EDISON

RedHill BioPharma

Company update

Successful Phase II with BEKINDA for IBS-D

Pharma & biotech

In October 2017, RedHill announced that one of its core assets, BEKINDA, significantly alleviated symptoms of patients with diarrhoea-predominant irritable bowel syndrome (IBS-D) in a Phase II trial. Although not comparable directly, the data look good in relation to two other recent drugs, Viberzi and Xifaxan, which had combined sales of $382m in 2016 after the launch in 2015 for this indication. We have increased our success probability for BEKINDA in IBS-D and now value RedHill at $449m or $21.1/ADS.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/15	0.0	(21.1)	(0.19)	0.0	N/A	N/A
12/16	0.1	(29.4)	(0.23)	0.0	N/A	N/A
12/17e	7.5	(47.4)	(0.25)	0.0	N/A	N/A
12/18e	30.0	(34.4)	(0.14)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

BEKINDA: Primary endpoint met in Phase II trial

BEKINDA (formerly RHB-102) is a once-daily, oral formulation of ondansetron. The Phase II trial was a randomised, two-arm study that enrolled 126 patients split 60:40 to receive either BEKINDA 12mg or a placebo for eight weeks. The primary endpoint was stool consistency compared to the baseline, as per the FDA guidance definition. 54.7% of patients in the active arm responded to treatment compared to 35.3% in the placebo group. This is a significant difference of 19.4% and compares well with other recent drugs approved for IBS-D – Viberzi (eluxadoline, Allergan) and Xifaxan (rifaximin, Valeant), for which the respective percentage rates were 13.5% and 10.5% (noting the limitations of making comparisons across different trials). Both Viberzi and Xifaxan were approved for IBS-D in 2015 and in 2016 had solid sales of $93m and $289m, respectively, in IBS-D (EvaluatePharma).

Two data readouts from Phase III trials in 2018

In 2018 all eyes will be on two Phase III data readouts. Top line results from the first Phase III trial RHB-104 for Crohn's disease (CD) are expected in mid-2018. The study is fully enrolled (n=331) as of November 2017. RHB-104 is a patented combination of three antibiotics (clarithromycin, rifabutin and clofazimine) in an oral capsule for the treatment of Crohn's disease patients. If proven effective, this could be a paradigm shifting treatment option in CD, in our view. A second set of top line data from confirmatory Phase III with TALICIA (RHB-105) for *H. pylori* infection is due in H218. TALICIA is a proprietary oral combination of two antibiotics (rifabutin and amoxicillin) and a proton pump inhibitor (omeprazole). In the first Phase III trial TALICIA achieved an 89.4% eradication rate meeting the primary endpoint of superiority over a 70% historical efficacy rate.

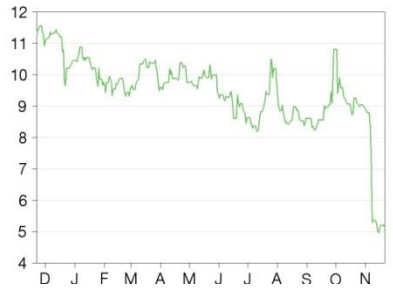
Valuation: Revised to $449m or $21.1/ADS

Our valuation increases to $449m from $414m (on a per share basis it decreases to $21.1/ADS due to share issue) mainly driven by the increased success probability for BEKINDA from 40% to 60% after the positive Phase II. Cash has improved after the share issue raised $20.6m net. Other near-term R&D events are the initiation of confirmatory Phase III with BEKINDA for gastroenteritis and the initiation of a Phase III trial with RHB-104 for nontuberculous mycobacteria infections (NTM).

