Q1-2018 Update Report and 12 months since Initiation 22 May, 2018

Net revenues for Q1-18 are lower than estimated; RedHill will have to raise capital in anticipation of its announcement of top-line Phase III results for Crohn's disease, expected in mid-2018; 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 21 May, 2018
(Source: TASE)

Closing price: NIS 2.53

Market cap: NIS 540M

# of shares: 213.4M

Stock performance (Y.T.D.): -28.7%

Daily-trading-vol. (12 mos.): NIS 841K

Stock target price: NIS 2.59

Frost & Sullivan Research & Consulting Ltd.
A: Abba Even 1, Herzliya Pituach
T: +972 (0) 9 950 2888
E: equity.research@frost.com
W: www.frost.com/equityresearch

Kobi Hazan - Lead Analyst
Credit to Experts: Dr. Tiran Rothman; Dr. Anna Cirmirakis; Daniel Grunstein

Company Overview

RedHill Biopharma Ltd. ("the Company" and/or "RedHill") is an Israeli publically-traded specialty biopharmaceutical company focused on the development and commercialization of late clinical-stage drugs candidates. The Company's main focus is advanced clinical development and commercialization in the US of orally-administered, proprietary, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer.

RedHill is currently promoting three gastrointestinal products and is advancing multiple clinical programs: three Phase III for gastrointestinal and inflammation indications and multiple Phase II for various indications including multiple myeloma, hepatocellular carcinoma, pancreatic cancer, and irritable bowel syndrome with diarrhea.

Highlights & Analysis

On 8 May 2018 RedHill released its financial report for Q1-2018, detailing the following:

Important top-line results expected over the next few months

- Top-line results from Phase III study with RHB-104 for Crohn's disease (MAP US study) expected in approximately 3 months. We analyze the RHB-104 asset in detail, in the following report.
- Top-line results from confirmatory Phase III study with TALICIA® for H. pylori infection (ERADICATE Hp2 study) expected Q4/2018

Redhill continues to present lower quarterly net revenues than expected ($4 miilion) of $2.4 million and gross profit of $1.5 million in Q1-2018.

Operating loss of $9.9 million in Q1-2018, reduced 30% over the previous quarter and expected according to the company to continue to decrease over the coming quarters.

- Debt-free balance sheet with $36.4 million in cash at the end of Q1-2018

RedHill announced it does not have plans to raise additional capital ahead of the MAP US Phase III study top-line results with RHB-104 for Crohn's disease. Albeit, the company has a burn rate of approx. $10 million per quarter, and with just $36.4 million in cash RedHill, in our understanding, will need to raise capital within 3-9 months.

We retain our current estimation of the company's equity value at $159.8 million (NIS 551.6M) corresponding to a target price ranging between NIS 2.54 and NIS 2.65; a mean of NIS 2.59.

- In our most recent valuation of 11 March 2018 we raised the target price to 2.59 from the price of 2.27 set on 14 December 2017.

Updates for Q1-2018

Q1-2018 Financial Results

Net Revenues for the first quarter of 2018 were $2.4 million, an increase of 22% from the fourth quarter of 2017.

Gross Profit for the first quarter of 2018 was $1.5 million, an increase of 40% from the fourth quarter of 2017. The company's gross profit margin increased from 54% for the fourth quarter of 2017 to 62% for the first quarter of 2018.

Research and Development Expenses for the first quarter of 2018 were $6.4 million, a decrease of 23% from the fourth quarter of 2017. The decrease from the fourth quarter of 2017 was mainly due to the completion of patient enrollment in the RHB-104 Phase III study for Crohn's disease (MAP US study).

Selling, Marketing and Business Development Expenses for the first quarter of 2018 were $3.2 million, a decrease of 18% from the fourth quarter of 2017. The decrease was due to the Company's cost reduction plan.

General and Administrative Expenses for the first quarter of 2018 were $1.9 million, a decrease of 23% from the fourth quarter of 2017. The decrease was due to the Company's cost reduction plan. Operating Loss for the first quarter of 2018 was $9.9 million, a decrease of 30% from fourth quarter of 2017. The decrease was due to the increase in net revenues and gross profit, and the decrease in operating expenses, as detailed above.

Net Cash Used in Operating Activities for the first quarter of 2018 was $9.5 million, compared to $14.2 million in the fourth quarter of 2017. The decrease was due to the Company's progress with the RHB-104 Phase III study for Crohn's disease (MAP US study) and the overall reduction in operating loss. Cash Balance as of March 31, 2018 was $36.4 million, compared to $46.2 million as of December 31, 2017. The decrease was a result of the Company's ongoing operating activities.

R&D highlights:

RHB-104 - Crohn's disease (first Phase III) The last patient enrolled in the first Phase III study with RHB-104 for Crohn's disease (MAP US study) has completed 26 weeks of treatment for primary endpoint evaluation. Top-line results from the MAP US study **are expected to be announced in approximately 3 months**.

TALICIA® (RHB-105) - H. pylori infection (confirmatory Phase III) (FDA Fast-Track QIDP status) To date, over 300 of the planned total of 444 patients have been enrolled in the ongoing confirmatory Phase III study with TALICIA® (RHB-105) for H. pylori infection (ERADICATE Hp2). RedHill expects to complete enrollment of the ERADICATE Hp2 study in the third quarter of 2018 and announce top-line results in the fourth quarter of 2018. Subject to a successful outcome and additional regulatory feedback, the ERADICATE Hp2 study is expected to complete the package required for a potential U.S. NDA for TALICIA®. The filing is planned for early 2019 and, if accepted for review, the FDA could potentially approve TALICIA® in the second half of 2019 following a priority NDA review.

BEKINDA® (RHB-102) 12 mg - IBS-D (Phase II) On January 16, 2018, RedHill announced positive final results from the Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The randomized, double-blind, placebo-controlled Phase II study successfully met its primary endpoint, improving stool consistency (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo (p-value=0.036). RedHill plans to meet with the FDA in the second quarter of 2018 to discuss the design for one or two pivotal Phase III studies.

YELIVA® (ABC294640) - cholangiocarcinoma (Phase IIa) (FDA Orphan Drug designation) To date, nine patients have been enrolled in the single-arm Phase IIa study with YELIVA® (ABC294640) for the treatment of cholangiocarcinoma (bile duct cancer). Enrollment is expected to be completed by the end of 2018. The study is being conducted at Mayo Clinic major campuses in Arizona and Minnesota, University of Texas MD Anderson Cancer Center and the Huntsman Cancer Institute, University of Utah Health, and is designed to enroll up to 39 patients.

