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): **May 9, 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. ☐

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

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Acceleron Pharma Inc. issued a press release announcing its financial results for the fiscal quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this Item, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release of Acceleron Pharma Inc. dated May 9, 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: May 9, 2019

Exhibit 99.1

Acceleron Reports First Quarter 2019 Operating and Financial Results

– Luspatercept Biologics License Application (BLA) and Marketing Authorization Application (MAA) submitted in April 2019 –

– Part 2 results from the ACE-083 Phase 2 trials in facioscapulohumeral muscular dystrophy (FSHD) expected in the second half of 2019 and Charcot-Marie-Tooth disease (CMT) anticipated in Q1 2020 –

– PULSAR and SPECTRA Phase 2 trials of sotatercept in pulmonary arterial hypertension (PAH) on track with topline results expected from PULSAR in 1H 2020 –

Cambridge, Mass. – May 9, 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 provided a corporate update and reported financial results for the first quarter ended March 31, 2019.

"With the submission of marketing applications for luspatercept in the U.S. and E.U. last month, we and our global collaboration partner, Celgene, are excited about the potential to bring a new therapy to patients with myelodysplastic syndromes and beta-thalassemia within the next year," said Habib Dable, President and Chief Executive Officer of Acceleron. "At the same time, our pulmonary program remains on track, with enrollment ongoing in two Phase 2 trials of sotatercept in PAH, and we are anticipating topline results from the placebo-controlled part of the Phase 2 trial of our locally-acting muscle agent, ACE-083, in FSHD during the second half of this year."

Development Program Highlights

Hematology

Luspatercept: Myelodysplastic Syndromes (MDS), Beta-Thalassemia, and Myelofibrosis (MF)
Luspatercept is an investigational first-in-class erythroid maturation agent (EMA) designed to address a late-stage erythroid maturation defect that results in chronic anemia and the need for regular red blood cell transfusions in adults with serious hematologic diseases. Luspatercept is part of the global collaboration between Acceleron and Celgene.

- Celgene recently submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for luspatercept in patients with MDS- and beta-thalassemia-associated anemia based on the safety and efficacy results of the pivotal Phase 3 studies MEDALIST and BELIEVE.

- The Companies expect to announce preliminary topline results from the Phase 2 trial of luspatercept in patients with MF in the second half of 2019.

- Enrollment is ongoing in the COMMANDS Phase 3 trial in patients with first-line lower-risk MDS and the BEYOND Phase 2 trial in patients with non-transfusion-dependent beta-thalassemia, with preliminary results expected from the BEYOND trial in 2020.

Neuromuscular Disease

ACE-083: Facioscapulohumeral Muscular Dystrophy (FSHD) and Charcot-Marie-Tooth Disease (CMT)
ACE-083 is an investigational locally-acting therapeutic designed to have a concentrated effect on muscle mass and strength in target muscles for diseases that cause focal muscle weakness. ACE-083 utilizes the "Myostatin+" approach to inhibit multiple TGF-beta superfamily ligands involved in muscle formation.

- Previously presented results from Part 1 of the Phase 2 trial evaluating ACE-083 in patients with FSHD were highlighted in an encore presentation at the Muscular Dystrophy Association (MDA) Clinical & Scientific Conference in April 2019.

- Preliminary results from Part 2 of the Phase 2 trial in patients with FSHD are expected in the second half of 2019.
- Previously presented results from Part 1 of the Phase 2 trial evaluating ACE-083 in patients with CMT will be highlighted in a platform presentation at the American Academy of Neurology (AAN) 71st Annual Meeting on May 10, 2019.
- Enrollment is ongoing in Part 2 of the Phase 2 trial in patients with CMT, with preliminary results expected in the first quarter of 2020.

Pulmonary Disease

Sotatercept: Pulmonary Arterial Hypertension (PAH)
Sotatercept is an investigational agent designed to be a selective ligand trap for members of the TGF-beta superfamily to rebalance BMPR2 signaling, which is a key molecular driver of PAH. In preclinical studies of PAH, sotatercept reversed pulmonary vessel muscularization and improved indicators of right heart failure.

- Enrollment is ongoing in the PULSAR Phase 2 trial in patients with PAH, with topline results expected in the first half of 2020.
- Enrollment is ongoing in the exploratory SPECTRA trial in patients with PAH, with preliminary results expected in 2020.
- A preclinical abstract of sotatercept in PAH has been accepted for presentation at the American Thoracic Society (ATS) 2019 International Conference on May 21, 2019.

Financial Results

- **Cash Position** – Cash, cash equivalents and investments as of March 31, 2019 were $513.1 million. As of December 31, 2018, the Company had cash, cash equivalents and investments of $291.3 million. Based on the Company's current operating plan and projections, it believes that current cash, cash equivalents and investments will be sufficient to fund projected operating requirements until such time as it expects to receive significant royalty revenue from luspatercept sales.
- **Revenue** – Collaboration revenue for the first quarter was $2.8 million. The revenue is all from the Company's partnership with Celgene and is primarily related to expenses incurred by the Company in support of luspatercept.
- **Costs and Expenses** – Total costs and expenses for the first quarter were $43.6 million. This includes R&D expenses of $32.8 million and G&A expenses of $10.8 million.
- **Net loss** – The Company's net loss for the first quarter ended March 31, 2019 was $38.1 million.

Conference Call and Webcast

The Company will host a webcast and conference call to discuss its first quarter 2019 financial results and provide an update on recent corporate activities on May 9, 2019, at 5:00 p.m. EDT.

The webcast will be accessible under "Events & Presentations" in the Investors/Media page of the Company's website at www.acceleronpharma.com. Individuals can participate in the conference call by dialing 877-312-5848 (domestic) or 253-237-1155 (international) and referring to the "Acceleron First Quarter 2019 Earnings Call."

The archived webcast will be available for replay on the Acceleron website approximately two hours after the event.

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.

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED BALANCE SHEET

(Amounts in thousands)

(unaudited)

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 214,490	$ 144,052
Short and long-term investments	298,615	147,260
Operating lease assets	27,817	—
Other assets	19,408	23,509
Total assets	$ 560,330	$ 314,821
Short-term and long-term operating lease liabilities	$ 30,455	$ —
Warrants to purchase common stock	1,607	1,491
Other liabilities	17,733	21,292
Total liabilities	49,795	22,784
Total stockholders' equity	510,535	292,037
Total liabilities and stockholders' equity	$ 560,330	$ 314,821

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

(unaudited)

	Three Months Ended March 31,	
	2019	2018
Revenue:		
Collaboration revenue	$ 2,780	$ 3,232
Costs and expenses:		
Research and development	32,771	23,431
General and administrative	10,814	7,441
Total costs and expenses	43,585	30,872
Loss from operations	(40,805)	(27,640)
Total other income, net	2,772	1,431
Loss before income taxes	(38,033)	(26,209)
Income tax provision	(20)	(10)
Net loss applicable to common stockholders- basic and diluted	$ (38,053)	$ (26,219)
Net loss per share applicable to common stockholders- basic and diluted	$ (0.74)	$ (0.58)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders	51,126	45,516

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 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 factors, 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 results of any clinical trial may not be predictive of the results or success of other clinical trials of the same product candidate, that the development of the Company's compounds will take longer and/or cost more than planned, that the Company or its collaboration partner, Celgene, will be unable to successfully complete the clinical development of the Company's compounds, that the Company or Celgene 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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