Sarepta Therapeutics Announces Third Quarter 2012 Financial Results and Recent Corporate Developments

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Positive 48-Week Results From Phase IIb DMD Study Supports Eteplirsen's Further Development, Regulatory and Manufacturing Activities; Strong Financial Position With Current Cash Balance of $57.4 Million

Nov 07, 2012 (Marketwire via COMTEX) --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, 2012, and provided an update of recent corporate developments.

"Our recent presentation of 48-week data with eteplirsen for the treatment of DMD highlights the potential disease-modifying effects of our drug and supports the continued advancement of eteplirsen and our broader DMD pipeline," said Chris Garabedian, President and CEO of Sarepta. "Our current cash balance of over $57 million provides a strong financial base as we prepare for the regulatory, manufacturing, and clinical development activities with eteplirsen that will take place throughout 2013."

Financial Results

For the third quarter of 2012, Sarepta reported an operating loss of $6.9 million, compared with an operating loss of $11.3 million in the third quarter of 2011. The decrease in the operating loss was primarily due to reductions in research and development related to non-DMD programs.

Revenue for the third quarter of 2012 was $7.6 million, a $0.1 million increase from the third quarter of 2011. The increase was primarily due to a $1.1 million increase in revenues from the Marburg portion of our July 2010 Ebola Marburg Department of Defense Contract. This increase was partially offset by $0.9 million of reduced revenues from the Ebola portion of the contract due to receiving a stop-work-order on August 2, 2012. Additionally, on October 2, 2012, the Department of Defense terminated for the convenience of the government the Ebola portion of the contract due to funding constraints. The termination of the Ebola portion of the contract does not affect the Company's ongoing Marburg activities.

Research and development expenses were $10.9 million for the third quarter of 2012, a $4.7 million decrease from the corresponding prior year quarter. The decrease was primarily due to a $4.0 million reduction in personnel-related costs and costs of non-DMD proprietary research and a $1.3 million decrease in DMD program costs. This decrease was partially offset by a $0.4 million increase in costs associated with the Marburg U.S. government contract.

General and administrative expenses were $3.6 million in the third quarter of 2012 compared to $3.2 million in the prior year quarter. The increase is primarily due to increased legal costs.

For the first nine months of 2012, Sarepta reported an operating loss of $19.3 million compared with an operating loss of $26.9 million in the first three quarters of 2011. The $7.6 million decrease in the operating loss is primarily due to $11.0 million of reduced operating expenses partially offset by $3.4 million of reduced revenues.

Revenue for the first nine months of 2012 was $30.0 million compared to $33.4 million in the first nine months of 2011. The decrease was primarily due to a $3.4 million reduction in the H1N1 U.S. government contract that was substantially completed in June 2011.

Research and development expenses were $39.6 million in the first nine months of 2012, an $8.6 million decrease from the first nine months of last year. The decrease was primarily due to a $5.6 million decrease in personnel-related costs and costs of non DMD proprietary research due to the December 2011 restructuring and a $2.6 million reduction in costs associated with the H1N1 U.S. government contract.

General and administrative expenses were $9.8 million in the first nine months of 2012, a decrease of $2.4 million compared to the first nine months of 2011. The decrease was primarily a result of a $2.0 million reduction in employee related costs associated with staff reductions in 2011 and a $0.5 million decrease in professional service costs.

Net loss for the third quarter of 2012 was $49.6 million ($2.17 per basic share), compared to net loss for the third quarter of

2011 of $4.0 million ($0.18 per basic share). The increase in net loss was primarily due to a $49.8 million increase in non-operating expenses due to the change in the valuation of Sarepta's outstanding warrants. This incremental non-cash expense is highly impacted based on the increase in Sarepta's stock price as described below. This increase in warrant valuation expense was partially offset by a $4.4 million decrease in operating loss.

Net loss for the nine months ended September 30, 2012 was $59.2 million ($2.61 per basic share), compared to net loss of $0.9 million ($0.04 per basic share) for the first nine months of 2011. The increase in net loss is due to a $65.7 million change in the valuation of Sarepta's outstanding warrants which was partially offset by a $7.6 million decrease in operating loss.

In connection with equity financings in 2007 and 2009, Sarepta issued warrants that are classified as liabilities and are adjusted to fair value on a quarterly basis through other income (loss). The amount of 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 third quarter of 2012 as compared to the year earlier quarter, the change in the warrant liability resulted in a $42.7 million charge to other income (loss). In the first nine months of 2012 compared to the similar period in 2011, the change in the warrant liability resulted in $40.2 million charge to other income (loss).

