

November 2, 2016

Foundation Medicine Announces 2016 Third Quarter Results and Recent Highlights

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine, Inc.](#) (NASDAQ:FMI) today reported financial and operating results for its third quarter ended September 30, 2016. Highlights for the quarter included:

- | Achieved third quarter revenue of \$29.4 million, 16% year-over-year growth;
- | Reported 11,627 clinical tests in the third quarter, 45% year-over-year growth;
- | Grew FoundationCORE[™], the company's molecular information knowledgebase, to nearly 100,000 patient cases;
- | Announced acceptance of FoundationOne[®] for Parallel Review by FDA and CMS. If approved, FoundationOne could be the first FDA-approved comprehensive genomic profiling (CGP) assay to incorporate multiple companion diagnostics to support precision medicine in oncology and would be offered as a covered benefit to Medicare beneficiaries nationwide;
- | Added new immunotherapy clinical markers, Tumor Mutational Burden (TMB) and Microsatellite Instability (MSI), to FoundationOne and FoundationOne Heme to help guide personalized immunotherapy-based treatment plans;
- | Published an additional 17 manuscripts in high-quality, peer-reviewed journals and delivered six podium and poster presentations at various medical and scientific meetings providing further evidence for the clinical impact of integrating CGP into routine cancer care;
- | Expanded patient access to CGP through Palmetto, the Medicare Administrative Contractor in North Carolina, who broadened a Local Coverage Determination, covering CGP for all stage IIIB and IV non-small cell lung cancer (NSCLC) patients at diagnosis by removing a patient's smoking status as a coverage factor.

Foundation Medicine reported total revenue of \$29.4 million in the third quarter of 2016, compared to \$25.4 million in the third quarter of 2015. Revenue from biopharmaceutical partners grew 77% to \$20.7 million in the third quarter of 2016, compared to \$11.7 million in the third quarter of 2015. The increase in revenue demonstrates the company's leading role in molecular information and the value of this information in informing and accelerating drug development for its oncology focused biopharmaceutical customers.

Revenue from clinical testing in the third quarter of 2016 was \$8.7 million, compared to \$13.7 million in the third quarter of 2015. The decrease was driven by various factors, the most significant of which was the transition in-network with a large national payer for stage IV NSCLC testing, which resulted in the termination of payments for testing in other indications.

The company reported 11,627 clinical tests in the third quarter of 2016, a 45% increase from the same quarter last year. This reported volume number includes 9,398 FoundationOne tests, 1,325 FoundationOne Heme tests and 904 FoundationACT[™] tests.

"Foundation Medicine delivered another solid quarter highlighted by strong biopharma revenue and record clinical testing volume," said Michael Pellini, M.D., chief executive officer of Foundation Medicine. "We believe our progress on building distinct, yet synergistic clinical and biopharma businesses, developing applications that enable patient access to therapies and clinical trials, aggressively working towards reimbursement coverage and payment for our comprehensive genomic profiling assays and pursuing parallel review with FDA and CMS for FoundationOne will drive continued growth and value creation."

The company's molecular information knowledgebase, FoundationCORE, grew to nearly 100,000 patient cases at the end of the third quarter. FoundationCORE is a unique asset and critical component of the value that Foundation Medicine delivers to its biopharmaceutical and physician customers. The increasing scale and breadth of this high quality, clinically relevant oncology data set derived from the company's testing platform continues to enhance clinical practice and help enable improved outcomes for patients.

Total operating expenses for the third quarter of 2016 were approximately \$44.9 million compared with \$35.6 million for the third quarter of 2015. Net loss was approximately \$31.3 million in the third quarter of 2016, or a \$0.90 loss per share. At September 30, 2016, the company held approximately \$167.9 million in cash, cash equivalents and marketable securities.

Recent Enterprise Highlights

- ┆ Announced a collaboration with Sarah Cannon Research Institute (SCRI) in which SCRI will utilize Foundation Medicine's full suite of assays to accelerate patient enrollment into clinical trials and facilitate data sharing across its network in the U.S.
- ┆ Selected as the molecular information provider of choice by The Leukemia & Lymphoma Society for its landmark Beat AML Master Trial, a prospective study aimed at delivering a precision medicine approach to treat newly diagnosed Acute Myeloid Leukemia patients.
- ┆ Announced the election of life sciences leader, Michael R. Dougherty, to its Board of Directors and the Board's Audit Committee. Mr. Dougherty joins as an independent director and fills an existing vacancy on the Board.

