RedHill Biopharma Reports First Quarter 2021 Financial Results and Operational Highlights

May 27, 2021

- **Q1/2021 net revenues of approximately $20.6 million compared to $1.1 million for Q1/2020; Cash balance[i] of approximately $92 million as of March 31, 2021, compared to approximately $115 million as of March 31, 2020**
- **Talicia® prescription volume grew 11% versus previous quarter; Movantik® new prescriptions in the first quarter 4% higher than Q1/2020[ii]**
- **Opaganib global Phase 2/3 study almost 100% enrolled**
- **Management to host webcast today, at 8:30 a.m. EDT**

TEL AVIV, Israel and RALEIGH, N.C., May 27, 2021 /PRNewswire/ -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today reported its financial results and operational highlights for the first quarter ended March 31, 2021.

Dror Ben-Asher, RedHill's Chief Executive Officer, said: "The progress of our two novel, oral COVID-19 programs has put RedHill at the forefront of oral COVID-19 therapeutics development. Opaganib, one of the most advanced and promising novel, dual-mode of action, oral drug candidates in development for COVID-19, now has almost 100% enrollment in its global 464-patient Phase 2/3 study in severe COVID-19." **Mr. Ben-Asher continued**: "Commercially, a strong end to the first quarter has set up 2021 for growth, reversing a slow start to the year across the industry. Movantik's new prescriptions in the first quarter outperformed the same quarter last year, while Talicia's growth in prescription volume, repeat prescribing and new prescribers will be key growth drivers going forward. With the U.S. now emerging from the shadows of COVID-19, patients returning to clinics and travel resuming, positively affecting Aemcolo's prospects, we are excited for the promise 2021 holds."

Micha Ben Chorin, Chief Financial Officer at RedHill, added: "A strong March helped rebalance quarterly revenues, as we maintained cash burn rate at previous quarter levels. With a healthy balance sheet, we are well-positioned to drive our late-stage R&D programs forward, as we work diligently to build on the upward trends across our core business."

Financial highlights for the quarter ended March 31, 2021[iii]

Net Revenues were approximately $20.6 million for the first quarter of 2021, a decrease of $0.9 million compared to the fourth quarter of 2020. The decrease was mainly attributable to typical cyclical trends in Movantik sales.

Gross Profit was approximately $10.3 million for the first quarter of 2021, a decrease of $0.5 million compared to the fourth quarter of 2020, maintaining a consistent gross margin of approximately 50%. The decrease was mainly attributable to the decrease in net revenues.

Research and Development Expenses were approximately $7.5 million for the first quarter of 2021, an increase of $1.3 million compared to the fourth quarter of 2020, mainly attributable to the progression of our COVID-19 development programs.

Selling, Marketing and General and Administrative Expenses were approximately $21.0 million for the first quarter of 2021, a decrease of $3.3 million compared to the fourth quarter of 2020. The decrease was mainly attributable to large non-recurring marketing investments made in the fourth quarter of 2020.

Operating Loss and Net Loss were approximately $18.2 million and $22.9 million, respectively, for the first quarter of 2021, compared to $19.7 million and $24.3 million, respectively, in the fourth quarter of 2020. The decrease was mainly attributable to the decrease in marketing expenses, as detailed above.

Net Cash Used in Operating Activities was approximately $12.3 million for the first quarter of 2021, a decrease of $0.4 million compared to the

fourth quarter of 2020.

Net Cash Provided by Financing Activities was approximately $58.7 million for the first quarter of 2021, comprised primarily of proceeds from equity offerings.

Cash Balance[1] as of March 31, 2021, was approximately $92.1 million.

Commercial Highlights

Movantik® (naloxegol)[iv]

Movantik ended the quarter strongly with a 4% increase in new prescriptions compared to the first quarter of 2020. Movantik market leadership position is holding strong at 75% U.S. market share, with focus on growth in 2021 and beyond. Movantik also continues to enjoy excellent coverage without restrictions in the PAMORA class for both commercial & government segments, with 88% of American commercial lives covered.

