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

May 2019
Commission File No.: 001-35773

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

21 Ha'arba'a Street, Tel Aviv, 64739, 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 Reports First Quarter 2019 Financial Results and Business Highlights*".

Exhibit 2: Registrant's condensed consolidated interim unaudited financial information as of March 31, 2019 and for the three months then ended.

This Form 6-K and related exhibits are 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) and on May 23, 2018 (Registration No. 333-225122) and its Registration Statements on Form F-3 filed with the Securities and Exchange Commission on February 25, 2016 (Registration No. 333- 209702) and on July 23, 2018 (Registration No. 333-226278) .

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.
(Registrant)

Date: May 7, 2019

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

Exhibit 1

RedHill Biopharma Reports First Quarter 2019 Financial Results and Operational Highlights

Key Highlights and Upcoming Milestones:

- **NDA submitted to the FDA for Talicia® for *H. pylori* infection, with potential U.S. commercial launch in Q4/2019, assuming FDA approval**
- **FDA meeting planned for H2/2019 to discuss design of confirmatory Phase 3 study and path to potential approval for RHB-104 for Crohn's disease**
- **Initiation of pivotal Phase 3 study expected in H2/2019 with RHB-204 for first-line treatment of pulmonary nontuberculous mycobacteria (NTM) infections**
- **Net revenues of $1.7 million, an increase of 28% over previous quarter**
- **Debt-free balance sheet with $45.5 million in cash as of March 31, 2019, with quarterly cash burn at its lowest in two years**

TEL-AVIV, Israel and RALEIGH, N.C., May 07, 2019 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on gastrointestinal (GI) diseases, today reported its financial results and operational highlights for the quarter ended March 31, 2019.

"We had a productive quarter with Talicia leading up to the NDA submission to the FDA, announced earlier today. With potential NDA approval as early as the fourth quarter of this year, we have expanded our highly experienced commercial management team and are advancing the preparations for the potential U.S. launch of Talicia with our established sales-force," **said Micha Ben Chorin, RedHill's chief financial officer.** "As of March 31, 2019, we have maintained a cash position of $45.5 million with a debt-free balance sheet and continued decrease of our quarterly cash burn to its lowest level in two years."

Operational Highlights:

Talicia (RHB-105)[1] - Eradication of *H. pylori* Infection

RedHill submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Talicia for the treatment of *H. pylori* infection following positive results from two Phase 3 studies and a positive pre-NDA meeting with the FDA earlier this year. Talicia was granted Qualified Infectious Disease Product (QIDP) designation by the FDA, including eligibility for six-month priority review and an additional three years of market exclusivity on top of the standard five years, for a total of eight years of U.S. market exclusivity. Assuming FDA approval, RedHill plans to launch Talicia in the U.S. in the fourth quarter of 2019 with the Company's dedicated sales force.

RedHill announced in January 2019 that it had received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for an additional new patent covering Talicia. The patent was subsequently granted and is valid until at least 2034. This is the fifth patent covering Talicia in the U.S. RedHill also announced in March 2019 that the European Patent Office (EPO) and the Japan Patent Office (JPO) accepted pending patent applications covering Talicia for *H. pylori* infection. The Japanese patent was subsequently granted and is valid until 2034.

RHB-104 - Crohn's Disease

RedHill plans to meet with the FDA in the second half of 2019 to discuss the development path toward potential approval of RHB-104**,** including the design of a confirmatory Phase 3 study. This meeting follows the positive results from the first Phase 3 study with orally-administered RHB-104 for the treatment of Crohn's disease (MAP US study). The MAP US study successfully met both its primary endpoint and its key secondary endpoints and presented the broad benefit of RHB-104 as an add-on therapy to standard-of-care treatments for Crohn's disease, including anti-TNFs. RedHill continues to assess additional data from the positive study as it becomes available.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

RedHill plans to initiate a pivotal Phase 3 study with RHB-204 for the treatment of pulmonary NTM infections in the second half of

2019, subject to completion of the ongoing supportive non-clinical program and additional input from the FDA. The study is intended to assess the efficacy and safety of RHB-204 and potentially support its approval as a stand-alone, first-line treatment for pulmonary NTM infections caused by Mycobacterium avium complex (MAC).

