EDISON

RedHill Biopharma

Company update

Positive Phase III with BEKINDA for gastroenteritis

Pharma & biotech

RedHill BioPharma delivered a flurry of news recently, including a major R&D milestone when a Phase III trial with BEKINDA 24mg showed that the drug was beneficial to gastroenteritis/gastritis patients. There are several inflection points still to come in 2017: a data readout from the BEKINDA Phase II trial with IBS-D patients, a second DSMB review of RHB-104 Phase III in Crohn's disease trial with an early termination option, and the meeting with the FDA to decide the further strategy with BEKINDA for gastroenteritis. We have increased our valuation to $390m (NIS1.42bn).

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.

R&D milestone: Successful Phase III with BEKINDA

On 14 June 2017, RedHill announced positive top-line results from its GUARD Phase III trial with gastroenteritis patients receiving BEKINDA 24mg, which is a once-daily, bi-modal release, oral formulation of antiemetic drug ondansetron. The primary endpoint was met with statistical significance and, as RedHill indicated, it will know whether another Phase III trial is needed after its meeting with the FDA, expected by October 2017. If approved, it could be the first once-daily formulation of ondansetron for acute gastroenteritis to reach the US and European markets.

Promotion of Donnatal and EnteraGam initiated

In line with guidance, RedHill began promotion of Donnatal and EnteraGam in the US in June 2017. This will be a key area of focus for us in the upcoming Q217 report, although we expect a more general update rather than any financial details at this early stage of commercialisation. As planned, RedHill has also initiated a second Phase III trial with RHB-105 (now branded as TALICIA) for *H. pylori* Infection, which will enrol 444 patients. This follows a successful Phase III trial, which showed that TALICIA eradicated *H. pylori* in 89.4% patients compared to historical 70% after standard-of-care and 63% in subsequent open-label treatment of the placebo arm patients in same trial (see our initiation report).

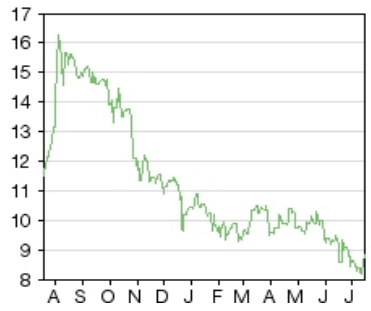
Valuation: Several inflection points in 2017 remain

We have increased our valuation to $390m (NIS1.42bn) or $22.7/ADS (NIS8.3/share), from $378m (NIS1.40bn) or $22.0/ADS (NIS7.9/share), partly due to rolling our model forward, but mainly after increasing our success probability for BEKINDA from 70% to 85%. RedHill expects more newsflow through H217. The second DSMB review of the first Phase III trial with RHB-104 for Crohn's disease is expected mid-2017 and will include an option for early termination; top-line results from the Phase II trial with BEKINDA for diarrhoea-predominant irritable bowel syndrome (IBS-D) are expected in September 2017; and the meeting with the FDA to decide the further development strategy with BEKINDA is expected by October.

17 July 2017

Price*	**US$8.81/ NIS3.09**
Market cap	**US$150m/ NIS531m**
*Priced as at 14 July 2017.	NIS3.53/US$
Net cash ($m) at end Q117 (including short-term investments)	61
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	(5.5)	(10.6)	(23.7)
Rel (local)	(6.3)	(15.4)	(32.9)
52-week high/low	US$16.3		US$8.2

Business description

RedHill BioPharma is a specialty pharma co 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 multiple sclerosis and BEKINDA for gastroenteritis and IBS-D. RedHill also promotes two GI products in the US.

Next events

Second DSMB review of RHB-104 Phase III trial in Crohn's disease	Late July, 2017
BEKINDA IBS-D Ph II top-line results	Sept 2017
FDA meeting and decision regarding second Phase III trial with BEKINDA	By October 2017

Analysts

Jonas Peciulis +44 (0)20 3077 5728

Juan Pedro Serrate +44 (0)20 3681 2534

healthcare@edisongroup.com

Edison profile page

BEKINDA 24mg Phase III top-line results positive

In the GUARD study BEKINDA was administered to gastroenteritis/gastritis patients in order to prevent vomiting. The trial was randomised, double-blind, placebo-controlled and enrolled 321 adults and children over the age of 12 and randomised at a ratio of 60:40 to receive either BEKINDA or placebo, respectively.

- The **primary endpoint** was the proportion of patients without further vomiting, without rescue medication, and who were not given intravenous hydration from 30 minutes post first dose of the study drug until 24 hours post dose compared to placebo.
- The **secondary endpoints** included frequency of vomiting, proportion of patients receiving rescue antiemetic therapy or intravenous fluids; requiring hospitalisation or returning to emergency department, time to resumption of normal activities and several others.