RHB-106 - encapsulated bowel cleanser licensed to Salix Pharmaceuticals RedHill recently amended its 2014 worldwide license agreement with Salix Pharmaceuticals related to RHB-106 encapsulated bowel cleanser, as well as additional related rights. The amendment clarifies the development efforts to be used by Salix, as well as provides for enhanced involvement by RedHill in certain intellectual property matters. In addition, the parties have agreed to increase the lower end of the range of royalty payments to be paid to RedHill on net sales from low single digits to high single digits, such that the potential royalties now range from high single digits up to low double digits. Milestone payments remain unchanged.

RHB-204 - nontuberculous mycobacteria (NTM) infections (planned pivotal Phase III) (FDA Fast-Track QIDP status) A pivotal Phase III study with RHB-204 for the treatment of nontuberculous mycobacteria (NTM) infections is expected to be initiated in the second half of 2018, subject to completion of a supportive non-clinical program and additional input from the FDA. RHB-204 is planned to be assessed as a first-line treatment of NTM disease caused by mycobacterium avium complex (MAC) infection.

Analysis

Net Revenues for the first quarter of 2018 were $2.4 million, lower than we expected in our coverage of RedHill's Annual 2017 report last month. **RedHill's sales of its GI drugs in Q3-2017 totaled approx. $1.5 million; in Q4-2017 $2 million and in Q1-2018 $2.4 a mild increase in revenues**. On the costs side the company is still expanding its sales force, as evident through high expenditure, it is worth examining the potential of future sales operations. Our data (based on the 'Orange book' which contains all drugs sales data) indicates, for example, that before Redhill was granted the rights for distribution of Donnatel, worldwide sales of this drug were $142M in 2015 and $139M in 2016, the majority of sales being in the US. We have also estimated, based on the same source, sales for the other two GI products for the upcoming years.

As the company doesn't share any relevant data with regard to its sales (for example, revenue sharing agreements, total gross sales), we assume a 5% revenue share based on our assumptions, and the US share of the global market, i.e. **RedHill's annual revenues are estimated at approximately $15.9M or approx. $4.0M per quarter, for 2018**.

Despite this first quarter of sales data, we still expect RedHill to increase its revenues to $4 million per quarter. Should the company succeed in doing so, we will adjust our estimations accordingly.

We addressed RedHill's new strategy in forming a sales force in the US in our initiation report of 12 July 2017. After years of successfully implementing a "standard" drug development strategy, with a business model based on licensing out its IP, the company has decided to expand its strategy and set up a sales organization in the US that will drive revenues from selling drugs.

Financially, RedHill maintains a debt-free balance sheet with $36.5M in cash at 31 March 2018. Based on the current net burn rate, **we assume RedHill will raise additional funds in the wake of its announcement of top-line results for RHB-104 due Q3-2018 or earlier.**

We evaluate the company's equity value at $159.8 million (NIS 551.6M) corresponding to a target price ranging between NIS 2.54 and NIS 2.65; a mean of NIS 2.59.

Y.T.D Trading Price of TASE:RDHL

Source: Google Finance

Upcoming Potential Catalysts

Program	Event	Significance	Timeline	Update
BEKINDA® - RHB-102	Top-line Phase II results (IBS-D)	Medium	**Sep 2017**	**Achieved**
(gastroenteritis & IBS-D)	Top-line Phase III results (gastroenteritis)	Medium	**Mid-2017**	**Achieved**
	Clinical Study Report (CSR) from the successful Phase III study (gastroenteritis)	Medium	**Q3-2017**	**Achieved**
RHB-103 - RIZAPORT® (Migraine)	U.S. NDA re-submission	Low	**Oct 2017**	**Achieved**
RHB-104	Meeting with Data and Safety Monitoring Board	High	**Mid-2017**	**Achieved**
(Crohn's Disease)	Group for the MAP U.S. Phase III study for Crohn's disease including safety and interim efficacy analysis, with evaluation of option of early stop for success for overwhelming efficacy.			
	Top-line results MAP US Phase III ongoing	High	**Mid-2018**	On track
	Initiation of pivotal Phase III study for first line treatment of Nontuberculous Mycobacteria (NTM)	High	**Mid-2018**	On track
TALICIA™ (RHB-105)	Initiation of a confirmatory Phase III study for	Medium	**Mid-2017**	**Achieved**
(*H. pylori*)	treatment of *H. pylori* infection			
	Top-line Phase III results	High	**H2-2018**	On track
YELIVA®	Initiation of Phase Ib study to evaluate YELIVA® as a radioprotectant for prevention of mucositis in head and neck cancer patients undergoing therapeutic radiotherapy	Medium	**Q3-2017**	**Achieved**
	Initiation of Phase IIa study with YELIVA® for cholangiocarcinoma	Medium	**Q3-2017**	**Achieved**
	Initiation of a Phase II study with YELIVA® for ulcerative colitis	Medium	**Q4-2017**	Delayed
MESUPRON	Initiation of Phase I/II study in Germany with MESUPRON for pancreatic cancer	Low	**H1-2018**	On track

Sources: Frost & Sullivan Analysis; RedHill.

Executive Summary

Investment Thesis

RedHill is a publicly-traded specialty biopharmaceutical company focused on the development and commercialization of late clinical-stage proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases, and cancer.

As described in our initiation report of 12 July 2017, RedHill is advancing multiple clinical programs, including three Phase III programs for gastrointestinal and inflammation indications and four Phase II programs for multiple indications including multiple myeloma, hepatocellular carcinoma, diffuse large B-cell lymphoma, Kaposi sarcoma, and irritable bowel syndrome with diarrhea. RedHill has several additional Phase I/II studies planned for the following indication; pancreatic cancer (Mesupron), chlangiocarcinoma, radioprotection (prevention of mucositis in head and neck cancer patients undergoing radiotherapy), and ulcerative colitis (YELIVA).

According to Frost & Sullivan estimates, the company addresses a combined market size of more than $10 billion.

Recently, after years of successfully implementing a "standard" drug development strategy, with a business model based on licensing out its IP, the Company has decided to expand its strategy and set up a sales organization in the US that will drive revenues from selling drugs. The Company will continue its current business model in Rest of World markets.

