

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): May 2, 2018

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))
- 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 May 2, 2018, Foundation Medicine, Inc. issued a press release announcing its financial and operating results for the quarter ended March 31, 2018. 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	<u>Press release issued by Foundation Medicine, Inc. dated May 2, 2018, furnished hereto.</u>

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Foundation Medicine, Inc. dated May 2, 2018, 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.

FOUNDATION MEDICINE, INC.

Date: May 2, 2018

By: /s/ Robert W. Hesslein

Robert W. Hesslein

Senior Vice President and General Counsel



NEWS RELEASE

FOR IMMEDIATE RELEASE

Foundation Medicine Announces 2018 First Quarter Results and Recent Highlights

CAMBRIDGE, Mass. –May 2, 2018—Foundation Medicine (NASDAQ:FMD) today reported financial and operational results for the first quarter ended March 31, 2018. Highlights for the quarter included:

- Posted revenue of \$52.8 million, 101% year-over-year growth;
- Reported 21,861 clinical tests, 57% year-over-year growth;
- Achieved broad Medicare coverage through a final National Coverage Determination (NCD) from the Centers for Medicare and Medicaid Services (CMS) for FoundationOne CDx™ across all solid tumors for eligible stage III and stage IV cancer patients;
- Launched FoundationOne CDx, the first FDA approved comprehensive genomic profiling assay for all solid tumors incorporating multiple companion diagnostics;
- Announced that an expanded version of FoundationACT®, which will include an expanded gene set and genomic biomarkers for microsatellite instability (MSI) and blood tumor mutational burden (bTMB), was granted Breakthrough Device designation (formerly Expedited Access Pathway) by the FDA;
- Announced a comprehensive gene expression profiling (GEP) program which leverages deep expertise in DNA and RNA sequencing to support precision oncology clinical research and development and identification of novel genomic and expression-based biomarkers for personalized cancer therapies;
- Partnered with Chugai Pharmaceutical Co. to commercialize the company's CGP tests in Japan, including the filing by Chugai of an application with the Ministry of Health, Labour and Welfare (MHLW) for approval of FoundationOne CDx in Japan;
- Announced a partnership with Roche and DIAN Diagnostics, a leading NGS diagnostics laboratory in China, to integrate Foundation Medicine's CGP assays into clinical patient care in mainland China; and
- Published 22 peer-reviewed manuscripts in medical and scientific journals and presented 35 podium talks and posters at scientific and medical meetings.

"Foundation Medicine delivered another strong quarter. Compared to the same quarter last year, we doubled revenue over last year and reported record clinical volume," stated Troy Cox, chief executive officer of Foundation Medicine. "Just four months into the year, we've made meaningful progress on our strategic priorities for 2018, including the achievement of Medicare coverage for FoundationOne CDx across all solid tumors for qualifying patients, new partnerships to expand our commercial presence in China and Japan, and new biopharma collaborations. In addition, we continued our focus on innovation by accelerating our path to potential regulatory approval of an expanded version of our liquid biopsy assay, FoundationACT, and by initiating the development of a gene expression profiling platform that could enhance biomarker discovery and clinical decision making particularly in the field of

immunotherapy. Our many accomplishments reinforce our leadership position and competitive differentiation and, most importantly, help enable access to personalized cancer care.”

Foundation Medicine reported total revenue of \$52.8 million in the first quarter of 2018, compared to \$26.3 million in the first quarter of 2017. Effective January 1, 2018, the company began recognizing revenue in accordance with FASB ASC Topic 606. The company adopted ASC Topic 606 utilizing the modified retrospective method. Additional details of the adoption of this new accounting standard and our revenue recognition policies will be included in the company’s first quarter 10-Q. A summary of revenue for the first quarter of 2018 compared to the first quarter of 2017 is as follows:

(\$ in millions)	First Quarter		% Change
	2018	2017	
Molecular Information Services			
Clinical	\$18.8	\$ 11.6	62%
Pharma	27.8	9.5	193%
Total Molecular Information Services	46.6	21.1	121%
Pharma R&D Services	6.2	5.2	19%
Total Revenue	<u>\$52.8</u>	<u>\$ 26.3</u>	101%

Revenue from clinical testing in the first quarter of 2018 grew 62% year over year and was driven by increasing clinical volume. The company reported 21,861 clinical tests in the first quarter of 2018, a 57% increase from the same quarter last year. This number includes 17,685 FoundationOne® tests, 2,005 FoundationOne®Heme tests, 2,123 FoundationACT® tests, and 48 FoundationFocus™ CDx BRCA tests.

