Press Release

RedHill Biopharma Reports 2016 First Quarter Financial Results

- **RedHill maintains a strong and debt-free balance sheet with approximately $53 million in cash at the end of the first quarter, allowing the Company to continue to diligently execute its strategic and operational plans, including its three ongoing Phase III gastrointestinal disease programs in the U.S.**

- **Key milestones in the first quarter of 2016 include:**

  - **Initiation of a Phase II study with BEKINDA™ for diarrhea-predominant irritable bowel syndrome (IBS-D)**
  - **Receipt of encouraging top-line interim results from a Phase IIa study with RHB-104 for multiple sclerosis**
  - **Receipt of final results from the successful first Phase III study with RHB-105 for treatment of *H. pylori* infection**
  - **A binding commercialization term-sheet for RIZAPORT™ for migraines in Spain**

- **Upcoming milestones expected in the second half of 2016 include:**

  - **Initiation of a confirmatory Phase III study with RHB-105 for treatment of *H. pylori* infection following a positive meeting with the FDA, announced earlier this week**
  - **Top-line results from the ongoing Phase III study with BEKINDA™ for gastroenteritis**
  - **Interim DSMB analysis of the RHB-104 ongoing Phase III study for Crohn's disease**

TEL-AVIV, Israel, April 20, 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 inflammatory and gastrointestinal diseases, including cancer, today reported its financial results for the quarter ended March 31, 2016.

Financial highlights for the quarter ended March 31, 2016:

Research and Development Expenses in the first quarter of 2016 were approximately $4.7 million, an increase of approximately $0.9 million, compared to approximately $3.8 million in the first quarter of 2015. The increase resulted primarily from clinical trial costs related to the ongoing Phase III MAP US clinical study with RHB-104 (Crohn's disease) and the preparations for several Phase II studies with YELIVA™ for multiple oncology, inflammatory and gastrointestinal indications.

General and Administrative Expenses in the first quarter of 2016 were approximately $1.2 million, an increase of approximately $0.3 million, compared to approximately $0.9 million in the first quarter of 2015. The increase was mainly due to professional fees associated with business development activities, intellectual property costs and share-based compensation costs.

Operating Loss in the first quarter of 2016 was approximately $5.9 million, an increase of approximately $1.1 million, compared to approximately $4.8 million in the first quarter of 2015. The increase was mainly in Research and Development Expenses and General and Administrative Expenses.

Net Cash Used in Operating Activities in the first quarter of 2016 was approximately $5.0 million, an increase of approximately $1.6 million, compared to approximately $3.4 million in the first quarter of 2015. The increase was mainly a result of an increase in research and development activities.

Net Cash Used in Investment Activities in the first quarter of 2016 was approximately $4.6 million, a decrease of approximately $2.5 million, compared to approximately $7.1 million in the first quarter of 2015. The decrease was mainly in bank deposit investments.

Cash Provided by Financing Activities in the first quarter of 2016 was immaterial, compared to approximately $13.2 million in the first quarter of 2015, resulting from a public offering in February 2015 in the U.S.

Cash Balance[1] as of March 31, 2016 was approximately $53.4 million, a decrease of approximately $5 million, compared to approximately $58.4 million as of December 31, 2015. The decrease was a result of the ongoing operations, mainly related to research and development activities.

Micha Ben Chorin, RedHill's CFO, said: "We made significant progress with our advanced clinical programs during the first quarter of 2016 and are excited about the potential milestones

[1] Including cash, bank deposits and short-term investments.

expected during the second half of 2016, including the interim DSMB analysis of the RHB-104 Phase III MAP US study for Crohn's disease, top-line results from the BEKINDA™ Phase III GUARD study for gastroenteritis and the initiation of a confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection. With a strong cash position of approximately $53 million at the end of the first quarter, we are well-positioned to execute our strategic and operational plans for 2016."

Conference Call and Webcast Information:

The Company will host a conference call on Wednesday, April 20, 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 five to ten minutes prior to the start of the call: **United States: +1-877-280-1254; International: +1-212-444-0481; and Israel: +972-3-763-0147. The access code for the call is 8920444.**

The conference call will be broadcasted simultaneously 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:

1. On February 8, 2016, RedHill announced a research collaboration with Leipzig-based Fraunhofer Institute for Cell Therapy and Immunology (IZI), a research unit of the Fraunhofer Society, one of the largest and most prominent applied research organizations in the world, for the evaluation of RedHill's Phase II-stage oncology drug candidate, RP101. The research collaboration tests RP101 in pre-clinical oncology models, including pancreatic cancer, in combination with standard-of-care chemotherapies to support existing Phase I and Phase II clinical data. Results from the studies are expected during the second quarter of 2016.

2. On February 10, 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-104. The patent, entitled *"Compositions Comprising Rifabutin, Clarithromycin, and Clofazamine and Uses Therof"* has since been issued and is valid through 2029. RedHill currently holds five U.S. patents and multiple international patents for RHB-104.

