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): **March 30, 2018 (March 30, 2018)**

SteadyMed Ltd.

(Exact name of registrant as specified in its charter)

Israel	**001-36889**	**Not applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 March 30, 2018, SteadyMed Ltd (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2017. 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 March 30, 2018

EXHIBIT INDEX

Exhibit Number	Exhibit Description
99.1	Press Release, dated March 30, 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: March 30, 2018

Exhibit 99.1

SteadyMed Provides Corporate Update and Reports Fourth Quarter and Full Year 2017 Financial Results

Company on Track for Trevyent™ NDA Resubmission

SAN RAMON, Calif., March 30, 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 fourth quarter and full year ended December 31, 2017.

Summary Q4 2017 and Recent Corporate Update:

- In November 2017, SteadyMed held an in-person Type A meeting with the Food and Drug Administration (FDA) regarding the necessary steps leading to a re-submission of its New Drug Application (NDA) for its lead drug candidate Trevyent that is in development for the treatment of Pulmonary Arterial Hypertension (PAH). The Company believes the meeting was collaborative and constructive and has agreed to a path forward with FDA that it expects will allow for the resubmission and acceptance of its Trevyent NDA before the end of 2018.

- In November 2017, the U.S. Court of Appeals affirmed the ruling by the Patent Trial and Appeal Board of the USPTO invalidating U.S. Patent No. 8,497,393 (the '393 patent) owned by United Therapeutics. The '393 patent related to a product made by a process to purify prostacyclin derivatives, such as treprostinil, the active pharmaceutical ingredient used in United Therapeutics' Remodulin® and SteadyMed's lead drug candidate Trevyent.

- In October, 2017, SteadyMed received a notice of allowance for its European patent application No. 13720085.3 relating to enhanced reduction of infusion-site pain for drug delivery devices.

- In March, 2018, the 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.

"I am pleased that we ended 2017 with clarity from the FDA on the steps necessary for re-submission of our Trevyent NDA. The pre-design verification (pre-DV) testing of our Trevyent product is progressing to plan and we remain on track to re-submit our NDA and, subject to review by FDA, have it accepted for filing by the end of 2018," said Jonathan Rigby, President and Chief Executive Officer of SteadyMed. "In addition, we ended 2017 with a cash balance of $32.5 million, bolstered by the proceeds of our successful April 2017 Private Placement and a warrant exercise by a large institutional shareholder. Overall, we believe that we are well positioned to execute on our primary strategic and operational objectives in 2018, and look forward to sharing updates of our progress with our shareholders."

Fourth Quarter 2017 Financial Results Compared to Fourth Quarter 2016 Financial Results

SteadyMed recorded licensing revenues of $109,000 in the fourth quarter of 2017, compared to revenues of $320,000 in the fourth quarter of 2016. The recorded revenues were attributable to the recognition of revenue from the $3 million upfront payment received from Cardiome during 2015, in connection with the license of rights to Trevyent in Europe, the Middle East and Canada. During the fourth quarter of 2017, SteadyMed completed its obligations to provide services associated with the $3 million upfront payment and completed the recognition of revenue associated with the payment.

For the fourth quarter ended December 31, 2017, SteadyMed reported a net loss of $5.9 million, or $0.22 per share, compared to a net loss of $2.4 million, or $0.12 per share for the fourth quarter ended December 31, 2016. The loss for the fourth quarter of 2016 would have been greater than the current period loss but for financial income of $4.1 million from the revaluation of warrants. The current quarter's calculation of loss per share is based on 26,599,494 weighted-average shares outstanding, versus 20,139,826 outstanding shares in the prior-year period.

Total operating expenses for the fourth quarter ended December 31, 2017 were $5.0 million, compared to $6.7 million for the quarter ended December 31, 2016. Research and development (R&D), general and administrative (G&A), and sales and marketing (S&M) expenses decreased during the quarter primarily resulting from cash conservation measures instituted by the Company in response to receiving the Refuse to File letter from the FDA at the end of August.

R&D expenses for the fourth quarter of 2017 were $3.2 million, compared to $4.6 million for the fourth quarter of 2016. The decrease in R&D expenses was primarily due to a decreased use of sub-contractor services and materials for Trevyent and our other development programs offset by an increase in depreciation and impairment of property and equipment.

G&A expenses for the fourth quarter of 2017 were $1.3 million, compared to $1.5 million for the fourth quarter of 2016. The decrease in G&A expenses was primarily due to a decrease in legal and intellectual property expenses partiallyoffset by an increase in personnel related costs.

S&M expenses for the fourth quarter of 2017 were $0.4 million compared to $0.7 million for the fourth quarter of 2016. The decrease in S&M was primarily due to a decrease in consulting fees related to pre- commercialization of Trevyent offset by an increase in personnel related costs.

In the fourth quarter of 2017, the Company recorded $1.0 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 $4.0 million in financial income for the fourth quarter of 2016 primarily as a result of the change in the fair value of the warrants issued in the August 2016 private placement.

Year Ended December 31, 2017 Financial Results Compared to Year Ended December 31, 2016 Financial Results

For the year ended December 31, 2017, SteadyMed recorded licensing revenues of $1,065,000, same as the year ended December 31, 2016. The recorded revenues were attributable to the recognition of revenue from the $3 million upfront payment received from Cardiome during 2015, as discussed above.

For the year ended December 31, 2017, SteadyMed reported a net loss of $23.2 million, or $0.95 per share, compared to a net loss of $25.9 million, or $1.59 per share for the year ended December 31, 2016. The current year's calculation of loss per share is based on 24,421,288 weighted-average shares outstanding, versus 16,253,975 outstanding shares in the prior-year period.

Total operating expenses for the year ended December 31, 2017 were $21.5 million, compared to $28.5 million for the year ended December 31, 2016. While all operating expense categories decreased in the current year period, R&D led the decrease resulting from activities and projects in the department winding down as the Company prepared and filed the Trevyent NDA with the FDA in June.

R&D expenses for the year ended December 31, 2017 were $14.6 million, compared to $20.9 million for the year ended December 31, 2016. The decrease in R&D expenses was primarily due to decreases in use of sub-contractor services and materials for Trevyent and travel offset by increases in personnel related costs and depreciation and impairment of property and equipment.

G&A expenses for the year ended December 31, 2017 were $5.2 million, compared to $5.6 million for the year ended December 31, 2016. The decrease in G&A expenses was primarily due to decreases in legal and intellectual property expenses and other G&A consultants.

S&M expenses for the year ended December 31, 2017 were $1.7 million compared to $1.9 million for the year ended December 31, 2016. The decrease in S&M was primarily due to a decrease in consulting fees related to pre-commercialization of Trevyent offset by an increase in personnel related costs.

For the year ended December 31, 2017, the Company recorded $2.8 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 and issuance costs allocated to those warrants. For the year ended December 31, 2016, the Company recorded $1.9 million in financial income primarily as a result of the change in the fair value of the warrants issued in the August 2016 private placement net of issuance costs allocated to those warrants.

As of December 31, 2017, SteadyMed had cash and cash equivalents of $32.5 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 and the Middle East. In March 2018, Cardiome sublicensed its' rights to sell Trevyent in Canada to Cipher Pharmaceuticals. 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 outcome of Inter Partes Review of U.S. Patent No. 8,497,393, 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 Annual Report on Form 10-K filed on March 30, 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.

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

	Year ended December 31,	
	2017	2016
Licensing Revenues	$ 1,065	$ 1,065
Operating expenses:		
Research and development	$ 14,605	$ 20,902
Marketing	1,741	1,921
General and administrative	5,154	5,640
Total operating expenses	21,500	28,463
Total operating loss	20,435	27,398
Financial expense (income), net	2,764	(1,901)
Loss before taxes on income	23,199	25,497
Taxes on income	6	372
Net loss	$ 23,205	$ 25,869
Net loss per share:		
Basic and diluted net loss per Ordinary Share	$ (0.95)	$ (1.59)
Weighted average number of Ordinary Shares used in computing basic and diluted net loss per share	24,421,288	16,253,975

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31,	
	2017	2016
Assets:		
Cash and cash equivalents	$ 32,453	$ 23,215
Property and equipment, net	5,307	4,549
Other assets	731	394
Total assets	$ 38,491	$ 28,158
Liabilities and shareholders' equity (deficit):		
Current liabilities	2,756	5,291
Deferred revenues	—	1,066
Liability related to warrants	11,343	7,078
Other non-current liabilities	581	412
Shareholders' equity (deficit)	23,811	14,311
Total liabilities and shareholders' equity (deficit)	$ 38,491	$ 28,158