EDGAR pro
by EDGAR Online

REDHILL BIOPHARMA LTD.

FORM 6-K
(Report of Foreign Issuer)

Filed 07/25/17 for the Period Ending 07/25/17

Telephone	972-3-541-3131
CIK	0001553846
Symbol	RDHL
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare

Powered By EDGAR Online
http://www.edgar-online.com
© Copyright 2017, EDGAR Online, Inc. All Rights Reserved.
Distribution and use of this document restricted under EDGAR Online, Inc. Terms of Use.

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 [X] 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 Reports 2017 Second Quarter Financial Results* "

Exhibit 1: Registrant's press release entitled " *RedHill Biopharma Reports 2017 Second Quarter Financial Results* ".

Exhibit 2: Registrant’s condensed consolidated interim unaudited financial information as of June 30, 2017 and for the three months then ended.

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 25, 2017

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

EXHIBIT 1

RedHill Biopharma Reports 2017 Second Quarter Financial Results

RedHill maintains a debt-free balance sheet with $51 million cash [1] at the end of the second quarter of 2017

Select recent milestones include:

- **Initial net revenues of approximately $0.5 million between June 12-30 following commencement of promotional activities in the U.S. by RedHill's GI-focused sales force with two GI specialty products, Donnatal ® and EnteraGam ®**
- **Positive top-line results from the Phase III GUARD study with BEKINDA ® (RHB-102) 24 mg for acute gastroenteritis and gastritis**
- **Initiation of the confirmatory Phase III study with TALICIA ™ (RHB-105) for the treatment of *H. pylori* infection**
- **Last patient out in the Phase II study with BEKINDA ® 12 mg for IBS-D**
- **Orphan Drug designation granted to YELIVA ® (ABC294640) for the treatment of cholangiocarcinoma**

Select potential milestones expected in the second half of 2017:

- **Second independent DSMB meeting of the RHB-104 first Phase III study for Crohn's disease, including an interim efficacy analysis and an evaluation of an option for early stop for success for overwhelming efficacy; DSMB recommendation is expected to be announced by early August 2017**
- **Top-line results from the BEKINDA ® 12 mg Phase II study for IBS-D, expected in September 2017**
- **Type B FDA meeting regarding the successful Phase III GUARD study with BEKINDA ® 24 mg, expected by October 2017**
- **Initiation of several Phase Ib and Phase II studies with YELIVA ® for cholangiocarcinoma, mucositis in head and neck cancer and ulcerative colitis, and with MESUPRON for pancreatic cancer**
- **Re-submission of the RIZAPORT ® NDA to the FDA, expected in October 2017**

TEL-AVIV, Israel and RALEIGH, N.C., July 25, 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 its financial results for the quarter ended June 30, 2017.

The Company will host a conference call on **Tuesday, July 25, 2017 at 9:00 am EDT** to review the financial results and business highlights. Dial-in details are included below.

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

Net Revenues for the second quarter of 2017 were approximately $0.5 million, compared to immaterial Net Revenues in the second quarter of 2016 and in the first quarter of 2017. The increase was due to the initiation, in mid-June 2017, of the U.S. promotional activities of Donnatal ® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) [3] and the sale of EnteraGam ® (serum-derived bovine immunoglobulin/protein isolate, SBI) [4].

Cost of Revenues for the second quarter of 2017 were $0.3 million, reflecting costs related to the initiation of the sale of EnteraGam ® in mid-June 2017.

Research and Development Expenses for the second quarter of 2017 were $8.4 million, an increase of $2.4 million or 40% compared to the second quarter of 2016. The increase was mainly due to the ongoing Phase III and Phase II studies with BEKINDA ® (RHB-102) for gastroenteritis and IBS-D, respectively, the ongoing Phase III study with RHB-104 for Crohn's disease, the ongoing and planned studies with YELIVA ® (ABC294640) for multiple indications, and the initiation of the ongoing confirmatory Phase III study with TALICIA ™ (RHB-105) [5] for *H. pylori* infection. Research and Development Expenses for the second quarter of 2017 increased by $0.3 million or 4% compared to the first quarter of 2017.

General and Administrative Expenses for the second quarter of 2017 were $1.9 million, an increase of $1.2 million compared to the second quarter of 2016. General and Administrative Expenses for the second quarter of 2017 increased by $0.6 million or 48% compared to the first 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 and enhanced professional services.

Selling, Marketing and Business Development Expenses for the second quarter of 2017 were $3.4 million, an increase of $3.0 million compared to $0.4 million in the second quarter of 2016, comprised only of Business Development Expenses. The increase 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 second quarter of 2017 was $13.5 million, an increase of $6.3 million or 88% compared to the second quarter of 2016. The increase was mainly due to an increase in Research and Development Expenses and Selling, Marketing and Business Development Expenses, as detailed above. Operating Loss for the second quarter of 2017 increased by $3.4 million or 34% compared to the first quarter of 2017. The increase was mainly due to an increase in Selling,

Marketing and Business Development Expenses, as detailed above.

