

**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): **June 4, 2019**

ACCELERON PHARMA INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36065
(Commission
File Number)

27-0072226
(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 June 4, 2019, Acceleron Pharma Inc. ("Acceleron") and Celgene Corporation ("Celgene") announced that the U.S. Food and Drug Administration (FDA) has accepted Celgene's Biologics License Application (BLA) for luspatercept, an investigational erythroid maturation agent, for the treatment of adult patients with very low to intermediate-risk myelodysplastic syndromes (MDS)-associated anemia who have ring sideroblasts and require red blood cell (RBC) transfusions, and for the treatment of adult patients with beta-thalassemia-associated anemia who require RBC transfusions. The FDA has granted Priority Review to this BLA for the evaluation of the beta-thalassemia indication and set a Prescription Drug User Fee Act (PDUFA), or target action, date of December 4, 2019. The FDA has also set a PDUFA date of April 4, 2020 for the evaluation of the MDS indication.

The safety and efficacy results provided in the application are from the pivotal phase 3 studies MEDALIST and BELIEVE, which evaluated the ability of luspatercept to effectively treat the anemia associated with MDS and beta-thalassemia, respectively. MEDALIST and BELIEVE were both presented at the 2018 American Society of Hematology annual meeting, where MEDALIST was included in the plenary session.

The companies also announced that Celgene's Marketing Authorization Application in the EU has been successfully validated and the review is now underway.

Luspatercept is an investigational therapy that is not approved for any use in any country.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between Acceleron and Celgene; the potential of luspatercept as a therapeutic drug; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that luspatercept will be successfully developed or complete necessary clinical phases. Forward-looking statements in this Current Report on Form 8-K could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; the ability to obtain, maintain and enforce patent and other intellectual property protection for luspatercept; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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.

Vice President, General Counsel and Secretary

Date: June 7, 2019