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): **August 6, 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** (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))

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 August 6, 2020, Acceleron Pharma Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 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 August 6, 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: August 6, 2020

Acceleron Reports Second Quarter 2020 Operating and Financial Results

- Acceleron recognized approximately $11.1 million in royalty revenue for Q2 2020 from approximately $55.0 million in net U.S. sales of REBLOZYL® (luspatercept-aamt) and a $25.0 million regulatory-based milestone from Bristol Myers Squibb -

- REBLOZYL, the first and only erythroid maturation agent, was approved by the European Commission (EC) to treat transfusion-dependent anemia in adults with myelodysplastic syndromes (MDS) or beta-thalassemia -

- PULSAR Phase 2 topline results presented at the American Thoracic Society (ATS) 2020 Virtual Conference -

- Acceleron plans to host an investor and analyst webinar to discuss the pivotal Phase 3 STELLAR trial design in October 2020 -

- Acceleron raised $492.5 million in net proceeds from a follow-on public offering of common stock, completed in July 2020 -

Cambridge, Mass. – August 6, 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 second quarter ended June 30, 2020.

“Acceleron had another productive quarter marked by additional regulatory approvals of REBLOZYL in the U.S. and E.U., strong product uptake resulting in subsequent royalty revenues, and multiple important updates for our lead program in pulmonary disease,” said Habib Dable, President and Chief Executive Officer of Acceleron. “Alongside our global collaboration partner, Bristol Myers Squibb, the U.S. commercial launch of REBLOZYL is off to a great start in only its second full quarter since we received our first approval late last year. We also continue to make progress in evaluating additional patient populations in which this erythroid maturation agent could potentially reduce or eliminate red blood cell transfusion burden in patients with anemia-related blood disorders.”

Added Mr. Dable: “Beyond our hematology franchise, we continue to make significant progress in advancing our pulmonary program in pulmonary arterial hypertension. Recently, we presented positive topline results from the Phase 2 PULSAR trial at the country’s premiere thoracic medical meeting, ATS 2020. In early October, we look forward to hosting a call to discuss the trial design for our first planned registrational trial, called STELLAR, which we expect to initiate by year-end. Our future development plan will support our long-term vision for sotatercept to become a backbone therapy for patients with PAH across all stages of disease.”

Program Highlights

Hematology

REBLOZYL (luspatercept-aamt): Myelodysplastic Syndromes (MDS), Beta-Thalassemia, and Myelofibrosis (MF)
REBLOZYL is the first and only approved erythroid maturation agent designed to promote red blood cell (RBC) production. Luspatercept is also being developed for the treatment of anemia in additional patient populations of MDS, beta-thalassemia, and MF. REBLOZYL is part of the global collaboration between Acceleron and Bristol Myers Squibb.

- Commercial launch of REBLOZYL:
  - The Company recognized approximately $11.1 million in royalty revenue from approximately $55.0 million of net U.S. sales of REBLOZYL in the second quarter of 2020. This compares with approximately $1.5 million in royalty revenue from approximately $8 million of net U.S. sales of REBLOZYL in the first quarter of 2020.

- 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).

- In June, the European Commission (EC) approved REBLOZYL 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; or
  - associated with beta thalassemia.

- The Centers for Medicare and Medicaid Services (CMS) established a REBLOZYL specific, permanent billing code (J code), which became effective on July 1, 2020.

- Six distinct clinical presentations highlighting new and long-term analyses from the pivotal Phase 3 MEDALIST and BELIEVE trials were presented at the American Society of Clinical Oncology 2020 (ASCO20) Virtual Scientific Program and the 25th Annual European Hematology Association (EHA25) Virtual Congress.

- 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+.

- 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 or early 2021.

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 June, Acceleron presented positive topline results of the PULSAR Phase 2 trial of sotatercept in patients with PAH during the “Breaking News: Clinical Trials in Pulmonary Medicine” session of the American Thoracic Society (ATS) 2020 Virtual Conference. The press release highlighting the presentation is available here.

- The Company expects to initiate the pivotal Phase 3 STELLAR trial in PAH by year-end 2020.

