EDISON

RedHill BioPharma

Q117 business update

Seeking recurring revenues; two readouts in 2017

Pharma & biotech

RedHill's Q117 business update described steady progress on both fronts: the R&D pipeline and planned commercialisation of the two products for gastrointestinal (GI) diseases via co-promotion or in-licensing deals. The initiation of promotional activities is expected in Q217 and data readouts from two mid- to late-stage clinical trials in Q2/Q317 will provide inflection points this year. Our valuation is slightly higher at NIS1.40bn ($378m).

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	0.1	(39.8)	(0.23)	0.0	N/A	N/A
12/18e	0.8	(36.6)	(0.21)	0.0	N/A	N/A

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

Financials: Steady R&D progress

RedHill reported $8.1m in R&D costs, a significant 74% jump y-o-y and 9% q-o-q, while G&A expenses were $1.3m, up 44% y-o-y and 12% q-o-q. As expected, increased cash burn was due to increasing clinical trial activities. The company reiterated its guidance that quarterly cash burn in 2017 will stabilise at c $10m; we therefore make no changes to our FY17 estimates. Following a successful $38m fund-raising in December 2016, RedHill ended Q117 with cash reserves of $61m. This implies cash reach well into 2018 and past several mid- to late-stage trial data readouts in Q2/Q317. Two new commercial GI products, Donnatal and EnteraGam, could provide a near-term revenue source.

Two data readouts and recurring revenues in 2017

After in-licensing a second GI product, EnteraGam, RedHill now plans to start promotion activities in Q217. This will transform RedHill into a vertically integrated, commercial-stage specialty GI pharma company. RedHill is in the process of setting up a US-based commercial business and plans to have more than 30 sales representatives ready at the end of Q217. While RedHill did not provide financial guidance or timing of when the business could become profitable, RedHill plans to start promoting both EnteraGam and Donnatal in Q217. RedHill plans to be able to use the established sales organisation to promote and distribute its own developed products, if approved. Looking forward, three mid- to late-stage catalysts will shape H217 for RedHill: the second DSMB review in mid-2017 with an early stop option for RHB-104 in the first Phase III for CD, BEKINDA top-line Phase III results in gastroenteritis in Q217 and top-line Phase II results in IBS-D in Q317.

Valuation: Slightly up to NIS1.40bn ($378m)

Our valuation of RedHill is NIS1.40bn ($378m) or NIS7.9/share ($22.0/ADS), slightly increased from NIS1.32bn ($369m) or NIS7.7/share ($21.6/ADS) due to rolling our model forward by one quarter. We keep all other assumptions unchanged and look forward to the upcoming R&D triggers in coming weeks.

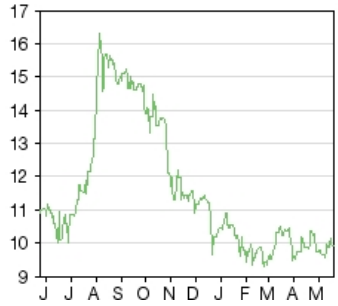
24 May 2017

Price*	**US$9.93/ NIS3.55**
Market cap	**US$169m/ NIS609m**

*Priced at 19 May 2017

NIS3.57/US$	
Net cash ($m) at end Q117 (including short term investments)	61
Shares in issue	171m
Free float	90%
Code	RDHL
Primary exchange	TASE
Secondary exchange (ADS/share 1:10)	NASDAQ

Share price performance



%	1m	3m	12m
Abs	0.8	0.5	(11.2)
Rel (local)	(0.2)	(0.1)	(23.1)

52-week high/low	US$16.3 / US$9.3

Business description

RedHill is a specialty pharma company with a 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 multiple sclerosis and BEKINDA for gastroenteritis and IBS-D.