BEKINDA® (RHB-102)[1] - Gastroenteritis and Gastritis and Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

RedHill is currently working toward a confirmatory Phase 3 study to support a potential NDA for BEKINDA® for acute gastroenteritis and gastritis. This study follows the successful completion of a first Phase 3 study with BEKINDA for acute gastroenteritis and gastritis and guidance provided by the FDA.

RedHill held a positive end-of-Phase 2 Type B meeting with the FDA to discuss the clinical and regulatory pathway toward potential U.S. approval of BEKINDA for the treatment of IBS-D. RedHill is currently finalizing the design of two pivotal Phase 3 studies with BEKINDA for IBS-D.

YELIVA® (opaganib, ABC294640)[1] - Cholangiocarcinoma

The ongoing Phase 2a study evaluating the activity of orally-administered YELIVA in advanced cholangiocarcinoma (bile duct cancer) continues to enroll patients in the second stage of the two-stage study design. Enrollment of the full cohort of 39 evaluable patients is expected to be completed by the end of 2019.

Commercial Highlights:

RedHill is continuing its preparations for the potential U.S. launch of Talicia in the fourth quarter of 2019 with its dedicated sales force. RedHill currently commercializes and promotes several GI-specialty products in select U.S. territories, including Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide)[2], EnteraGam® (serum-derived bovine immunoglobulin/protein isolate SBI)[3] and Mytesi® (crofelemer 125 mg delayed-release tablets)[4].

Financial highlights for the quarter ended March 31, 2019[5]

- ***Net Revenues*** of $1.7 million in the first quarter of 2019, an increase of 28% compared to the fourth quarter of 2018. The growth was attributable to an increase in revenues from promoted products.
- ***Gross Profit*** of $1.3 million in the first quarter of 2019, compared to $0.8 million in the fourth quarter of 2018, with gross margin increased from 57% to 76%. The growth was attributable to an increase in revenues from promoted products.
- ***Research and Development Expenses*** of $5.4 million in the first quarter of 2019, compared to $5.8 million in the fourth quarter of 2018, resulting from the successful finalization of the confirmatory Phase 3 study with Talicia.
- ***Selling, Marketing and Business Development Expenses*** of $3.1 million in the first quarter of 2019, compared to $3.2 million in the fourth quarter of 2018.
- ***General and Administrative Expenses*** of $2.0 million in the first quarter of 2019, compared to $1.9 million in the fourth quarter of 2018.
- ***Operating Loss*** of $9.2 million in the first quarter of 2019, compared to $10 million in the fourth quarter of 2018. The decrease in Operating Loss was primarily due to the increase in Gross Profit and the decrease in Research and Development Expenses, as described above.
- ***Net Cash Used in Operating Activities*** of $7.5 million in the first quarter of 2019, compared to $8.2 million in the fourth quarter of 2018.
- ***Cash Balance***[6] as of March 31, 2019, was $45.5 million, compared to $53.2 million as of December 31, 2018.

Conference Call and Webcast Information:

The Company will host a conference call today, May 7, 2019, at 8:30 a.m. EDT to review the financial results and operational highlights. The conference call will be broadcast live on the Company's website, http://ir.redhillbio.com/events.

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-

866-966-1396, International: +1-631-510-7495 and Israel: +972-3-721-7998. The access code for the call is: 1777567. A replay of the webcast will be available for 30 days on the Company's website, http://ir.redhillbio.com/events.

About RedHill Biopharma Ltd.

