® (RHB-102) -** a once-daily oral pill formulation of ondansetron with an ongoing Phase III study for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON -** a Phase II-stage first-in-class, orally-administered uPA inhibitor, targeting gastrointestinal and other solid tumors and (vii) **RIZAPORT® (RHB-103) -** an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in Germany in October 2015.

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 establish and maintain corporate collaborations; (vi) 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; (vii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) 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; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xii) competitive companies and technologies within the Company's industry; and (xiii) the impact of the political and security situation in Israel on the Company's business. 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 25, 2016. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.

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REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
	U.S. dollars in thousands			
REVENUES	—	1	1	3
RESEARCH AND DEVELOPMENT EXPENSES, net	7,038	3,901	17,745	12,820
GENERAL, ADMINISTRATIVE AND BUSINESS DEVELOPMENT EXPENSES	1,416	692	3,807	2,420
OPERATING LOSS	8,454	4,592	21,551	15,237
FINANCIAL INCOME	109	1,420	548	889
FINANCIAL EXPENSES	599	120	17	182
FINANCIAL EXPENSES (INCOME), net	490	(1,300)	(531)	(707)
LOSS AND COMPREHENSIVE LOSS	8,944	3,292	21,020	14,530
LOSS PER ORDINARY SHARE (U.S. dollars):				
Basic	0.07	0.03	0.17	0.14
Diluted	0.07	0.04	0.17	0.14

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

	September 30, 2016	December 31, 2015
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	6,772	21,516
Bank deposits	22,203	36,622
Financial assets at fair value through profit or loss	11,528	—
Prepaid expenses and receivables	2,030	2,372
	42,533	60,510
NON-CURRENT ASSETS:		
Bank deposits	140	134
Fixed assets	147	124
Intangible assets	6,060	6,060
	6,347	6,318
TOTAL ASSETS	48,880	66,828
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	5,288	3,514
Payable in respect of intangible asset purchase	2,000	2,000
	7,288	5,514
NON-CURRENT LIABILITIES:		
Derivative financial instruments	1,107	1,237
TOTAL LIABILITIES	8,395	6,751
EQUITY:		
Ordinary shares	344	343
Additional paid-in capital	120,730	120,621
Warrants	1,057	1,057
Accumulated deficit	(81,646)	(61,944)
TOTAL EQUITY	40,485	60,077
TOTAL LIABILITIES AND EQUITY	48,880	66,828

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	U.S. dollars in thousands			
OPERATING ACTIVITIES:				
Comprehensive loss	(8,944)	(3,292)	(21,020)	(14,530)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	449	339	1,318	955
Depreciation	11	9	32	26
Unrealized losses (gains) on derivative financial instruments	585	(1,343)	(130)	(722)
Fair value gains on financial assets at fair value through profit or loss	(10)	—	(72)	—
Revaluation of bank deposits	(108)	(16)	(255)	(6)
Exchange differences in respect of cash and cash equivalents	(36)	83	(77)	136
	891	(928)	816	389
Changes in assets and liability items:				
Decrease in prepaid expenses and receivables	150	341	342	1,843
Increase in accounts payable and accrued expenses	533	133	1,774	500
	683	474	2,116	2,343
Net cash used in operating activities	(7,370)	(3,746)	(18,088)	(11,798)
INVESTING ACTIVITIES:				
Purchase of fixed assets	(10)	(6)	(55)	(13)
Purchase of intangible assets	—	(45)	—	(1,620)
Change in investment in current bank deposits	14,668	(7,500)	14,668	(9,500)
Maturity of non-current bank deposits	—	10,000	—	10,000
Purchase of financial assets at fair value through profit or loss	(3,976)	—	(11,456)	—
Net cash provided by (used in) investing activities	10,682	2,449	3,157	(1,133)
FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares, net of expenses	—	41,486	—	54,684
Exercise of options into ordinary shares, net	—	38	110	74
Net cash provided by financing activities	—	41,524	110	54,758
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,312	40,227	(14,821)	41,827
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	36	(83)	77	(136)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	3,424	7,439	21,516	5,892
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	6,772	47,583	6,772	47,583
Supplementary information on interest received in cash	133	87	185	167
Supplementary information on investing activities not involving cash flows - Purchase of intangible assets	—	—	—	2,000