EDISON

RedHill Biopharma

Q217 results

First sales of GI specialty products

Pharma & biotech

RedHill's strategy to diversify into commercial specialty pharma business has born first fruits with initial sales booked in Q217, in line with previously guided timelines to initiate the marketing activities. The US organisation is now fully set up and markets two GI products: Donnatal (co-promoted with Concordia Healthcare) and EnteraGam (exclusive licence to sell from Entera Health). We now include the two products in our RedHill valuation, which is increased to $414m or $23.4/ADS. Notably, RedHill recently added a third product, Esomeprazole Strontium, to its US portfolio, which we could potentially add to our valuation assuming successful initiation of promotional activities in coming weeks.

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	15.0	(41.4)	(0.24)	0.0	N/A	N/A
12/18e	30.0	(32.5)	(0.19)	0.0	N/A	N/A

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

Timely start of the commercial operations

With its Q217 financial results RedHill reported the first sales of $483k from the newly set up US commercial business. This only corresponds to the last two weeks in June, when the company started the marketing activities, therefore we take it as a good start. Gross profit margin was 44%, but it is too early to see whether this is a representative level. Q217 R&D expenses of $8.4m were largely in line with our expectations. G&A costs came in at $1.9m, up from $740k a year ago, while S&M spend was $3.4m, up from $424k. The y-o-y increase in both items was related to the new US business, which is now fully established with all necessary hires.

No changes to RHB-104 Phase III protocol

On 31 July 2017, RedHill announced that a second DSMB review with an early termination option concluded that the Phase III study with RHB-104 for Crohn's disease can continue with no modifications, implying no unexpected significant safety issues. The DSMB committee reviewed safety and efficacy data from the first 222 subjects who have completed week 26 assessments. The success/futility hurdle chosen by RedHill was very high (p = 0.003), therefore our main scenario was that the study would continue unchanged. Over 300 of the planned 410 subjects have been enrolled and the completion of recruitment is expected in H118.

Valuation: Upped to $414m or $24.1/ADS

We have added the US commercial business with two products to our model and increased our RedHill valuation to $414m (NIS1.50bn) or $24.1/ADS (NIS8.5/share), from $390m (NIS1.42bn) or $22.7/ADS (NIS8.3/share). We note that this business is still in an early stage and we will revise our assumptions once more data are available. Income from the three products will be a major focus in upcoming quarterly reports. Other near-term catalysts include meeting with the FDA to clarify further development of BEKINDA for gastroenteritis by October 2017, and top-line results from Phase II with IBS-D patients in September 2017 (Exhibit 2).

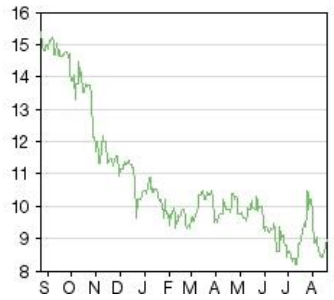
22 August 2017

Price	**US$8.98/ NIS3.21**
Market cap	**US$153m/ NIS551m**

*Priced at 18 August 2017

	NIS3.64/US$
Net cash ($m) at end Q217 (including short-term investments)	51.1
Shares in issue	171.6m
Free float	90%
Code	RDHL
Primary exchange	TASE
Secondary exchange (ADS/share 1:10)	NASDAQ

Share price performance



%	1m	3m	12m
Abs	(0.2)	(9.6)	(42.5)
Rel (local)	1.2	(11.8)	(48.1)
52-week high/low	US$15.5		US$8.2

Business description

RedHill BioPharma is a specialty 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

BEKINDA IBS-D Ph II top-line results	Sept 2017
FDA meeting and decision regarding second Phase III trial with BEKINDA	Oct 2017
Start of promotion of Esomeprazole Strontium product in the US	H217

Analyst

Jonas Peciulis +44 (0)20 3077 5728

healthcare@edisongroup.com

Edison profile page

US commercial operations up and running

Donnatal: Co-promotion agreement with Concordia

As a reminder, RedHill signed the co-promotion deal with Concordia Pharmaceuticals in January 2017 and gained certain rights to promote Donnatal (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine hydrobromide) in selected regions in the US, while Concordia will continue to be responsible for the manufacturing and supply. Both companies will share the revenues generated from the promotion of Donnatal by RedHill based on an agreed split between them, which was not disclosed. No upfront or milestone payments were involved.

