

August 8th, 2017

RedHill Biopharma Ltd.: The Strategic Expansion and Clinical Progress are in line with the Company's plans. Stock Target Price Unchanged.

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

Highlights

- The company published its quarterly report on the 25th of July 2017 addressing few recent milestones and achievements:
 - Initial net revenues of approximately \$0.5 million, following commencement of promotional activities in the U.S. by RedHill's GI-focused sales force with two GI specialty products, Donnatal® and EnteraGam®.
 - Positive top-line results from the Phase III GUARD study with BEKINDA® (RHB-102) 24 mg for acute gastroenteritis and gastritis; Last patient out in the Phase II study with BEKINDA® 12 mg for IBS-D.
 - Initiation of the confirmatory Phase III study with TALICIA™ (RHB-105) for the treatment of *H. pylori* infection.
 - Announcement of a Unanimous Positive DSMB Recommendation for Continuation of the Phase III Study with RHB-104 for Crohn's Disease
 - Orphan Drug designation granted to YELIVA® for the treatment of cholangiocarcinoma
- Financially, RedHill maintains a debt-free balance sheet with \$51.2 million cash at the end of the second quarter of 2017.
- **RedHill has just begun selling both Donnatal and EnteraGam, but it's still too early to know the impact on continued growth of the company.**
- **RedHill's burn-rate and operating loss were already considered in our analysis dated July, 12th 2017.**
- **We assume the company will raise additional funds, based on current burn rate and clinical and operational plans by mid-2018.**
- **Thus, there is no change in the company's equity value (\$214.1 million/NIS 762.2); and in our target price range of NIS 4.36-NIS 4.52 (a mean of NIS 4.44).**
- Below is RedHill's current multiple clinical programs (Source: RedHill):

Product**		Indication	Pre-Clinical	Phase I/II	Phase III	NDA/Marketed
GI & Inflammation	Donnatal®	IBS and acute enterocolitis***	U.S. CO-PROMOTION			
	EnteraGam®	Chronic diarrhea and loose stools****	U.S. EXCLUSIVE LICENSE			
	TALICIA™ (RHB-105)	<i>H. pylori</i> infection	Successful first U.S. Phase III completed; Confirmatory U.S. Phase III ongoing			
	RHB-104	Crohn's disease	Phase III MAP US study and Phase III MAP US2 extension study are ongoing			
		Multiple sclerosis	Successfully completed Phase IIa study			
	BEKINDA® (RHB-102)	Gastroenteritis	Successful top-line results from Phase III U.S. study			
		IBS-D	Phase II U.S. study ongoing			
RHB-106	Bowel cleanser	Worldwide rights licensed to Salix Pharmaceuticals				
Oncology/GI Inflammation	YELIVA® (ABC294640)	Multiple indications	Multiple Phase I/II studies ongoing and planned			
	MESUPRON	Pancreatic cancer	Completed Phase II studies including in pancreatic cancer			
Other	RIZAPORT® (RHB-103)	Migraine	U.S. NDA filed - re-submission of NDA planned following CL			
			EUROPEAN MAA APPROVED UNDER THE EUROPEAN DECENTRALIZED PROCEDURE			

Closing price: NIS 3.14

Market cap: NIS 538.6 million

of shares: 171.6 million

Stock performance (YTD): -44%

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

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			EUROPEAN MAA APPROVED UNDER THE EUROPEAN DECENTRALIZED PROCEDURE			

Quarterly updates

RedHill has achieved scheduled milestones during the second quarter, including positive top-line results from the Phase III GUARD study with BEKINDA® 24 mg for acute gastroenteritis, initiation of the confirmatory Phase III study with TALICIA for the treatment of *H. pylori* infection, and the initiation of commercial activities in the U.S. by the company's sales force with Donnatal® and EnteraGam®, which generated initial net revenues of approximately \$0.5 million in the second half of June.

Financial analysis of Q2 financial report

The Net Revenues for the second quarter of 2017 were approximately \$0.5 million, compared to immaterial Net Revenues in the second quarter of 2016 and in the first quarter of 2017. The increase was due to the initiation of the U.S. promotional activities of Donnatal® and the sales of EnteraGam® in mid-June 2017.

The Cost of Revenues for the second quarter of 2017 was \$0.3 million, reflecting costs related to the initiation of the sale of the drugs. The Research and Development Expenses for the second quarter of 2017 were \$8.4 million, an increase of 40% compared to the second quarter of 2016. The increase was mainly due to the ongoing Phase III and Phase II studies with BEKINDA® (RHB-102) for gastroenteritis and IBS-D, respectively, the ongoing Phase III study with RHB-104 for Crohn's disease, the ongoing and planned studies with YELIVA® for multiple indications, and the initiation of the ongoing confirmatory Phase III study with TALICIA® (RHB-105) for *H. pylori* infection.

