

FOUNDATION MEDICINE, INC.

FORM 8-K (Current report filing)

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Address	150 SECOND STREET CAMBRIDGE, MA, 02141
Telephone	617-418-2200
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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): November 1, 2017

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

(IRS 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))
- 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 2.02. Results of Operations and Financial Condition.

On November 1, 2017, Foundation Medicine, Inc. issued a press release announcing its financial and operating results for the quarter ended September 30, 2017. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Foundation Medicine, Inc. dated November 1, 2017, furnished hereto.

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: November 1, 2017

FOUNDATION MEDICINE, INC.

By: /s/ Robert W. Hesslein _____

Robert W. Hesslein

Senior Vice President and General Counsel

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Foundation Medicine, Inc. dated November 1, 2017, furnished hereto.

Foundation Medicine Announces 2017 Third Quarter Results and Recent Highlights

CAMBRIDGE, Mass.--(BUSINESS WIRE)--November 1, 2017--Foundation Medicine, Inc. (NASDAQ: FMI) today reported financial and operating results for its third quarter ended September 30, 2017. Results and business highlights for the quarter included:

- Achieved third quarter revenue of \$42.7 million, 45% year-over-year growth;
- Reported 17,474 clinical tests in the third quarter, 50% year-over-year growth;
- Presented validation data for FoundationOne CDx™ at the World Conference on Lung Cancer which demonstrated high concordance with multiple FDA-approved companion diagnostics across multiple solid tumor cancer types. FoundationOne CDx is currently under the Parallel Review process with FDA and CMS;
- Presented validation data for a novel assay measuring tumor mutational burden in blood (bTMB) at the European Society for Medical Oncology (ESMO) providing evidence that response to immunotherapy can be predicted using a blood sample. Based on these findings, the bTMB assay is being integrated as part of Roche/Genentech's prospective, randomized Phase III Blood First Assay Screening Trial (BFAST) as a companion diagnostic assay to investigate bTMB as a non-invasive biomarker of response to first-line atezolizumab in advanced NSCLC patients; and
- Published 19 manuscripts in high-quality, peer-reviewed journals and delivered 21 podium and poster talks at various medical and scientific meetings.

“Foundation Medicine made great progress in the third quarter as evidenced by record revenue and clinical volume,” said Troy Cox, chief executive officer of Foundation Medicine. “Our recent accomplishments, including progress with the parallel review process with FDA and CMS for FoundationOne CDx, expanding relationships with our biopharma partners, and driving continued innovation in our molecular information solutions pipeline with bTMB, continue to position our company for further growth, and competitive differentiation to transform cancer care.”

Foundation Medicine reported total revenue of \$42.7 million in the third quarter of 2017, compared to \$29.4 million in the third quarter of 2016. Revenue from biopharmaceutical customers was \$29.6 million in the third quarter of 2017, compared to \$20.7 million in the third quarter of 2016. The results of 2,817 tests were reported to biopharmaceutical customers in this year's third quarter.

Revenue from clinical testing in the third quarter of 2017 was \$13.1 million, compared to \$8.7 million in the third quarter of 2016. The company reported 17,474 tests to clinicians in the third quarter of 2017, a 50% increase from the same quarter last year. This number includes 14,398 FoundationOne® tests, 1,478 FoundationOne® Heme tests, 1,488 FoundationACT® tests, and 110 FoundationFocus™ CDx BRCA tests.

Total operating expenses for the third quarter of 2017 were approximately \$56.0 million, compared with \$44.9 million for the third quarter of 2016. The increase in operating expenses was partially driven by investments in product development such as FoundationOne CDx and bTMB, investments in the company's technology infrastructure, and certain non-recurring cash and non-cash expenses.

Net loss was approximately \$32.6 million in the third quarter of 2017, or a \$0.90 loss per share. At September 30, 2017, the company held approximately \$76.8 million in cash, cash equivalents and marketable securities.

Based on the new revenue reporting the company initiated last quarter, Molecular Information Services revenue was \$28.4 million, including \$13.1 million in revenue generated from our clinical customers, and \$15.3 million in revenue generated from our biopharma customers during the third quarter. Pharma Research and Development Services revenue was \$14.3 million.

2017 Outlook

Foundation Medicine's business and financial outlook for 2017 is the following:

- The company expects 2017 revenue will be in the range of \$135 million to \$145 million.
- The company is increasing clinical volume guidance and now expects to deliver between 64,000 and 66,000 clinical tests in 2017.
- The company expects 2017 operating expenses will be in the range of \$215 million and \$225 million.
- The company expects to advance its comprehensive genomic profiling assay, FoundationOne CDx, through the FDA and CMS Parallel Review process with a decision anticipated in the fourth quarter of 2017.
- The company expects to continue reimbursement progress and pursue additional coverage decisions for its CGP assays.