Financial Income , net for the second quarter of 2017 was $2.5 million, an increase of $1.9 million compared to the second quarter of 2016. Financial Income, net for the second quarter of 2017 increased by $1.0 million or 67% compared to the first quarter of 2017. The increase from the comparable periods was mainly due to a fair value gain on derivative financial instruments.

Net Cash Used in Operating Activities for the second quarter of 2017 was $9.7 million, an increase of $4 million or 70% compared to the second 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 second quarter of 2017 decreased by $0.6 million or 6% compared to the first quarter of 2017.

Net Cash Used in Investing Activities for the second quarter of 2017 was $4.9 million, an increase of $1.9 million or 67% compared to the second quarter of 2016. Net Cash Used in Investing Activities for the second quarter of 2017 decreased by $13.7 million compared to the first quarter of 2017. The decrease was mainly due to change in short-term investments.

Cash Balance [6] as of June 30, 2017, was $51 million, a decrease of $15 million, compared to $66 million as of December 31, 2016, and a decrease of $10 million compared to March 31, 2017. The decrease was a result of the ongoing operations, mainly related to research and development activities and the establishment of the U.S. commercial operations.

Micha Ben Chorin, RedHill's CFO, said: "We are pleased with the important milestones achieved during the second quarter, including positive top-line results from the Phase III GUARD study with BEKINDA ® 24 mg for acute gastroenteritis, initiation of the confirmatory Phase III study with TALICIA ™ for the treatment of *H. pylori* infection, and the initiation of promotional activities in the U.S. by our GI-focused sales force with Donnatal ® and EnteraGam ® , which generated encouraging initial net revenues of approximately $0.5 million in the second half of June alone. Our cash position of $51 million at the end of the second quarter should allow us to continue to execute our strategic plans, diligently advance our late-stage clinical programs and pursue the acquisition of additional commercial GI products in the U.S."

Conference Call and Webcast Information:

The Company will host a conference call on **Tuesday, July 25, 2017 at 9:00 am EDT** to review the financial results and business highlights.

To participate in the conference call, please dial the following numbers 15 minutes prior to the start of the call: **United States: +1-877-280-2342; International: +1-212-444-0412; and Israel: +972-3-763-0146. The access code for the call is 5090357.**

The conference call will be broadcasted live and 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 April 4, 2017, RedHill announced that the FDA had granted YELIVA ® Orphan Drug designation for the treatment of cholangiocarcinoma. Orphan Drug designation would allow RedHill to benefit from a seven-year marketing exclusivity period for the indication, if approved, as well as other development incentives to develop YELIVA ® for cholangiocarcinoma. A Phase IIa clinical study with YELIVA ® in patients with advanced, unresectable, intrahepatic and extrahepatic cholangiocarcinoma is planned to be initiated in the third quarter of 2017.

2. On April 5, 2017, RedHill announced the signing of an exclusive license agreement with Entera Health Inc. ("Entera Health"), granting RedHill the exclusive U.S. rights to EnteraGam ® (serum-derived bovine immunoglobulin/protein isolate, SBI), a commercially-available medical food intended for the dietary management of chronic diarrhea and loose stools, which must be administered under medical supervision. Under the terms of the agreement, RedHill will pay Entera Health royalties based on net sales generated from the sale of EnteraGam ® by RedHill.

3. On April 13, 2017, RedHill, together with IntelGenx Corp., announced that the Ministry of Health of Luxembourg had granted national marketing authorization for RIZAPORT ® (5 mg and 10 mg), a thin-film for the treatment of acute migraines. The national marketing authorization was granted in Luxembourg on the basis of the European Decentralized Procedure (DCP), in which Luxembourg served as the Concerned Member State. The approval in Luxembourg marked the completion of the current marketing approval process for RIZAPORT ® under the European DCP. The re-submission of the RIZAPORT ® NDA to the FDA is expected in October 2017.

4. On April 24, 2017, RedHill announced the enrollment of the last patient in the Phase II study with BEKINDA ® 12 mg for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). On July 17, 2017, RedHill announced that the last patient had completed the treatment course and the last follow-up visit. Top-line results are expected in September 2017. The randomized, double-blind, placebo-controlled Phase II study is evaluating the efficacy and safety of BEKINDA ® 12 mg in adults 18 years and older who suffer from IBS-D. The study enrolled 127 subjects at 16 clinical sites in the U.S.

5. In May 2017, RedHill adopted an Expanded Access Program (EAP), allowing patients with life-threatening diseases potential access to RedHill's investigational new drugs that have not yet received regulatory marketing approval. Expanded access (sometimes referred to as "compassionate use") is possible outside RedHill's clinical trials, under certain eligibility criteria, when a certain investigational new drug is needed to treat life-threatening condition and there is some clinical evidence suggesting that the drug might be effective in that condition. Following the adoption of the program, RedHill continues to receive patient requests to obtain access to investigational drugs. Therefore, subject to evaluation of eligibility and all the necessary regulatory and other approvals, RedHill is likely to provide certain patients with an investigational new drug under the EAP. Further information about RedHill's EAP can be found on the Company's website at: http://www.redhillbio.com/expandedaccess.

