

January 9, 2017

Foundation Medicine Reports Preliminary 2016 Results

Achieves Total Revenue of Approximately \$116.9 Million, a 25% Year Over Year Increase

Reports 43,686 Clinical Tests in 2016, a 32% Year Over Year Increase

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Foundation Medicine](#) (NASDAQ:FMI) today announced preliminary unaudited total revenue of approximately \$28.8 million in the fourth quarter of 2016 and approximately \$116.9 million for the full year ended December 31, 2016, an 11% and 25% increase from the \$26.1 million and \$93.2 million recorded in the fourth quarter and full year ended December 31, 2015, respectively. Revenue from biopharmaceutical companies is expected to be approximately \$19.0 million in the fourth quarter of 2016 and approximately \$78.8 million for the full year ended December 31, 2016, compared to \$14.1 million and \$44.0 million in the fourth quarter and full year ended December 31, 2015, respectively. Revenue from clinical testing is expected to be approximately \$9.8 million in the fourth quarter of 2016 and approximately \$38.1 million for the full year ended December 31, 2016, compared to \$12.0 million and \$49.2 million in the fourth quarter and full year ended December 31, 2015, respectively.

The company reported 12,788 clinical tests to ordering physicians in the fourth quarter of 2016, compared to a total of 8,286 tests reported during the fourth quarter of 2015. A total of 43,686 clinical tests were reported to ordering physicians for the full year ended December 31, 2016, compared to 32,998 clinical tests reported in 2015. Cash, cash equivalents and marketable securities at December 31, 2016, was approximately \$143 million.

"Foundation Medicine evolved significantly in 2016, most notably through continued growth in clinical and biopharma product demand and utilization, product diversification through the launch of FoundationACT™ and the achievement of FoundationFocus™ CDx_{BRCA}, our first FDA-approved companion diagnostic, and expanded reimbursement coverage with third party and government payers," stated Michael J. Pellini, M.D., chief executive officer of Foundation Medicine. "As we look ahead to 2017, we believe we are well positioned for continued growth and further competitive differentiation, particularly as a result of our ongoing Parallel Review process with FDA and CMS for FoundationOne®."

2016 Enterprise Highlights:

- | Announced acceptance of FoundationOne for Parallel Review by FDA and CMS. The FDA also accepted Foundation Medicine's request for review as part of its Expedited Access Pathway (EAP) for breakthrough devices. 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.
- | Launched FoundationACT, the company's ctDNA assay, to clinical customers. FoundationACT was developed with the same rigorous analytical validation standards as FoundationOne and FoundationOne Heme.
- | Received FDA Approval of FoundationFocus CDx_{BRCA} as a companion diagnostic for Rubraca™ (rucaparib) for the treatment of women with ovarian cancer. FoundationFocus is the first next generation sequencing companion diagnostic approved by the FDA and marks important progress towards the development of the company's universal pan-cancer companion diagnostic assay.
- | Expanded patient access to CGP through Palmetto, a 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 patients at diagnosis.
- | 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.
- | Grew biopharmaceutical revenue by approximately 79% in 2016 and added several new molecular information, SmartTrials™ and companion diagnostic collaborations.
- | Increased FoundationCORE™, the company's molecular information database, to more than 100,000 clinical cases.
- | Expanded the company's laboratory footprint to include sites at Research Triangle Park (RTP) in North Carolina and Penzberg, Germany. The RTP facility became operational in September, increasing operational flexibility and broadening commercial opportunities. Once operational, the Penzberg location will support continued growth and

expansion in Europe through our commercial collaboration with Roche.

- 1 Published 72 peer-reviewed manuscripts in top medical and scientific journals and presented 129 podium talks and posters at scientific and medical meetings.

2017 Outlook

Dr. Pellini continued, "As we enter the year transitioning the chief executive officer post to Troy Cox, which will be completed in early February, we look forward to advancing our patient-centric mission and improving patient access to precision cancer care."

As part of Foundation Medicine's commitment to being a partner for the patient journey, the company expects to advance a number of key business objectives in 2017. These include: advancing its universal, pan-cancer companion diagnostic assay through the FDA and CMS parallel review process to decision and launch in the second half of 2017; broadening Medicare and third-party payer coverage for its clinical CGP products; growing clinical volume across its product portfolio, including expanded global market presence; and expanding its biopharma business, including additional companion diagnostic collaborations and SmartTrials clinical trial access programs.

Complete 2016 fourth quarter and full year financial results will be announced during the company's fourth quarter and fiscal year 2016 financial results conference call in February. The company also anticipates providing 2017 financial guidance at that time. This press release contains certain unaudited financial results for the company. These unaudited results could change as a result of further review by the company's management and its independent auditors.

Dr. Pellini is scheduled to present at the 35th Annual J.P. Morgan Healthcare Conference on Tuesday, January 10, 2017, at 9:00 a.m. PST, in San Francisco. A live, listen-only webcast of the presentation and breakout session 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 presentation and breakout session and will be archived on the company's website for two weeks.

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 FoundationACT[™], FoundationFocus[™] 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 benefits of FoundationOne, FoundationOne Heme, FoundationACT and FoundationFocus CDx_{BRCA} to physicians and patients in the treatment of cancer; the benefits provided by a FDA-approved version of FoundationOne; the scope and timing of any approval of FoundationOne 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 the growth of clinical volumes within and outside the United States. 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 as a medical device or that CMS does not decide to offer FoundationOne as a covered benefit under Medicare; the FDA or CMS is delayed in the completion of the Parallel Review process; the company's new 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 expectations and beliefs regarding the future conduct and growth of its 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 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. With respect to Foundation Medicine's estimated cash, total revenue, clinical revenue and biopharma revenue, clinical tests and other financial and business results as of and for the year ended December 31, 2016, it should be noted that this information is unaudited and that the company has not finalized its financial and business results for the three and twelve months ended December 31, 2016. 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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