

ACCELERON PHARMA INC

FORM 8-K (Current report filing)

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Address	128 SIDNEY STREET CAMBRIDGE, MA 02139
Telephone	617-649-9200
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Sector	Healthcare
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**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): **April 27, 2017**

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))

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 April 27, 2017, Acceleron Pharma Inc. issued a press release titled "Acceleron Provides Clinical Development Updates on Luspatercept Program."

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 April 27, 2017

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/ John D. Quisel, J.D., Ph.D.

John D. Quisel, J.D., Ph.D.

Senior Vice President and General Counsel

Date: April 27, 2017

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
99.1	Press release of Acceleron Pharma Inc. dated April 27, 2017



Acceleron Provides Clinical Development Updates on Luspatercept Program

- Enrollment in MEDALIST and BELIEVE Phase 3 studies now expected to be completed in Q2 2017 -

- Acceleron and Celgene to initiate an additional Phase 3 trial in first-line, lower-risk MDS in early 2018 to expand opportunity beyond ongoing MEDALIST study -

CAMBRIDGE, MA – April 27, 2017 – Acceleron Pharma Inc. (NASDAQ: XLRN), a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of innovative therapeutics to treat serious and rare diseases, today announced updates on the luspatercept clinical programs under its collaboration with Celgene. Luspatercept is an investigational compound being evaluated in two pivotal Phase 3 trials for the treatment of myelodysplastic syndromes (MDS) and beta-thalassemia.

“Our pivotal luspatercept studies continue to gain momentum as enrollment nears completion, and new clinical data support the drug’s expanded development in patient groups in need of more treatment options,” commented Habib Dable, President and Chief Executive Officer of Acceleron. “We now look forward to reporting topline results from the MEDALIST and BELIEVE Phase 3 studies in mid-2018 as we work together with Celgene to evaluate the full clinical potential of luspatercept.”

Updated Phase 3 Clinical Trials Enrollment Guidance

Acceleron and Celgene provided updated guidance on the anticipated completion of patient enrollment for the MEDALIST and BELIEVE Phase 3 studies of luspatercept in MDS and beta-thalassemia, respectively. Based on accelerating rates of patient recruitment, the companies expect to achieve full enrollment of both studies in the second quarter of 2017, versus previous guidance of the second half of 2017.

New Phase 3 Clinical Trial

Acceleron and Celgene also plan to initiate a third Phase 3 trial of luspatercept. The new Phase 3 trial, expected to be initiated in early 2018, will evaluate luspatercept treatment versus standard-of-care in the first-line treatment setting for MDS patients. Current first-line, standard-of-care treatment for lower-risk MDS patients includes erythropoiesis-stimulating agents (ESAs) and/or regular red blood cell transfusions. The ongoing MEDALIST Phase 3 trial is evaluating luspatercept in ESA-refractory or -ineligible MDS patients.

Luspatercept Data at the Upcoming MDS Symposium

Acceleron and Celgene plan to report updated Phase 2 data on luspatercept in first-line, lower-risk MDS patients in an oral presentation at the 14th International Symposium on MDS on Saturday, May 6, 2017, in Valencia, Spain.

About Luspatercept

Luspatercept is a modified activin receptor type IIB fusion protein that acts as a ligand trap for members in the Transforming Growth Factor-Beta (TGF-beta) superfamily involved in the late stages of erythropoiesis (red blood cell production). Luspatercept regulates late-stage erythrocyte (red blood cell) precursor cell differentiation and maturation. This mechanism of action is distinct from that of erythropoietin (EPO), which stimulates the proliferation of early-stage erythrocyte precursor cells. Acceleron and Celgene are jointly developing luspatercept as part of a global collaboration. Acceleron and Celgene are enrolling Phase 3 clinical trials that are designed to evaluate the safety and efficacy of luspatercept in patients with myelodysplastic syndromes (the "MEDALIST" study) and in patients with beta-thalassemia (the "BELIEVE" study). For more information, please visit www.clinicaltrials.gov.

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

About Acceleron

Acceleron is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of innovative therapeutics to treat serious and rare diseases. Its pioneering research platform leverages the powerful biology behind the body's ability to rebuild and repair its own cells and tissues. This approach to drug discovery has generated four therapeutic candidates that are currently in clinical trials. The Company's lead therapeutic candidate, luspatercept, is being evaluated in Phase 3 studies for the treatment of the hematologic diseases myelodysplastic syndromes (MDS) and beta-thalassemia under a global partnership with Celgene Corp. Acceleron is also advancing clinical programs in the fields of oncology and neuromuscular diseases and has a comprehensive preclinical research effort targeting fibrotic and other serious diseases.

For more information, please visit www.acceleronpharma.com. Follow Acceleron on Social Media: [@AcceleronPharma](https://twitter.com/AcceleronPharma) and [LinkedIn](https://www.linkedin.com/company/acceleron-pharma).

Cautionary Note on 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 luspatercept, the timeline for clinical development and regulatory approval of the Company's compounds, the expected timing for the reporting of data from ongoing trials, and the structure of the Company's planned or pending clinical trials. The words "anticipate," "appear," "believe," "continue," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "predict," "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.

Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks that preclinical testing of the Company's compounds and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that data may not be available when the Company expects it to be, that the Company or its collaboration partner, Celgene, will be

unable to successfully complete the clinical development of the Company's compounds, that the development of the Company's compounds will take longer or cost more than planned, that the Company or Celgene may be delayed in initiating, enrolling or completing any clinical trials, that the Company's drug discovery activities may not yield drug candidates for which the Company can commence clinical trials at the rate at which the Company currently anticipates or at all, and that the Company's compounds will not receive regulatory approval or become commercially successful products.

Other risks and uncertainties include those identified under the heading "Risk Factors" included in the Company's Annual Report on Form 10-K which was filed with the Securities and Exchange Commission (SEC) on March 1, 2017, 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 reflect the Company's current views with respect to future events, and the Company does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Contacts:

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Source: Acceleron Pharma

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