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 28, 2018**

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	**02139**
(Address of principal executive offices)	(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 June 28, 2018, Celgene Corporation and Acceleron Pharma Inc. issued a joint press release titled "Celgene and Acceleron Announce Luspatercept Achieved Primary and Key Secondary Endpoints in Phase III 'MEDALIST' Study in Patients with Low-to-Intermediate Risk Myelodysplastic Syndromes."

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 Celgene Corporation and Acceleron Pharma Inc. dated June 28, 2018

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: June 28, 2018

Exhibit 99.1

CELGENE AND ACCELERON ANNOUNCE LUSPATERCEPT ACHIEVED PRIMARY AND KEY SECONDARY ENDPOINTS IN PHASE III 'MEDALIST' STUDY IN PATIENTS WITH LOW-TO-INTERMEDIATE RISK MYELODYSPLASTIC SYNDROMES

Results showed significant improvement in red blood cell transfusion independence compared to placebo

Safety profile generally consistent with previously published data

Regulatory submissions planned in the United States and Europe in the first half of 2019

SUMMIT, N.J. and CAMBRIDGE, Mass. (June 28, 2018) — Celgene Corporation (NASDAQ: CELG) and Acceleron Pharma Inc. (NASDAQ: XLRN) today announced results from a phase III, randomized, double-blind, multi-center clinical study (MEDALIST). Luspatercept achieved a highly statistically significant improvement in the primary endpoint of red blood cell (RBC) transfusion independence of at least 8 consecutive weeks during the first 24 weeks compared to placebo.

MEDALIST evaluated the efficacy and safety of luspatercept versus placebo in patients with IPSS-R very low, low or intermediate risk myelodysplastic syndromes (MDS) with chronic anemia and refractory to, intolerant of, or ineligible for treatment with an erythropoietin-stimulating agent (ESA), ring sideroblast-positive and require frequent RBC transfusions.

In addition to achieving the primary endpoint of the study, luspatercept also met the key secondary endpoint of demonstrating a highly statistically significant improvement in RBC transfusion independence of at least 12 consecutive weeks during the first 24 weeks. Modified hematologic improvement-erythroid (IWG mHI-E), a meaningful secondary endpoint, was also achieved.

Adverse events observed in the study were generally consistent with previously published data.

"This result from the phase III MEDALIST trial demonstrates the potential clinical benefit of luspatercept as an erythroid maturation agent for the treatment of chronic anemia in patients with low-to-intermediate risk MDS," said Jay Backstrom, M.D., Chief Medical Officer for Celgene. "Based on these results, we look forward to preparing the dossier for global regulatory submissions and also investigating the clinical potential of luspatercept in ESA-naïve, low-to-intermediate risk MDS patients through the initiation of our phase III COMMANDS study."

"We are truly encouraged by the top-line results of MEDALIST and the potential to benefit the tens of thousands of patients suffering from low-to-intermediate risk MDS worldwide. We would like to thank the patients and investigators involved in the trial," said Habib Dable, President and Chief Executive Officer of Acceleron. "With other ongoing research in beta-thalassemia and myelofibrosis, we remain committed to exploring the potential of luspatercept to address a range of anemia-related diseases."

Data from MEDALIST will be submitted to a future medical meeting in 2018. The companies plan to submit regulatory applications in the United States and Europe in the first half of 2019.

Luspatercept is not approved for any indication in any geography.

About Luspatercept

Luspatercept is a first-in-class erythroid maturation agent (EMA) that is believed to regulate late-stage red blood cell maturation. Acceleron and Celgene are jointly developing luspatercept as part of a global collaboration. Phase III clinical trials continue to evaluate the safety and efficacy of luspatercept in patients with MDS (the MEDALIST trial) and in patients with beta-thalassemia (the BELIEVE trial). A Phase III trial is being planned in first-line, lower-risk, MDS patients (the COMMANDS trial). The BEYOND Phase II trial in non-transfusion-dependent beta-thalassemia and a Phase II trial in myelofibrosis are ongoing. For more information, please visit www.clinicaltrials.gov.

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: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

About Acceleron

Acceleron is a Cambridge-based, 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 franchise with two distinct Myostatin+ agents, ACE-083 and ACE-2494, and a 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 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," "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 any product candidate will be successfully developed or complete necessary preclinical and clinical phases, that the results of any clinical study will be predictive for other clinical studies of the same product candidate, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any 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 and preclinical studies, 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; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates ; 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 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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