3. On March 1, 2016, RedHill announced that it had completed enrollment of over half of the planned 270 patients in the Phase III MAP US study for Crohn's disease in the U.S. and additional countries. Interim DSMB analysis of the study is expected in the second half of 2016.

4. On March 10, 2016, RedHill announced the publication of an article evaluating the therapeutic potential of YELIVA™ (ABC294640), the Company's orally-administered first-in-class Sphingosine kinase-2 (SK2) selective inhibitor, for the treatment of cholangiocarcinoma (bile duct cancer). The article, describing non-clinical studies conducted with YELIVA™, was authored by scientists from the Mayo Clinic Cancer Center, the Hollings Cancer Center at the Medical University of South Carolina and Apogee Biotechnology Corporation. The authors

concluded that these findings provide preliminary insight into the possible use of YELIVA™ as an anticancer drug for cholangiocarcinoma treatment, as well as novel evidence that SK2 may be a rational therapeutic target in the treatment of this cancer.

5. On March 29, 2016, RedHill and its co-development partner for RIZAPORT, IntelGenx Corp., announced that they had entered into a binding term sheet with Grupo JUSTE S.A.Q.F ("Grupo JUSTE") granting Grupo JUSTE the exclusive license to commercialize RIZAPORT™ in Spain and a right of first refusal for additional territories. Under the term sheet, subject to remaining conditions, a definitive agreement is planned to be entered into within 60 days of the execution of the term sheet. Under the term sheet, RedHill and IntelGenx Corp. will 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. Commercial launch in Spain is estimated to take place in the second half of 2017. RedHill also reported that a new U.S. formulation patent covering RIZAPORT™ was issued by the USPTO on April 5, 2016. The patent is valid until 2034.

6. On March 31, 2016, RedHill announced encouraging top-line interim results from its ongoing CEASE-MS Phase IIa proof-of-concept (PoC) clinical study evaluating fixed oral dose RHB-104 in patients treated for relapsing-remitting multiple sclerosis (RRMS). The ongoing CEASE-MS, single-arm, open-label study was designed with a series of exploratory endpoints to evaluate the safety and potential efficacy of fixed oral dose RHB-104 as an add-on therapy to interferon beta-1a in 18 patients treated for RRMS. Interim results after completion of the 24-week treatment period of the study demonstrated positive safety and clinical signals and support further clinical development based on encouraging preliminary data. Additional data reads are due at week 48 following a 24-week follow-up treatment period with interferon beta-1a, without RHB-104 add-on. The top-line interim results demonstrated an annualized relapse rate (ARR) at 24 weeks of 0.288 in the modified intent-to-treat (mITT) population and 0.0 in the per-protocol (PP) population, comparing favorably with previously reported pivotal studies of interferon beta-1a therapies Avonex® (0.67)[2] and Rebif® (0.87-0.91)[3]. 88% of the mITT patient population and 100% of the PP patient population were relapse free at 24 weeks, comparing favorably with previously reported pivotal data on the use of Rebif® (75%) in comparison with Avonex® (63%) as standalone first line therapies[4]; No patients in the CEASE-MS study relapsed after week 8 of treatment. With only a single active T1 post gadolinium lesion noted among all patients followed, combined unique active lesions (CUAs) - the primary outcome measure in the study - were almost entirely MRI T2 lesions; Although not powered for efficacy, a reduction in total MRI T2 lesion volume was observed at 24 weeks as compared to baseline, suggesting a decreased burden of disease and comparing favorably with previously reported Avonex®[5] and Rebif®[6] data.

[2] Jacobs LD et al.: Ann Neurol 1996;39:285-294.

[3] 1.73 – 1.82 over 2 years; PRISMS Study Group: Lancet 1998; 352: 1498–504.

[4] EVIDENCE Trial, Panitch H et al.: Neurology 2002;59:1496–1506.

[5] Cohen J A et al.: Oral Fingolimod or Intramuscular Interferon for Relapsing Remitting Multiple Sclerosis. NEJM. 2010, 362: 402-15.

[6] Cohen J A et al.: Alemtuzumab versus Interferon Beta 1a as First-Line Treatment for Patients with Relapsing-Remitting Multiple Sclerosis: a Randomised Controlled Phase 3 Trial. The Lancet. 2012, 380: 1819-28.

7. On April 11, 2016, RedHill announced that it had initiated a randomized, double-blind, placebo-controlled, 2-arm parallel group Phase II clinical study in the U.S. evaluating the safety and efficacy of BEKINDA™ 12 mg in patients with diarrhea-predominant irritable bowel syndrome (IBS-D). The study is expected to be conducted in 12 clinical sites in the U.S. and to enroll 120 patients who will be randomized 60:40 to receive either BEKINDA™ 12 mg or a placebo, once daily, for a period of eight weeks. The primary endpoint for the study is the proportion of patients in each treatment group with response in stool consistency as compared to baseline, per FDA guidance definition. Secondary endpoints include the proportion of patients in each treatment group who are pain responders and the proportion of patients in each treatment group who are responders to the combined endpoints of stool consistency and pain, per FDA guidance definition.

