

Quarterly Report

November 27, 2017

RedHill Biopharma Ltd.: Q3 results did not meet expectations mainly with GI drug sales; financially, capital raising of \$20.6M (NIS 1.94 per share) positions Redhill with sufficient funds until 2018.

Primary exchange: TASE

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

Symbol: TASE, NASDAQ: RDHL

Sector: Biotechnology

Sub-sector: Drug Development

Stock target price: NIS 2.41

As of 26 November, 2017

(source: TASE)

Closing price: NIS 1.77

Market cap: NIS 376.7M

of shares: 212.7M

Stock performance (YTD): -61%

Daily-trading-vol. (12 months):
NIS 1.2 million

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Company overview

RedHill Biopharma Ltd. ("the Company" and/or "RedHill") is an Israeli publicly-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

The company published its quarterly report on the 20th of November 2017, addressing few recent milestones and achievements:

- RedHill has no loans, with \$39.6 million in cash at the end of the third quarter of 2017. In addition, in an underwritten public offering of the Company's American Depositary Shares (ADSs, November 13, 2017), the company raised net proceeds of approximately \$20.6M (\$5.5 per 1 ADS).
- Net. revenues of approximately \$1.5 million in Q3/2017 from the promotion of three GI-specialty products in the U.S., Donnatal[®], EnteraGam[®] (launched in June) and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg (launched mid-September).
- Top-line results from the first Phase III study with RHB-104 for Crohn's disease (MAP US study) expected in mid-2018; patient enrollment completed.
- Top-line results from the confirmatory Phase III study with TALICIA[™] (RHB-105) (ERADICATE HP2 study) for the treatment of *H. pylori* infection, expected in H2/2018.
- Initiation of pivotal Phase III study with RHB-104 for first line treatment of Nontuberculous Mycobacteria (NTM) infections expected in H1/2018.
- Successful top-line results from the Phase II study with BEKINDA[®] (RHB-102) 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D).

Analysis

- We addressed RedHill's new strategy in forming a sales force in the US in our initiation report dated July 12th, 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.
- According to the company Q3 report, Redhill sales of its two GI drugs in the Q3 were \$1M, lower to our initial estimated \$3.5M. **Our assumptions were based on 10% revenue sharing from GI drug sales. The Company did not disclose detailed information on sales and revenues progress such as revenues per drug, revenue sharing models, number of customers, etc.**
- **We now assume that revenues for 2017 will be lower than was predicted by us and have modified the revenue models accordingly.**
- **Financially, RedHill maintains a debt-free balance sheet with \$39.6M cash at the end of the third quarter of 2017, with additional \$20.6M from its capital raising (total of \$60.2M).**
- **The company raised capital in a \$5.5 per 1 ADS (NIS 1.94 per share) at a discount. It is also worth mentioning that overall RedHill's share decreased at about 60% last month.**
- **Thus, upside remains, but we evaluate the company's equity value at \$145.4 million/NIS 511.8M (previously was \$214.1M/NIS 762.2M) ; and stock target price ranges between NIS 2.35-NIS 2.47 (a mean of NIS 2.41).**

Quarterly updates

Public offering

RedHill announced the closing underwritten public offering of 4,090,909 American Depositary Shares (“ADSs”), each representing ten of its ordinary shares, at a public offering price of \$5.50 per ADS. Gross proceeds from the sale of the ADSs by RedHill before underwriting discounts and commissions and other offering expenses were approximately \$22.5 million. RedHill has also granted the underwriters a 30-day option to purchase up to 613,636 additional ADSs at the public offering price.

Financial analysis of Q3 financial report

Financial highlights for the quarter ended September 30, 2017 Net Revenues for the third quarter of 2017 were approximately \$1.5 million, compared to \$0.5 million in the second quarter of 2017. The increase was due to the promotional activities of Donnatal^{®3} and the sale of EnteraGam^{®4} and the initial promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg⁵ in mid-September 2017.