- Acceleron plans to host an investor and analyst webinar to discuss the Phase 3 STELLAR trial design in October 2020.

- In the second quarter, sotatercept was granted Breakthrough Therapy and Priority Medicines (PRIME) designations for the treatment of patients with PAH by the FDA and EMA, respectively.

- Preclinical research describing the underlying biology behind sotatercept’s potential as a novel therapy in PAH were published in the journal of *Science Translational Medicine* in May.

- Enrollment is ongoing in the exploratory SPECTRA trial in patients with PAH, with preliminary results expected in the first half of 2021.

Corporate Highlights

- In July, Acceleron closed a follow-on public offering of common stock, including the full exercise of the underwriters' option to purchase additional shares, for net proceeds of $492.5 million.

- In June, Christopher Hite was appointed to the Board of Directors. Mr. Hite brings more than 20 years of industry experience in advising hundreds of healthcare companies on projects ranging from mergers and acquisitions to capital formation.

Financial Results

- **Cash Position** - Cash, cash equivalents, and investments as of June 30, 2020 were $389.8 million, as compared to $453.8 million as of December 31, 2019. Based on Acceleron's current operating plan and projections, the Company believes that its cash, cash equivalents, and investments, together with the net proceeds of $492.5 million from its recent public offering of common stock and expected royalty revenue from REBLOZYL sales, will be sufficient to fund the Company's projected operating requirements for the foreseeable future.

- **Revenue** - Revenue for the second quarter of 2020 was $39.8 million, which includes $3.7 million of cost share revenue, $11.1 million of royalty revenue from net U.S. sales of REBLOZYL, and the recognition of a $25.0 million regulatory-based milestone for the approval of REBLOZYL in Europe. This compares with total revenue of $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 in the first quarter of 2020. All revenue was derived from the Company's partnership with Bristol Myers Squibb.

- **Costs and Expenses** - Total costs and expenses for the second quarter of 2020 were $58.7 million. This includes R&D expenses of $38.3 million and SG&A expenses of $20.4 million.

- **Net Loss** - The Company's net loss for the second quarter of 2020 was $18.5 million.

Conference Call and Webcast

The Company will host a webcast and conference call to discuss its second quarter 2020 financial results and provide an update on recent corporate activities on August 6, 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 Second 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, REBLOZYL® (luspatercept-aamt) is the first and only erythroid maturation agent approved in the United States and Europe for the treatment of anemia in certain blood disorders. REBLOZYL is part of a global collaboration partnership with Bristol Myers Squibb. The Companies co-promote REBLOZYL in the United States and 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)

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 283,521	$ 237,677
Short and long-term investments	106,289	216,169
Operating lease - right of use asset, net	21,116	23,908
Other assets	68,509	27,152
Total assets	$ 479,435	$ 504,906
Operating lease liability - right of use, short-term and long-term	$ 23,407	$ 26,384
Warrants to purchase common stock	3,516	1,856
Other liabilities	30,893	27,190
Total liabilities	57,816	55,430
Total stockholders' equity	421,619	449,476
Total liabilities and stockholders' equity	$ 479,435	$ 504,906

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Collaboration revenue	$ 39,752	$ 27,666	$ 44,096	$ 30,447
Costs and expenses:				
Research and development	38,251	34,765	75,917	67,536
Selling, general and administrative	20,414	14,037	38,663	24,851
Total costs and expenses	58,665	48,802	114,580	92,387
Loss from operations	(18,913)	(21,136)	(70,484)	(61,940)
Other income, net	466	3,230	1,113	6,003
Loss before income taxes	(18,447)	(17,906)	(69,371)	(55,937)
Income tax (provision) benefit	(4)	44	(20)	24
Net loss	$ (18,451)	$ (17,862)	$ (69,391)	$ (55,913)
Net loss per share- basic and diluted	$ (0.34)	$ (0.34)	$ (1.29)	$ (1.08)
Weighted-average number of common shares used in computing net loss per share- basic and diluted	53,860	52,689	53,610	51,912

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 may take longer and/or cost more than planned or accelerate faster than currently expected, that the Company or its collaboration partner, Bristol Myers Squibb ("BMS"), may 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 may 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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