RedHill Biopharma Ltd. (Nasdaq: RDHL) (Tel-Aviv Stock Exchange: RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S.: **Donnatal®** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam®** - a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi®** - an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. RedHill's key clinical late-stage development programs include: (i) **Talicia® (RHB-105)** for the treatment of *Helicobacter pylori* infection with a U.S. NDA submitted; (ii) **RHB-104,** with positive top-line results from a first Phase 3 study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA® (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; (v) **YELIVA® (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107,** a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its therapeutic candidates; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number of additional studies that the Company may be required to conduct and the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings, approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates; (v) the Company's ability to successfully commercialize and promote Donnatal®, EnteraGam®, Mytesi® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg; (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; and (xiv) competition from other companies and technologies within the Company's industry. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on February 26, 2019. 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.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
	U.S. dollars in thousands	
NET REVENUES	1,737	2,445
COST OF REVENUES	417	930
GROSS PROFIT	1,320	1,515
RESEARCH AND DEVELOPMENT EXPENSES, net	5,372	6,416
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,136	3,170
GENERAL AND ADMINISTRATIVE EXPENSES	2,025	1,924
OPERATING LOSS	9,213	9,995
FINANCIAL INCOME	374	134
FINANCIAL EXPENSES	1,031	74
FINANCIAL EXPENSES (INCOME), net	657	(60)
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	9,870	9,935
LOSS PER ORDINARY SHARE, basic and diluted (U.S. dollars)	0.03	0.05
WEIGHTED AVERAGE OF ORDINARY SHARES (in thousands)	283,687	213,192

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

	March 31, 2019	**December 31, 2018**
	Unaudited	**Audited**
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	23,014	29,005
Bank deposits	6,145	8,271
Financial assets at fair value through profit or loss	16,374	15,909
Trade receivables	1,419	958
Prepaid expenses and other receivables	1,243	1,876
Inventory	1,288	769
	49,483	56,788
NON-CURRENT ASSETS:		
Bank deposits	145	140
Fixed assets	146	163
Right-of-use assets	3,040	—

Intangible assets	5,320	5,320
	8,651	5,623
TOTAL ASSETS	58,134	62,411
CURRENT LIABILITIES:		
Accounts payable	4,413	3,324
Lease liabilities	713	—
Accrued expenses and other current liabilities	6,962	7,057
	12,088	10,381
NON-CURRENT LIABILITIES:		
Derivative financial instruments	1,317	344
Lease liabilities	2,354	—
Royalty obligation	500	500
	4,171	844
TOTAL LIABILITIES	16,259	11,225
EQUITY:		
Ordinary shares	767	767
Additional paid-in capital	219,505	219,505
Accumulated deficit	(178,397)	(169,086)
TOTAL EQUITY	41,875	51,186
TOTAL LIABILITIES AND EQUITY	58,134	62,411

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
	U.S. dollars in thousands	
OPERATING ACTIVITIES:		
Comprehensive loss	(9,870)	(9,935)
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	559	806
Depreciation	231	22
Fair value adjustments on derivative financial instruments	973	(50)
Fair value losses (gains) on financial assets at fair value through profit or loss	(52)	99
Revaluation of bank deposits	(10)	90
Exchange differences in respect of lease liabilities	5	—
Exchange differences in respect of cash and cash equivalents	(16)	14
	1,690	981
Changes in assets and liability items:		
Increase in trade receivables	(461)	(281)
Decrease in prepaid expenses and other receivables	633	1,271

Decrease (increase) in inventory	(519)	93
Increase (decrease) in accounts payable	1,089	(2,081)
Increase (decrease) in accrued expenses and other current liabilities	(95)	456
	647	(542)
Net cash used in operating activities	**(7,533)**	**(9,496)**
INVESTING ACTIVITIES:		
Purchase of fixed assets	(6)	(13)
Change in investment in current bank deposits	2,131	(131)
Purchase of financial assets at fair value through profit or loss	(633)	(1,046)
Proceeds from sale of financial assets at fair value through profit or loss	220	1,950
Net cash provided by investing activities	**1,712**	**760**
FINANCING ACTIVITIES:		
Exercise of options into ordinary shares	—	355
Principal elements of lease payments	(186)	—
Repayment of payable in respect of intangible asset purchase	—	(500)
Net cash used in financing activities	**(186)**	**(145)**
DECREASE IN CASH AND CASH EQUIVALENTS	(6,007)	(8,881)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	16	(14)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,005	16,455
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	23,014	7,560
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	163	267
SUPPLEMENTARY INFORMATION ON NON-CASH INVESTING ACTIVITIES		
Acquisition of right-of-use assets by means of lease liabilities	1,580	—

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[1] Talicia® (RHB-105), BEKINDA® (RHB-102) and YELIVA® (opaganib, ABC294640) are investigational new drugs, not available for commercial distribution.

