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): November 30, 2017

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 8.01. Other Events.

On November 30, 2017, Foundation Medicine, Inc. issued a press release announcing approval from the U.S. Food and Drug Administration for FoundationOne CDx™. A copy of the press release is filed as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Foundation Medicine, Inc. dated November 30, 2017.

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 1, 2017

FOUNDATION MEDICINE, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by Foundation Medicine, Inc. dated November 30, 2017.

Exhibit 99.1

FDA Approves Foundation Medicine's FoundationOne CDx™, the First and Only Comprehensive Genomic Profiling Test for All Solid Tumors Incorporating Multiple Companion Diagnostics

--Landmark approval advances personalized cancer care as an estimated 1 in 3 patients across five common advanced cancers are expected to match with an FDA-approved therapy--

--The Centers for Medicare and Medicaid Services issued a preliminary National Coverage Determination (NCD) for FoundationOne CDx, improving access to molecular information for personalized healthcare--

CAMBRIDGE, Mass.--(BUSINESS WIRE)--November 30, 2017--Foundation Medicine, Inc. (NASDAQ:FMI) today announced that the U.S. Food and Drug Administration (FDA) approved FoundationOne CDx ™, the company's comprehensive companion diagnostic test for solid tumors. FoundationOne CDx is intended for use by health care professionals to help inform cancer treatment management in accordance with professional guidelines for patients with solid tumors. The first and only FDA-approved test of its kind for all solid tumors, FoundationOne CDx is a diagnostic test that acts as:

- a comprehensive companion diagnostic to identify patients who may benefit from treatment with specific FDA-approved targeted therapies;
- a comprehensive genomic profiling (CGP) test that includes genomic biomarkers to help inform the use of other targeted oncology therapies, including immunotherapies;
- a tool for physicians that identifies patient opportunities for clinical trial participation; and,
- an FDA-approved platform for companion diagnostic development for biopharma companies developing precision therapeutics.

FoundationOne CDx assesses all classes of genomic alterations in 324 genes known to drive cancer growth, providing potentially actionable information to help guide treatment decisions. It is also indicated as a companion diagnostic for patients with certain types of non-small cell lung cancer (NSCLC), melanoma, colorectal cancer, ovarian cancer or breast cancer to identify those patients who may benefit from treatment with one of 17 on-label targeted therapies, including 12 therapies currently approved as first-line therapy for their respective indications. FoundationOne CDx also reports genomic biomarkers, such as microsatellite instability (MSI) and tumor mutational burden (TMB), that can help inform the use of immunotherapies; genomic alterations in other genes relevant to patient management; and, relevant clinical trial information.

Based on previous CGP testing conducted by Foundation Medicine, it is estimated that approximately 1 in 3 patients across five common advanced cancers are expected to match with an FDA approved therapy. [1] The number of matched on-label therapies indicated on FoundationOne CDx is expected to increase over time as Foundation Medicine and its biopharma partners pursue FDA approval for additional companion diagnostics on the platform. Today, approximately 50% of new cancer drugs in development are projected to have a companion biomarker. [2]

Concurrent with FDA approval, the Centers for Medicare and Medicaid Services (CMS) issued a preliminary National Coverage Determination (NCD) for FoundationOne CDx. The draft NCD would provide coverage for FDA-approved companion diagnostic claims, as well as a pathway for additional coverage with evidence development in other solid tumor types. The final policy is expected to issue during the first quarter of 2018 following public comment of the preliminary NCD and an administrative period.

“Today we know that many people with cancer do not receive biomarker testing, let alone the comprehensive genomic testing they need to be efficiently matched to the best therapeutic option,” said Andrea Ferris, President and CEO of LUNGevity Foundation. “This FDA approval means that, in one test, patients can access therapies where companion diagnostics have been established for their cancer while getting a broad tumor profile that can identify the therapies and clinical trials they could most benefit from. Along with the preliminary national coverage determination, this has the potential to democratize next-generation sequencing, lowering the barriers for patients treated in the community to access these biomarker-driven treatments.”

“Comprehensive genomic profiling is the gateway to precision medicine. This decision from the FDA and CMS, which may lead to coverage for Medicare patients, represents an important step forward in improving patient and clinician access to precision medicine – both in setting a new quality standard for this type of testing and offering potentially improved healthcare coverage,” said Ankur R. Parikh, DO, Medical Director of Precision Medicine, Cancer Treatment Centers of America. “Access to important genomic information is a critical step in being able to offer innovative and targeted treatment options.”

FoundationOne CDx results are delivered in an integrated report that identifies alterations matched to FDA approved therapies, identifies additional alterations in genes known to drive cancer growth, furnishes information about genomic biomarkers, including MSI and TMB, provides relevant clinical trial information, and includes interpretive content developed in accordance with professional guidelines in oncology for patients with any solid tumor.

“Today’s historic parallel review decision from the FDA and CMS represents a major advancement in personalized cancer care,” said Troy Cox, chief executive officer at Foundation Medicine. “Physicians will have an FDA-approved test for all solid tumors in their toolkit that can inform targeted and immunotherapy selection, as well as identify patient opportunities for clinical trial participation. Beyond its implications for patient care, we expect that FoundationOne CDx will provide biopharma companies with an FDA-approved platform that can help accelerate drug development and enable personalized oncology care. On behalf of the Foundation Medicine team, I’d like to thank FDA and CMS for their leadership and collaboration as we continue to work through the parallel review process with a shared mission of transforming cancer care.”

