Press Release

RedHill Biopharma Strengthens Long-Term Commercial Value of REBYOTA® with 16-Month U.S. Patent Extension Through November 2036

Newly awarded 478-day patent term extension, to November 30, 2036, adds nearly 16 months to the term of a U.S. patent covering REBYOTA, which RedHill believes strengthens the long-term value of a key FDA-approved commercial asset

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Latest development builds on RedHill's recently announced acquisition of two commercial gastrointestinal products from Ferring, positioning the Company to pursue potential growth and long-term shareholder value

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REBYOTA and CLENPIQ® generated combined 2025 net sales of $37.5 million, providing an established commercial foundation for RedHill's strategic growth

RALEIGH, N.C., and TEL-AVIV, Israel, November 23, 2026 -- RedHill Biopharma Ltd. (Nasdaq: RDHL) ("RedHill" or the "Company"), a specialty biopharmaceutical company, today announced the award of an approximately 16-month patent term extension for Rebyota.

The 478-day Rebyota patent term extension (PTE) was granted for U.S. Patent No. 9,675,648, with the USPTO's final determination extending the patent from its original expiration date of August 10, 2035, through November 30, 2036.

"This patent extension is another important win for RedHill and our shareholders, coming at a pivotal moment in our Company's evolution. We have recently taken a major step forward in transforming RedHill's business through the acquisition of two established, FDA-approved gastrointestinal products with combined 2025 net sales of $37.5 million. Now, we are adding nearly 16 months of patent protection to REBYOTA, which we believe enhances the long-term commercial potential to such asset," **said Guy Goldberg, Chief Business Officer of RedHill.** "We agreed to acquire REBYOTA and CLENPIQ for $12 million upfront, funded by our $18 million sale of Talicia®. We believe this represents an attractive opportunity to establish a scalable commercial GI franchise with meaningful

growth potential. With REBYOTA's extended patent term and a favorable competitive development in the bowel preparation market following the withdrawal of PLENVU®, we believe RedHill is increasingly well positioned to capitalize on its commercial portfolio."

Building a Stronger Commercial Foundation

RedHill's recent strategic transactions represent a significant evolution in its business model, adding established commercial products to complement its proprietary development pipeline.

The Company's growing gastrointestinal portfolio includes:

- **REBYOTA – Extended patent protection through November 2036:** A first-in-class, single-dose, FDA-approved microbiota-based therapy indicated for the prevention of recurrent *C. difficile* infection. REBYOTA generated approximately $17 million in 2025 net sales and has received FDA Breakthrough Therapy and Orphan Drug designations. The therapy was approved by the FDA in 2022 and by Health Canada in 2025.
- **CLENPIQ – Established commercial product with a favorable competitive environment:** An FDA-approved, ready-to-drink, low-volume bowel preparation for colonoscopy. The Company believes that the recent withdrawal of a competing product PLENVU from the market may present a potential opportunity to strengthen CLENPIQ's competitive position within the ready-to-drink, low-volume bowel preparation segment.
- **A Commercial Platform Designed for Growth:** The acquisition of REBYOTA and CLENPIQ, with combined 2025 net sales of $37.5 million, is expected to provide RedHill with an established product portfolio and an opportunity to leverage its gastrointestinal commercial capabilities to pursue growth and additional value-creating opportunities. Historical net sales are not necessarily indicative of future results.

Together, these developments mark important progress in RedHill's transition toward a commercially focused business with established products, an extended intellectual property runway and opportunities for future growth.

About Rebyota®

Rebyota, a first-in-class microbiota-based therapy, is indicated for the prevention of recurrence of Clostridioides difficile infection in individuals 18 years of age and older, following antibiotic treatment for recurrent *C. difficile* infection.

FDA-approved in 2022 and Health Canada-approved in 2025, Rebyota has U.S. Breakthrough Therapy and Orphan Drug designations.

Rebyota (fecal microbiota, live – jslm) is a pre-packaged, single-dose 150 mL microbiota suspension for rectal administration consisting of a liquid mix of live microbes. Rebyota is administered by a healthcare professional in one visit.

