NEWS RELEASE

RedHill Received Talicia® Licensing Payments Totaling $1.1 Million

2025-08-18

RedHill has received its first Talicia sales milestone payment as well as royalties and other payments, totaling $1.1 million, following the first ex-U.S. commercial launch of Talicia in 2024

Talicia is the first FDA-approved rifabutin-based product specifically designed to treat Helicobacter pylori (H. pylori), a bacterial infection with high and rising resistance rates that affects over 50% of the world's adult population[1] and is the strongest risk factor for gastric cancer and peptic ulcer disease

Talicia is the leading branded first-line therapy prescribed by U.S. gastroenterologists[2] for treatment of H. pylori infection and was granted a Qualified Infectious Disease Product (QIDP) designation by the FDA, providing eligibility for a total of eight years of U.S. market exclusivity; Talicia is patent protected through 2042

RALEIGH, N.C., Aug. 18, 2025 /PRNewswire/ -- **RedHill Biopharma Ltd.** (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced that it has received its first Talicia[3] ex-U.S. sales milestone, royalties and other payments totaling approximately $1.1 million.

"The presence of H. pylori infection is the strongest risk factor for gastric cancer and peptic ulcer disease and there is a significant global medical need for a highly effective first-line H. pylori therapy," **said Rick Scruggs, President, RedHill Biopharma Inc. & Chief Commercial Officer**. "H. pylori is a major public health concern, with over 50% of the world's adult population infected. Talicia offers the best hope for patients and physicians in an era of increased resistance with clarithromycin-based therapies[4],[5]. As we work to bring Talicia to more patients globally, we continue our discussions with potential partners and expect to secure additional non-dilutive ex-US licensing revenue streams.

Clarithromycin-based triple therapy continues to wane in effectiveness. A 2021 study demonstrated only 68.5% eradication with traditional clarithromycin-based triple therapy, which declined further to 32% in patients harboring resistant H. pylori organisms[6]. Clarithromycin-based treatment efficacy has also been reported to be negatively impacted by patient obesity or diabetic status, neither of which impacts Talicia's safety or efficacy, according to data from post-approval post-hoc analysis[7],[8]. In contrast, in the pivotal Phase 3 study, Talicia demonstrated up to 90% eradication of H. pylori infection in adherent patients ($p<0.0001$) with minimal to zero antibiotic resistance to rifabutin, a key component of Talicia, detected[9].

About H. pylori

H. pylori is a bacterial infection that affects approximately 35%[10] of the U.S. population, with an estimated 1.6 million patients treated annually[11]. Worldwide, more than 50% of the population has H. pylori infection, which is classified by the WHO as a Group 1 carcinogen. It remains the strongest known risk factor for gastric cancer[12] and a major risk factor for peptic ulcer disease[13] and gastric mucosa-associated lymphoid tissue (MALT) lymphoma[14]. More than 27,000 Americans are diagnosed with gastric cancer annually[15]. Eradication of H. pylori is becoming increasingly difficult, with current therapies failing in approximately 25-40% of patients who remain H. pylori-positive due to high resistance of H. pylori to antibiotics – especially clarithromycin – which is still commonly used in standard combination therapies[16].

About Talicia

Talicia is the only low-dose rifabutin-based therapy approved for the treatment of H. pylori infection and is designed to address the high resistance of H. pylori bacteria seen with other antibiotics. The high rates of H. pylori resistance to clarithromycin have led to significant rates of treatment failure with clarithromycin-based therapies and are a strong public health concern, as highlighted by the ACG and FDA in recent years.

Talicia is a novel, fixed-dose, all-in-one oral capsule combination of two antibiotics (amoxicillin and rifabutin) and a proton pump inhibitor (PPI) (omeprazole). In November 2019, Talicia was approved by the U.S. FDA for the treatment of H. pylori infection in adults. In the pivotal Phase 3 study, Talicia demonstrated 84% eradication of H.

pylori infection in the intent-to-treat (ITT) group vs. 58% in the active comparator arm ($p<0.0001$). Minimal to zero resistance to rifabutin, a key component of Talicia, was detected in RedHill's pivotal Phase 3 study. Further, in an analysis of data from this study, it was observed that subjects who were confirmed adherent to their therapy had response rates of 90.3% in the Talicia® arm vs. 64.7% in the active comparator arm.

Talicia is eligible for a total of eight years of U.S. market exclusivity under its Qualified Infectious Disease Product (QIDP) designation and is also covered by U.S. patents which extend patent protection until 2042 with additional patents and applications pending and granted in various territories worldwide.

Talicia is approved and commercialized in the United States and the United Arab Emirates.

TALICIA: INDICATION AND IMPORTANT SAFETY INFORMATION

Talicia is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of Helicobacter pylori infection in adults.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Talicia and other antibacterial drugs, Talicia should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION

Talicia contains omeprazole, a proton pump inhibitor (PPI), amoxicillin, a penicillin-class antibacterial and rifabutin, a rifamycin antibacterial. It is contraindicated in patients with known hypersensitivity to any of these medications, any other components of the formulation, any other beta-lactams or any other rifamycin.