27 November 2017

Price*	**US$5.16/ NIS1.84**
Market cap	**US$110m/ NIS392m**
*Priced at 22 November 2017	NIS3.57/US$
Net cash ($m) at end Q317 + proceeds of $20.6m net from share issue	60.2
Shares in issue	212.7m
Free float	90%
Code	RDHL
Primary exchange	TASE
Secondary exchange (ADS/share 1:10)	NASDAQ

Share price performance



%	1m	3m	12m
Abs	(44.9)	(42.4)	(55.3)
Rel (local)	(45.4)	(46.2)	(62.2)
52-week high/low	US$11.6	US$5.0	

Business description

RedHill BioPharma is a speciality pharma company with an R&D pipeline focusing on GI and inflammatory and gastrointestinal diseases, while earlier-stage assets also target various cancers. The most advanced products are RHB-105 for H. pylori infection, RHB-104 for Crohn's disease and NTM infections and BEKINDA for gastroenteritis and IBS-D. RedHill also promotes three GI products in the US.

Next events

Top line results from first Phase III trial with RHB-104 for Crohn's disease	Mid-2018
Top line results from confirmatory Phase III trial with TALICIA for *H. pylori*	H218
Initiation of pivotal Phase III trial with RHB-104 for NTM infections	H118

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Edison profile page

Financials and valuation

We have increased our RedHill valuation to $449m (NIS1.63bn) from $414m (NIS1.50bn). On a per share basis our valuation is reduced to $21.1/ADS (NIS7.7/share) from $24.1/ADS (NIS8.5/share) due to the share issue. The main reasons for the higher absolute valuation is the increase in success probability for BEKINDA in IBS-D from 40% to 60%, rolling our model forward, which was slightly offset by our lowered commercial GI product sales expectations for 2017.

RedHill raised approximately $20.6m net in November by issuing c 4.1m American Depositary Shares (ADS=10 shares; 24% of the previously outstanding share number). This extends cash reach into 2019, according to our model.

RedHill's reported Q317 sales of $1.5m are assumed to be mainly from the two marketed GI products EnteraGam and Donnatal ($0.5m booked in the last two weeks of June 2017), while marketing of Esomeprazole Strontium DR capsules 49.3mg began in September 2017. R&D costs were up by 15% to $8.1m y-o-y (down 4% q-o-q) due to ongoing late stage clinical studies. Q317 G&A and S&M combined expenses were $6.5m, up by $5.0m y-o-y mainly due to the new US commercial organisation. The Q317 operating loss was $14.0m versus $8.5m a year ago. As noted, the main reason for the increase in cash burn is the establishment of the US commercial business. RedHill has indicated that it expects cash burn to decrease going forward with the growing sales of the GI products.

We note that RedHill did not provide the split of the products behind the $1.5m in sales because they are still at an early stage of commercialisation. In our previous report we looked in detail at the potential of Donnatal and EnteraGam and described the assumptions on which we have included the two products in our model. Both products have been marketed by previous owners, therefore we see potential for a rapid sales build up. We forecast around $15m sales from both products in 2017, but noted that visibility was still low. Given the first full quarter of sales was $1.5m, we have cut our 2017 expectations to $7.5m also allowing room for the company's third product, Esomeprazole Strontium DR capsules 49.3mg. At present we keep our 2018 sales estimates intact. We have fine-tuned our other financial forecasts and now expect an operating loss of $49.8m in 2017 and $34.4m in 2018 compared to $41.4m and $32.5m previously.