The successful implementation of this new strategy will result in RedHill having a sales platform for its future late-stage drugs candidates. This approach will elevate the Company within the value chain and position it as a player in the Gastrointestinal & Inflammation (GI&I) market rather than as a development company.

We evaluate this strategic turning point with high potential, positioning Red Hill as a long-term investment, however, with a relative risk during the coming years due to its minimal sales experience in “big pharma” and an unknown level of receptiveness by physicians.

However, the new strategy has additional implications, including;

1. Headcount will be nearly doubled with the recruitment of a US-based sales and marketing staff
2. Management will need to focus on marketing, sales, distribution, logistics, reimbursement and collection
3. Investors will start to benchmark the Company against other drug companies, and not only drug development companies
4. Building a sales organization requires significant investment and costs during initial years.

The Company is led by a management team, Board of Directors and Advisory Board based in Israel, the U.S., Canada and Europe, with extensive managerial, financial and transactional experience, as well as a successful track record in bringing patented drugs to the market, at both large and small pharma companies.

Company Activity and Strategy

RedHill Biopharma Ltd. (“the Company" and/or "RedHill”) is a publicly traded specialty biopharmaceutical company focused on the development and commercialization of late clinical-stage proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. The Company is also undertaking a strategic transition towards revenue-generation via a recently announced US co-promotion agreement for Donnatal® and a license agreement for US rights to EnteraGam®.

The Company’s business model is “finance” orientated, based on a lean, fully outsourced business model that relies on effective project management and is built on expertise, supported by the Company's Board of Directors and Advisory Board, based in Israel, the US, Canada, and Europe.

RedHill assembled an experienced gastrointestinal commercial team in the US and initiated promotion of Donnatal® and EnteraGam®, further enhancing its capabilities.

The majority of RedHill's product pipeline comprises therapeutic candidates acquired from pharmaceutical companies that encountered cash flow or operational difficulties, resulting in low purchasing prices and leading to maximal potential capitalization of those assets. RedHill's pipeline can be segmented into two primary groups; (1) new, patent-protected formulations of existing drugs and (2) new, patent-protected fixed-dose combination drugs - a formulation of two or more existing drugs, combined in a single dosage form. Drug candidates in both groups are designed to improve the currently approved drugs they are based on. Such improvements may include more convenient administration forms, reduced daily administrations, improved safety and efficacy profiles, introduction to new therapeutic indications and reduced costs of treatment. A third group is a New Chemical Entity (NCE), a drug that contains no active moiety and has been approved by the FDA in any other application such as YELIVA® and MESUPRON®.

The Company's focus on such therapeutic products lowers the risks associated with clinical development since those products are based on previously approved drugs, with proven safety and efficacy data. Additionally, the development of such products usually involves reduced costs and faster time to market compared to the development of new chemical entities (see the "505(b)(2) regulatory pathway"), which further enhances potential profitability. RedHill’s flagship products, RHB-104, RHB-105, and Yeliva, have the greatest market potential. For instance, RHB-104 for Crohn’s disease has a potentially significant impact on the affected population (see more information on the 505(b) (2) regulatory pathway in Appendix B of our initiation report of 12 July 2017).

The following section analyses RHB-104 as this product will be RedHill’s main growth engine in the coming months.

RHB-104: antibiotics combination for the treatment of Crohn's disease

Background

Crohn's Disease

Crohn's disease (CD) is a chronic inflammatory condition of the gastrointestinal tract. CD, which along with ulcerative colitis (UC) and indeterminate colitis, belongs to a group of conditions known as inflammatory bowel diseases (IBD) with an unknown etiology. All IBD-related pathologies are associated with intestinal inflammation, resulting from uncontrolled inflammatory processes in the gastrointestinal (GI) tract lining, which involves the attack of the tissues by the body's own immune system (i.e. auto-immune disease). CD generally affects the lower part of the small intestine, but can actually affect any area of the GI tract from the mouth down to the anus (Figure 1). The inflammation in CD often spreads deep into the layers of the affected bowel tissue. Symptoms associated with CD do vary from patient to patient, but some are more common than others and include abdominal pain, severe diarrhea, rectal bleeding, and loss of appetite leading to malnutrition.

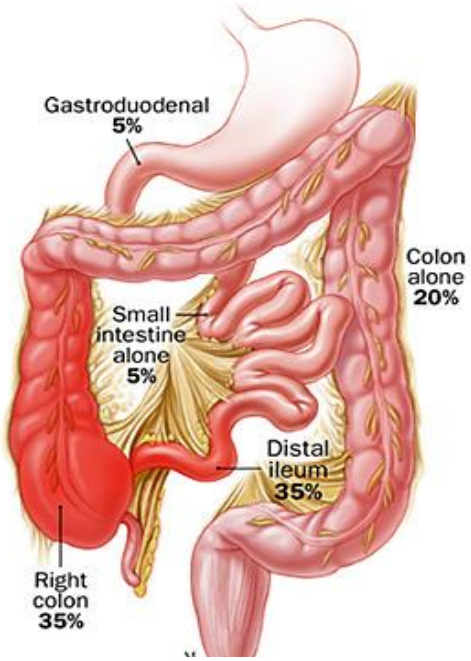


Figure 1: Anatomic distribution of Crohn's disease in the GI tract
(Source: Johns Hopkins Gastroenterology and Hepatology website)

CD complications include abscesses and fistulae, bowel obstructions, perianal disease and colon cancer. Abscesses and fistulae are formed due to the extension of fissure or ulcers through the intestinal wall, with the terminal ileum (the distal part of the small intestine) the most likely point of origin for abscesses, occurring in 15–20% of CD patients. Fistulae occur in 20–40% of patients. Obstructions, mainly in the small intestine, usually result from intestinal mucosa thickening due to acute inflammation, adhesions, and scarring. Bowel obstructions are a major trigger for surgical intervention among CD patients. Perianal disease is a frequent complication characterized by fissures, fistulae or abscesses in the anal region. CD patients have an elevated risk for developing colon cancer, which is regarded to be related to disease severity, duration, and age of onset.