Donnatal is a proprietary combination of established compounds, which has anticholinergic (slows down the motility of intestinal muscles) and barbiturate (mild sedation) effects and has been classified by the FDA as possibly effective as adjunctive therapy in irritable bowel syndrome and acute enterocolitis. The initial term of the co-promotion agreement with Concordia is for three years. Donnatal was acquired by Concordia in 2014 and constituted 7.9% of Concordia's total sales in 2016. According to Bloomberg, Donnatal's sales grew rapidly from $11.4m in 2012 to $63.0m in 2016. However, over the past three years sales fluctuated, with $57.5m in 2014, $70.7m in 2015 and $63.0m in 2016. In its 2016 annual report, Concordia cited competitive pressure from non-FDA approved generic copies of the drug. In one case, Concordia initiated a litigation trial against Method Pharmaceuticals challenging its advertising of the generic version initiated in 2016. As reported by both Concordia and RedHill in March 2017, the court awarded Concordia treble damages of $2.2m, concluding that Method wilfully engaged in false advertising. This likely strengthens Donnatal's marketing position. In our view, however, further sales data are needed to evaluate Donnatal's growth potential. This will be one of our key focus areas in the next several quarterly reports from RedHill.

EnteraGam: Exclusive rights to sell from Entera Health

EnteraGam is the second product RedHill has added to its commercial portfolio. In April 2017, the company signed an agreement with US-based medical food developer and manufacturer 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 an FDA-regulated medical food intended for the dietary management of chronic diarrhoea and loose stools and has to be administered under medical supervision.

Originally developed by Entera Health, EnteraGam was launched in 2013 and targeted chronic diarrhoea and loose stools in diarrhoea-predominant irritable bowel syndrome (IBS-D) patients, although increasing data suggest it can be used for chronic diarrhoea due to various causes. EnteraGam is a serum-derived bovine immunoglobulin/protein isolate (SBI) with a proposed mechanism of action of restoring gut balance. RedHill already has one product, Bekinda (a once-daily oral formulation of ondansetron), for IBS-D in Phase II, although it is a drug with a different mechanism of action and therefore not a direct competitor. Instead, we see operational synergy as RedHill will gain experience and know-how in targeting IBS-D patients ahead of the launch of Bekinda, assuming the data is supportive.

Since Entera Health is privately held, only a limited amount of information is available about the potential of the product. EnteraGam was launched in 2013 and, according to Bloomberg, sales were $326k in 2013, $5.6m in 2014, $16.6m in 2015 and $6.2m in 2016. Overall, the launch seemed to be encouraging sales-wise, although we note the dip in 2016 was substantial. According to the deal announcement, since EnteraGam was introduced in the US in 2013, in total some three million doses have been administered to patients, so clearly there has been traction with the

product among the patients. Our focus will be on whether RedHill's promotion will resume the growth of EnteraGam's potential.

Esomeprazole strontium – latest addition to GI portfolio

On 17 August 2017, RedHill announced the US commercialisation agreement with ParaPRO to promote third GI speciality product esomeprazole strontium branded as Esomeprazole Strontium Delayed-Release (DR) Capsules 49.3mg. This is in line with the company's previous statements that it may seek to expand the US GI product portfolio. No upfront or milestone payments were involved in the agreement, while the parties will share the revenues generated from the promotion of the product by RedHill based on an agreed upon split. The initial term of the commercialisation agreement is three years.