2016 Outlook

Foundation Medicine's business and financial outlook for 2016 is the following:

- ┆ The company continues to expect 2016 revenue will be in the range of \$110 to \$120 million.
- ┆ The company is increasing the bottom-end of its clinical volume guidance range and now expects to deliver between 40,000 and 41,000 FoundationOne and FoundationOne Heme clinical tests in 2016.
- ┆ The company continues to expect operating expenses will be in the range of \$175 and \$185 million.

Conference Call and Webcast Details

The company will conduct a conference call today, Wednesday, November 2nd at 4:30 p.m. Eastern Time to discuss its financial performance for the 2016 third quarter and other business activities, including matters related to future performance. To access the conference call via phone, dial 1-855-420-0652 from the United States and Canada, or dial 1-484-365-2939 internationally, and for either number reference Foundation Medicine and provide the passcode 96220274. 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[®] and FoundationOne[®] are registered trademarks, and FoundationCORE[™] and FoundationACT[™] 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 benefits of our products to clinicians, payers and biopharmaceutical companies in the treatment of cancer and the recognition by physicians, payers and patients of the differentiating characteristics of our tests; the number of tests to be conducted, the generation of revenue, and the incurrence of operating expenses in 2016, including any changes to earlier guidance; expectations of continued growth or competitive differentiation; any approval of FoundationOne as a medical device by the FDA and any coverage decision by CMS; payer support for comprehensive genomic profiling, including coverage decisions by Medicare and third-party payers; the ability of FoundationOne to inform therapeutic choices in acute myeloid leukemia, including leading to physician-directed therapy changes and to improve patient outcomes; and statements regarding the ability of FoundationOne and FoundationOne Heme to identify and predict the likelihood of response to immunotherapies. 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 Foundation Medicine's test, revenue or operating expense projections may turn out to be inaccurate because of the preliminary nature of the forecasts; the

company's products do not perform as expected; acceptance into the Parallel Review process does not benefit the company; the company's expectations and beliefs regarding the future conduct and growth of Foundation Medicine's business are inaccurate; Foundation Medicine is unable to secure additional coverage decisions, achieve profitability, to compete successfully, to manage its growth, or to develop its molecular information platform; the company's TMB and/or MSI analyses do not perform as expected or the results thereof are not widely accepted or useful in clinical practice; physicians may not be able to obtain access to relevant targeted therapies, immunotherapies or clinical trials matched to molecular findings identified by the company's tests as readily as expected; and the risks described under the caption "Risk Factors" in Foundation Medicine's Quarterly Report on Form 10-K for the year ended December 31, 2015, 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.

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,	
	2016	2015	2016	2015
Revenue	\$ 29,426	\$ 25,399	\$ 88,041	\$ 67,152
Costs and expenses:				
Cost of revenue	15,946	10,370	39,291	28,236
Selling and marketing	14,654	14,267	42,928	36,630
General and administrative	13,012	9,199	34,739	41,810
Research and development	17,238	12,174	49,194	31,118
Total costs and expenses	60,850	46,010	166,152	137,794
Loss from operations	(31,424)	(20,611)	(78,111)	(70,642)
Other income (expense):				
Interest income	199	15	585	31
Interest expense	(57)	—	(57)	—
Total other income (expense)	142	15	528	31
Net loss	<u>\$ (31,282)</u>	<u>\$ (20,596)</u>	<u>\$ (77,583)</u>	<u>\$ (70,611)</u>
Net loss per common share applicable to common stockholders, basic and diluted	<u>\$ (0.90)</u>	<u>\$ (0.60)</u>	<u>\$ (2.24)</u>	<u>\$ (2.19)</u>
Weighted-average common shares outstanding, basic and diluted	<u>34,949,785</u>	<u>34,347,593</u>	<u>34,701,013</u>	<u>32,290,972</u>

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

	September 30, December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 77,847	\$ 117,763
Marketable securities	90,038	89,607
Accounts receivable, net	13,718	7,765

Inventory	11,959	7,992
Prepaid expenses and other current assets	2,973	6,517
Total current assets	196,535	229,644
Marketable securities	—	24,939
Property and equipment, net	42,041	41,333
Restricted cash	1,395	1,395
Other assets	2,345	678
Total assets	<u>\$ 242,316</u>	<u>\$ 297,989</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 12,005	\$ 10,469
Accrued expenses and other current liabilities	22,263	12,822
Deferred revenue	2,451	4,459
Current portion of deferred rent	2,250	2,146
Total current liabilities	38,969	29,896
Other non-current liabilities	8,971	10,404
Total stockholders' equity	194,376	257,689
Total liabilities and stockholders' equity	<u>\$ 242,316</u>	<u>\$ 297,989</u>

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