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RedHill Biopharma

Q120 company update

Movantik acquisition completed; sales booked

Pharma & biotech

RedHill is now promoting Aemcolo for travellers' diarrhoea (since December 2019), Talicia for H. pylori eradication (since March 2020) and the most recent addition, Movantik, for opioid-induced constipation (acquired from AstraZeneca on 1 April 2020). Movantik is an established product and AstraZeneca reported 2019 sales of $96m in the US, so it is a significant addition to RedHill's portfolio. In April, the company booked $7.3m Movantik sales, which seems a good result given this was the peak month of the COVID-19 pandemic. Promotion of the novel drugs, Talicia and Aemcolo, is affected by the ongoing pandemic and RedHill had to postpone certain promotional activities, but we believe the potential of these drugs is intact. Our valuation is $593m or $16.5 per ADS.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/18	8.4	(38.8)	(0.17)	0.0	N/A	N/A
12/19	6.3	(42.1)	(0.14)	0.0	N/A	N/A
12/20e	93.0	(9.7)	(0.03)	0.0	N/A	N/A
12/21e	137.0	3.2	0.01	0.0	N/A	N/A

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

First sales of Movantik booked

The company finalised its acquisition of Movantik from AstraZeneca on 1 April 2020, in line with planned timelines, which is an achievement in itself given the ongoing pandemic and worldwide restrictions limiting business activities. April, with sales of $7.3m, was the first and full month that RedHill started to promote the new drug. AstraZeneca reported 2019 Movantik sales of $96m. With the caveat that no reliable inferences can be made from one month's data, RedHill's sales seem to have held up well given that imposed restrictions in the US were at a peak in April.

COVID-19: Challenges and opportunities

In our last report we highlighted that the COVID-19 pandemic presented not only challenges, but also an opportunity as RedHill's two assets at earlier R&D stages have antiviral activity against corona viruses. In early April, RedHill made its Phase IIa stage asset opaganib (Yeliva) available for compassionate use in severe-to-critical COVID-19 patients. Following early insights from the compassionate use programme, RedHill filed for an IND with the FDA, which was approved in May. A randomized, double-blind, placebo-controlled Phase IIa study with severe-to-critical COVID-19 patients (n=40) is about to start.

Valuation: $593m or $16.5 per ADS

Our RedHill valuation is somewhat lower at $593m or $16.5 per ADS, versus $638m or $18.1 per ADS previously, which is mainly technical, as we now include the debt ($78.2m at end Q120) used to acquire Movantik in our net cash calculation. As described above, a significant part of that amount has already been paid to AstraZeneca. In our previous report, we had already included Movantik's sales potential in our model, which led to an upgrade of our estimates. Our near-term estimate revisions have had only a small negative effect, which was largely counterbalanced by rolling the model forward.

29 May 2020

Price	**US$7.0**
Market cap	**US$251m**
Net cash ($m) at end Q120; $52.5m payment to AstraZeneca for Movantik was made on 1 April 2020	115.1
Shares in issue	358.9m
Free float	90%
Code	RDHL
Primary exchange	Nasdaq

Share price performance

%	1m	3m	12m
Abs	(18.6)	72.8	(10.4)
Rel (local)	(22.8)	69.6	(16.6)
52-week high/low	US$8.89		US$3.51

Business description

Speciality pharma company RedHill Biopharma focuses on gastrointestinal diseases and promotes several GI products in the US. The commercial portfolio includes Movantik (opioid-induced constipation), Talicia (H. pylori eradication) and Aemcolo (travellers' diarrhoea). The most advanced R&D assets are RHB-204 for NTM, RHB-104 for Crohn's disease, BEKINDA for gastroenteritis and IBS-D.

