2017 Annual Report

11 March, 2018

Net revenues for 2017 totaled $4M, and met our expectations. We expect Redhill to raise capital in anticipation of its announcement of top-line Phase III results for Crohn's disease, expected in mid-2018; Price target raised to NIS 2.59

Primary Exchange: TASE

Secondary exchange: NASDAQ
(ADS/share 1:10)

Ticker: TASE, NASDAQ: RDHL

Sector: Biotechnology

Industry: Drug Development

Data as at 8 March, 2018
(Source: TASE)

Closing price: NIS 2.10

Market cap: NIS 447.6M

# of shares: 212.7M

Stock performance (Y.T.D.): -44%

Daily-trading-vol. (12 mos.): NIS 890M

Stock target price: NIS 2.59

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Company Overview

RedHill Biopharma Ltd. ("the Company" and/or "RedHill") is an Israeli publically-traded specialty biopharmaceutical company focused on the development and commercialization of late clinical-stage drugs candidates. The Company's main focus is advanced clinical development and commercialization in the US of orally-administered, proprietary, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer.

RedHill is currently promoting three gastrointestinal products and is advancing multiple clinical programs: three Phase III for gastrointestinal and inflammation indications and multiple Phase II for various indications including multiple myeloma, hepatocellular carcinoma, pancreatic cancer, and irritable bowel syndrome with diarrhea.

Highlights & Analysis

On 22 February 2017 RedHill released its Q4 and annual financial reports for 2017:

Net revenues of $2M and gross profit of $1.1M for Q4-2017, up 31% and 84%, respectively, over corresponding periods in 2016.

RedHill sales of GI drugs totaled approx. $1.5M for Q3-2017, $2M for Q4-2017, and $4M for the year 2017. We estimate 2018 quarterly revenues for RedHill's three GI drugs at $4M.

A debt-free balance sheet with $46.2M in cash at the end of 2017.

RHB-104: Phase III study for Crohn's Disease - top-line results expected mid-2018.

RedHill maintains a debt-free balance sheet with $46.4M in cash at 31 December 2017. Based on the current net burn rate, we assume RedHill will raise additional funds around Q3-2018 when top-line results for RHB-104 are expected.

TALICIA®: confirmatory Phase III study for H. pylori Infection - top-line results expected H2-2018. RHB-104: Initiation of pivotal Phase III study, a potential first-line treatment for nontuberculous mycobacteria (NTM) infections - expected mid-2018.

We evaluate the company's equity value at $159.8 million (NIS 551.6M) corresponding to a target price ranging between NIS 2.54 and NIS 2.65; a mean of NIS 2.59.

In our most recent valuation (14 December 2017), we decreased the company's equity value to $137.0M (NIS 485.0M) from $145.4M (NIS 514.7M) as per our Q3-2017 report (27 November 2017). The valuation of 13 December 2017 corresponded to a target price ranging between NIS 2.22 and NIS 2.33; a mean of NIS 2.27. Based on the company's financial results in 2017 which met our expectations, and its strong financial structure, and in light of its on track clinical development with top-line results for RHB-104 expected Q3-2018; the company's value has been raised.

Updates for Q4-2017

Q4-2017 Financial Results

Net Revenues for Q4-2017 were $2.0M, an increase of 31% from Q3-2017. Net Revenues for Q4-2016 were $0.1M, the substantial increase due to U.S. commercial operations which began in mid-2017.

Cost of Revenues for Q4-2017 were $0.9M, due to Cost of Goods Sold and royalties relating to commercialization activities. Cost of Revenues for Q3-2017 were $0.9M. There were no Cost of Revenues for Q4-2016.

Gross Profit for Q4-2017 was $1.1M, an increase of 84% from Q3-2017, primarily due to the increase in Net Revenues, as detailed above.

Research and Development Expenses for Q4-2017 were $7.5M. The increase from Q4-2016 was mainly due to the ongoing confirmatory Phase III study with TALICIA®2 for H. pylori infection.

Selling, Marketing and Business Development Expenses for Q4-2017 were $3.8M, a decrease of 8% from Q3-2017. The decrease was primarily due to a decrease in marketing material expenses. Selling, Marketing and Business Development Expenses for Q4-2016 were $0.4M. The Company recognized selling and marketing expenses for the first time in 2017 due to the establishment and advancement of the Company's U.S. commercial operations.

