
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **May 15, 2018**

SteadyMed Ltd.

(Exact name of registrant as specified in its charter)

Israel
(State or other jurisdiction of
incorporation)

001-36889
(Commission File Number)

Not applicable
(IRS Employer
Identification No.)

**5 Oppenheimer Street
Rehovot 7670105, Israel**
(Address of principal executive offices, including zip code)

925-272-4999
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 15, 2018, SteadyMed Ltd issued a press release announcing its financial results for the quarter ended March 31, 2018. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated May 15, 2018

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 hereunto duly authorized.

STEADYMED LTD.

By: /s/ David Nassif
David W. Nassif
Chief Financial Officer

Date: May 15, 2018

SteadyMed Provides Corporate Update and Reports First Quarter 2018 Financial Results

SAN RAMON, Calif., May 15, 2018 — SteadyMed Ltd. (Nasdaq: STDY), a specialty pharmaceutical company focused on the development of drug product candidates to treat orphan and high-value diseases with unmet parenteral delivery needs, today provided a corporate update and announced its financial results for the first quarter ended March 31, 2018.

Summary Corporate Update:

- On April 29, 2018, SteadyMed and United Therapeutics Corporation (NASDAQ: UTHR) entered into a definitive merger agreement under which United Therapeutics will acquire SteadyMed for \$4.46 per share in cash at closing and an additional \$2.63 per share in cash upon the achievement of a milestone related to the commercialization of Trevyent[®]. The transaction, including the \$75 million in contingent consideration, is valued at \$216 million.
- The validation and verification work on our lead drug product candidate Trevyent[®], that is in development for the treatment of Pulmonary Arterial Hypertension (PAH), is ongoing and the Trevyent NDA remains on track for resubmission before the end of 2018.
- In March 2018, SteadyMed received a notice of allowance for U.S. Patent Application No. 14/456,416. The patent covers our PatchPump Drug Delivery Device broadly, including its ECell displacement generating battery and prefilled drug reservoir.

“We are pleased that our progress towards NDA re-submission for Trevyent is on track for later this year,” said Jonathan Rigby, President and Chief Executive Officer of SteadyMed. “In addition, we believe that the proposed merger with United Therapeutics will help us realize our commitment to bring Trevyent to market to improve the lives of patients with PAH.”

First Quarter 2018 Financial Results Compared to First Quarter 2017 Financial Results

SteadyMed recorded licensing revenues of \$0 in the first quarter of 2018, compared to revenues of \$315,000 in the first quarter of 2017. In the fourth quarter 2017, SteadyMed completed the recognition of revenue associated with the \$3 million upfront payment received from Cardiome in 2015.

For the first quarter ended March 31, 2018, SteadyMed reported a net loss of \$10.4 million, or \$0.39 per share, compared to a net loss of \$18.6 million, or \$0.92 per share for the first quarter ended March 31, 2017. The current quarter’s calculation of loss per share is based on 26,572,719 weighted-average shares outstanding versus 20,139,826 shares outstanding in the prior-year period.

Total operating expenses for the first quarter ended March 31, 2018 were \$6.1 million, compared to \$6.0 million for the quarter ended March 31, 2017. The increase in operating expenses was primarily attributable to an increase in general and administrative (G&A) expenses offset by decreases in research and development (R&D) expenses and sales and marketing (S&M) expenses.

R&D expenses for the first quarter of 2018 were \$3.9 million, compared to \$4.1 million for the first quarter of 2017. The decrease in R&D expenses was primarily due to a decrease in use of sub-contractor services and materials for Trevyent and our other development programs.

G&A expenses for the first quarter of 2018 were \$2.0 million, compared to \$1.3 million for the first quarter of 2017. The increase in G&A expenses was primarily due to an increase in legal expenses related to the recently-announced merger agreement with United Therapeutics.

S&M expenses for the first quarter of 2018 were \$0.1 million compared to \$0.6 million for the first quarter of 2017. The decrease in S&M was primarily due to decreases in consulting fees and salary expenses associated with the scaling back of the pre-commercialization plan for Trevyent in response to the refusal to file letter from the FDA for the Trevyent NDA.

In the first quarter of 2018, the Company recorded \$4.2 million in financial expense primarily as a result of the change in the fair value of the warrants issued in the April 2017 and August 2016 private placements compared to \$12.7 million in financial expense for the first quarter of 2017 primarily as a result of the change in the fair value of the warrants issued in the August 2016 private placement.

As of March 31, 2018, SteadyMed had cash and cash equivalents of \$26.6 million.

About SteadyMed

SteadyMed Ltd. is a specialty pharmaceutical company focused on the development of drug products to treat orphan and high value diseases with unmet parenteral delivery needs. The company's lead drug product candidate is Trevyent[®], a development stage drug product that combines SteadyMed's PatchPump[®] technology with treprostinil, a vasodilatory prostacyclin analogue to treat pulmonary arterial hypertension (PAH). SteadyMed intends to commercialize Trevyent in the U.S. and has signed an exclusive license and supply agreement with Cardiome Pharma Corp. for the commercialization of Trevyent in Europe, Canada and the Middle East. SteadyMed has offices in San Ramon, California and Rehovot, Israel. For additional information about SteadyMed please visit www.steadymed.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements about the company's ability to advance its development-stage product candidates, including Trevyent, statements about the potential benefits of our development-stage product candidates and our PatchPump technology, statements about the potential benefits of orphan drug designation, and statements about our ability to obtain and maintain regulatory approval of our development-stage product candidates. Forward-looking statements reflect the company's current views with respect to certain current and future events and are subject to various risks, uncertainties and assumptions that could cause actual results to differ materially. Risks and uncertainties include, but are not limited to, the risk that Trevyent does not demonstrate clinical superiority to existing parenteral treprostinil products, that Trevyent is not approved for commercialization by the FDA, that Trevyent is not granted orphan drug exclusivity, and the risk that drug development involves a lengthy and expensive process with uncertain outcome. The risks, uncertainties and assumptions referred to above are discussed in detail in our reports filed with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q filed on May 15, 2018.

The company does not undertake to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date hereof except as may be required by law.

Contacts:

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars in thousands (except share data)

	Three months ended	
	March 31,	
	2018	2017
	<u>Unaudited</u>	
Licensing Revenues	\$ 0	\$ 315
Operating expenses:		
Research and development	\$ 3,921	\$ 4,101
Sales and marketing	136	588
General and administrative	2,023	1,316
Total operating expenses	<u>6,080</u>	<u>6,005</u>
Total operating loss	6,080	5,690
Financial expense, net	4,159	12,721
Loss before taxes on income	10,239	18,411
Taxes on income	116	148
Net loss	<u>\$ 10,355</u>	<u>\$ 18,559</u>
Net loss per share:		
Basic and diluted net loss per Ordinary Share	<u>\$ 0.39</u>	<u>\$ 0.92</u>
Weighted average number of Ordinary Shares used in computing basic and diluted net loss per share	<u>26,572,719</u>	<u>20,139,826</u>

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	<u>March 31,</u> <u>2017</u> <u>Unaudited</u>	<u>December 31,</u> <u>2017</u>
Assets:		
Cash and cash equivalents	\$ 26,639	\$ 32,453
Property and equipment, net	5,798	5,307
Other assets	<u>728</u>	<u>731</u>
Total assets	<u>\$ 33,165</u>	<u>\$ 38,491</u>
Liabilities and shareholders' equity (deficit):		
Current liabilities	3,190	2,756
Liability related to warrants	15,544	11,343
Other non-current liabilities	596	581
Shareholders' equity	<u>13,835</u>	<u>23,811</u>
Total liabilities and shareholders' equity	<u>\$ 33,165</u>	<u>\$ 38,491</u>