Exhibit 1: RedHill sum-of-the parts valuation

Product	Launch	Peak sales ($m)	NPV ($m)	NPV/ADS ($)	Probability (%)	rNPV ($m)	rNPV/ADS ($)
RHB-105 – *H. pylori* infection	2021	86	93.5	4.4	70%	63.0	3.0
RHB-104 – Crohn's disease	2023	145	56.3	2.6	40%	14.1	0.7
– Multiple sclerosis	2025	422	204.4	9.6	20%	52.9	2.5
BEKINDA – Gastroenteritis	2019	21	37.9	1.8	85%	32.1	1.5
– IBS-D	2023	201	128.0	6.0	60%	88.2	4.2
YELIVA – r/r MM	2025	565	241.3	11.4	10%	49.1	2.3
– Advanced HCC	2025	649	135.9	6.4	10%	33.8	1.6
– DLBCL	2025	156	69.3	3.3	10%	18.4	0.9
Rizaport – Migraine	Market	20	12.2	0.6	100%	12.2	0.6
Donnatal & EnteraGam – specialty GI products	Market	51	24.6	1.2	100%	24.6	1.2
Net cash end Q217 (including other financial assets)			60.2		100%	60.2	2.8
Valuation			**1,063.4**	**47.2**		**448.5**	**21.1**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. IBS-D = irritable bowel syndrome; r/r MM = refractory/relapse multiple myeloma; advanced HCC = hepatocellular carcinoma; DLBCL = diffuse large B-cell lymphoma.

Exhibit 2: Financial summary

$'000s	2015	2016	2017e	2018e
December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	3	101	7,500	30,000
Cost of Sales	0	0	(4,550)	(9,100)
Gross Profit	3	101	2,950	20,900
Research and development	(17,771)	(25,241)	(34,254)	(30,931)
EBITDA	(21,866)	(30,499)	(49,725)	(34,166)
Operating Profit (before amort. and except.)	(22,002)	(30,543)	(49,804)	(34,386)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(22,002)	(30,543)	(49,804)	(34,386)
Net Interest	912	1,173	2,434	0
Profit Before Tax (norm)	(21,090)	(29,370)	(47,370)	(34,386)
Profit Before Tax (reported)	(21,090)	(29,370)	(47,370)	(34,386)
Tax	0	0	0	0
Profit After Tax (norm)	(21,090)	(29,370)	(47,370)	(34,386)
Profit After Tax (reported)	(21,090)	(29,370)	(47,370)	(34,386)
Average Number of Shares Outstanding (m)	110.8	128.5	190.4	253.6
EPS - normalised ($)	(0.19)	(0.23)	(0.25)	(0.14)
EPS - normalised & fully diluted ($)	(0.19)	(0.24)	(0.25)	(0.14)
EPS - (reported) ($)	(0.19)	(0.23)	(0.25)	(0.14)
Dividend per share ($)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	39.3	69.7
EBITDA Margin (%)	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A
BALANCE SHEET				
Fixed Assets	6,318	6,397	7,728	10,044
Intangible Assets	6,060	6,095	7,130	8,165
Tangible Assets	124	165	461	1,742
Investments	134	137	137	137
Current Assets	60,510	67,815	44,161	8,734
Stocks	0	0	250	250
Debtors	2,372	1,661	4,200	4,200
Cash	21,516	53,786	19,216	4,284
Other*	36,622	12,368	20,495	0
Current Liabilities	(5,514)	(5,356)	(9,979)	(9,574)
Creditors	(5,514)	(5,356)	(9,979)	(9,574)
Short term borrowings	0	0	0	0
Long Term Liabilities	(1,237)	(6,155)	(4,300)	(4,300)
Long term borrowings	0	0	0	0
Other long term liabilities	(1,237)	(6,155)	(4,300)	(4,300)
Net Assets	60,077	62,701	37,610	4,904
CASH FLOW				
Operating Cash Flow	(17,826)	(28,258)	(45,633)	(32,892)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(14)	(85)	(375)	(1,500)
Acquisitions/disposals	0	0	0	0
Financing	54,792	36,017	20,600	0
Other**	(21,328)	24,596	(9,162)	19,460
Dividends	0	0	0	0
Net Cash Flow	15,624	32,270	(34,570)	(14,932)
Opening net debt/(cash)	(5,892)	(21,516)	(53,786)	(19,216)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(21,516)	(53,786)	(19,216)	(4,284)

Source: RedHill's accounts, Edison Investment Research. Note: *Short-term investments. **Includes short-term investments converted to cash and cash equivalents.

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