The onset of CD frequently occurs in adolescence or early adulthood, and the disease's course spans throughout the lifetime of the patient, requiring long-term care. CD progression is characterized by periods of active inflammation and symptoms, termed relapse, and periods of symptom improvement and termed remission. The time period between relapse and remission is individual and can rarely be predicted.[1]

Although significant progress has been achieved in interpreting aspects of the molecular pathogenesis of CD, the disease's etiological origins remain unknown and widely debated, as no single factor has consistently met the criteria necessary to be recognized as the sole or major cause of this condition. At present, CD is considered a result of multifactorial causes, including genetic, immune-related, environmental, and infectious triggers.

[1] https://www.crohnsandcolitis.org.uk/. Accessed 28th of June 2017

The MAP connection

Mycobacterium avium subspecies paratuberculosis (MAP) is a gram-positive, small rod-shaped bacterium, characterized by a unique cell wall structure rich in complex lipids (Figure 2). This thick and chemically distinctive cell wall is largely responsible for the bacteria's robust nature, both within the host cell and in the environment, by providing an increased resistance to low pH, high temperature, and a variety of chemicals, and resulting in high endurance and pathogenic potential in harsh and varied environments. MAP bacteria are able to evade host defenses and their resistance mechanisms allow them to survive within phagosomal compartments for more than two weeks.

Historically, Crohn's disease has been suspected to be associated with bacterial infection, with MAP being the prominent candidate. This suspicion became a viable theory only during the 1980's, following successful growth of MAP bacteria from patients with Crohn's disease.. Since then, data has been generated to establish an association between MAP infection and Crohn's disease[2]. More specifically, it is claimed by some that CD is caused by an interaction between MAP bacteria and the immune system in individuals with a predisposition to the pathological inflammatory reaction[3]. However, controversy exists over the nature of this association, and scientists are still debating whether MAP infection is the sole cause of Crohn's disease or only a contributing factor for the disease's development in some patients. This theory has also been reviewed and investigated by Food Safety Authorities in the United Kingdom, Ireland and the European Union, and all have concluded that the evidence for MAP being a causative agent for Crohn's disease is inconclusive. The main arguments of each side are presented in the following table.

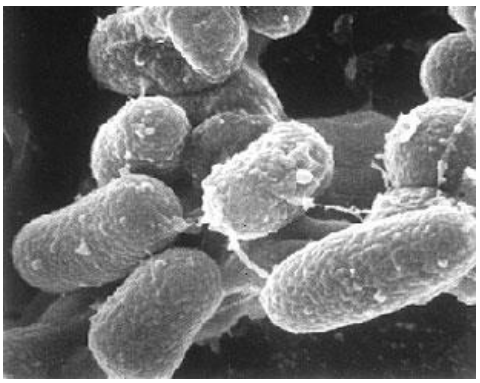


Figure 2: Scanning electron micrograph of MAP bacteria.
(Source: microbewiki.kenyon.edu)

[2] Martin Feller et al. Mycobacterium avium subspecies paratuberculosis and Crohn's disease: a systematic review and meta-analysis. The Lancet Infectious Diseases 2007:607-613
[3] Robert J Greenstein. Is Crohn's disease caused by a mycobacterium? Comparisons with leprosy, tuberculosis, and Johne's disease. The Lancet Infectious Diseases 2003:507-514

Pro and con arguments for MAP as a sole causative factor in CD

	MAP is the sole cause of CD	MAP is a contributing factor in some CD patients
Pathological similarity	MAP is the etiologic agent of Johne's disease – a mammalian disease that resembles some clinical and pathological aspects of Crohn's disease. MAP isolated from a Crohn's disease patient induced Johne's disease in goats and mice.	Other microbial species have been detected in Crohn's disease patients such as M. avium complex, Helicobacter species, Listeria monocytogenes an, E coli, Bacteriodes vulgaris and measles virus.
Means of transmission	MAP is transmitted to humans through various means, including infected water, milk, and meat.	
Prevalence in CD patients	MAP infection appears to be present in about 30-50% of CD patients, and is more prevalent in CD patients than in Ulcerative Colitis patients[4][5]. There are also other publications demonstrating prevalence of MAP in CD patients as high as 92%[6]	The presence of MAP in a patient's tissues does not prove causality. MAP has been detected in some healthy controls and in patients with other inflammatory bowel disorders
MAP detection	Current MAP detection methods are sub-optimal	Not all patients with Crohn's Disease have MAP infections.
Anti-mycobacterial treatment	Existing anti-mycobacterial drugs are not efficient enough to eliminate this resistant bacterium	So far there have not been sufficient studies showing that anti-mycobacterial drugs do cure CD.
Contra-indication with steroid therapy	NA	The widespread steroid-based treatment of Crohn's patients would be contra-indicated in a mycobacterial disease, making the disease worse rather than better.
Epidemiology	MAP has been convincingly epidemiologically correlated with CD patients in Wales and Sardinia.	Isolated clusters of cases do not necessarily indicate a comprehensive effect.

Currently, there is insufficient scientific evidence to prove a causal link between Johne's disease (or MAP) in animals and Crohn's disease in humans. Most investigators acknowledge that Crohn's disease is unlikely a single disease entity and probably represents a syndrome with multiple etiologies. However, MAP infection could be the sole cause, or at least a major contributing factor, for a significant sub-population of Crohn's disease patients.

Market, standard of care and unmet needs

Approximately 1 million residents in North America and 2.5 million in Europe are estimated to have IBD[7]. The incidence of Crohn's disease itself ranges from 5.0 - 10.7 per 100,000 person-years globally. However, it is estimated that the real number of patients is considerably higher due to under-diagnosis.

There is geographical as well as ethnic variation observed. The condition is more common in urban areas and in northern developed countries, although it has been observed to be on the increase in developing nations.

[4] Sandborn WJ. The Present and Future of Inflammatory Bowel Disease Treatment. Gastroenterology & Hepatology. 2016;12(7):438-441
[5] Selby et al. Two-year combination antibiotic therapy with clarithromycin, rifabutin, and clofazimine for Crohn's disease. Gastroenterology. 2007;132(7):2313-9
[6] Bull, Tim J. et al. "Detection and Verification of Mycobacterium Avium Subsp. paratuberculosis in Fresh Ileocolonic Mucosal Biopsy Specimens from Individuals with and without Crohn's Disease." Journal of Clinical Microbiology 41.7 (2003): 2915–2923. PMC. Web. 29 June 2017.
[7] Gilaad G. Kaplan The global burden of IBD: from 2015 to 2025. Nature Reviews Gastroenterology & Hepatology 12, 720–727 (2015)

Historically, the geographic distribution of Crohn's disease proposed a north-south gradient of incidence, as the disease was originally recognized in Northern Europe and North America. However, recent data have shown increased prevalence also in South Africa and Australia (Figure 3). Generally, urban areas have higher disease incidence rates compared to rural populations. Several ethnic minorities, such as Jews originating from Europe (Ashkenazi Jews) and individuals of Scandinavian descent are at increased risk.

