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 4, 2019**

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))

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) Effective April 5, 2019, Robert K. Zeldin, M.D. is no longer employed by Acceleron Pharma Inc. ("Acceleron") in his position as Executive Vice President and Chief Medical Officer at Acceleron.

Item 8.01 Other Events.

On April 4, 2019, Acceleron issued a press release announcing the discontinuation of development of ACE-2494, a systemic muscle agent the company had been studying in a Phase 1 healthy volunteer trial for the potential treatment of neuromuscular disorders.

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.

On April 5, 2019, Acceleron and Celgene Corporation ("Celgene") issued a press release announcing that Celgene has submitted a Biologics License Application (BLA) for luspatercept 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.

A copy of the press release is attached as Exhibit 99.2 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 4, 2019
99.2	Press release of Celgene Corporation and Acceleron Pharma Inc. dated April 5, 2019

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.
Executive Vice President and Chief Business Officer

Date: April 5, 2019

Acceleron Discontinues Development of Phase 1 Molecule ACE-2494

Cambridge, Mass. – April 4, 2019 – Acceleron Pharma Inc. (NASDAQ:XLRN), a leading biopharmaceutical company in the discovery and development of TGF-beta superfamily therapeutics to treat serious and rare diseases, today announced it is discontinuing development of ACE-2494, a systemic muscle agent the company had been studying in a Phase 1 healthy volunteer trial for the potential treatment of neuromuscular disorders.

“Although ACE-2494 showed promising early signs of target engagement in our recently completed Phase 1 trial, the frequency of anti-drug antibodies (ADAs) observed among participants has led us to discontinue the program,” said Habib Dable, President and Chief Executive Officer of Acceleron. “The formation of ADAs was not associated with any adverse event, but the ADA profile is not consistent with a clinical program that Acceleron would advance. We greatly appreciate the efforts of those who participated in this trial, and plan to leverage the clinical data to help inform future drug discovery efforts in neuromuscular disease.”

About Acceleron

Acceleron is a clinical-stage biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases. The Company's leadership in the understanding of TGF-beta 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, neuromuscular, and pulmonary diseases. In hematology, the Company and its global collaboration partner, Celgene, are developing luspatercept for the treatment of chronic anemia in myelodysplastic syndromes, beta-thalassemia, and myelofibrosis. Acceleron is also advancing its neuromuscular program with ACE-083, a locally-acting Myostatin+ agent in Phase 2 development in facioscapulohumeral muscular dystrophy and Charcot-Marie-Tooth disease and is conducting a Phase 2 pulmonary program with sotatercept in pulmonary arterial hypertension.

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 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 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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Acceleron Pharma Inc.

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Matt Fearer, 617-301-9557
Director, Corporate Communications

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Exhibit 99.2

CELGENE CORPORATION AND ACCELERON PHARMA ANNOUNCE SUBMISSION OF LUSPATERCEPT BIOLOGICS LICENSE APPLICATION TO U.S. FDA

BLA submission includes both myelodysplastic syndromes and beta-thalassemia indications

EMA marketing application for both indications planned for Q2:19

Summit, N.J. & Cambridge, Mass. — (April 5, 2019) — Celgene Corporation (NASDAQ: CELG) and Acceleron Pharma Inc. (NASDAQ: XLRN) today announced that Celgene has submitted a Biologics License Application (BLA) for luspatercept, an 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 submission is based on the safety and efficacy results of the pivotal phase 3 studies MEDALIST and BELIEVE, both recently presented at the American Society of Hematology annual meeting, where MEDALIST was included in the plenary session.

"There remains a high unmet medical need for patients with MDS or beta-thalassemia who suffer from the effects of their disease-related anemia. The primary treatment option for these patients currently is chronic transfusion of red blood cells which can be associated with complications such as iron overload," said Jay Backstrom, M.D., Chief Medical Officer for Celgene. "New treatment options are urgently needed for these patients. With this submission, we look forward to working with the Agency to deliver luspatercept to patients with these serious blood diseases."