So far, RedHill has released top-line results, with the final study report to come in Q317. The reported results included:

- The primary endpoint was met with statistical significance even though RedHill noted that there was a high positive outcome rate in the placebo arm, which hindered achieving an even higher statistical significance.
- In the intent-to-treat population[1] 65.6% of BEKINDA treated patients (n = 192) met the primary outcome compared to 54.3% of placebo patients (n = 129) (21% improvement in efficacy, p = 0.04). Correcting for randomisation error, the difference was larger with 65.8% (BEKINDA) compared to 53.9% (placebo) (p = 0.03).
- In per-protocol (PP) analysis[2] 69.5% of BEKINDA treated patients (n = 177) met the primary outcome compared to 54.9% of placebo patients (n = 122) (27% improvement in efficacy, p = 0.01).
- BEKINDA 24mg was also shown to be safe and well-tolerated.

Next steps

BEKINDA top-line data are positive; however, as RedHill indicated, additional clinical studies may be required prior to potential submission of a New Drug Application (NDA), which will be clarified after meeting with the FDA, expected by October 2017. In an ideal scenario no additional trials would be needed, and the company could file for the NDA right away, which is a scenario we use in our model. However, if an additional trial is needed, we still see a high chance of success partly based on the results from the current study, but also on the fact that ondansetron (BEKINDA's API) is already being used off label (originally it was developed for nausea and vomiting associated with chemotherapy, radiotherapy and operations) and has been shown to have a beneficial effect in children suffering from gastroenteritis.[3] This implies that there is already at least some consensus that the drug is likely beneficial for gastroenteritis patients and RedHill is aiming to back it with data and receive a label with this indication. If approved, it could be the first once-daily oral formulation of ondansetron for acute gastritis and gastroenteritis to reach the US and European markets. Given that generic ondansetron is already routinely used off-label in this setting, BEKINDA's ability to gain

[1] Intent-to-treat population (ITT) analysis includes every subject, who is randomized according to randomized treatment assignment. It ignores noncompliance, protocol deviations, withdrawal, and anything that happens after randomization. The logic is that such method would likely mimic the real world and the estimate of treatment effect is generally conservative.

[2] Per-protocol population is defined as a subset of the ITT population who completed the study without any major protocol violations.

[3] Z. Fedorowicz et al. Antiemetics for reducing vomiting related to acute gastroenteritis in children and adolescents. The Cochrane Library, 7 September 2011.

market share will rely on its competitive advantage, which is an extended release formulation and it will be used on-label compared to standard ondansetron.

BEKINDA 12mg is also being studied in the Phase II trial for diarrhoea-predominant irritable bowel syndrome (IBS-D) in Phase II. Enrolment of patients has been completed and top-line results are expected in September 2017. We reviewed BEKINDA's potential in this indication in our initiation report.

Valuation

Our RedHill valuation has increased to $390m (NIS1.42bn) or $22.7/ADS (NIS8.3/share), from $378m (NIS1.40bn) or $22.0/ADS (NIS7.9/share) previously, due to rolling our model forward, but mainly due to increasing our success probability for BEKINDA in gastroenteritis from 70% to 85%. Our typical Phase III probability of success is 90-95%. Cautiously we use 85% to reflect the uncertainty as to the need for another Phase III trial.

Our financial forecasts are unchanged and 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 them when more details emerge about the commercial setup 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 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	89.4	5.2	70%	60.2	3.5
RHB-104 – Crohn's disease	2023	145	53.8	3.1	40%	13.5	0.8
– Multiple sclerosis	2025	422	195.4	11.4	20%	50.6	2.9
BEKINDA – Gastroenteritis	2019	21	36.2	2.1	85%	30.7	1.8
– IBS-D	2023	201	122.4	7.1	40%	65.4	3.8
YELIVA – r/r MM	2025	565	230.7	13.4	10%	46.9	2.7
– Advanced HCC	2025	649	129.9	7.6	10%	32.3	1.9
– DLBCL	2025	156	66.2	3.9	10%	17.6	1.0
Rizaport – Migraine	Market	20	11.5	0.7	100%	11.5	0.7
Net cash end Q117 (including other financial assets)			61.0			100%	3.6
Valuation			**996.6**	**54.5**		**389.6**	**22.7**