Figure 3: Geographic segmentation of Crohn's disease incidence rates.
The rates range between >7 cases per 100,000 people (red) to <1 per 100,000 (blue)[8]
Source: Johns Hopkins Gastroenterology and Hepatology website)

The 2014 global Crohn's disease therapeutics market was estimated at $3.17 billion. Over the next years, this market is predicted to expand moderately at a CAGR of 3% and reach $4.2 billion by 2020[7]. The US will continue to hold the highest market share followed by Canada and Japan. The slow expected market growth is attributed mainly to patent expiries of commonly prescribed therapies, such as Remicade and Entocort EC and the subsequent launch of generics / biosimilars.

Since the causation of Crohn's Disease has not been fully understood, conventional treatment is directed almost exclusively at suppressing the inflammatory processes, although the dysregulation of the immune system is likely secondary to the disease's actual trigger. This anti-inflammatory therapeutic strategy is usually efficient in the short term, but the disease almost invariably relapses. The standard approach to CD management is divided into treatment of an active disease (induction of clinical response and remission), and maintenance therapy, aimed at maintaining clinical remission and prevent relapses. Treatment for active disease is given to the point of symptomatic remission, with maximal improvement expected to occur within 12 to 16 weeks. Surgery is used for removal of cancerous/pre-cancerous lesions, bowel obstructions, or when the disease is medically intractable. Since CD is highly variable among patients, as well as during the course of the disease in specific patients, therapeutic regimens are adjusted according to the disease's location, severity, and associated complications. Therapeutic approaches are further individualized according to the symptomatic response and tolerance to medical intervention.

[8] Economou and Pappas. New Global Map of Crohn's Disease: Genetic, Environmental and Socioeconomic Correlations. Inflamm Bowel Dis 2007, 14 (5): 709–720

Current CD management is based on several drug classes:

Anti-Inflammatory Drugs

5-aminosalicylic acid (5-ASA) derivatives (mesalamine, mesalazine, and sulfasalazine) are bowel-specific anti-inflammatory agents. These drugs are metabolized in the GI tract, which enables them to exert their pharmacological effects at the site of inflammation (the intestinal mucosa), rather than systemically. 5-ASA derivatives have few adverse effects. Drugs of this class are typically used for inducing remission in mild to moderate disease and are not very effective for patients with active disease limited to the small intestine, or as maintenance therapy.

Steroid Drugs

Corticosteroids (such as prednisolone and budesonide) are very efficient for short-term symptom improvement and induction of remission. A newer type of corticosteroid, budesonide (Entocort EC), works faster than traditional steroids and is associated with fewer side effects. Corticosteroids are often combined with a 5-ASA drug for inducing remission.

While corticosteroids are an integral part of therapy for moderate to severe CD, chronic treatment is associated with numerous side effects, ranging from insomnia and hyperactivity to diabetes, osteoporosis, high blood pressure, glaucoma and an increased susceptibility to infections. Additionally, more than 50% of patients treated acutely with corticosteroids become steroid dependent or steroid resistant.

Immuno-suppressant drugs

Immuno-suppressant therapy (azathioprine, 6-mercaptopurine, and methotrexate) alters the immune response by inhibition and suppression of cellular components of the immune system. This therapy has been shown to be effective for both inducing and maintaining remission; however, two to three months of Immuno-suppressant therapy are usually required before results are achieved. These drugs are usually indicated for inducing remission in patients that have not responded to corticosteroids/5-ASA therapy, as first-line remission maintenance therapy, and as a mechanism for steroid sparing. Potential side effects of the drugs in this class include fever, rash, nausea, leukopenia, hepatitis, increased susceptibility to infections and pancreatitis. Those drugs are not approved by the FDA for the treatment of Crohn's disease.

Antibiotics

Antibiotic treatment, mainly Metronidazole and Ciprofloxacin, is currently used in Crohn's disease following intestinal surgery, for the treatment of perianal disease complications, and for the treatment of infection or abscess. So far, controlled clinical trials with anti-bacterial agents have not been consistent in terms of their effectiveness for treating active disease, and their efficacy in maintaining remission has yet to be properly evaluated in clinical trials.

Biologic Therapies

Anti-TNFα antibodies, such as Infliximab (Remicade), Adalimumab (Humira) and Certolizumab pegol (Cimzia), as well as integrin receptor antagonists such as vedolizumab (Entyvio) and Natalizumab (Tysabri), and Targeting Interleukin-12 and Interleukin-23 cytokines ustekinumab (Stelara), are relatively new and potent biologic agents used for treatment of several inflammatory diseases, including CD. These treatments are approved for patients with moderate to severe active disease, refractory to immuno-suppressants, as a third line therapy. These drugs have also shown efficacy in sustaining clinical remission with re-infusion at 8-week intervals.

Drawbacks of treatment with anti-TNFα antibodies include invasive administration (intravenous or subcutaneous), high treatment costs ($13,000-20,000 a year), loss of response (in nearly 60% of patients during the first year of treatment), and adverse events, such as reactivation of latent tuberculosis, acute and

delayed hypersensitivity, development of antibodies against the therapy and anergy (lack of reaction to infections by the body's defense mechanisms).

Main brand names of the different drug classes used for the treatment of CD are presented in the following table.