Next events

Second DSMB review of RHB-104 Phase	Q217
BEKINDA Phase III for gastroenteritis top-line results III in CD	Mid-2017
BEKINDA IBS-D Phase II top-line results	Q317

Analysts

Jonas Peciulis +44 (0)20 3077 5728

Juan Pedro Serrate +44 (0)20 3681 2534

healthcare@edisongroup.com

Edison profile page

Plenty of catalysts in 2017

We expect RedHill to deliver plenty of news flow this year providing opportunities for value inflection. Main events include:

- **RHB-104 interim analysis and early termination option in mid-2017.** The second DSMB review of the first Phase III trial in CD is expected in mid-2017 with the option for early termination if overwhelming efficacy or futility is demonstrated. If the study is not stopped the enrolment of an expected 410 CD patients should be completed by end-2017. The study explores RHB-104's, a patented combination of three generic antibiotics (clarithromycin, rifabutin and clofazimine), efficacy in CD patients representing a novel approach aimed at treating *Mycobacterium avium paratuberculosis* (MAP) infection which, according to numerous studies, may be one of the causative agents of CD.
- **Two data readouts from BEKINDA studies around Q2/Q317.** BEKINDA is a once-daily, bi-modal extended release, oral formulation of ondansetron:
  - Top-line results from the Phase III trial with BEKINDA (24mg) in acute gastroenteritis are expected in Q217. According to RedHill's discussions with the FDA, this study could be sufficient to file for an NDA, conditional upon, among other things, achieving highly significant positive results and future review and guidance from the FDA.
  - BEKINDA (12mg) is also being explored in Phase II trial with IBS-D patients, with top-line results expected in Q317.

  If approved, BEKINDA (24mg) could be the first 5-HT3 antiemetic drug indicated for the treatment of acute gastroenteritis and gastritis in the US. The opportunity for BEKINDA in IBS-D is potentially greater than in gastroenteritis, given the chronic nature of the disorder and the currently underpenetrated market due to a need for more effective treatments.
- **Initiation of promotion for GI products Donnatal and EnteraGam planned in Q2/17**. RedHill is in the process of setting up a US-based commercial business and plans to have more than 30 sales representatives ready at the end of Q217. While the company did not provide financial guidance or timing when the US business could become profitable, RedHill plans to start promoting both products in Q217, which will mark RedHill's transformation into a vertically integrated, commercial stage specially GI pharma company.
  - Donnatal (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) was the first GI product, for which RedHill announced a co-promotion agreement with Concordia in January 2017. RedHill gained certain rights to promote Donnatal in selected regions in the US. It is an established product with an existing market and classified by the FDA as possibly effective in irritable bowel syndrome and acute enterocolitis. Donnatal was acquired by Concordia in 2014, with 2016 sales reaching around $65m (7.9% of Concordia's sales).
  - In April 2017, RedHill announced an agreement with US-based medical food company Entera Health for exclusive rights to market EnteraGam in the US. In exchange, RedHill will pay tiered royalties, but notably no upfront or milestone payments. EnteraGam is a medical food intended for the dietary management of chronic diarrhoea and has to be administered under medical supervision. EnteraGam is a serum-derived bovine immunoglobulin/protein isolate (SBI) with a proposed mechanism of action of restoring gut balance. Net sales of EnteraGam in 2016 were more than $5m, substantial for a medical food product, in our view.

Steady progress in R&D and on a commercial front

Other news from RedHill include the last patient enrolled in the BEKINDA Phase II study for IBS-D, FDA orphan drug designation for YELIVA for the treatment of cholangiocarcinoma and marketing approval of Rizaport for migraines in Luxembourg. RedHill also indicated that besides the currently ongoing three clinical studies with YELIVA in multiple myeloma, hepatocellular carcinoma (HCC) and diffuse large B-cell lymphoma (DLBCL), there are plans to initiate at least three more trials H217 in cholangiocarcinoma, ulcerative colitis and for radioprotection during radiation therapy in head and neck cancer patients. The status of RedHill's current R&D and commercial pipeline is summarised in the table below.

