

# REDHILL BIOPHARMA LTD.

## **FORM 6-K** (Report of Foreign Issuer)

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 6-K**

**Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

For the month of July 2017  
Commission File No.: 001-35773

**REDHILL BIOPHARMA LTD.**  
(Translation of registrant's name into English)

**21 Ha'arba'a Street, Tel Aviv, 64739, Israel**  
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.  
Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Attached hereto and incorporated by reference herein is a press release issued by the Registrant entitled:

*"RedHill Biopharma Announces Unanimous Positive DSMB Recommendation for Continuation of the Phase III Study with RHB-104 for Crohns Disease"*

This Form 6-K is incorporated by reference into the Company's Registration Statements on Form S-8 filed with the Securities and Exchange Commission on May 2, 2013 (Registration No. 333-188286) and on October 29, 2015 (Registration No. 333-207654) and its Registration Statement on Form F-3 filed with the Securities and Exchange Commission on February 23, 2017 (Registration No. 333- 209702).

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REDHILL BIOPHARMA LTD.  
(Registrant)

Date: July 31, 2017

By: /s/ Dror Ben-Asher  
Dror Ben-Asher  
Chief Executive Officer

## RedHill Biopharma Announces Unanimous Positive DSMB Recommendation for Continuation of the Phase III Study with RHB-104 for Crohn's Disease

- **The independent Data and Safety Monitoring Board (DSMB) reviewed safety and efficacy data, of which RedHill remains blinded, from the first 222 subjects who have completed week 26 assessments in the Phase III MAP US study**
- **To date, over 300 of the planned 410 subjects, have been randomized in the Phase III MAP US study**
- **An open-label extension Phase III study (the MAP US2 study) is ongoing in parallel in patients who remain out of remission after 26 weeks of blinded study therapy in the MAP US study**

TEL-AVIV, Israel and RALEIGH, N.C., July 31, 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, orally-administered, small molecule drugs for gastrointestinal and inflammatory diseases and cancer, today reported, following a second pre-planned meeting to assess the safety and efficacy data from its ongoing first Phase III study with RHB-104 for Crohn's disease (the MAP US study) by an independent Data and Safety Monitoring Board (DSMB), that it has received a unanimous positive recommendation from the DSMB to continue the study as planned.

The independent DSMB reviewed safety and efficacy data, of which RedHill remains blinded, from the first 222 subjects who have completed week 26 assessments in the Phase III MAP US study. In December 2016, a first pre-planned independent DSMB meeting reviewed safety data from the MAP US study and provided a unanimous recommendation to continue the study as planned.

**Ira Kalfus, MD, Medical Director at RedHill, said:** "RHB-104 is a potentially ground-breaking new therapy for Crohn's disease. The DSMB has reviewed the unblinded interim safety and activity results of the Phase III MAP US study, and we are very encouraged by its unanimous recommendation to continue the study through randomization of all planned 410 subjects, with no changes to the protocol, investigator's brochure, study conduct or informed consent form. We continue to enroll subjects and expect to complete enrollment in the study in the first half of 2018. I would like to thank the DSMB members for their professional and independent assessment of the study data and for their positive recommendation."

RHB-104 is a proprietary, orally-administered, potentially ground-breaking, antibiotic combination therapy with potent intracellular, antimycobacterial and anti-inflammatory properties, targeting a suspected underlying bacterial infectious cause of Crohn's disease, *Mycobacterium avium subspecies paratuberculosis* (MAP).

The MAP US study is a randomized, double-blind, placebo-controlled first Phase III study evaluating the safety and efficacy of RHB-104 in patients with moderately to severely active Crohn's disease (defined as CDAI between 220 and 450). The MAP US study is being conducted in up to 150 clinical sites in the U.S, Canada, Europe, Israel, Australia and New Zealand. Additional clinical data will need to be generated to support a U.S. New Drug Application (NDA) for RHB-104. The primary endpoint of the MAP US study is disease remission, defined as a reduction in Crohn's Disease Activity Index (CDAI) to less than 150 at week 26.

To date, over 300 of the planned 410 subjects, have been randomized in the MAP US study. A third, safety-focused, independent DSMB meeting is expected to be held when 75% of the planned 410 subjects have completed 26 weeks of study participation. Completion of recruitment for the MAP US study is expected in the first half of 2018.

