EDISON

RedHill Biopharma

Q219 company results

TALICIA will dominate newsflow in H219

Pharma & biotech

RedHill's Q219 results released on 23 July 2019 described steady progress across its pipeline, with TALICIA the centre of attention as the PDUFA date (2 November 2019) approaches. Based on the data released, we assign a high likelihood of FDA approval due to the clean dataset from the Phase III trials. From a commercial perspective, RedHill also appears to be ready with a US team in operation since mid-2017. Although potential approval and launch of TALICIA will dominate H219 newsflow, other notable R&D developments include initiation of the pivotal Phase III trial with RHB-204 in NTM infections and a meeting with the FDA to discuss further development of RHB-104 in Crohn's disease. Our valuation is virtually unchanged.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/17	4.0	(45.5)	(0.26)	0.0	N/A	N/A
12/18	8.4	(38.8)	(0.17)	0.0	N/A	N/A
12/19e	10.0	(39.5)	(0.14)	0.0	N/A	N/A
12/20e	13.0	(36.8)	(0.13)	0.0	N/A	N/A

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

PDUFA date 2 November 2019

On 3 July 2019, RedHill announced that the FDA has accepted for review the new drug application (NDA) for TALICIA for the treatment of Helicobacter pylori infection. As TALICIA is a designated Qualified Infectious Disease Product (QIDP), the FDA also granted a priority review, which shortens the usual review time from the standard 10 months to six months. As a result, 2 November 2019 was set as the target Prescription Drug User Fee Act (PDUFA) date. Please see our previous reports for more detail on the market opportunity for TALICIA.

Slight opex increase to prepare for TALICIA launch

In Q219, revenues were $1.6m (Q119: $1.7m, Q218: $2.4m). 2018 was the first full year that RedHill promoted its speciality GI products, and there are therefore a limited number of data points on which to base our forecasts. Total 2018 sales were $8.4m and we keep our 2019 $10.0m sales forecast unchanged. RedHill maintained a high gross margin of 73% Q219. Operating loss of $12.4m increased from $9.2m in Q119, mainly due to the one-off PDUFA payment of $2.6m, expansion of its commercial team with several senior hires, as announced in May 2019, and further preparations for the potential commercial launch of TALICIA in the US in Q419. Cash and cash equivalents were $34.9m at the end of Q219, which currently cover activities into 2020 in our model (but exclude income from TALICIA).

Valuation: $518m or $18.3 per ADS

Our RedHill valuation is virtually unchanged at $518m or $18.3 per ADS, as we maintain the long-term valuation assumptions described in our previous reports. The updated lower cash position was offset by rolling our model forward (Exhibit 2). TALICIA's launch is the main catalyst this year, while the planned initiation of the pivotal Phase III study with RHB-204 for nontuberculous mycobacteria (NTM) infections in H219 is a notable R&D event.

30 July 2019

Price	**US$6.97**
Market cap	**US$198m**
	NIS3.60/US$
Net cash ($m) at end Q219	34.9
Shares in issue	283.7m
Free float	90%
Code	RDHL
Primary exchange	TASE
Secondary exchange (ADS 1:10)	NASDAQ

Share price performance

%	1m	3m	12m
Abs	4.2	(14.3)	(28.2)
Rel (local)	1.4	(16.5)	(33.0)
52-week high/low	US$9.35		US$5.18

Business description

RedHill is a speciality company with an R&D pipeline focusing on gastrointestinal (GI) and inflammatory diseases; earlier-stage assets also target various cancers. The most advanced products are TALICIA for *H. pylori* infection, RHB-104 for Crohn's disease (CD), RHB-204 for nontuberculous mycobacteria (NTM) infections and BEKINDA for gastroenteritis and IBS-D.

Next events

Expected FDA response on TALICIA's NDA	2 November
Initiation of pivotal Phase III trial with RHB-204 for NTM infections	Q419
FDA meetings to discuss Phase III trial with RHB-104 in CD	H219

