
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934**

For the month of November 2020
Commission File No.: 001-35773

REDHILL BIOPHARMA LTD.
(Translation of registrant's name into English)

21 Ha'arba'a Street, Tel Aviv, 6473921, Israel
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ___

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ___

Attached hereto and incorporated by reference herein are the following:

[Exhibit 1: Registrant's press release entitled "RedHill Biopharma Provides Q3/2020 Results and Highlights, Including 300% Talicia Prescription Growth"](#).

[Exhibit 2: Registrant's condensed consolidated interim unaudited financial information as of September 30, 2020 and for the three and nine months then ended.](#)

Exhibits 1 (solely with respect to the Financial highlights for the third quarter, ended September 30, 2020, Liquidity and Capital Resources, Commercial Highlights, R&D Highlights, the Condensed Consolidated Interim Statements of Comprehensive Loss, Condensed Consolidated Interim Statements of Financial Position and Condensed Consolidated Interim Statements of Cash Flows) and Exhibit 2 to this Report on Form 6-K are hereby incorporated by reference into the Company's Registration Statements on Form S-8 filed with the Securities and Exchange Commission on May 2, 2013 (Registration No. 333-188286), on October 29, 2015 (Registration No. 333-207654), on July 25, 2017 (Registration No. 333-219441), on May 23, 2018 (Registration No. 333-225122) and on July 24, 2019 (File No. 333-232776) and its Registration Statements on Form F-3 filed with the Securities and Exchange Commission on February 25, 2016 (Registration No. 333-209702), on July 23, 2018 (File No. 333-226278) and on July 24, 2019 (File No. 333-232777)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REDHILL BIOPHARMA LTD.
(the "Registrant")

Date: November 12, 2020

By: /s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

RedHill Biopharma Provides Q3/2020 Results and Highlights, Including 300% Talicia Prescription Growth

Q3/2020 net revenues of approximately \$21 million, with gross profit of \$10.6 million, or approximately 51%, up from \$6.7 million and approximately 32% in Q2/2020

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Strong growth for Talicia[®] with approximately 300% quarter-over-quarter prescription growth and rapid expansion of the prescriber base; Talicia achieved national coverage for 167 million lives since launch, with additional coverage expected

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Two consecutive quarters of Movantik[®] prescription (TRx) growth, reversing the trend of prescription decline prior to RedHill acquisition

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Opaganib's COVID-19 global Phase 2/3 study advancing rapidly with nearly 50% of patients enrolled and U.S. Phase 2 study over 90% enrolled; Initiated manufacturing ramp-up in preparation for potential emergency use applications as early as Q1/2021

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Commencing Phase 3 study with RHB-204 for first-line treatment of pulmonary NTM infections

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Cash balance of approximately \$51 million as of September 30, 2020

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

TEL AVIV, Israel and RALEIGH, N.C., Nov. 12, 2020 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today reported its financial results and operational highlights for the third quarter ended September 30, 2020.

Dror Ben-Asher, RedHill's Chief Executive Officer, said: "Despite the challenging pandemic environment, we have shown the strength of our commercial organization. Our extensive promotional efforts for Talicia delivered 300% quarter-over-quarter prescription growth, as well as rapid expansion of the prescriber base alongside national payor coverage for 167 million Americans. Movantik prescriptions grew for a second consecutive quarter - reversing the trend of prescription decline prior to its acquisition by RedHill." **Mr. Ben-Asher continued:** "Our global Phase 2/3 and U.S. Phase 2 studies with opaganib for COVID-19 are quickly approaching completion and are supplemented by data demonstrating opaganib's complete inhibition of SARS-CoV-2 viral replication. We have also initiated manufacturing ramp-up in preparation for potential emergency use applications for opaganib in the first quarter of 2021. We are initiating the Phase 3 study of RHB-204 as an oral first-line therapy for pulmonary NTM infections, a disease with a significant unmet need and no FDA-approved first-line treatment."

Micha Ben Chorin, Chief Financial Officer at RedHill, added: "This has been another positive quarter for the Company. We have significantly increased gross profit from 32% in the second quarter to 51% thanks to our new agreement with Daiichi Sankyo Inc. We expect the trend of increasing Movantik prescriptions to continue. We are pleased with the successful transition of Movantik from AstraZeneca and expect savings in operating expenses, as well as higher distribution service agreement fees to apply. We continue to effectively manage our cash position and continue to work toward operational break-even next year."

Financial highlights for the third quarter ended September 30, 2020¹

Net Revenues of \$20.9 million, continuing at a similar level to that in the second quarter of 2020. The increase in gross revenues, as well as in the number of scripts for Talicia and Movantik, were partially offset by the voluntary discontinuation of our legacy products.

Cost of Revenues of \$10.3 million, compared to \$14.2 million in the second quarter of 2020. The decrease was attributable to the reduced royalty rate payable to Daiichi Sankyo, Inc. for Movantik following the new agreement between the companies.

Gross Profit of \$10.6 million, compared to \$6.7 million in the second quarter of 2020. Gross profit of 51%, up from 32% in the second quarter, is attributable to the lower royalties payable.

Research and Development Expenses were \$4.3 million, compared to \$3.2 million in the second quarter of 2020. The increase was primarily attributable to the progression of the opaganib COVID-19 studies and to initiation activities for the Phase 3 study with RHB-204 for NTM infections.

Selling, Marketing and Business Development Expenses were \$13.4 million, compared to \$10 million in the second quarter of 2020. The increase was primarily attributable to the expansion of commercialization activities related to Talicia and Movantik, as well as to the payment received in the second quarter under the U.S. Small Business Administration Payroll Protection Program (PPP) which was recorded as a reduction in expenses.

General and Administrative Expenses were \$7.3 million, compared to \$6 million in the second quarter of 2020. The increase was primarily attributable to the payment received in the second quarter under the PPP which was recorded as a reduction from expenses.

Operating Loss was \$14.5 million, compared to \$12.5 million in the second quarter of 2020. The increase was primarily attributable to the expansion of commercialization activities related to Talicia and Movantik and investment in the studies with opaganib and RHB-204, partially offset by the increase in gross profit, as described above.

Net Loss was \$18.6 million, compared to \$16 million in the second quarter of 2020. The increase was primarily attributable to the increase in operating loss, as detailed above, and the increase in financing expenses due to the financial liability related to the new agreement with Daiichi Sankyo.

Net Cash Used in Operating Activities was \$9.2 million, compared to \$15 million in the second quarter of 2020. The decrease was primarily attributable to positive changes in working capital.

Net Cash Provided by Financing Activities was \$12 million, compared to \$5.5 million in the second quarter of 2020. The increase was primarily attributable to the increase in proceeds from the Company's "at-the-market" (ATM) facility and a reduction in restricted cash.

Liquidity and Capital Resources

Cash Balance² as of September 30, 2020, was \$50.9 million, compared to \$53.1 million as of June 30, 2020. The decrease was primarily attributable to the net cash used in operating activities, as detailed above, partially offset by proceeds of \$9.1 million from the Company's ATM in the third quarter of 2020.

Subsequent to September 30, 2020, and through November 11, 2020, 240,614 American Depositary Shares (ADSs) of the Company were issued under the Company's ATM facility, generating additional net proceeds of approximately \$2.3 million.

Commercial Highlights:

Movantik[®] (naloxegol)³

The Company has completed the transition of Movantik from AstraZeneca and achieved two consecutive full quarters of RedHill-led prescription. Additionally, the Company has targeted a larger prescriber base that has driven a 2.1% increase in unique prescribers of Movantik. This growth reverses a steady decline in prescriptions prior to RedHill acquiring the rights to Movantik, representing a shift in the trend and pointing to both a successful transition by RedHill and the prospects for continuing growth for Movantik.

