November 13, 2017

RedHill Biopharma Reports 2017 Third Quarter Financial Results

- **RedHill maintains a debt-free balance sheet with $39.6 million in cash[1] at the end of the third quarter of 2017**
- **In addition, an underwritten public offering of the Company's American Depositary Shares (ADSs) is scheduled to be closed today, November 13, 2017, subject to customary terms and conditions, for aggregate net proceeds of approximately $20.6 million, after deducting underwriting discounts and commissions and other offering expenses**
- **Net revenues of approximately $1.5 million in Q3/2017 from the promotion of three GI-specialty products in the U.S., Donnatal®, EnteraGam® (launched in June) and Esomeprazole Strontium Delayed-Release Capsules 49.3 mg (launched mid-September)**
- **Decrease quarterly cash burn rate and continued revenue growth are expected in 2018**
- **Increased focus on partnerships and U.S. co-promotion of select RedHill development programs**

Select recent and potential milestones:

- **Top-line results from the first Phase III study with RHB-104 for Crohn's disease (MAP US study) expected in mid-2018; patient enrollment completed**
- **Top-line results from the confirmatory Phase III study with TALICIA™ (RHB-105) (ERADICATE HP2 study) for the treatment of *H. pylori* infection, expected in H2/2018**
- **Initiation of pivotal Phase III study with RHB-104 for first line treatment of Nontuberculous Mycobacteria (NTM) infections expected in H1/2018**
- **Successful top-line results from the Phase II study with BEKINDA® (RHB-102) 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D)**

TEL-AVIV, Israel and RALEIGH, N.C., Nov. 13, 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 and inflammatory diseases and cancer, today reported its financial results for the quarter ended September 30, 2017.

The Company will host a conference call **today, November 13, 2017 at 9:00 am EST** to review the financial results and business highlights. Dial-in details are included below.

Financial highlights for the quarter ended September 30, 2017[2]

Net Revenues for the third quarter of 2017 were approximately $1.5 million, compared to $0.5 million in the second quarter of 2017. The increase was due to the promotional activities of Donnatal®[3] and the sale of EnteraGam®[4] and the initial promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg[5] in mid-September 2017.

Cost of Revenues for the third quarter of 2017 was $0.9 million, due to the sale of EnteraGam®, compared to $0.3 million in the second quarter of 2017, also due to the sale of EnteraGam ® and reflecting the cost of goods sold and royalties.

Gross Profit for the third quarter of 2017 was $0.6 million, compared to $0.2 million in the second quarter of 2017. The increase was due to higher revenues from the sale of EnteraGam® and from the promotion of Donnatal® and due to the initial promotion of Esomeprazole Strontium Delayed-Release Capsules 49.3 mg in mid-September 2017.

Research and Development Expenses for the third quarter of 2017 were $8.1 million, an increase of $1.1 million or 15% compared to the third quarter of 2016. The increase was mainly due to the ongoing confirmatory Phase III study with TALICIA™ (RHB-105) for *H. pylori* infection, the Phase III and Phase II studies with BEKINDA® (RHB-102) for gastroenteritis and IBS-D, respectively, and the ongoing and planned studies with YELIVA® (ABC294640)[7] for multiple indications. *Research and Development Expenses* for the third quarter of 2017 decreased by $0.3 million or 4% compared to the second quarter of 2017.

General and Administrative Expenses for the third quarter of 2017 were $2.3 million, an increase of $1.2 million compared to the third quarter of 2016. *General and Administrative Expenses* for the third quarter of 2017 increased by $0.3 million compared to the second quarter of 2017. The increase from the comparable periods was mainly due to the establishment and advancement of the Company's U.S. commercial operations in the first quarter of 2017.

Selling, Marketing and Business Development Expenses for the third quarter of 2017 were $4.2 million, an increase of $3.8 million compared to $0.4 million in the third quarter of 2016, comprised only of Business Development Expenses. *Selling, Marketing and Business Development Expenses* for the third quarter of 2017 increased by $0.8 million or 24% compared to the second quarter of 2017. The increase from the comparable periods was mainly due to the establishment and advancement of the Company's U.S. commercial operations. *The Company recognized Selling and Marketing Expenses* in 2017 *for the first time*.

