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): November 12, 2013

Sarepta Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**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.

On November 12, 2013, Sarepta Therapeutics, Inc. (the "Company") announced via press release the Company's results for the three and nine months ended September 30, 2013. A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On November 12, 2013, the Company announced via press release updates relating to its most recent meeting with the U.S. Food and Drug Administration. A copy of the Company's press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

The information in this report is furnished pursuant to Item 2.02 and Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, and 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. This information 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 and Item 7.01of this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Earnings press release dated November 12, 2013.
99.2	Regulatory update press release dated November 12, 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 and Chief Accounting Officer

Date: November 12, 2013

EXHIBIT INDEX

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99.1	Earnings press release dated November 12, 2013.
99.2	Regulatory update press release dated November 12, 2013.

Exhibit 99.1

Sarepta Investor Contact:
Erin Cox
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Sarepta Media Contact:
Jim Baker
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Sarepta Therapeutics Announces Third Quarter
2013 Financial Results and Recent Corporate Developments

Ongoing discussions with FDA remain a priority to advance eteplirsen program in Duchenne muscular dystrophy;

Updated guidance lowers full-year operating loss to $80-90 million range;

Strong financial position with approximately $281 million in cash and other investments at quarter end

CAMBRIDGE, MA, November 12, 2013 – Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a developer of innovative RNA-based therapeutics, today reported financial results for the three and nine months ended September 30, 2013, and provided an update of recent corporate developments.

"We look forward to continuing to work with the FDA to keep the eteplirsen program moving forward," said Chris Garabedian, president and chief executive officer of Sarepta. "Our cash position is strong as we continue to scale up manufacturing and advance our follow-on DMD drug candidates toward clinical development."

Financial Results

For the third quarter of 2013, Sarepta reported a non-GAAP net loss of $21.3 million, or $0.63 per share, compared to a non-GAAP net loss of $6.1 million for the third quarter of 2012, or $0.27 per share. The incremental loss is primarily the result of a $3.4 million decrease in contract revenues as well as an $11.8 million increase in non-GAAP operating expenses, excluding the effects of stock-based compensation and restructuring expenses.

On a GAAP basis, the net loss for the third quarter of 2013 was $42.0 million, or $1.24 per share (including $3.5 million of stock-based compensation expense and restructuring expense), compared with a net loss of $49.6 million for the third quarter of 2012, or $2.17 per share (including $0.7 million of stock-based compensation expense). The decrease in net loss is the result of a $25.6 million decrease in expense incurred due to the change in valuation of our outstanding warrants offset by a $3.4 million decrease in contract revenues and a $14.6 million increase in operating expenses.

Revenue for the third quarter of 2013 was $4.2 million, down from $7.6 million for the third quarter of 2012. The $3.4 million decrease was primarily 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 termination of the Ebola portion did not impact the Marburg portion of the contract. Revenues from the Marburg portion of the contract also decreased during the third 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 and two other research agreements.

Non-GAAP research and development expenses were $19.9 million for the third quarter of 2013, compared to $10.6 million for the third quarter of 2012, an increase of $9.3 million. GAAP research and development expenses were $21.1 million for the third quarter of 2013 (including $1.2 million of stock-based compensation expense and restructuring expense), compared to $10.9 million for the third quarter of 2012 (including $0.3 million of stock-based compensation expense), an increase of $10.2 million.

Non-GAAP general and administrative expenses were $5.7 million for the third quarter of 2013, compared to $3.1 million for the third quarter of 2012, an increase of $2.6 million. GAAP general and administrative expenses were $8.0 million for the third quarter of 2013 (including $2.3 million of stock-based compensation expense), compared to $3.6 million for the third quarter of 2012 (including $0.4 million of stock-based compensation expense), an increase of $4.4 million.

The increased operating expenses were primarily caused by corporate growth as the Company continues the development of its programs in Duchenne Muscular Dystrophy (DMD).

The company had cash, cash equivalents and restricted investments related to our letters of credit of $281.4 million as of September 30, 2013 compared to $187.7 million

as of December 31, 2012, an increase of $93.7 million. The increase in cash and cash equivalents was primarily due to $125 million in proceeds from the issuance of approximately 3.4 million shares of common stock under the At-the-Market (ATM) equity financing that was put in place in July 2013 and $18.9 million in proceeds from the exercise of warrants and stock options, offset by cash used to fund our ongoing operations.

The warrant liability is primarily affected by changes in the company's stock price. In the third quarter of 2013, the appreciation in the company's stock price caused the warrant valuation to increase, which resulted in a non-cash warrant valuation expense of $17.2 million. In the third quarter of 2012, the company's stock price increase resulted in a non-cash warrant valuation expense of $42.7 million. All remaining warrants outstanding at September 30, 2013, if not exercised, will expire no later than August of 2014.

In addition to the GAAP financial measures set forth in this press release, the Company has included certain non-GAAP measurements: non-GAAP research and development expenses, non-GAAP general and administrative expenses, non-GAAP operating expenses, non-GAAP net loss, and non-GAAP basic and diluted net loss per share, which present operating results on a basis adjusted for certain items. The Company uses these non-GAAP measures as key performance measures for the purpose of evaluating performance internally. The Company also believes these non-GAAP measures provide the Company's investors with useful information regarding the Company's historical operating results. These non-GAAP measures are not intended to replace the presentation of the Company's financial results in accordance with GAAP. Use of the terms non-GAAP research and development expenses, non-GAAP general and administrative expenses, non-GAAP operating expenses, non-GAAP net loss, and non-GAAP basic and diluted net loss per share may differ from similar measures reported by other companies. All relevant non-GAAP measures are reconciled from their respective GAAP measures in the attached table "Reconciliation of GAAP to non-GAAP net loss."

Recent Corporate Developments

Duchenne Muscular Dystrophy Program

- Announced data through Week 96 from the Phase IIb open-label extension study of eteplirsen in patients with DMD. Results through nearly two years showed a continued stabilization of walking ability in eteplirsen-treated patients evaluable on the 6-minute walk test (6MWT). Eteplirsen was well tolerated and there were no reported clinically significant treatment-related adverse events, no treatment-related serious adverse events, hospitalizations or discontinuations through 96 weeks. These data were presented at the 18th International Congress of the World Muscle Society on October 3.

- Announced a new nationwide program from Parent Project Muscular Dystrophy (PPMD) to assist individuals with DMD in accessing genetic testing. Through the new program, called Decode Duchenne, PPMD will offer genetic testing at no cost to eligible patients who are unable to access testing due to barriers such as a lack of or insufficient insurance coverage. Sarepta will provide support for the initiative.
- Announced Let's Skip Ahead, a new online resource center for families affected by DMD and their healthcare providers. The new website, available at www.skipahead.com, provides information and educational resources about exon skipping and upcoming Sarepta clinical trials.

Conference Call

The conference call may be accessed by dialing 888.895.5271 for domestic callers and 847.619.6547 for international callers. The passcode for the call is 35957586. Please specify to the operator that you would like to join the "Sarepta Third Quarter Earnings Call." The conference call will be webcast live under the investor relations section of Sarepta's website at www.sarepta.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 November 26, 2013 by calling 888.843.7419 or 630.652.3042 and entering access code 35957586.

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.sarepta.com.

Forward-Looking Statements and Information

This press release contains forward-looking statements. These forward-looking statements generally can be identified by use of words such as "believes or belief," "anticipates," "plans," "expects," "will," "intends," "potential," "possible," "advance" and similar expressions. These forward-looking statements include statements about the development of eteplirsen and its efficacy, potency and utility as a potential treatment for DMD, the potential for the use of dystrophin to predict significant clinical benefit, the clinical significance of our 6mwt results to date, the timing of clinical studies and the timing and potential for regulatory submissions and meetings.

Each forward-looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others: subsequent clinical trials may fail to demonstrate the safety and efficacy of eteplirsen or replicate results; treatment of patients with DMD using eteplirsen may not lead to significant clinical benefit; any of Sarepta's drug candidates, including eteplirsen, may fail in development, may not receive required regulatory approvals (including Subpart H accelerated approval), or may not become commercially viable due to delays or other reasons; and those identified under the heading "Risk Factors" in Sarepta's Annual Report on Form 10-K for the full year ended December 31, 2012 and as updated by our 2013 third quarter 10-Q, and filed with the Securities and Exchange Commission (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 Company's filings with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. 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)
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2013	*2012*	*2013*	*2012*
Revenues from grants and research contracts	$ 4,168	$ 7,574	$ 11,593	$ 29,993
Operating expenses:				
Research and development	21,087	10,914	47,833	39,568
General and administrative	8,014	3,565	21,195	9,761
Operating loss	(24,933)	(6,905)	(57,435)	(19,336)
Other non-operating income (loss):				
Interest income and other, net	63	67	281	270
Loss on change in warrant valuation	(17,160)	(42,716)	(46,011)	(40,154)
Net loss	$(42,030)	$(49,554)	$(103,165)	$(59,220)
Net loss per share – basic and diluted	$ (1.24)	$ (2.17)	$ (3.17)	$ (2.61)
Shares used in per share calculations – basic and diluted	33,943	22,824	32,588	22,691