The General and Administrative Expenses for the second quarter of 2017 were \$1.9 million, an increase of \$1.2 million compared to the second quarter of 2016. General and Administrative Expenses for the second quarter of 2017 increased by \$0.6 million or 48% compared to the first 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 and enhanced professional services.

The Selling, Marketing, and Business Development Expenses for the second quarter of 2017 were \$3.4 million, an increase of \$3.0 million compared to \$0.4 million in the second quarter of 2016, comprised only of Business Development Expenses. The increase was mainly due to the establishment and advancement of the Company's U.S. commercial operations.

The Operating Loss for the second quarter of 2017 was \$13.5 million, an increase of \$6.3 million or 88% compared to the second quarter of 2016. The increase was mainly due to an increase in Research and Development Expenses and Selling, Marketing and Business Development Expenses, as detailed above. The Operating Loss for the second quarter of 2017 increased by \$3.4 million or 34% compared to the first quarter of 2017. The increase was mainly due to an increase in Selling, Marketing, and Business Development Expenses.

The Cash Balance as of June 30, 2017, was \$51.2 million, a decrease of \$15 million, compared to \$66 million as of December 31, 2016, and a decrease of \$10 million compared to March 31, 2017. The decrease was a result of the ongoing operations, mainly related to research and development activities and the establishment 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.

We believe that a successful implementation of this new strategy will result in RedHill having a sales platform for its future late-stage drug candidates. We evaluate this strategic turning point with high potential, positioning RedHill as a long-term investment, however, with a relative risk during the next coming years due to minimal sales experience in the “big pharma” playground and an unknown level of acceptance by physicians.

To wit, the Company’s quarterly data does not affect our target price, as no significant changes have occurred since initiation of coverage on July 12th. RedHill began selling both Donnatal and EnteraGam, but it is still too early to know the impact on the continued growth of the company. Also, RedHill's burn-rate and operating loss include in our analysis from the July 12th, 2017. We assume the company will raise additional funds, based on current burn rate and clinical and operational plans no later than mid-2018.

Thus, there is no change in the company’s equity value (\$214.1 million/NIS 762.2); and in our target price range of NIS 4.36-NIS 4.52 (a mean of NIS 4.44).

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	
	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	
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
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		2018/2019
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	
	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	31.3.2017	30.6.2017
Total Revenues	12	7,014	3	101	0	483
Cost of Revenue	0	1,050	0	0	0	272
Net Revenue	12	5,964	3	101	0	211
Net Research and development expenses	8,100	12,700	17,771	25,241	8,137	16,571
General and administrative expenses	2,684	4,011	4,134	5,403	1,315	3,255
Selling, Marketing and BD expenses	0	0	0	0	605	3,981
Other income	0	100		0	0	-
Other expenses	0	0	100	0	45	45
Operating loss	10,772	10,647	22,002	30,543	10,102	23,641
Financial income	158	319	1,124	1,548	1,556	4,078
Financial expenses	14	383	212	375	50	56
Other financial income (expenses), net	144	64	912	1,173	1,506	4,022
Loss and comprehensive loss	10,628	10,711	21,090	29,370	8,596	19,619

Balance Sheet

	In thousands \$					
	2013	2014	2015	2016	30.6.2017	
Current assets						
Cash and cash equivalents	11,851	5,892	21,516	53,786	15,319	
Bank deposits	19	17,053	36,622	55	15,407	
Financial assets at fair value through profit or loss	243	0	0	12,313	20,340	
Prepaid expenses and receivables	488	3,074	2,372	1,661	4,484	
Total current assets	12,601	26,019	60,510	67,815	55,550	
Non-current assets						
Bank deposits	81	78	134	137	150	
Fixed assets	103	146	124	165	235	
Intangible assets	1,555	2,615	6,060	6,095	6,050	
Total non-current assets	1,739	2,839	6,318	6,397	6,435	
Total assets	14,340	28,858	66,828	74,212	61,985	
Current liabilities						
Accounts payable and accrued expenses	2,415	1,720	3,514	3,356	8,560	
Payable in respect of intangible asset purchase	0	0	2,000	2,000	2,000	
Total current liabilities	2,415	1,720	5,514	5,356	10,560	
Non-current liabilities						
Derivative financial instruments	0	2,125	1,237	6,155	2,622	
Total non-current liabilities	0	2,125	1,237	6,155	2,622	
Total Liabilities	2,415	3,845	6,751	11,511	13,182	
Total Equity	11,925	25,011	60,077	62,701	48,803	
Total liabilities and equity	14,340	28,856	66,828	74,212	61,985	

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