Exhibit 1: Update on RedHill's R&D and commercial pipeline

Product	Stage	Indication	Recent progress and selected upcoming events
R&D products			
RHB-105 rifabutin+ amoxicillin+ omeprazole	Ph III	*H. pylori* infection	The first Phase III study delivered positive results in March 2016. Following a meeting with the FDA, a confirmatory Phase III is planned to be initiated in Q217.
RHB-104 clarithromycin+ clofazimine+ rifabutin	Ph III	Crohn's disease	Passed safety interim DSMB review in Q416. By January 2017, 254 out of planned 410 patients were enrolled. In October 2016, RedHill introduced an option for early termination of the first Phase III study with CD patients if overwhelming efficacy or futility is demonstrated during **the second DSMB review in mid-2017**. If the study is not stopped, the enrolment should be completed by end-2017. RedHill also initiated a 52-week, open-label extension study intended to assess the safety and efficacy of RHB-104 in patients who have completed 26 weeks of treatment in the ongoing Phase III study and remain with active CD.
	Ph IIa	r/r multiple sclerosis	Phase IIa study (CEASE-MS) of RHB-104 in r/r multiple sclerosis delivered final results in December 2016 and echoed promising interim findings earlier in 2016. RedHill's current focus is on CD, which is the primary indication for RHB-104, and progress with the MS indication will depend on insights from the ongoing Phase III for CD and potential interest from partners.
BEKINDA ext. release tab. ondansetron	Ph III	Gastroenteritis	In February 2017, RedHill announced that the last patient had been enrolled to the Phase III (GUARD) trial in the US for gastroenteritis. **Top-line results from Phase III study expected in Q217.**
	Ph II	IBS-D	In April 2017, RedHill announced that the last patient had been enrolled to the Phase II trial in the US for IBS-D. **Top line results from Phase II with IBS-D patients expected in Q317.**
YELIVA sphingosine kinase-2 inhibitor	Ph Ib/II	r/r multiple myeloma	The first patient was dosed in the Phase Ib/II study, which was initiated in September 2016 and seeks to enrol up to 77 patients.
	Ph II	HCC	Phase II initiated in October 2016 and seeks to enrol up to 39 patients.
	Ph I/II	DLBCL / Kaposi sarcoma	Phase I/II study was initiated in June 2015 and seeks to enrol up to 33 patients.
	Phase IIa	Cholangiocar-cinoma	A Phase IIa study in patients with advanced, unresectable cholangiocarcinoma is planned for Q317.
	Ph Ib	Radioprotectant	A Phase Ib study of oral mucositis in head and neck cancer patients undergoing radiotherapy is expected to be initiated in Q317.
	Phase II	Ulcerative colitis	A Phase II study to evaluate the efficacy of YELIVA in patients with moderate to severe ulcerative colitis is planned to be initiated in H217.
Other R&D opportunities	**RHB-106**, capsules of sodium picosulphate for bowel preparation for abdominal procedures; licensed to Salix Pharmaceuticals in February 2014, which was acquired by Valeant Pharmaceuticals in March 2015. It has yet to clarify further development plans.		
	Mesupron, protease inhibitor, for solid tumours; in-licensed from Wilex in June 2014, which explored Mesupron in 10 clinical studies including two Phase II studies in advanced pancreatic cancer and metastatic breast cancer. RedHill plans to initiate a Phase I/II in H217 in patients with unresectable pancreatic cancer in combination with first-line chemotherapeutic agents.		
Commercial-stage products			
Donnatal phenobarbital, hyoscyamine, atropine sulfate, scopolamine	Market	IBS/enterocolitis	In January 2017, RedHill announced a co-promotion deal with Concordia Pharmaceuticals for Donnatal in the US. Donnatal was acquired by Concordia in 2014 and had sales of around $65m in 2016 (7.9% of Concordia's sales). RedHill is setting up its commercial organisation in the US and plans to initiate promotional activities in Q217.
EnteraGam serum-derived bovine immuno-globulin/protein isolate (SBI)	Market	Dietary management of chronic diarrhoea and loose stools	In April 2017, RedHill announced an agreement with US-based medical food company Entera Health for exclusive rights to market EnteraGam in the US. In exchange, RedHill will pay tiered royalties, but notably no upfront or milestone payments. EnteraGam is a medical food and has to be administered under medical supervision. RedHill plans to commercialise EnteraGam using its new US-based commercial business operation with the promotion activities starting in Q217.
Rizaport oral thin film rizatriptan	Market	Migraine	In contrast to Donnatal and EnteraGam RedHill will not commercialise Rizaport directly, but will seek distribution arrangements. Rizaport is being co-developed with IntelGenx since 2010. Re-submission of NDA expected in Q317. Received MAA approval in Germany in October 2015 and in Luxembourg in April 2017 under the European Decentralized Procedure. First commercialisation agreement in Spain signed with Grupo Juste (now Exeltis) in July 2016. Second agreement with Pharmatronic granting an exclusive licence to register and commercialise Rizaport in South Korea in December 2016.

