



RedHill Biopharma Provides Semi-Annual Business Update

April 9, 2018

TEL-AVIV, Israel and RALEIGH, N.C., April 09, 2018 (GLOBE NEWSWIRE) -- RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company primarily focused on late clinical-stage development and commercialization of proprietary drugs for gastrointestinal diseases and cancer, today provided a business update of its main activities and key highlights expected in 2018, including two Phase III readouts.

Key Highlights:

- **Top-line results from the ongoing Phase III study with RHB-104 for Crohn's disease (MAP US study) are expected in mid-2018.** Enrollment of all 331 subjects in the study has been completed and the last patient to reach the primary endpoint assessment (remission at week 26) is expected by early May 2018.
- **Top-line results from the ongoing confirmatory Phase III study with TALICIA[®](RHB-105)¹ for *H. pylori* infection (ERADICATE Hp 2 study) are expected in H2/2018.** To date, approximately 60% out of a planned total of 444 subjects have been enrolled in the study. TALICIA[®] was previously granted QIDP fast-track designation by the FDA, including an extended market exclusivity period, if approved.
- **Amendment to RHB-106 agreement with Salix Pharmaceuticals.** RedHill and Salix recently amended their 2014 worldwide license agreement relating to the 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.
- **Expected continued quarterly revenue growth.** Net revenues in the fourth quarter of 2017 were \$2 million, an increase of 31% over the third quarter of 2017. RedHill expects continued quarter over quarter net revenue growth. RedHill's sales force of approximately 40 sales representatives is calling on thousands of gastroenterologists across the U.S.
- **Continued cost reduction in 2018.** Cash to be used in operating activities is expected to continue to gradually decrease on average to approximately \$8.5 million per quarter during 2018. RedHill's cash position was approximately \$46 million at the end of 2017, with no debt.

Additional Updates:

- **First five patients 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 Phase IIa study was recently initiated 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 planned to enroll up to 39 patients. YELIVA[®] was granted Orphan Drug designation by the FDA for the treatment of cholangiocarcinoma.
- **Ongoing discussions with the FDA on planned Phase III development programs for BEKINDA[®] (RHB-102) for acute gastroenteritis and for IBS-D.** Following the positive results of the Phase III study with BEKINDA[®] 24 mg for acute gastroenteritis (GUARD study) and guidance provided by the FDA, RedHill is currently in discussions with the FDA on the design of a confirmatory Phase III study to support a potential New Drug Application (NDA). Following positive results of the Phase II study with BEKINDA[®] 12 mg for IBS-D, 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.
- **A pivotal Phase III study with RHB-104 for the treatment of nontuberculous mycobacteria (NTM) infections (QIDP fast-track designation, including an extended market exclusivity period, if approved) is expected to be initiated in H2/2018, subject to completion of a supportive non-clinical program and additional input from the FDA.** RHB-104 is planned to be assessed as a first-line treatment of NTM disease caused by *mycobacterium avium complex* (MAC) infection.

About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) is a specialty biopharmaceutical company, primarily focused on the development and commercialization of late clinical-stage, proprietary drugs for the treatment of gastrointestinal diseases and cancer. RedHill commercializes and promotes three gastrointestinal products in the U.S.: **Donnatal[®]** - a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis; **Esomeprazole Strontium Delayed-Release Capsules 49.3 mg** -

a prescription proton pump inhibitor indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal conditions; and **EnteraGam®**- a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools. RedHill's key clinical-stage development programs include: (i) **TALICIA® (RHB-105)** for the treatment of *Helicobacter pylori* infection with an ongoing confirmatory Phase III study and positive results from a first Phase III study; (ii) **RHB-104** with an ongoing first Phase III study for Crohn's disease and a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102)** with positive results from a Phase III study for acute gastroenteritis and gastritis and positive results from a Phase II study for IBS-D; (iv) **YELIVA® (ABC294640)**, a first-in-class SK2 selective inhibitor, targeting multiple oncology, inflammatory and gastrointestinal indications, with an ongoing Phase IIa study for cholangiocarcinoma; (v) **RHB-106**, an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) **RHB-107 (formerly MESUPRON)**, a Phase II-stage first-in-class, serine protease inhibitor, targeting cancer and inflammatory gastrointestinal diseases. More information about the Company is available at: www.redhillbio.com.

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. 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, risks and uncertainties associated with (i) the initiation, timing, progress and results of the Company's research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts; (ii) the Company's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; (iii) the extent and number 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; (v) the Company's ability to successfully promote Donnatal® and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg and commercialize EnteraGam®; (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, preclinical 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; and (xiv) competition from other companies and technologies within the Company's industry. 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 February 22, 2018. 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.

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¹ TALICIA® (RHB-105), YELIVA® (ABC294640) and BEKINDA® are investigational new drugs, not available for commercial distribution.

[Primary Logo](#)

Source: RedHill Biopharma Ltd.