



December 5, 2017

RedHill Biopharma Provides 2017 Year-End Business Update

TEL-AVIV, Israel and RALEIGH, N.C., Dec. 05, 2017 (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 2017 year-end summary of its main activities and key milestones expected in 2018.

- 1 **Cost reduction plan.** Cash balance¹ at the end of 2017 is expected to be approximately \$45 million, with no debt. A cost reduction plan is in place to gradually reduce the average quarterly cash burn rate in 2018 to approximately \$8.5 million.
- 1 **Increasing resource optimization and focus on GI, including termination of RIZAPORT® license.** Given the Company's increasing focus on gastrointestinal (GI) diseases and in particular its two key Phase III GI programs with near-term data points and blockbuster potential for Crohn's disease and *H. pylori* infection, a notice has been provided to IntelGenx Corp. (TSXV: IGX; OTCQX: IGXT) that RedHill will terminate, effective January 6, 2018, its co-development and commercialization agreement for the non-core migraine drug product candidate, RIZAPORT®, for which a recent Incomplete Response Letter has been received from the FDA.
- 1 **Top-line results from the ongoing Phase III study with RHB-104 for Crohn's disease expected mid-2018.** Enrollment of all 331 subjects in the MAP US study has been completed and the last patient to reach the primary endpoint assessment (remission at week 26) is expected by May 2018.
- 1 **Top-line results from the ongoing confirmatory Phase III study with TALICIA™ (RHB-105)² for *H. pylori* infection are expected in H2/2018.** To date, 136 patients out of a planned total of 444 subjects have been enrolled. TALICIA™ was previously granted QIDP fast track designation from FDA.
- 1 **A pivotal Phase III study with RHB-104 for the treatment of nontuberculous mycobacteria (NTM) infections is expected to be initiated in H1/2018, subject to additional input from the FDA.** RHB-104 will be assessed as a first-line treatment of pulmonary NTM disease caused by *Mycobacterium avium complex* (MAC) infection, for which QIDP fast-track designation was previously granted by the FDA.
- 1 **A single-arm Phase IIa study with YELIVA® (ABC294640)³ for the treatment of cholangiocarcinoma (bile duct cancer) is expected to be initiated in the coming weeks at Mayo Clinic and MD Anderson.** YELIVA® was granted Orphan Drug designation by the FDA for the treatment of cholangiocarcinoma.
- 1 **Managed Markets Activity.** RedHill is expanding U.S. managed care access and coverage to its commercial products by securing multiple agreements with top managed care organizations.

Dror Ben-Asher, RedHill's CEO, said: "With a cost reduction and resource optimization plan in place for 2018 and 2019, we are focusing on delivering the two rapidly-approaching Phase III data read-outs with RHB-104 for Crohn's disease and TALICIA™ for *H. pylori* infection, which, if approved, have blockbuster potential, given the limitations of available therapies."

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 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)** - an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful results from a first Phase III study and an ongoing confirmatory Phase III study; (ii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study, a completed proof-of-concept Phase IIa study for multiple sclerosis, and a planned pivotal Phase III study for nontuberculous mycobacteria (NTM)

infections; (iii) **YELIVA® (ABC294640)** - an orally-administered, first-in-class SK2 selective inhibitor with a planned Phase IIa study for cholangiocarcinoma; (iv) **BEKINDA® (RHB-102)** - a once-daily oral pill formulation of ondansetron with successful top-line results from a Phase III study in acute gastroenteritis and gastritis and successful top-line results from a Phase II study in IBS-D; (v) **RHB-106** - an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd. and (vi) **MESUPRON** - a Phase II-stage first-in-class, orally-administered protease inhibitor, targeting pancreatic 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 market Donnata® and 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 23, 2017. 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.

¹ Including cash, short-term investments and non-current bank deposits.

² TALICIA™ (RHB-105) is an investigational new drug, not available for commercial distribution.

³ YELIVA® (ABC294640) is an investigational new drug, not available for commercial distribution.

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