Sarepta Therapeutics Announces Fourth Quarter and Full-Year 2012 Financial Results and Recent Corporate Developments

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Upcoming Meetings With FDA Will Determine Fastest Path to Pursue Eteplirsen Approval; Additional Drugs for Duchenne Muscular Dystrophy (DMD) Continue to Progress Through Preclinical Development; 2013 Financial Guidance of $18-24 Million in Revenues; $85-115 Million in Operating Loss; Cash Balance of $187 Million at Year-End 2012

CAMBRIDGE, MA -- (MARKETWIRE) -- 03/07/13 -- Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a developer of innovative RNA-based therapeutics, today reported financial results for the three months and full year ended December 31, 2012, and provided an update of recent corporate developments.

"Last year was a transformational year for Sarepta as we achieved tremendous progress with our lead DMD product candidate, eteplirsen, which demonstrated safety and efficacy that highlights its potential to be a major advance in the treatment of this disease," said Chris Garabedian, president and chief executive officer of Sarepta Therapeutics. "We look forward to our upcoming meetings with the FDA to discuss our eteplirsen data and to determine the fastest path toward potential approval, along with our plans to supply the market in the event of an early approval."

Financial Results

For the fourth quarter of 2012, Sarepta reported an operating loss of $10.4 million, compared with an operating loss of $9.0 million in the fourth quarter of 2011. The incremental loss is the result of a $6.3 million decrease in government contract revenues offset by a $4.9 million decrease in operating expenses.

Revenue for the fourth quarter of 2012 was $7.3 million, down from the $13.6 million in the fourth quarter of 2011. The $6.3 million decrease was due to the August 2012 stop-work-order and subsequent termination 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 due to the timing of activities throughout the normal progression of the contract. These decreases were partially offset by revenue from the intramuscular administration contract with the U.S. government for the Marburg virus that started in August 2012.

Research and development expenses were $12.8 million in the fourth quarter of 2012, compared to $18.7 million in the fourth quarter of 2011, a decrease of $5.9 million. The decrease was primarily attributable to termination of the Ebola portion of the government contract, reduced spending on the Marburg portion of the government contract due to the timing of activities and reduced spending associated with DMD and other proprietary research. This decrease was partially offset by increased spending related to the intramuscular administration contract.

General and administrative expenses in the fourth quarter of 2012 were $4.9 million, compared to $3.9 million in the fourth quarter of 2011, an increase of $1.0 million. The increase was the result of additional personnel costs associated with key positions hired in the second half of 2012.

For the full year 2012, the operating loss was $29.7 million, compared to an operating loss of $35.9 million for the prior year. The $6.2 million improvement was the result of a $14.5 million decrease in research and development expenses and a $1.4 million decrease in general and administrative expenses partially offset by a $9.7 million decrease in revenue from government contracts.

Revenue for the full year 2012 decreased to $37.3 million from $47.0 million in 2011 primarily due to the Ebola stop-work-order, the termination of the Ebola portion of the Ebola Marburg contract in the second half of 2012 and the completion of the H1N1/influenza contract with the U.S. government in June 2011.

Research and development expenses were $52.4 million for 2012, compared to $66.9 million for the prior year, a $14.5 million decrease. The decrease was due primarily to reduced costs related to the Ebola portion of the Ebola Marburg government contract, the completion of the H1N1 contract in 2011 and a reduction in our overall non-DMD proprietary research.

General and administrative expenses for 2012 were $14.6 million, compared to $16.0 million for 2011, a decrease of $1.4 million. The decrease was primarily due to reduced professional service costs and severance costs compared to the prior year.

The net loss for the fourth quarter of 2012 was $62.1 million, or $2.36 per share, compared to a net loss for the fourth quarter of 2011 of $1.4 million, or $0.06 per share. The net loss for the full year 2012 was $121.3 million, or $5.14 per share, compared to a net loss in 2011 of $2.3 million, or $0.11 per share. The increase in the net loss for both the fourth quarter and the year was primarily due to the change in the valuation of outstanding warrants to purchase common stock described below.

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 during each financial reporting period which causes the warrant liability to fluctuate as the market price of Sarepta's stock fluctuates. In the fourth quarter of 2012, the increase in Sarepta's stock price resulted in the warrant valuation increasing which resulted in other expense of $51.8 million. In the fourth quarter of 2011, the decrease in Sarepta's stock price resulted in other income of $7.4 million. For the full year 2012, the change in the warrant valuation resulted in other expense of $91.9 million while in 2011, the decrease in the warrant valuation resulted in other income of $33.0 million.