Conference Call and Webcast Details

The company will conduct a conference call today, Wednesday, November 1st at 4:30 p.m. Eastern Time to discuss its financial performance for the 2017 third quarter and other business activities, including matters related to future performance. To access the conference call via phone, dial 1-877-270-2148 from the United States or dial 1-412-902-6510 internationally. 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 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).

Foundation Medicine[®], *FoundationOne*[®] and *FoundationACT*[®] are registered trademarks, and *FoundationOne CDx*[™] and *FoundationFocus*[™] are trademarks, of Foundation Medicine, Inc.

Cautionary Note Regarding Forward-Looking Statements

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 value of the company's business; the benefits of our products to physicians, biopharmaceutical companies, payers, and patients in the treatment of cancer and personalized cancer care; the company's financial and operational forecasts, including projections regarding the generation of revenue, the number of tests to be conducted, the incurrence of operating expenses, the timing of product development, and the expansion of reimbursement progress, including any changes to any earlier guidance; the benefits provided by a FDA-approved and CMS-covered FoundationOne CDx and progress with the Parallel Review process with FDA and CMS; the scope and timing of any approval of FoundationOne CDx as a medical device by the FDA and any coverage decision by CMS; strategies for achieving Medicare coverage decisions at the local or national level and new and expanded coverage from third-party payers; and use of any funds from its credit facility. 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 the FDA does not approve FoundationOne CDx as a medical device or that CMS does not decide to offer FoundationOne CDx as a covered benefit under Medicare; the FDA or CMS is delayed in the completion of the Parallel Review process; the company's facilities in North Carolina and Germany do not facilitate the company's ability to achieve its business objectives; the company's distribution partner outside the United States is not able to achieve market penetration in new and existing markets as quickly or as extensively as projected; Foundation Medicine's relationships with third-party or government payers do not increase or expand; Foundation Medicine is unable to sustain or grow relationships with biopharmaceutical partners; the company's revenue, test or operating expense projections may turn out to be inaccurate because of the preliminary nature of the forecasts; the company's expectations and beliefs regarding the future conduct and growth of the company's business are inaccurate; Foundation Medicine is unable to achieve profitability, to compete successfully, to manage its growth, or to develop its molecular information platform; 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.

- Financial Tables to Follow -

FOUNDATION MEDICINE, INC.
Condensed Consolidated Balance Sheets
(In thousands)
(unaudited)

	<u>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 76,814	\$ 63,617
Marketable securities	—	79,402
Accounts receivable	15,496	10,213
Inventory	10,400	10,438
Prepaid expenses and other current assets	4,612	5,251
Total current assets	<u>107,322</u>	<u>168,921</u>
Property and equipment, net	39,136	41,486
Restricted cash	2,305	1,395
Other assets	1,796	2,233
Total assets	<u>\$ 150,559</u>	<u>\$ 214,035</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 16,178	\$ 11,898
Accrued expenses and other current liabilities	28,246	20,578
Deferred revenue	1,998	5,851
Current portion of deferred rent	1,439	2,324
Total current liabilities	<u>47,861</u>	<u>40,651</u>
Other non-current liabilities	9,261	8,538
Indebtedness to Roche – non-current	30,000	—
Total stockholders' equity	<u>63,437</u>	<u>164,846</u>
Total liabilities and stockholders' equity	<u>\$ 150,559</u>	<u>\$ 214,035</u>

FOUNDATION MEDICINE, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Molecular information services	\$ 28,368	\$ 18,719	\$ 79,763	\$ 61,331
Pharma research and development services	14,290	10,707	24,227	26,710
Total revenue	<u>42,658</u>	<u>29,426</u>	<u>103,990</u>	<u>88,041</u>
Costs and expenses:				
Cost of molecular information services	19,128	15,946	58,727	39,291
Selling and marketing	16,556	14,654	50,107	42,928
General and administrative	17,001	13,012	49,926	34,739
Research and development	<u>22,399</u>	<u>17,238</u>	<u>68,657</u>	<u>49,194</u>
Total costs and expenses	<u>75,084</u>	<u>60,850</u>	<u>227,417</u>	<u>166,152</u>
Loss from operations	(32,426)	(31,424)	(123,427)	(78,111)
Other (expense) income, net:				
Interest (expense) income, net	(278)	142	(132)	528
Other income	<u>60</u>	<u>—</u>	<u>204</u>	<u>—</u>
Net loss	<u>\$ (32,644)</u>	<u>\$ (31,282)</u>	<u>\$ (123,355)</u>	<u>\$ (77,583)</u>
Net loss per common share applicable to common stockholders, basic and diluted	<u>\$ (0.90)</u>	<u>\$ (0.90)</u>	<u>\$ (3.45)</u>	<u>\$ (2.24)</u>
Weighted-average common shares outstanding, basic and diluted	36,086,169	34,949,785	35,726,711	34,701,013

CONTACT:

Foundation Medicine, Inc.

Media Contact:

Lee-Ann Murphy, 617-245-3077

pr@foundationmedicine.com

or

Investor Contact:

Kimberly Brown, 617-418-2215

ir@foundationmedicine.com