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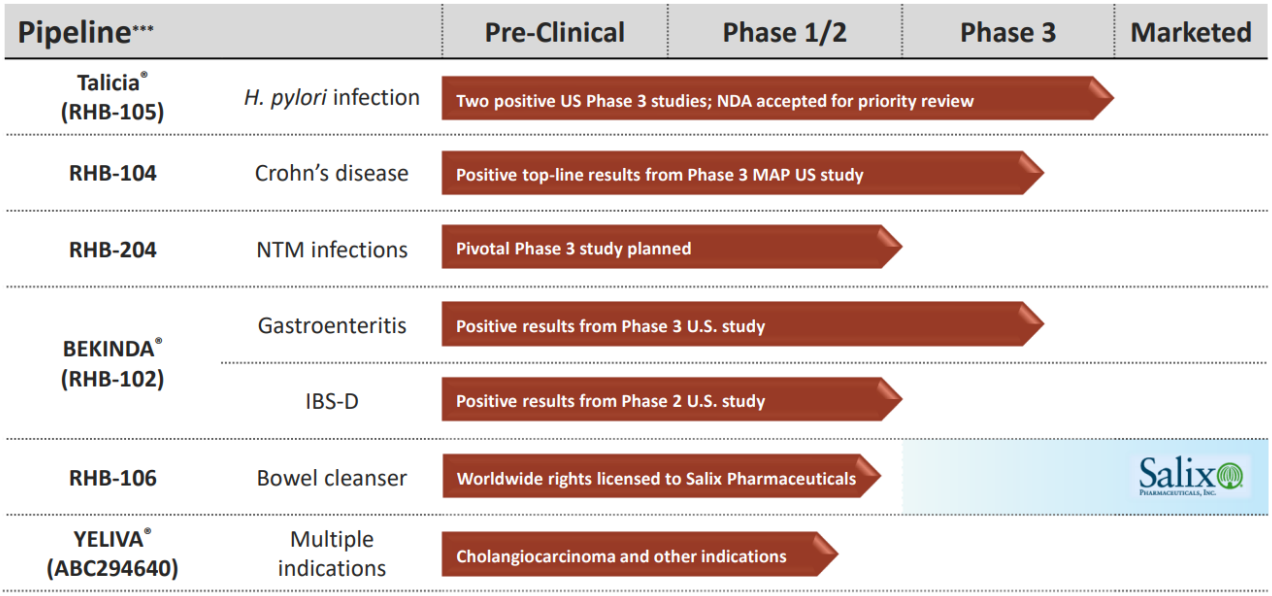
Edison profile page

Update on other R&D projects

RedHill's update on other R&D programmes described mostly steady progress across the pipeline:

- RedHill plans to meet the FDA in H219 to discuss further development of **RHB-104** (clarithromycin, rifabutin and clofazimine). Positive results from the first Phase III with RHB-104 for Crohn's disease were reported in August 2018 (details in our previous notes). The next likely step is a confirmatory Phase III trial.
- A pivotal Phase III trial with **RHB-204** (clarithromycin, clofazimine and rifabutin) for first-line pulmonary NTM infections is expected to start in Q419. This is still subject to completion of the 'ongoing supportive non-clinical program' and additional input from the FDA. The upcoming Phase III study could be sufficient for the approval of RHB-204 as a standalone, first-line treatment for pulmonary NTM infections caused by *Mycobacterium avium complex* (MAC). The NTM infections indication is the latest addition to RedHill's R&D pipeline and we reviewed the potential of RHB-204 for these difficult-to-diagnose and difficult-to-treat NTM infections in our outlook report. RHB-204 was also granted QIDP designation by the FDA for the treatment of NTM Infections, which should also include such benefits as priority review, fast-track designation and extended market exclusivity. RedHill provided some additional details about potential timelines during the analyst call Q&A session. The expected primary endpoint for accelerated approval should be six months of treatment, which will be followed with an additional treatment through 15 months. In the case of a successful outcome, the drug could be approved around end-2021, which makes it one of the lead programmes in the pipeline currently when it comes to time to market. Our model assumes approval process in 2022 and market launch in 2023 and is therefore more conservative than the preliminary indications from RedHill, but we will review it once the trial design is clear and enrolment starts.
- RedHill is also working on two indications for **BEKINDA** (bimodal extended release, once-daily, ondansetron) – acute gastroenteritis and diarrhoea-predominant irritable bowel syndrome (IBS-D). The company met with the FDA after the positive results from the first Phase III trial with BEKINDA for gastroenteritis and is now designing a confirmatory Phase III study in this indication. Similarly, RedHill is finalising the design of two pivotal Phase III studies with BEKINDA for IBS-D after a positive Phase II trial. No specific timelines have been provided.
- **YELIVA** (SK2 inhibitor) is undergoing a Phase IIa study in cholangiocarcinoma, with the study expected to be fully enrolled (n=39) by the end of 2019. In addition, YELIVA is being explored in two other investigator-led clinical trials in refractory/relapsed multiple myeloma and advanced hepatocellular carcinoma.