FoundationOne CDx is the first solid tumor comprehensive genomic profiling test reviewed by the FDA and CMS in their Parallel Review program. FDA approval was based on analytic validation and concordance studies with FDA-approved assays. FoundationOne CDx is expected to be commercially available following finalization of the NCD from CMS.

Conference Call and Webcast Details
Foundation Medicine will conduct a conference call to discuss FDA approval and the draft national coverage determination from CMS for FoundationOne CDx on Friday, December 1 at 8:30 a.m. ET. To access the conference call via phone, dial 1-877-270-2148 from the United States and Canada, or dial 1-412-902-6510 internationally, and for either number reference Foundation Medicine. Dial in approximately ten minutes prior to the start of the call. The live, listen-only webcast of the conference call may be accessed by visiting the investors section of the company's website at investors.foundationmedicine.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the company's website for two weeks following the call.

About FoundationOne CDx™
FoundationOne CDx™ is a next generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The test is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed below in accordance with the approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. The FoundationOne CDx assay is a single-site assay performed at Foundation Medicine, Inc.

- *EGFR* exon 19 deletions and EGFR exon 21 L858R alterations, which may indicate efficacy of erlotinib, afatinib or gefitinib in patients with NSCLC.
- *EGFR* exon 20 T790M alterations which may indicate efficacy of osimertinib in NSCLC patients
- *ALK* rearrangements which may indicate efficacy of crizotinib, alectinib or certinib in NSCLC patients
- BRAF V600E which may indicate efficacy of dabrafenib in combination with trametinib in NSCLC patients
- *BRAF* V600E which may indicate efficacy of vemurafenib or dabrafenib in melanoma patients
- *BRAF* V600E and V600K which may indicate efficacy of trametinib or cobimetinib in combination with vemurafenib in melanoma patients
- *ERBB2* (HER2) amplification which may indicate efficacy of trastuzumab, pertuzumab orado-trastuzumab-emtansine in patients with breast cancer
- *KRAS* wild-type (absence of mutations in codons 12 and 13) which may indicate efficacy of cetuximab in patients with colorectal cancer
- *KRAS* wild-type (absence of mutations in exons 2, 3 and 4) and *NRAS* wild-type (absence of mutations in exons 2, 3 and 4) which may indicate efficacy of panitumumab in patients with colorectal cancer
- *BRCA1/2* alterations which may indicate efficacy of rucaparib in patients with ovarian cancer

For more information about FoundationOne CDx, visit http://www.FoundationMedicine.com .

About Foundation Medicine
Foundation Medicine (NASDAQ:FMI) is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the genomic changes that contribute to each patient's unique cancer. The company offers a full suite of comprehensive genomic profiling assays to identify the molecular alterations in a patient's cancer and match them with relevant targeted therapies, immunotherapies and clinical trials. Foundation Medicine's molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer. For more information, please visit http://www.FoundationMedicine.com or follow Foundation Medicine on Twitter (@FoundationATCG).

Cautionary Note Regarding Forward-Looking Statements for Foundation Medicine

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the ability of FoundationOne CDx to enhance patient access to targeted therapies, immunotherapies, and clinical trials, including the number of patients who will be matched to an on-label therapy; the ability of a comprehensive genomic profiling assay, including FoundationOne CDx, to improve patient outcomes; the benefits of our products to physicians, biopharmaceutical companies, payers, and patients in the treatment of cancer and personalized cancer care, including whether the number of on-label therapies indicated on FoundationOne CDx will increase over time; the benefits provided by an FDA-approved and CMS-covered FoundationOne CDx assay; any anticipated adoption of FoundationOne CDx for patient treatment; potential healthcare coverage of FoundationOne CDx by CMS for patients, including Medicare and Medicare Advantage patients; the scope and timing of any coverage decision by CMS, including the timing of issuance of any final NCD; and the timing of any launch of FoundationOne CDx. All such 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 the risks that CMS does not issue a final NCD or issues a final NCD with a revised scope of coverage; CMS is delayed in the completion of the Parallel Review process; Foundation Medicine is not able to provide FoundationOne CDx for commercial use in the manner or on the timeline currently anticipated by management; Foundation Medicine is unable to sustain or grow relationships with hospitals, physicians, and biopharmaceutical partners; and the risks described under the caption "Risk Factors" in Foundation Medicine's Annual Report on Form 10-K for the year ended December 31, 2016, which is on file with the Securities and Exchange Commission, as well as other risks detailed in Foundation Medicine's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Foundation Medicine undertakes no duty to update this information unless required by law.

[1] Estimates are projections based on a genomic database of patients with non-small cell lung cancer (NSCLC), melanoma, colorectal cancer, ovarian cancer or breast cancer who have received CGP testing from Foundation Medicine as of August 2017; these are the five cancer types for which FoundationOne CDx is approved to detect alterations that have associated on-label FDA approved therapies.

[2] Developments in Cancer Treatments, Market Dynamics, Patient Access and Value - Global Oncology Trend Report 2015. IMS Institute for Healthcare Informatics. Available at: http://keionline.org/sites/default/files/IIHI_Oncology_Trend_Report_2015.pdf .

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