ACCELERON PHARMA INC

FORM 8-K
(Current report filing)

Filed 09/19/17 for the Period Ending 09/18/17

Address	128 SIDNEY STREET
	CAMBRIDGE, MA, 02139
Telephone	617-649-9200
CIK	0001280600
Symbol	XLRN
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): **September 18, 2017**

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))

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 1.01 Entry into a Material Definitive Agreement.

On September 18, 2017, Acceleron Pharma Inc. (the "Company") and Celgene Corporation ("Celgene") entered into an Amended and Restated Collaboration, License and Option Agreement (the "Amended Agreement") that amends and restates their existing Collaboration, License and Option Agreement, dated as of February 20, 2008 and amended as of August 2, 2011 (the "Original Agreement"), related to the development of the Company's therapeutic candidate, sotatercept, as well as the investigation and development of other protein-based product candidates incorporating ActRIIA. The agreement between the parties pertaining to the Phase 3 therapeutic candidate luspatercept (the "Luspatercept Agreement") was not amended.

Under the Amended Agreement, Celgene granted the Company worldwide rights to develop and commercialize sotatercept for the treatment, prevention, modulation and diagnosis of pulmonary hypertension in humans. In addition, Celgene agreed not to develop or commercialize in the field of pulmonary hypertension any compound developed under the Amended Agreement or the Luspatercept Agreement. The Company agreed not to develop or commercialize any compound developed under the Amended Agreement or the Luspatercept Agreement in any field outside of pulmonary hypertension. The Company has the right to license, transfer or sell its rights to develop and commercialize sotatercept in pulmonary hypertension, subject to Celgene's right of first negotiation.

All costs related to the Company's development and commercialization of sotatercept in pulmonary hypertension will be funded solely by the Company. The Company is not required to make any upfront payments or milestone payments to Celgene in connection with the Company's development and commercialization of sotatercept in pulmonary hypertension. If sotatercept is commercialized to treat pulmonary hypertension and the Company recognizes such revenue, then Celgene will be eligible to receive a royalty in the low twenty percent range on global net sales. In certain circumstances Celgene may recognize revenue related to the commercialization of sotatercept in pulmonary hypertension, and in this scenario, the Company will be eligible to receive a royalty from Celgene such that the economic position of the parties is equivalent to the scenario in which the Company recognizes such revenue. With respect to the development and commercialization of sotatercept outside of pulmonary hypertension or the development and commercialization of any other compound under the Amended Agreement, the terms of the Original Agreement remain unchanged, and Celgene will continue to have responsibility to fund and conduct all such development and commercialization activities, with the Company eligible to receive tiered royalty payments in the low-to-mid twenty percent range on global net sales.

Pursuant to the Amended Agreement, Celgene will provide to the Company certain quantities of Celgene's existing clinical supply of sotatercept at no cost to the Company. For clinical or commercial supply of sotatercept in excess of that which is agreed under the Amended Agreement, Celgene can elect to provide the Company with such clinical and commercial supply of sotatercept at a negotiated price or provide a tech transfer to the Company to enable the Company to manufacture on its own behalf. Under the Amended Agreement, the conduct of the collaboration is managed by a Joint Development Committee and Joint Commercialization Committee. In the event of a deadlock of a committee, the Company shall determine the resolution of issues specifically related to the development or commercialization of sotatercept in pulmonary hypertension (other than pricing which shall be determined by consensus), and Celgene shall determine the resolution of all other issues. The Joint Commercialization Committee will oversee commercialization of sotatercept and sotatercept pricing will be determined by mutual agreement of the Company and Celgene in the Joint Commercialization Committee.

The Amended Agreement is terminable by either party upon a breach that is uncured and continuing or by Celgene for convenience on a country by country or product by product basis, or in its entirety. Celgene may also terminate the Amended Agreement, in its entirety or on a product by product basis, for failure of a product to meet a development or clinical trial endpoint. Termination for cause by us or termination by Celgene for convenience or failure to meet an endpoint will have the effect of terminating the applicable license to Celgene and the rights granted to Acceleron with respect to the development of sotatercept in pulmonary hypertension shall become irrevocable. Termination for cause by either party shall result in reducing the remaining royalties due to the breaching party by a certain percentage. Upon termination by Celgene for convenience or for failure to meet an endpoint, Celgene and the Company will enter into a termination agreement pursuant to which, among other things, Celgene will continue to be eligible to receive a royalty in the low twenty percent range on global net sales of sotatercept in pulmonary hypertension.

The foregoing description of the Amended Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Amended Agreement, a redacted copy of which will be filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarterly period ended September 30, 2017, and upon filing will be incorporated herein by reference. The Company intends to submit a Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the Amended Agreement. The omitted material will be included in the request for confidential treatment.

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/ John D. Quisel, J.D., Ph.D.
John D. Quisel, J.D., Ph.D.
Senior Vice President and General Counsel

Date: September 19, 2017