Exhibit 1: RedHill's R&D pipeline



** Estimated timeline/indication in the pipeline is subject to changes in development plans and regulatory requirements/clarifications, including complementary /additional studies ; ** For full prescribing information see: Donnatal: www.Donnatal.com; Mytesi: www.Mytesi.com ; EnteraGam® https://bit.ly/2N3q7DW; *** BEKINDA®, YELIVA® and Talicia® are proposed tradenames which are subject to FDA review and approval*

Source: RedHill Biopharma

Exhibit 2: Sum-of-the-parts RedHill valuation

Product	Launch	Peak sales ($m)	NPV ($m)	NPV/share ($)	Probability	rNPV ($m)	rNPV/share ($)
TALICIA, - *H. pylori* infection	2020	86	148.2	5.2	90%	133.1	4.7
RHB-104, - Crohn's disease	2023	145	82.4	2.9	50%	37.2	1.3
RHB -204, - NTM infections	2024	50	54.2	1.9	30%	14.5	0.5
BEKINDA, - Gastroenteritis	2022	21	33.6	1.2	85%	28.2	1.0
- IBS-D	2023	201	158.4	5.6	60%	115.8	4.1
YELIVA, - Cholangiocarcinoma	2024	115	185.5	6.5	10%	14.3	0.5
- r/r MM	2025	565	283.4	10.0	10%	72.5	2.6
- Advanced HCC	2025	649	170.8	6.0	10%	53.9	1.9
GI specialty products	Market	48	13.5	0.5	100%	13.5	0.5
Net cash (last reported)			34.9		100%	34.9	1.2
Valuation			**1,165.0**	**39.8**		**517.9**	**18.3**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. IBS-D = irritable bowel syndrome; r/r MM = refractory/relapsed multiple myeloma; HCC = hepatocellular carcinoma; NTM = nontuberculous mycobacteria.

Exhibit 3: Financial summary

$'000s	2016	2017	2018	2019e	2020e
December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	101	4,007	8,360	10,000	13,000
Cost of Sales	0	(2,126)	(2,837)	(3,500)	(4,550)
Gross Profit	101	1,881	5,523	6,500	8,450
Research and development	(25,241)	(32,969)	(24,862)	(22,684)	(22,976)
EBITDA	(30,499)	(51,891)	(39,241)	(39,451)	(36,732)
Operating Profit (before amort. and except.)	(30,543)	(51,972)	(39,331)	(39,545)	(36,831)
Intangible Amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other	0	0	0	0	0
Operating Profit	(30,543)	(51,972)	(39,331)	(39,545)	(36,831)
Net Interest	1,173	6,428	511	0	0
Profit Before Tax (norm)	(29,370)	(45,544)	(38,820)	(39,545)	(36,831)
Profit Before Tax (reported)	(29,370)	(45,544)	(38,820)	(39,545)	(36,831)
Tax	0	0	0	0	0
Profit After Tax (norm)	(29,370)	(45,544)	(38,820)	(39,545)	(36,831)
Profit After Tax (reported)	(29,370)	(45,544)	(38,820)	(39,545)	(36,831)
Average Number of Shares Outstanding (m)	128.5	176.6	231.2	283.8	284.1
EPS - normalised ($)	(0.23)	(0.26)	(0.17)	(0.14)	(0.13)
EPS - normalised fully diluted (c)	(24.00)	(25.79)	(16.79)	(13.93)	(12.97)
EPS - (reported) ($)	(0.23)	(0.26)	(0.17)	(0.14)	(0.13)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	46.9	66.1	65.0	65.0
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets	6,397	5,667	5,623	9,592	9,551
Intangible Assets	6,095	5,285	5,320	5,355	5,390
Tangible Assets	165	230	163	92	16
Investments	137	152	140	4,145	4,145
Current Assets	67,815	51,676	56,788	20,897	5,134
Stocks	0	653	769	1,300	1,300
Debtors	1,661	4,818	2,834	2,834	2,834
Cash	53,786	16,455	29,005	16,763	1,000
Other*	12,368	29,750	24,180	0	0
Current Liabilities	(5,356)	(11,830)	(10,381)	(12,302)	(12,302)
Creditors	(5,356)	(11,830)	(10,381)	(12,302)	(12,302)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(6,155)	(448)	(844)	(4,525)	(22,874)
Long term borrowings	0	0	0	0	(18,349)
Other long term liabilities	(6,155)	(448)	(844)	(4,525)	(4,525)
Net Assets	62,701	45,065	51,186	13,662	(20,490)
CASH FLOW					
Operating Cash Flow	(28,258)	(44,769)	(34,462)	(35,864)	(34,054)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(85)	(146)	(23)	(23)	(23)
Acquisitions/disposals	0	0	0	0	0
Financing	36,017	25,653	42,263	0	0
Other**	24,596	(18,069)	4,772	23,645	(35)
Dividends	0	0	0	0	0
Net Cash Flow	32,270	(37,331)	12,550	(12,242)	(34,112)
Opening net debt/(cash)	(21,516)	(53,786)	(16,455)	(29,005)	(16,763)
HP finance leases initiated	0	0	0	0	0
Other	0	0	0	0	0
Closing net debt/(cash)	(53,786)	(16,455)	(29,005)	(16,763)	17,349

Source: RedHill accounts, Edison Investment Research. Note: *Bank deposits and financial assets at fair value. **Includes bank deposits converted to cash and cash equivalents.

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