Source: Edison Investment Research. Note: IBS-D = irritable bowel disease with diarrhoea; r/r =relapsing-remitting multiple sclerosis/ refractory or relapsed multiple myeloma; DLBCL = diffuse large B-cell lymphoma; HCC = hepatocellular carcinoma

Valuation

We value RedHill at NIS1.40bn ($378m) or NIS7.9/share ($22.0/ADS), a slight increase from NIS1.32bn ($369m) or NIS7.7/share ($21.6/ADS) previously due to rolling our model forward. We keep all other assumptions in our model unchanged, as detailed in our initiation report. We do not yet include the Donnatal co-promotion and EnteraGam deals in our valuation, but will revisit it when more details emerge about the commercial set-up, the initiation of promotional activities and initial sales potential. Existing funds provide cash reach well into 2018. We assume $5.0m of illustrative financing for 2018 included nominally as long-term debt on the balance sheet (as per Edison's policy).

Exhibit 2: Sum-of-the parts RedHill valuation

Product	Launch	Peak sales, $m	NPV ($m)	NPV/ADS, ($)	Probability	rNPV ($m)	rNPV/ADS ($)
RHB-105 - *H. pylori* infection	2021	86	87.6	5.1	70%	59.0	3.4
RHB-104 - Crohn's disease	2023	145	52.7	3.1	40%	13.2	0.8
- Multiple sclerosis	2025	422	191.4	11.2	20%	49.5	2.9
BEKINDA - Gastroenteritis	2019	21	35.5	2.1	70%	24.6	1.4
- IBS-D	2023	201	119.9	7.0	40%	64.0	3.7
YELIVA - r/r MM	2025	565	226.0	13.2	10%	46.0	2.7
- Advanced HCC	2025	649	127.3	7.4	10%	31.7	1.8
- DLBCL	2025	156	64.9	3.8	10%	17.2	1.0
Rizaport - Migraine	Market	20	11.3	0.7	100%	11.3	0.7
							0.0
Net cash (including other financial assets)			61.0	61.0		100%	61.0
Valuation			**977.5**	**53.4**		**377.5**	**22.0**

