

Edgar Filing: Sarepta Therapeutics, Inc. - Form 8-K

(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 Instructions 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

Earlier today, Sarepta Therapeutics, Inc. (the “Company”) presented 9-month functional and creatine kinase (CK) data from baseline from the 4 patients in the Phase 1 open-label study of the Company’s micro-dystrophin gene therapy candidate for Duchenne muscular dystrophy. As of the conference call this morning, Patient 3’s last CK measured 18,855 at Day 270, the last date measured. After the conference call, the Company received an update on Patient 3, whose Day 360 visit was today (March 25, 2019). Patient 3’s CK level dropped to 6,410. The Company is sharing this new information in light of the proximity of this measure to this morning’s update. The Company does not intend to provide further updates on this Phase 1 study while the confirmatory trials are ongoing.

The information in this report furnished pursuant to Item 7.01 shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

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/ Douglas S. Ingram
Douglas S. Ingram
President and Chief Executive Officer

Date: March 25, 2019