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): **November 5, 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 November 5, 2020, Acceleron Pharma Inc. issued a press release announcing its financial results for the fiscal quarter ended September 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 November 5, 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: November 5, 2020

Acceleron Reports Third Quarter 2020 Operating and Financial Results

- Acceleron recognized approximately $19.3 million in royalty revenue for Q3 2020 from approximately $96 million in net sales of REBLOZYL® (luspatercept-aamt) -

- REBLOZYL, the first and only erythroid maturation agent, was approved by Health Canada for the treatment of transfusion-dependent anemia in adults with beta-thalassemia -

- Registrational STELLAR Phase 3 trial of sotatercept in patients with pulmonary arterial hypertension (PAH) on track to initiate by year-end 2020 -

Cambridge, Mass. – November 5, 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 third quarter ended September 30, 2020.

“Acceleron has made significant progress this year with continued market expansion and adoption of REBLOZYL, and the finalization of the global regulatory path for sotatercept in PAH,” said Habib Dable, President and Chief Executive Officer of Acceleron. “Months into the commercial launch of REBLOZYL, we and our partner Bristol Myers Squibb continue to see strong product uptake in the U.S. along with initial sales contributions from the recent availability of REBLOZYL in certain E.U. countries. Adding to the momentum, we successfully expanded the global reach of REBLOZYL with its recent approval by Health Canada.”

Added Mr. Dable: “As our hematology franchise continues to grow, we are advancing our pulmonary program, with a primary focus in PAH. Encouraged by the impressive topline results from our PULSAR Phase 2 trial, we look forward to multiple presentations on sotatercept at the upcoming virtual meeting of the AHA 2020 Scientific Sessions next week as our team is preparing to initiate our registrational Phase 3 trial, called STELLAR.”

Program Highlights

Hematology

REBLOZYL (luspatercept-aamt):
REBLOZYL is the first and only approved erythroid maturation agent designed to promote late-stage red blood cell (RBC) production. REBLOZYL is part of the global collaboration between Acceleron and Bristol Myers Squibb.

- Commercial Launch of REBLOZYL:
  - The Company recognized approximately $19.3 million in royalty revenue from approximately $96 million in net sales of REBLOZYL in the third quarter of 2020. This compares with approximately $11.1 million in royalty revenue from approximately $55 million in net sales of REBLOZYL in the second quarter of 2020.

- Regulatory:
  - In September, Acceleron and partner Bristol Myers Squibb announced that Health Canada approved REBLOZYL for the treatment of adult patients with red blood cell transfusion-dependent anemia associated with beta(β)-thalassemia.

- Clinical Development:
  - 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 first-line lower-risk myelodysplastic syndromes

  - Bristol Myers Squibb expects to initiate the INDEPENDENCE Phase 3 trial in patients with myelofibrosis in Q1 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 research published in Science Translational Medicine, sotatercept (RAP-011) reversed pulmonary vessel muscularization and improved indicators of right heart failure in models of PAH.

- In October, the Company highlighted the trial design for its upcoming registrational STELLAR Phase 3 trial in patients with PAH, which it plans to initiate by year-end 2020.
- The Company plans to present the 24-week echocardiography results from the PULSAR Phase 2 trial at the virtual 2020 American Heart Association (AHA) Scientific Sessions taking place November 13-17. In addition, preliminary interim results from the SPECTRA Phase 2 trial will be presented at the congress.
- Results from the open-label extension period of the PULSAR Phase 2 trial and additional results from the ongoing SPECTRA Phase 2 trial are expected in the first half of 2021.
- The Company expects to initiate the HYPERION (early intervention) Phase 3 trial and the ZENITH (later intervention) Phase 3 trial in expanded PAH populations in the middle 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 $492.4 million.
- In September, Laura J. Hamill was appointed to the Board of Directors. Ms. Hamill has more than three decades of experience in the biopharma industry.

Financial Results

- **Cash Position** - Cash, cash equivalents and investments as of September 30, 2020 were $887.4 million, compared with $453.8 million as of December 31, 2019. Based on Acceleron's current operating plan and projections, the Company believes that its current cash, cash equivalents and investments, along with the 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 third quarter of 2020 was $22.6 million, which includes $3.3 million of cost share revenue and $19.3 million of royalty revenue from net 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 third quarter of 2020 were $61.8 million. This includes R&D expenses of $40.8 million and SG&A expenses of $21.0 million.
- **Net Loss** - The Company's net loss for the third quarter of 2020 was $39.2 million.

Conference Call and Webcast

The Company will host a webcast and conference call to discuss its third quarter 2020 financial results and provide an update on recent corporate activities on November 5, 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 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 Third 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, Europe, and Canada 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 North America 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 (PAH), having recently presented positive topline results of the PULSAR Phase 2 trial. The Company is currently planning multiple Phase 3 trials with the potential to support its long-term vision of establishing sotatercept as a backbone therapy for patients with PAH at all stages of the disease.

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)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 729,685	$ 237,677
Short and long-term investments	157,676	216,169
Operating lease - right of use asset, net	19,660	23,908
Other assets	40,744	27,152
Total assets	$ 947,765	$ 504,906
Operating lease liability - right of use, short-term and long-term	$ 21,851	$ 26,384
Warrants to purchase common stock	—	1,856
Other liabilities	30,778	27,190
Total liabilities	52,629	55,430
Total stockholders' equity	895,136	449,476
Total liabilities and stockholders' equity	$ 947,765	$ 504,906

ACCELERON PHARMA INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands except per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Collaboration revenue	$ 22,561	$ 4,208	$ 66,656	$ 34,655
Costs and expenses:				
Research and development	40,747	37,630	116,663	105,125
Selling, general and administrative	21,042	15,501	59,705	40,394
Total costs and expenses	61,789	53,131	176,368	145,519
Loss from operations	(39,228)	(48,923)	(109,712)	(110,864)
Other (expense), income net	(6)	3,520	1,108	9,523
Loss before income taxes	(39,234)	(45,403)	(108,604)	(101,341)
Income tax (provision) benefit	(11)	34	(31)	58
Net loss	$ (39,245)	$ (45,369)	$ (108,635)	$ (101,283)
Net loss per share- basic and diluted	$ (0.66)	$ (0.86)	$ (1.95)	$ (1.94)
Weighted-average number of common shares used in computing net loss per share- basic and diluted	59,640	52,882	55,635	52,239

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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