Esomeprazole Strontium belongs to the proton pump inhibitor (PPI) class and is indicated in several disorders where lowering gastric acid production is beneficial, eg prevention or treatment of gastric/duodenal ulcers, gastroesophageal reflux disease (heartburn) or esophagitis. PPIs encompass several compounds and are considered the most potent inhibitors of acid secretion available with a good safety profile. PPIs interfere in the last step of the gastric acid secretion and largely surpassed in popularity another class of heartburn drugs H2-receptor antagonists, eg ranitidine or cimetidine. Esomeprazole was first introduced as Nexium (esomeprazole magnesium) by AstraZeneca in 2001 and generated $5.2bn in peak sales in 2007 (EvaluatePharma). With patents expiring and generic versions appearing, Nexium sales have been decreasing lately, however, globally Nexium still brought in $2.8bn. Esomeprazole strontium being a different salt (approved via 505(b)(2) new drug application pathway) is differentiated from Nexium and its generic versions.

For the time being we do not include it in our valuation, but will revisit the product once RedHill starts the promotion in coming weeks. We will also be focusing on any potential new information about the competitive advantages in this rapidly developing PPI landscape.

Financials

Although the majority of commercial details about the arrangements between RedHill and its partners for both products remain undisclosed, we now introduce Donnatal and EnteraGam into our valuation following the timely initiation of the co-promotion activities and initial sales booked. We use the following assumptions:

- **Donnatal:**
  We use average Donnatal end-user sales over the past three years of $64m. The actual share of the existing market, which RedHill is now responsible for, remains undisclosed. In its 2016 annual report Concordia explained that it eliminated its sales team working with Donnatal and instead engaged with RedHill, but it still planned to continue to promote Donnatal in US territories outside the scope of the agreement with RedHill. For the purpose of our model, we use a split 80:20 (RedHill/Concordia). Using $64m as an example, this would imply that RedHill's share is $51m. According to the deal, this amount would be split between the companies. We assume that RedHill would retain one-third, which in a typical distribution model would imply a 50% mark up. We therefore arrive at a calculated $17m in revenues for RedHill per year. Clearly the goal of both companies is to grow the sales as was the case previously; however, the developments with the competition over the past few years prompts us to take a conservative stance until more sales data are available. We assume moderate 7% long-term growth of total Donnatal sales, which implies close to 2% growth in revenues for RedHill.

- **EnteraGam:**
  Unlike the co-promotion and revenue share agreement with Concordia, RedHill acquired exclusive rights from Entera Health to sell EnteraGam in the US. We assume that EnteraGam sales will bounce back to around the level seen in 2015 ($16.6m) and then assume a long-term growth rate of 7%. We use a gross margin of 50% in our model and assume RedHill will pay a combined 20% in royalties to Entera Health.

Our combined sales forecasts of both products are $15.0m for 2017 and $30.0m for 2018, with gross profit of $10.5m and $20.9m, respectively. For the time being RedHill does not report separate business segments, however, looking at Q217 financial results, the combined increase in G&A and S&M was $4.2m, largely incurred to set up the US business. In our model we include a cost base of $16m (combined US G&A and S&M) a year to run the organisation responsible for marketing both products and assume 3% long-term growth. Notably, the US business may be expanded even further as RedHill indicated that it actively seeks to acquire additional products. Our model implies 2018 to be a break-even year for the US business.

Ramping up R&D pipeline

In January 2017, RedHill announced that the FDA has granted RHB-104 Qualified Infectious Disease Product (QIDP) for the treatment of Nontuberculous Mycobacteria (NTM) Infection. In its semi-annual update RedHill reported that it will now proceed with a Phase III study, which is expected to start in Q118, subject to the FDA's approval of the trial protocol. The QIDP designation allows it to benefit from fast-track status, priority review and it will also receive an additional five years of US market exclusivity. NTM infections are defined as any mycobacterial pathogen other than *Mycobacterium tuberculosis* (the cause of tuberculosis) or *Mycobacterium leprae* (the cause of leprosy) and encompass more than 140 species of mycobacteria, which can infect various organs. The infections are difficult to diagnose, difficult to treat and it has been suggested that the prevalence rate is more common than tuberculosis in the industrialised world[1].