General and Administrative (G&A) Expenses for Q4-2017 were $2.5M, an increase of 11% from Q3-2017. G&A Expenses for Q4-2016 were $1.2M. The increase from the comparable periods was mainly due to the establishment and advancement of the Company's U.S. commercial operations.

Operating Loss for Q4-2017 was $14.4M, compared to $9.0M in Q4-2016. The increase was mainly due to the establishment of the company's U.S. commercial operations.

Financial Income, net for Q4-2017 was $4.0M, compared to $0.6M for Q4-2016. The increase was mainly due to a fair value gain on derivative financial instruments resulting from a decrease in the valuation of non-tradeable warrants, accounted as non-current liabilities. Net Cash Used in Operating Activities for Q4-2017 was $14.2M, up 39%, compared to $10.2M in Q4-2016. The increase was a direct result of the increase in operating loss, as detailed above.

2017 Annual Financial Results

Net Revenues for 2017 were $4.0M, compared to $0.1M for 2016. The increase was due to the initiation of the company's U.S. commercial operations in mid-2017.

Cost of Revenues for 2017 were $2.1M, due to Cost of Goods Sold and royalties relating to commercialization activities. There were no Cost of Revenues for 2016.

Gross Profit for 2017 was $1.9M, compared to $0.1M for 2016. The increase was due to the initiation of the company's U.S. commercial activities in mid-2017.

Research and Development Expenses for 2017 were $33.0M, compared to $25.2M for 2016. The increase was mainly due to the ongoing confirmatory Phase III study with TALICIA® and from the Phase I/II studies with YELIVA®.

Selling, Marketing and Business Development Expenses for 2017 were $12.0M, compared to $1.6M for 2016, which was comprised of business development expenses only.

General and Administrative Expenses for 2017 were approximately $8.0M, compared to $3.8M for 2016. The increase was mainly due to the establishment and advancement of the Company's U.S. commercial operations in 2017.

Operating Loss for 2017 was $52.0M, compared to $30.5M for 2016. The increase was due to additional research and development activities, as well as the establishment and advancement of the Company's U.S commercial operations in 2017, as detailed above.

Financial Income, net for 2017 was $6.4M, compared to $1.2M for 2016. The increase was mainly related to a fair value gain on derivative financial instruments. Net Cash Used in Operating Activities for 2017 was $44.8M, compared to $28.3M for 2016. The increase was a direct result of the increase in Operating Loss, as detailed above.

Cash Balance as at December 31, 2017 was $46.2M, a decrease of $20M, compared to $66.2M as at December 31, 2016, and an increase of $6.8M, compared to $39.4M as at September 30, 2017. The changes in the Cash Balance resulted mainly from Net Cash Provided by Financing Activities and Net Cash Used in Operating Activities.

N.B: RedHill announced a public offering of 4,090,909 American Depositary Shares ("ADS'") on 8 November 2017, at a price of $5.50 per ADS; **a discount of more than 30%** based on the average price in the days prior to the announcement. Gross proceeds from the sale of ADS' by RedHill before underwriting discounts and commissions and other offering expenses were approximately $22.5M.

R&D highlights:

TALICIA® (RHB-105) - H. pylori infection (confirmatory Phase III) (FDA Fast-Track QIDP status).

In June 2017, RedHill initiated a confirmatory Phase III study with TALICIA® (RHB-105) for H. pylori infection (ERADICATE Hp2 study). To date, approximately 50% of the planned 444 patients have been enrolled in the study. **Top-line results are expected in the second half of 2018.**

RHB-104 - Crohn's disease (Phase III).

In March 2017, RedHill initiated an open-label extension Phase III study to the MAP US study (MAP US2 study). RHB-104 - nontuberculous mycobacteria (NTM) infections (planned pivotal Phase III) (FDA Fast-Track QIDP status) RedHill plans, subject to further input from the U.S. Food & Drug Administration (FDA), to initiate in mid-2018 a pivotal Phase III study to assess the safety and efficacy of RHB-104 as potential first-line treatment for nontuberculous mycobacteria (NTM) infections caused by mycobacterium avium complex (MAC) infection.