6. On June 13, 2017, RedHill announced the initiation of the promotion of two gastrointestinal specialty products, Donnatal ® and EnteraGam ® in the U.S. RedHill's U.S. commercial operations, headquartered in Raleigh, NC, include a gastrointestinal-focused sales force of more than 30 sales representatives

promoting Donnatal ® and EnteraGam ® in select U.S. territories.

7. On June 14, 2017, RedHill announced positive top-line results from the Phase III GUARD study with BEKINDA ® (RHB-102) 24 mg for acute gastroenteritis and gastritis. The study successfully met its primary endpoint of efficacy in the treatment of acute gastroenteritis and gastritis. BEKINDA ® 24 mg was found to be safe and well tolerated in this indication. The randomized, double-blind, placebo-controlled Phase III GUARD study evaluated the efficacy and safety of BEKINDA ® 24 mg in treating acute gastroenteritis and gastritis. 321 adults and children over the age of 12 were enrolled at 21 clinical sites in the U.S. and randomized in a 60:40 ratio to receive either BEKINDA ® 24 mg or placebo, respectively. The primary endpoint of the study was the proportion of patients without further vomiting, without rescue medication, and who were not given intravenous hydration from 30 minutes post first dose of the study drug until 24 hours post dose, compared to placebo. A Type B FDA meeting is expected to take place by October 2017. Top-line results indicated that the Phase III GUARD study successfully met its primary endpoint in the Intent to Treat (ITT) population (p = 0.04), despite high positive outcome rate in the placebo arm. BEKINDA ® 24 mg improved the efficacy outcome by 21%; 65.6% of BEKINDA ® -treated patients as compared to 54.3% of placebo patients (p = 0.04; n=192 in the BEKINDA ® group and n=129 in the placebo group). Correcting for a randomization error, the difference in effect is greater with 65.8% vs. 53.9% favoring BEKINDA ® 24 mg vs. placebo in reaching the primary endpoint of the study (p = 0.03). In per-protocol (PP) analysis of patients who met all protocol entry criteria and for which the diagnosis of gastroenteritis was confirmed (n=177 in the BEKINDA ® group and n=122 in the placebo group), BEKINDA ® 24 mg improved the efficacy outcome by 27%; 69.5% of patients in the BEKINDA ® group vs. 54.9% in the placebo group (p = 0.01).

8. On June 15, 2017, RedHill announced the initiation of the confirmatory Phase III study with RHB-105, newly branded as TALICIA ™ , for the treatment of *H. pylori* infection (the ERADICATE Hp2 study). The two-arm, randomized, double-blind, active comparator, confirmatory Phase III study is planned to enroll 444 non-investigated dyspepsia patients with confirmed *H. pylori* infection in up to 65 clinical sites in the U.S., with a primary endpoint of eradication of *H. pylori* infection at 42 through 70 days after initiation of treatment. Subject to a successful outcome and any additional regulatory feedback, the confirmatory Phase III study is expected to complete the package required for a potential U.S. NDA for TALICIA ™ .

9. On July 12, 2017, RedHill announced that the second independent Data and Safety Monitoring Board (DSMB) meeting of the first RHB-104 Phase III study for Crohn's disease (the MAP US study) is expected to convene in late July 2017 and will assess the safety and efficacy of RHB-104 in the first 222 subjects who have completed week 26 assessments. The DSMB meeting will include an interim efficacy analysis and an evaluation of an option for early stop for success for overwhelming efficacy. The DSMB's recommendation is planned to be announced by early August 2017. To date, approximately 300 patients of the planned total of 410 patients have been enrolled in the ongoing Phase III MAP US study.

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 breast-feeding 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 [7] , 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 [8] .

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 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 ®** , a prescription oral adjunctive drug used in the treatment of IBS and acute enterocolitis, 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 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.

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.

[1] Including cash and short-term investments.

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

[6] Including cash and short-term investments

[7] 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.

[8] 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.

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

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	U.S. dollars in thousands		U.S. dollars in thousands	
NET REVENUES	483	1	483	1
COST OF REVENUE	272	—	272	—
RESEARCH AND DEVELOPMENT EXPENSES, net	8,434	6,031	16,571	10,707
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,376	* 424	3,981	* 736
GENERAL AND ADMINISTRATIVE EXPENSES	1,940	* 740	3,255	* 1,655
OTHER EXPENSES	—	—	45	—
OPERATING LOSS	13,539	7,194	23,641	13,097
FINANCIAL INCOME	2,523	666	4,078	1,025
FINANCIAL EXPENSES	7	24	56	4
FINANCIAL INCOME, net	2,516	642	4,022	1,021
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	11,023	6,552	19,619	12,076
LOSS PER ORDINARY SHARE (U.S. dollars)				
Basic	0.06	0.05	0.11	0.09
Diluted	0.06	0.06	0.11	0.10