[2] Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription drug, classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. For more information, please see the prescribing information: http://www.donnatal.com/wp-content/uploads/2015/02/2015-02-18-Risk-Benefit-information-DTC-REV.-SE.pdf.

[3] EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is a commercially-available medical food, intended for the dietary management of chronic diarrhea and loose stools due to specific intestinal disorders, which must be administered under medical supervision.

[4] Mytesi® (crofelemer 125 mg delayed-release tablets) is a first-in-class anti-secretory prescription drug approved by the U.S. FDA for the symptomatic relief of non-infectious diarrhea in adults with HIV/AIDS on anti-retroviral therapy. For more information, see the prescribing information: http://mytesi.com/assets/mytesi_package_insert_june_2016.pdf.

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

[6] Including cash and short-term investments (bank deposits and financial assets at fair value).

Exhibit 2

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

(UNAUDITED)

MARCH 31, 2019

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

(UNAUDITED)

MARCH 31, 2019

TABLE OF CONTENTS

REDHILL BIOPHARMA LTD.

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

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

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Accumulated deficit	(178,397)	(169,086)
TOTAL EQUITY	41,875	51,186
TOTAL LIABILITIES AND EQUITY	58,134	62,411

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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 JANUARY 1, 2019	767	219,505	(169,086)	51,186
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2019:				
Share-based compensation to employees and service providers	—	—	559	559
Comprehensive loss	—	—	(9,870)	(9,870)
BALANCE AT MARCH 31, 2019	767	219,505	(178,397)	41,875
BALANCE AT JANUARY 1, 2018	575	177,434	(132,944)	45,065
CHANGES IN THE THREE-MONTH PERIOD ENDED MARCH 31, 2018:				
Share-based compensation to employees and service providers	—	—	806	806
Exercise of options into ordinary shares	2	353	—	355
Comprehensive loss	—	—	(9,935)	(9,935)
BALANCE AT MARCH 31, 2018	577	177,787	(142,073)	36,291

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 March 31,	
	2019	2018
	U.S. dollars in thousands	
OPERATING ACTIVITIES:		
Comprehensive loss	(9,870)	(9,935)
Adjustments in respect of income and expenses not involving cash flow:		
Share-based compensation to employees and service providers	559	806
Depreciation	231	22
Fair value adjustments on derivative financial instruments	973	(50)
Fair value losses (gains) on financial assets at fair value through profit or loss	(52)	99
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The accompanying notes are an integral part of these condensed consolidated financial statements.

NOTE 1 - GENERAL:

a. General

RedHill Biopharma Ltd. (the "Company"), incorporated in Israel on August 3, 2009, together with its wholly-owned subsidiary, RedHill Biopharma Inc. (the "Subsidiary"), incorporated in Delaware, U.S. on January 19, 2017, is a specialty biopharmaceutical company, primarily focused on late-stage clinical development and commercialization of drugs for gastrointestinal ("GI") diseases.

The Company is primarily engaged in the research and development of its therapeutic candidates and, since January 2017, has pursued its commercial activities in the U.S. through its wholly-owned Subsidiary.

In February 2011, the Company listed its securities on the Tel-Aviv Stock Exchange ("TASE") and from December 2012 through July 2018, the Company's American Depositary Shares ("ADSs") were listed on the NASDAQ Capital Market. Since July 2018, the Company's ADSs have been listed on the NASDAQ Global Market ("NASDAQ").