Next events

Initiation of pivotal Phase III study with RHB-204 for NTM infections	Q320
Initiation of the Phase IIa study with opaganib for COVID-19 patients	Q2/Q320
Updates on the promotion of the commercial portfolio drugs	2020

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Edison profile page

Commercial portfolio update

Movantik: An established drug, latest addition to portfolio

We introduced the newest addition to RedHill's portfolio, Movantik, in our previous report. The company finalised the acquisition from AstraZeneca on 1 April 2020, in line with planned timelines, which is an achievement in itself given the ongoing pandemic and worldwide restrictions. With regard to further COVID-19 effects, RedHill highlighted in its Q120 presentation that the commercial team has continued to provide support to prescribers. As the lockdown restrictions are easing in certain areas, the salesforce is resuming more active promotion with in-person visits.

Movantik is the first oral PAMORA drug approved by the FDA and recommended in the guidelines from the American Gastroenterological Association (AGA) and the National Comprehensive Cancer Network (NCCN). Movantik was originally developed by Nektar Therapeutics, which out-licensed it to AstraZeneca in 2009. The drug was approved by the FDA in 2014 and launched in the US in 2015. AstraZeneca described Movantik as an 'important established medicine and the divestment to RedHill will ensure its continued availability for patients'.

Talicia and Aemcolo: Both novel GI drugs now launched

Aemcolo and Talicia were launched in December 2019 and March 2020, respectively. Express Scripts and Prime Therapeutics have already added Talicia to their formularies, while RedHill is working to increase coverage further. As Talicia was only launched at the end of the quarter, no financial data were reported with the Q120 results. In addition, promotion was affected by the ongoing COVID-19 pandemic. While it is still too early to estimate the full impact of the pandemic, RedHill indicated that certain activities related to the promotion of these drugs during the launch phase have been affected and postponed by approximately one quarter. In addition, the launch of Aemcolo, which is indicated for travellers' diarrhoea, was affected by widespread restrictions on international travel. Nevertheless, RedHill is confident that in a more normalised business and healthcare provision environment, its salesforce will resume promotion at full capacity. The company also highlighted strong interest in the novel drugs from healthcare professionals.

R&D update

Rapidly progressing COVID-19 programme

Opaganib is a sphingosine kinase-2 (SK2) inhibitor and has broad potential in oncology and inflammatory diseases, as well as anti-viral properties. In early April, RedHill made its Phase IIa stage asset opaganib (Yeliva) available for compassionate use in severe-to-critical COVID-19 patients. The company also reported findings from the first six patients who were hospitalised in Israel, hypoxic and required high-flow supplemental oxygenation. All six patients demonstrated improvement in clinical symptoms and biomarkers, including a reduced requirement for supplemental oxygenation, higher lymphocyte counts and decreased C-reactive protein levels. All patients were weaned from oxygen and at no stage during the treatment was mechanical ventilation needed. RedHill continues to work with all stakeholders involved to expand the compassionate use of opaganib in several countries. This will allow it to generate retrospective data and insight in a cost-effective way.

Following early insights from the compassionate use of opaganib, RedHill filed for an IND with the FDA, which was approved in May. This will be a randomized, double-blind, placebo-controlled Phase IIa study with the goal of enrolling up to 40 patients with severe-to-critical COVID-19 infection requiring hospitalisation and high-flow supplemental oxygenation. The study is about to start in US centres.

RedHill also has another asset, RHB-107 (upamostat). RHB-107 is an inhibitor of the S1 family of trypsin-like serine proteases with potential for use in the treatment of cancer, inflammatory lung diseases and irritable bowel syndrome. Based on its possible mechanism of action, RHB-107 was selected for in vitro testing by the US National Institute of Allergy and Infectious Diseases (NIAID).

