**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 9, 2013**

# Sarepta Therapeutics, Inc.

**(Exact name of registrant as specified in its charter)**

| **Oregon** | **001-14895** | **93-0797222** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**215 First Street**
**Suite 7**
**Cambridge, MA 02142**
**(Address of principal executive offices, including zip code)**

**(857) 242-3700**
**(Registrant's telephone number, including area code)**

**(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 (see General Instruction A.2. below):

☐ 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))

**Item 2.02 Results of Operations and Financial Condition.**

*The information in this report furnished pursuant to Item 2.02, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 2.02 of this report.*

On May 9, 2013, Sarepta Therapeutics, Inc. (the "Company") announced via press release the Company's results for the three month period ended March 31, 2013. A copy of the Company's press release is attached hereto as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release dated May 9, 2013. |

**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.

**Sarepta Therapeutics, Inc.**

By: /s/ Sandesh Mahatme
Sandesh Mahatme
Senior Vice President, Chief Financial Officer

Date: May 9, 2013

## EXHIBIT INDEX

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press release dated May 9, 2013. |

**Exhibit 99.1**

Sarepta Investor Contact:
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Sarepta Media Contact:
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**Sarepta Therapeutics Announces First Quarter 2013 Financial Results and Recent Corporate Developments**

***Documents Requested by FDA for Accelerated Approval Consideration of Eteplirsen Will Be Submitted This Month***

***Clinical, Regulatory, and Manufacturing Activities Continue to Progress for Eteplirsen and Additional Duchenne Muscular Dystrophy Drug Candidates***

***Strong Cash Balance of $175 Million at Quarter-End***

**CAMBRIDGE, MA, May 9, 2013 —** Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a developer of innovative RNA-based therapeutics, today reported financial results for the three months ended March 31, 2013, and provided an update of recent corporate developments.

"We are encouraged by our initial interactions with the U.S. Food and Drug Administration regarding a potential accelerated approval regulatory path for eteplirsen for the treatment of Duchenne muscular dystrophy, and we are finalizing a response to the FDA's request for more data to help us determine the feasibility of this pathway," said Chris Garabedian, president and chief executive officer of Sarepta Therapeutics. "In parallel, we continue to advance the clinical, regulatory, and manufacturing activities for eteplirsen and our additional DMD product candidates to build a successful franchise in this important disease area."

**Financial Results**

For the first quarter of 2013, Sarepta reported a Non-GAAP operating loss of $13.3 million, compared to a Non-GAAP operating loss of $6.1 million for the first quarter of 2012. The incremental loss is primarily the result of a $6.7 million decrease in government contract revenues as well as a $0.5 million increase in operating expenses.

On a GAAP basis, the operating loss for the first quarter of 2013 was $15.4 million (including $2.1 million of stock-based employee compensation expense and restructuring expense), compared with an operating loss of $6.9 million for the first quarter of 2012 (including $0.8 million of stock-based employee compensation expense and restructuring expense). The incremental loss is the result of a $6.7 million decrease in government contract revenues and a $1.8 million increase in operating expenses.

Revenue for the first quarter of 2013 was $4.5 million, down from $11.2 million for the first quarter of 2012. The $6.7 million decrease was due to the August 2012 stop-work-order and subsequent termination for convenience of the Ebola portion of the Ebola-Marburg U.S. government contract due to a lack of available U.S. government funding. The Ebola termination did not impact the Marburg portion of the contract. Revenues from the Marburg portion of the contract also decreased during the first quarter of 2013 due to the timing of activities throughout the normal progression of the contract. These decreases were partially offset by revenue from the intramuscular administration (IM) contract with the U.S. government for the Marburg virus that started in August 2012.

Non-GAAP research and development expenses were $13.0 million for the first quarter of 2013, compared to $14.5 million for the first quarter of 2012, a decrease of $1.5 million. GAAP research and development expenses were $13.8 million for the first quarter of 2013 (including $0.8 million of stock-based employee compensation expense and restructuring expense), compared to $14.8 million for the first quarter of 2012 (including $0.3 million of stock-based employee compensation expense and restructuring expense), a decrease of $1.0 million.

Non-GAAP general and administrative expenses were $4.8 million for the first quarter of 2013, compared to $2.8 million for the first quarter of 2012, an increase of $2.0 million. GAAP general and administrative expenses were $6.1 million for the first quarter of 2013 (including $1.3 million of stock-based employee compensation expense and restructuring expense), compared to $3.3 million for the first quarter of 2012 (including $0.5 million of stock-based employee compensation expense and restructuring expense), an increase of $2.8 million.

The increased operating expenses were primarily caused by corporate growth as the Company continues the development of its programs in Duchenne muscular dystrophy and infectious diseases.

The Non-GAAP net loss for the first quarter of 2013 was $13.0 million, or $0.41 per share, compared to a net loss from the first quarter of 2012 of $6.0 million, or $0.27 per share. On a GAAP basis, the net loss for the first quarter of 2013 was $42.1 million, or $1.32 per share, compared to a net loss from the first quarter of 2012 of $17.7 million, or $0.78 per share.

Sarepta had cash, cash equivalents and invested cash of $175.2 million as of March 31, 2013 compared to $187.7 million as of December 31, 2012, a decrease of $12.5 million. The cash was used to fund our ongoing operations in the first quarter of 2013.

In connection with prior equity financings, Sarepta issued warrants that are classified as current liabilities and are adjusted to fair value on a quarterly basis with the change in fair value being included in net loss. The amount included in net loss is a non-cash item as Sarepta is not required to expend any cash to settle the warrant liability. The warrant liability is primarily affected by changes in Sarepta's stock price. In the first quarter of 2013, the appreciation in Sarepta's stock price caused the warrant valuation to increase, which resulted in other expense of $26.9 million. In the first quarter of 2012, an increase in Sarepta's stock price resulted in other expense of $10.9 million. The warrant revaluation charges as well as stock-based employee compensation expense and restructuring costs related to our corporate move to Cambridge, are excluded from our Non-GAAP results.

Adjusted or Non-GAAP financial measures provide investors and management with supplemental measures of operating performance and trends that facilitate comparisons between the periods before, during and after certain expenses occur that would not otherwise be apparent on a GAAP basis because certain charges do not affect the Company's basic operations and also do not meet GAAP definitions.

**Recent Corporate Developments**

*Duchenne Muscular Dystrophy (DMD) Program*

- Announced updated data from Study 202, an ongoing Phase IIb open-label extension study of eteplirsen in patients with Duchenne muscular dystrophy (DMD). Results at 74 weeks showed a continued stabilization of walking ability in eteplirsen-treated patients evaluable on the 6-minute walk test (6MWT). As previously reported, Study 202 met its primary endpoint of increased novel dystrophin as assessed by muscle biopsy at week 48 and is now in the long-term extension phase in which patients continue to be followed for safety and clinical outcomes.
- Announced the Company and the University of Western Australia (UWA) entered into an exclusive, worldwide licensing agreement for intellectual property rights to potential exon-skipping drug candidates for the treatment of Duchenne muscular dystrophy (DMD). The agreement enables the Company to develop its exon-skipping pipeline with new candidates based on its proprietary phosphorodiamidate morpholino oligomer (PMO) technology to address the majority of patients with the disorder worldwide. The deal expands an agreement first signed in 2008, which supported the development of several exon-skipping drugs including eteplirsen, Sarepta's lead clinical candidate for the treatment of patients with DMD who have a genotype amenable to skipping of exon 51.
- Provided an update on discussions with the U.S. Food and Drug Administration (FDA) regarding a potential application for accelerated approval of eteplirsen for the treatment of DMD. The FDA requested that Sarepta provide additional information from the existing eteplirsen dataset to inform a decision on the acceptability of this dataset for a New Drug Application (NDA) filing under the Subpart H Accelerated Approval regulatory pathway. This feedback was provided in meeting minutes from an End-of-Phase II meeting with Sarepta and the FDA's Division of Neurology Products that occurred in the first quarter.

*Infectious Disease Programs*

- Announced that the first patient was dosed in the Phase I study with AVI-7100, the Company's lead drug candidate with a novel mechanism of action and potentially broad-spectrum activity against influenza viruses, including Tamiflu-resistant virus strains. The Company entered into a Clinical Trial Agreement (CTA) with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). This CTA builds upon the development of AVI-7100 that was previously supported under a contract with the U.S. Department of Defense which enabled preclinical development through completion of the first cohort of a Phase I single ascending dose (SAD) clinical trial to provide initial human safety data.
- Announced that the Company has initiated dosing in a Phase 1 multiple ascending dose (MAD) trial of AVI-7288, the Company's lead drug candidate for the treatment of Marburg virus infection. The Phase I MAD study is designed to characterize the safety,

tolerability and pharmacokinetics of AVI-7288 after repeat dosing in healthy adult volunteers. The initiation of this study follows the successfully completed Phase 1 single ascending dose study, which showed AVI-7288 was well tolerated in healthy volunteers. Sarepta is developing AVI-7288 under a contract from the U.S. Department of Defense through the Joint Project Manager Transformational Medical Technologies (JPM-TMT) Project Management Office. AVI-7288 utilizes Sarepta's advanced and proprietary PMO*plus*® chemistry.

**Conference Call and Slides**

Sarepta Therapeutics will hold a financial results and corporate update conference call today at 8:00 a.m., Eastern Time (5:00 a.m. Pacific Time). The conference call may be accessed by dialing 800.446.2782 for domestic callers and 847.413.3235 for international callers. The passcode for the call is 34783365. Please specify to the operator that you would like to join the "Sarepta First Quarter 2013 Earnings Call." The conference call and slides will be webcast live under the investor relations section of Sarepta's website at www.sareptatherapeutics.com and will be archived there following the call for 90 days. Please connect to Sarepta's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. An audio replay will be available through May 23, 2013 by calling 888.843.7419 or 630.652.3042 and entering access code 34783365.

**About Sarepta Therapeutics**

Sarepta Therapeutics is focused on developing first-in-class RNA-based therapeutics to improve and save the lives of people affected by serious and life-threatening rare and infectious diseases. Sarepta's diverse pipeline includes its lead program eteplirsen, for Duchenne muscular dystrophy, as well as potential treatments for some of the world's most lethal infectious diseases. Sarepta aims to build a leading, independent biotech company dedicated to translating its RNA-based science into transformational therapeutics for patients who face significant unmet medical needs. For more information, please visit us at www.sareptatherapeutics.com.

***Forward-Looking Statements and Information***

*In order to provide Sarepta's investors with an understanding of its current results and future prospects, this press release contains statements that are forward-looking. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements*

*include statements about the safety, efficacy, development and potential of Sarepta's product candidates, the potential and timing for regulatory submissions and meetings, the potential and timing for regulatory filings, review and approval of Sarepta's product candidates (including under Subpart H Accelerated Approval), Sarepta's ability to establish and protect intellectual property rights, Sarepta's timing and ability to manufacture product candidates and Sarepta's estimates regarding its future revenue, operating loss, cash reserves and expenses and expectations regarding future success and funding from government and other sources.*

*These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: clinical trials may not demonstrate safety and efficacy of any of Sarepta's drug candidates and/or Sarepta's antisense-based technology platform; development of any of Sarepta's drug candidates may not result in funding from the U.S. government in the anticipated amounts or on a timely basis, if at all; scale-up of manufacturing may not be successful and any of Sarepta's drug candidates may fail in development, may not receive required regulatory approvals (including Subpart H accelerated approval), or be delayed to a point where they do not become commercially viable; Sarepta may need additional funds to conduct research and development efforts; and those risks identified under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012, and filed with the Securities and Exchange Commission, as well as the other information we file with the SEC.*

*Any of the foregoing risks could materially and adversely affect Sarepta's business, results of operations and the trading price of Sarepta's common stock. For a detailed description of risks and uncertainties Sarepta faces, you are encouraged to review the official corporate documents filed with the Securities and Exchange Commission. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.*

**Sarepta Therapeutics, Inc.**
(A Development-Stage Company)
(in thousands, except per share amounts)
(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Revenues from grants and research contracts | $ 4,474 | $ 11,212 |
| Operating expenses: | | |
| Research and development | 13,762 | 14,805 |
| General and administrative | 6,127 | 3,281 |
| Operating loss | (15,415) | (6,874) |
| Other non-operating income (loss): | | |
| Interest income and other, net | 237 | 96 |
| Loss on change in warrant liability | (26,906) | (10,926) |
| Net loss | $ (42,084) | $ (17,704) |
| Net loss per share – basic and diluted* | $ (1.32) | $ (0.78) |
| Shares used in per share calculations – basic and diluted* | 31,813 | 22,624 |

* All net loss per share and shares used in per share calculations have been adjusted to reflect a one for six reverse stock-split that was approved by the shareholders and the Board of Directors and effected in July 2012.

**Sarepta Therapeutics, Inc.**
(A Development-Stage Company)
Reconciliation of GAAP to Non-GAAP Net Loss
(in thousands, except per share amounts)
(unaudited)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2013 | 2012 |
| Net loss – GAAP | $ (42,084) | $(17,704) |
| Research and development: | | |
| Stock-based compensation expense | 530 | 253 |
| Restructuring expense | 264 | 16 |
| Total Research and development Non-GAAP adjustments | 794 | 269 |
| General and administrative: | | |
| Stock-based compensation expense | 1,141 | 455 |
| Restructuring expense | 198 | 37 |
| Total General and administrative Non-GAAP adjustments | 1,339 | 492 |
| Other non-operating income (loss): | | |
| Loss on change in warrant liability | 26,906 | 10,926 |
| Net loss – Non-GAAP[1] | $ (13,045) | $ (6,017) |
| Net loss per share – basic and diluted* | $ (0.41) | $ (0.27) |
| Shares used in per share calculations – basic and diluted* | 31,813 | 22,624 |

[1] Non-GAAP operating loss differs from Non-GAAP net loss due to $237,000 and $96,000 of net interest income for March 31, 2013 and March 31, 2012, respectively.

***BALANCE SHEET HIGHLIGHTS***
(in thousands)

| | March 31, 2013 | December 31, 2012 |
|---|---|---|
| Cash, cash equivalents and investments | $175,169 | $187,661 |
| Total assets | 193,340 | 204,993 |
| Total liabilities | 106,059 | 81,314 |
| Total shareholders' equity | $ 87,281 | $ 123,679 |

# # #