Cost of Revenues for the third quarter of 2017 was \$0.9 million, due to the sale of EnteraGam[®], compared to \$0.3 million in the second quarter of 2017, also due to the sale of EnteraGam[®] and reflecting the cost of goods sold and royalties. Gross Profit for the third quarter of 2017 was \$0.6 million, compared to \$0.2 million in the second quarter of 2017. The increase was due to higher revenues from the sale of EnteraGam[®] and from the promotion of Donnatal[®] and due to the initial promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in mid-September 2017.

Research and Development Expenses for the third quarter of 2017 were \$8.1 million, an increase of \$1.1 million or 15% compared to the third quarter of 2016. The increase was mainly due to the ongoing confirmatory Phase III study with TALICIA[™] (RHB-105) for H. pylori infection, the Phase III and Phase II studies with BEKINDA[®] (RHB-102) for gastroenteritis and IBS-D, respectively, and the ongoing and planned studies with YELIVA[®] (ABC294640)⁷ for multiple indications. Research and Development Expenses for the third quarter of 2017 decreased by \$0.3 million or 4% compared to the second quarter of 2017.

General and Administrative Expenses for the third quarter of 2017 were \$2.3 million, an increase of \$1.2 million compared to the third quarter of 2016. General and Administrative Expenses for the third quarter of 2017 increased by \$0.3 million compared to the second quarter of 2017. The increase from the comparable periods was mainly due to the establishment and advancement of the Company’s U.S. commercial operations in the first quarter of 2017. Selling, Marketing and Business Development Expenses for the third quarter of 2017 were \$4.2 million, an increase of \$3.8 million compared to \$0.4 million in the third quarter of 2016, comprised only of Business Development Expenses. Selling, Marketing and Business Development Expenses for the third quarter of 2017 increased by \$0.8 million or 24% compared to the second quarter of 2017. The increase from the comparable periods was mainly due to the establishment and advancement of the Company’s U.S. commercial operations. The Company recognized Selling and Marketing Expenses in 2017 for the first time.

Operating Loss for the third quarter of 2017 was \$14 million, an increase of \$5.5 million or 65% compared to the third quarter of 2016. Operating Loss for the third quarter of 2017 increased by \$0.4 million or 3% compared to the second quarter of 2017. The increase from the comparable periods was mainly due to an increase in Selling, Marketing and Business Development Expenses, Research and Development Expenses, and General and Administrative Expenses, as detailed above. Financial Expenses, net for the third quarter of 2017 was \$1.5 million, an increase of \$1.1 million compared to the third quarter of 2016. Financial Income, net for the second quarter of 2017 was \$2.5 million. The

changes from the comparable periods were mainly due to variations in the fair value of the derivative financial instruments, which is affected by share price variations.

Net Cash Used in Operating Activities for the third quarter of 2017 was \$10.6 million, an increase of \$3.2 million or 43% compared to the third quarter of 2016. The increase was mainly due to the increase in Operating Loss.

Cash Balance as of September 30, 2017, was \$39.6 million, a decrease of \$26.7 million, compared to \$66.3 million as of December 31, 2016, and a decrease of \$11.6 million compared to June 30, 2017. The decrease was a result of the ongoing operations, mainly related to research and development activities and the establishment and advancement of the U.S. commercial operations.

Analysis

We addressed RedHill's new strategy in forming a sales force in the US in our initiation report dated July 12th, 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 two GI drugs in the Q3 were \$1M. Although the company still expanding its sales force as we can see in the expenses side, we have some concerns on its future sales. 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, sales were \$142M in 2015 and \$139M in 2016. We have assumed in our model similar sales with 10% revenues sharing based on our assumptions, i.e. Redhill annual revenues were estimated in approximately in \$14M or in other words a \$3.5M for one quarter.

We now assume that revenues for 2017 will be lower than was predicted by us and have modified the revenue models accordingly. Financially, RedHill maintains a debt-free balance sheet with \$39.6M cash at the end of the third quarter of 2017 with additional \$20.6M from its capital raising (total of \$60.2M). The company raised capital in a \$5.5 per 1 ADS (NIS 1.94 per share) at a discount. It is also worth mentioning that overall RedHill's share decreased at about 60% last month.