Opaganib (Yeliva) for cholangiocarcinoma and prostate cancer

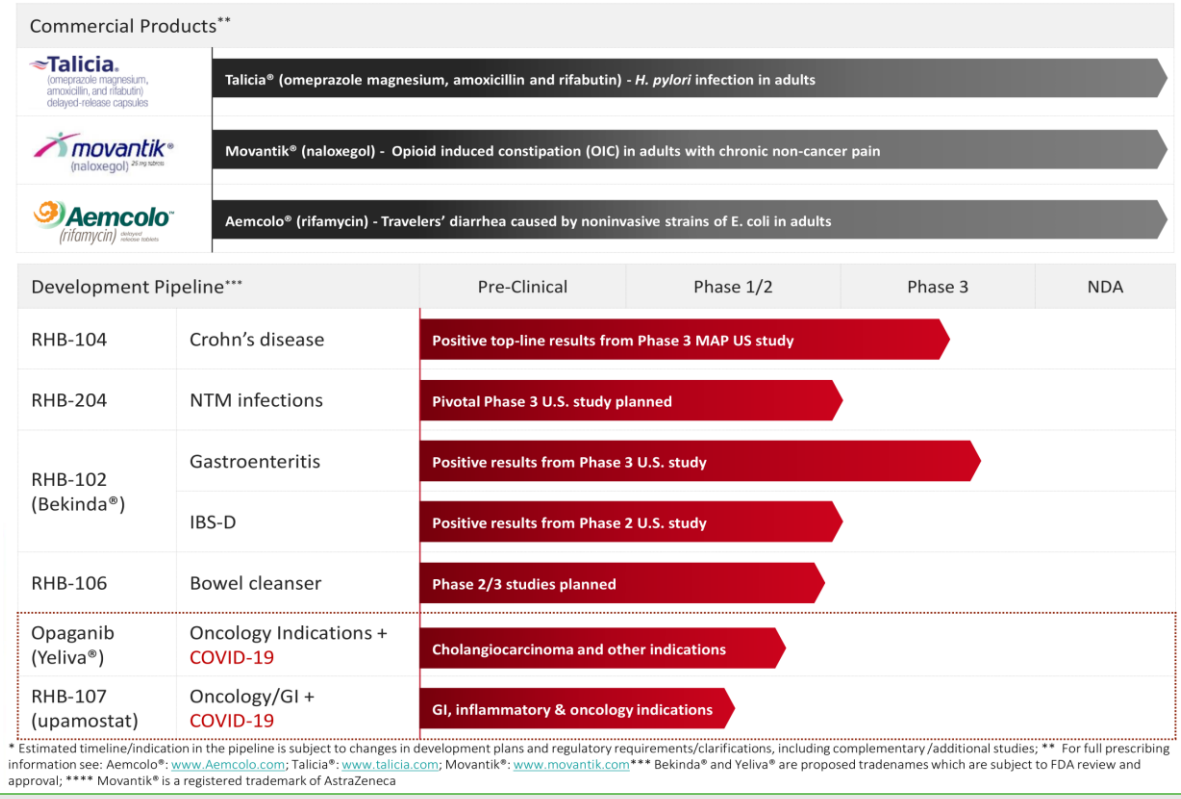
Enrolment in a Phase IIa trial with opaganib is complete, with a total of 39 cholangiocarcinoma patients. RedHill reported that preliminary data shows signs of activity and that these findings will be presented at a conference before the end of this year. While the data are still early, they could provide the first insights into clinical activity. The Medical University of South Carolina (MUSC) also initiated an investigator-sponsored (supported by the National Cancer Institute grant) study with opaganib in prostate cancer and patient enrolment is ongoing.

RedHill seems confident in this asset and is expanding the programme in cholangiocarcinoma. The company added a second arm to the study, in which opaganib will be combined with hydroxychloroquine. Enrolment will start when the COVID-19 pandemic improves. For clarity, the fact that opaganib will be combined with hydroxychloroquine is a coincidence. This drug (or derivatives) are currently attracting strong research interest as potential agents against COVID-19. RedHill mentioned it has been working on the potential of this combination for a while now. There will also be a third arm added, where opaganib will be combined with RedHill's other asset RHB-107 (upamostat).

RHB-204 for NTM infections

Supportive preclinical studies are complete, with positive results and RedHill plans to initiate a single, pivotal Phase III evaluating RHB-204 as a first-line, standalone treatment for pulmonary nontuberculous mycobacterium (NTM) infections caused by Mycobacterium avium complex (MAC) in Q320, subject to further input from the FDA.

