

**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): December 20, 2019

Fulcrum Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38978
(Commission
File Number)

47-4839948
(IRS Employer
Identification No.)

26 Landsdowne Street
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(Zip Code)

Registrant's telephone number, including area code: (617) 651-8851

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 (see General Instruction A.2. below):

- 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 Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	FULC	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 1.01. Entry into a Material Definitive Agreement

On December 20, 2019, Fulcrum Therapeutics, Inc. (the “Company”) entered into a collaboration and license agreement (the “Agreement”) with Acceleron Pharma Inc. (“Acceleron”) pursuant to which the Company granted Acceleron an exclusive worldwide license under certain intellectual property rights to make, have made, use, sell, have sold, import, export, distribute and have distributed, market, have marketed, promote, have promoted, or otherwise exploit molecules and products directed against or expressing certain biological targets identified by the Company for the treatment, prophylaxis, or diagnosis of a targeted indication within the pulmonary disease space (the “Indication”).

Pursuant to a mutually agreed research plan, the Company will perform assay screening and related research activities to identify and validate potential gene targets for further research, development, manufacture and commercialization by Acceleron. Upon completion of the research activities, the Company will deliver a data package to Acceleron with respect to the gene targets identified by the Company in the conduct of the research activities for the treatment, prophylaxis, or diagnosis of the Indication. Within a designated period of receipt of the data package, Acceleron will have the right to designate a specified number of the biological targets identified by the Company for Acceleron’s research, development, manufacture and commercialization of products or molecules directed to such targets for the treatment, prophylaxis, or diagnosis of any disease (the “Targets”). If Acceleron does not designate any Targets during the designated period, then the Agreement will automatically terminate. If Acceleron designates one or more Targets, then Acceleron will be obligated to use commercially reasonable efforts to seek regulatory approval for one product directed to a Target in certain specified countries. Upon receipt of regulatory approval for any product directed to a Target, Acceleron must use commercially reasonable efforts to commercialize such product in certain specified countries.

While the Company is performing the research activities pursuant to the research plan and for a specified period thereafter, the Company may not research, develop, manufacture, commercialize, use, or otherwise exploit any compound or product for the treatment, prophylaxis, or diagnosis of the Indication other than for Acceleron. While the Company is performing the research activities pursuant to the research plan and for a specified period thereafter, other than for Acceleron, the Company may not research, develop, manufacture, commercialize, use, or otherwise exploit any compound or product for the treatment, prophylaxis, or diagnosis of the Indication that is directed against certain specified biological targets identified by the Company in the performance of the research activities.

Acceleron may also request that the Company perform medicinal chemistry services related to the generation and optimization of molecules directed against or expressing biological targets for the treatment, prophylaxis, or diagnosis of the Indication beyond the scope of the research plan. If the Company agrees to provide such medicinal chemistry services, the Company and Acceleron will negotiate to determine the scope, timeline and budget for such medicinal chemistry services.

Under the Agreement, Acceleron will make a \$10.0 million upfront payment to the Company within fifteen days of signing the Agreement. The Company will be entitled to research milestone payments of up to \$18.5 million in the aggregate upon achievement of specified research milestones. Additionally, the Company will be entitled to development milestone payments of up to \$135.0 million in the aggregate upon the first achievement of specified clinical and regulatory milestones by a product directed to a Target, and up to \$67.5 million in the aggregate upon the second achievement of specified clinical and regulatory milestones by a product directed to a Target. The Company will also be entitled to sales milestone payments of up to \$145.0 million in the aggregate upon the achievement of one-time aggregate annual worldwide net sales milestones for the first product directed to a Target to achieve such milestones, and up to \$72.5 million in the aggregate upon the achievement of one-time aggregate annual worldwide net sales milestones for the second product directed to a Target to achieve such milestones. Acceleron will also pay the Company tiered royalties ranging from a mid single-digit percentage to a low double-digit percentage based on Acceleron’s, and any of its affiliates’ and sublicensees’, annual worldwide net sales of products directed to any Target. The royalties are payable on a product-by-product basis during a specified royalty term, and may be reduced in specified circumstances.

The Agreement continues on a country-by-country and Target-by-Target basis until the last to expire royalty term for a product directed to such Target, at which time the Agreement expires with respect to such Target in such country. Either party has the right to terminate the Agreement if the other party has materially breached in the performance of its obligations under the Agreement and such breach has not been cured within the applicable cure period. Acceleron also has the right to terminate the Agreement for convenience in its entirety or on a Target-by-Target and molecule-by-molecule basis with respect to any molecule directed against a Target.

The foregoing description of the terms of the Agreement is qualified in its entirety by reference to the full text of the Agreement, a copy of which the Company intends to file with the Securities and Exchange Commission (the “SEC”) as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2019.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding whether the collaboration will yield any Targets, potential milestone payments or royalty payments in connection with the collaboration and the potential benefits of the collaboration. All statements, other than statements of historical facts, contained in this Current Report on Form 8-K, including statements regarding the Company’s strategy, future operations, future financial position, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “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. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with each party’s ability to perform its obligations under the Agreement, the sufficiency of the Company’s cash resources to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements on its expected timeline and other important factors discussed in the “Risk Factors” sections contained in the Company’s quarterly and annual reports on file with the SEC. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the “Risk Factors” section, as well as discussions of potential risks, uncertainties and other important factors, in the Company’s most recent filings with the SEC. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company’s views as of the date hereof and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

FULCRUM THERAPEUTICS, INC.

Date: December 30, 2019

By: /s/ Robert J. Gould

Name: Robert J. Gould

Title: President and Chief Executive Officer