Sarepta Therapeutics Announces First Quarter 2016 Financial Results and Recent Corporate Developments

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 5, 2016-- Sarepta Therapeutics, Inc.(NASDAQ:SRPT), a developer of innovative RNA-targeted therapeutics, today reported financial results for the three months ended March 31, 2016, and provided an update of recent corporate developments.

“The Peripheral and Central Nervous System Advisory Committee met last week to review eteplirsen for the treatment of Duchenne muscular dystrophy amenable to exon 51 skipping, and we await our May 26 PDUFA date,” said Edward Kaye, M.D., Sarepta’s interim chief executive officer and chief medical officer. “Following the FDA’s decision, we plan to provide a clinical and corporate update.”

Financial Results

For the first quarter of 2016, Sarepta reported a non-GAAP net loss of $52.5 million, or $1.15 per share, compared to a non-GAAP net loss of $47.4 million for the first quarter of 2015, or $1.15 per share. The incremental loss of $5.1 million was primarily the result of increased operating expenses.

On a GAAP basis, the net loss for the first quarter of 2016 was $59.8 million, or $1.31 per share (including $7.2 million of stock-based compensation and restructuring expenses), compared to a net loss of $61.6 million, or $1.49 per share (including $14.2 million of stock-based compensation) for the first quarter of 2015.

No revenue was recognized for the three months ended in both March 31, 2016 and 2015.

Non-GAAP research and development expenses were $35.9 million for the first quarter of 2016, compared to $36.7 million for the first quarter of 2015, a decrease of $0.8 million. GAAP research and development expenses were $38.8 million for the first quarter of 2016 (including $3.0 million of stock-based compensation and restructuring expenses), compared to $39.2 million for the first quarter of 2015 (including $2.4 million of stock-based compensation), a decrease of $0.3 million.

Non-GAAP general and administrative expenses were $16.6 million for the first quarter of 2016, compared to $11.0 million for the first quarter of 2015, an increase of $5.6 million. GAAP general and administrative expenses were $20.9 million for the first quarter of 2016 (including $4.3 million of stock-based compensation and restructuring expenses), compared to $22.7 million for the first quarter of 2015 (including $11.7 million of stock-based compensation), a decrease of $1.8 million.

The Company had $140.6 million in cash, cash equivalents, short-term investments and restricted cash as of March 31, 2016 compared to $204.0 million as of December 31, 2015, a decrease of $63.4 million. The decrease was due to the use of cash to fund the Company's ongoing operations, commercial launch activities and related inventory build.

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 expense adjustments, 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 expense adjustments, 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

--Sarepta Issues Statement on Advisory Committee Meeting Outcome for Use of Eteplirsen in the Treatment for Duchenne Muscular Dystrophy Amenable to Exon 51 Skipping

--Sarepta Therapeutics Announces FDA Advisory Committee Meeting to Review Eteplirsen as a Treatment for Duchenne Muscular Dystrophy Amenable to Exon 51 Skipping

Corporate Updates

--Sarepta Therapeutics Announces Long Term Plan to Consolidate Facilities within Massachusetts

About Sarepta Therapeutics

Sarepta Therapeutics is a biopharmaceutical company focused on the discovery and development of unique RNA-targeted therapeutics for the treatment of rare, infectious and other diseases. The Company is primarily focused on rapidly advancing the development of its potentially disease-modifying DMD drug candidates, including its lead DMD product candidate, eteplirsen, designed to skip exon 51. Sarepta is also developing therapeutics for the treatment of rare, infectious and other diseases. For more information, please visit us at www.sarepta.com.

Forward-Looking Statements

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,” “may,” “intends,” “prepares,” “looks,” “potential,” “possible” and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements relating to Sarepta’s future operations, financial performance, business plans, priorities and development of product candidates including: Sarepta awaiting its PDUFA date of May 26, 2016 and plans to provide a clinical and corporate update following the FDA’s decision. These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: the FDA may not provide eteplirsen with marketing approval by the applicable PDUFA date or at all; we may not be able to comply with all FDA requests, including with respect to our eteplirsen NDA submission and the addendums we have submitted to the FDA or with respect to our ongoing or planned clinical trials, in a timely manner or at all; we may not be able to complete clinical trials required by the FDA for approval of our products or any submissions made in connection with our pipeline of product candidates; the results of our ongoing research and development efforts and clinical trials for our product candidates including eteplirsen and technologies may not be positive or consistent with prior results or demonstrate a safe treatment benefit or support an NDA filing, positive advisory committee recommendation or marketing approval by the FDA or other regulatory authority; we may not be able to execute on our business plans including meeting our expected or planned regulatory milestones and timelines, clinical development plans and bringing our product candidates to market, including the planned commercialization of eteplirsen, for various reasons including possible limitations of Company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner or at all, and regulatory, court or agency decisions, such as decisions by the United States Patent and Trademark Office with respect to patents that cover our product candidates; and those risks identified under the heading “Risk Factors” in Sarepta’s most recent Annual Report on Form 10-K for the year ended December 31, 2015 or Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by Sarepta which you are encouraged to review.

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.

Internet Posting of Information

We routinely post information that may be important to investors in the 'For Investors' section of our web site at www.sarepta.com. We encourage investors and potential investors to consult our website regularly for important information about us.

Sarepta Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2016	**2015**
Revenues from grants and research contracts	$ -	$ -
Operating expenses:		
Research and development	38,826	39,165
General and administrative	20,876	22,697
Operating loss	(59,702)	(61,862)
Other income (loss):		
Interest (expense) income and other, net	(68)	303
Net loss	$ (59,770)	$ (61,559)
Net loss per share - basic and diluted	$ (1.31)	$ (1.49)
Shares used in per share calculation basic and diluted	45,697	41,324

Sarepta Therapeutics, Inc.

Reconciliation of GAAP to Non-GAAP Net Loss

(in thousands, except per share amounts)

(unaudited)

	Three months ended March 31,	
	2016	**2015**
Net loss - GAAP	$ (59,770)	$ (61,559)
Research and development:		
Stock-based compensation expense	2,448	2,446
Restructuring Expense	502	-
Total research and development non-GAAP adjustments 1	2,950	2,446
General and administrative:		
Stock-based compensation expense	4,241	11,710
Restructuring Expense	31	-
Total general and administrative non-GAAP adjustments 1	4,272	11,710
Other non-operating loss:		
(Gain) loss on change in warrant valuation non-GAAP adjustment	-	-
Net loss - non-GAAP	$ (52,548)	$ (47,403)
Non-GAAP net loss per share - basic and diluted	$ (1.15)	$ (1.15)
Shares used in per share calculations - basic and diluted	45,697	41,324

[1] Non-GAAP operating expense adjustments are comprised of total general and administrative non-GAAP adjustments and total research and development non-GAAP adjustments. Total non-GAAP operating expense adjustments were $7,222 and $14,156 for the three months ended March 31, 2016 and 2015, respectively.

Sarepta Therapeutics, Inc.

Balance Sheet Highlights

(in thousands)

(unaudited)

	March 31, 2016	December 31, 2015
Cash, cash equivalents and short-term investments	$ 129,156	$ 192,491
Restricted investments	11,478	11,478
Total assets	213,364	273,782
Total liabilities	74,402	83,435
Total stockholders' equity	$ 138,962	$ 190,347

Source: Sarepta Therapeutics, Inc.

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