Leading marketed Crohn's disease therapies[9]

Trade name (Generic name)	Company	Patent expiry	Sales (2016)*	Remarks
5-aminosalicylic acid (5-ASA) derivatives				
Asacol/Asacol HD (Mesalazine)	Allergan	2013 / 2021(HD)	$618.5m (2015)	- Coated with a pH-sensitive acrylic polymer, releases 5-ASA in the distal ileum and colon. - Asacol HD is a double dose tablet. - ASACOL® HD lost exclusivity on August 1, 2016.
Pentasa (Mesalamine)	Shire/Ferring	Expired (2012)	$305.8m (2015)	Coated granules that release 5-ASA in the upper GI tract, ileum, and colon.
Lialda (Mesalazine)	Shire	2020	$684.4m (2015)	A sustained release version of Pentasa for once daily administration.
Corticosteroids				
Entocort EC (Budenoside)	AstraZeneca / Perrigo	Expired (2012)	~$90m	Sustained-release capsules. The first drug to be approved by FDA for use in children with the active disease.
Biologic Therapies				
Remicade (infliximab)	Janssen	2013-14	$6,966m	Infliximab-dyyb (Inflectra), a biosimilar to Remicade
Humira (adalimumab)	AbbVie	2016-18	$16,078m	Adalimumab-atto (Amjevita), a biosimilar to Humira.
Cimzia (Certolizumab pegol)	UCB	2024	$1,170m (2015)	
Tysabri (Natalizumab)	Biogen	2015	$1,964m	
Entyvio (Vedolizumab)	Takeda		$241m (2015)	Approval date May 20th, 2014
Stelara (ustekinumab)	Janssen	2022	$3,232m	Anticipated peak year sales $399.5M in 2022

*Sales figure represents income from all approved therapeutic indications.

Source: Evaluate Pharma; Frost & Sullivan

[9] Sandborn WJ. The Present and Future of Inflammatory Bowel Disease Treatment. Gastroenterology & Hepatology. 2016;12(7):438-441

Current treatment guidelines of Crohn's, especially in mild-to-moderate disease manifestations, have not changed dramatically in the past years. The market introduction of anti-TNF antibodies shifted treatment guidelines of the moderate-to-severe disease forms, but treatment prices and side effects prevent those therapies from widely advancing to earlier lines of therapy.

The major unmet needs in current Crohn's disease management include an extension of remission periods and delaying the need for surgery and for treatment with steroids/immuno-suppressants. Those treatment options have major safety issues and should be ideally avoided. Another important issue that needs to be addressed is lowering the risk of serious infections in moderate-to-severe disease.

RHB-104

RHB-104 is a patented combination of three generic antibiotic agents - clarithromycin, clofazimine, and rifabutin, in a single capsule for the treatment of Crohn's disease. This treatment's rationale is based on the assumption that CD, at least in some patients, is caused by the presence of MAP bacterium. The drug is currently developed for the treatment of moderate-to-severe active Crohn's disease in adults. However, RedHill obtained an FDA Orphan Drug status for RHB-104 for the treatment of CD in the pediatric population and may pursue a regulatory approval for this population as well.

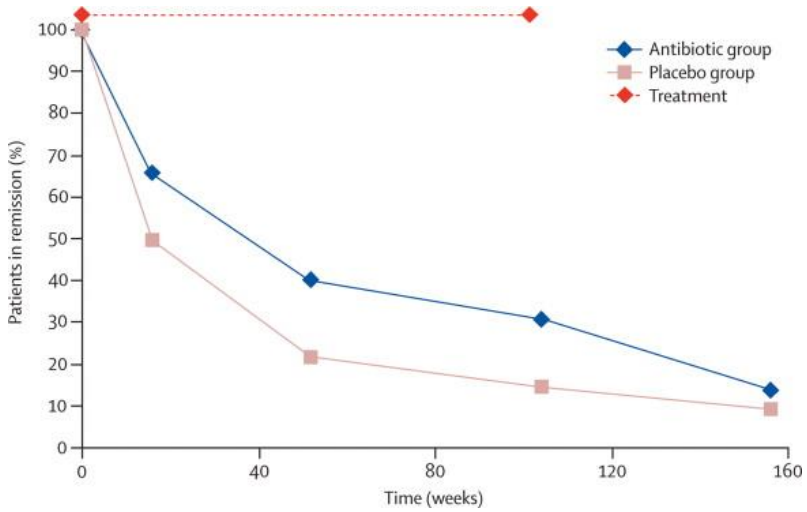
RHB-104 is based on the studies Professor Thomas Borody, a leading investigator of therapeutic approaches for GI diseases and infections, who formulated the original anti-MAP triple therapy. The triple therapy formula was initially licensed by Pharmacia, which conducted several clinical trials with it prior to its merger with Pfizer, which discontinued the drug's development. Eventually, RHB-104 was acquired by RedHill in 2010 from Giaconda Ltd, a publicly traded Australian company.

In 2011, RedHill acquired the exclusive rights to two separate patented technologies for the identification of the presence of MAP bacteria from the laboratory of Professor Naser of the University of Central Florida in Orlando and from the University of Minnesota. Later on, RedHill entered into an agreement with Q^2 Solutions (formerly Quest Diagnostics Ltd.) to develop a commercial Polymerase Chain Reaction (PCR) diagnostic test for MAP bacteria DNA in the blood, based on the acquired technology. The Company also initiated a collaboration with Baylor College of Medicine intended to further advance the efforts to develop a companion diagnostic for MAP. According to the Company, PCR technology is the most promising approach currently available and it is focusing its efforts in that direction. The development of a company ion diagnostic is expected to contribute to the understanding of the role of MAP infection in CD.

Clinical development

Several clinical trials were conducted with an earlier combination of the drug including two Phase II studies (in 2002 and 2005), a Phase III study (published in 2007) and a pediatric study in Australia (published in 2013). The Phase III study was designed to assess the efficacy of the treatment in the reduction of recurrent disease symptoms (disease relapses) during 12, 24 and 36 months, among patients that responded to an initial 16-week treatment. The study's secondary objective was to assess the rate of patients whose clinical condition improved (induction of remission) within the first 16 weeks of treatment.

The study's primary endpoint of reducing long-term relapse rate was not met, due to underpowering of the study; however, the percentage of subjects that achieved remission at week 16 of the treatment was significantly higher compared to patients treated with placebo[8]. A re-analysis of the study's results based on the intent-to-treat (ITT) principle (ITT analysis includes every subject who is randomized according to randomized treatment assignment. It ignores non-compliance, protocol deviations, withdrawal, and anything that happens after randomization) found a statistically significant advantage for the therapy over the placebo, in terms of remission rates, that lasted as long as the therapy was administered.



The therapeutic effect of clarithromycin, rifabutin, and clofazamine combination treatment (RHB-104 – blue line) vs. placebo (red) over time for patients with Crohn's disease.
(Source: Behr and Hanley, The Lancet 2008[10].