The companies also plan to submit a marketing application to the European Medicines Agency in the second quarter of 2019.

"The BLA submission is a key milestone for Acceleron and a credit to our longstanding collaboration with Celgene," said Habib Dable, President and Chief Executive Officer of Acceleron. "We believe luspatercept's positive clinical trial results demonstrate its potential as a novel treatment for patients with lower-risk MDS as well as in beta-thalassemia. All involved have worked diligently to develop luspatercept for patients with chronic anemias associated with these serious blood disorders."

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

About Luspatercept
Luspatercept is a first-in-class erythroid maturation agent (EMA) that regulates late-stage red blood cell maturation. Acceleron and Celgene are jointly developing luspatercept as part of a global collaboration. A phase 3 trial (COMMANDS) in ESA-naïve, lower-risk MDS patients, the BEYOND phase 2 trial in non-transfusion-dependent beta-thalassemia, and a phase 2 trial in myelofibrosis are ongoing. For more information, please visit www.clinicaltrials.gov.

About MEDALIST
MEDALIST is a phase 3, randomized, double blind, placebo-controlled, multi-center study evaluating the safety and efficacy of luspatercept in adults with very low-, low-, or intermediate-risk myelodysplastic syndromes (MDS). All patients were RBC transfusion dependent and were either refractory or intolerant to prior erythropoiesis-stimulating agent (ESA) therapy or were ESA naïve with endogenous serum

erythropoietin ≥ 200 U/L and had no prior treatment with disease modifying agents. The median age of the patients enrolled in the trial was 71 years in the luspatercept treatment group and 72 years in the placebo group. Median transfusion burden in both treatment arms was 5 RBC units/8 weeks. 229 patients were randomized to receive either luspatercept 1.0 mg/kg (153 patients) or placebo (76 patients) by subcutaneous injection once every 21 days. The study was conducted at 65 sites in 11 countries.

About BELIEVE
BELIEVE is a phase 3, randomized, double blind, placebo-controlled multicenter study comparing luspatercept + best supportive care (BSC) versus placebo + BSC in adults with beta-thalassemia patients who require regular RBC transfusions. The median age of the patients was 30 years in both treatment arms. 336 patients were randomized to receive either luspatercept 1.0 mg/kg (224 patients) or placebo (112 patients) by subcutaneous injection every 21 days for up to 48 weeks. Crossover to the luspatercept treatment groups was allowed after unblinding based on the recommendation of an independent Data Safety Monitoring Committee; patients treated with luspatercept will be followed for up to 3 years. The study was conducted at 65 sites in 15 countries.

About Celgene
Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com.

Follow Celgene on Social Media: Twitter, Pinterest, LinkedIn, Facebook and YouTube.

About Acceleron
Acceleron is a clinical-stage biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases. The Company's leadership in the understanding of TGF-beta 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, neuromuscular, and pulmonary diseases. In hematology, the Company and its global collaboration partner, Celgene, are developing luspatercept for the treatment of chronic anemia in myelodysplastic syndromes, beta-thalassemia, and myelofibrosis. Acceleron is also advancing its neuromuscular program with ACE-083, a locally-acting Myostatin+ agent in Phase 2 development in facioscapulohumeral muscular dystrophy and Charcot-Marie-Tooth disease and is conducting a Phase 2 pulmonary program with sotatercept in pulmonary arterial hypertension.

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FORWARD-LOOKING STATEMENTS
This press release 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 press release 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 and with respect to Celgene includes risk factors related to the proposed transaction between Bristol-Myers Squibb and Celgene, such as, but not limited to, the risks that: management's time and attention is diverted on transaction related issues; disruption from the transaction makes it more difficult to maintain business, contractual and operational relationships; and Bristol-Myers Squibb, Celgene or the combined company is unable to retain key personnel. Any forward-looking statements contained in this press release 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.

Hyperlinks are provided as a convenience and for informational purposes only. Neither Celgene nor Acceleron bears responsibility for the security or content of external websites or websites outside of their respective control.

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