RedHill acquired the global rights to Movantik from AstraZeneca, excluding Europe and Canada, and has, this quarter, 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)⁴

Since RedHill launched Talicia in the U.S. in March 2020, the Company has focused its efforts on the groundwork needed for

ongoing and rapid growth, including expansion of the prescriber base. This has resulted in a 300% quarter-on-quarter increase in Talicia prescriptions. This growth is supported by major additions of Talicia as a preferred brand on leading national formularies - achieving coverage for 167 million lives in the commercial and governmental segments. Further formulary additions are expected in the near future, in addition to the previously announced listings of Talicia on the national formularies of Prime Therapeutics, EnvisionRx, and Express Scripts.

R&D Highlights

COVID-19 (SARS-CoV-2) Program: Opaganib (ABC294640, Yeliva®)⁵

Following encouraging compassionate use results published⁶ last quarter, the late-stage development program for opaganib in patients with severe COVID-19 pneumonia has progressed rapidly. The Company is currently enrolling patients in two randomized, double-blind, parallel-arm, placebo-controlled studies with opaganib in patients with severe COVID-19 pneumonia requiring hospitalization and treatment with supplemental oxygen:

- | Enrollment in the U.S. Phase 2 study (NCT04414618) is over 90% complete and top-line data is expected before the end of this year, subject to recruitment completion. The study has passed two pre-scheduled safety reviews by an independent Safety Monitoring Committee (SMC) with unanimous recommendations to continue the study without change.
- | A global Phase 2/3 study (NCT04467840) is advancing rapidly and is approaching 50% enrollment. Approved in six countries and active across 20 clinical sites to date, the study is on track to enroll up to 270 patients.
- | The studies are intended to support potential emergency use applications as early as the first quarter of 2021, subject to positive results.

On September 8, 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.

The Company also entered into collaborations with European and Canadian suppliers for large-scale ramp-up of opaganib manufacturing in preparation for potential emergency use authorizations, further strengthening manufacturing capabilities and capacity for opaganib. RedHill continues to expand manufacturing capacity with additional supply agreements expected to be finalized in the coming weeks.

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. In September 2020, opaganib was awarded a grant from Pennsylvania's COVID-19 Vaccines, Treatments and Therapies Program, which supports the rapid advancement of promising novel COVID-19 therapies.

COVID-19 (SARS-CoV-2) Program: RHB-107 (upamostat)⁷

In recently released *in vitro* results, RedHill's second COVID-19 drug candidate, RHB-107, a novel, orally-administered serine protease inhibitor, strongly inhibited SARS-CoV-2 viral replication. The Company has submitted an Investigational New Drug (IND) application to the FDA for a U.S. Phase 2/3 study with RHB-107 in moderate COVID-19 patients treated in an outpatient setting, a different population to opaganib which is being evaluated in hospitalized patients with severe COVID-19 disease. The study is planned to be initiated early in 2021.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

RedHill announced in July 2020 that the U.S. FDA had cleared its IND application for a 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. RedHill is currently initiating the Phase 3 study of RHB-204 in the U.S. The study aims to enroll 125 patients in up to 40 sites across the U.S.

The Company recently announced that RHB-204 had been granted FDA Orphan Drug Designation. This, along with RHB-204's 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, and in light of these data, input from key opinion leaders and preclinical research that had been conducted at Mayo Clinic, RedHill initiated enrollment for a second cohort, evaluating opaganib in combination with hydroxychloroquine, an anti-autophagy agent.

In light of preclinical findings demonstrating that treatment with opaganib and RHB-107 (upamostat, WX-671) in combination resulted in tumor regression, 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.

RedHill recently announced that it had received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a new patent application related to the use of opaganib and RHB-107 for the treatment of solid tumor cancers. The patent is expected to extend IP protection for the combination until 2036.

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.

Exclusive Licensing and Manufacturing Agreement with Cosmo Pharmaceuticals

RedHill announced in August 2020 that it had entered into a binding term sheet with Cosmo Pharmaceuticals N.V. (SIX: COPN) (Cosmo) for an exclusive licensing and manufacturing agreement for multiple products.

COVID-19 Impact Update

RedHill's primary concern during the COVID-19 pandemic continues to be the safety and protection 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, November 12, 2020, at 8:30 a.m. EST** to present the third quarter financial results and operational highlights.

The webcast and accompanying slides will be broadcast live on the Company's website: <http://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: 4549918.**

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 adults⁸, **Talicia** for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults⁹, and **Aemcolo**[®] for the treatment of travelers' diarrhea in adults¹⁰. RedHill's key clinical late-stage development programs include: (i) **RHB-204**, with a planned Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (ii) **opaganib (Yeliva)**[®], 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-104**, with positive results from a first Phase 3 study for Crohn's disease; (iv) **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; (v) **RHB-107**, a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory

gastrointestinal diseases and is also being evaluated for COVID-19 and (vi) **RHB-106**, an encapsulated bowel preparation. More information about the Company is available at www.redhillbio.com.

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; the risk of a delay in the closing of the exclusive licensing and manufacturing agreement with Cosmo, the risk that the transaction with Cosmo will close on different terms than the terms of the binding term sheet, if it will close at all; the risk that the U.S. Phase 2 clinical study evaluating opaganib will not be successful and the risk of delay in the completion of the enrollment for this study; the risk that the Company will not expand the Phase 2/3 study to additional countries; the risk of a delay in the date that the Phase 2 study and Phase 2/3 study will deliver data for emergency use applications, if at all; the development risks of early-stage discovery efforts for a disease that is still little understood, including difficulty in assessing the efficacy of opaganib for the treatment of COVID-19, if at all; intense competition from other companies developing potential treatments and vaccines for COVID-19; the effect of a potential occurrence of patients suffering serious adverse events using opaganib under the compassionate use programs; the risk of a delay in the enrollment of the Phase 3 study with RHB-204 and that the study will not be successful; the risk of delay in initiation of the U.S. Phase 2/3 study with RHB-107 in patients with moderate COVID-19 treated in an outpatient setting; the risk that the Company will not succeed to show operational break-even next year, 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[®], 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, preclinical 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 continued employment 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.

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

| | Three Months Ended | | Nine Months Ended | |
|---|----------------------------------|----------------|--------------------------|----------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| | U.S. dollars in thousands | | | |
| NET REVENUES | 20,943 | 1,401 | 42,898 | 4,701 |
| COST OF REVENUES | 10,337 | 629 | 26,240 | 1,471 |
| GROSS PROFIT | 10,606 | 772 | 16,658 | 3,230 |
| RESEARCH AND DEVELOPMENT EXPENSES, net | 4,323 | 2,799 | 10,302 | 15,143 |
| SELLING, MARKETING AND BUSINESS | | | | |
| DEVELOPMENT EXPENSES | 13,414 | 4,892 | 32,384 | 12,175 |
| GENERAL AND ADMINISTRATIVE EXPENSES | 7,329 | 2,925 | 17,948 | 7,349 |
| OPERATING LOSS | 14,460 | 9,844 | 43,976 | 31,437 |
| FINANCIAL INCOME | 42 | 170 | 339 | 1,075 |
| FINANCIAL EXPENSES | 4,220 | 161 | 8,205 | 251 |
| FINANCIAL EXPENSES (INCOME), net | 4,178 | (9) | 7,866 | (824) |
| LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD | <u>18,638</u> | <u>9,835</u> | <u>51,842</u> | <u>30,613</u> |
| LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars): | <u>0.05</u> | <u>0.03</u> | <u>0.14</u> | <u>0.11</u> |
| WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands) | <u>372,893</u> | <u>283,687</u> | <u>359,428</u> | <u>283,687</u> |