Operating Loss for the third quarter of 2017 was $14 million, an increase of $5.5 million or 65% compared to the third quarter of 2016. *Operating Loss* for the third quarter of 2017 increased by $0.4 million or 3% compared to the second quarter of 2017. The increase from the comparable periods was mainly due to an increase in Selling, Marketing and Business Development Expenses, Research and Development Expenses, and General and Administrative Expenses, as detailed above.

Financial Expenses, net for the third quarter of 2017 was $1.5 million, an increase of $1.1 million compared to the third quarter of 2016. Financial Income, net for the second quarter of 2017 was $2.5 million. The changes from the comparable periods were mainly due to variations in the fair value of the derivative financial instruments, which is affected by share price variations.

Net Cash Used in Operating Activities for the third quarter of 2017 was $10.6 million, an increase of $3.2 million or 43% compared to the third quarter of 2016. The increase was mainly due to the increase in Operating Loss, as detailed above. *Net Cash Used in Operating Activities* for the third quarter of 2017 increased by $0.8 million or 8% compared to the second quarter of 2017.

Net Cash Provided by Investing Activities for the third quarter of 2017 was $13.9 million, an increase of $3.2 million or 30% compared to the third quarter of 2016. Net Cash Used in Investing Activities for the second quarter of 2017 was $4.9 million. The changes from the comparable periods were mainly due to changes in bank deposits and financial assets at fair value through profit or loss.

Cash Balance[7] as of September 30, 2017, was $39.6 million, a decrease of $26.7 million, compared to $66.3 million as of December 31, 2016, and a decrease of $11.6 million compared to June 30, 2017 . The decrease was a result of the ongoing operations, mainly related to research and development activities and the establishment and advancement of the U.S. commercial operations.

"The third quarter of 2017 was the first full quarter of revenues generation from the promotion of Donnatal® and EnteraGam®, with $1.5 million in net revenues. We anticipate net revenues to continue to grow following initiation of the promotion of Esomeprazole Strontium DR capsules 49.3 mg in mid-September," **said Micha Ben Chorin, RedHill's CFO.** "We expect a decrease in quarterly cash burn rate along with continued revenue growth in 2018. Our cash balance at the end of the third quarter of approximately $39.6 million, along with expected net proceeds of approximately $20.6 million from the November 2017 underwritten public offering of ADSs, should allow us to achieve significant milestones in 2018, including Phase III top-line results with RHB-104 for Crohn's disease, expected in mid-2018, and confirmatory Phase III top-line results with TALICIA™ (RHB-105) for *H. pylori* infection, expected in the second half of 2018."

Conference Call and Webcast Information:

The Company will host a conference call **today, Monday, November 13, 2017 at 9:00 am EST** to review the financial results and business highlights.

To participate in the conference call, please dial one of the following numbers 15 minutes prior to the start of the call: **United States: +1-877-280-2296; International: +1-212-444-0896; and Israel:**

+972-3-763-0147. The access code for the call is: 2543708.

The conference call will be broadcasted live and will be available for replay on the Company's website, http://ir.redhillbio.com/events.cfm, for 30 days. Please access the Company's website at least 15 minutes ahead of the conference call to register, download and install any necessary audio software.

Recent operational highlights:

1. On July 31, 2017, RedHill reported, following a second pre-planned meeting by an independent Data and Safety Monitoring Board (DSMB) 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), that it had received a unanimous recommendation from the DSMB to continue the study as planned. The DSMB reviewed safety and efficacy data, of which RedHill remains blinded, from the first 222 subjects who had completed week 26 assessments in the Phase III MAP US study.