* Reclassified

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

	June 30, 2017	December 31, 2016
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	15,319	53,786
Bank deposits	15,407	55
Financial assets at fair value through profit or loss	20,340	12,313
Trade receivables and contract assets	778	99
Prepaid expenses and other receivables	3,096	1,562
Inventory	610	—
	55,550	67,815
NON-CURRENT ASSETS:		
Bank deposits	150	137
Fixed assets	235	165
Intangible assets	6,050	6,095
	6,435	6,397
TOTAL ASSETS	61,985	74,212
CURRENT LIABILITIES:		
Accounts payable	1,145	60
Accrued expenses and other current liabilities	7,415	3,296
Payable in respect of intangible asset purchase	2,000	2,000
	10,560	5,356

NON-CURRENT LIABILITIES:		
Derivative financial instruments	2,622	6,155
TOTAL LIABILITIES	13,182	11,511
EQUITY:		
Ordinary shares	458	441
Additional paid-in capital	156,587	150,838
Warrants	—	1,057
Accumulated deficit	(108,242)	(89,635)
TOTAL EQUITY	48,803	62,701
TOTAL LIABILITIES AND EQUITY	61,985	74,212

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

	Three months ended June 30,		Six months ended June 30,	
	2017	**2016**	**2017**	**2016**
	U.S. dollars in thousands		**U.S. dollars in thousands**	
OPERATING ACTIVITIES:				
Comprehensive loss	(11,023)	(6,552)	(19,619)	(12,076)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	705	495	1,012	869
Depreciation	18	11	32	21
Write-off of intangible assets	—	—	45	—
Unrealized gains on derivative financial instruments	(2,251)	(514)	(3,513)	(715)
Fair value loses (gains) on financial assets at fair value through profit or loss	64	(54)	79	(62)
Revaluation of bank deposits	(87)	(89)	(105)	(147)
Exchange differences in respect of cash and cash equivalents	(119)	41	(361)	(41)
	(1,670)	(110)	(2,811)	(75)
Changes in assets and liability items:				
Increase in trade receivables and contract assets	(778)	—	(679)	—
Decrease (increase) in prepaid expenses and other receivables	(421)	(248)	(1,534)	192
Increase in Inventory	(610)	—	(610)	—
Increase in accrued expenses	1,124	(224)	1,085	323
Increase in accounts payable and accrued expenses	3,650	1,397	4,119	918
	2,965	925	2,381	1,433
Net cash used in operating activities	(9,728)	(5,737)	(20,049)	(10,718)
INVESTING ACTIVITIES:				
Purchase of fixed assets	(102)	(16)	(102)	(45)
Change in investment in current bank deposits	284	(2,000)	(15,260)	—
Purchase of financial assets at fair value through profit or loss	(10,500)	(908)	(13,953)	(7,480)
Proceeds from sale of financial assets at fair value through profit or loss	5,447	—	5,847	—
Net cash used in investing activities	(4,871)	(2,924)	(23,468)	(7,525)
FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares, net of expenses	—	—	1,282	—
Exercise of warrants and options into ordinary shares, net of expenses	175	100	3,407	110
Net cash provided by financing activities	175	100	4,689	110

DECREASE IN CASH AND CASH EQUIVALENTS	(14,424)	(8,561)	(38,828)	(18,133)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	119	(41)	361	41
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,624	12,026	53,786	21,516
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	15,319	3,424	15,319	3,424
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	130	4	201	95

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 FINANCIAL INFORMATION

(UNAUDITED)

JUNE 30, 2017

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION

(UNAUDITED)

JUNE 30, 2017

TABLE OF CONTENTS

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	U.S. dollars in thousands			
NET REVENUES	483	1	483	1
COST OF REVENUES	272	—	272	—
GROSS PROFIT	211	1	211	1
RESEARCH AND DEVELOPMENT EXPENSES	8,434	6,031	16,571	10,707
SELLING, MARKETING AND BUSINESS DEVELOPMENT EXPENSES	3,376	*424	3,981	*736
GENERAL AND ADMINISTRATIVE EXPENSES	1,940	*740	3,255	*1,655
OTHER EXPENSES	—	—	45	—
OPERATING LOSS	13,539	7,194	23,641	13,097
FINANCIAL INCOME	2,523	666	4,078	1,025
FINANCIAL EXPENSES	7	24	56	4
FINANCIAL INCOME, net	2,516	642	4,022	1,021
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	11,023	6,552	19,619	12,076
LOSS PER ORDINARY SHARE (U.S. dollars)				
Basic	0.06	0.05	0.11	0.09
Diluted	0.06	0.06	0.11	0.10

The accompanying notes are an integral part of these condensed consolidated financial statements.