RedHill has also increased its effort to develop an undisclosed new proprietary experimental therapy developed in-house to tackle Ebola virus disease. In collaboration with the US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), RedHill will initiate a non-clinical, proof-of-concept study in Q417 to evaluate the potential of the asset. According to RedHill, this follows encouraging findings in the preliminary preclinical studies.

Valuation

Our RedHill valuation has increased to $414m (NIS1.50bn) or $24.1/ADS (NIS8.5/share), from $390m (NIS1.42bn) or $22.7/ADS (NIS8.3/share) previously, mainly due to the inclusion of the commercial business, which we value at $30.8m using a 12.5% discount rate. We caution that this business is still in a very early stage and we will revise our assumptions once more data are available. Existing funds should provide cash reach well into 2018.

[1] R. M. Raju et al. Leveraging Advances in Tuberculosis Diagnosis and Treatment to Address Nontuberculous Mycobacterial Disease. *Emerging Infectious Diseases*. 2016;22(3):365-369.

Exhibit 1: 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	90.2	5.3	70%	60.7	3.5
RHB-104 – Crohn's disease	2023	145	54.3	3.2	40%	13.6	0.8
– Multiple sclerosis	2025	422	197.1	11.5	20%	51.0	3.0
BEKINDA – Gastroenteritis	2019	21	36.5	2.1	85%	30.9	1.8
– IBS-D	2023	201	123.4	7.2	40%	65.9	3.8
YELIVA – r/r MM	2025	565	232.7	13.6	10%	47.3	2.8
– Advanced HCC	2025	649	131.0	7.6	10%	32.6	1.9
– DLBCL	2025	156	66.8	3.9	10%	17.7	1.0
Rizaport – Migraine	Market	20	11.7	0.7	100%	11.7	0.7
Donnatal & EnteraGam – specialty GI products	Market	51	30.8	1.8	100%	30.8	1.8
Net cash end Q217 (including other financial assets)			51.1			51.1	3.0
Valuation			**1,025.6**	**56.8**		**413.5**	**24.1**

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

Product	Stage	Indication	Recent progress and upcoming events
R&D products			
TALICIA (RHB-105) rifabutin+ amoxicillin+ omeprazole	Ph III	*H. pylori* infection	The first Phase III study delivered positive final results in March 2016. Following a meeting with the FDA, a confirmatory Phase III trial was initiated in June 2017. The study is expected to enrol 444 subjects and compare TALICIA versus a high dose amoxicillin and omeprazole regimen. TALICIA has Qualified Infectious Disease Product (QIDP) designation from the FDA.
RHB-104 clarithromycin+ clofazimine+ rifabutin	Ph III	Crohn's disease	First Phase III study (n = 410) is ongoing and passed a second DSMB review (safety and interim efficacy analysis) in July 2017, with recommendation to continue without any changes to the protocol. Completion of patient enrolment is expected in H118. 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.
	Ph III	Nontuberculous mycobacteria (NTM) infections	In light of recent FDA guidance, RedHill will initiate a pivotal Phase III trial with RHB-104 as a first-line therapy for NTM infections in Q118, subject to approval of the study protocol by the FDA. RHB-104 has been granted QIDP designation by the FDA for the treatment of NTM infections, which allows it to benefit from fast-track status, priority review and it will also receive an additional five years of US market exclusivity.
BEKINDA ext. release tab. ondansetron	Ph III	Gastroenteritis	On 14 June 2017, RedHill announced positive top-line results from its GUARD Phase III trial with gastroenteritis patients receiving BEKINDA 24mg. The primary endpoint was met with statistical significance. **RedHill will meet with the FDA and will announce the outcome in October 2017 whether another Phase III trial is needed.**
	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 the Phase II with IBS-D patients are expected in September 2017.**
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/IIa	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 Q417.
	Ph Ib	Radioprotectant	A Phase Ib study of oral mucositis in head and neck cancer patients undergoing radiotherapy is expected to be initiated in Q417.
	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 Q417.
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 H118 in patients with unresectable pancreatic cancer in combination with first-line chemotherapeutic agents.		
	RedHill's proprietary experimental therapy for the treatment of Ebola virus disease is being developed in collaboration with the US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). A non-clinical, proof-of-concept study to evaluate the potential will be initiated in Q417.		
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 $63m in 2016, according to Bloomberg. RedHill has set up its commercial organisation in the US and initiated promotional activities in June 2017.
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 started commercialising EnteraGam using its US-based commercial business operation in June 2017.
Esomeprazole Strontium Delayed-Release (DR) Capsules	Market	Lowers gastric acid production	In August 2017, RedHill announced the US commercialisation agreement with ParaPRO to promote esomeprazole strontium branded as Esomeprazole Strontium Delayed-Release (DR) Capsules 49.3mg. No upfront or milestone payments were involved in the agreement, while the parties will share the revenues based on an agreed upon split. The initial term of the commercialisation agreement is three years.
Rizaport oral thin film rizatriptan	Market	Migraine	In contrast to Donnatal and EnteraGam, RedHill will not commercialise Rizaport directly, but will seek licensing arrangements. Rizaport is being co-developed with IntelGenx since 2010. Re-submission of NDA expected in October 2017. 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.