Sarepta had cash and cash equivalents of $187.7 million as of December 31, 2012, an increase of $147.8 million from December 31, 2011. This increase was primarily due to the completion of public stock offerings during the second half of 2012 which raised net proceeds of $154.3 million and warrant exercises that raised an additional $20.6 million. These sources of funds were partially offset by $29.7 million of cash used for operations during the year.

2013 Guidance

For 2013, Sarepta anticipates that revenue will be in the $18 to $24 million range and that loss from operations will be in the $85 to $115 million range. The revenue guidance is based on the assumption that Sarepta will continue to receive funding from its current government contracts for Marburg. If Sarepta does not continue to receive this funding, its revenue guidance would change significantly. Additionally, the operating loss guidance is largely based on continuing development and scale up manufacturing for eteplirsen and our follow-on DMD drugs.

Recent Corporate Developments

Duchenne Muscular Dystrophy (DMD) Program

-- Announced updated data from Study 202, its open-label, Phase IIb extension study of eteplirsen for the treatment of DMD. Patients treated with eteplirsen for 62 weeks and evaluable on ambulatory measures (modified Intent-to-Treat population) maintained a statistically significant clinical benefit on the primary clinical outcome measure, the 6-minute walk test (6MWT), compared to patients who received placebo for 24 weeks followed by 38 weeks of eteplirsen treatment.

-- Announced a collaboration for the development of an additional exon-skipping drug targeting exon 53, its fourth drug in development, in support of Sarepta's broad-based program for the treatment of DMD. Sarepta's collaboration is with University College London's (UCL) scientist, Professor Francesco Muntoni, MD, the Dubowitz Neuromuscular Centre, the Institute of Child Health and other scientists from the EU and US. The EU Health Innovation-1 2012 Collaborative research grant will support certain IND-enabling activities and clinical proof of concept studies for an exon 53-skipping therapeutic.

Infectious Disease Programs

-- Announced positive results from a non-human primate study of AVI-7288, the Company's lead drug candidate for the treatment of Marburg virus infection. The data showed that intramuscular administration of AVI-7288 resulted in survival rates up to 100 percent in treated subjects, similar to efficacy observed in previous studies that evaluated the drug when administered by intravenous injection.

-- Announced that 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), to conduct a 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.

Corporate Developments

-- Priced an underwritten public offering in December 2012 of an aggregate of 4,950,495 shares of its common stock at a price to the public of $25.25 per share, raising $125 million.

Conference Call

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 34143150. Please specify to the operator that you would like to join the "Sarepta Fourth Quarter and Full-Year 2012 Earnings Call." The conference call will be webcast live under the events 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 March 14, 2013 by calling 888.843.7419 or 630.652.3042 and entering access code 34143150.

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 review and approval of Sarepta's product candidates, Sarepta's ability to manufacture product candidates and Sarepta's estimates regarding its future revenue, operating loss and expenses and expectations regarding future success, revenue 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.

Any of the foregoing risks could materially and adversely affect Sarepta's business, results of operations and the trading price of Saretpa'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 December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Revenues, from grants and research contracts	$ 7,336	$ 13,585	$ 37,329	$ 46,990
Operating expenses:				
Research and development	12,834	18,701	52,402	66,862
General and administrative	4,868	3,884	14,630	16,055
Operating loss	(10,366)	(9,000)	(29,703)	(35,927)
Other income (loss):				
Interest income, and other, net	83	147	354	587
Gain (loss) on change in warrant valuation	(51,784)	7,443	(91,938)	33,022
Net income (loss)	$ (62,067)	$ (1,410)	$ (121,287)	$ (2,318)
Net income (loss) per share -- basic and diluted*	$ (2.36)	$ (0.06)	$ (5.14)	$ (0.11)
Shares used in per share calculations -- basic and diluted*	26,313	22,624	23,602	21,599

* All net income (loss) per share and shares used in the 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.

BALANCE SHEET HIGHLIGHTS

(in thousands)

	December 31, 2012	December 31, 2011
Cash and cash equivalents	$ 187,661	$ 39,904
Total current assets	193,908	45,184
Total assets	204,993	54,368
Total current liabilities	78,886	20,601
Total shareholders' equity	$ 123,679	$ 31,017

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