*Reclassified

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(Unaudited)

	June 30, 2017	December 31, 2016
	U.S. dollars in thousands	
CURRENT ASSETS:		
Cash and cash equivalents	15,319	53,786
Bank deposits	15,407	55
Financial assets at fair value through profit or loss	20,340	12,313
Trade receivables and contract assets	778	99
Prepaid expenses and other receivables	3,096	1,562
Inventory	610	—
	55,550	67,815
NON-CURRENT ASSETS:		
Bank deposits	150	137
Fixed assets	235	165
Intangible assets	6,050	6,095
	6,435	6,397
TOTAL ASSETS	61,985	74,212
CURRENT LIABILITIES:		
Accounts payable	1,145	60
Accrued expenses and other current liabilities	7,415	3,296
Payable in respect of intangible asset purchase	2,000	2,000
	10,560	5,356
NON-CURRENT LIABILITIES:		
Derivative financial instruments	2,622	6,155
TOTAL LIABILITIES	13,182	11,511
EQUITY:		
Ordinary shares	458	441
Additional paid-in capital	156,587	150,838
Warrants	—	1,057
Accumulated deficit	(108,242)	(89,635)
TOTAL EQUITY	48,803	62,701
TOTAL LIABILITIES AND EQUITY	61,985	74,212

The accompanying notes are an integral part of these condensed consolidated financial statements.

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(Unaudited)

	Ordinary shares	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	U.S. dollars in thousands				
BALANCE AT APRIL 1, 2017	455	156,415	—	(97,924)	58,946
CHANGES IN THE THREE-MONTH PERIOD ENDED JUNE 30, 2017:					
Share-based compensation to employees and service providers	—	—	—	705	705
Exercise of options into ordinary shares	3	172	—	—	175
Comprehensive loss	—	—	—	(11,023)	(11,023)
BALANCE AT JUNE 30, 2017	458	156,587	—	(108,242)	48,803
BALANCE AT APRIL 1, 2016	343	120,631	1,057	(67,094)	54,937
CHANGES IN THE THREE-MONTH PERIOD ENDED JUNE 30, 2016:					
Share-based compensation to employees and service providers	—	—	—	495	495
Exercise of options into ordinary shares	1	99	—	—	100
Comprehensive loss	—	—	—	(6,552)	(6,552)
BALANCE AT JUNE 30, 2016	344	120,730	1,057	(73,151)	48,980

The accompanying notes are an integral part of these condensed consolidated financial statements.

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(Unaudited)

	Ordinary shares	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2017	441	150,838	1,057	(89,635)	62,701
CHANGES IN THE SIX-MONTH PERIOD ENDED JUNE 30, 2017:					
Share-based compensation to employees and service providers	—	—	—	1,012	1,012
Issuance of ordinary shares, net of expenses	3	1,279	—	—	1,282
Exercise of warrants and options into ordinary shares	14	3,413	—	—	3,427
Warrants expiration	—	1,057	(1,057)	—	—
Comprehensive loss	—	—	—	(19,619)	(19,619)
BALANCE AT JUNE 30, 2017	458	156,587	—	(108,242)	48,803
BALANCE AT JANUARY 1, 2016	343	120,621	1,057	(61,944)	60,077
CHANGES IN THE SIX-MONTH PERIOD ENDED JUNE 30, 2016:					
Share-based compensation to employees and service providers	—	—	—	869	869
Exercise of options into ordinary shares	1	109	—	—	110
Comprehensive loss	—	—	—	(12,076)	(12,076)
BALANCE AT JUNE 30, 2016	344	120,730	1,057	(73,151)	48,980

The accompanying notes are an integral part of these condensed consolidated financial statements

REDHILL BIOPHARMA LTD.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	U.S. dollars in thousands			
OPERATING ACTIVITIES:				
Comprehensive loss	(11,023)	(6,552)	(19,619)	(12,076)
Adjustments in respect of income and expenses not involving cash flow:				
Share-based compensation to employees and service providers	705	495	1,012	869
Depreciation	18	11	32	21
Write-off of intangible asset	—	—	45	—
Unrealized gains on derivative financial instruments	(2,251)	(514)	(3,513)	(715)
Fair value losses (gains) on financial assets at fair value through profit or loss	64	(54)	79	(62)
Revaluation of bank deposits	(87)	(89)	(105)	(147)
Exchange differences in respect of cash and cash equivalents	(119)	41	(361)	(41)
	(1,670)	(110)	(2,811)	(75)
Changes in assets and liability items:				
Increase in trade receivables and contract assets	(778)	—	(679)	—
Decrease (increase) in prepaid expenses and other receivables	(421)	(248)	(1,534)	192
Increase in inventory	(610)	—	(610)	—
Increase (decrease) in accounts payable	1,124	(224)	1,085	323
Increase in accrued expenses	3,650	1,397	4,119	918
	2,965	925	2,381	1,433
Net cash used in operating activities	(9,728)	(5,737)	(20,049)	(10,718)
INVESTING ACTIVITIES:				
Purchase of fixed assets	(102)	(16)	(102)	(45)
Change in investment in current bank deposits	284	(2,000)	(15,260)	—
Purchase of financial assets at fair value through profit or loss	(10,500)	(908)	(13,953)	(7,480)
Proceeds from sale of financial assets at fair value through profit or loss	5,447	—	5,847	—
Net cash used in investing activities	(4,871)	(2,924)	(23,468)	(7,525)
FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares, net of expenses	—	—	1,282	—
Exercise of warrants and options into ordinary shares, net of expenses	175	100	3,407	110
Net cash provided by financing activities	175	100	4,689	110
DECREASE IN CASH AND CASH EQUIVALENTS	(14,424)	(8,561)	(38,828)	(18,133)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	119	(41)	361	41
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	29,624	12,026	53,786	21,516
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	15,319	3,424	15,319	3,424
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	130	4	201	95

The accompanying notes are an integral part of these condensed consolidated financial statements.