Talicia is contraindicated in patients receiving rilpivirine-containing products.

Talicia is contraindicated in patients receiving delavirdine or voriconazole.

Serious and occasionally fatal hypersensitivity reactions have been reported with omeprazole, amoxicillin and rifabutin.

Drug-induced enterocolitis syndrome (DIES) has been reported with use of amoxicillin, a component of Talicia.

Severe cutaneous adverse reactions (SCAR) (e.g., Stevens-Johnson syndrome (SJS), Toxic epidermal necrolysis (TEN)) have been reported with rifabutin, amoxicillin, and omeprazole. Additionally, drug reaction with eosinophilia and

systemic symptoms (DRESS) has been reported with rifabutin.

Acute Tubulointerstitial Nephritis has been observed in patients taking PPIs and penicillins.

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range from mild diarrhea to fatal colitis.
Talicia may cause fetal harm. Talicia is not recommended for use in pregnancy. Talicia may reduce the efficacy of hormonal contraceptives. An additional non-hormonal method of contraception is recommended when taking Talicia.

Talicia should not be used in patients with hepatic impairment or severe renal impairment.

Cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE) have been reported in patients taking PPIs. These events have occurred as both new onset and exacerbation of existing autoimmune disease.

The most common adverse reactions (≥1%) were diarrhea, headache, nausea, abdominal pain, chromaturia, rash, dyspepsia, oropharyngeal pain, vomiting, and vulvovaginal candidiasis.

To report SUSPECTED ADVERSE REACTIONS, contact RedHill Biopharma INC. at 1-833-ADRHILL (1-833-237-4455) or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Full prescribing information for Talicia is available at **www.Talicia.com**

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a specialty biopharmaceutical company primarily focused on U.S. development and commercialization of drugs for gastrointestinal diseases, infectious diseases and oncology. RedHill promotes the FDA-approved gastrointestinal drug **Talicia®,** for the treatment of Helicobacter pylori (H. pylori) infection in adults[3]. RedHill's key clinical late-stage development programs include: (i) **opaganib (ABC294640)**, a first-in-class, orally administered sphingosine kinase-2 (SPHK2) selective inhibitor with anti-inflammatory, antiviral, and anticancer activity, targeting multiple indications with U.S. government and academic collaborations for development for radiation and chemical exposure indications such as GI-Acute Radiation Syndrome (GI-ARS), a Phase 2/3 program for hospitalized COVID-19, and a Phase 2 study in prostate cancer in combination with darolutamide; (ii) **RHB-204**, a next-generation optimized formulation of RHB-104, with a planned Phase 2 study for Crohn's disease (based on RHB-104's positive Phase 3 Crohn's disease study results) and Phase 3-stage for pulmonary nontuberculous mycobacteria (NTM) disease; (iii) **RHB-107** (**upamostat**), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, is in late-stage development as a

treatment for non-hospitalized symptomatic COVID-19 and is also targeting multiple other cancer and inflammatory gastrointestinal diseases; and (iv) **RHB-102**, with potential UK submission for chemotherapy and radiotherapy induced nausea and vomiting, positive results from a U.S. Phase 3 study for acute gastroenteritis and gastritis and positive results from a U.S. Phase 2 study for IBS-D. RHB-102 is partnered with Hyloris Pharma (EBR: HYL) for worldwide development and commercialization outside North America.

More information about the Company is available at **www.redhillbio.com** / **X.com/RedHillBio**.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and may discuss investment opportunities, stock analysis, financial performance, investor relations, and market trends. Such statements, including, but not limited to, statements regarding the intended use of net proceeds from the offering, may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words and include statements regarding the risk that the Company will not comply with the listing requirements of the Nasdaq Capital Market ("Nasdaq") to remain listed for trading on Nasdaq, the addition of new revenue generating products, out-licensing of the Company's development pipeline assets, timing of opaganib's development for Acute Radiation Syndrome, non-dilutive development funding from RHB-107 and its inclusion in a key platform study. Forward-looking statements are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control and cannot be predicted or quantified, and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, market and other conditions, the risk that the addition of new revenue generating products or out-licensing transactions will not occur; the risk that acceptance onto the RNCP Product Development Pipeline will not guarantee ongoing development or that any such development will not be completed or successful; the risk that the FDA does not agree with the Company's proposed development plans for opaganib for any indication, the risk that observations from preclinical studies are not indicative or predictive of results in clinical trials; the risk that the FDA pre-study requirements will not be met and/or that the Phase 3 study of RHB-107 in COVID-19 outpatients will not be approved to commence or if approved, will not be completed or, should that be the case, that we will not be successful in obtaining alternative non-dilutive development funding for RHB-107, the risk that HB-107's late-stage development for non-hospitalized COVID-19 will not benefit from the resources redirected from the terminated RHB-204 Phase 3 study, that the Phase 2/3 COVID-19 study for RHB-107 may not be successful and, even if successful, such studies and results may not be sufficient for regulatory applications, including emergency use or marketing applications, and that additional COVID-19 studies for opaganib and RHB-107 are likely to be required, as well as risks and uncertainties associated with the risk that the Company will not successfully commercialize its products; as well as risks and uncertainties

associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, pre-clinical studies, clinical trials, and other therapeutic candidate development efforts, and the timing of the commercial launch of its commercial products and ones it may acquire or develop in the future; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its pre-clinical studies or clinical trials or the development of a commercial companion diagnostic for the detection of MAP; (iii) the extent and number and type of additional studies that the Company may be required to conduct and the Company's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings, approvals and feedback; (iv) the manufacturing, clinical development, commercialization, and market acceptance of the Company's therapeutic candidates and Talicia®; (v) the Company's ability to successfully commercialize and promote Talicia® and Aemcolo®; (vi) the Company's ability to establish and maintain corporate collaborations; (vii) the Company's ability to acquire products approved for marketing in the U.S. that achieve commercial success and build its own marketing and commercialization capabilities; (viii) the interpretation of the properties and characteristics of the Company's therapeutic candidates and the results obtained with its therapeutic candidates in research, pre-clinical studies or clinical trials; (ix) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (x) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; (xi) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xii) estimates of the Company's expenses, future revenues, capital requirements and needs for additional financing; (xiii) the effect of patients suffering adverse experiences using investigative drugs under the Company's Expanded Access Program; (xiv) competition from other companies and technologies within the Company's industry; and (xv) the hiring and employment commencement date of executive managers. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 20-F filed with the SEC on April 8, 2024. All forward-looking statements included in this press release are made only as of the date of this press release. The Company assumes no obligation to update any written or oral forward-looking statement, whether as a result of new information, future events or otherwise unless required by law.

Logo: **https://mma.prnewswire.com/media/1334141/5268648/RedHill_Biopharma_Logo.jpg**

Company contact:
Adi Frish
Chief Corporate & Business Development Officer
RedHill Biopharma
adi@redhillbio.com
+972-54-6543-112

Category: Commercial

[1.] Hooi JKY et al. Global Prevalence of Helicobacter pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology 2017; 153:420-429.
[2.] IQVIA XPO Data on file.
[3.] Talicia® (omeprazole magnesium, amoxicillin and rifabutin) is indicated for the treatment of H. pylori infection in adults. For full prescribing information see: **www.Talicia.com**.
[4.] Savoldi, A., et al., Prevalence of Antibiotic Resistance in Helicobacter pylori: A Systematic Review and Meta-analysis in World Health Organization Regions. Gastroenterology, 2018. 155(5): p. 1372-1382 e17.
[5.] Park, J.Y., et al., Helicobacter pylori Clarithromycin Resistance and Treatment Failure Are Common in the USA. Dig Dis Sci, 2016. 61(8): p. 2373-2380.
[6.] Chey, W.D., et al., Vonoprazan Triple and Dual Therapy for Helicobacter pylori Infection in the United States and Europe: Randomized Clinical Trial. Gastroenterology, 2022. 163(3): p. 608-619.
[7.] Diabetes Data on File.
[8.] Kao, J.Y., Helicobacter pylori eradication by low-dose rifabutin triple therapy (RHB-105) is unaffected by high body mass index. GastroHep, 2021. 3(7): p. 426-434.
[9.] Graham DY, Canaan Y, Maher J, Wiener G, Hulten KG, Kalfus IN. Rifabutin-based triple therapy (RHB-105) for Helicobacter pylori eradication: a double-blind, randomized, controlled trial. Ann Intern Med. 2020;172(12):795-802.
[10.] Hooi JKY et al. Global Prevalence of Helicobacter pylori Infection: Systematic Review and Meta-Analysis. Gastroenterology 2017; 153:420-429.
[11.] IQVIA Custom Study for RedHill Biopharma, 2019.
[12.] Lamb A et al. Role of the Helicobacter pylori–Induced inflammatory response in the development of gastric cancer. J Cell Biochem 2013;114.3:491-497.
[13.] NIH – Helicobacter pylori and Cancer, September 2013.
[14.] Hu Q et al. Gastric mucosa-associated lymphoid tissue lymphoma and Helicobacter pylori infection: a review of current diagnosis and management. Biomarker research 2016;4.1:15.
[15.] National Cancer Institute, Surveillance, Epidemiology, and End Results Program (SEER).
[16.] Malfertheiner P. et al. Management of Helicobacter pylori infection - the Maastricht IV/ Florence Consensus Report, Gut 2012;61:646-664; O'Connor A. et al. Treatment of Helicobacter pylori Infection 2015, Helicobacter 20 (S1) 54-61; Venerito M. et al. Meta-analysis of bismuth quadruple therapy versus clarithromycin triple therapy for empiric primary treatment of Helicobacter pylori infection. Digestion 2013;88(1):33-45.

View original content:**https://www.prnewswire.com/news-releases/redhill-received-talicia-licensing-payments-totaling-1-1-million-302532195.html**

SOURCE RedHill Biopharma Ltd.