In March 2021, the Company announced that RedHill Biopharma Inc., AstraZeneca AB, AstraZeneca Pharmaceuticals LP and Nektar Therapeutics had entered into a settlement and license agreement with MSN Pharmaceuticals, Inc. and MSN Laboratories PVT. LTD. (MSN) resolving their patent litigation in the U.S. in response to MSN's Abbreviated New Drug Application (ANDA) seeking approval by the U.S. Food and Drug Administration (FDA) to market a generic version of Movantik. Under the terms of the settlement agreement, MSN may not sell a generic version of Movantik in the U.S. until October 1, 2030 (subject to FDA approval) or earlier under certain circumstances.

In February 2021, the Company also announced an agreement with Cosmo Pharmaceuticals N.V. to manufacture Movantik, securing high-quality manufacturing capacity for our current largest commercial product.

Talicia® (omeprazole magnesium, amoxicillin and rifabutin)[v]

Talicia continued to achieve new launch year milestones. Talicia achieved 11% growth in prescription volume and a 39% increase in the number of repeat prescribers compared to the previous quarter, positioning the brand and RedHill for continued growth in 2021 as clinician visits resume and diagnostic labs reopen fully. The quarter ended strongly, resulting in the highest levels of monthly and weekly prescription volume and number of prescribers since launch. Overall, Talicia continues to show growth in total prescribers and repeat prescribing, and March's performance indicates ongoing momentum for accelerated growth for the remainder of 2021.

Talicia's growth is supported by an increased commercial coverage of 77%, compared to 69% in the fourth quarter of 2020. Further formulary additions are expected, adding to the previously announced listings of Talicia on the national formularies of Prime Therapeutics, EnvisionRx and Express Scripts.

Aemcolo® (rifamycin)[vi]

RedHill has implemented plans, including re-launching active field promotion, to support, and build on, the initial momentum that Aemcolo was generating pre-COVID-19 travel restrictions. The Company expects that these plans will drive a resurgence of interest in Aemcolo once travel restrictions are lifted and international travel from the U.S. returns to significant levels.

In January 2021, the Company reported that its partner, Cosmo Pharmaceuticals, announced it had successfully completed its Phase 2 Proof-of-Concept (POC) clinical trial of rifamycin SV-MMX 600 mg in patients with diarrhea-predominant irritable bowel syndrome (IBS-D). As part of an exclusive license agreement between RedHill and Cosmo Pharmaceuticals from October 2019 for the U.S. rights to Aemcolo (rifamycin), RedHill maintains certain rights, including a right of first refusal, in relation to rifamycin SV-MMX 600 mg in the U.S.

R&D Highlights

COVID-19 Program: Opaganib (ABC294640, Yeliva®)[vii]

The global Phase 2/3 study of orally-administered, opaganib in patients with severe COVID-19 pneumonia requiring hospitalization and treatment with supplemental oxygen (NCT04467840) is now almost 100% enrolled. Last patient out will occur approximately six weeks after the final patient is randomized. This puts opaganib amongst the first novel investigational COVID-19 oral pills to deliver late-stage data.

The study has passed four Data Safety Monitoring Board reviews, including a futility review. The fourth DSMB review, conducted in April, was based on an analysis of unblinded safety data from the first 255 patients treated for at least 14 days, extending the total opaganib safety database to approximately 380 patients.

Opaganib has shown dual anti-inflammatory and antiviral activity and is host-targeted, and therefore expected to be effective against emerging viral variants with various mutations in the spike protein.

The Company recently announced receipt of a Notice of Allowance for a U.S. patent application covering the use of opaganib for the treatment of COVID-19 with a term extending until at least 2041. The Company also previously announced that it had signed collaborations with several U.S., European and Canadian suppliers, including with Cosmo Pharmaceuticals for large-scale ramp-up of opaganib manufacturing, further strengthening manufacturing capabilities and capacity of opaganib.

In view of the upcoming completion of enrollment, RedHill is evaluating the regulatory path for opaganib with a focus on those countries currently most affected by COVID-19. The regulatory path, including potential submissions of emergency use applications in those countries, is subject to whether the data generated by the ongoing Phase 2/3 study is sufficiently positive and supportive, as well as the specific requirements in each country. The strength of the safety and efficacy data generated from the opaganib studies will be key to regulatory applications. Additional studies to support the potential of such applications and the use or marketing of opaganib are likely to be required. For example, the FDA has indicated we will need to complete additional studies to support applications in the U.S. Evaluations and discussions continue with the FDA, EMA and regulators in other countries.

The Company continues its discussions with U.S. and other government agencies and non-governmental organizations around potential funding to support the development and manufacturing scale-up of opaganib.

COVID-19 Program: RHB-107 (upamostat)[viii]

In February 2021, RedHill announced dosing of the first patient in the U.S. Phase 2/3 COVID-19 study with novel, orally-administered, RHB-107 (upamostat). The study with once-daily RHB-107 is evaluating treatment of non-hospitalized patients with symptomatic COVID-19 who do not require supplemental oxygen - the vast majority of COVID-19 patients.

RHB-107 is a novel, orally-administered, serine protease inhibitor. It is also host-targeting and therefore also expected to be effective against emerging viral variants with mutations in the spike protein. In previously announced *in vitro* results, RHB-107 strongly inhibited SARS-CoV-2 viral replication.

The Company recently announced receipt of a Notice of Allowance for a U.S. patent application covering the use of RHB-107 for the treatment of COVID-19 with a term extending until at least 2041.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Disease

A U.S. Phase 3 study is ongoing to evaluate the efficacy and safety of RHB-204 in adults with pulmonary NTM disease caused by *Mycobacterium avium* Complex (MAC) infection.

The FDA also granted Fast Track designation for RHB-204 in January 2021, providing early and frequent communications and a rolling review of any New Drug Application (NDA). RHB-204 is also eligible for NDA Priority Review and Accelerated Approval.

RHB-204 was granted FDA Orphan Drug designation and Qualified Infectious Disease Product designation, extending its U.S. market exclusivity to a potential total of 12 years upon potential FDA approval.

Opaganib - Cholangiocarcinoma and Prostate Cancer

The Phase 2a study evaluating the activity of opaganib in advanced cholangiocarcinoma (bile duct cancer) is ongoing. Enrollment has been completed for the first cohort of 39 patients, evaluating the activity of orally-administered opaganib as a stand-alone treatment. Preliminary data from this cohort indicated a signal of activity in a number of subjects with advanced cholangiocarcinoma. Enrollment is ongoing for a second cohort, evaluating opaganib in combination with hydroxychloroquine, an anti-autophagy agent.

In light of preclinical findings demonstrating tumor regression following combination treatment with opaganib and RHB-107 (upamostat), RedHill plans to add an additional cohort to the ongoing Phase 2a study, evaluating opaganib in combination with RHB-107, subject to discussions with the FDA. Opaganib was granted FDA Orphan Drug designation for the treatment of cholangiocarcinoma.

An additional Phase 2 study with opaganib in prostate cancer is ongoing at the Medical University of South Carolina (MUSC). The study is supported by a National Cancer Institute grant awarded to MUSC with additional support from RedHill.

Conference Call and Webcast Information:

The Company will host a webcast today, **Thursday, May 27, 2021, at 8:30 a.m. EDT**, during which it will present key highlights for the first quarter of 2021.

The webcast including slides will be broadcast live on the Company's website, **https://ir.redhillbio.com/events,** and will be available for replay for 30 days.