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

| | September 30, 2020 | December 31, 2019 |
|---|----------------------------------|------------------------------|
| | Unaudited | Audited |
| | U.S. dollars in thousands | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | 26,198 | 29,023 |
| Bank deposits | 6,187 | 10,349 |
| Financial assets at fair value through profit or loss | 2,407 | 8,500 |
| Trade receivables | 12,424 | 1,216 |
| Prepaid expenses and other receivables | 4,635 | 2,244 |
| Inventory | 5,100 | 1,882 |
| | <u>56,951</u> | <u>53,214</u> |
| NON-CURRENT ASSETS: | | |
| Restricted cash | 16,153 | 152 |
| Fixed assets | 473 | 228 |
| Right-of-use assets | 5,448 | 3,578 |
| Intangible assets | 89,956 | 16,927 |
| | <u>112,030</u> | <u>20,885</u> |
| TOTAL ASSETS | <u><u>168,981</u></u> | <u><u>74,099</u></u> |
| CURRENT LIABILITIES: | | |
| Accounts payable | 6,569 | 4,184 |
| Lease liabilities | 1,546 | 834 |
| Accrued expenses and other current liabilities | 23,536 | 5,598 |
| | <u>31,651</u> | <u>10,616</u> |
| NON-CURRENT LIABILITIES: | | |
| Borrowing | 80,266 | — |
| Payable in respect of intangible assets purchase | 23,739 | — |
| Lease liabilities | 4,079 | 2,981 |
| Royalty obligation | 500 | 500 |
| | <u>108,584</u> | <u>3,481</u> |
| TOTAL LIABILITIES | <u>140,235</u> | <u>14,097</u> |
| EQUITY: | | |
| Ordinary shares | 1,025 | 962 |
| Additional paid-in capital | 284,806 | 267,403 |
| Accumulated deficit | (257,085) | (208,363) |
| TOTAL EQUITY | <u>28,746</u> | <u>60,002</u> |
| TOTAL LIABILITIES AND EQUITY | <u><u>168,981</u></u> | <u><u>74,099</u></u> |

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(Unaudited)

| | Three Months Ended | | Nine Months Ended | |
|--|---------------------------|-----------------------|--------------------------|------------------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| U.S. dollars in thousands | | | | |
| OPERATING ACTIVITIES: | | | | |
| Comprehensive loss | (18,638) | (9,835) | (51,842) | (30,613) |
| Adjustments in respect of income and expenses not involving cash flow: | | | | |
| Share-based compensation to employees and service providers | 1,695 | 782 | 3,120 | 2,278 |
| Depreciation | 470 | 288 | 1,237 | 744 |
| Amortization and impairment of intangible assets | 2,109 | — | 4,958 | — |
| Unpaid interest expenses related to borrowing and payable in respect of intangible assets purchase | 2,039 | — | 3,656 | — |
| Fair value adjustments on derivative financial instruments | — | (5) | — | (336) |
| Fair value losses (gains) on financial assets at fair value through profit or loss | 31 | 14 | 68 | (73) |
| Exchange differences and revaluation of bank deposits | 5 | 180 | (160) | 112 |
| | <u>6,349</u> | <u>1,259</u> | <u>12,879</u> | <u>2,725</u> |
| Changes in assets and liability items: | | | | |
| Decrease (increase) in trade receivables | 6,146 | 110 | (11,208) | 105 |
| Decrease (increase) in prepaid expenses and other receivables | 235 | (23) | (2,391) | (462) |
| Increase in inventories | (350) | (135) | (3,218) | (1,192) |
| Increase (decrease) in accounts payable | 1,261 | 51 | 2,385 | 1,470 |
| Increase (decrease) in accrued expenses and other current liabilities | (4,174) | (321) | 17,521 | 1,087 |
| | <u>3,118</u> | <u>(318)</u> | <u>3,089</u> | <u>1,008</u> |
| Net cash used in operating activities | <u>(9,171)</u> | <u>(8,894)</u> | <u>(35,874)</u> | <u>(26,880)</u> |
| INVESTING ACTIVITIES: | | | | |
| Purchase of fixed assets | (166) | (1) | (357) | (135) |
| Purchase of intangible assets | (735) | — | (53,368) | — |
| Change in investment in current bank deposits | — | 6,000 | 4,200 | 4,931 |
| Purchase of financial assets at fair value through profit or loss | — | (9) | — | (2,584) |
| Proceeds from sale of financial assets at fair value through profit or loss | 2,075 | 5,748 | 6,025 | 7,848 |
| Net cash provided by (used in) investing activities | <u>1,174</u> | <u>11,738</u> | <u>(43,500)</u> | <u>10,060</u> |
| FINANCING ACTIVITIES: | | | | |
| Proceeds from issuance of ordinary shares, net of issuance costs | 9,137 | — | 15,500 | — |
| Exercise of options into ordinary shares | 53 | — | 53 | — |
| Proceeds from long-term borrowings, net of transaction costs | (784) | — | 78,061 | — |
| Increase in restricted cash | — | — | (20,000) | — |
| Decrease in restricted cash | 4,000 | — | 4,000 | — |
| Payment of principal with respect to lease liabilities | (450) | (206) | (1,186) | (591) |
| Net cash provided by (used in) financing activities | <u>11,956</u> | <u>(206)</u> | <u>76,428</u> | <u>(591)</u> |
| INCREASE (DECREASE) IN CASH AND CASH | | | | |

| | | | | |
|--|---------------|---------------|---------------|---------------|
| EQUIVALENTS | 3,959 | 2,638 | (2,946) | (17,411) |
| EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS | (33) | 1 | 121 | 40 |
| BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | <u>22,272</u> | <u>8,995</u> | <u>29,023</u> | <u>29,005</u> |
| BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD | <u>26,198</u> | <u>11,634</u> | <u>26,198</u> | <u>11,634</u> |
| SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH | <u>71</u> | <u>284</u> | <u>320</u> | <u>609</u> |
| SUPPLEMENTARY INFORMATION ON INTEREST PAID IN CASH | <u>2,147</u> | <u>48</u> | <u>4,507</u> | <u>71</u> |
| SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING AND FINANCING ACTIVITIES: | | | | |
| Acquisition of right-of-use assets by means of lease liabilities | <u>533</u> | <u>—</u> | <u>2,738</u> | <u>2,681</u> |
| Purchase of intangible assets posted as payable | <u>12,511</u> | <u>—</u> | <u>24,619</u> | <u>—</u> |
| Purchase of an intangible asset in consideration for issuance of shares | <u>1,914</u> | <u>—</u> | <u>1,914</u> | <u>—</u> |

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

²Including cash, short-term investments (bank deposits and financial assets at fair value) and restricted cash.

³Movantik[®] (naloxegol) is indicated for opioid-induced constipation (OIC). Full prescribing information see: www.movantik.com.

⁴Talicia[®] (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of *H. pylori* infection in adults. For full prescribing information see: www.Talicia.com.

⁵Opaganib (ABC294640, Yeliva[®]) is an investigational new drug, not available for commercial distribution.

⁶The article was authored by Ramzi Kurd, MD, Shaare-Zedek Medical Center; Eli Ben-Chetrit, MD, Shaare-Zedek Medical Center and Hebrew University Faculty of Medicine; Hani Karamah MD, Shaare-Zedek Medical Center and Maskit Bar-Meir, MD, Shaare-Zedek Medical Center and Hebrew University Faculty of Medicine. See full text here: <https://www.medrxiv.org/content/10.1101/2020.06.20.20099010v1?rss=1>.

⁷RHB-107 (upamostat) is an investigational new drug, not available for commercial distribution.

⁸Full prescribing information for Movantik[®] (naloxegol) is available at: www.Movantik.com.