2. On September 13, 2017, RedHill announced that it had initiated promotion of Esomeprazole Strontium DR Capsules 49.3 mg in the U.S. Esomeprazole Strontium DR Capsules 49.3 mg is a U.S. Food and Drug Administration (FDA)-approved, proprietary, prescription proton pump inhibitor (PPI) indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal (GI) conditions[9]. On August 17, 2017, RedHill announced that it had entered into a commercialization agreement with ParaPRO LLC, an Indiana-based specialty pharmaceutical company, granting RedHill the exclusive rights to promote Esomeprazole Strontium DR Capsules 49.3 mg to gastroenterologists in certain U.S. territories.

3. On September 18, 2017, RedHill announced that it had received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a new patent covering the use of two of RedHill's Phase II-stage proprietary investigational compounds, YELIVA® and MESUPRON (upamostat)[10] in combination with a known antibiotic. Upon issuance, on top of existing intellectual property (IP) protection covering the individual compounds, the new patent will provide RedHill with IP protection covering its combination for the potential treatment of cancer, prevention of cancer recurrence or progression and inhibition of growth and proliferation of cancer cells.

4. On October 3, 2017, RedHill announced positive top-line results from the Phase II study with BEKINDA® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). The study successfully met its primary endpoint, improving primary efficacy outcome of stool consistency. RedHill plans one or more pivotal Phase III studies with BEKINDA® 12 mg in IBS-D. RedHill further announced that, following the positive results from its Phase III GUARD study with BEKINDA® 24 mg in acute gastroenteritis and gastritis, the Company met with the FDA to discuss the results and the clinical and regulatory path towards potential marketing approval of BEKINDA® 24 mg in the U.S. Following the positive FDA guidance meeting, the Company is currently working with the FDA to design the confirmatory Phase III study to support a New Drug Application (NDA) with BEKINDA® 24 mg for acute gastroenteritis and gastritis.

5. On October 20, 2017, RedHill announced that the FDA granted MESUPRON (upamostat) Orphan Drug designation for the adjuvant treatment of pancreatic cancer. The Orphan Drug designation allows RedHill to benefit from various incentives to develop MESUPRON for this indication, including a seven-year marketing exclusivity period for the indication, if approved. Following the recent identification of a new mechanism of action for MESUPRON, inhibition of trypsin, RedHill is currently evaluating potential utilization of MESUPRON in several GI indications.

6. On October 23, 2017, RedHill announced that it had received a Notice of Allowance from the USPTO for a new patent covering RHB-104 for relapsing-remitting multiple sclerosis (MS), which is expected to be valid until 2032, once granted.

7. On November 1, 2017, RedHill announced, together with IntelGenx Corp. ("IntelGenx"), that they had resubmitted the 505(b)(2) New Drug Application (NDA) for RIZAPORT® 10 mg to the FDA. If the RIZAPORT® NDA resubmission is deemed complete and permits a full review by the FDA, a Prescription Drug User Fee Act (PDUFA) date is expected to be set by the FDA for the first half of 2018.

8. On November 9, 2017, RedHill announced that the last patient had been enrolled in the Phase III study with RHB-104 for Crohn's disease (MAP US study). The study enrolled 331 subjects across approximately 150 clinical sites in the U.S., Canada, Europe, Israel, Australia and New Zealand. Top-line results are expected to be announced in mid-2018. On October 2, 2017, RedHill announced that it had curtailed the target sample size in the Phase III study with RHB-104 for Crohn's disease (MAP US study) from 410 to approximately 325 subjects, while maintaining statistical power of over 80% with a treatment effect of 15%.

Financial Highlights:

On November 9, 2017, RedHill announced the pricing of its underwritten public offering, announced on November 8, 2017, for a total number of 4,090,909 American Depositary Shares (ADSs), each representing ten of its ordinary shares, at a public offering price of $5.50 per ADS. Gross proceeds from the sale of the ADSs by RedHill before underwriting discounts and commissions and other offering expenses are expected to be approximately $22.5 million. The offering is scheduled to be closed today, subject to customary closing conditions. RedHill has also granted the underwriters a 30-day option to purchase up to 613,636 additional ADSs at the public offering price. Cantor Fitzgerald & Co. and Nomura Securities International, Inc. are acting as joint book-running managers for the offering. SMBC Nikko Securities America, Inc. is acting as lead manager and H.C. Wainwright & Co., LLC and Roth Capital Partners, LLC are acting as co-managers for the offering. The Company intends to use the proceeds from the offering to fund clinical development programs, for potential acquisitions, to support commercial operations and for general corporate purposes.

