Press Release

RedHill Biopharma Provides Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

Financials:

Full year 2020 net revenues of approximately $64 million, with gross profit of approximately $27.5 million

Solid cash balance of approximately $100 million as of March 4, 2021

Planned commercial operational breakeven by the end of 2021

Commercial Highlights:

Talicia: Consistent month-over-month prescription growth despite pandemic conditions, with 52% new prescription growth in Q4/2020 compared to Q3/2020

Movantik: Market leadership position holding strong and well-positioned for further growth in 2021

R&D Highlights:

Two advanced programs at the forefront of global COVID-19 novel therapeutics development:

- *Opaganib: Ongoing global Phase 2/3 study in hospitalized patients approximately two thirds enrolled, data expected Q2/2021; Positive U.S. Phase 2 data reported*
- *RHB-107: Ongoing U.S. Phase 2/3 study in symptomatic non-hospitalized patients*

RHB-204: Ongoing Phase 3 study for pulmonary NTM disease as oral first-line treatment

Management to host webcast today, at 8:30 a.m. EDT

TEL AVIV, Israel and RALEIGH, NC, March 18, 2021, RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today reported its financial results and operational highlights for the year ended December 31, 2020.

Dror Ben-Asher, RedHill's Chief Executive Officer, said: "2020 was a year that our team looks back on with a sense of immense achievement. While navigating the challenging conditions caused by the pandemic, we have delivered broad commercial growth culminating in a very strong end to 2020 for both Movantik and Talicia". **Mr. Ben-Asher continued**: "At the same time, we have rapidly progressed two novel oral COVID-19 therapies to Phase 3 stage development, covering both hospitalized and non-hospitalized patients and have reported positive clinical and preclinical data, positioning RedHill at the forefront of novel COVID-19 therapeutics development worldwide. With strong momentum across both commercial and R&D operations, we expect 2021 to be a breakout year."

Micha Ben Chorin, Chief Financial Officer at RedHill, added: "RedHill is delivering on a clear strategy designed to enable us to achieve fast growth and increased profit margin. We have been diligent in maintaining a solid balance sheet and we expect to achieve commercial operational breakeven by the end of this year."

Financial highlights for the year ended December 31, 2020

Net Revenues were approximately $64 million for the year ended December 31, 2020, an increase of $58 million compared to the year ended December 31, 2019, attributed to revenues generated from the commercialization of Movantik and Talicia initiated in 2020. Net revenues for the fourth quarter of 2020 were approximately $21.5 million, an increase of $0.5 million compared to the third quarter of 2020, with a 12% increase in product delivery.

Gross Profit was approximately $27.5 million for the year ended December 31, 2020, an increase of $23.5 million compared to the year ended December 31, 2019, primarily due to the increase in net revenues.

Research and Development Expenses were approximately $16.5 million for the year ended December 31, 2020, mainly attributable to the development of our COVID-19 therapeutics and the Phase 3 study of RHB-204 for pulmonary NTM disease, and were, in total, lower than the research and development expenses for the year ended December 31, 2019.

Selling, Marketing and Business Development Expenses were approximately $49 million for the year ended December 31, 2020, compared to approximately $18 million for the year ended December 31, 2019. The increase was attributable to the expansion of our U.S. sales force and marketing activities, in support of the launch of Talicia and post-acquisition commercialization of Movantik.

General and Administrative Expenses were approximately $25 million for the year ended December 31, 2020, compared to approximately $11 million for the year ended December 31, 2019. The increase was mainly attributable to the expansion of commercialization activities related to the Talicia launch and the Movantik acquisition from AstraZeneca.

Operating Loss was approximately $64 million for the year ended December 31, 2020, compared to approximately $43 million for the year ended December 31, 2019. The increase was attributable to the expansion of our commercial operations.

Net Loss was approximately $76 million for the year ended December 31, 2020, compared to approximately $42 million for the year ended December 31, 2019. The increase was attributable to factors mentioned above, as well as interest expenses mainly related to the royalty and debt financing in the first quarter of 2020.

