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ASIA EDITION

RedHill BioPharma reports Q1 2019 results

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RedHill announced in January 2019 that it had received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for an additional new patent covering Talicia.



RedHill Biopharma, a specialty biopharmaceutical company primarily focused on gastrointestinal (GI) diseases reported its financial results and operational highlights for the quarter ended March 31, 2019.

“We had a productive quarter with Talicia leading up to the NDA submission to the FDA, announced earlier today. With potential NDA approval as early as the fourth quarter of this year, we have expanded our highly experienced commercial management team and are advancing the preparations for the potential U.S. launch of Talicia with our established sales-force,” said Micha Ben Chorin, RedHill’s chief financial officer. “As of March 31, 2019, we have maintained a cash position of $45.5 million with a debt-free balance sheet and continued decrease of our quarterly cash burn to its lowest level in two years.”

Operational Highlights:

Talicia (RHB-105) - Eradication of *H. pylori* Infection

RedHill submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Talicia for the treatment of *H. pylori*infection following positive results from two Phase 3 studies and a positive pre-NDA meeting with the FDA earlier this year. Talicia was granted Qualified Infectious Disease Product (QIDP) designation by the FDA, including eligibility for six-month priority review and an additional three years of market exclusivity on top of the standard five years, for a total of eight years of U.S. market exclusivity. Assuming FDA approval, RedHill plans to launch Talicia in the U.S. in the fourth quarter of 2019 with the Company’s dedicated sales force.

RedHill announced in January 2019 that it had received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for an additional new patent covering Talicia. The patent was subsequently granted and is valid until at least 2034. This is the fifth patent covering Talicia in the U.S. RedHill also announced in March 2019 that the European Patent Office (EPO) and the Japan Patent Office (JPO) accepted pending patent applications covering Talicia for*H. pylori* infection. The

Japanese patent was subsequently granted and is valid until 2034.

RHB-104 - Crohn's Disease

RedHill plans to meet with the FDA in the second half of 2019 to discuss the development path toward potential approval of RHB-104**,** including the design of a confirmatory Phase 3 study. This meeting follows the positive results from the first Phase 3 study with orally-administered RHB-104 for the treatment of Crohn's disease (MAP US study). The MAP US study successfully met both its primary endpoint and its key secondary endpoints and presented the broad benefit of RHB-104 as an add-on therapy to standard-of-care treatments for Crohn's disease, including anti-TNFs. RedHill continues to assess additional data from the positive study as it becomes available.

RHB-204 - Pulmonary Nontuberculous Mycobacteria (NTM) Infections

RedHill plans to initiate a pivotal Phase 3 study with RHB-204 for the treatment of pulmonary NTM infections in the second half of 2019, subject to completion of the ongoing supportive non-clinical program and additional input from the FDA. The study is intended to assess the efficacy and safety of RHB-204 and potentially support its approval as a stand-alone, first-line treatment for pulmonary NTM infections caused by Mycobacterium avium complex (MAC).

BEKINDA (RHB-102) - Gastroenteritis and Gastritis and Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

RedHill is currently working toward a confirmatory Phase 3 study to support a potential NDA for BEKINDA for acute gastroenteritis and gastritis. This study follows the successful completion of a first Phase 3 study with BEKINDA for acute gastroenteritis and gastritis and guidance provided by the FDA.

RedHill held a positive end-of-Phase 2 Type B meeting with the FDA to discuss the clinical and regulatory pathway toward potential U.S. approval of BEKINDA for the treatment of IBS-D. RedHill is currently finalizing the design of two pivotal Phase 3 studies with BEKINDA for IBS-D.

YELIVA (opaganib, ABC294640) - Cholangiocarcinoma

The ongoing Phase 2a study evaluating the activity of orally-administered YELIVA in advanced cholangiocarcinoma (bile duct cancer) continues to enroll patients in the second stage of the two-stage study design. Enrollment of the full cohort of 39 evaluable patients is expected to be completed by the end of 2019.

Commercial Highlights:

RedHill is continuing its preparations for the potential U.S. launch of Talicia in the fourth quarter of 2019 with its dedicated sales force. RedHill currently commercializes and promotes several GI-specialty products in select U.S. territories, including Donnatal (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide), EnteraGam (serum-derived bovine immunoglobulin/protein isolate SBI) and Mytesi (crofelemer 125 mg delayed-release tablets).

Financial highlights for the quarter ended March 31, 2019[5]

- ***Net Revenues*** of $1.7 million in the first quarter of 2019, an increase of 28% compared to the fourth quarter of 2018. The growth was attributable to an increase in revenues from promoted products.

- ***Gross Profit*** of $1.3 million in the first quarter of 2019, compared to $0.8 million in the fourth quarter of 2018, with gross margin increased from 57% to 76%. The growth was attributable to an increase in revenues from promoted products.

- ***Research and Development Expenses*** of $5.4 million in the first quarter of 2019, compared to $5.8 million in the fourth quarter of 2018, resulting from the successful finalization of the confirmatory Phase 3 study with Talicia.

- ***Selling, Marketing and Business Development Expenses*** of $3.1 million in the first quarter of 2019, compared to $3.2 million in the fourth quarter of 2018.

- ***General and Administrative Expenses*** of $2.0 million in the first quarter of 2019, compared to $1.9 million in the fourth quarter of 2018.

- ***Operating Loss*** of $9.2 million in the first quarter of 2019, compared to $10 million in the fourth quarter of 2018. The decrease in Operating Loss was primarily due to the increase in Gross Profit and the decrease in Research and

Development Expenses, as described above.

- ***Net Cash Used in Operating Activities*** of $7.5 million in the first quarter of 2019, compared to $8.2 million in the fourth quarter of 2018.

- ***Cash Balance*** as of March 31, 2019, was $45.5 million, compared to $53.2 million as of December 31, 2018.

RedHill Biopharma is a specialty biopharmaceutical company, primarily focused on the development and commercialization of clinical late-stage, proprietary drugs for the treatment of gastrointestinal diseases. RedHill commercializes and promotes several gastrointestinal products in the U.S.: **Donnatal -** a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **EnteraGam -** a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools and **Mytesi -** an anti-diarrheal drug indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. RedHill's key clinical late-stage development programs include: (i) **Talicia (RHB-105)** for the treatment of *Helicobacter pylori* infection with a U.S. NDA submitted; (ii) **RHB-104,** with positive top-line results from a first Phase 3 study for Crohn's disease; (iii) **RHB-204,** with a planned pivotal Phase 3 study for pulmonary nontuberculous mycobacteria (NTM) infections; (iv) **BEKINDA (RHB-102),** with positive results from a Phase 3 study for acute gastroenteritis and gastritis and positive results from a Phase 2 study for IBS-D; (v) **YELIVA (ABC294640),** a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase 2a study for cholangiocarcinoma; (vi) **RHB-106,** an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vii) **RHB-107,** a Phase 2-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases.