

Sarepta Therapeutics, Inc.
Form 8-K
September 04, 2012

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.)

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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 | Description |
|---------|-------------|
|---------|-------------|

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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: /s/ Christopher Garabedian
Christopher Garabedian
President and Chief Executive Officer

Date: September 4, 2012

EXHIBIT INDEX

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. |