In October 2017, RedHill announced that it had curtailed the target sample size in the MAP US study from 410 to approximately 331 subjects, while maintaining statistical power. In July 2017, RedHill reported, following a second pre-planned meeting by an independent Data and Safety Monitoring Board (DSMB) to assess safety and efficacy data from the MAP US study, that it had received a unanimous recommendation from the DSMB to continue with the study as planned.

In November 2017, RedHill completed enrollment of its first Phase III study with RHB-104 for Crohn's disease (MAP US study). **Top-line results are expected in mid-2018**.

BEKINDA® (RHB-102).

24 mg - Acute gastroenteritis and gastritis (Phase III)

In June 2017, RedHill announced positive results from the first Phase III study with BEKINDA® 24 mg for acute gastroenteritis and gastritis (GUARD study). The randomized, double-blind, placebo-controlled study successfully met its primary endpoint of efficacy and BEKINDA® 24 mg was found to be safe and well tolerated in this indication. RedHill met with the FDA to discuss the study results and the clinical and

regulatory path towards potential marketing approval of BEKINDA® 24 mg in the U.S. **Following the guidance provided at the meeting, RedHill is currently working with the FDA to design a confirmatory Phase III study to support a potential New Drug Application (NDA) with BEKINDA® 24 mg for acute gastroenteritis and gastritis.**

12 mg - IBS-D (Phase II)

In January 2018, RedHill announced positive final results from the Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). RedHill plans to meet with the FDA in the first half of 2018 to discuss plans for one or two pivotal Phase III studies with BEKINDA® 12 mg for IBS-D to support a potential NDA.

YELIVA® (ABC294640) – cholangiocarcinoma (bile duct cancer) (Phase IIa) (FDA Orphan Drug designation)

In December 2017, RedHill initiated a Phase IIa study with YELIVA®. The single-arm Phase IIa study is evaluating YELIVA® as a single agent in patients suffering from advanced, unresectable intrahepatic, perihilar and extrahepatic cholangiocarcinoma. The study is planned to enroll up to 39 patients at Mayo Clinic major campuses in Arizona and Minnesota and The University of Texas MD Anderson Cancer Center.

RHB-107 (MESUPRON) - gastrointestinal and other solid tumor cancers (Orphan Drug designation for pancreatic cancer)

In October 2017, RHB-107 (MESUPRON) was granted FDA Orphan Drug designation for the treatment of pancreatic cancer. The Orphan Drug designation allows RedHill to benefit from various incentives to develop RHB-107 for this indication, including a seven-year marketing exclusivity period for the indication, if approved. Following the recent identification of a new mechanism of action for RHB-107, inhibition of trypsin-3, **RedHill is currently evaluating potential utilization of RHB-107 in several gastrointestinal indications.**

Analysis

As part of RedHill's strategy to set the stage for the potential launch of its proprietary, late-clinical stage gastrointestinal products, if aand when approved by the FDA, the company established U.S. commercial operations in early 2017. RedHill's U.S. commercial operations, with offices in Raleigh, NC, include a gastrointestinal-focused sales force of approximately forty sales representatives. As part of this initiative, RedHill launched Donnatal® and EnteraGam® in June 2017, and Esomeprazole Strontium DR Capsules (49.3 mg) in September 2017. The company continues to pursue the acquisition of additional commercial gastrointestinal products in the U.S.