8. On April 18, 2016, RedHill announced that it had concluded a positive Type B Meeting with the U.S. Food and Drug Administration (FDA) regarding the path to marketing approval of RHB-105 and the planned confirmatory Phase III study for the treatment of *H. pylori* infection. The FDA confirmed, subject to final minutes of the meeting, the planned two-arm, randomized, double-blind, active comparator design of the confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection, expected to be initiated in the second half of 2016. Based on FDA feedback, and subject to successful completion, the planned confirmatory Phase III study, along with the successfully completed first Phase III study and data from a supportive PK program, are expected to support a U.S. New Drug Application (NDA) for RHB-105. The announcement followed the successful final results from the first Phase III clinical study with RHB-105 for the eradication of *H. pylori* (the ERADICATE Hp study) reported on March 8, 2016. The Phase III Clinical Study Report (CSR) confirmed the positive top-line results. The study successfully met its primary endpoint of superiority over historical standard-of-care (SoC) eradication rate levels of 70%, with high statistical significance ($p<0.001$). The final results demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105. RHB-105 has been granted Qualifying Infectious Disease Product (QIDP) designation by the FDA, providing a Fast-Track development pathway, as well as Priority Review status, potentially leading to a shorter review time by the FDA of a NDA, if filed. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity, in addition to the standard exclusivity period, for a total of 8 years of market exclusivity.

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 inflammatory and gastrointestinal diseases, including cancer. RedHill's current 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 in the U.S. for acute gastroenteritis and gastritis and a Phase II study for IBS-D; (iv) **RHB-106 -** an encapsulated bowel

preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640) -** an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON® -** a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101 -** currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **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; and (ix) **RHB-101 -** a once-daily oral pill formulation of the cardio drug carvedilol.

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.

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended March 31	
	2016	**2015**
	U.S. dollars in thousands	
REVENUES	-	1
RESEARCH AND DEVELOPMENT EXPENSES, net	4,676	3,829
GENERAL AND ADMINISTRATIVE EXPENSES	1,227	927
OPERATING LOSS	5,903	4,755
FINANCIAL INCOME	380	286
FINANCIAL EXPENSES	1	173
FINANCIAL INCOME, net	379	113
LOSS AND COMPREHENSIVE LOSS	5,524	4,642
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.04	0.05
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES (in thousands)	127,129	93,678

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

	March 31 2016	December 31 2015
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	12,026	21,516
Bank deposits	34,674	36,622
Financial assets at fair value through profit or loss	6,580	-
Prepaid expenses and receivables	1,932	2,372
	55,212	60,510
NON-CURRENT ASSETS:		
Bank deposits	140	134
Fixed assets	143	124
Intangible assets	6,060	6,060
	6,343	6,318
TOTAL ASSETS	61,555	66,828
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	3,582	3,514
Payable in respect of intangible asset purchase	2,000	2,000
	5,582	5,514
NON-CURRENT LIABILITIES:		
Derivative financial instruments	1,036	1,237
TOTAL LIABILITIES	6,618	6,751
EQUITY:		
Ordinary shares	343	343
Additional paid-in capital	120,631	120,621
Warrants	1,057	1,057
Accumulated deficit	(67,094)	(61,944)
TOTAL EQUITY	54,937	60,077
TOTAL LIABILITIES AND EQUITY	61,555	66,828

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended March 31	
	2016	2015
	U.S. dollars in thousands	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Comprehensive loss	(5,524)	(4,642)
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	374	322
Depreciation	10	9
Unrealized gain on derivative financial instruments	(201)	(248)
Fair value gains on financial assets at fair value through profit or loss	(8)	
Revaluation of bank deposits	(58)	(4)
Exchange differences in respect of cash and cash equivalents	(82)	167
Changes in assets and liability items:		
Decrease in prepaid expenses and receivables	440	706
Increase in accounts payable and accrued expenses	68	318
	543	1,270
Net cash used in operating activities	(4,981)	(3,372)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(29)	(2)
Purchase of intangible assets	-	(75)
Purchase of financial assets at fair value through profit or loss	(6,572)	-
Change in investment in current bank deposits	2,000	(7,000)
Net cash used in investing activities	(4,601)	(7,077)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of ordinary shares, net of expenses	-	13,198
Exercise of options into ordinary shares	10	-
Net cash provided by financing activities	10	13,198
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(9,572)	2,749
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	82	(167)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	21,516	5,892
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	12,026	8,474
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	94	26
SUPPLEMENTARY INFORMATION ON INVESTING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of intangible assets	-	3,425

The accompanying notes are an integral part of these financial statements.