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Immediate Report **31 July, 2018**

RedHill Biopharma announces positive top-line results from Phase III study of RHB-104 in Crohn's Disease; remission rates at week-52 are low by market comparison; Redhill plans to raise additional capital to support future clinical development; target price remains at NIS 2.59

Primary Exchange: TASE

Secondary exchange: NASDAQ (ADS/share 1:10)

Ticker: TASE, NASDAQ: RDHL

Sector: Biotechnology

Industry: Drug Development

Data as at 30 July, 2018
(Source: TASE)

Closing price: NIS 3.55

Market cap: NIS 758M

# of shares: 213.4M

Stock performance (12 mos.): 0%

Daily-trading-vol. (12 mos.): NIS 1.0M

Stock target price: NIS 2.59

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Highlights & Preliminary Analysis

On 30 July 2018, RedHill released an immediate update, detailing the following:

About RHB-104, and its clinical trials

- RHB-104 is a combination therapy for Crohn's disease. The drug combines three well studied antibiotics (Clarithromycin, Clofazimine and Rifabutin) that have anti-bacterial and anti-inflammatory activities.
- The first phase III clinical trial (MAP US) assessed the Efficacy and Safety of Fixed-dose Combination of RHB-104 ; its results were published , 30th July 2018.
  - The MAP US randomized, double-blind, placebo-controlled first Phase III study of RHB-104 enrolled 331 subjects with moderately to severely active Crohn's disease (defined as CDAI between 220 and 450) in the U.S., Canada, Europe, Australia, New Zealand and Israel.
  - Subjects randomly received RHB-104 or placebo, on-top of baseline background medication including; 5-ASAs, corticosteroids, immunomodulators or anti-TNFα agents.
- Additionally, an open-label extension Phase III study (MAP US2 study) is ongoing to evaluate the safety and efficacy of RHB-104 in subjects who remain with active Crohn's disease (CDAI ≥ 150) after 26 weeks of blinded study therapy in the Phase III MAP US study.

Top-line results from Phase III study with RHB-104 for Crohn's disease (MAP US study) have been released.

- RHB-104 met the primary endpoint of the trial, achieving remission (CDAI <150) by week 26. The proportions were 37% vs. 23% in the placebo group (p=0.013).
- RHB-104 patients had a statistically significant greater response at week 26 (defined as a decrease ≥100 in CDAI from the baseline) compared to placebo (44% vs. 31%, p= 0.028). RHB-104 patients demonstrated statistically significant early remission rates, i.e. by week 16 (42% vs. 29%, p= 0.019).
- RHB-104 patients demonstrated statistically significant durable remission over weeks 16-52, defined as continuous remission throughout the period, (18% vs. 9%, p= 0.038), demonstrating an improvement of 100% over placebo.
- At 52 weeks of treatment, remission in RHB-104 continued to be favorable to placebo (27% vs. 20%, p= 0.155)

Due to the fact that Crohn's disease is chronic and needs to be treated daily, loss of activity at week 52 is not enough, in our view, for Crohn's patients. The company is currently enrolling patients for a trial investigating this endpoint.

- Irrespective of this clinical trial and its results, Redhill will engage in a confirmatory phase III trial based on FDA requirements. These clinical studies will be prolonged for few years until reaching FDA milestone.

Biological drugs (such as Stelara and Risankizumab) have remission rates of ~50% at week 52, this trial produced a figure of only 27% (and the statistic is not significant, at p=15.5%). Further data regarding the patients that completed the trial and the dropout rate is not mentioned.

- The drug's activity is reduced from week 16 to week 52; therefore the drug's durability should be examined. In addition, when testing antibiotics, antibiotic resistance ability should be tested.

We maintain our previous evaluation of the company and retain our target price of NIS 2.59. We assume Redhill to soon raise significant capital to support its forthcoming confirmatory Phase III trial for RHB-104.

This is an initial analysis of the trial results; we will elaborate further in our quarterly report for Q2, which will be published in the next few weeks.

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Credit to Experts: Dr. Tiran Rothman; Daniel Grunstein; Dr. Hadar Cohen-Halevy

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