Limitation of Use: Rebyota is not indicated for the treatment of *C. difficile* infection.

Important Safety Information
You should not receive Rebyota if you have a history of a severe allergic reaction (e.g., anaphylaxis) to Rebyota or any of its components.
You should report to your doctor any infection you think you may have acquired after administration.
Rebyota may contain food allergens.
Most common side effects may include stomach pain (8.9%), diarrhea (7.2%), bloating (3.9%), gas (3.3%), and nausea (3.3%).
Rebyota has not been studied in patients below 18 years of age.
Clinical studies did not determine if adults 65 years of age and older responded differently than younger adults.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088.
Please click to see the full Prescribing Information.

About Clenpiq®

CLENPIQ® (sodium picosulfate, magnesium oxide, and anhydrous citric acid) oral solution is a ready-to-drink, low-volume bowel preparation used to cleanse the colon prior to colonoscopy. It combines sodium picosulfate, a stimulant laxative, with magnesium oxide and anhydrous citric acid, which form magnesium citrate, an osmotic laxative.

Indication
CLENPIQ is indicated for cleansing of the colon as a preparation for colonoscopy in adults and pediatric patients 9 years of age and older.

Important Safety Information
CLENPIQ is contraindicated in patients with severe renal impairment, gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, or hypersensitivity to any of its ingredients.
Bowel preparations, including CLENPIQ, can cause serious fluid and electrolyte disturbances, which may lead to cardiac arrhythmias, seizures and renal impairment. Patients should maintain adequate hydration
before, during and after use. Particular caution is required in patients with conditions or taking medications that increase the risk of fluid and electrolyte disturbances, seizures, renal impairment or cardiac arrhythmias.

CLENPIQ may cause colonic mucosal ulceration and has been associated with ischemic colitis. Caution should also be exercised in patients with severe active ulcerative colitis or an impaired gag reflex due to the risk of regurgitation or aspiration.
CLENPIQ may reduce the absorption of other orally administered medicines. The most common adverse reactions in adults include nausea, headache, hypermagnesemia, dehydration or dizziness, and abdominal pain. In pediatric patients 9 to 16 years of age, the most common adverse reactions include nausea, vomiting and abdominal pain.
Please see the full Prescribing Information and Medication Guide for CLENPIQ: www.clenpiq.com

About RedHill Biopharma

RedHill Biopharma Ltd. (Nasdaq: RDHL) is a U.S. specialty biopharmaceutical company focused primarily on the development and commercialization of proprietary drugs for gastrointestinal diseases, infectious diseases and oncology. RedHill promotes the FDA-approved gastrointestinal therapies **Rebyota®**, for the prevention of recurrent *C. diff* infection (rCDI), and the bowel preparation treatment, **Clenpiq®**. RedHill's key clinical late-stage development programs include: (i) **RHB-102 (Bekinda®)**, with a potential UK MAA for oncology support (chemotherapy and radiotherapy induced nausea and vomiting (CINV/RINV)), positive results from a U.S. Phase 3 study for acute gastroenteritis and gastritis, positive results from a U.S. Phase 2 study for IBS-D and is Phase 2-ready for GLP-1/GIP-associated GI intolerance; (ii) **opaganib (ABC294640),** a first-in-class, orally administered, sphingosine kinase-2 (SPHK2) selective inhibitor with anticancer, anti-inflammatory and antiviral activity, targeting multiple indications including; prostate cancer, with an ongoing Phase 2 study in combination with darolutamide; neuroblastoma, in collaboration with Penn State University, and for which it has FDA Orphan Drug and Rare Pediatric Disease designations with potential for a Priority Review Voucher (PRV); multiple myeloma with US National Cancer Institute (NCI) grant-funded planned Phase1b/2 clinical studies in partnership with University of Oklahoma, and virus-induced acute respiratory distress syndrome (ARDS); (iii) **RHB-204**, a next-generation optimized formulation of RHB-104, with a Phase 2-ready study for Crohn's disease (based on RHB-104's positive U.S. Phase 3 Crohn's disease study results); and (iv) **RHB-107** (**upamostat**), an oral broad-acting, host-directed, serine protease inhibitor with potential for pandemic preparedness, including COVID-19 and influenza and also targeting multiple cancer and inflammatory gastrointestinal diseases.

