# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

# FORM 8-K

# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 29, 2012

# Sarepta Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Oregon (State or other jurisdiction of incorporation) 001-14895 (Commission File Number) 93-0797222 (IRS Employer Identification No.)

3450 Monte Villa Parkway, Suite 101 Bothell, WA 98021 (Address of principal executive offices, including zip code)

(425) 354-5038 (Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

# Item 1.01 Entry Into a Material Definitive Agreement

On August 29, 2012, Sarepta Therapeutics, Inc. (the "Company") was awarded a new contract (the "JPM-TMT agreement") from the U.S. Department of Defense's Joint Project Manager Transformational Medical Technologies ("JPM-TMT") program, a component of the U.S. Department of Defense's Joint Program Executive Office for Chemical and Biological Defense. The contract provides funding to the Company in the amount of 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. Under a separate, pre-existing contract with JPM-TMT, the Company is developing AVI-7288 as an intravenous formulation.

The foregoing description of the terms of the JPM-TMT agreement does not purport to be a complete description and is qualified in its entirety by reference to the JPM-TMT agreement that will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2012.

On September 4, 2012, the Company issued a press release announcing its entry into the JPM-TMT agreement, a copy of which is attached to this Report as Exhibit 99.1.

## Item 7.01 Regulation FD Disclosure

As previously reported, on August 2, 2012, the Company received a stop-work order from the U.S. Department of Defense (the "DoD") with respect to the Ebola portion of the contract for Advanced Development of Hemorrhagic Fever Virus Therapeutics (the "ADHFVT contract"). The original stop-work order was in effect through September 1, 2012 unless further extended by the DoD. On August 31, 2012, the Company received notice from the DoD that the stop-work order would be extended until September 30, 2012. At or prior to that time the DoD will either: (1) terminate the Ebola portion of the contract; (2) cancel the stop-work order; or (3) again extend the stop-work order period. The lower end of the Company's previously issued annual 2012 revenue guidance range assumes no additional revenue from the Ebola portion of the ADHFVT contract in 2012. On September 4, 2012, the Company issued a press release announcing the extension of the stop-work order, a copy of which is attached to this Report as Exhibit 99.1.

### Item 8.01 Other Events

On August 31, 2012, the Company and a third-party manufacturer entered into an ordinary course manufacturing agreement to construct manufacturing facility modifications, which will enable the Company to prepare for larger scale production of drug related materials in support of eteplirsen and other Duchenne muscular dystrophy drug products. Pursuant to the agreement, the Company will make two cash payments to the third party in an aggregate amount of \$2.75 million by October 12, 2012, which payments will incrementally increase the Company's cash burn for the third and fourth quarters of 2012. In consideration for those payments, the Company will receive credit up to a maximum aggregate amount of \$2.75 million against future amounts payable to the third-party manufacturer for materials manufactured utilizing the modified facility.

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are identified by such words as "anticipate," "believe," "expect," "will" and words of similar import and are based on current expectations that involve risks and uncertainties, such as the Company's plans, objectives, expectations and intentions. All statements other than historical or current facts are forward-looking statements, including, without limitation, statements about the Company's ability to prepare for larger scale production of drug related materials. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. The Company does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

### Item 9.01 Financial Statements and Exhibits

(d) Exhibits

#### Exhibit Number Description

99.1 Press release regarding JPM-TMT agreement for intramuscular administration of AVI-7288 and extension of the Ebola program stop-work order dated September 4, 2012.

# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# Sarepta Therapeutics, Inc.

By: <u>/s/ Christopher Garabedian</u>

Christopher Garabedian President and Chief Executive Officer

Date: September 4, 2012

# Exhibit Number Description 99.1

Press release regarding JPM-TMT agreement for intramuscular administration of AVI-7288 and extension of the Ebola program stop-work order dated September 4, 2012.





