

**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): **April 8, 2020**

**ACCELERON PHARMA INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36065**  
(Commission  
File Number)

**27-0072226**  
(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 8.01 Other Events.**

On April 8, 2020, Acceleron Pharma Inc. issued a press release announcing that the U.S. Food and Drug Administration has granted Breakthrough Therapy designation to sotatercept for the treatment of patients with pulmonary arterial hypertension (World Health Organization Group 1).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits.**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
99.1	<a href="#">Press Release of Acceleron Pharma Inc. dated April 8, 2020</a>
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: April 9, 2020



## Acceleron Receives FDA Breakthrough Therapy Designation for Sotatercept in Pulmonary Arterial Hypertension

*Sotatercept granted first FDA Breakthrough Therapy designation in pulmonary arterial hypertension since the Agency established the designation in 2013*

**Cambridge, Mass. – April 8, 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 announced that the United States Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to sotatercept for the treatment of patients with pulmonary arterial hypertension (PAH) (World Health Organization Group 1).

“In January of this year, we reported positive topline results from our PULSAR Phase 2 placebo-controlled trial of sotatercept in patients with PAH,” said Habib Dable, President and Chief Executive Officer of Acceleron. “Based on the results, we believe that sotatercept has the potential to shift the current treatment paradigm and provide significant benefit to patients with PAH on top of currently available therapies. Thus, we’re thrilled that the FDA has granted this Breakthrough Therapy designation—a first for an Acceleron-discovered medicine and for a therapeutic candidate in PAH—as it supports and aligns with our mission to deliver novel therapeutic options to patients in need as quickly as possible.”

The FDA’s Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy designation require preliminary clinical evidence that demonstrates the drug may provide substantial improvement on at least one clinically significant endpoint over available therapy. A Breakthrough Therapy designation conveys more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers, and eligibility for rolling review and priority review. For more information please visit the FDA website at [www.fda.gov](http://www.fda.gov).

In 2019, the FDA granted Orphan Drug designation for Sotatercept in PAH.

### **About Sotatercept**

Sotatercept is an investigational agent designed to be a selective ligand trap for members of the TGF-beta superfamily to rebalance BMPR-II 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. Recent topline analysis of the PULSAR Phase 2 trial of sotatercept in patients with PAH revealed the trial met the primary as well as key and other secondary endpoints, with adverse events consistent with previously published data on sotatercept in other diseases. Sotatercept, which is part of a licensing agreement with Bristol Myers Squibb, is also being evaluated in the SPECTRA Phase 2 trial in patients with PAH. For more information, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Sotatercept is an investigational therapy that is not approved for any use in any country.

### **About PAH**

PAH is a rare and chronic, rapidly progressing disorder characterized by the constriction of small pulmonary arteries and elevated blood pressure in the pulmonary circulation. PAH results in significant strain on the heart, often leading to limited physical activity, heart failure, and reduced life expectancy. The 5-year survival rate for patients with PAH is approximately 57%. Available therapies generally act by promoting the dilation of pulmonary vessels without addressing the underlying cause of the disease. As a



result, PAH often progresses rapidly for many patients despite standard of care treatment. A growing body of research has implicated imbalances in BMP and TGF-beta signaling as a primary driver of PAH in familial, idiopathic, and acquired forms of the disease.

## 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 and pulmonary diseases. In hematology, Acceleron and its global collaboration partner, Bristol-Myers Squibb, are co-promoting newly approved REBLOZYL® (luspaterecept-aamt), the first and only approved erythroid maturation agent, in the United States and are developing luspaterecept for the treatment of chronic anemia in 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.

For more information, please visit [www.acceleronpharma.com](http://www.acceleronpharma.com). Follow Acceleron on social media: [@AcceleronPharma](https://twitter.com/AcceleronPharma) and [LinkedIn](https://www.linkedin.com/company/acceleron).

## Forward-Looking Statements

*This press release contains forward-looking statements about Acceleron's strategy, future plans and prospects, including statements regarding the development of sotatercept in PAH, the timeline for clinical development and regulatory approval of sotatercept in PAH, the expected timing for reporting of data from ongoing clinical trials, and the potential of Acceleron's compounds as therapeutic drugs. The words "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "possible," "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 Acceleron's compounds and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that regulatory approval of Acceleron's compounds in one indication or country may not be predictive of approval in another indication or country, that the development of Acceleron's compounds will take longer and/or cost more than planned, that Acceleron will be unable to successfully complete the clinical development of Acceleron's compounds, that Acceleron may be delayed in initiating, enrolling or completing any clinical trials, that Acceleron's compounds will not receive regulatory approval or become commercially successful products, and that Breakthrough Therapy designation may not expedite the development or review of sotatercept. These and other risks and uncertainties are identified under the heading "Risk Factors" included in Acceleron's most recent Annual Report on Form 10-K, and other filings that Acceleron 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 Acceleron does not undertake and specifically disclaims any obligation to update any forward-looking statements.*



Source: Acceleron Pharma

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