Sarepta Therapeutics Announces Third Quarter 2013 Financial Results and Recent Corporate Developments

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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 -- (Marketwired) -- 11/12/13 -- 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 18^{th} 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

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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).

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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

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Source: Sarepta Therapeutics, Inc.