To participate in the conference call, please dial one of the following numbers 15 minutes prior to the start of the call: **United States: +1-877-870-9135; International: +1-646-741-3167 and Israel: +972-3-530-8845; the access code for the call is: 8506238.**

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on gastrointestinal and infectious diseases. RedHill promotes the gastrointestinal drugs, **Movantik®** for opioid-induced constipation in adults, **Talicia®** for the treatment of *Helicobacter pylori (H. pylori)* infection in adults, and **Aemcolo®** for the treatment of travelers' diarrhea in adults. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with an ongoing Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) disease; (ii) **opaganib (Yeliva®, ABC294640)**, a first-in-class SK2 selective inhibitor targeting multiple indications with a Phase 2/3 program for COVID-19 and Phase 2 studies for prostate cancer and cholangiocarcinoma ongoing; (iii) **RHB-107** (**upamostat**), a serine protease inhibitor in a U.S. Phase 2/3 study as treatment for symptomatic COVID-19, and targeting multiple other cancer and inflammatory gastrointestinal diseases; (iv) **RHB-104**, with positive results from a first Phase 3 study for Crohn's disease; (v) **RHB-102** (**Bekinda®**), with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com / https://twitter.com/RedHillBio.

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 include statements regarding planned commercial operational breakeven by the end of 2021 and regarding achieving fast growth and increased profit margin. 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 of a delay in completion of enrollment for the Phase 2/3 COVID-19 study for opaganib and the Phase 2/3 COVID-19 study for RHB-107, delay in top-line data from the Phase 2/3 COVID-19 study for opaganib, that the Phase 2/3 COVID-19 study for opaganib and the Phase 2/3 COVID-19 study for RHB-107 may not be successful and, even if successful, such studies and results may not be sufficient for regulatory applications, including emergency use or marketing applications, and that additional COVID-19 studies for opaganib are likely to be required, and for

RHB-107 may be required, by regulatory authorities to support such potential applications and the use or marketing of opaganib and/or RHB-107, as the case may be, for COVID-19 patients, that opaganib and RHB-107 will not be effective against emerging viral variants, as well as risks and uncertainties associated with the risk that the Company will not successfully commercialize its products; as well as risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, pre-clinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its commercial products and ones it may acquire or develop in the future; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its pre-clinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number and type 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 and Talicia®; (v) the Company's ability to successfully commercialize and promote Talicia®, and Aemcolo® and Movantik®; (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, pre-clinical studies or clinical trials; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on March 18, 2021. 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
Chief Corporate and Business Development Officer
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

Media contacts:
U.S.: Bryan Gibbs, Finn Partners
+1 212 529 2236
bryan.gibbs@finnpartners.com
UK: Amber Fennell, Consilium
+44 (0) 7739 658 783
fennell@consilium-comms.com

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
	2021	2020
	U.S. dollars in thousands	
NET REVENUES	20,575	1,056
COST OF REVENUES	10,253	1,715
GROSS PROFIT	10,322	(659)
RESEARCH AND DEVELOPMENT EXPENSES	7,484	2,765
SELLING AND MARKETING EXPENSES	13,895	9,006
GENERAL AND ADMINISTRATIVE EXPENSES	7,095	4,586
OPERATING LOSS	18,152	17,016
FINANCIAL INCOME	(42)	(214)
FINANCIAL EXPENSES	4,753	355
FINANCIAL EXPENSES, net	4,711	141
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	22,863	17,157
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars):	0.05	0.05
WEIGHTED AVERAGE OF ORDINARY SHARE (in thousands)	429,603	352,696