Ongoing development

RedHill is currently running a first Phase III study with RHB-104 for the treatment of moderate-to-severe active Crohn's disease. This study will differ from the previous Australian Phase III study in several aspects:

- RHB-104 is a single formulation of all three antibiotics, unlike the triple therapy formula that was used in the Australian study, which comprised three different pills.
- RHB-104 includes increased doses of two out of the three antibiotic agents, as it was suspected that the doses used in the Australian study were sub-optimal.
- The treatment protocol includes titration of the drug to a maximal dose.
- Different clinical endpoints.

The first Phase III study is currently being conducted in North America, Europe, Israel, Australia and New Zealand, under an Investigational New Drug (IND) application ("MAP US Study") through the 505(b) (2) regulatory pathway. The IND application is a process by which a drug developer receives authorization from the US FDA to perform clinical trials in the US to study an unapproved drug treatment. The MAP US Study is a multi-center, randomized, double-blind, placebo-controlled study that was initiated in Q3 2013. In the MAP US Study, 410 CD patients with the active disease will receive RHB-104 or placebo over a 26-week period to determine efficacy and safety, with an additional six months' follow-up period.

The primary endpoint for the study is the state of remission at week 26 in the treatment arm, compared to the placebo arm. Secondary and exploratory endpoints will include state of response at 26 weeks, maintenance of remission through week 52 and efficacy outcome measures in relation to the presence of MAP bacterial infection.

A 1st safety-focused DSMB (Data and Safety Monitoring Board) was held in December 2016. The DSMB recommended continuing the study as planned. A 2nd DSMB meeting is expected to take place in mid-2017 to discuss safety and efficacy, with an evaluation of an option for early-stop for success. A 3rd safety-focused DSMB meeting will be expected once 75% of subjects complete 26 weeks of study participation. It is expected that patient enrollment will be completed by the end of 2017.

In addition, an open-label extension study was initiated in Q1 2017 for all subjects in the MAP US study with Crohn's Disease Activity Index (CDAI)>150 at 26 weeks.

[10] Behr and Hanley. Antimycobacterial therapy for Crohn's disease: a reanalysis. The Lancet Infectious Diseases 2008, 8(6): 344

As mentioned earlier, RedHill received an Orphan Drug status for RHB-104 for the treatment of pediatric CD patients. Single site, a retrospective study was conducted independently of RedHill by Professor Thomas Borody, MD in Australia and the results were presented at the American College of Gastroenterology 2013 Annual Scientific Meeting and published in The American Journal of Gastroenterology. The results of the study showed clinical remission in 8 out of 10 pediatric Crohn's disease patients with mild adverse events and with no subjects requiring dose adjustment. One patient was excluded due to secondary infection and one patient was non-compliant.

In addition to developing a treatment for CD, RedHill has also acquired the exclusive rights to several technologies and is developing a companion MAP diagnostic test with Q^2 Solutions (Quest Diagnostics). This diagnostic test is aimed at identifying the presence of MAP bacteria in CD patients.

RHB-104 is covered by several issued and pending patents with various patent expiry dates.

Pipeline Competition

The CD therapeutics pipeline is robust and varied, with several first-in-class molecules in late-stage clinical development. The launch of those products is expected to balance the anticipated arrival of several generic/biosimilar drugs (mainly for Entocort EC and Remicade) and expand the current market.

The CD therapeutics pipeline can be segmented into small molecules, biologic therapies, and cell-based therapies. The more advanced drug candidates of each class are presented in the following table.

Advanced Crohn's disease therapeutics pipeline (Phase III drugs)

Drug	Company	Development stage	Mechanism of action	Remarks
Small molecules				
Vercirnon	GSK/ ChemoCentryx	Phase III	C-C chemokine receptor type-9 antagonist	Vercirnon is a Phase III-ready drug candidate for the potential treatment of patients with moderate-to-severe Crohn's disease, a chronic inflammatory condition of the gastrointestinal tract
Mongersen	Celgene	Phase III	Gene expression inhibitor, SMAD7 inhibitor	Oral antisense oligonucleotide
Filgotinib	Abbott	Phase III	Janus kinase 1 inhibitor	The first Janus kinase (JAK) inhibitor showing efficacy in moderate-to-severe Crohn's disease patient
Masitinib	AB Science	Phase III	Tyrosine kinase inhibitor	
Biologic Therapies				
Etrolizumab	Roche	Phase III	Alpha4beta7 integrin antagonist	Humanized Monoclonal antibody
Infliximab	Pfizer	Phase III	Tumor necrosis factor alpha antagonist	Monoclonal antibody therapy
Cell-based therapies				
PROCHYMAL	Osiris Therapeutics	Phase III	Adult human mesenchymal stem cells	Intravenous infusion of adult human mesenchymal stem cells for treatment-refractory moderate-to-severe CD.

Source: Data generated from Pharmaprojects

Small molecules

The CD small molecule pipeline consists of improvements in currently used drugs, as well as molecules aimed at new therapeutic targets. The first group contains several new formulations of budesonide (a corticosteroid) offering sustained or targeted release of the drug in the intestines. The latter group takes up the majority of the small molecules pipeline and comprises molecules with various anti-inflammatory activities, including inhibition of pro-inflammatory cytokines, potentiation of anti-inflammatory cytokines, inhibition of pro-inflammatory cell signaling, and inhibition of gut-specific lymphocyte homing.

There are numerous small molecules being developed, including but not limited to Mongersen (GED-0301, Celgene) - an investigational oral antisense oligonucleotide targeting Smad7; Ozanimod (Celgene) - an oral agonist of the sphingosine-1-phosphate subtype 1 (S1P1) receptor; Xeljanz (Tofacitinib citrate, Pfizer) - an oral, small-molecule Janus kinase inhibitor; and ABT-494 (Upadacitinib, Abbvie) - a JAK1 selective inhibitor.

Biologic therapies

The biologic therapies pipeline consists mainly of monoclonal antibodies (mAbs) targeting several inflammation-associated proteins, such as interleukins and integrins. Most of these mAbs are tested for their ability to induce remission, as well as to maintain it, in patients that failed or are intolerant to anti-TNFα therapy. Clinical data shows that at least some of those antibodies are successful at both.