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 3: Financial summary

$000s	2012	2013	2014	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue	16	12	7,014	3	101	100	750
Cost of Sales	0	0	0	0	0	(60)	(450)
Gross Profit	16	12	7,014	3	101	40	300
Research and development	(6,455)	(8,100)	(12,700)	(17,771)	(25,241)	(34,254)	(30,931)
EBITDA	(9,016)	(10,748)	(10,570)	(21,866)	(30,499)	(39,836)	(36,534)
Operating Profit (before amort. and except.)	(9,040)	(10,772)	(10,647)	(22,002)	(30,543)	(39,887)	(36,588)
Intangible Amortisation	0	0	0	0	0	0	0
Exceptionals	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0
Operating Profit	(9,040)	(10,772)	(10,647)	(22,002)	(30,543)	(39,887)	(36,588)
Net Interest	(1,286)	144	(64)	912	1,173	109	0
Profit Before Tax (norm)	(10,326)	(10,628)	(10,711)	(21,090)	(29,370)	(39,777)	(36,588)
Profit Before Tax (reported)	(10,326)	(10,628)	(10,711)	(21,090)	(29,370)	(39,777)	(36,588)
Tax	0	0	0	0	0	0	0
Profit After Tax (norm)	(10,326)	(10,628)	(10,711)	(21,090)	(29,370)	(39,777)	(36,588)
Profit After Tax (reported)	(10,326)	(10,628)	(10,711)	(21,090)	(29,370)	(39,777)	(36,588)
Average Number of Shares Outstanding (m)	52.6	62.4	86.6	110.8	128.5	169.6	173.7
EPS - normalised ($)	(0.20)	(0.17)	(0.12)	(0.19)	(0.23)	(0.23)	(0.21)
EPS - normalised and fully diluted ($)	(0.20)	(0.17)	(0.13)	(0.19)	(0.24)	(0.23)	(0.21)
EPS - (reported) ($)	(0.20)	(0.17)	(0.12)	(0.19)	(0.23)	(0.23)	(0.21)
Dividend per share ($)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	100.0	100.0	100.0	40.0	40.0
EBITDA Margin (%)	N/A	N/A	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	N/A	N/A
BALANCE SHEET							
Fixed Assets	1,533	1,739	2,837	6,318	6,397	6,386	6,405
Intangible Assets	1,345	1,555	2,615	6,060	6,095	6,130	6,165
Tangible Assets	113	103	146	124	165	119	103
Investments	75	81	76	134	137	137	137
Current Assets	18,563	12,601	26,019	60,510	67,815	32,947	1,978
Stocks	0	0	0	0	0	0	0
Debtors	198	488	3,074	2,372	1,661	1,978	1,978
Cash	16,814	11,851	5,892	21,516	53,786	30,969	0
Other	1,551	262	17,053	36,622*	12,368*	0	0
Current Liabilities	(1,078)	(2,415)	(1,720)	(5,514)	(5,356)	(8,575)	(7,575)
Creditors	(1,078)	(2,415)	(1,720)	(5,514)	(5,356)	(8,575)	(7,575)
Short term borrowings	0	0	0	0	0	0	0
Long Term Liabilities	0	0	(2,125)	(1,237)	(6,155)	(6,155)	(11,114)
Long term borrowings	0	0	0	0	0	0	(4,959)
Other long term liabilities	0	0	(2,125)	(1,237)	(6,155)	(6,155)	(6,155)
Net Assets	19,018	11,925	25,011	60,077	62,701	24,603	(10,306)
CASH FLOW							
Operating Cash Flow	(6,795)	(8,436)	(12,229)	(17,826)	(28,258)	(35,145)	(35,855)
Net Interest	0	0	0	0	0	0	0
Tax	0	0	0	0	0	0	0
Capex	(8)	(14)	(70)	(14)	(85)	(5)	(38)
Acquisitions/disposals	0	0	0	0	0	0	0
Financing	6,550	2,280	24,369	54,792	36,017	0	0
Other	2,997	1,207	(18,029)	(21,328)	24,596**	12,333**	(35)
Dividends	0	0	0	0	0	0	0
Net Cash Flow	2,744	(4,963)	(5,959)	15,624	32,270	(22,817)	(35,928)
Opening net debt/(cash)	(14,070)	(16,814)	(11,851)	(5,892)	(21,516)	(53,786)	(30,969)
HP finance leases initiated	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0
Closing net debt/(cash)	(16,814)	(11,851)	(5,892)	(21,516)	(53,786)	(30,969)	4,959

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

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Frankfurt +49 (0)69 78 8076 960
Schumannstrasse 34b
60325 Frankfurt
Germany

London +44 (0)20 3077 5700
280 High Holborn
London, WC1V 7EE
United Kingdom

New York +1 646 653 7026
245 Park Avenue, 39th Floor
10167, New York
US

Sydney +61 (0)2 8249 8342
Level 12, Office 1205, 95 Pitt Street,
Sydney , NSW 2000
Australia

Tel Aviv +44 (0)20 3734 1007
Medinat Hayehudim 60
Herzilya Pituach, 46766
Israel