

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

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Aug 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 six months ended June 30, 2012, and provided an update of recent corporate developments.

"We have made significant progress in demonstrating efficacy with two distinct applications of our technology and two different backbone chemistries," said Chris Garabedian, President and CEO of Sarepta. "The clinical benefit seen with eteplirsin in Duchenne muscular dystrophy, along with the efficacy results with delayed treatment in Marburg-infected non-human primates, provide strong validation of the potential of our platform technology."

Financial Results

For the second quarter of 2012, Sarepta reported an operating loss of \$5.6 million, compared with an operating loss of \$10.1 million in the second quarter of 2011. The decrease in the operating loss is primarily due to reductions in research and development and general and administrative expenses.

Revenue for the second quarter of 2012 was \$11.2 million, a \$0.4 million decrease from the second quarter of 2011. The decrease was due to a \$0.9 million decrease in the H1N1 flu contract that was substantially completed in June of last year partially offset by a \$0.6 million increase in revenues associated with the ongoing Ebola Marburg government contract.

Research and development expenses were \$13.8 million for the second quarter of 2012, a reduction of \$3.9 million from the corresponding prior year quarter. The decrease was primarily due to a \$1.0 million decrease in DMD program costs, a \$0.8 million decrease in costs associated with the completion last year of the H1N1 U.S. government contract and a \$2.1 million reduction in personnel related costs and costs of non DMD proprietary research.

General and administrative expenses were \$2.9 million in the second quarter of 2012 compared to \$4.0 million in the prior year quarter. The decrease is primarily due to reduced salaries, severance and other employee related costs.

For the first six months of 2012, Sarepta reported an operating loss of \$12.4 million compared with an operating loss of \$15.7 million in the first half of 2011. The decrease is primarily due to \$6.7 million of reduced operating expenses partially offset by \$3.5 million of reduced revenues.

Revenue for the first six months of 2012 was \$22.4 million compared to \$25.9 million in the first six months of 2011. The decrease was primarily due to a \$3.2 million reduction in the H1N1 U.S. government contract that was substantially completed in June 2011.

Research and development expenses were \$28.7 million in the first six months of 2012, a \$3.9 million decrease from the first six months of last year. The decrease was primarily due to a \$2.0 million decrease in personnel related costs and costs of non DMD proprietary research, a \$1.9 million reduction in costs associated with the H1N1 U.S. government contract and a \$0.6 million decrease in spending on the Ebola and Marburg contract. These decreases were partially offset by a \$0.7 million increase in spending on DMD programs.

General and administrative expenses were \$6.2 million in the first six months of 2012, a decrease of \$2.8 million compared to the first six months of 2011. The decrease was primarily a result of a \$2.0 million decrease in employee related costs and a \$0.4 million decrease in professional service costs.

Net income for the second quarter of 2012 was \$8.0 million (\$0.36 per basic share), compared to net income for the second quarter of 2011 of \$1.3 million (\$0.06 per basic share). The \$6.7 million increase in net income was primarily due a \$4.6 million decrease in operating loss and an increase of \$2.2 million in other income associated with the change in the valuation of Sarepta's outstanding warrants as described below. The net loss for the six months ended June 30, 2012 was \$9.7 million, (\$0.43 per basic share), compared to a net income for the first six months of 2011, or \$3.1 million (\$0.15 per basic share). The \$12.8 million decrease in net income is due to a \$16.0 million change in the valuation of Sarepta's outstanding warrants as described below

partially offset by a \$3.2 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 second quarter of 2012 as compared to the year earlier quarter, the change in the warrant liability resulted in a \$2.2 million increase in other income. In the first six months of 2012 compared to the similar period in 2011, the change in the warrant liability resulted in \$16.0 million reduction in other income.

Sarepta had cash and cash equivalents of \$24.5 million as of June 30, 2012, a \$6.1 million decrease from March 31, 2012. The decrease is primarily due to \$5.7 million of cash used in operations during the second quarter of 2012. This is a reduction of \$3.3 million from the \$9.0 million of cash used in operating activities for the first quarter of 2012.

Financial Guidance

On August 2, 2012, Sarepta received a stop-work order on the Ebola virus portion of the U.S. government contract for Advanced Development of Hemorrhagic Fever Virus Therapeutics due to recently imposed funding constraints. The stop-work order does not apply to the Marburg portion of the contract. If the stop-work order is not lifted, Sarepta anticipates 2012 full year revenue will be in the \$37 to \$43 million range and operating loss will be in the \$25 to \$30 million range.