Exhibit 1: RedHill's product portfolio and R&D pipelines



Source: RedHill

Financials

RedHill booked Q120 sales of $1.1m, which came from its speciality GI products (Donnatal, EnteraGam and Mytesi). Going forward, these products will no longer be the driver, as RedHill decided to discontinue the promotion of these products and from now on will focus on its GI drugs Talicia, Aemcolo and Movantik. We had previously adjusted our revenue estimates to take account of this.

RedHill reported sales of Movantik of $7.3m in April alone, the first full month of promotion after it was acquired from AstraZeneca. We had already included Movantik sales in our model in our last report, which is an established product, and make no changes to our forecasts. With regards to Talicia and Aemcolo, as described above, the COVID-19 pandemic presents significant challenges for promotion of the novel products. We therefore reduced our near-term sales estimates for these drugs somewhat to reflect the delay of full promotion activities by one quarter, but see the peak potential as intact. Our updated total sales for 2020 and 2021 are $93.0m (vs $99.0m previously) and $137.0m (vs $141.0m previously), respectively.

Q120 operating expenses were $16.4m vs $7.9m in Q119, reflecting a y-o-y increase due to a higher level of commercial activities. In Q120, S&M costs were $9.0m (vs $3.1m in Q119), G&A costs were $4.6m (vs $2.0m), while R&D expenses decreased to $2.8m vs $5.4m in Q119. We had already assumed an increase in costs associated with the US organisation and commercialisation of the GI drugs. This is somewhat counterbalanced by lower R&D spending. In addition, the delay in certain promotional activities should lead to lower than expected spending during pandemic restrictions. After fine-tuning our spending forecasts, our near-term EBIT estimates are a loss of $9.7m in 2020 (vs $14.0m previously), but a profit of $3.2m in 2021 (vs $9.6m previously).

Reported cash and cash equivalents were $115.1m at the end of Q120. In conjunction with the acquisition of Movantik, RedHill entered into a royalty-backed term loan totalling $115m from HealthCare Royalty Partners (HCR). During Q120, RedHill received a total of $80m and made an upfront payment of $52.5m to AstraZeneca on 1 April 2020. The cash balance following completion of the transaction was $62.5m. RedHill could still receive, if needed, a total of $35m from HCR depending on certain commercial conditions. In addition, in May 2020 RedHill carried out a small private placement of 618k of ADSs (compared to 35.3m ADSs outstanding) raising $4.7m.

This available non-dilutive funding allowed RedHill to ramp up its salesforce, which it needs to optimise promotion of the three products. Both Talicia and Aemcolo were launched recently, so by the end of FY20 initial performance will provide insights into the commercial potential of these products and should also serve as a catalyst for the share price.

Valuation

Our RedHill valuation is somewhat lower at $593m or $16.5 per ADS, versus $638m or $18.1 per ADS previously. The decrease is mainly a technical adjustment, in that we now include end Q120 debt of $78.2m in our net cash calculation. As described above, a significant part of that amount has already been paid to AstraZeneca. In our previous report we had already included Movantik's sales potential in our model, which led to an upgrade of our estimates. The near-term (mainly COVID-19 related) estimate revisions have only a small negative effect, which was largely counterbalanced by rolling the model forward. As previously, we include RedHill's most advanced R&D assets with unchanged assumptions.