There are numerous biologic therapies being developed including but not limited to Medi2070 (AstraZeneca/Allergan) – a fully human IgG2 monoclonal antibody that selectively binds the p19 subunit of IL-23 an (anti-cytokine antibodies); Etrolizumab (Roche) - a humanized IgG1 MAb targeting the beta 7 integrin subunit; and PF-00547659 (Pfizer/ licensed to Shire worldwide) - a fully human IgG2 monoclonal antibody targeting MAdCAM on endothelial cells.

Neovacs is taking a different approach, designed to solve the major problems associated with anti-TNF Abs - allergic reactions and loss of response. Neovacs' TNF Kinoid is an active TNFα immunization that stimulates the body's immune system to produce its own antibodies against TNFα. This product is in the pre-clinical state for Crohn’s indication.

Cell-based therapies

These treatments are developed as last line therapies, for patients that have failed all other treatment options. Stem cell treatments, developed by Osiris, are based on the ability of such cells to act as immune modulators by secreting anti-inflammatory mediators. TxCell is taking a different approach to cell-based treatment with OvaSave - a T cell-based vaccine, based on the patient's own T-cells that are activated and infused back into the blood circulation.

Summary of the competitive analysis

In addition to therapies that are being developed for CD as a primary indication, other anti-inflammatory treatments, which are currently marketed or developed for the treatment of other autoimmune/inflammatory indications (such as rheumatoid arthritis or psoriasis) may be repositioned to the CD market. Regardless of the therapeutic approach, characteristics of new treatments for Crohn's should include an extension of remission periods/improvement of remission induction, a good safety profile, fast therapeutic effect and convenient administration in regard to administration route and intervals.

The entire CD therapeutics pipeline is addressed at modulating the inflammatory processes associated with the disease. Moreover, the majority of the drug candidates are directed at moderate to severe CD and aims to dethrone the anti-TNF antibodies, which are responsible for the large share of revenues in the CD market due to their high costs. Clinical advantages over the currently used therapies, in terms of better efficacy and

safety, will influence market penetration of upcoming drugs, with oral enzyme inhibitors having great potential due to their easier administration route compared to the injected antibodies.

Unlike its pipeline competitors, RHB-104 is not an anti-inflammatory agent yet some of the RHB-104 components have an anti-inflammatory effect. This differentiation from the bulk could be an advantage, should this drug candidate prove to be efficient in inducing remission without safety issues. However, the different mechanism of action of RHB-104, and the fact that its relation to CD is not widely accepted in the scientific community could interfere with the drug's commercial potential and complicated ramp-up period, if clinical efficacy will not be remarkable. In our view, utilization of a validated MAP detection kit to screen MAP positive patients can greatly influence the clinical success of RHB-104, and its revenue generation accordingly.

As most repositioned drugs, should RHB-104 reach the market, its sales could be hampered by the off-label use of separate generic antibiotic agents. However, in the specific case of RHB-104, such a scenario is less probable since off-label use will require physicians to prescribe three different pills compared to a single capsule. In addition, the proposed treatment protocol of RHB-104, that includes dose titration, will complicate such off-label use.

Another barrier for wide use of the RHB-104 is limited accessibility to one of the antibiotics, clofazimine, which can be distributed by the World Health Organization as well as the US Department of Health and Human Services. It can also be accessed through Novartis Expanded Access Program for eligible nontuberculous mycobacterial patients. It is not commercially available and generally requires name-based individual import permit for use.

Exploring an additional indication for RHB-104 – Multiple Sclerosis

Based on the same scientific rationale described earlier for the use of anti-MAP treatment for CD, i.e. an infectious background for inflammatory diseases, RedHill is exploring a possible use of RHB-104 for the treatment of Multiple Sclerosis (MS). MS is a neurological autoimmune disease in which the body's immune system attacks the protective myelin sheath around the axons of neurons in the brain and spinal cord. The damage to the myelin causes irreversible nerve deterioration that results in physical and cognitive disabilities.

In December 2016, RedHill completed a Phase IIa proof of concept study to assess the efficacy and safety of fixed-dose combination RHB-104 as add-on therapy to interferon beta-1a in patients treated for relapsing remitting multiple sclerosis.

RedHill also performed multiple pre-clinical studies with RHB-104 for varied indications, including rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), type 1 diabetes (T1D) and psoriasis. In addition, this molecule was granted QIDP designation by FDA for the treatment of nontuberculous mycobacteria (NTM).

Appendix

Appendix I - Financial Reports

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION (USD 000s)	December 31, 2017	March 31, 2018
CURRENT ASSETS:		
Cash and cash equivalents	16,455	7,560
Bank deposits	13,163	13,206
Financial assets at fair value through profit or loss	16,587	15,584
Trade receivables	1,528	1,809
Prepaid expenses and other receivables	3,290	2,019
Inventory	653	560
Total Current Assets	**51,676**	**40,738**
NON-CURRENT ASSETS:		
Bank deposits	152	150
Fixed assets	230	221
Intangible assets	5,285	5,285
Total Non-Current Assets	**5,667**	**5,656**
TOTAL ASSETS	**57,343**	**46,394**
CURRENT LIABILITIES:		
Accounts payable	4,805	2,724
Accrued expenses and other current liabilities	6,025	6,481
Payable in respect of intangible asset purchase	1,000	500
Total Current Liabilities	**11,830**	**9,705**
NON-CURRENT LIABILITIES: Derivative financial instruments	**448**	**398**
TOTAL LIABILITIES	**12,278**	**10,103**
EQUITY:		
Ordinary shares	575	577
Additional paid-in capital	177,434	177,787
Accumulated deficit	-132,944	-142,073
TOTAL EQUITY	**45,065**	**36,291**
TOTAL LIABILITIES AND EQUITY	**57,343**	**46,394**

Consolidated Statement of Profit and Loss	March 31, 2018	March 31, 2017
	U.S. dollars in thousands	
Net Revenues	2,445	—
Cost of Revenues	930	—
Gross Profit	**1,515**	**—**
Research and Development Expenses, Net	6,416	8,137
Selling, Marketing and Business Development Expenses	3,170	605
General and Administrative Expenses	1,924	1,315
Other Expenses	—	45
Operating Loss	**9,995**	**10,102**
Financial Income Net	60	1,506
Loss and Comprehensive Loss for the Period	**9,935**	**8,596**
Loss per ordinary share, basic and diluted (USD)	0.05	0.05

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Kobi Hazan
T: +972 (0) 9 950 2888
E: equity.research@frost.com

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