Recent Corporate Developments

Duchenne Muscular Dystrophy (DMD) Program

-- Announced treatment with Sarepta's exon-skipping compound, eteplirsen, achieved a significant clinical benefit on the primary clinical outcome, the 6-minute walk test (6MWT), over a placebo/delayed treatment cohort in a Phase IIb trial in DMD patients. Eteplirsen administered once weekly at 50mg/kg over 36 weeks resulted in a 69.4 meter benefit compared to patients who received placebo for 24 weeks followed by 12 weeks of treatment with eteplirsen in the open-label extension.

Infectious Disease Programs

-- Announced that the Food and Drug Administration (FDA) has agreed to allow Sarepta to proceed with a single oligomer, AVI-7537, in studies in both humans and non-human primates to support the safety and efficacy of post-exposure prophylaxis against Ebola virus infection. Data from this program was presented at the Oligonucleotide and Peptide® Research, Technology and Product Development (TIDES) conference in May 2012, where the data from a confirmatory study demonstrated survival of 75% and 63% in nonhuman primates administered AVI-7537 and AVI-6002, respectively, compared to 0% in the both the AVI-7539 and placebo groups. Based on these results, the Company concluded that AVI-7537 is the active component in AVI-6002 and that further development would proceed accordingly with the single oligomer component AVI-7537.

-- Announced Sarepta's lead therapeutic drug candidate for the Marburg virus, AVI-7288, demonstrated between 83% and 100% survival in a non-human primate study exploring the drug's effect when treatment is delayed to various time points post-infection. The study demonstrated a significantly higher rate of survival among non-human primates treated with AVI-7288 compared to 0% survival rate in the placebo-treated group when treatment was administered up to 96-hours post infection.

Corporate Developments

--Announced company name change to Sarepta Therapeutics and ticker symbol change to SRPT. Concurrently, effected a one-for-six reverse stock split.

-- Received a letter from the listing qualifications department staff of The NASDAQ Stock Market LLC, stating that Sarepta regained compliance with NASDAQ's minimum \$1.00 per share bid price requirement.

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 and international callers. The

passcode for the call is 33002736. Please specify to the operator that you would like to join the "Sarepta second 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 August 14, 2012 by calling 888.843.7419 or 630.652.3042 and entering access code 33002736.

About Sarepta Therapeutics

Sarepta Therapeutics -- formerly AVI BioPharma -- 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 Sarepta'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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues, from grants and research contracts	\$ 11,207	\$ 11,585	\$ 22,419	\$ 25,881
Operating expenses:				
Research and development	13,849	17,750	28,654	32,551

General and administrative	2,915	3,960	6,196	8,986
Operating loss	<u>(5,557)</u>	<u>(10,125)</u>	<u>(12,431)</u>	<u>(15,656)</u>
Other income (loss):				
Interest income, and other, net	107	151	203	241
Gain (loss) on change in warrant valuation	<u>13,488</u>	<u>11,253</u>	<u>2,562</u>	<u>18,527</u>
Net income (loss)	<u>\$ 8,038</u>	<u>\$ 1,279</u>	<u>\$ (9,666)</u>	<u>\$ 3,112</u>
Net income (loss) per share -- basic*	<u>\$ 0.36</u>	<u>\$ 0.06</u>	<u>\$ (0.43)</u>	<u>\$ 0.15</u>
Net income (loss) per share -- diluted*	<u>\$ 0.35</u>	<u>\$ 0.06</u>	<u>\$ (0.43)</u>	<u>\$ 0.14</u>
Shares used in per share calculations -- basic*	<u>22,624</u>	<u>22,348</u>	<u>22,624</u>	<u>20,558</u>
Shares used in per share calculations -- diluted*	<u>22,658</u>	<u>23,153</u>	<u>22,624</u>	<u>21,670</u>

* 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)

	June 30,	December 31,
	2012	2011
Cash and cash equivalents	\$ 24,491	\$ 39,904
Total current assets	33,232	45,184
Total assets	42,101	54,368
Total current liabilities	17,131	20,601
Total shareholders' equity	\$ 22,500	\$ 31,017

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