Molecular Information Services revenue from biopharmaceutical companies was very strong and was driven by clinical study sample testing. The company reported 7,184 tests to biopharmaceutical customers in the first quarter of 2018 compared to 1,802 tests in the first quarter of 2017.

Total operating expenses for the first quarter of 2018 were \$62.0 million compared with \$55.0 million for the first quarter of 2017. Net loss was \$37.4 million in the first quarter of 2018, or \$1.02 loss per share.

Cash and cash equivalents at March 31, 2018 was approximately \$60.3 million, including \$30 million borrowed during the first quarter under the company’s Credit Facility Agreement with Roche Finance.

2018 Outlook

- The company expects 2018 revenue will be in the range of \$200 million to \$220 million.
- The company expects to deliver between 90,000 and 100,000 clinical tests in 2018.

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- The company expects operating expenses will be in the range of \$250 million to \$260 million in 2018.

Conference Call and Webcast Details

The company will conduct a conference call today, Wednesday, May 2nd at 4:30 p.m. Eastern Time to discuss its financial performance for the 2018 first quarter and other business activities, including matters related to future performance. To access the conference call via phone, dial 1-844-784-1732 from the United States or dial 1-412-902-6714 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 *FoundationCORE™* 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 the company's 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, and the incurrence of operating expenses, including any changes to any earlier guidance; the scope and timing of any approval of the company's new liquid biopsy assay as a medical device by the FDA; the benefits provided by development of a gene expression profiling platform; and the use of any funds from the company's 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 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; the company's relationships with third-party or government payers do not increase or expand; the company 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; the company 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, 2017, 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.

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FOUNDATION MEDICINE, INC.
Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Revenue:		
Molecular information services	\$ 31,943	\$ 15,594
Related-party molecular information services from Roche	14,648	5,504
Pharma research and development services	4,782	1,087
Related-party pharma research and development services from Roche	1,467	4,143
Total revenue	52,840	26,328
Costs and expenses:		
Cost of molecular information services	21,279	17,117
Cost of related-party molecular information services from Roche	5,948	900
Selling and marketing	17,480	16,436
General and administrative	20,695	15,277
Research and development	23,859	23,285
Total costs and expenses	89,261	73,015
Loss from operations	(36,421)	(46,687)
Other (expense) income, net:		
Interest (expense) income, net	(994)	90
Other income	—	144
Net loss	\$ (37,415)	\$ (46,453)
Net loss per common share applicable to common stockholders, basic and diluted	\$ (1.02)	\$ (1.31)
Weighted-average common shares outstanding, basic and diluted	36,792,980	35,426,296

FOUNDATION MEDICINE, INC.
Supplemental Revenue Information

(In thousands)
(unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Clinical:		
Molecular information services	\$15,589	\$10,649
Related-party molecular information services from Roche	<u>3,198</u>	<u>970</u>
Total clinical revenue	\$18,787	\$11,619
Pharma:		
Molecular information services	\$16,354	\$ 4,945
Related-party molecular information services from Roche	11,450	4,534
Pharma research and development services	4,782	1,087
Related-party pharma research and development services from Roche	<u>1,467</u>	<u>4,143</u>
Total pharma revenue	<u>\$34,053</u>	<u>\$14,709</u>
Total revenue	<u>\$52,840</u>	<u>\$26,328</u>

FOUNDATION MEDICINE, INC.
Condensed Consolidated Balance Sheets

(In thousands)
(unaudited)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,293	\$ 71,404
Accounts receivable	32,222	19,967
Receivable due from Roche	9,099	10,159
Inventory	16,411	13,171
Prepaid expenses and other current assets	<u>13,003</u>	<u>9,118</u>
Total current assets	131,028	123,819
Property and equipment, net	41,607	41,119
Restricted cash	2,305	2,305
Other assets	<u>2,225</u>	<u>1,760</u>
Total assets	<u>\$177,165</u>	<u>\$ 169,003</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 25,865	\$ 21,926
Accrued expenses and other current liabilities	22,393	36,745
Deferred revenue	2,867	2,212
Roche related-party deferred revenue	4,801	3,742
Current portion of deferred rent	<u>1,836</u>	<u>1,818</u>
Total current liabilities	57,762	66,443
Other non-current liabilities	10,507	10,892
Indebtedness to Roche – non-current	90,000	60,000
Total stockholders' equity	<u>18,896</u>	<u>31,668</u>
Total liabilities and stockholders' equity	<u>\$177,165</u>	<u>\$ 169,003</u>