FOUNDATION MEDICINE, INC.

FORM 8-K
(Current report filing)

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Address	150 SECOND STREET CAMBRIDGE, MA, 02141
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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): February 28, 2018

Foundation Medicine, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36086**	**27-1316416**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

150 Second Street **Cambridge, MA**	**02141**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (617) 418-2200

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.

Amended and Restated Ex-US Commercialization Agreement

On February 28, 2018, Foundation Medicine, Inc., a Delaware corporation (the "Company"), entered into an Amended and Restated Ex-US Commercialization Agreement (the "Agreement") with F. Hoffmann-La Roche Ltd ("Roche"). The Agreement amends and restates that certain Ex-US Commercialization Agreement, effective as of April 7, 2015, as amended, between the Company and Roche, and sets forth the terms and conditions of the parties' respective obligations with respect to the commercialization of the Company's clinical diagnostic testing commercial products worldwide, excluding the United States and any other countries excluded pursuant to the terms of the Agreement (the "Territory").

Pursuant to the Agreement, Roche has the exclusive right in the Territory to commercialize the Company's existing clinical diagnostic testing commercial products (FoundationOne ®, FoundationOne ® Heme, FoundationACT ®, and FoundationOne CDx ™); any clinical diagnostic testing commercial products developed under the Immunotherapy, ctDNA or CDx Testing Development Platforms (each as defined in the Collaboration Agreement, dated as of January 11, 2015, as amended, by and between the Company on the one hand and Roche and Hoffmann-La Roche Inc. on the other hand); and any other products upon mutual agreement (collectively, the "Products"). Roche also holds a right of first negotiation with respect to the commercialization in the Territory of any of the Company's future clinical diagnostic products, excluding *in vitro* diagnostic kit products, companion diagnostic products developed by the Company for third parties, and standalone data or molecular information products.

In connection with Roche's commercial launch of a given Product in a country or region in the Territory, Roche must, among other things, establish and maintain a dedicated sales force (which is prohibited from promoting, and may not be directly compensated by the sale of, oncology therapeutics), provide marketing messaging with respect to such Product that is consistent with FMI's messaging relating to such Product in the United States, appoint a dedicated medical science liaison, and provide customer support for such Product. In the event that Roche fails to satisfy its commercial launch requirements set forth in the Agreement for a given Product, then, after a specified cure period, the Company will have the right to terminate Roche's exclusive commercialization rights in such country. The Company is responsible for preparing and submitting applications for regulatory approvals for the Products (other than FoundationOne CDx) in the Territory, and Roche has agreed to reasonably assist FMI with such applications.

Pursuant to the Agreement, the parties have established the process by which FoundationOne CDx will replace FoundationOne in each country in the Territory in which the Company determines to commercially launch FoundationOne CDx. The Company controls the regulatory strategy and all regulatory filings relating to FoundationOne CDx. In addition, the Company may, at its election, designate Roche as its local regulatory partner in any country in the Territory to assist with such FoundationOne CDx filings. In any regulated markets in the Territory in which Roche serves as the Company's regulatory partner for such filings, Roche is required to establish a firewall to protect third party proprietary information received in connection with such filings, and the Company has the right to audit Roche's compliance with such firewall obligations.

In the event that Roche fails to commercially launch FoundationOne CDx in a given country based on the timeline established by the Company pursuant to the terms of the Agreement, then Roche will have a specified cure period, after which it will pay the Company an agreed upon penalty payment and, if such failure continues for an additional specified cure period after such payment, the Company will have the right to terminate Roche's exclusive commercialization rights in such country. In addition, if Roche fails to satisfy any of its other commercialization obligations with respect to FoundationOne CDx, after a specified cure period, the Company will have the right to terminate Roche's exclusive commercialization rights in such country.

Roche will pay the Company agreed upon royalties and commercial milestone payments for the sale of the Products. In addition, Roche has agreed to pay certain costs associated with the regulatory filings for FoundationOne CDx. Further, if Roche does not meet agreed upon minimum revenue requirements for FoundationOne, FoundationOneHeme, FoundationACT, or FoundationOne CDx tests in three consecutive years in a given country in the Territory, then the Company has the right to terminate Roche's exclusive commercialization rights in such country.

The initial term of the Agreement expires on April 7, 2020 and may be extended by Roche for additional two-year periods. Roche has the right to terminate the Agreement, either in whole or on a country-by-country or Product-by-Product basis, without cause, upon six months' prior written notice after the initial term. In addition, either party may terminate the Agreement in the event of the other party's material breach of its obligations under the Agreement.

The foregoing description of the Agreement and the transactions contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Agreement, a redacted copy of which will be filed as an exhibit to the Company's reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and upon filing will be incorporated herein by reference. The Company intends to submit a FOIA Confidential Treatment Request to the United States Securities and Exchange Commission pursuant to Rule 24b-2 under the Exchange Act, requesting that it be permitted to redact certain portions of the 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.

Date: March 5, 2018

FOUNDATION MEDICINE, INC.

By: /s/ Robert W. Hesslein
Robert W. Hesslein
Senior Vice President and General Counsel