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

$000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	3	101	100	750
Cost of Sales	0	0	(60)	(450)
Gross Profit	3	101	40	300
Research and development	(17,771)	(25,241)	(34,254)	(30,931)
EBITDA	(21,866)	(30,499)	(39,836)	(36,534)
Operating Profit (before amort. and except.)	(22,002)	(30,543)	(22,002)	(30,543)
Intangible Amortisation	0	0	0	0
Exceptionals	0	0	0	0
Other	0	0	0	0
Operating Profit	(22,002)	(30,543)	(39,887)	(36,588)
Net Interest	912	1,173	109	0
Profit Before Tax (norm)	(21,090)	(29,370)	(39,777)	(36,588)
Profit Before Tax (reported)	(21,090)	(29,370)	(39,777)	(36,588)
Tax	0	0	0	0
Profit After Tax (norm)	(21,090)	(29,370)	(39,777)	(36,588)
Profit After Tax (reported)	(21,090)	(29,370)	(39,777)	(36,588)
Average Number of Shares Outstanding (m)	110.8	110.8	128.5	169.6
EPS – normalised ($)	(0.19)	(0.23)	(0.23)	(0.21)
EPS – normalised and fully diluted ($)	(0.19)	(0.24)	(0.23)	(0.21)
EPS – (reported) ($)	(0.19)	(0.23)	(0.23)	(0.21)
Dividend per share ($)	0.0	0.0	0.0	0.0
Gross Margin (%)	100.0	100.0	40.0	40.0
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	6,386	6,405
Intangible Assets	6,060	6,095	6,130	6,165
Tangible Assets	124	165	119	103
Investments	134	137	137	137
Current Assets	60,510	67,815	32,947	1,978
Stocks	0	0	0	0
Debtors	2,372	1,661	1,978	1,978
Cash	21,516	53,786	30,969	0
Other	36,622*	12,368*	0	0
Current Liabilities	(5,514)	(5,356)	(8,575)	(7,575)
Creditors	(5,514)	(5,356)	(8,575)	(7,575)
Short term borrowings	0	0	0	0
Long Term Liabilities	(1,237)	(6,155)	(6,155)	(11,114)
Long term borrowings	0	0	0	(4,959)
Other long term liabilities	(1,237)	(6,155)	(6,155)	(6,155)
Net Assets	60,077	62,701	24,603	(10,306)
CASH FLOW				
Operating Cash Flow	(17,826)	(28,258)	(35,145)	(35,855)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(14)	(85)	(5)	(38)
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	(22,817)	(35,928)
Opening net debt/(cash)	(5,892)	(21,516)	(53,786)	(30,969)
HP finance leases initiated	0	0	0	0
Other	0	0	0	0
Closing net debt/(cash)	(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.

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the Financial Conduct Authority. Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison and is not regulated by the Australian Securities and Investment Commission. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

EDISON ISRAEL DISCLAIMER

Disclosure regarding the scheme to enhance the awareness of investors to public companies in the technology and biomed sectors that are listed on the Tel Aviv Stock Exchange and participate in the scheme (hereinafter respectively "the Scheme", "TASE", "Participant" and/or "Participants"). Edison Investment Research (Israel) Ltd, the Israeli subsidiary of Edison Investment Research Ltd (hereinafter respectively "Edison Israel" and "Edison"), has entered into an agreement with the TASE for the purpose of providing research analysis (hereinafter "the Agreement"), regarding the Participants and according to the Scheme (hereinafter "the Analysis" or "Analyses"). The Analysis will be distributed and published on the TASE website (Maya), Israel Security Authority (hereinafter "the ISA") website (Magna), and through various other distribution channels. The Analysis for each participant will be published at least four times a year, after publication of quarterly or annual financial reports, and shall be updated as necessary after publication of an immediate report with respect to the occurrence of a material event regarding a Participant. As set forth in the Agreement, Edison Israel is entitled to fees for providing its investment research services. The fees shall be paid by the Participants directly to the TASE, and TASE shall pay the fees directly to Edison. Subject to the terms and principals of the Agreement, the Annual fees that Edison Israel shall be entitled to for each Participant shall be in the range of $35,000-50,000. As set forth in the Agreement and subject to its terms, the Analyses shall include a description of the Participant and its business activities, which shall inter alia relate to matters such as: shareholders; management; products; relevant intellectual property; the business environment in which the Participant operates; the Participant's standing in such an environment including current and forecasted trends; a description of past and current financial positions of the Participant; and a forecast regarding future developments in and of such a position and any other matter which in the professional view of the Edison (as defined below) should be addressed in a research report (of the nature published) and which may affect the decision of a reasonable investor contemplating an investment in the Participant's securities. To the extent it is relevant, the Analysis shall include a schedule of scientific analysis of an expert in the field of life sciences. An "equity research abstract" shall accompany each Equity Research Report, describing the main points addressed. The full scope reports and reports where the investment case has materially changed will include a thorough analysis and discussion. Short update notes, where the investment case has not materially changed, will include a summary valuation discussion. The Agreement with TASE regarding the participation of Edison in the scheme for the research analysis of public companies does not and shall not constitute an approval or consent on the part of TASE or the ISA or any other exchange on which securities of the Company are listed, or any other securities' regulatory authority which regulates the issuance of securities by the Company to the content of the Report or to the recommendation contained therein. A summary of this report is also published in the Hebrew language. In the event of any contradiction, inconsistency, discrepancy, ambiguity or variance between the English Report and the Hebrew summary of said Report, the English version shall prevail; and a note to this effect shall appear in any Hebrew summary of a Report. Edison is regulated by the Financial Conduct Authority. According to Article 12.3.2, Chapter 12 of the Conduct of Business Sourcebook, Edison, which produces or disseminates non-independent research, must ensure that it: 1) is clearly identified as a marketing communication; and 2) contains a clear and prominent statement that (or, in the case of an oral recommendation, to the effect that) it: a) has not been prepared in accordance with legal requirements designed to promote the independence of investment research; and b) is not subject to any prohibition on dealing ahead of the dissemination of investment research. The financial promotion rules apply to non-independent research as though it were a marketing communication.

EDISON INVESTMENT RESEARCH DISCLAIMER

 This report has been prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Aus and any access to it, is intended only for "wholesale clients" within the meaning of the Australian Corporations Act. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2017. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.

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