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

To date the Company has out-licensed on an exclusive worldwide basis only one of its therapeutic candidates 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 March 31, 2019, the Company has an accumulated deficit, and its activities have been funded primarily through public and private offerings of the Company's securities.

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 may not be sufficient to complete the research and development of all or any of the Company's therapeutic candidates or to 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.

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 reputation, 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 May 6, 2019.

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

a. The Company's condensed consolidated interim financial statements for the three months ended March 31, 2019 (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, which 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, 2018 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 months ended March 31, 2019 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, 2018, except for the adoption of International Financing Reporting Standard No. 16 "Leases" ("IFRS 16"), effective from January 1, 2019, as set forth below.

b. The impact of the adoption of IFRS 16 and the new accounting policies that have been applied from January 1, 2019, are disclosed in note 3 below.

NOTE 3 – CHANGES IN ACCOUNTING POLICIES:

a. The Company has adopted IFRS 16 retrospectively from January 1, 2019, but has not restated comparative figures for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. The reclassifications and the adjustments arising from the new accounting rules are therefore recognized in the statement of financial position at the date of initial application.

b. On adoption of IFRS 16, the Company recognized lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 "Leases". These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of January 1, 2019. The weighted average of lessee's incremental annual borrowing rate applied to the lease liabilities on January 1, 2019, was 6.9%.

The lease liabilities recognized in the statement of financial position at the date of intial application were approximately $1.7 million, of which approximately $0.9 million were current lease liabilities and $0.8 million non-current lease liabilities. The associated right-of-use assets were measured at the amount equal to the lease liability and as a result, there was no impact on retained earnings on January 1, 2019.

On January 27, 2019, the Company signed an amendment to one of its leases, to extend the lease period for 7 years. As a result, the Company remeasured the lease liability by discounting the revised lease payments using a revised discount rate, which was the lessee's incremental borrowing rate at the effective date of the modification. The Company accounted for the remeasurement of the lease liability as an additional amount of approximately $1.6 million by making a corresponding adjustment to the right-of-use asset.

The recognized right-of-use assets as of January 1, 2019 and March 31, 2019 relate to the following types of assets: properties of approximately $1 million and approximately $2.5 million, respectivelty, and vehicles of $0.7 million and $0.5 million, respectively.

In applying IFRS 16 for the first time, the Company used the practical expedient permitted by the standard with regard to the accounting for operating leases with a remaining lease term of less than 12 months as of January 1, 2019, as short-term leases.

The Company has also elected not to reassess whether a contract is, or contains a lease at the date of initial application. Instead, for contracts entered into before the transition date, the Company relied on its assessment made by applying IAS 17 and IFRIC 4 to determining whether an arrangement contains a lease.

c. Through the end of the 2018 financial year, the leases of offices and cars by the Company and its Subsidiary were classified as operating leases and payments made were charged to profit or loss on a straight-line basis over the period of the lease.

From January 1, 2019, the leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Company. Each lease payment is allocated between the relative liability and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments: fixed payments (including in-substance fixed payments) and variable lease payments which are based on an index or a rate.

The lease payments are discounted using the lessee's incremental borrowing rate, being the rate that the lessee would have to pay to borrow the funds necessary to obtain an asset of similar value in a similar economic environment with similar terms and conditions.

Right-of-use assets are measured at cost, being the amount of the initial measurement of the lease liability.

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprised of IT-equipment and small items of office furniture.

NOTE 4 - SHARE-BASED PAYMENTS:

a. The following is information on options granted during the three months ended March 31, 2019:

	Number of options granted				
	According to the Award Plan of the Company				
Date of grant	Other than to directors (1)	To directors	Total	Exercise price for 1 ordinary share ($)	Fair value of options on date of grant in U.S. dollars in thousands (2)
February 2019	1,580,000	—	1,580,000	0.89	62

1) The options will vest as follows: for directors and employees of the Company and its 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 employees of the Company and its 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.

The options include both options exercisable into the Company's ordinary shares and options exercisable into the Company's ADSs.

2) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $0.78, expected volatility: 58.27%, risk-free interest rate: 2.67% and the expected term was derived based on the contractual term of the options, the expected exercise behavior and expected post-vesting forfeiture rates.

b. On December 27, 2018, the BoD approved a 3-year extension of the exercise period of fully-vested options exercisable into the Company's ordinary shares granted to a consultant that were originally scheduled to expire in February 2019. Accordingly, 400,000 options were extended with the new terms: the exercise price will increase by 50% to $1.08 per ordinary share, respectively, and will not be exercisable within one year of the extension. The total incremental fair value of the options as of the date of the extension was approximately $0.1 million and was recorded immediately to the Statements of Comprehensive Loss.

c. In February 2019, the BoD also approved a grant of options to a member of the BoD, serving as an employee of the Subsidiary, exercisable into 30,000 of the Company's ADSs (equivalent to 300,000 ordinary shares), on the same terms detailed in a(1) above. The grant is subject to the approval of a general meeting of the Comapny’s shareholders.

NOTE 5 - NET REVENUES:

	Three Months Ended March 31,	
	2019	**2018**
	U.S dollars in thousands	
Commercialization of product	594	1,618
Promotional services	1,143	827
Total Net Revenues	1,737	2,445

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		
March 31, 2019:			
Assets -			
Financial assets at fair value through profit or loss	16,374	—	16,374
Liabilities -			
Derivative financial instruments	—	1,317	1,317
December 31, 2018:			
Assets -			
Financial assets at fair value through profit or loss	15,909	—	15,909
Liabilities -			
Derivative financial instruments	—	344	344

During the three months ended March 31, 2019, there were no transfers of financial assets and liabilities between levels 1, 2 or 3 of fair value measurements. There have been no changes in the methodologies used since December 31, 2018.

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

The following table presents the change in derivative financial liabilities measured at level 3 for the three months ended March 31, 2019, and 2018:

	Three Months Ended March 31,	
	2019	2018
	U.S. dollars in thousands	
Balance at beginning of period	344	448
Fair value adjustments recognized in profit or loss	973	(50)
Balance at end of the period	1,317	398

The above-mentioned derivative financial liability represents warrants issued under the December 2016 offering with net settlement provision.

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

The fair value of the above-mentioned derivative financial liability is computed using the Black-Scholes option pricing model. The fair value of the derivative financial liability as of March 31, 2019, is based on the price of an ADS on March 31, 2019, and on the following key parameters: risk-free interest rate of 2.42% and an average standard deviation of 64.87%. The fair value of the derivative financial liability as of December 31, 2018, was based on the price of an ADS on December 31, 2018, and on the following key parameters: risk-free interest rate of 2.63% and an average standard deviation of 60.55%.

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.

NOTE 7 – SEGMENT INFORMATION

The Company has two segments, Commercial Operations and Research and Development. The following tables present net revenues and operating loss for the Company's segments for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31, 2019		
	Commercial Operations	Research and Development	Consolidated
	U.S. dollars in thousands		
Net revenues	1,737	—	1,737
Operating loss	2,267	6,946	9,213

	Three Months Ended March 31, 2018		
	Commercial Operations	Research and Development	Consolidated
	U.S. dollars in thousands		
Net revenues	2,445	—	2,445
Operating loss	2,095	7,900	9,995

NOTE 8 – EVENT SUBSEQUESNT TO MARCH 31, 2019:

On May 6, 2019, the BoD approved a grant of options to purchase 3,695,000 ordinary shares to employee, consultants and advisory board members of the Company, and options to purchase 199,500 ADSs to employees of the Company’s subsidiary, under the Company’s Award Plan. The estimated fair value of the options on the grant date was approximately $2.3 million.

On the same date, the BoD also approved, subject to the approval of a general meeting of the Comapny’s shareholders, a grant of options to purchase 1,500,000 ordinary shares and options to purchase 7,500 ADSs to the Company’s CEO and members of the BoD, under the Company’s Award Plan.