About Esomeprazole Strontium Delayed-Release Capsules 49.3 mg[12]:
Esomeprazole Strontium Delayed-Release Capsules 49.3 mg is indicated for adults:

- for the short-term treatment (4-8 weeks) of heartburn and other symptoms associated with gastroesophageal reflux disease (GERD) and/or in healing and symptomatic resolution of erosive esophagitis (EE).
- to reduce the risk of stomach ulcers in some people taking non-steroidal anti-inflammatory drugs (NSAIDs) (controlled studies did not extend beyond 6 months).
- in combination with amoxicillin 1000 mg and clarithromycin 500 mg is indicated for the treatment of patients with a stomach infection (*Helicobacter pylori*) and duodenal ulcer disease.
- is indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.

Important Safety Information about Esomeprazole Strontium Delayed-Release Capsules 49.3 mg:

- Esomeprazole strontium is contraindicated in patients with known hypersensitivity to proton pump inhibitors. For information about contraindications of antibacterial agents (clarithromycin and amoxicillin) indicated in combination with esomeprazole strontium, refer to the contraindications section of their package inserts.
- Symptomatic response to therapy does not rule out the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in adult patients who have a suboptimal response or an early symptomatic relapse after completing treatment with a proton pump inhibitor (PPI). In older patients, also consider an endoscopy.
- Acute interstitial nephritis has been observed in patients taking PPIs. Discontinue esomeprazole strontium if acute interstitial nephritis develop.
- PPI therapy may be associated with increased risk of Clostridium difficile-associated diarrhea. This diagnosis should be considered for diarrhea that does not improve.
- PPI therapy may be associated with an increased risk of osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose (multiple daily doses) and long-term (a year or longer) therapy.
- Cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE) have been reported in patients taking PPIs, including esomeprazole. These events included both new onset and exacerbations. If signs or symptoms consistent with CLE or SLE are noted with esomeprazole strontium, discontinue and refer the patient to a specialist. Most patients improve with discontinuation of the PPI alone in 4 to 12 weeks.
- Avoid concomitant use of esomeprazole strontium with clopidogrel, due to a reduction in plasma concentrations of the active metabolite of clopidogrel. When using esomeprazole strontium consider alternative anti-platelet therapy.
- Daily treatment with any acid-suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B12). Rare reports of cyanocobalamin deficiency occurring with acid-suppressing therapy have been reported in the literature.
- Hypomagnesemia has been reported rarely with prolonged treatment with PPI therapy and may require discontinuing PPI therapy.
- Concomitant use of esomeprazole strontium and St. John's wort or rifampin can substantially decrease esomeprazole strontium concentrations. Avoid concomitant use.
- Literature suggests that concomitant use of PPIs with methotrexate (primarily at high dose; see methotrexate prescribing information) may elevate and prolong serum levels of methotrexate and/or its metabolite, possibly leading to methotrexate toxicities. In high-dose methotrexate administration, a temporary withdrawal of the PPI may be considered in some patients.
- Concomitant use of esomeprazole strontium and atazanavir or nelfinavir is not recommended. esomeprazole strontium is expected to increase the plasma levels of saquinavir. Consider dose reduction of saquinavir.
- Patients treated with PPIs and warfarin concomitantly may need to be monitored for increases in INR and prothrombin time. Esomeprazole may interfere with the absorption of drugs for which gastric pH affects bioavailability (e.g., ketoconazole, iron salts, erlotinib, digoxin and mycophenolate mofetil).
- Esomeprazole strontium may increase systemic exposure of cilastozol and one of its active metabolites. Consider dose reduction of cilastozol.