Thus, we evaluate the company's equity value at \$145.4 million/NIS 511.8M (previously was \$214.1M/NIS 762.2M); and a target price range of NIS 2.35-NIS 2.47 (a mean of NIS 2.41).

Upcoming Potential Catalysts

Program	Event	Significance	Timeline	Update
BEKINDA® - RHB-102 (gastroenteritis & IBS-D)	Top-line Phase II results (IBS-D)	Medium	Sep 2017	Achieved
	Top-line Phase III results (gastroenteritis)	Medium	Mid-2017	Achieved
	Clinical Study Report (CSR) from the successful Phase III study (gastroenteritis)	Medium	Q3 2017	
RHB-103 - RIZAPORT® (Migraine)	U.S. NDA re-submission	Low	Oct 2017	Achieved
RHB-104 (Crohn's Disease)	Meeting with Data and Safety Monitoring Board 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	High	Mid-2017	Achieved
	Op-line results MAP US Phase III ongoing		Q3/2018	
	Initiation of pivotal Phase III study for first line treatment of Nontuberculous Mycobacteria (NTM) infections		H1/2018	
TALICIA™ (RHB-105) (H. pylori)	Initiation of a confirmatory Phase III study for treatment of <i>H. pylori</i> infection	Medium	Mid-2017	Achieved
	Top-line Phase III results	High		Q4/2018
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	
	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	
MESUPRON	Initiation of Phase I/II study in Germany with MESUPRON for pancreatic cancer	Low	Q4 2017	

Source: Frost & Sullivan analysis

Appendix

Appendix - Financial Reports

Profit and Loss Statement

	In thousands \$					
	2013	2014	2015	2016	30.9.2016	30.9.2017
Total Revenues	12	7,014	3	101	1	2,006
Cost of Revenue	0	1,050	0	0	0	1,207
Net Revenue	12	5,964	3	101	0	799
Net Research and development expenses	8,100	12,700	17,771	25,241	17,745	24,677
General and administrative expenses	2,684	4,011	4,134	5,403	2,669	5,513
Selling, Marketing and BD expenses	0	0	0	0	1,137	8,170
Other income	0	100		0	0	-
Other expenses	0	0	100	0	0	45
Operating loss	10,772	10,647	22,002	30,543	21,551	37,606
Financial income	158	319	1,124	1,548	548	2,541
Financial expenses	14	383	212	375	17	66
Other financial income (expenses), net	144	64	912	1,173	531	2,475
Loss and comprehensive loss	10,628	10,711	21,090	29,370	21,020	35,131

Balance Sheet

	In thousands \$				
	2013	2014	2015	2016	30.9.2017
Current assets					
Cash and cash equivalents	11,851	5,892	21,516	53,786	18,663
Bank deposits	19	17,053	36,622	55	8,127
Financial assets at fair value through profit or loss	243	0	0	12,313	12,645
Prepaid expenses and receivables	488	3,074	2,372	1,661	4,380
Total current assets	12,601	26,019	60,510	67,815	43,815
Non-current assets					
Bank deposits	81	78	134	137	149
Fixed assets	103	146	124	165	250
Intangible assets	1,555	2,615	6,060	6,095	6,085
Total non-current assets	1,739	2,839	6,318	6,397	6,484
Total assets	14,340	28,858	66,828	74,212	50,299
Current liabilities					
Accounts payable and accrued expenses	2,415	1,720	3,514	3,356	11,031
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	12,031
Non-current liabilities					
Derivative financial instruments	0	2,125	1,237	6,155	4,307
Total non-current liabilities	0	2,125	1,237	6,155	4,307
Total Liabilities	2,415	3,845	6,751	11,511	16,338
Total Equity	11,925	25,011	60,077	62,701	33,961
Total liabilities and equity	14,340	28,856	66,828	74,212	50,299

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