

Foundation Medicine, Inc.
Form 8-K
December 20, 2016

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 19, 2016

Foundation Medicine, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36086
(Commission File Number)

27-1316416
(I.R.S. Employer
Identification No.)

150 Second Street

Cambridge, MA
(Address of principal executive offices)

02141
(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))

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Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On December 19, 2016, Foundation Medicine, Inc. obtained approval from the U.S. Food and Drug Administration (FDA) for FoundationFocus CDx_{BRCA} for use as a companion diagnostic to aid in identifying women with ovarian cancer for whom treatment with Rubraca (rucaparib), a therapy developed by Clovis Oncology, Inc., is being considered. FoundationFocus CDx_{BRCA} is a next generation sequencing assay for qualitative detection of *BRCA1* and *BRCA2* alterations in ovarian tumor tissue. If a patient is positive for any of the deleterious *BRCA* gene mutations, the patient may be eligible for treatment with Rubraca.

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: December 20, 2016

FOUNDATION MEDICINE, INC.

By: /s/ Robert W. Hesslein
Robert W. Hesslein

Senior Vice President and General Counsel