NOTE 1 - GENERAL:

a. General

RedHill Biopharma Ltd. (the "Company") headquartered in Israel, together with its subsidiary, is a specialty biopharmaceutical company 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. The Company is also promoting since June 2017, in the U.S. through its subsidiary, Donnatal ® , a prescription oral adjunctive drug for the treatment of IBS and acute enterocolitis, as well as EnteraGam ® , a medical food intended for the dietary management, under medical supervision, of chronic diarrhea and loose stools.

In February 2011, the Company listed its securities on the Tel-Aviv Stock Exchange ("TASE"). Since December 2012, the Company's American Depositary Shares ("ADSs") have been listed on the NASDAQ Capital Market ("NASDAQ").

The Company's registered address is at 21 Ha'arba'a St, Tel-Aviv, Israel.

The Company is engaged in the research and development of most of its therapeutic candidates and to date has out-licensed on an exclusive world-wide basis only one of its therapeutic candidates and has had two additional regional exclusive out-licensing transactions with another therapeutic candidate . Accordingly, there is no assurance that the Company's business will generate positive cash flow. Through June 30, 2017, the Company has an accumulated deficit and its activities have been funded through public and private offerings of the Company's securities.

The Company plans to further fund its future operations through commercialization of its therapeutic candidates and Donnatal ® and EnteraGam ® , out-licensing certain programs and raising additional capital. The Company's current cash resources are not sufficient to complete the research development and commercialization of all of the Company's therapeutic candidates and Donnatal ® and EnteraGam ® . Management expects that the Company will incur more losses as it continues to focus its resources on advancing these products based on a prioritized plan that will result in negative cash flows from operating activities. The Company believes its existing capital resources should be sufficient to fund its current and planned operations for at least the next 12 months.

If the Company is unable to continue to commercialize or further out-license its therapeutic candidates and Donnatal ® and EnteraGam ® , or obtain future financing, the Company may be forced to delay, reduce the scope of, or eliminate one or more of its research, development programs or commercialization programs related to these products, any of which may have a material adverse effect on the Company's business, financial condition and results of operations.

b. Approval of the condensed consolidated interim financial statements

These condensed consolidated interim financial statements were approved by the Board of Directors on July 24, 2017.

NOTE 2 - BASIS OF PREPARATION OF THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS:

a. The Company's condensed consolidated interim financial statements for the three and six months ended June 30, 2017 and 2016 (the "Condensed Consolidated Interim Financial Statements") have been prepared in accordance with International Accounting Standard IAS 34, "Interim Financial Reporting". These Condensed Consolidated Interim Financial Statements, which are unaudited, do not include all disclosures necessary for a complete statement of financial position, results of operations and cash flow in conformity with generally accepted accounting principles. The Condensed Consolidated Interim Financial Statements should be read in conjunction with the annual financial statements as of December 31, 2016 and for the year then ended and their accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as published by the International Accounting Standards Board ("IASB"). The results of operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year or for any other interim period.

The Condensed Consolidated Interim Financial Statements as of June 30, 2017 and for the three and six months then ended include for the first time the accounts of the Company and its subsidiary. Intercompany transactions and balances are eliminated on consolidation.
The accounting policies applied in the preparation of the Condensed Consolidated Interim Financial Statements are consistent with those applied in the preparation of the annual financial statements as of December 31, 2016. For more information, see Note 3 below, describing new additional accounting policies adopted by the Company with respect to its new operation.

b. Standards and interpretations to existing standards that are not yet in effect and have not been early adopted by the Company:

International Financial Reporting Standard No. 9 "Financial Instruments" (hereafter - IFRS

IFRS 9, 'Financial instruments', addresses the classification, measurement and recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income and fair value through profit or loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. Further, the expected credit losses model replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in the Company's own credit risk in other comprehensive income for liabilities designated at fair value through profit or loss.

The standard is effective for accounting periods beginning on or after 1 January, 2018. The Company is currently assessing the impact of IFRS 9.

International Financial Reporting Standard No. 16 "Leases" ("IFRS 16")

IFRS 16 defines a lease as a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration. Under IFRS 16, lessees have to recognize a lease liability reflecting future lease payments and a 'right-of-use asset' for almost all lease contracts. The standard replaces the current guidance in IAS 17. The standard is effective for annual periods beginning on or after January 1, 2019. The Company is currently assessing the impact of adopting IFRS 16.

NOTE 3 - NEW ACCOUNTING POLICIES:

a. Revenues from contracts with customers

In May 2014, the IASB issued the new revenue recognition standard, IFRS 15. IFRS 15 replaces much of the prescriptive and diverse guidance in today's accounting literature.

Its purpose, among other things, is to remove inconsistencies in existing revenue recognition frameworks and to provide more useful information to financial statements users.