Sarepta Investor and Media Contact: Erin Cox 425.354.5140 ecox@sareptatherapeutics.com

## Sarepta Therapeutics Awarded \$3.9 Million Contract By U.S. Government to Evaluate Feasibility of an Alternate Route of Administration of its Lead Therapeutic Candidate for Treatment of Marburg Virus

**CAMBRIDGE, MA, September 4, 2012** – Sarepta Therapeutics, Inc. (NASDAQ: SRPT), a developer of innovative RNA-based therapeutics, today announced that it 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 U.S. Department of Defense's Joint Project Manager Transformational Medical Technologies (JPM-TMT) program.

"The ability to administer drugs via an intramuscular route represents a major reduction in the logistical burden on the Warfighter, and also provides a highly practical way to treat many people quickly during an emergency," said Chris Garabedian, President and CEO. "Our ultimate goal is to provide an effective medical countermeasure for Marburg virus where none currently exists."

The new contract will allow Sarepta to evaluate the tolerability, pharmacokinetics, and efficacy of intramuscular AVI-7288. Under a separate, pre-existing contract with JPM-TMT, Sarepta is developing AVI-7288 as an intravenous formulation.

Sarepta also announced today that the U.S. Department of Defense (DoD) is extending the period of the temporary stop-work order on the Ebola portion of the Company's pre-existing contract with JPM-TMT for advanced development of therapeutics for both Marburg virus and Ebola virus. By September 30, 2012, the DoD will either: (1) terminate the Ebola portion of the contract; (2) cancel the stop-work order; or (3) again extend the stop-work order period. On August 2, 2012, Sarepta received a temporary stop-work order with respect to its Ebola program due to recently imposed funding constraints at the DoD.

# **About Marburg Virus**

Marburg hemorrhagic fever is a severe and potentially fatal disease in humans first recognized in 1967. It is caused by an RNA virus of the Filoviridae family and is understood to be endemic to Africa. The Marburg virus is classified as a Category A bioterrorism agent by the Centers for Disease Control and Prevention, or CDC, and was determined to pose a material threat to

national security and public health by the Secretary of Homeland Security in 2006. Onset of the disease is often sudden, and the symptoms include fever, chills, nausea, vomiting, chest pain and diarrhea. Increasingly severe symptoms may also include massive hemorrhaging and multiple organ dysfunctions. There are currently no treatments for Marburg virus infection beyond supportive care.

# About Sarepta's PMOplus® Chemistry

PMOplus® chemistry is an advanced generation of Sarepta's phosphorodiamidate morpholino oligomer, or PMO, technology pioneered by Sarepta. The PMO platform is designed to provide a stable chemistry backbone with superior drug-like characteristics for Sarepta's advanced RNA-based therapeutics. PMOplus® chemistry includes specific molecular charges positionally inserted into the PMO's inherent charge-neutral backbone. PMOplus® has potentially broad therapeutic applications and has thus far shown to be particularly effective in increasing the potency of PMO-based oligomers.

# About JPM-TMT

JPM-TMT is a component of the U.S. Department of Defense's Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). JPM-TMT aims to protect the Warfighter from emerging infectious diseases, genetically altered, and unknown biological threats. Through strategic investments and partnerships with innovative biotech firms, pharmaceutical corporations, other government agencies, and academic institutions, JPM-TMT facilitates the advanced development and acquisition of adaptable platform technologies, broad-spectrum medical countermeasures, and innovative systems to enhance our nation's biodefense response capability. For more information, visit <u>www.jpmtmt.mil</u>.

### **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 lifethreatening rare and infectious diseases. The Company'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 <u>www.sareptatherapeutics.com</u>.

#### 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-

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looking statements. These forward-looking statements include statements about the development of Sarepta's product candidates, their efficacy, potency and utility in the treatment of rare and infectious diseases, their potential to treat a broad number of human diseases and Sarepta's studies.

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 AVI-7288 may not result in funding from JPM-TMT 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 Sarepta's reports 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.