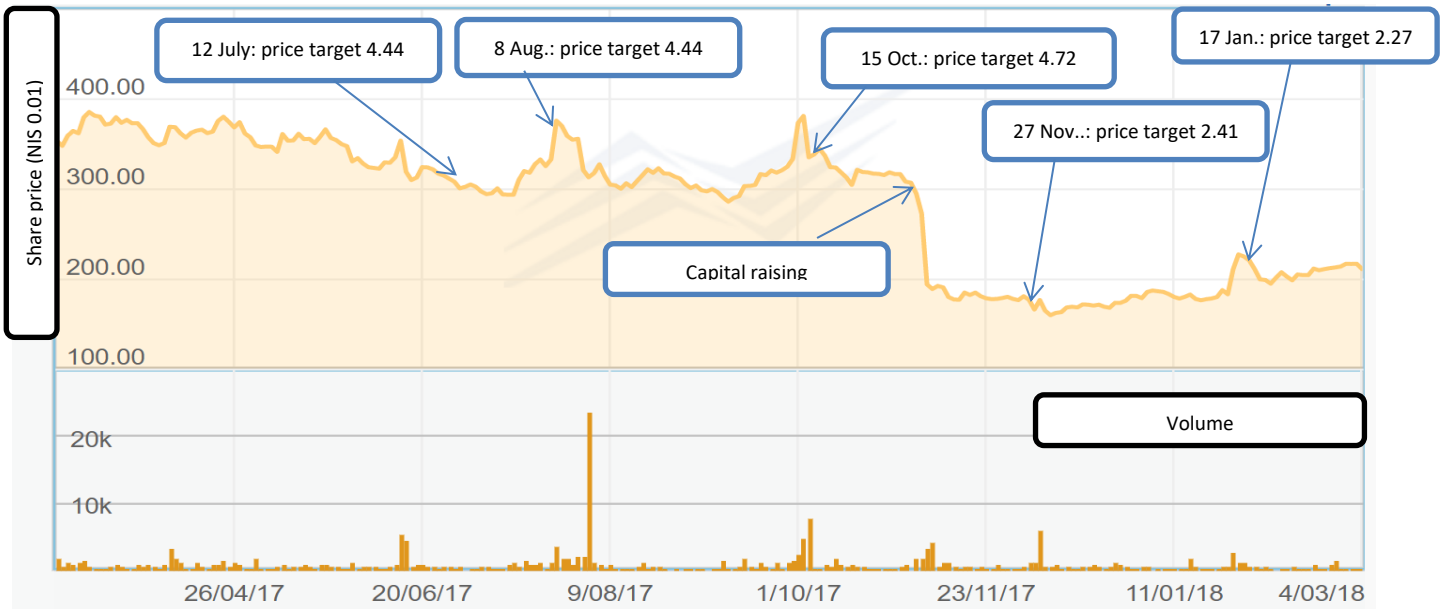
We addressed RedHill's new strategy in forming a sales force in the US in our initiation report of 12 July 2017. After years of successfully implementing a "standard" drug development strategy, with a business model based on licensing out its IP, the company has decided to expand its strategy and set up a sales organization in the US that will drive revenues from selling drugs.

Redhill sales of its GI drugs in Q3-2017 totaled approx. $1.5M; in Q4-2017, $2M and throughout 2017 $4M in sales were generated. Although the company is still expanding its sales force, as evident through high expenditure, it is worth examining the potential of future sales operations. Our data (based on the 'Orange book' which contains all drugs sales data) indicates, for example, that before Redhill was granted the rights for distribution of Donnatel, worldwide sales of this drug were $142M in 2015 and $139M in 2016, the majority of sales being in the US. We have also estimated, based on the same source, sales for the other two GI products for the upcoming years. We assume a 5% revenue share based on our assumptions, and the US share of the global market, i.e. **Redhill annual revenues are estimated at approximately $15.9M or approx. $4.0M per quarter, for 2018**.

Financially, RedHill maintains a debt-free balance sheet with $46.4M in cash at 31 December 2017. Based on the current net burn rate, **we assume Redhill will raise additional funds in the wake of its announcement of top-line results for RHB-104 due Q3-2018.**

In our most recent valuation (14 December 2017), we decreased the company's equity value to $137.0M (NIS 485.0M) from $145.4M (NIS 514.7M) as per our Q3-2017 report (27 November 2017). The valuation of 13 December 2017 corresponded to a target price ranging between NIS 2.22 and NIS 2.33; a mean of NIS 2.27. Based on the company's financial results in 2017 which met our expectations, and its strong financial structure, and in light of its on track clinical development with top-line results for RHB-104 expected Q3-2018; the company's value has been raised. **We evaluate the company's equity value at $159.8 million (NIS 551.6M) corresponding to a target price ranging between NIS 2.54 and NIS 2.65; a mean of NIS 2.59..**

Below is our year to date review of our analysis (source: TASE website):