- In adults, adverse reactions (ARs) reported at a frequency of 1% or greater with esomeprazole strontium include headache, diarrhea, nausea, flatulence, abdominal pain, constipation, and dry mouth.
- Safety and effectiveness of esomeprazole strontium have not been established in pediatric patients. Not recommended for use in pediatric patients.
- Safety of esomeprazole strontium has not been studied in patients with severe renal impairment. Not recommended for use in patients with severe renal impairment.

Talk to your doctor or healthcare professional. Please see Prescribing information including Medication Guide for Esomeprazole Strontium Delayed-Release Capsules at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=53240ab5-98e7-4050-b640-e09c1271899a&type=display

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About Donnatal®:

Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide), a prescription drug, is classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. Donnatal® slows the natural movements of the gut by relaxing the muscles in the stomach and intestines. Donnatal® comes in two formulations: immediate release Donnatal® Tablets and immediate release Donnatal® Elixir, a fast-acting liquid.

Important Safety Information about Donnatal®:

Donnatal® is contraindicated in patients who have glaucoma, obstructive uropathy, obstructive disease of the gastrointestinal tract, paralytic ileus, unstable cardiovascular status, severe ulcerative colitis, myasthenia gravis, hiatal hernia with reflux esophagitis, or known hypersensitivity to any of the ingredients. Patients who are pregnant or breastfeeding or who have autonomic neuropathy, hepatic or renal disease, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, tachycardia or hypertension should notify their doctor before taking Donnatal®. Side effects may include: dryness of the mouth, urinary retention, blurred vision, dilation of pupils, rapid heartbeat, loss of sense of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia, nausea, vomiting and allergic reactions which may be severe.

Further information, including prescribing information, can be found on www.donnatal.com.

Please see the following website for complete important safety information about Donnatal®:
http://www.donnatal.com/professionals/important-safety-information/

To report suspected adverse reactions, contact Concordia Pharmaceuticals Inc. at 1-877-370-1142 or email: medicalinformation@concordiarx.com, or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

About EnteraGam®:

EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is a medical food product intended for the dietary management of chronic diarrhea and loose stools. EnteraGam® must be administered under medical supervision. EnteraGam® binds microbial components[13], such as toxic substances released by bacteria, that upset the intestinal environment. This helps prevent them from penetrating the lining of the intestine, which may contribute to chronic diarrhea and loose stools in people who have specific intestinal disorders[14].

Safety Information about EnteraGam®:

EnteraGam® contains beef protein; therefore, patients who have an allergy to beef or any other component of EnteraGam® should not take this product. EnteraGam® has not been studied in pregnant women, in women during labor and delivery, or in nursing mothers. The choice to administer EnteraGam® during pregnancy, labor and delivery, or to nursing mothers is at the clinical discretion of the prescribing physician.

EnteraGam® does not contain any milk-derived ingredients such as lactose, casein or whey. EnteraGam® is gluten-free, dye-free and soy-free.

Please see full Product Information.

To report suspected adverse reactions, contact Entera Health, Inc. at 1-855-4ENTERA (1-855-436-8372), or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

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 and inflammatory diseases and cancer. RedHill promotes three gastrointestinal products in the U.S. and its clinical stage pipeline includes treatments for gastrointestinal indications, pancreatic cancer and acute migraines: **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 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 a planned pivotal Phase III study for nontuberculous mycobacteria (NTM) infections; (iii) **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; (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 inflammatory gastrointestinal diseases and (vii) **RIZAPORT® (RHB-103) -** an oral thin-film formulation of rizatriptan for acute migraines, with a U.S. NDA resubmitted to the FDA and marketing authorization received in two EU member states under the European Decentralized Procedure (DCP).

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 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.