Net Cash Used in Operating Activities was approximately $49 million for the year ended December 31, 2020, compared to approximately $41 million for the year ended December 31, 2019. The increase was attributable to the increase in operating loss, as described above.

Net Cash Used in Investing Activities was approximately $36 million for the year ended December 31, 2020, primarily related to the $52.5 million upfront payment to AstraZeneca for the acquisition of Movantik, partially offset by inflow from current bank deposits and financial assets at fair value through profit or loss.

Net Cash Provided by Financing Activities was approximately $84 million for the year ended December 31, 2020, comprised primarily from financing inflow of approximately $102 million, mainly in debt and equity, partially offset by $16 million classified as restricted cash.

Liquidity and Capital Resources

Cash Balance[1] as of December 31, 2020, was approximately $46 million. Cash balance as of March 4, 2021 was approximately $100 million.

Commercial Highlights

Movantik® (naloxegol)[2]

The Company has completed three full quarters of Movantik promotion following its acquisition from AstraZeneca, achieving: A reversal of the trend of declining new prescriptions prior to the acquisition, maintaining Movantik's position as a segment-leading brand and ending 2020 strongly recording the second highest monthly new prescription volume of 2020 in December.

RedHill acquired the global rights to Movantik from AstraZeneca, excluding Europe and Canada, subsequently adding Israel rights, and replaced a co-commercialization agreement with Daiichi Sankyo (assigned under the agreement with AstraZeneca), with a new royalty-bearing agreement that resulted in RedHill assuming full control over brand strategy and commercialization activities for Movantik in the U.S. and increasing gross margin.

Talicia® (omeprazole magnesium, amoxicillin and rifabutin)[3]

Despite the challenging pandemic environment, the Company has persisted in its efforts to support the launch and rapid growth of Talicia, in particular in expanding the prescriber base. This has resulted in the strong accumulation of new Talicia prescribers in the second half of 2020 and consistent month-over-month prescription growth despite pandemic conditions. Talicia ended 2020 strongly, with 52% new prescription growth in the fourth quarter of 2020, as compared to the previous quarter, and achieving its highest weekly new prescription volume in December.

This growth is supported by the addition of Talicia as a preferred brand on leading national formularies, approaching 70% U.S. commercial coverage in the fourth quarter, with further formulary additions expected to add to the previously announced listings of Talicia on the national formularies of Prime Therapeutics, EnvisionRx, and Express Scripts.

Aemcolo® (rifamycin)[4]
The Company has implemented plans 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.

R&D Highlights

COVID-19 Program: Opaganib (ABC294640, Yeliva®)[5]
The late-stage development program for novel, orally-administered, opaganib in patients with severe COVID-19 pneumonia is progressing rapidly. Opaganib has demonstrated dual anti-inflammatory and antiviral activity, targeting a human cell component involved in viral replication and therefore expected to be effective against emerging viral strains with mutations in the spike protein.

The global Phase 2/3 randomized, double-blind, parallel-arm, placebo-controlled study of opaganib in patients with severe COVID-19 pneumonia requiring hospitalization and treatment with supplemental oxygen (NCT04467840), is rapidly advancing in a total of 8 countries and approximately 40 recruiting sites, with additional expansion ongoing. The study has passed three Data Safety Monitoring Board reviews, including a futility review, which is suggestive that the study is progressing as expected. The 464-patient study has already enrolled approximately two thirds of the patients and is expected to deliver top-line data in the second quarter of 2021.

In December 2020, the Company reported positive top-line safety and efficacy data from the U.S. Phase 2 study with opaganib in patients with COVID-19 pneumonia, in which opaganib demonstrated greater improvement in reducing oxygen requirement by end of treatment on Day 14, on top of standard-of-care. The Phase 2 data also showed no material safety differences between the opaganib and placebo treatment arms - further adding to the growing opaganib safety database.

