UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): **March 9, 2020**

ACCELERON PHARMA INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-36065**	**27-0072226**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

128 Sidney Street **Cambridge, MA** (Address of principal executive offices)	**02139** (Zip Code)

Registrant's telephone number, including area code: **(617) 649-9200**

Not Applicable

(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:

☐ 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))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Ticker Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 per share	XLRN	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company 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 8.01 Other Events.

On March 9, 2020, Acceleron Pharma Inc. (the "Company") issued a press release announcing that treatment with ACE-083 in patients with Charcot-Marie-Tooth disease did not demonstrate functional improvement in the Phase 2 trial, and that the Company will discontinue development of ACE-083.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release of Acceleron Pharma Inc. dated March 9, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

ACCELERON PHARMA INC.

By: /s/ Adam M. Veness, Esq.
Adam M. Veness, Esq.
Senior Vice President, General Counsel and Secretary

Date: March 9, 2020

Acceleron Announces Topline Results from the Phase 2 Trial of ACE-083 in Patients with Charcot-Marie-Tooth Disease

– ACE-083 did not achieve statistically significant improvements in functional endpoints relative to placebo –

– Acceleron to discontinue development of ACE-083 –

Cambridge, Mass. – March 9, 2020 – Acceleron Pharma Inc. (NASDAQ:XLRN), a biopharmaceutical company dedicated to the discovery, development, and commercialization of TGF-beta superfamily therapeutics to treat serious and rare diseases, today announced that treatment with ACE-083 in patients with Charcot-Marie-Tooth disease (CMT) did not demonstrate functional improvement in the Phase 2 trial.

ACE-083 demonstrated a statistically significant increase in mean total muscle volume, the trial's primary endpoint. However, the increase did not translate to statistically significant improvements in any of the functional or quality of life secondary endpoints when compared to placebo. As a result, Acceleron is discontinuing development of ACE-083.

"Unfortunately, over the course of multiple clinical trials, our myostatin-plus hypothesis has not resulted in the functional outcomes necessary to provide clinically meaningful benefits for patients with neuromuscular diseases," said Habib Dable, President and Chief Executive Officer of Acceleron. "We wish to thank all of the patients, families, caregivers, and investigators for their support and participation in this research. I also want to acknowledge our team's hard work and commitment to executing robust Phase 2 trials that have provided us the data necessary to make the difficult but informed investment decision to discontinue the program."

Dable added: "We will now focus our resources on two main disease areas of hematology with REBLOZYL in anemia and pulmonary with sotatercept in PAH, along with our ongoing preclinical efforts in TGF-beta protein superfamily-based discovery and research."

In this Phase 2 trial in patients with CMT, ACE-083 was generally well tolerated. Adverse events were mostly mild to moderate (Grade 1 or 2) and largely injection-site related. Acceleron plans to present results of the study at the American Academy of Neurology Annual Meeting in April.

CMT Phase 2 Trial Design

The two-part Phase 2 clinical trial was designed to evaluate ACE-083 in CMT patients with muscle weakness in the tibialis anterior (TA), a muscle in the lower leg involved in ankle dorsiflexion (raising the foot at the ankle). Part 1 was an open-label, dose-escalation study, with ACE-083 administered by injection into the TA muscle once every 3 weeks in 18 patients to evaluate safety and increases in muscle volume over a 3-month treatment period. Part 2 was a randomized, double-blind, placebo-controlled study using the optimal dose level selected in Part 1. A total of 44 patients were randomized and treated with either placebo or ACE-083 in Part 2 and were evaluated for changes in muscle volume, fat fraction, strength, function, quality of life, and safety over a 6-month primary treatment period, followed by a 6-month open-label treatment period.

For additional information about this clinical trial, please visit www.clinicaltrials.gov.

About Acceleron

Acceleron is a biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases. Acceleron's leadership in the

understanding of TGF-beta superfamily biology and protein engineering generates innovative compounds that engage the body's ability to regulate cellular growth and repair.

Acceleron focuses its research and development efforts in hematologic and pulmonary diseases. In hematology, Acceleron and its global collaboration partner, Bristol-Myers Squibb, are co-promoting newly approved REBLOZYL® (luspatercept-aamt), the first and only approved erythroid maturation agent, in the United States and are developing luspatercept for the treatment of chronic anemia in myelodysplastic syndromes and myelofibrosis. Acceleron is also developing sotatercept for the treatment of pulmonary arterial hypertension, having recently reported positive topline results of the Phase 2 PULSAR trial and actively enrolling patients in the Phase 2 SPECTRA trial.

For more information, please visit www.acceleronpharma.com. Follow Acceleron on Social Media: @AcceleronPharma and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements about the Company's strategy, future plans and prospects, including statements regarding the development of the Company's compounds, the timeline for clinical development and regulatory approval of the Company's compounds and the expected timing for reporting of data from ongoing clinical trials. The words "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "potential," "project," "should," "target," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Actual results could differ materially from those included in the forward-looking statements due to various risks and uncertainties, including, but not limited to, that data from clinical trials may not be predictive of the results or success of other clinical trials, that the development of the Company's compounds will take longer and/or cost more than planned, that the Company will be unable to successfully complete the clinical development of the Company’s compounds, that the Company may be delayed in initiating, enrolling or completing any clinical trials, and that the Company's compounds will not receive regulatory approval or become commercially successful products. These and other risks and uncertainties are identified under the heading "Risk Factors" included in the Company's most recent Annual Report on Form 10-K, and other filings that the Company has made and may make with the SEC in the future.

The forward-looking statements contained in this press release are based on management’s current views, plans, estimates, assumptions and projections with respect to future events, and the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Source: Acceleron Pharma

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