⁹Full prescribing information for Talicia[®] (omeprazole magnesium, amoxicillin and rifabutin) is available at: www.Talicia.com.

¹⁰Full prescribing information for Aemcolo[®] (rifamycin) is available at: www.Aemcolo.com.

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REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION
(UNAUDITED)
September 30, 2020

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

(UNAUDITED)

September 30, 2020

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REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------|------------------------------------|---------|
| | 2020 | 2019 | 2020 | 2019 |
| | U.S. dollars in thousands | | | |
| NET REVENUES | 20,943 | 1,401 | 42,898 | 4,701 |
| COST OF REVENUES | 10,337 | 629 | 26,240 | 1,471 |
| GROSS PROFIT | 10,606 | 772 | 16,658 | 3,230 |
| RESEARCH AND DEVELOPMENT EXPENSES, net | 4,323 | 2,799 | 10,302 | 15,143 |
| SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES | 13,414 | 4,892 | 32,384 | 12,175 |
| GENERAL AND ADMINISTRATIVE EXPENSES | 7,329 | 2,925 | 17,948 | 7,349 |
| OPERATING LOSS | 14,460 | 9,844 | 43,976 | 31,437 |
| FINANCIAL INCOME | 42 | 170 | 339 | 1,075 |
| FINANCIAL EXPENSES | 4,220 | 161 | 8,205 | 251 |
| FINANCIAL EXPENSES (INCOME), net | 4,178 | (9) | 7,866 | (824) |
| LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD | 18,638 | 9,835 | 51,842 | 30,613 |
| LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars): | 0.05 | 0.03 | 0.14 | 0.11 |
| WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands) | 372,893 | 283,687 | 359,428 | 283,687 |

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

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

| | September 30, 2020 | December 31, 2019 |
|---|---------------------------|----------------------|
| | U.S. dollars in thousands | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | 26,198 | 29,023 |
| Bank deposits | 6,187 | 10,349 |
| Financial assets at fair value through profit or loss | 2,407 | 8,500 |
| Trade receivables | 12,424 | 1,216 |
| Prepaid expenses and other receivables | 4,635 | 2,244 |
| Inventory | 5,100 | 1,882 |
| | 56,951 | 53,214 |
| NON-CURRENT ASSETS: | | |
| Restricted cash | 16,153 | 152 |
| Fixed assets | 473 | 228 |
| Right-of-use assets | 5,448 | 3,578 |
| Intangible assets | 89,956 | 16,927 |
| | 112,030 | 20,885 |
| TOTAL ASSETS | 168,981 | 74,099 |
| CURRENT LIABILITIES: | | |
| Accounts payable | 6,569 | 4,184 |
| Lease liabilities | 1,546 | 834 |
| Accrued expenses and other current liabilities | 23,536 | 5,598 |
| | 31,651 | 10,616 |
| NON-CURRENT LIABILITIES: | | |
| Borrowing | 80,266 | — |
| Payable in respect of intangible assets purchase | 23,739 | — |
| Lease liabilities | 4,079 | 2,981 |
| Royalty obligation | 500 | 500 |
| | 108,584 | 3,481 |
| TOTAL LIABILITIES | 140,235 | 14,097 |
| EQUITY: | | |
| Ordinary shares | 1,025 | 962 |
| Additional paid-in capital | 284,806 | 267,403 |
| Accumulated deficit | (257,085) | (208,363) |
| TOTAL EQUITY | 28,746 | 60,002 |
| TOTAL LIABILITIES AND EQUITY | 168,981 | 74,099 |

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

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(Unaudited)

| | Ordinary shares | Additional paid-in capital | Accumulated deficit | Total equity |
|---|---------------------------|-------------------------------|------------------------|-----------------|
| | U.S. dollars in thousands | | | |
| BALANCE AT JULY 1, 2020 | 986 | 273,742 | (240,142) | 34,586 |
| CHANGES IN THE THREE-MONTHS PERIOD ENDED SEPTEMBER 30, 2020: | | | | |
| Share-based compensation to employees and service providers | — | — | 1,695 | 1,695 |
| Issuance of ordinary shares, net of expenses | 31 | 9,106 | — | 9,137 |
| Share-based payment in consideration for intangible assets | 8 | 1,906 | — | 1,914 |
| Exercise of options into ordinary shares | * | 52 | — | 52 |
| Comprehensive loss | — | — | (18,638) | (18,638) |
| BALANCE AT SEPTEMBER 30, 2020 | <u>1,025</u> | <u>284,806</u> | <u>(257,085)</u> | <u>28,746</u> |
| BALANCE AT JULY 1, 2019 | 767 | 219,505 | (188,368) | 31,904 |
| CHANGES IN THE THREE-MONTHS PERIOD ENDED SEPTEMBER 30, 2019: | | | | |
| Share-based compensation to employees and service providers | — | — | 782 | 782 |
| Comprehensive loss | — | — | (9,835) | (9,835) |
| BALANCE AT SEPTEMBER 30, 2019 | <u>767</u> | <u>219,505</u> | <u>(197,421)</u> | <u>22,851</u> |
| BALANCE AT JANUARY 1, 2020 | 962 | 267,403 | (208,363) | 60,002 |
| CHANGES IN THE NINE-MONTHS PERIOD ENDED SEPTEMBER 30, 2020: | | | | |
| Share-based compensation to employees and service providers | — | — | 3,120 | 3,120 |
| Issuance of ordinary shares, net of expenses | 55 | 15,445 | — | 15,500 |
| Share-based payment in consideration for intangible assets | 8 | 1,906 | — | 1,914 |
| Exercise of options into ordinary shares | * | 52 | — | 52 |
| Comprehensive loss | — | — | (51,842) | (51,842) |
| BALANCE AT SEPTEMBER 30, 2020 | <u>1,025</u> | <u>284,806</u> | <u>(257,085)</u> | <u>28,746</u> |
| BALANCE AT JANUARY 1, 2019 | 767 | 219,505 | (169,086) | 51,186 |
| CHANGES IN THE NINE-MONTHS PERIOD ENDED SEPTEMBER 30, 2019: | | | | |
| Share-based compensation to employees and service providers | — | — | 2,278 | 2,278 |
| Comprehensive loss | — | — | (30,613) | (30,613) |
| BALANCE AT SEPTEMBER 30, 2019 | <u>767</u> | <u>219,505</u> | <u>(197,421)</u> | <u>22,851</u> |

* Represents amounts less than \$1 thousand.