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 September 30,		*Nine Months Ended September 30,*	
	2013	*2012*	*2013*	*2012*
Net loss – GAAP	$(42,030)	$(49,554)	$(103,165)	$(59,220)
Research and development:				
Stock-based compensation expense	1,155	271	2,409	783
Restructuring expense	54	—	397	16
Total research and development non-GAAP adjustments[2]	1,209	271	2,806	799
General and administrative:				
Stock-based compensation expense	2,332	421	5,067	1,057
Restructuring expense	—	—	329	37
Total general and administrative non-GAAP adjustments[2]	2,332	421	5,396	1,094
Other non-operating loss:				
Loss on change in warrant valuation non-GAAP adjustment	17,160	42,716	46,011	40,154
Net loss – non-GAAP[1]	$(21,329)	$ (6,146)	$ (48,952)	$(17,173)
Non-GAAP net loss per share – basic and diluted	$ (0.63)	$ (0.27)	$ (1.50)	$ (0.76)
Shares used in per share calculations – basic and diluted	33,943	22,824	32,588	22,691

[1] Non-GAAP operating loss differs from non-GAAP net loss due to $63 and $67 of net interest income for the three months ended September 30, 2013 and September 30, 2012, respectively, and due to $281 and $270 of net interest income for the nine months ended September 30, 2013 and September 30, 2012, respectively (in thousands).

[2] Non-GAAP operating expense adjustments are comprised of total general and administrative non-GAAP adjustments plus total research and development non-GAAP adjustments. Total non-GAAP operating expense adjustments were $3,541 and $692 for the three months ended September 30, 2013 and 2012, respectively. Total non-GAAP operating expense adjustments were $8,202 and $1,893 for the nine months ended September 30, 2013 and 2012, respectively (in thousands).

Sarepta Therapeutics, Inc.
(A Development-Stage Company)
Balance Sheet Highlights
(in thousands)
(unaudited)

	September,30 2013	*December 31, 2012*
Cash and cash equivalents	$ 273,644	$ 187,661
Restricted investments	7,807	—
Total assets	304,479	204,993
Total liabilities	57,495	81,314
Total stockholders' equity	$ 246,984	$ 123,679

Exhibit 99.2

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Sarepta Therapeutics Announces FDA Considers NDA Filing for Eteplirsen Premature in Light of Recent Competitive Drug Failure and Recent DMD Natural History Data

FDA questions dystrophin as a biomarker due to failed studies of other investigational drugs for DMD;

FDA questions 6-minute walk test results for eteplirsen, suggesting study population should be stable over two-year timeframe due to recent natural history data;

FDA requests further discussion on endpoints, design of confirmatory clinical study

CAMBRIDGE, Mass. – November 12, 2013 – Sarepta Therapeutics, Inc. (NASDAQ: SRPT) today provided an update on its discussions with the U.S. Food and Drug Administration (FDA) regarding its planned New Drug Application (NDA) submission and confirmatory clinical study with eteplirsen for the treatment of Duchenne muscular dystrophy (DMD). Citing recent developments since Sarepta's last meeting with the agency, including a failed study with a competitive product and recent natural history data in DMD, the FDA indicated the new data raise "considerable doubt" about both the dystrophin biomarker and the supportive clinical efficacy assessed on the 6-minute walk test (6MWT) in the Phase IIb clinical study of eteplirsen. As a result of these recent data, the FDA stated that they "currently consider an NDA filing for eteplirsen as premature."

"We are very disappointed with the FDA's decision to reconsider their openness to a potential NDA filing based on our current data and the resultant impact this change may have on our efforts to achieve an earlier approval of eteplirsen," said Chris Garabedian, president and chief executive officer of Sarepta Therapeutics. "We strongly believe in the potential of eteplirsen to address a serious unmet medical need in DMD and we are committed to its development. Our team at Sarepta recognizes the urgency of families who are seeking new treatments, and we will continue to work with the FDA on an acceptable confirmatory study design and, in parallel, seek to address their concerns regarding a potential NDA filing based on our current dataset."

The FDA provided the feedback in pre-meeting comments and clarified them in a meeting with Sarepta that took place late last week to discuss the eteplirsen clinical program.

Excerpts from the FDA's pre-meeting comments on reconsidering an NDA filing included:

> *"Since our last meeting, a large phase 3 trial of drisapersen, a drug with a similar mechanism of action, was reported to be negative, despite increased expression of dystrophin. The disconnect between increased expression of dystrophin and clinical efficacy for drisapersen, combined with previous negative reports for PTC124, another drug thought to act by increasing dystrophin, raises considerable doubt about the biomarker, and consequentially, its ability to reasonably likely predict clinical benefit."*
>
> *"…the quantity of dystrophin that might be necessary to be considered reasonably likely to predict clinical benefit is even less clear; small or perhaps even moderate increases are seemingly not enough, at least in the subpopulation of boys studied so far. An adequately validated quantitative assay for dystrophin now seems a prerequisite to further consideration of the biomarker as supportive of approval. Since our last meeting, our concern about the shortcomings of your current quantification methods has grown."*
>
> *"Recent natural history data in DMD indicate that a baseline 6-Minute Walk Test (6MWT) □350 meters predicts continued general stability for such patients, not the 75- to 83-meter yearly decline you suggest in the meeting package. Thus, considerable doubt is also cast on the efficacy support provided by your ongoing open-label study (4658-us-202, 96-week data submitted), in which baseline 6MWT was >350 m for all patients."*
>
> *"…the expected variability of 6MWT values appears sufficient to explain differences between arms on which the post-hoc analysis was based. Because of this, together with our lack of confidence in the capacity of your dystrophin biomarker to predict clinical benefit, we currently consider an NDA filing for eteplirsen as premature."*

Additional excerpts from the FDA's pre-meeting comments on the eteplirsen confirmatory study design included:

> *"Recent trial failures in DMD suggest it may be productive to re-examine study enrollment criteria and endpoints."*

"…it seems worthwhile to consider selection of other endpoints and/or populations for the next trial of eteplirsen. We stress that we would still accept 6MWT in an appropriately powered study; however, because 6MWT excludes both younger boys who cannot perform such a demanding test, and older boys who are no longer ambulatory, we are concerned that seemingly avoidable limitations on enrollment could undermine study feasibility. Many possible combinations of endpoints and subpopulations appear possible. Motor scales that measure a broader range of function and demand less sustained effort than 6MWT could be appropriate for a much wider range of boys, perhaps including non-ambulatory boys. To allow inclusion of a broader range of patients, a study could also be designed that mathematically combined findings from, for example, an ambulation endpoint in less advanced patients with findings from an upper-limb or respiratory endpoint in more advanced patients. We remain open to consideration of endpoints and populations you may suggest."

"…we believe that a placebo-controlled trial would be the most likely method for developing interpretable evidence of efficacy for eteplirsen, because efficacy endpoints in DMD are effort-dependent and susceptible to bias, and the natural history is highly variable and has recently improved with steroid use and advances in ancillary care. We would like to discuss the perceived barriers to conducting such a trial with you."

The FDA's request to discuss different clinical endpoints, combined endpoints, and different DMD subpopulations for a confirmatory clinical study, along with their questions about dystrophin as a biomarker and the need for a placebo-controlled study, will delay the initiation of dosing in the eteplirsen confirmatory study until at least the second quarter of 2014. A follow up meeting with FDA has been scheduled to take place this month to discuss the confirmatory study design.

Conference Call Information

Sarepta will hold a conference call to discuss this update in addition to the Company's third quarter financial results today at 8:00 a.m. EDT (5:00 a.m. PDT). The conference call may be accessed by dialing 888.895.5271 for domestic callers and 847.619.6547 for international callers. The passcode for the call is 35957586. Please specify to the operator that you would like to join the "Sarepta Third Quarter Earnings Call." The conference call will be webcast live under the investor relations section of Sarepta's website at www.sarepta.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 November 26, 2013 by calling 888.843.7419 or 630.652.3042 and entering access code 35957586.

About Duchenne Muscular Dystrophy

DMD is an X-linked rare degenerative neuromuscular disorder causing severe progressive muscle loss and premature death. DMD affects approximately one in every 3,500 boys born worldwide. A devastating and incurable muscle-wasting disease, DMD is associated with specific errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. Progressive muscle weakness in the lower limbs spreads to the arms, neck and other areas. Eventually, increasing difficulty in breathing due to respiratory muscle dysfunction requires ventilation support, and cardiac dysfunction can lead to heart failure. The condition is universally fatal, and death usually occurs before the age of 30.

About Eteplirsen

Eteplirsen is Sarepta's lead drug candidate and is designed to address the underlying cause of DMD by enabling the production of a functional dystrophin protein. Data from clinical studies of eteplirsen in DMD patients have demonstrated a broadly favorable safety and tolerability profile and restoration of dystrophin protein expression.

Eteplirsen uses Sarepta's novel phosphorodiamidate morpholino oligomer (PMO)-based chemistry and proprietary exon-skipping technology to skip exon 51 of the dystrophin gene enabling the repair of specific genetic mutations that affect approximately 13 percent of the total DMD population. By skipping exon 51, eteplirsen may restore the gene's ability to make a shorter, but still functional, form of dystrophin from messenger RNA, or mRNA. Promoting the synthesis of a truncated dystrophin protein is intended to stabilize or significantly slow the disease process and prolong and improve the quality of life for patients with DMD.

Sarepta is also developing other PMO-based exon-skipping drug candidates intended to treat additional patients with DMD.

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. The Company'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.sarepta.com.

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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 Company’s filings with the SEC. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

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