Company contact:
Adi Frish
Senior VP Business Development & Licensing
RedHill Biopharma
+972-54-6543-112
adi@redhillbio.com

IR contact (U.S.):
Marcy Nanus
Senior Vice President
The Trout Group
+1-646-378-2927
Mnanus@troutgroup.com

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
	U.S. dollars in thousands			
NET REVENUES	1,523	—	2,006	1
COST OF REVENUES	935	—	1,207	—
GROSS PROFIT	588	—	799	1
RESEARCH AND DEVELOPMENT EXPENSES, net	8,106	7,038	24,677	17,745
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	4,189	*402	8,170	1,138
GENERAL AND ADMINISTRATIVE EXPENSES	2,258	*1,014	5,513	2,669
OTHER EXPENSES	—	—	45	—
OPERATING LOSS	13,965	8,454	37,606	21,551
FINANCIAL INCOME	150	109	2,541	548
FINANCIAL EXPENSES	1,697	599	66	17
FINANCIAL EXPENSES (INCOME), net	1,547	490	(2,475)	(531)
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	15,512	8,944	35,131	21,020
LOSS PER ORDINARY SHARE, BASIC AND DILUTED (U.S. dollars)	0.09	0.07	0.21	0.17

*Reclassified

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(Unaudited)

	September 30, 2017	December 31, 2016
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	18,663	53,786
Bank deposits	8,127	55
Financial assets at fair value through profit or loss	12,645	12,313
Trade receivables and contract assets	1,399	*99
Prepaid expenses and other receivables	2,760	*1,562
Inventory	221	—
	43,815	67,815
NON-CURRENT ASSETS:		
Bank deposits	149	137
Fixed assets	250	165
Intangible assets	6,085	6,095
	6,484	6,397
TOTAL ASSETS	50,299	74,212
CURRENT LIABILITIES:		
Accounts payable	1,882	*60
Accrued expenses and other current liabilities	9,149	*3,296
Payable in respect of intangible asset purchase	1,000	2,000
	12,031	5,356
NON-CURRENT LIABILITIES:		
Derivative financial instruments	4,307	6,155

TOTAL LIABILITIES	16,338	11,511
EQUITY:		
Ordinary shares	459	441
Additional paid-in capital	156,616	150,838
Warrants	—	1,057
Accumulated deficit	(123,114)	(89,635)
TOTAL EQUITY	33,961	62,701
TOTAL LIABILITIES AND EQUITY	50,299	74,212

*Reclassified

REDHILL BIOPHARMA LTD.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
	U.S. dollars in thousands			
OPERATING ACTIVITIES:				
Comprehensive loss	(15,512)	(8,944)	(35,131)	(21,020)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	640	449	1,652	1,318
Depreciation	26	11	58	32
Write-off of intangible asset	—	—	45	—
Unrealized losses (gains) on derivative financial instruments	1,685	585	(1,828)	(130)
Fair value losses (gains) on financial assets at fair value through profit or loss	(12)	(10)	67	(72)
Revaluation of bank deposits	(3)	(108)	(108)	(255)
Exchange differences in respect of cash and cash equivalents	46	(36)	(315)	(77)
	2,382	891	(429)	816
Changes in assets and liability items:				
Increase in trade receivables and contract assets	(621)	—	(1,300)	—
Decrease (increase) in prepaid expenses and other receivables	336	150	(1,198)	342
Decrease (increase) in inventory	389	—	(221)	—
Increase (decrease) in accounts payable	737	*(417)	1,822	*(94)
Increase in accrued expenses	1,734	*950	5,853	*1,868
	2,575	683	4,956	2,116
Net cash used in operating activities	(10,555)	(7,370)	(30,604)	(18,088)
INVESTING ACTIVITIES:				
Purchase of fixed assets	(41)	(10)	(143)	(55)
Purchase of intangible assets	(1,035)	—	(1,035)	—
Change in investment in current bank deposits	7,284	14,668	(7,976)	14,668
Purchase of financial assets at fair value through profit or loss	(978)	(3,976)	(14,931)	(11,456)
Proceeds from sale of financial assets at fair value through profit or loss	8,685	—	14,532	—
Net cash provided by (used in) investing activities	13,915	10,682	(9,553)	3,157
FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares, net of expenses	—	—	1,282	—
Exercise of warrants and options into ordinary shares, net of expenses	30	—	3,437	110
Net cash provided by financing activities	30	—	4,719	110
DECREASE (INCREASE) IN CASH AND CASH EQUIVALENTS	3,390	3,312	(35,438)	(14,821)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(46)	36	315	77
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	15,319	3,424	53,786	21,516
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	18,663	6,772	18,663	6,772
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	153	133	354	185

*Reclassified

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

[2] All financial highlights are approximate and are rounded to the nearest hundreds of thousands.