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

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|----------------|------------------------------------|-----------------|
| | 2020 | 2019 | 2020 | 2019 |
| U.S. dollars in thousands | | | | |
| OPERATING ACTIVITIES: | | | | |
| Comprehensive loss | (18,638) | (9,835) | (51,842) | (30,613) |
| Adjustments in respect of income and expenses not involving cash flow: | | | | |
| Share-based compensation to employees and service providers | 1,695 | 782 | 3,120 | 2,278 |
| Depreciation | 470 | 288 | 1,237 | 744 |
| Amortization and impairment of intangible assets | 2,109 | — | 4,958 | — |
| Unpaid interest expenses related to borrowing and payable in respect of intangible assets purchase | 2,039 | — | 3,656 | — |
| Fair value adjustments on derivative financial instruments | — | (5) | — | (336) |
| Fair value losses (gains) on financial assets at fair value through profit or loss | 31 | 14 | 68 | (73) |
| Exchange differences and revaluation of bank deposits | 5 | 180 | (160) | 112 |
| | <u>6,349</u> | <u>1,259</u> | <u>12,879</u> | <u>2,725</u> |
| Changes in assets and liability items: | | | | |
| Decrease (increase) in trade receivables | 6,146 | 110 | (11,208) | 105 |
| Decrease (increase) in prepaid expenses and other receivables | 235 | (23) | (2,391) | (462) |
| Increase in inventories | (350) | (135) | (3,218) | (1,192) |
| Increase (decrease) in accounts payable | 1,261 | 51 | 2,385 | 1,470 |
| Increase (decrease) in accrued expenses and other current liabilities | (4,174) | (321) | 17,521 | 1,087 |
| | <u>3,118</u> | <u>(318)</u> | <u>3,089</u> | <u>1,008</u> |
| Net cash used in operating activities | (9,171) | (8,894) | (35,874) | (26,880) |
| INVESTING ACTIVITIES: | | | | |
| Purchase of fixed assets | (166) | (1) | (357) | (135) |
| Purchase of intangible assets | (735) | — | (53,368) | — |
| Change in investment in current bank deposits | — | 6,000 | 4,200 | 4,931 |
| Purchase of financial assets at fair value through profit or loss | — | (9) | — | (2,584) |
| Proceeds from sale of financial assets at fair value through profit or loss | 2,075 | 5,748 | 6,025 | 7,848 |
| Net cash provided by (used in) investing activities | 1,174 | 11,738 | (43,500) | 10,060 |
| FINANCING ACTIVITIES: | | | | |
| Proceeds from issuance of ordinary shares, net of issuance costs | 9,137 | — | 15,500 | — |
| Exercise of options into ordinary shares | 53 | — | 53 | — |
| Proceeds from long-term borrowings, net of transaction costs | (784) | — | 78,061 | — |
| Increase in restricted cash | — | — | (20,000) | — |
| Decrease in restricted cash | 4,000 | — | 4,000 | — |
| Payment of principal with respect to lease liabilities | (450) | (206) | (1,186) | (591) |
| Net cash provided by (used in) financing activities | 11,956 | (206) | 76,428 | (591) |
| INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS | 3,959 | 2,638 | (2,946) | (17,411) |
| EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS | (33) | 1 | 121 | 40 |
| BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD | 22,272 | 8,995 | 29,023 | 29,005 |
| BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD | 26,198 | 11,634 | 26,198 | 11,634 |
| SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH | | | | |
| | 71 | 284 | 320 | 609 |
| SUPPLEMENTARY INFORMATION ON INTEREST PAID IN CASH | | | | |
| | 2,147 | 48 | 4,507 | 71 |
| SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING AND FINANCING ACTIVITIES: | | | | |
| Acquisition of right-of-use assets by means of lease liabilities | 533 | — | 2,738 | 2,681 |
| Purchase of intangible assets posted as payable | 12,511 | — | 24,619 | — |
| Purchase of an intangible asset in consideration for issuance of shares | 1,914 | — | 1,914 | — |

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

NOTE 1 - GENERAL:

a. General:

- 1) RedHill Biopharma Ltd. (the “Company”), incorporated in Israel on August 3, 2009, together with its wholly-owned subsidiary, RedHill Biopharma Inc. (“RedHill Inc.”), incorporated in Delaware, U.S. on January 19, 2017, is a specialty biopharmaceutical company primarily focused on gastrointestinal (“GI”) diseases and infectious diseases.

The Company’s ordinary shares were traded on the Tel-Aviv Stock Exchange (“TASE”) from February 2011 to February 2020, after which the Company voluntarily delisted from trading on the TASE, effective February 13, 2020. The Company’s American Depositary Shares (“ADSs”) were traded on the Nasdaq Capital Market from December 27, 2012 and have been listed on the Nasdaq Global Market (“Nasdaq”) since July 20, 2018.

The Company’s registered address is 21 Ha’arba’a St, Tel-Aviv, Israel.

- 2) Since the Company established its commercial presence in the U.S. in 2017, it has promoted or commercialized various GI-related products that were either developed internally, acquired through in-licensing or through co-promotion agreements. As of the date of approval of these financial statements, the Company commercializes in the U.S., Talicia[®], for the treatment of *Helicobacter pylori* infection in adults, which is the only product approved by the U.S. Food and Drug Administration (“FDA”) being developed internally by the Company, Movantik[®], for the treatment of opioid-induced constipation, and Aemcolo[®] (rifamycin), for traveler’s diarrhea.

On February 23, 2020, RedHill Inc. entered into an exclusive license agreement (the “License Agreement”) with AstraZeneca AB (“AstraZeneca”) pursuant to which AstraZeneca granted RedHill Inc. exclusive, worldwide (excluding Europe, Canada and Israel) commercialization and development rights to Movantik[®] (naloxegol). In addition, RedHill Inc. entered into a supply agreement (“Supply Agreement”) and a transitional services agreement (“TSA”) with AstraZeneca, pursuant to which AstraZeneca provides RedHill Inc. certain technology transfers and related materials for an agreed period to enable the Company to manufacture and distribute Movantik[®] through its own supply chain, as well as various other supporting services over certain agreed periods. On October 6, 2020, the parties amended the License Agreement to grant RedHill Inc. also the exclusive commercialization and development rights to Movantik[®] (naloxegol) in Israel. See note 3b below.

- 3) To date, the Company has out-licensed only one of its therapeutic candidates in an exclusive worldwide license agreement, which the Company decided to terminate, effective December 25, 2019, and has generated limited revenues from its commercial activities. Accordingly, there is no assurance that the Company’s business will generate sustainable positive cash flows. Through September 30, 2020, the Company has an accumulated deficit and its activities have been funded primarily through public and private offerings of the Company’s securities and borrowing. See note 3a below.

The Company plans to further fund its future operations through commercialization and out-licensing of its therapeutic candidates, commercialization of in-licensed or acquired products and raising additional capital through equity or debt financing or through non-dilutive financing. The Company’s current cash resources are not sufficient to complete the research and development of all of its therapeutic candidates and to fully support its commercial operations until generation of sustainable positive cash flows. Management expects that the Company will incur additional losses as it continues to focus its resources on advancing the development of its therapeutic candidates, as well as advancing its commercial operations, based on a prioritized plan that will result in negative cash flows from operating activities. The Company believes its existing capital resources should be sufficient to fund its current and planned operations for at least the next 12 months.

The current COVID-19 pandemic has presented substantial public health and economic challenges around the world and specifically in the Company's target markets in the U.S., affecting employees, patients, communities and business operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted at this stage. The Company took actions designed to mitigate the potential impact of the COVID-19 pandemic on its business operations and to date, the COVID-19 pandemic has not caused significant disruptions to the supply chain and the Company has sufficient supply on hand to meet U.S. commercial demand. A number of the Company's commercial activities have been impacted by the COVID-19 pandemic, including some launch sales and marketing activities for Talicia® for *H. pylori* infection and Aemcolo® for travelers' diarrhea. Although no major disruptions, other than manageable impact on its development and commercial activities, the Company continues to assess the potential impact of the COVID-19 pandemic on its business and operations, including on its sales, expenses, supply chain, financial resources and clinical trials. See also note 3d regarding the impairment test performed by the Company.

If the Company is unable to out-license, sell or commercialize its therapeutic candidates, generate sufficient and sustainable revenues from its commercial operations, or obtain future financing, the Company may be forced to delay, reduce the scope of, or eliminate one or more of its research and development or commercialization programs, any of which may have a material adverse effect on the Company's business, financial condition or results of operations.

b. Approval of the condensed consolidated interim financial statements:

These condensed consolidated interim financial statements were approved by the Board of Directors (the "BoD") on November 11, 2020.