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 may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims,"

"believes," "hopes," "potential" or similar words, and include, among others, statements regarding the duration, scope and commercial significance of patent protection for Rebyota, including the patent term extension; the expected closing, timing and funding of the acquisition of Rebyota and Clenpiq from Ferring; the potential commercial performance of Rebyota and Clenpiq; the potential effect of the withdrawal of PLENVU on the market for bowel preparations and on Clenpiq; the Company's commercial strategy, growth prospects and transition toward a commercially focused business; and the creation of shareholder value. 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: the risk that the Company may be unable to successfully transition, integrate, manufacture, supply or commercialize Rebyota and Clenpiq, including its dependence on Ferring or other third parties for supply and transition services; the risk that the historical net sales of Rebyota and Clenpiq under Ferring's ownership are not indicative of future net sales under the Company's ownership; the risk that the patent term extension for Rebyota or the underlying patent may be challenged, invalidated, held unenforceable or circumvented, or may not provide meaningful commercial protection; the risk that competitors may develop or market products that compete with Rebyota or Clenpiq, and that the withdrawal of PLENVU may not result in increased sales of Clenpiq or may be temporary; the risk that in vitro results are not predictive of results in animals or humans; the risk that the Company may not commence or complete a clinical study of RHB-204 in a MAP-positive CD patient population, or that any such study may be delayed, the risk that MAP detection diagnostics do not perform as expected or are not available on acceptable terms, the anticipated use of NCI grant funding for the planned Phase 1b and Phase 2 trials for opaganib; planned enrollment, timing and design of the Phase 1b and Phase 2 trials and the potential benefits, if any, of opaganib in combination with CAR T-cell therapy; the risk that the NCI funding may be reduced, delayed or terminated, or may be affected by broader uncertainty regarding government funding; the risks arising with trials conducted by a third party not controlled by RedHill; the risk that the trials may be delayed or may not demonstrate safety or efficacy; the risk that the acquisition of commercialization rights for Rebyota® and Clenpiq does not result in the planned commercial growth; the risk that opaganib is not accepted into Ebola virus disease control programs, or if accepted, that it does not demonstrate efficacy; the risk that development of RHB-204 for Crohn's disease may not be completed, or if completed may not be approved or may not achieve commercial success; the risk that opaganib is not effective against the indications for which we develop our products; the risk that RHB-102 (Bekinda) does not effectively reduce GLP-1/GIP-related nausea, vomiting and diarrhea; the risk regarding the Company's ability to regain and maintain compliance with Nasdaq's listing requirements, including the minimum bid price requirement; the risk that the addition of new revenue generating products or out-licensing transactions will not occur; the risk that the Company will not receive future milestone payments under its existing agreements or that they will be less than anticipated; the risk of current uncertainty regarding U.S. government research and development funding and that the U.S. government is under no obligation to continue to support development of our products and can cease such support at any time; the risk that the FDA does not agree with the Company's proposed development plans for its programs; the risk that the Company's

development programs and studies 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 studies may be required; 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 any necessary commercial companion diagnostics; (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 commercial products; (v) the Company's ability to establish and maintain corporate collaborations; (vi) 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; (vii) 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; (viii) the implementation of the Company's business model, strategic plans for its business and therapeutic candidates; (ix) the scope of protection the Company is able to establish and maintain for intellectual property rights covering its therapeutic candidates and commercial products and its ability to operate its business without infringing the intellectual property rights of others; (x) parties from whom the Company licenses its intellectual property defaulting in their obligations to the Company; (xi) the Company's ability to collect on its judgment against Kukbo; (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 27, 2026. 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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