In September 2020, RedHill announced that opaganib demonstrated potent inhibition of SARS-CoV-2, achieving complete blockage of viral replication, as measured after three days incubation, in an *in*

vitro model of human bronchial tissue, comparing favorably with remdesivir, the positive control in the study. Furthermore, treatment of cells infected with SARS-CoV-2 with opaganib did not compromise cell membrane integrity, a measure of cell viability and drug safety, further demonstrating opaganib's promising potential for treating patients with COVID-19. On top of its anti-inflammatory mechanism, opaganib is also one of very few orally available broad-spectrum antivirals in advanced clinical evaluation for treating COVID-19.

The Company also signed collaborations with several U.S., European and Canadian suppliers, including with Cosmo Pharmaceuticals NV (SIX: COPN) for large-scale ramp-up of opaganib manufacturing, further strengthening manufacturing capabilities and capacity for opaganib.

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

COVID-19 Program: RHB-107 (upamostat)[6]

In February 2021, RedHill announced dosing of the first patient in the U.S. Phase 2/3 COVID-19 outpatient study with novel, orally-administered, RHB-107 (upamostat). The study with once-daily RHB-107 is evaluating treatment of patients with symptomatic COVID-19 who do not require hospitalization - the vast majority of COVID-19 patients. The study allows patients to remain in the comfort of their home yet be monitored at a level previously possible only in a hospital setting, enabling increased compliance and retention rates.

RHB-107 is a novel, orally-administered, serine protease inhibitor targeting human cell factors involved in viral entry and is therefore 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.

RHB-204[7] - Pulmonary Nontuberculous Mycobacteria (NTM) Disease

In November 2020, RedHill commenced its U.S. Phase 3 study 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). Having already been granted Qualified Infectious Disease Product (QIDP) designation, RHB-204 is also eligible for NDA Priority Review and Accelerated Approval.

In October 2020, the Company announced that RHB-204 had been granted FDA Orphan Drug Designation. This, along with the previously granted QIDP designation, extends U.S. market exclusivity for RHB-204 to a potential total of 12 years upon 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 has been 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.

COVID-19 Impact Update

RedHill's primary concern during the COVID-19 pandemic continues to be the safety and health of its employees, patients, colleagues, and the communities to which we belong.

Operationally, the actions the Company took to mitigate the impact of the COVID-19 pandemic continue to serve us well, with minimal effect on our ongoing operational and supply chain activities. Promotional activity has now been largely re-instated, where safe to do so, and in adherence to social distancing and other public health guidelines. RedHill will continue to assess the potential impact of COVID-19 on its business and operations.

Conference Call and Webcast Information:

The Company will host a conference call and live webcast today, **Thursday, March 18, 2021, at 8:30 a.m. EDT** to present the fourth quarter and full year 2020 financial results and operational highlights.

The webcast and 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: 1830718.**

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 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 4, 2020. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise unless required by law.

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REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,		
	2020	**2019**	**2018**
	U.S. dollars in thousands		
NET REVENUES	64,359	6,291	8,360
COST OF REVENUES	36,892	2,259	2,837
GROSS PROFIT	27,467	4,032	5,523
RESEARCH AND DEVELOPMENT EXPENSES	16,491	17,419	24,862
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	49,285	18,333	12,486
GENERAL AND ADMINISTRATIVE EXPENSES	25,375	11,481	7,506
OPERATING LOSS	63,684	43,201	39,331
FINANCIAL INCOME	270	1,335	678
FINANCIAL EXPENSES	12,759	438	167
FINANCIAL EXPENSES (INCOME), net	12,489	(897)	(511)
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR	76,173	42,304	38,820