NOTE 2 - BASIS OF PREPARATION OF THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS:

The Company's condensed consolidated interim financial statements for the three and nine months ended September 30, 2020 (the "Condensed Consolidated Interim Financial Statements"), have been prepared in accordance with International Accounting Standard IAS 34, "Interim Financial Reporting". These Condensed Consolidated Interim Financial Statements, that are unaudited, do not include all the information and disclosures that would otherwise be required in a complete set of annual financial statements and should be read in conjunction with the annual financial statements as of December 31, 2019, and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as published by the International Accounting Standards Board ("IASB"). The results of operations for the three and nine months ended September 30, 2020, are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

The accounting policies applied in the preparation of the Condensed Consolidated Interim Financial Statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2019.

NOTE 3 - SIGNIFICANT EVENTS DURING THE CURRENT REPORTING PERIOD:

a. Borrowing:

1. General

On February 23, 2020 (“Closing Date”) RedHill Inc. entered into a credit agreement and certain security documents (the “Credit Agreement”) with HCR Collateral Management, LLC (“HCRM”).

Under the terms of the Credit Agreement, RedHill Inc. received on March 12, 2020, a \$30 million term loan to support its commercial operations. On March 31, 2020, RedHill Inc. received an additional \$50 million term loan to fund the acquisition of rights to Movantik[®] from AstraZeneca.

For each quarter for the period from January 1, 2021 to December 31, 2029, HCRM will receive royalties of 4% of the Company’s worldwide net revenues, subject to a \$75 million cap per annum, as well as interest on the outstanding term loan to be computed as the 3-month LIBOR rate (“LIBOR”), subject to a 1.75% floor rate, plus 8.2% fixed rate, which will be decreased to 6.7% upon achievement of certain net revenue targets for the trailing four quarters ending March 31, 2021.

The term loans mature in six years with no principal payments required in the first three years. In case certain net revenue targets are not met, principal payments will be accelerated and commence following the two-year anniversary of the Closing Date. The term loans can be prepaid at RedHill Inc.’s discretion, subject to customary prepayment fees, which decrease over time. Upon the prepayment or repayment of all or any portion of the term loans, RedHill Inc. will pay HCRM 4% on the principal amount of the term loan being repaid or prepaid as an exit fee.

The borrowings under the Credit Agreement are secured by a first priority lien on substantially all of the current and future assets of RedHill Inc., all assets related in any material respect to Talicia[®], and all of the equity interests in RedHill Inc. The Credit Agreement also restricts the ability of RedHill Inc. to make certain payments, including paying dividends, to the Company prior to the full repayment of the term loan facility.

The Credit Agreement contains certain customary affirmative and negative covenants. The Credit Agreement also contains a financial covenant requiring RedHill Inc. to maintain a minimum level of cash, as well as a covenant requiring it to maintain minimum net sales, beginning with the fiscal quarter ending June 30, 2022. The minimum level of cash is relative to the amount borrowed under the term loan facility.

The Credit Agreement contains defined events of default, in certain cases subject to a grace period, following which the lenders may declare any outstanding principal and unpaid interest immediately due and payable.

As of September 30, 2020, the minimum level of cash, which relates to the term loans is \$16 million.

2. Accounting treatment

A financial liability is recognized for each tranche upon drawdown, at the amount drawn less transaction costs attributable to that tranche.

Upon initial recognition, the effective interest rate is calculated by estimating the future cash flows throughout the expected life of that tranche, taking into account the transaction costs allocated to each tranche. The Company determined that the basis of the royalty payments due to HCRM, the Company's worldwide net revenues, is a non-financial variable and specific to the Company.

Moreover, the royalty feature is an integral part of the terms and conditions of the term loans and cannot be transferred or settled separately from the term loan. Therefore, the royalties feature is not classified separately, does not meet the definition of a derivative, and is not measured separately. Instead, the royalty feature and other net revenues features are taken into account in estimating the effective interest rate.

Determining the weighted effective interest rate requires certain judgment related to the estimation of the timing and amounts of the Company's future worldwide net revenues.

The weighted effective interest rate on the Closing Date was approximately 16.5%.

Each tranche drawn down is subsequently measured at amortized cost. The effective interest rate is re-estimated at each interest rate determination date, as defined in the Credit Agreement, by updating per the LIBOR, if needed, taking into account the LIBOR floor (that is considered to be closely related to the host debt contract and is not separated from the host debt).

Furthermore, revisions to estimated amounts or timing of future cash flows, if needed, shall adjust the amortized cost of each tranche drawn down to reflect the present value of actual and revised estimated contractual cash flows, discounted using the original effective interest rate (adjusted for changes in the LIBOR, as described above). The adjustment will be recognized in profit or loss as a financial income or expense.

As described above, the Credit Agreement contains a financial covenant requiring the Company to maintain a level of cash liquidity, on any business day from the Closing Date to the maturity date, in accounts that are subject to HCRM's control. Therefore, the amounts of minimum cash and cash equivalents are excluded from cash and cash equivalents in the Statements of Financial Position and the Statements of Cash Flows. Instead, these amounts are presented as restricted cash in the Statements of Financial Position and the movements in this restricted cash are presented as financing activities in the Statements of Cash Flows. The minimum cash amounts are restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period and therefore are presented as non-current assets until 12 months prior to the term loan maturity dates.

b. Movantik® acquisition:

1. General

In connection with the agreements mentioned in note 1a(2) above, on April 1, 2020 (“Effective Date”), RedHill Inc. made an upfront payment of \$52.5 million to AstraZeneca, and the License Agreement, the Supply Agreement and the TSA became effective. Under the terms of the License Agreement, as amended on July 14, 2020, RedHill Inc. agreed to pay a further non-contingent payment of \$15.5 million in December 2021.

RedHill Inc. will also assume responsibility for sales-based royalty, currently at a rate of 20%, as well as sales-based potential milestone payments that AstraZeneca is required to pay to Nektar Therapeutics (“Nektar”), the originator of Movantik®. The Company considers the likelihood of having to pay the milestone payments or increased royalties as negligible.

In addition, AstraZeneca transferred on the Effective Date to RedHill Inc. a co-commercialization agreement with Daiichi Sankyo, Inc. (“DSI”) for Movantik® in the U.S, according to which, RedHill Inc. would share costs and pay sales-based payments to DSI under that agreement. Effective July 1, 2020, RedHill Inc. and DSI replaced this agreement with a new royalty-bearing agreement. See note 3c below.

Under the terms of the License Agreement, RedHill Inc. assumes responsibility over the Abbreviated New Drug Application litigations initiated by AstraZeneca and Nektar against Apotex, Inc. and Apotex Corp. (together “Apotex”) and against MSN Laboratories (“MSN”) in December 2018 and against Aurobindo Pharma U.S.A (“Aurobindo”) in November 2019, in the United States District Court for the District of Delaware. In the complaints, it is alleged that the generic companies’ versions of Movantik®, if approved and marketed, would infringe a Movantik®-related patent set to expire in April 2032 (U.S. Patent No. 9,012,469). There exist other Orange Book-listed patents covering Movantik®, the last of which to expire is U.S. Patent No. 7,786,133 (expected expiry in September 2028), which have not been challenged by the generic companies.

2. Accounting treatment

The Company accounted for the acquisition of rights to Movantik® as an asset acquisition, that does not constitute a business, for the following considerations:

- (a) The Supply Agreement provides RedHill Inc. with the ability to purchase finished products and materials from AstraZeneca during a transition period at approximately fair value, without acquiring AstraZeneca's organized workforce or existing processes required to manufacture Movantik®. That is, RedHill Inc. does not purchase an in-place manufacturing process nor any specialized equipment required for the manufacturing process, but instead, the purpose of the Supply Agreement is to enable RedHill Inc. to establish its own manufacturing capabilities, whether directly or through a third party, that would also require obtaining relevant regulatory approvals, which presumably will take a significant period of time.
- (b) The TSA is intended to allow a smooth transition of the different activities related to Movantik® for a relatively short period and is not intended for RedHill Inc. to acquire AstraZeneca's organized workforce, supply chain or distribution processes. The TSA has been terminated on September 30, 2020.

