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 11, 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 May 11, 2020, Acceleron Pharma Inc. issued a press release announcing its financial results for the fiscal quarter ended March 31, 2020. 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 11, 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: May 11, 2020

Acceleron Reports First Quarter 2020 Operating and Financial Results

- REBLOZYL® (luspatercept-aamt), a first-in-class erythroid maturation agent, was approved by the U.S. FDA to treat anemia in adults with lower-risk myelodysplastic syndromes (MDS) -

- REBLOZYL received positive CHMP opinion for the treatment of adults with transfusion-dependent anemia in lower-risk MDS and beta-thalassemia -

- Pivotal Phase 3 MEDALIST and BELIEVE trial results published in New England Journal of Medicine -

- Sotatercept granted Breakthrough Therapy designation by FDA and Priority Medicines (PRIME) designation by EMA for the treatment of patients with pulmonary arterial hypertension (PAH) -

- PULSAR Phase 2 topline results are expected to be presented in an American Thoracic Society (ATS) 2020 web-based conference session by the end of June 2020 -

Cambridge, Mass. – May 11, 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 first quarter ended March 31, 2020.

“Acceleron is off to a strong start in 2020, propelled by one of the most eventful time periods in the Company’s history,” said Habib Dable, President and Chief Executive Officer of Acceleron. “The breadth and depth of our hematology program has been on full display, owing to the publication of the MEDALIST and BELIEVE Phase 3 luspatercept trial results in the prestigious *New England Journal of Medicine* and the recent FDA approval of REBLOZYL for the treatment of anemia in a population of patients with lower-risk MDS. We’re thrilled that this first-in-class erythroid maturation agent, having received approvals in two distinct indications over a span of just five months, is now available in the US to patients who have long needed a new option for treating their chronic anemias.”

Added Mr. Dable: “Our scientific expertise in leveraging the therapeutic potential of the TGF-beta superfamily of proteins is delivering equally exciting results in pulmonary disease. With great enthusiasm, we announced that the PULSAR Phase 2 trial of sotatercept in patients with PAH met its primary and key secondary endpoints-underscoring our belief that sotatercept could eventually alter the current treatment paradigm. Following the results, sotatercept was granted Breakthrough Therapy designation by the FDA and PRIME designation by the EMA. We look forward to presenting topline results from PULSAR in a virtual meeting of the ATS as well as interactions with health authorities as we prepare for future Phase 3 development of sotatercept on our path to potential global registration.”

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, and MF. REBLOZYL is part of the global collaboration between Acceleron and Bristol Myers Squibb.

- In April, Acceleron and partner Bristol Myers Squibb announced the FDA approved REBLOZYL for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks in adult patients with very low- to intermediate-risk MDS with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

- The *New England Journal of Medicine* published results from the pivotal Phase 3 MEDALIST and BELIEVE trials.

- In April, REBLOZYL received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the treatment of adult patients with:
    - transfusion-dependent anemia due to very low-, low- and intermediate-risk MDS with ring sideroblasts, who had an unsatisfactory response or are ineligible for erythropoietin-based therapy; and
    - transfusion-dependent anemia associated with beta thalassemia

- Bristol Myers Squibb expects to initiate the Phase 3 INDEPENDENCE trial in patients with MF on concomitant JAK 2 inhibitor therapy who require RBC transfusions by year-end 2020.

- The BEYOND Phase 2 trial in adult patients with non-transfusion-dependent beta-thalassemia is ongoing, with topline results expected by year-end 2020 or early 2021.

- Enrollment is ongoing in the COMMANDS Phase 3 trial in patients with treatment-naïve, lower-risk MDS, with topline results expected in 2022.

Pulmonary

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, 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 were generally consistent with previously published data on sotatercept in other diseases.

    - PULSAR Phase 2 topline results are expected to be presented in an American Thoracic Society (ATS) 2020 web-based session by the end of June 2020.

    - Acceleron plans to host a webcast and conference call for investors and analysts following the ATS 2020 virtual presentation to discuss highlights from the PULSAR trial results.

- In April, sotatercept was granted Breakthrough Therapy designation by the FDA for the treatment of patients with PAH (World Health Organization Group 1).

- The EMA recently granted Priority Medicines (PRIME) designation to sotatercept for the treatment of patients with PAH.

- Enrollment is ongoing in the exploratory SPECTRA trial in patients with PAH, with preliminary results expected in 2020.

Financial Results

- **Cash Position -** Cash, cash equivalents and investments as of March 31, 2020 were $415.6 million, as compared to $453.8 million as of December 31, 2019. 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** - Revenue for the first quarter of 2020 was $4.3 million, which includes $2.8 million of cost share revenue, and $1.5 million of royalty revenue from net U.S. sales of REBLOZYL. All revenue was derived from the Company's partnership with Bristol Myers Squibb.

- **Costs and Expenses** - Total costs and expenses for the first quarter of 2020 were $55.9 million. This includes R&D expenses of $37.7 million and SG&A expenses of $18.3 million.

- **Net Loss** - The Company's net loss for the first quarter of 2020 was $50.9 million.

Conference Call and Webcast

The Company will host a webcast and conference call to discuss its first quarter 2020 financial results and provide an update on recent corporate activities on May 11, 2020, 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 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 2020 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 commercialization, research, and development efforts in hematologic and pulmonary diseases. In hematology, Acceleron and its global collaboration partner, Bristol Myers Squibb, are co-promoting REBLOZYL® (luspatercept-aamt), the first and only approved erythroid maturation agent, in the United States for the treatment of anemia in certain blood disorders. The Companies are also developing luspatercept for the treatment of anemia in patient populations of MDS, beta-thalassemia, and myelofibrosis. In pulmonary, Acceleron is developing sotatercept for the treatment of pulmonary arterial hypertension, having recently reported positive topline results of the Phase 2 PULSAR trial.

For more information, please visit acceleronpharma.com. Follow Acceleron on social media: @AcceleronPharma and LinkedIn.

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED BALANCE SHEET

(Amounts in thousands)

(unaudited)

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 277,486	$ 237,677
Short and long-term investments	138,077	216,169
Operating lease - right of use asset, net	22,531	23,908
Other assets	26,068	27,152
Total assets	$ 464,162	$ 504,906
Operating lease liability - right of use, short-term and long-term	$ 24,918	$ 26,384
Warrants to purchase common stock	3,304	1,856
Other liabilities	22,118	27,190
Total liabilities	50,340	55,430
Total stockholders' equity	413,822	449,476
Total liabilities and stockholders' equity	$ 464,162	$ 504,906

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

(unaudited)

	Three Months Ended March 31, 2020	
	2020	2019
Revenue:		
Collaboration revenue:	$ 4,344	$ 2,780
Costs and expenses:		
Research and development	37,663	32,771
Selling, general and administrative	18,253	10,814
Total costs and expenses	55,916	43,585
Loss from operations	(51,572)	(40,805)
Other income, net	648	2,772
Loss before income taxes	(50,924)	(38,033)
Income tax provision	(15)	(20)
Net loss	$ (50,939)	$ (38,053)
Net loss per share- basic and diluted	$ (0.95)	$ (0.74)
Weighted-average number of common shares used in computing net loss per share- basic and diluted	53,361	51,126

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, that preclinical testing of the Company's compounds and data from 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, Quarterly Report on Form 10-Q, 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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