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

Product	Launch	Peak sales ($m)	NPV ($m)	NPV/share ($)	Probability	rNPV ($m)	rNPV/share ($)
GI specialty products (including **Talicia, Aemcolo** and **Movantik**)	Marketed		415.3	11.6	100%	415.3	11.57
RHB-104 - Crohn's disease	2023	145	96.1	2.7	50%	48.1	1.34
RHB -204 - NTM infections	2024	50	61.8	1.7	30%	17.3	0.48
Bekinda - Gastroenteritis	2022	21	39.2	1.1	85%	33.1	0.92
- IBS-D	2023	201	119.6	3.3	60%	78.4	2.18
Yeliva - Cholangiocarcinoma	2024	115	206.8	5.8	10%	16.9	0.47
Net cash/(debt) (end-Q120 adj.)*			(15.7)		100%	(15.7)	(0.44)
Valuation			**923.2**	**26.16**		**593.4**	**16.54**

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. IBS-D = irritable bowel syndrome; NTM = nontuberculous mycobacteria. *Includes 1 April 2020 Movantik acquisition.

Exhibit 3: Financial summary

$'000s	2018	2019	2020e	2021e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	8,360	6,291	93,006	136,969
Cost of Sales	(2,837)	(2,259)	(33,652)	(49,013)
Gross Profit	5,523	4,032	59,354	87,956
Research and development	(24,862)	(17,419)	(11,200)	(11,200)
EBITDA	(39,241)	(41,988)	(9,513)	3,377
Operating Profit (before amort. and except.)	(39,331)	(42,985)	(9,651)	3,208
Intangible Amortisation	0	(216)	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(39,331)	(43,201)	(9,651)	3,208
Net Interest	511	897	0	0
Profit Before Tax (norm)	(38,820)	(42,088)	(9,651)	3,208
Profit Before Tax (reported)	(38,820)	(42,304)	(9,651)	3,208
Tax	0	0	0	(802)
Profit After Tax (norm)	(38,820)	(42,088)	(9,651)	2,406
Profit After Tax (reported)	(38,820)	(42,304)	(9,651)	2,406
Average Number of Shares Outstanding (m)	231.2	296.9	355.9	359.2
EPS - normalised ($)	(0.17)	(0.14)	(0.03)	0.01
EPS - normalised fully diluted (c)	(16.79)	(14.17)	(2.71)	0.67
EPS - (reported) ($)	(0.17)	(0.14)	(0.03)	0.01
Dividend per share ($)	0.0	0.0	0.0	0.0
Gross Margin (%)	66.1	64.1	63.8	64.2
EBITDA Margin (%)	N/A	N/A	N/A	2.5
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	2.3
BALANCE SHEET				
Fixed Assets	5,623	20,885	73,450	88,484
Intangible Assets	5,320	16,927	69,462	84,497
Tangible Assets	163	228	258	257
Investments	140	3,730	3,730	3,730
Current Assets	56,788	53,214	78,725	69,124
Stocks	769	1,882	1,882	1,882
Debtors	2,834	3,460	3,460	3,460
Cash	29,005	29,023	54,534	44,933
Other*	24,180	18,849	18,849	18,849
Current Liabilities	(10,381)	(10,616)	(10,616)	(10,616)
Creditors	(10,381)	(10,616)	(10,616)	(10,616)
Short term borrowings	0	0	0	0
Long Term Liabilities	(844)	(3,481)	(82,981)	(82,981)
Long term borrowings	0	0	(80,000)	(80,000)
Other long-term liabilities	(844)	(3,481)	(2,981)	(2,981)
Net Assets	51,186	60,002	58,577	64,011
CASH FLOW				
Operating Cash Flow	(34,462)	(40,749)	(6,486)	6,404
Net Interest	0	0	0	0
Tax	0	0	0	(802)
Capex	(23)	(168)	(168)	(168)
Acquisitions/disposals	0	0	0	0
Financing	42,263	36,305	4,700	0
Other**	4,772	4,630	(52,535)	(15,035)
Dividends	0	0	0	0
Net Cash Flow	12,550	18	(54,489)	(9,601)
Opening net debt/(cash)	(16,455)	(29,005)	(29,023)	25,466
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)***	(29,005)	(29,023)	25,466	35,067

Source: RedHill Biopharma accounts, Edison Investment Research. Note: *Bank deposits and financial assets at fair value. **Mainly Movantik acquisition payments to AstraZeneca. ***Net cash does not include bank deposits and financial assets.

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