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): **February 27, 2020**

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))

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 2.02 Results of Operations and Financial Condition.

On February 27, 2020, Acceleron Pharma Inc. issued a press release announcing its financial results for the fourth quarter and year ended December 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 February 27, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.
Senior Vice President, General Counsel and Secretary

Date: February 27, 2020

Acceleron Reports Fourth Quarter and Full Year 2019 Operating and Financial Results

- REBLOZYL® (luspatercept-aamt), a first-in-class erythroid maturation agent, was approved by the U.S. FDA for the treatment of anemia in adult patients with beta-thalassemia who require regular red blood cell transfusions; FDA review of the sBLA for the lower-risk myelodysplastic syndromes indication is ongoing -

- Multiple clinical presentations reviewed at the 61st American Society of Hematology (ASH) Annual Meeting; MEDALIST trial results published in New England Journal of Medicine -

- The PULSAR Phase 2 trial of sotatercept in patients with pulmonary arterial hypertension (PAH) achieved its primary and key secondary endpoints -

Cambridge, Mass. - February 27, 2020 - Acceleron Pharma Inc. (Nasdaq: XLRN), a biopharmaceutical company dedicated to the discovery, development, and commercialization of TGF-beta superfamily therapeutics to treat serious and rare diseases, today provided a corporate update and reported financial results for the fourth quarter and full year ended December 31, 2019.

“2019 was a pivotal year for Acceleron as we achieved the most important milestone to date in our 16-year history-our first U.S. FDA approval,” said Habib Dable, President and Chief Executive Officer of Acceleron. “In November, REBLOZYL® (luspatercept-aamt) became the first and only FDA approved erythroid maturation agent and is now indicated to treat anemia in adults with beta-thalassemia who require regular red blood cell transfusions. The approval of REBLOZYL® marks a huge victory for patients with beta-thalassemia, who-up until now-have been waiting for a better way to treat their anemia. It is also a validation of Acceleron’s scientific platform leveraging our expertise in the TGF-beta superfamily of proteins and our unwavering commitment to develop and commercialize medicines to treat serious and rare diseases.”

Continued Mr. Dable: “While our hematology program remains a top priority, we are equally excited by the progress we are making in pulmonary disease. We recently announced positive topline results from the PULSAR Phase 2 trial of sotatercept for the treatment of PAH. These data introduce the possibility that sotatercept could potentially change the way physicians currently treat patients with PAH. We look forward to presenting the detailed topline results at the American Thoracic Society 2020 International Conference in May and to our upcoming interactions with health authorities as we plan to globally develop and, if approved, commercialize sotatercept in PAH. We also expect to announce topline results from our Phase 2 neuromuscular program in Charcot-Marie-Tooth disease in March.”

Development Program Highlights

Hematology

REBLOZYL® (luspatercept-aamt): Myelodysplastic Syndromes (MDS), Beta-Thalassemia, and Myelofibrosis (MF)
REBLOZYL® is the first and only U.S. FDA approved erythroid maturation agent designed to promote red blood cell production through a novel mechanism. Luspatercept-aamt is being developed to treat anemia in patients with beta-thalassemia, MDS, or MF. REBLOZYL® is part of the global collaboration between Acceleron and Bristol-Myers Squibb.

- In November 2019, Acceleron and partner Bristol-Myers Squibb announced the FDA approved REBLOZYL® for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions. The companies are also seeking approval of luspatercept-aamt for the treatment of anemia in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who have ring sideroblasts and require red blood cell (RBC) transfusions. The FDA target action date for the MDS indication is April 4, 2020.

- In January 2020, the *New England Journal of Medicine* published results from MEDALIST, the pivotal Phase 3 study evaluating the use of luspatercept-aamt to treat anemia in adult patients with very low- to intermediate-risk MDS who have ring sideroblasts and require RBC transfusions.

- Six clinical abstracts of luspatercept-aamt were presented at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando in December 2019, including:

- Long-term results from two pivotal Phase 3 trials, the MEDALIST and BELIEVE trials;
- Initial results from a Phase 2 trial in patients with anemia associated with MF.

- The Company and partner Bristol-Myers Squibb announced plans for a pivotal Phase 3 study, called INDEPENDENCE, of luspatercept-aamt in adult patients with anemia associated with MF who are being treated with JAK inhibitor therapy and require RBC transfusions. The study is expected to open in 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 (RAP-011) reversed pulmonary vessel muscularization and improved indicators of right heart failure.

- In January 2020, Acceleron reported that the PULSAR Phase 2 trial in patients with PAH met its primary and key secondary endpoints. Sotatercept was generally well tolerated in the trial and adverse events observed in the study were generally consistent with previously published data on sotatercept in other diseases.
    - The PULSAR topline results are expected to be presented at the American Thoracic Society's (ATS) 2020 International Conference in Philadelphia, Pennsylvania, on May 15 to 20, 2020.
- Enrollment is ongoing in the SPECTRA trial in patients with PAH, with preliminary results expected in 2020.

Additional Pulmonary Updates

- The Company entered into a collaboration and license agreement with Fulcrum Therapeutics to identify small molecules designed to modulate specific pathways associated with a targeted indication within the pulmonary disease space.

Neuromuscular Disease

ACE-083: 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.

- Topline results from Part 2 of the Phase 2 trial in patients with CMT are expected in March 2020.

Corporate Highlights

- In December, Jay T. Backstrom, M.D., M.P.H., formerly Chief Medical Officer of Celgene, joined Acceleron's senior leadership team as Head of Research and Development.
- Kemal Malik, M.B. B.S., was appointed to the Board of Directors effective January 1, 2020. Dr. Malik has served on the Board of Management of Bayer AG since 2014, with responsibility for Innovation across the Bayer group.

Financial Results

- **Cash Position** – Cash, cash equivalents and investments as of December 31, 2019 were $453.8 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 REBLOZYL® sales.

- **Revenue** – Collaboration revenue for the year was $74.0 million. The revenue was all derived from the Company's partnership with Bristol-Myers Squibb and is primarily related to expenses incurred by the Company in support of REBLOZYL®, as well as one-time gross milestone payments totaling $60.0 million earned upon the FDA acceptance of the BLA and EMA validation of the MAA of REBLOZYL® in June, and the FDA approval of REBLOZYL® in November 2019.

- **Costs and Expenses** – Total costs and expenses for the year were $210.4 million. This included R&D expenses of $154.0 million and G&A expenses of $56.4 million.

- **Net Loss** – The Company's net loss for the year ended December 31, 2019 was $124.9 million.

Conference Call and Webcast

The Company will host a webcast and conference call to discuss its fourth quarter and full year financial results for 2019 and provide an update on recent corporate activities on February 27, 2020, at 5:00 p.m. EST.

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 Fourth Quarter and Full Year 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 biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases. Acceleron's leadership in the understanding of TGF-beta superfamily 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, pulmonary, and neuromuscular diseases. In hematology, Acceleron and its global collaboration partner, Bristol-Myers Squibb, are co-promoting newly approved REBLOZYL® (luspatercept-aamt), the first and only approved erythroid maturation agent, in the United States and are developing luspatercept for the treatment of chronic anemia in myelodysplastic syndromes and myelofibrosis. Acceleron is developing sotatercept for the treatment of pulmonary arterial hypertension, having recently reported positive topline results of the Phase 2 PULSAR trial and actively enrolling patients in the Phase 2 SPECTRA trial. The company is also advancing its neuromuscular program with ACE-083, a locally-acting Myostatin+ agent in Phase 2 development in Charcot-Marie-Tooth disease.

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)

	December 31,	
	2019	2018
Cash and cash equivalents	$ 237,677	$ 144,052
Short and long-term investments	216,169	147,260
Operating lease assets	23,908	—
Other assets	27,152	23,509
Total assets	$ 504,906	$ 314,821
Short-term and long-term operating lease liabilities	$ 26,384	$ —
Warrants to purchase common stock	1,856	1,491
Other liabilities	27,190	21,293
Total liabilities	55,430	22,784
Total stockholders' equity	449,476	292,037
Total liabilities and stockholders' equity	$ 504,906	$ 314,821

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	$ 39,338	$ 3,816	$ 73,993	$ 13,991
Costs and expenses:				
Research and development	48,852	29,867	153,953	103,902
Selling, general and administrative	16,067	10,755	56,485	34,503
Total costs and expenses	64,919	40,622	210,438	138,405
Loss from operations	(25,581)	(36,806)	(136,445)	(124,414)
Total other income, net	2,002	2,036	11,525	5,516
Loss before income taxes	(23,579)	(34,770)	(124,920)	(118,898)
Income tax benefit	4	36	62	27
Net loss	$ (23,575)	$ (34,734)	$ (124,858)	$ (118,871)
Net loss per share - basic and diluted	$ (0.44)	$ (0.75)	$ (2.38)	$ (2.59)
Weighted-average number of common shares used in computing net loss per share	53,087	46,227	52,453	45,898

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 and commercialization of the Company's compounds, the timeline for clinical development and regulatory approval of the Company's compounds, the expected timing for reporting of data from ongoing clinical trials, the Company's future cash position and the potential of REBLOZYL® (luspatercept-aamt) as a therapeutic drug. 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, 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 trials may not be predictive of the results or success of other clinical trials, that regulatory approval of the Company's compounds in one indication or country may not be predictive of approval in another indication or country, that the development of the Company's compounds will take longer and/or cost more than planned or accelerate faster than currently expected, that the Company or its collaboration partner, Bristol-Myers Squibb Corporation ("BMS"), will be unable to successfully complete the clinical development of the Company's compounds, that the Company or BMS 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

Contacts:
Acceleron Pharma Inc.
Investors:
Todd James, (617) 649-9393
Senior Vice President, Corporate Affairs and Investor Relations

or

Media:
Matt Fearer, (617) 301-9557
Director, Corporate Communications

###