The total acquisition consideration, including upfront payment, discounted present value of the deferred payment and directly attributable transaction costs amounted to approximately \$65 million. Since all acquired assets are intended to generate revenues from sales of Movantik[®] and have a similar useful life, the Company attributed this consideration to a single intangible asset representing the acquired rights to Movantik[®]. The intangible asset shall be amortized commencing the Effective Date on a straight-line basis over its useful life, which was estimated at approximately 10.5 years from the Effective Date.

With respect to sales-based royalties and milestone payments aforementioned, the Company applied an accounting policy, pursuant to which these variable payments shall not be included in the initial measurement of the cost of the intangible asset acquired, as they are not a present obligation of RedHill Inc. The sales-based royalties are expensed as incurred and recognized under Cost of Revenues.

Through September 30, 2020, AstraZeneca provided, among other services, Sales Order-To-Cash (SOTC) services. During this period, AstraZeneca remitted to RedHill Inc. the Sales Margin, as defined in the TSA, for the products sold and RedHill Inc. paid a fee of 4.5% of Net Revenues, as well as non-sales-based fees and out-of-pocket costs for the services rendered. The Company determined that AstraZeneca does not control the product before it is transferred to the end customers (the wholesalers) since Redhill Inc. has the significant risks and rewards of holding the product rather than AstraZeneca. In addition, RedHill Inc. is primarily responsible for fulfilling the obligation to provide Movantik[®] to customers, including for acceptability. Moreover, RedHill Inc. bears the inventory risk and has discretion over pricing and discounts and AstraZeneca has limited ability in entering into new agreements with customers or changing commercial terms of existing agreements. Therefore, the Company concluded that RedHill Inc. is a principal in providing Movantik[®] during the SOTC period, and it will recognize revenues in the gross amount of consideration to which it expects to be entitled in exchange for the finished products transferred to the customers (the wholesalers). The fees and out-of-pocket costs shall be expensed as incurred.

c. DSI Agreement:

As described in note 3.b(1) above, as part of the Movantik transaction, the Company undertook the pre-existing co-commercialization agreement with DSI, under which the Company and DSI share certain costs while paying DSI a significant share from its sales volume of Movantik.

Effective July 1, 2020, RedHill Inc. and DSI replaced the co-commercialization agreement with a new royalty-bearing agreement, under which RedHill Inc. bears all responsibilities and costs for commercializing Movantik[®] in the U.S. During the term of this new agreement, RedHill Inc. will pay DSI a mid-teen royalty rate on net sales of Movantik[®] in the U.S. in addition to \$5.1 million in December 2021 and \$5 million in July of each of the years 2022 and 2023. Concurrently, the Company also entered into a security purchase agreement, under which DSI received 283,387 ADSs as a partial consideration in relation to Movantik[®].

The Company recognized an intangible asset in the amount of approximately \$12.5 million. This amount includes approximately \$10.5 million for the present value of the abovementioned payments, recognized against a corresponding financial liability and approximately \$2 million for the ADSs issued to DSI.

The intangible asset recognized has similar estimated useful life as the intangible asset discussed in note 3b(2) above and shall be amortized on a straight-line basis over its useful life.

d. Intangible assets impairment:

Following the outbreak of the COVID-19 pandemic and its significant impact on worldwide travel, the Company expects a continued decrease in U.S. outbound travel and the potential market for Aemcolo[®], for traveler's diarrhea, and therefore has recalculated the recoverable amount of the intangible asset related to Aemcolo[®]. During the three months ended March 31, 2020, the Company adjusted the recoverable amount to approximately \$10.5 million and recognized an impairment loss of \$0.8 million. The significant changes in assumptions are related to an expected decrease in the annual travelling incidence (a percentage of the U.S. population) from 2020 through 2023, as well as a change in the weighted average cost of capital ("WACC") used to discount the asset's cash flows from 15.4% as of December 31, 2019, to 17.2% as of the date of the recalculation on March 31, 2020. The impairment loss was recognized under Cost of Revenues in the Consolidated Statements of Comprehensive Loss, and it is attributable in full to the Commercial Operations segment. As there were no indicators for impairment of any of the other intangible assets, the Company did not specifically evaluate their recoverable amounts.

As of September 30, 2020, the Company reviewed if there is an indication of additional impairment of the Aemcolo[®] asset. The Company determined that there is no additional indication for impairment with respect to this asset related to the Aemcolo[®] product and therefore no additional assessment was required for this asset.

e. At-the-market equity offering program:

During the nine months ended September 30, 2020, the Company sold 1,892,782 ADSs under an "at-the-market" equity offering program ("ATM program") at an average price of \$8.39 per ADS. Net proceeds to the Company, following issuance expenses of approximately \$0.4 million, were approximately \$15.5 million. The sales are under the Company's sales agreement with SVB Leerink LLC ("Leerink") which provides that, upon the terms and subject to the conditions and limitations in the sales agreement, the Company may elect from time to time, to offer and sell its ADSs having aggregate gross sales proceeds of up to \$60 million through the ATM program, under which Leerink acts as the sales agent. The issuance and sale of ADSs by the Company under the ATM program are being made pursuant to the Company's shelf registration statement declared effective on July 31, 2018.

f. Payroll Protection Program:

In April 2020, RedHill Inc. received approximately \$2.3 million loan under the U.S. Small Business Administration Payroll Protection Program ("PPP") which was created under the Coronavirus Aid, Relief and Economic Security Act. The loan has a term of two years and bears a fixed interest rate of 1% per annum, with the initial six months of interest deferred. Under the PPP, repayment of the loan, including interest, may be forgiven based on payroll expenses, rent, utilities and other qualifying expenses incurred in the eight weeks following receipt of the loan, provided that RedHill Inc. will adhere to specific requirements outlined in the PPP. The Company estimates that there is reasonable assurance that RedHill Inc. will comply with the conditions associated with forgiveness of the loan and that the loan will be forgiven, and therefore accounted for the PPP loan as a government grant, recognizing it in the statements of comprehensive loss, as a reduction of operating expenses.

NOTE 4 - SHARE-BASED PAYMENTS:

The following is information on options granted during the nine months ended September 30, 2020:

| Date of grant | Number of options granted | | | Exercise price for 1 ADS (\$) | Fair value of options on date of grant in U.S. dollars in thousands (3) |
|----------------------|---|----------------------------|------------------|--------------------------------------|--|
| | According to the Award Plan of the Company | | | | |
| | Other than to directors (1) | To directors (1)(2) | Total | | |
| January 2020 | 95,000 | — | 95,000 | 6.56 | 243 |
| February 2020 | 52,500 | — | 52,500 | 6.05 | 119 |
| March 2020 | 285,000 | 144,000 | 429,000 | 4.87 | 970 |
| May 2020 | 143,000 | 75,000 | 218,000 | 6.84-7.84 | 831 |
| June 2020 | 767,500 | — | 767,500 | 7.72 | 2,671 |
| July 2020 | 12,500 | — | 12,500 | 7.69 | 45 |
| August 2020 | 55,500 | — | 55,500 | 8.31-9.19 | 264 |
| | <u>1,411,000</u> | <u>219,000</u> | <u>1,630,000</u> | | <u>5,143</u> |

- 1) The options will vest as follows: for directors, employees and consultants of the Company and the Company's subsidiary who had provided services exceeding one year as of the grant date, options will vest in 16 equal quarterly installments over a four-year period. For directors, employees and consultants of the Company and the Company's subsidiary who had not provided services exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over 12 equal quarterly installments. During the contractual term, the options will be exercisable, either in full or in part, from the vesting date until the end of 10 years from the date of grant.
- 2) The general meeting of the Company's shareholders held on May 4, 2020 (the "May 2020 AGM"), subsequent to approval of the Company's BoD, approved the grant of 219,000 options under the Company's stock options plan to directors and to the Company's Chief Executive Officer.
- 3) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: exercise price of the Company's ADS: \$4.87-\$9.19, expected volatility: 57.73%-62.90%, risk-free interest rate: 0.64%-1.51% and the expected term was derived based on the contractual term of the options, the expected exercise behavior and expected post-vesting forfeiture rates.
- 4) During the nine months ended September 30, 2020, the BoD approved a 3-year extension of the exercise period of fully vested options exercisable into the Company's ADS granted to employees and consultants that were originally scheduled to expire in March 2021, April 2021 and May 2021. Accordingly, options to purchase 300,500 ADSs were extended. The total incremental fair value of the options as of the date of the extension was approximately \$0.5 million and was recorded to the Statements of Comprehensive Loss immediately.