Upcoming Potential Catalysts

Program	Event	Significance	Timeline	Update
BEKINDA® - RHB-102	Top-line Phase II results (IBS-D)	Medium	**Sep 2017**	**Achieved**
(gastroenteritis & IBS-D)	Top-line Phase III results (gastroenteritis)	Medium	**Mid-2017**	**Achieved**
	Clinical Study Report (CSR) from the successful Phase III study (gastroenteritis)	Medium	**Q3-2017**	**Achieved**
RHB-103 - RIZAPORT® (Migraine)	U.S. NDA re-submission	Low	**Oct 2017**	**Achieved**
RHB-104	Meeting with Data and Safety Monitoring Board	High	**Mid-2017**	**Achieved**
(Crohn's Disease)	Group for the MAP U.S. Phase III study for Crohn's disease including safety and interim efficacy analysis, with evaluation of option of early stop for success for overwhelming efficacy.			
	Top-line results MAP US Phase III ongoing	High	**Mid-2018**	On track
	Initiation of pivotal Phase III study for first line treatment of Nontuberculous Mycobacteria (NTM)	High	**Mid-2018**	On track
TALICIA™ (RHB-105)	Initiation of a confirmatory Phase III study for	Medium	**Mid-2017**	**Achieved**
(*H. pylori*)	treatment of *H. pylori* infection			
	Top-line Phase III results	High	**H2-2018**	On track
YELIVA®	Initiation of Phase Ib study to evaluate YELIVA® as a radioprotectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy	Medium	**Q3-2017**	**Achieved**
	Initiation of Phase IIa study with YELIVA® for cholangiocarcinoma	Medium	**Q3-2017**	**Achieved**
	Initiation of a Phase II study with YELIVA® for ulcerative colitis	Medium	**Q4-2017**	Delayed
MESUPRON	Initiation of Phase I/II study in Germany with MESUPRON for pancreatic cancer	Low	**H1-2018**	On track

Sources: Frost & Sullivan Analysis; RedHill.

Appendix

Appendix I - Financial Reports

Profit and Loss Statement as of 31 December 2017 (USD 000s)					
	2013	**2014**	**2015**	**2016**	**2017**
Total Revenues	**12**	**7,014**	**3**	**101**	**4,007**
Cost of Revenues	0	1,050	0	0	2,126
Net Revenues	**12**	**5,964**	**3**	**101**	**1,881**
Net R&D expenses	8,100	12,700	17,771	25,241	32,969
G&A expenses	2,684	4,011	4,134	5,403	8,025
Selling, Marketing and BD expenses	0	0	0	0	12,014
Other income	0	100		0	-
Other expenses	0	0	100	0	845
Operating loss	**10,772**	**10,647**	**22,002**	**30,543**	**51,972**
Financial income	158	319	1,124	1,548	6,505
Financial expenses	14	383	212	375	77
Other financial income (expenses), net	144	64	912	1,173	6,428
Loss and comprehensive loss	**10,628**	**10,711**	**21,090**	**29,370**	**45,544**

Balance Sheet as of 31 December 2017 (USD 000s)					
Current assets	**2013**	**2014**	**2015**	**2016**	**2017**
Cash and cash equivilents	11,851	5,892	21,516	53,786	16,455
Bank deposits	19	17,053	36,622	55	13,163
Financial assets at fair value through profit or loss	243	0	0	12,313	16,587
Prepaid expenses, receivables and inventory	488	3,074	2,372	1,661	5,471
Total current assets	**12,601**	**26,019**	**60,510**	**67,815**	**51,676**
Bank deposits	81	78	134	137	152
Fixed assets	103	146	124	165	230
Intangible assets	1,555	2,615	6,060	6,095	5,285
Total non-current assets	**1,739**	**2,839**	**6,318**	**6,397**	**5,667**
Total assets	**14,340**	**28,858**	**66,828**	**74,212**	**57,343**
Accounts payable and accrued expenses	2,415	1,720	3,514	3,356	10,830
Payable in respect of intangible asset purchase	0	0	2,000	2,000	1,000
Total current liabilities	**2,415**	**1,720**	**5,514**	**5,356**	**11,830**
Derivative financial instruments	0	2,125	1,237	6,155	448
Total non-current liabilities	**0**	**2,125**	**1,237**	**6,155**	**448**
Total Liabilities	**2,415**	**3,845**	**6,751**	**11,511**	**12,278**
Total Equity	**11,925**	**25,011**	**60,077**	**62,701**	**45,065**
Total liabilities and equity	**14,340**	**28,856**	**66,828**	**74,212**	**57,343**

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