Exhibit 3: Financial summary

$000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	3	101	15,000	30,000
Cost of Sales	0	0	(4,550)	(9,100)
Gross Profit	3	101	10,450	20,900
Research and development	(17,771)	(25,241)	(34,254)	(30,931)
EBITDA	(21,866)	(30,499)	(41,370)	(32,192)
Operating Profit (before amort. and except.)	(22,002)	(30,543)	(22,002)	(30,543)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(22,002)	(30,543)	(41,477)	(32,468)
Net Interest	912	1,173	109	0
Profit Before Tax (norm)	(21,090)	(29,370)	(41,367)	(32,468)
Profit Before Tax (reported)	(21,090)	(29,370)	(41,367)	(32,468)
Tax	0	0	0	0
Profit After Tax (norm)	(21,090)	(29,370)	(41,367)	(32,468)
Profit After Tax (reported)	(21,090)	(29,370)	(41,367)	(32,468)
Average Number of Shares Outstanding (m)	110.8	128.5	169.6	171.8
EPS - normalised ($)	(0.19)	(0.23)	(0.24)	(0.19)
EPS – normalised & fully diluted ($)	(0.19)	(0.24)	(0.24)	(0.19)
EPS - (reported) ($)	(0.19)	(0.23)	(0.24)	(0.19)
Dividend per share ($)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	69.7	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	7,075	8,334
Intangible Assets	6,060	6,095	6,130	6,165
Tangible Assets	124	165	808	2,032
Investments	134	137	137	137
Current Assets	60,510	67,815	31,978	1,978
Stocks	0	0	0	0
Debtors	2,372	1,661	1,978	1,978
Cash	21,516	53,786	30,000	0
Other*	36,622	12,368	0	0
Current Liabilities	(5,514)	(5,356)	(9,885)	(9,358)
Creditors	(5,514)	(5,356)	(9,885)	(9,358)
Short term borrowings	0	0	0	0
Long Term Liabilities	(1,237)	(6,155)	(6,155)	(8,731)
Long term borrowings	0	0	0	(2,576)
Other long term liabilities	(1,237)	(6,155)	(6,155)	(6,155)
Net Assets	60,077	62,701	23,013	(7,776)
CASH FLOW				
Operating Cash Flow	(17,826)	(28,258)	(35,369)	(31,040)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(14)	(85)	(750)	(1,500)
Acquisitions/disposals	0	0	0	0
Financing	54,792	36,017	0	0
Other**	(21,328)	24,596	12,333	(35)
Dividends	0	0	0	0
Net Cash Flow	15,624	32,270	(23,786)	(32,575)
Opening net debt/(cash)	(5,892)	(21,516)	(53,786)	(30,000)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(21,516)	(53,786)	(30,000)	2,576

Source: Edison Investment Research, RedHill BioPharma 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
295 Madison Avenue, 18th Floor
10017, 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