NOTE 5 - NET REVENUES:

| | Three Months Ended September 30, 2019 | | Nine Months Ended September 30, 2019 | |
|--------------------|--|--------------|---|--------------|
| | 2020 | 2019 | 2020 | 2019 |
| | U.S dollars in thousands | | U.S dollars in thousands | |
| Movantik® revenues | 19,396 | — | 39,347 | — |
| Other revenues (1) | 1,547 | 1,401 | 3,551 | 4,701 |
| | <u>20,943</u> | <u>1,401</u> | <u>42,898</u> | <u>4,701</u> |

- 1) For the three- and nine-month periods ended September 30, 2019, \$0.3 million and \$2.5 million, respectively, were attributed to the promotional services, and \$1 million and \$2.2 million, respectively, were attributed to commercialization of products. In 2020, the Company terminated the promotional agreements and recognized immaterial revenues from promotional services.

NOTE 6 - FINANCIAL INSTRUMENTS:

a. Fair value hierarchy:

The following table presents Company assets and liabilities measured at fair value:

| | Level 1 | Level 3 | Total |
|---|----------------------------------|----------------|--------------|
| | U.S. dollars in thousands | | |
| September 30, 2020: | | | |
| Assets - | | | |
| Financial assets at fair value through profit or loss | 2,407 | — | 2,407 |
| December 31, 2019: | | | |
| Assets - | | | |
| Financial assets at fair value through profit or loss | 8,500 | — | 8,500 |

During the three and nine months ended September 30, 2020, there were no transfers of financial assets and liabilities between Levels 1, 2, or 3 fair value measurements. There have been no changes in the methodologies used since December 31, 2019.

b. Fair value measurements using significant unobservable input (Level 3):

The following table presents the changes in derivative financial liabilities measured at Level 3 for the three and nine months ended September 30, 2020, and 2019:

| | Three Months Ended | | Nine Months Ended | |
|---|----------------------------------|-------------|--------------------------|-------------|
| | September 30, | | September 30, | |
| | 2020 | 2019 | 2020 | 2019 |
| | U.S. dollars in thousands | | | |
| Balance at beginning of period | — | 13 | — | 344 |
| Fair value adjustments recognized in profit or loss | — | (5) | — | (336) |
| Balance at end of the period | <u>—</u> | <u>8</u> | <u>—</u> | <u>8</u> |

The fair value of the above-mentioned derivative financial liabilities that are not traded in an active market is determined by using valuation techniques. The Company used its judgment to select a variety of methods and made assumptions that are mainly based on market conditions at the end of each reporting period.

- c. The carrying amount of cash equivalents, current and non-current bank deposits, receivables, account payables and accrued expenses approximate their fair value due to their short-term characteristics.

The present value of Payable in respect of intangible assets purchase is approximately the fair value of the liabilities as was recognized close to the end of the reporting period. The fair value of the borrowing is approximately \$79 million as of September 30, 2020.

NOTE 7 - SEGMENT INFORMATION:

The Company has two segments, Commercial Operations and Research and Development. The following table presents net revenues and operating loss for the Company's segments for the three and nine months ended September 30, 2020 and 2019:

| | <u>Three Months Ended September 30,</u> | | | <u>Nine Months Ended September 30,</u> | | |
|----------------|---|---------------------------------|---------------------|--|---------------------------------|---------------------|
| | <u>2020</u> | | | <u>2020</u> | | |
| | <u>Commercial Operations</u> | <u>Research and Development</u> | <u>Consolidated</u> | <u>Commercial Operations</u> | <u>Research and Development</u> | <u>Consolidated</u> |
| | <u>U.S. dollars in thousands</u> | | | <u>U.S. dollars in thousands</u> | | |
| Net revenues | 20,943 | — | 20,943 | 42,898 | — | 42,898 |
| Operating loss | 8,134 | 6,326 | 14,460 | 28,466 | 15,510 | 43,976 |

| | <u>Three Months Ended September 30,</u> | | | <u>Nine Months Ended September 30,</u> | | |
|----------------|---|---------------------------------|---------------------|--|---------------------------------|---------------------|
| | <u>2019</u> | | | <u>2019</u> | | |
| | <u>Commercial Operations</u> | <u>Research and Development</u> | <u>Consolidated</u> | <u>Commercial Operations</u> | <u>Research and Development</u> | <u>Consolidated</u> |
| | <u>U.S. dollars in thousands</u> | | | <u>U.S. dollars in thousands</u> | | |
| Net revenues | 1,401 | — | 1,401 | 4,701 | — | 4,701 |
| Operating loss | 5,100 | 4,744 | 9,844 | 10,971 | 20,466 | 31,437 |

NOTE 8 - COSMO PHARMACEUTICALS N.V. BINDING TERM SHEET:

On August 12, 2020, the Company entered into a binding term sheet with Cosmo Pharmaceuticals N.V. (“Cosmo”) with respect to an exclusive license agreement (the “Cosmo License Agreement”) and a manufacturing agreement for multiple products (the “Cosmo Supply Agreement”).

Under the Cosmo License Agreement, in return for the exclusive European rights to a novel next-generation therapy for the eradication of *H. pylori* infection (the “New Drug”) that the companies intend to co-develop, the parties agreed to a cost split of 70% RedHill and 30% Cosmo. In addition, Cosmo is expected to pay the Company an amount of \$7 million upon signing of the License agreement as well as additional \$2 million upon EU marketing approval. The Company is also expected to receive 30% royalties of net sales of the New Drug in Europe.

Upon execution of the proposed Cosmo Supply Agreement, Cosmo will be the exclusive worldwide manufacturer of the New Drug as well as of Movantik[®] and RHB-204 for pulmonary nontuberculous mycobacteria (NTM) infections (“RHB-204”). In consideration for Cosmo’s costs and expenses related to tech transfer, formulation and development work in respect of these three products, the Company is expected to pay Cosmo €5.5 million.

In addition, Cosmo is expected to pay RedHill \$5 million upon the signing of the Cosmo Supply Agreement, and potentially an additional \$7 million in two milestone payments upon the occurrence of events related to the RHB-204 development. In return, Cosmo will be entitled to 15% royalties of worldwide net sales of RHB-204.

As of the date of approval of these financial statements, the Company and Cosmo are in negotiations over the definitive agreements.

NOTE 9 - EVENT SUBSEQUENT TO SEPTEMBER 30, 2020:

Subsequent to September 30, 2020, and through November 11, 2020, the Company sold 240,614 ADSs under the ATM program at an average price of \$9.7 per ADS for aggregate net proceeds of approximately \$2.3 million, net of issuance expenses of approximately \$0.1 million.