[3] Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is a prescription drug, classified as possibly effective as an adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. For more information, please see the prescribing information: http://www.donnatal.com/wp-content/uploads/2015/02/2015-02-18-Risk-Benefit-information-DTC-REV.-SE.pdf.

[4] EnteraGam® (serum-derived bovine immunoglobulin/protein isolate, SBI) is a commercially-available medical food, intended for the dietary management of chronic diarrhea and loose stools due to specific intestinal disorders, which must be administered under medical supervision.

[5] Esomeprazole Strontium Delayed-Release (DR) Capsules 49.3 mg is an FDA-approved, proprietary, prescription proton pump inhibitor, indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal (GI) conditions. For more information, please see the prescribing information: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=53240ab5-98e7-4050-b640-e09c1271899a&type=display.

[6] Esomeprazole Strontium Delayed-Release (DR) Capsules 49.3 mg is an FDA-approved, proprietary, prescription proton pump inhibitor, indicated for adults for the treatment of gastroesophageal reflux disease (GERD) and other gastrointestinal (GI) conditions. For more information, please see the prescribing information: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=53240ab5-98e7-4050-b640-e09c1271899a&type=display.

[7] TALICIA™, BEKINDA® and YELIVA® are investigational new drugs, not available for commercial distribution.

[8] Including cash and short-term investments and non-current bank deposits.

[9] For more information, please see the prescribing information: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=53240ab5-98e7-4050-b640-e09c1271899a&type=display.

[10] MESUPRON is an investigational new drug, not available for commercial distribution.

[11] Xifaxan® (rifaximin) prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2010/022554lbl.pdf; Viberzi® (eluxadoline) prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2015/206940s000lbl.pdf; Average absolute difference from reported Phase III studies; The theoretical comparison between the BEKINDA® Phase II study results and reported data from studies of IBS-D-approved therapies serves as a general benchmark for the effect size observed with BEKINDA® and should not be construed as a direct and/or equal comparison given that the studies were not identical in design, patient population and treatment period. For example, in the Xifaxan® Phase III studies, the referenced efficacy endpoints were evaluated over a period of 4 weeks after 2 weeks of drug administration, and in the Viberzi® Phase III studies, the referenced efficacy endpoints were evaluated after the drug was administered and evaluated for 12 weeks. The studies were not conducted head-to head in the same patient population.

[12] Esomeprazole Strontium Delayed-Release Capsules is also available in a 24.65 mg dose. RedHill promotes the Esomeprazole Strontium Delayed-Release Capsules 49.3 mg formulation only.

[13] Horgan A, Maas K, Henderson A, Detzel C, Weaver E. Serum-derived bovine immunoglobulin/protein isolate binds to pathogen-associated molecular patterns. Poster presented at: Federation of American Societies for Experimental Biology; April 26-30, 2014; San Diego, CA.

[14] Petschow BW, Burnett B, Shaw AL, Weaver EM, Klein GL. Serum-derived bovine immunoglobulin/protein isolate: postulated mechanism of action for management of enteropathy. Clin Exp Gastroenterol. 2014;7:181-190. Gasbarrini A, Lauritano EC, Garcovich M, Sparano L, Gasbarrini G. New insights into the pathophysiology of IBS: intestinal microflora, gas production and gut motility. Eur Rev Med Pharmacol Sci. 2008;12 Suppl 1:111-117.

Source: RedHill Biopharma Ltd.