



## Press Release

### **RedHill Biopharma Issues Letter to Shareholders**

#### **Open Letter to Shareholders Presents Select Potential Upcoming Milestones and Goals for 2016**

**TEL-AVIV, Israel, February 9, 2016** RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) (“RedHill” or the “Company”), an Israeli biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for inflammatory and gastrointestinal diseases, including cancer, today issued the following open letter to its shareholders:

Dear RedHill shareholders,

As we have now moved into 2016, we wish to share with you some of the Company’s potential upcoming milestones and goals for the calendar year.

The last several months have been volatile and challenging for the pharmaceutical industry, driven by political discussions of drug pricing and reimbursement and broader market concerns, which have required management's complete focus and tenacity. Despite the uncertain market conditions, the pace of our business activities has not slowed down; RedHill’s late clinical-stage pipeline enjoys continued positive momentum and continued to mature in 2015, which was a dynamic and exciting year for the Company. We appreciate the ongoing support you have shown us.

Heading into 2016, we continue to make significant progress with our three ongoing Phase III-stage programs targeting the gastrointestinal (GI) indications of Crohn’s disease, *H. pylori* infection and gastroenteritis. In parallel, we are pursuing a number of Phase II-stage development programs targeting oncology and inflammatory diseases. With several potential catalysts and value drivers on the horizon, a few of the Company’s potential upcoming milestones are outlined below:

- We are scheduled to meet with the FDA in early April to discuss the planned confirmatory Phase III study with RHB-105 for the treatment of *H. pylori* infection. The planned meeting with the FDA follows positive top-line results from the ERADICATE Hp first Phase III study with RHB-105, which successfully met its primary endpoint, demonstrating 89.4% efficacy in eradicating *H. pylori* with high statistical significance ( $p < 0.001$ ). The FDA has granted RHB-105 a Qualified Infectious Disease Product (QIDP) designation under the GAIN Act, allowing for a

total of eight years of market exclusivity, Fast-Track development and Priority Review status which shortens review time for future marketing applications.

- The MAP US Phase III study with RHB-104 for the treatment of Crohn's disease continues to enroll patients according to plan, with interim analysis expected in the second half of 2016. If successful, RHB-104 is expected to become a potential paradigm changer in the treatment of Crohn's disease.
- Another potential milestone expected during the second half of 2016 is the top-line results from the GUARD Phase III study with BEKINDA™ (RHB-102) for acute gastroenteritis and gastritis. If approved for marketing by the FDA, BEKINDA™ is expected to be the first-ever 5-HT3 antagonist drug indicated for acute gastroenteritis, targeting a potential worldwide market estimated to exceed \$650 million annually.
- In the coming weeks, we expect to receive and announce top-line interim results from our CEASE-MS Phase IIa proof-of-concept study exploring RHB-104 as an add-on therapy to interferon beta-1a in patients treated for relapsing-remitting multiple sclerosis (RRMS).
- Also in the coming weeks, we plan to commence a Phase II study with BEKINDA™ (RHB-102) for irritable bowel syndrome with diarrhea (IBS-D), subject to regulatory clearance. The U.S. potential market for IBS-D treatments is estimated to exceed \$1.25 billion by 2020.

RedHill is backed by strong U.S. healthcare institutional investors and maintains a strong and debt-free balance sheet with approximately \$58 million at the end of 2015, allowing us, with no current plans to raise additional capital, to continue to aggressively and diligently execute our plans. We have put in motion an intensive investor relations program to ensure increased awareness, shareholder communication and corporate transparency.

We continue to advance extensive business development activities in relation to both potential partnerships for commercialization of some of our products and for vertical integration in the U.S. through the acquisition of FDA-approved specialty drugs.

We see many great growth opportunities for RedHill in 2016. With a solid scientific foundation and a highly capable, committed and motivated team focused on execution, RedHill is well-positioned to become a specialty pharma company, primarily focused on the key therapeutic areas of GI and inflammation in the U.S.

In the coming weeks, we plan to provide the first semi-annual comprehensive R&D update for 2016, covering our advanced development pipeline.

We want to thank you for your interest in RedHill and for your continued support.

Sincerely,

Dror Ben-Asher  
Chairman and Chief Executive Officer

**About RedHill Biopharma Ltd.:**

RedHill Biopharma Ltd. (NASDAQ/TASE: RDHL) is an emerging Israeli biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of inflammatory and gastrointestinal diseases, including cancer. RedHill's current pipeline of proprietary products includes: (i) **RHB-105** - an oral combination therapy for the treatment of *Helicobacter pylori* infection with successful top-line results from a first Phase III study; (ii) **RHB-104** - an oral combination therapy for the treatment of Crohn's disease with an ongoing first Phase III study; (iii) **BEKINDA™ (RHB-102)** - a once-daily oral pill formulation of ondansetron with an ongoing Phase III study in the U.S. for acute gastroenteritis and gastritis; (iv) **RHB-106** - an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA™ (ABC294640)** - an orally-administered first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications with a Phase I/II study initiated for refractory/relapsed diffuse large B-cell lymphoma (DLBCL); (vi) **MESUPRON®** - a Phase II-stage first-in-class uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumors; (vii) **RP101** - currently subject to an option-to-acquire by RedHill, RP101 is a Phase II-stage first-in-class Hsp27 inhibitor, administered by oral tablet, targeting pancreatic and other gastrointestinal cancers; (viii) **RIZAPORT™ (RHB-103)** - an oral thin film formulation of rizatriptan for acute migraines, with a U.S. NDA currently under discussion with the FDA and marketing authorization received in Germany in October 2015; and (ix) **RHB-101** - a once-daily oral pill formulation of the cardio drug carvedilol.

*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 establish and maintain corporate collaborations; (vi) the interpretation of the properties and characteristics of the Company's therapeutic candidates and of the results obtained with its therapeutic candidates in research, preclinical studies or clinical trials; (vii) the implementation of the Company's*

*business model, strategic plans for its business and therapeutic candidates; (viii) 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; (ix) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (x) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xi) competitive companies and technologies within the Company's industry; and (xii) the impact of the political and security situation in Israel on the Company's business. 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 26, 2015. All forward-looking statements included in this Press Release are made only as of the date of this Press Release. We assume no obligation to update any written or oral forward-looking statement unless required by law.*

**Company contact:**

Adi Frish  
Senior VP Business Development &  
Licensing  
RedHill Biopharma  
+972-54-6543-112  
[adi@redhillbio.com](mailto:adi@redhillbio.com)

**IR contact (U.S.):**

Marcy Nanus  
Senior Vice President  
The Trout Group  
+1-646-378-2927  
[Mnanus@troutgroup.com](mailto:Mnanus@troutgroup.com)