Sarepta had cash and cash equivalents of $38.0 million as of September 30, 2012, a $13.5 million increase from June 30, 2012. The increase is primarily due to $19.9 million of net proceeds from stock sales under the At-The-Market (ATM) equity financing that was put in place in September 2012 and $1.2 million from the exercise of stock options. These increases were partially offset by $7.8 million of cash used in operations during the third quarter of 2012. Additionally, between October 1 and November 6, 2012 Sarepta received $16.4 million in net proceeds from sales under the ATM and $5.6 million from the exercise of outstanding warrants for a cash balance of $57.4 million as of November 7, 2012. Under the ATM program, the Company sold an aggregate of 1,429,120 shares in the third quarter, and an additional 554,686 shares since October 1, 2012, in open market trading, for an aggregate of 1,983,806 total shares. Additionally, the Company issued 531,913 shares since October 1, 2012 upon the exercise of warrants.

Financial Guidance

Sarepta currently estimates full year 2012 revenue will be at the lower end of the previously issued guidance of $37 to $43 million. Additionally, operating loss is expected to be within the previous disclosed range of $25 to $30 million.

Recent Corporate Developments

Duchenne Muscular Dystrophy (DMD) Program

-- Presented preclinical safety data showing eteplirsen was well tolerated up to the maximum dose of 320 mg/kg in a 9 month repeat dose toxicity evaluation in cynomolgus monkeys, at the 8th Annual Oligonucleotide Therapeutic Society meeting.

-- Presented 48-week data from a Phase IIb study evaluating eteplirsen for the treatment for boys with DMD in a late-breaker abstract session at the 17th Annual International World Muscle Society in Perth, Australia.

-- Announced treatment with its lead exon-skipping compound, eteplirsen, met the primary efficacy endpoint, increase in novel dystrophin, at 48 weeks and achieved a significant clinical benefit on the primary clinical outcome, the 6-minute walk test (6MWT) over the placebo/delayed treatment cohort through 48 weeks in a Phase IIb extension trial in DMD patients.

Infectious Disease Programs

-- Announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for its lead infectious disease drug candidates, AVI-7288 and AVI-7537, for the treatment of Marburg virus and Ebola virus, respectively.

-- Announced that the FDA granted Fast Track status for the development of its lead infectious disease drug candidates, AVI-7288 and AVI-7537, for the treatment of Marburg virus and Ebola virus, respectively. Sarepta has been developing these platform-based therapeutics under a U.S. Department of Defense (DoD) contract managed by the Joint Project Manager Transformational Medical Technologies (JPM-TMT) Project Management Office, a component of the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD).

-- Presented efficacy data that AVI-7288 provides significant survival benefit when treatment is initiated up to four days after Marburg virus Infection in cynomolgus macaques at the 52nd Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) Annual Meeting.

-- Announced Sarepta received notice from the DoD that the Ebola portion of the Company's contract for the advanced development of hemorrhagic fever virus therapeutics was terminated for the convenience of the government due to funding constraints.

-- Announced the Company has been awarded a new contract for approximately $3.9 million to evaluate the feasibility of an intramuscular route of administration using AVI-7288, the Company's candidate for treatment of Marburg virus. The contract is with the DoD's JPM-TMT program.

Corporate Developments

-- Strengthened executive management team with the appointment of Sandy Mahatme and Ty Howton as senior vice president, chief financial officer and senior vice president, general counsel, respectively.

-- Announced transition of corporate headquarters from Bothell, WA to Cambridge, MA.

Conference Call

Sarepta Therapeutics will hold a financial results and corporate update conference call today at 5:00 p.m., Eastern Time (2:00 p.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 33674533. Please specify to the operator that you would like to join the "Sarepta Third Quarter 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 November 14, 2012 by calling 888.843.7419 or 630.652.3042 and entering access code 33674533.

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 development of Sarepta's product candidates, the expected timing of results from the extension study of eteplirsen, the potential for the creation of novel dystrophin to lead to clinically meaningful benefits over a longer course of treatment with eteplirsen and Sarepta's estimates regarding its future revenue 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; and any of Sarepta's drug candidates may fail in development, may not receive required regulatory approvals, 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 September 30,		Nine Months Ended September 30,	
	2012	**2011**	**2012**	**2011**
Revenues, from grants and research contracts	$ 7,574	$ 7,524	$ 29,993	$ 33,405
Operating expenses:				
Research and development	10,914	15,610	39,568	48,161
General and administrative	3,565	3,185	9,761	12,171
Operating loss	(6,905)	(11,271)	(19,336)	(26,927)
Other income (loss):				
Interest income, and other, net	67	199	270	440
Gain (loss) on change in warrant valuation	(42,716)	7,052	(40,154)	25,579
Net income (loss)	$ (49,554)	$ (4,020)	$ (59,220)	$ (908)
Net income (loss) per share-- basic and diluted*	$ (2.17)	$ (0.18)	$ (2.61)	$ (0.04)
Shares used in per share calculations-- basic and diluted*	22,824	22,623	22,691	21,254

* 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)

	September 30, 2012	**December 31, 2011**
Cash and cash equivalents	$ 37,987	$ 39,904
Total current assets	42,159	45,184
Total assets	53,082	54,368

Total current liabilities		55,200		20,601
Total shareholders' equity (deficit)	$	(4,566)	$	31,017

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