In the second quarter of 2017, the Company adopted retrospectively IFRS 15 as of January 1, 2017, for all periods presented. The adoption of IFRS 15 did not have an effect on neither the revenues recognized in prior periods nor to accumulated deficits as of January 1, 2015.

IFRS 15 introduces a five-step model for recognizing revenue from contracts with customers, as follows:

1. Identify the contract with a customer.

2. Identify the performance obligations in the contract.

3. Determine the transaction price.

4. Allocate the transaction price to the performance obligations in the contract.

5. Recognize revenue when (or as) the entity satisfies a performance obligation.

Revenues from promotional services

The Company recognizes revenue from promotional services related to Donnatal ® as it satisfies its performance obligation over time, in an amount of the consideration it expects to be entitled to, taking into consideration the constraint on variable consideration stipulated in IFRS 15.

Revenues from sale of products

Principal versus agent considerations

When another party is involved in providing goods or services to a customer, the Company analyses whether the Company acts as a principal or an agent in the transaction, based on whether the Company obtains control of the product before it is transferred to the customer, using the indicators provided in IFRS 15.

In the sale of EnteraGam ®, the Company is determined to be the principal in the arrangement (rather than an agent of Entera Health), therefore, revenue in the amount the Company is entitled to from its customers is recognized on a gross basis.

The Company recognizes revenues from the sale of EnteraGam ®, when control of the product is transferred to the customers, at a point in time.

The transaction price in these arrangements is the consideration the Company expects to be entitled to from the customer, taking into consideration the existence of variable considerations, such as the product's right of return and certain other promotional discounts provided to customers.

Revenues from out-licensing of the Company's intellectual property

Revenue incurred in connection with the out-licensing of a right to use the Company’s intellectual property is recognized at a point in time.

The transaction price contains variable considerations contingent upon the licensee achieving certain milestones as well as sales-based royalties, in accordance with the relevant agreement.

Revenue from achieving additional milestones is recognized only when it is highly probable that a significant reversal of cumulative revenues will not occur, usually upon achievement of the specific milestone, in accordance with the relevant agreement.

Sales-based royalties are not included in the transaction price, rather they are recognized as incurred, due to the specific exception for sales-based royalties in licensing of intellectual property.

Practical expedients and exemptions

The Company expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded as sales and marketing expenses.

b. Inventories

Inventories are stated at the lower of cost or net realizable value with cost determined using the first-in, first-out method. The Company recognized, for the first time an amount of $108 thousand in inventories as a cost of revenues during the three months ended June 30, 2017.

The Company continually evaluates inventories for potential losses due to excess, obsolete or slow-moving inventory by comparing sales history and sales projections to the inventory on hand. When evidence indicates the carrying value of a product may not be recoverable, a charge is recorded to reduce the inventory to its current net realizable value.

c. Trade receivables and contract assets

Financial assets included in trade receivables and contract assets are recognized initially at fair value. Subsequent to initial recognition they are measured at amortized cost using the effective interest rate method, less any impairment losses.

d. Advertising and promotional expenses

Advertising and promotional costs, including free products and samples distributed to customers, are recognized as an expense when incurred.

NOTE 4 - EQUITY:

a. On January 3, 2017, the underwriters for the Company's 2016 underwritten public offering partially exercised their option and purchased 133,104 ADSs for approximately $1.28 million. Following the partial exercise of the underwriters' option, the underwritten public offering and the concurrent registered direct offering totaled 3,846,519 ADSs and warrants to purchase 2,025,458 ADSs, representing aggregate gross proceeds from both offerings of approximately $39.4 million before deducting underwriting discounts and commissions, placement agent fees and other offering expenses.

b. During the six months ended June 30, 2017, the Company received notifications of exercise with respect to options that had been issued to directors and consultants of the Company. Accordingly, the Company issued 2,808,750 ordinary shares for approximately $777 thousand.

c. During the six months ended June 30, 2017, the Company received notifications of exercise with respect to non-tradable warrants that had been issued in 2014 to investors in the form of private placements. Accordingly, the Company issued 2,526,320 ordinary shares for approximately $2.63 million.

NOTE 5 - SHARE-BASED PAYMENTS:

a. On March 23, 2017, the Board of Directors of the Company granted 3,025,000 options to employees and consultants of the Company under the Company's stock options plan. The fair value of the options on the date of grant was $1.45 million.

Each option is exercisable into one ordinary share at an exercise price of $1.08 per share. The options will vest as follows: for employees and consultants of the Company who had provided services exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For employees and consultants of the Company who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments.

The options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant.

The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $1.03, expected volatility: 50.05%, risk-free interest rate: 2.23% and expected useful life to exercise: 7 years.

b. On March 23, 2017, the Board of Directors of the Company granted 62,500 options to purchase ADSs to employees of the Company under the Company's stock options plan. The fair value of the options on the date of grant was $327 thousand.

Each option is exercisable into one of the Company's ADSs at an exercise price of $10.80 per ADS. The options will vest as follows: for employees and consultants of the Company who had provided services exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For employees and consultants of the Company who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments.