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	March 31, 2021	December 31, 2020
	Unaudited	Audited
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	75,972	29,295
Bank deposits	16	17
Financial assets at fair value through profit or loss	—	481
Trade receivables	23,306	28,655
Prepaid expenses and other receivables	4,094	5,521
Inventory	9,270	6,526
	112,658	70,495
NON-CURRENT ASSETS:		
Restricted cash	16,158	16,164
Fixed assets	553	511
Right-of-use assets	4,702	5,192
Intangible assets	86,052	87,879
	107,465	109,746
TOTAL ASSETS	220,123	180,241
CURRENT LIABILITIES:		
Accounts payable	6,536	11,553
Lease liabilities	1,636	1,710
Allowance for deductions from revenue	22,677	18,343
Accrued expenses and other current liabilities	25,446	24,082
Payable in respect of intangible assets purchase	10,334	17,547
	66,629	73,235
NON-CURRENT LIABILITIES:		
Borrowing	82,524	81,386
Payable in respect of intangible assets purchase	13,788	7,199
Lease liabilities	3,391	3,807
Royalty obligation	750	750
	100,453	93,142
TOTAL LIABILITIES	167,082	166,377
EQUITY:		
Ordinary shares	1,309	1,054
Additional paid-in capital	354,057	293,144
Accumulated deficit	(302,325)	(280,334)
TOTAL EQUITY	53,041	13,864
TOTAL LIABILITIES AND EQUITY	220,123	180,241

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2021	2020
	U.S. dollars in thousands	
OPERATING ACTIVITIES:		
Comprehensive loss	(22,863)	(17,157)
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	872	802
Depreciation	492	350
Amortization and impairment of intangible assets	1,827	1,076
Non-cash interest expenses related to borrowing and payable in respect of intangible assets purchase	2,639	104
Fair value losses (gains) on financial assets at fair value through profit or loss	6	75

Exchange differences and revaluation of bank deposits	46	(159)
	5,882	2,248
Changes in assets and liability items:		
Decrease (increase) in trade receivables	5,349	(501)
Decrease in prepaid expenses and other receivables	1,428	971
Increase in inventories	(2,744)	(885)
Decrease in accounts payable	(5,017)	(999)
Increase in accrued expenses and other liabilities	1,364	6,030
Increase (decrease) in allowance for deductions from revenue	4,334	(331)
	4,714	4,285
Net cash used in operating activities	**(12,267)**	**(10,624)**
INVESTING ACTIVITIES:		
Purchase of fixed assets	(88)	(242)
Change in investment in current bank deposits	—	3,200
Transactions costs related to purchase of intangible assets	—	(1,183)
Proceeds from sale of financial assets at fair value through profit or loss	475	2,225
Net cash provided by (used in) investing activities	**387**	**4,000**
FINANCING ACTIVITIES:		
Proceeds from long-term borrowings, net of transaction costs	—	79,345
Proceeds from issuance of ordinary shares, net of issuance costs	57,941	—
Exercise of options into ordinary shares	3,227	—
Repayment of payable in respect of intangible asset purchase	(2,125)	—
Increase in restricted cash	—	(20,000)
Payment of principal with respect to lease liabilities	(383)	(261)
Net cash provided by financing activities	**58,660**	**59,084**
INCREASE IN CASH AND CASH EQUIVALENTS	46,780	52,460
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(103)	131
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,295	29,023
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	75,972	81,614
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	19	178
SUPPLEMENTARY INFORMATION ON INTEREST PAID IN CASH	1,990	231
SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	—	1,575
Long-term borrowings transaction costs	—	1,284

[i] Including cash, cash equivalents, short-term investments (bank deposits and financial assets at fair value) and restricted cash

[ii] First quarter 2020 was the last quarter for Movantik as an Astra Zeneca product

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

[iv] Movantik® (naloxegol) is indicated for opioid-induced constipation (OIC). Full prescribing information see: www.movantik.com.

[v] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of *H. pylori* infection in adults. For full prescribing information see: www.Talicia.com.

[vi] Aemcolo® (rifamycin) indicated for the treatment of travelers' diarrhea caused by noninvasive strains of *Escherichia coli* in adults. For full prescribing information see: www.aemcolo.com

[vii] Opaganib (ABC294640, Yeliva®) is an investigational new drug, not available for commercial distribution.

[viii] RHB-107 (upamostat) is an investigational new drug, not available for commercial distribution.

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