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2020	2019
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	29,295	29,023
Bank deposits	17	10,349
Financial assets at fair value through profit or loss	481	8,500
Trade receivables	28,655	1,216
Prepaid expenses and other receivables	5,521	2,244
Inventory	6,526	1,882
	70,495	53,214
NON-CURRENT ASSETS:		
Restricted cash	16,164	152
Fixed assets	511	228
Right-of-use assets	5,192	3,578
Intangible assets	87,879	16,927
	109,746	20,885
TOTAL ASSETS	180,241	74,099
CURRENT LIABILITIES:		
Accounts payable	11,553	4,184
Lease liabilities	1,710	834
Allowance for deductions from revenue	18,343	1,267
Accrued expenses and other current liabilities	24,082	4,331
Payable in respect of intangible assets purchase	17,547	—
	73,235	10,616
NON-CURRENT LIABILITIES:		
Borrowing	81,386	—
Payable in respect of intangible assets purchase	7,199	—
Lease liabilities	3,807	2,981
Royalty obligation	750	500
	93,142	3,481
TOTAL LIABILITIES	166,377	14,097
EQUITY:		
Ordinary shares	1,054	962
Additional paid-in capital	293,144	267,403
Accumulated deficit	(280,334)	(208,363)
TOTAL EQUITY	13,864	60,002
TOTAL LIABILITIES AND EQUITY	180,241	74,099

REDHILL BIOPHARMA LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2020	2019	2018
	U.S. dollars in thousands		
OPERATING ACTIVITIES:			
Comprehensive loss	(76,173)	(42,304)	(38,820)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	4,202	3,027	2,678
Depreciation	1,710	997	90
Amortization and impairment of intangible assets	7,035	216	—
Non-cash interest expenses related to borrowing and payable in respect of intangible assets purchase and royalty obligation	6,032	—	—
Fair value adjustments on derivative financial instruments	—	(344)	(104)
Fair value losses (gains) on financial assets at fair value through profit or loss	94	(27)	137
Exchange differences and revaluation of bank deposits	101	24	138
	19,174	3,893	2,939
Changes in assets and liability items:			
Decrease (increase) in trade receivables	(27,439)	(258)	570
Decrease (increase) in prepaid expenses and other receivables	(3,277)	(368)	1,414
Increase in inventories	(4,644)	(1,113)	(116)
Increase (decrease) in accounts payable	7,369	860	(1,481)
Increase (decrease) in accrued expenses and other liabilities	19,335	(2,726)	722
Increase in allowance for deductions from revenue	17,076	1,267	310
	8,420	(2,338)	1,419
Net cash used in operating activities	**(48,579)**	**(40,749)**	**(34,462)**
INVESTING ACTIVITIES:			
Purchase of fixed assets	(406)	(168)	(23)
Purchase of intangible assets	(53,368)	(35)	(35)
Change in investment in current bank deposits	10,200	(2,069)	4,869
Purchase of financial assets at fair value through profit or loss	—	(4,325)	(6,976)
Proceeds from sale of financial assets at fair value through profit or loss	7,925	11,761	7,517
Net cash provided by (used in) investing activities	**(35,649)**	**5,164**	**5,352**
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, net of issuance costs	23,867	36,300	41,902
Exercise of options into ordinary shares	52	5	361
Proceeds from long-term borrowings, net of transaction costs	78,061	—	—
Increase in restricted cash	(20,000)	—	—
Decrease in restricted cash	4,000	—	—
Payment of principal with respect to lease liabilities	(1,610)	(796)	—
Repayment of payable in respect of intangible asset purchase	—	—	(500)
Net cash provided by financing activities	**84,370**	**35,509**	**41,763**
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	142	(76)	12,653
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	130	94	(103)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,023	29,005	16,455
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	29,295	29,023	29,005
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	414	753	728
SUPPLEMENTARY INFORMATION ON INTEREST PAID IN CASH	6,654	251	—
SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Acquisition of right-of-use assets by means of lease liabilities	2,930	2,805	—
Purchase of intangible assets posted as payable	24,619	—	—
Purchase of an intangible asset in consideration for issuance of shares	1,914	11,788	—

[1] Including cash, cash equivalents, short-term investments (bank deposits and financial assets at fair value) and restricted cash.
[2] Movantik® (naloxegol) is indicated for opioid-induced constipation (OIC). Full prescribing information see: www.movantik.com.
[3] 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.
[4] 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
[5] Opaganib (ABC294640, Yeliva®) is an investigational new drug, not available for commercial distribution.
[6] RHB-107 (upamostat) is an investigational new drug, not available for commercial distribution.
[7] RHB-204 is an investigational new drug, not available for commercial distribution.