



NEWS RELEASE

RedHill Biopharma Announces Record Quarterly Revenues and First Commercial Operations Breakeven

2/17/2022

Business update (unaudited and preliminary estimated fourth quarter financial data[1]):

- Record Q4/2021 total net revenues estimated to be in the range of \$22-24 million vs. \$21.6 million in Q3/2021 and \$21.5 in Q4/2020
- Estimated to have achieved commercial operations breakeven in Q4/2021 and expect profitable commercial operations in 2022 (both non-GAAP EBITDA)[2]
- Cash balance[3] of \$54.2 million as of December 31, 2021, an increase from Q3/2021 (\$51.5 million) and Q4/2020 (\$45.9 million as of December 31, 2020)
- Substantial decrease in operational and development expenses following implementation of a cost-efficiency plan
- Customer-facing salesforce strengthened through internal realignment and now includes 120 sales professionals
- Record Talicia® quarterly new prescriptions, increase of 26.5% vs. Q3/2021, and 78.4% vs. Q4/2020
- Movantik® growth continues, new prescriptions increased by 2.4% vs. Q3/2021 and 4.5% vs. Q4/2020

TEL AVIV, Israel and RALEIGH, N.C., Feb. 17, 2022 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today provided a business update for the fourth quarter of 2021, including certain estimated unaudited preliminary financial data.

Dror Ben-Asher, RedHill's Chief Executive Officer, said: "Strong sales growth momentum in the face of the persistent pandemic environment, coupled with strengthening our salesforce through internal realignment to

include 120 customer-facing sales professionals, disciplined cost-control measures and the potential addition of products synergistic to our existing commercial basket, are planned to bring us closer to commercial operations profitability in 2022. In parallel, our compact R&D team continues to display tremendous creativity and drive in progressing RedHill's robust late clinical-stage pipeline. In particular, extensive discussions are ongoing with regulators in multiple countries regarding potential pathways to approval of orally-administered opaganib, likely the first novel oral drug candidate to have shown an improvement in viral clearance in severe hospitalized COVID-19 patients."

The Company intends to announce its audited fourth quarter and full year 2021 results in the coming weeks. The preliminary financial data ranges described herein have not been audited and are subject to adjustment based on the Company's completion of year-end financial close processes.

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^[4], **Talicia**[®] for the treatment of Helicobacter pylori (H. pylori) infection in adults^[5], and **Aemcolo**[®] for the treatment of travelers' diarrhea in adults^[6]. 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 (ABC294640)**, a first-in-class oral 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)**, an oral 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**, 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/ 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 in this press release include, but are not limited to, the Company's unaudited preliminary financial information for the fourth quarter ended December 31, 2021. The preliminary financial information set forth in this press release is subject to the completion of the Company's audit process and is subject to change. The estimated preliminary financial data included in this press release should not be viewed as a substitute for the Company's annual financial statements prepared in accordance with International Financial Reporting Standards as

issued by the International Accounting Standards Board. There can be no assurance that the estimated preliminary financial data or the expected commercial operations profitability in 2022 will be realized, and you are cautioned not to place undue reliance on the preliminary financial information, which reflects management's current expectations and anticipated results of operations, all of which are subject to known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements, market trends, or industry results to differ materially from those expressed or implied by such forward-looking statements. The preliminary financial data described in this press release will be adjusted based on the Company's completion of year-end financial close processes. 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 top-line data from Part A of the Phase 2/3 study of once-daily oral RHB-107 in non-hospitalized patients with symptomatic COVID-19, that 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 and RHB-107 are likely to be required, 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 contacts:

Adi Frish

Chief Corporate and Business Development Officer

RedHill Biopharma

+972-54-6543-112

adi@redhillbio.com

Media contacts:

U.S. / UK: Amber Fennell, Consilium

+44 (0) 7739 658 783

fennell@consilium-comms.com

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[1] The estimated unaudited financial condition and data of operations as of and for the fourth quarter ended December 31, 2021 presented above are preliminary and are subject to change based upon the completion of the Company's quarter-end closing procedures and further financial review. The Company's independent registered public accounting firm has not audited, reviewed, compiled or performed any procedures with respect to this preliminary financial information. The Company's actual results may differ from these estimates as a result of the completion of the Company's quarter-end closing procedures, review adjustments and other developments that may arise between now and the time the Company's financial results for the fourth quarter are finalized; The Company's auditor, Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, has not audited, reviewed, or compiled these estimates.

[2] Commercial operations non-GAAP EBITDA excludes: financial expenses, depreciation, amortization, intangible assets impairment and share-based compensation expenses.

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

[4] Full prescribing information for Movantik[®] (naloxegol) is available at: www.Movantik.com.

[5] Full prescribing information for Talicia[®] (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.

[6] Full prescribing information for Aemcolo[®] (rifamycin) is available at: www.Aemcolo.com.

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