Additionally, an open-label extension Phase III study (the MAP US2 study) is ongoing to further assess the safety and efficacy of RHB-104 in patients who remain out of remission (CDAI  $\geq$  150) after 26 weeks of blinded study therapy in the ongoing Phase III MAP US study.

The clinical studies with RHB-104 are registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), a web-based service of the U.S. National Institutes of Health, which provides access to information on publicly and privately supported clinical studies.

### About RHB-104:

Currently in a first Phase III study for the treatment of Crohn's disease (the MAP US study), RHB-104 is a proprietary, orally-administered, potentially ground-breaking oral antibiotic combination therapy, with potent intracellular, antimycobacterial and anti-inflammatory properties. RHB-104 is based on increasing evidence supporting the hypothesis that Crohn's disease is related to *Mycobacterium avium subspecies paratuberculosis* (MAP) infection in susceptible patients. The development of RHB-104 is consistent with the growing awareness of the possibility that a bacterially-induced dysregulated immune system may contribute to the pathogenesis of various autoimmune diseases of unknown etiology. Clinical trials conducted with earlier formulations of RHB-104 include an Australian Phase III study conducted by Pharmacia/Pfizer. RedHill has conducted several supportive studies with the current formulation of RHB-104 and a long-term population pharmacokinetic (pop-PK) study is ongoing as part of the Phase III MAP US study. Additionally, an open-label extension Phase III study (the MAP US2 study) is ongoing to assess the safety and efficacy of RHB-104 in subjects who have completed week 26 assessments in the ongoing Phase III MAP US study and remain with active Crohn's disease (CDAI  $\geq$  150) at week 26. RHB-104 is covered by several issued and pending patents. RedHill also completed a Phase IIa, proof-of-concept clinical study, evaluating RHB-104 as an add-on therapy to interferon beta-1a in subjects treated for relapsing-remitting multiple sclerosis (the CEASE MS study), with top-line final results suggesting meaningful positive safety and clinical signals upon 24 weeks of treatment with RHB-104 as an add-on therapy, thereby supporting further clinical development. RHB-104 was granted Qualified Infectious Disease Product (QIDP) designation by the U.S. FDA for the treatment of nontuberculous mycobacteria (NTM) infections, providing a Fast-Track development pathway, as well as NDA Priority Review and an additional five years of U.S. market exclusivity, if approved. RedHill is in discussions with the FDA regarding the development of RHB-104 development program for NTM infections.

### About RedHill Biopharma Ltd.:

RedHill Biopharma Ltd. (NASDAQ:RDHL) (Tel-Aviv Stock Exchange:RDHL) is a specialty biopharmaceutical company headquartered in Israel, primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. RedHill promotes two gastrointestinal products in the U.S. - **Donnatal**<sup>®</sup>, a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, and **EnteraGam**<sup>®</sup>, a medical food intended for the dietary management, under medical supervision, of

chronic diarrhea and loose stools. RedHill's clinical-stage pipeline includes: (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 QIDP status for nontuberculous mycobacteria (NTM) infections; (iii) **BEKINDA® (RHB-102)** - a once-daily oral pill formulation of ondansetron with successful top-line results in a Phase III study for acute gastroenteritis and gastritis and an ongoing Phase II study for IBS-D; (iv) **RHB-106** - an encapsulated bowel preparation licensed to Salix Pharmaceuticals, Ltd.; (v) **YELIVA® (ABC294640)** - a Phase II-stage, orally-administered, first-in-class SK2 selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; (vi) **MESUPRON** - a Phase II-stage first-in-class, orally-administered protease inhibitor, targeting pancreatic cancer and other solid tumors and (vii) **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 two EU member states under the European Decentralized Procedure (DCP). More information about the Company is available at: [www.redhillbio.com](http://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 Donnatal® 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 of 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; and (xii) estimates of the Company's expenses, future revenues capital requirements and the Company's needs for additional financing; (xiii) the Company's Expanded Access Program, which allows patients with life-threatening diseases potential access, subject to regulatory and other approvals, to RedHill's investigational new drugs that have not yet received regulatory marketing approval, if a patient suffers an adverse experience using such investigative drug, potentially adversely affecting the clinical development program of that investigational product or the Company generally; (xiv) competitive 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. We assume no obligation to update any written or oral forward-looking statement unless required by law.*

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