The options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant.

The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ADS: $10.36, expected volatility: 58.09%, risk-free interest rate: 2.23% and expected useful life to exercise: 7 years.

c. Following a general meeting of the Company's shareholders held on May 11, 2017, and subsequent to the approval of the Company's Board of Directors on March 23, 2017, the Company allocated an aggregate of 1,140,000 options under the Company's stock options plan to the Company's directors at an exercise price equal to $1.09 per share, excluding 500,000 options to the Company's Chief Executive Officer at an exercise equal to $1.08 per share. The fair value of the options on the date of grant was $517 thousand.

Each option allocated to non-executive directors of the Company is exercisable into one ordinary share. The options will vest as follows: for directors who had provided services exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For directors who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments.

The options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant.

The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: exercise price equal to either $1.08 or $1.09 per share, price of the Company's ordinary share: $1.00, expected volatility: 49.77%, risk-free interest rate: 2.20% and expected useful life to exercise: 7 years.

NOTE 6 – NET REVENUES:

The Company's net revenues for the three and six months ended June 30, 2017 consist of r evenues from the sale of products and revenues from promotional services.

NOTE 7 - FINANCIAL INSTRUMENTS:

a. Fair value hierarchy

The following table presents Company assets and liabilities measured at fair value:

	Level 1	Level 3	Total
	U.S. dollars in thousands		
June 30, 2017:			
Assets -			
Financial assets at fair value through profit or loss	20,340	—	20,340
Liabilities -			
Derivative financial instruments	—	2,622	2,622
December 31, 2016:			
Assets -			
Financial assets at fair value through profit or loss	12,313	—	12,313
Liabilities -			
Derivative financial instruments	—	6,155	6,155

During the six-month period ended June 30, 2017, there were no transfers of financial assets and liabilities between Levels 1, 2 or 3 fair value measurements. There have been no changes in the methodologies used at June 30, 2017 since December 31, 2016.

b. Fair value measurements using significant unobservable input (Level 3)

The following table presents the change in derivative financial liabilities measured at level 3 for the periods ended June 30, 2017 and 2016:

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
	U.S. dollars in thousands			
Balance at beginning of the period	4,873	1,036	6,155	1,237
Amounts classified to equity	—	—	(20)	—
Amounts recognized in profit or loss	(2,251)	(514)	(3,513)	(715)
Balance at the end of the period	2,622	522	2,622	522

The fair value of the above-mentioned derivative financial instruments that are not traded in an active market is determined by using valuation techniques. The Company uses its judgment to select a variety of methods and make assumptions that are mainly based on market conditions at the end of each reporting period.

The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the warrants issued in 2016 as of June 30, 2017 is based on the price of an ordinary share on June 30, 2017 and based on the following key parameters: risk-free interest rate of 1.45% and an average standard deviation of 45.58%. The fair value of the above warrants as of December 31, 2016, was computed based on the price of an ordinary share on December 31, 2016 and based on the following key parameters: risk-free interest rate of 1.48% and an average standard deviation of 52.94%.

c. The carrying amount of cash and cash equivalents, current and non-current bank deposits, receivables and account payables and accrued expenses approximate their fair values.

NOTE 8 - LOSS PER ORDINARY SHARE:

a. Basic

The basic loss per share is calculated by dividing the comprehensive loss by the weighted average number of ordinary shares in issue during the period.

	Three months ended June 30,		Six months ended June 30,	
	2017	2016	2017	2016
Comprehensive loss (U.S. dollars in thousands)	11,023	6,552	19,619	12,076
Weighted average number of ordinary shares outstanding during the period (in thousands)	171,640	127,344	170,640	127,237
Basic loss per share (U.S. dollars)	0.06	0.05	0.11	0.09

b. Diluted

The diluted loss per share for the three and six months-period ended June 30, 2017 is identical to the basic loss per share since the effect of potential dilutive shares is anti-dilutive. Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares, which is calculated using the Treasury Method. The Company has two categories of dilutive potential ordinary shares: warrants issued to investors and options issued to employees and service providers. The effect of options issued to employees and service providers is anti-dilutive.

	Three months ended June 30,		Six months ended June 30,	
	2017	**2016**	**2017**	**2016**
Comprehensive loss (U.S. dollars in thousands)	11,023	6,552	19,619	12,076
Adjustment for financial income of warrants	—	514	—	715
Loss used to determine diluted loss per share	11,023	7,066	19,619	12,791
Weighted average number of ordinary shares outstanding during the period (in thousands)	171,640	127,344	170,640	127,237
Adjustment for warrants	—	171	—	13
Weighted average number of ordinary shares for diluted loss per share (in thousands)	171,640	127,515	170,640	127,250
Diluted loss per share (U.S. dollars)	0.06	0.06	0.11	0.10

NOTE 9 - SUBSEQUENT EVENTS:

On July 24, 2017, the Board of Directors of the Company granted 237,500 options to purchase ADSs and 70,000 options to purchase ordinary shares to employees of the Company under the Company's stock options plan. The estimated fair value of the options on the date of grant is $1.2 million.