October 20, 2013

OUTPERFORM

Reason for report:

INITIATION

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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

FOUNDATION MEDICINE, INC.

Lots of Questions, One Big Answer; Initiating at Outperform

• **Bottom Line**: While we acknowledge the Foundation Medicine (FMI) story carries with it several questions (reimbursement, barriers, clinical utility), we believe these issues will resolve over time, and that investors will keep their eyes on the big market opportunity that is high content molecular profiling for cancer therapeutics. FMI's FoundationOne test represents the most compelling shot on goal in this market, in our view. Thus, we initiate coverage with an Outperform rating and $39 price target.

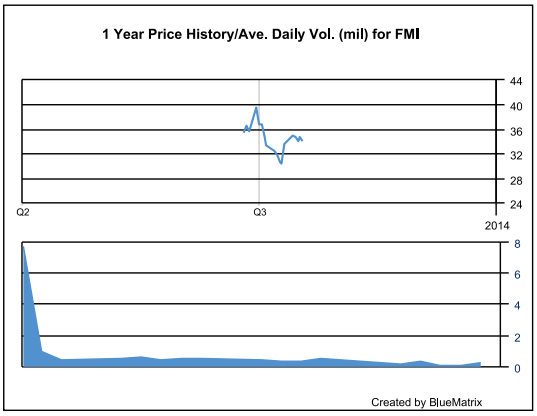
• **Large and underpenetrated market opportunity.** We believe the market opportunity for high content tumor profiling tests, which assess hundreds of genes to determine course of therapy, totals ~1M patients in the U.S. today. FMI is a leader in this market with clinical volume of >2,700 tests in 1H:13, which suggests the market is only minimally penetrated to date.

• **Test design, delivery address market need.** We believe FMI's FoundationOne test for solid tumors uniquely addresses the market need. A healthy pipeline of targeted oncology therapeutics drives the need for larger rather than smaller profiling panels as the number of genes which convey sensitivity to therapies has continued to increase. The breadth of FMI's 236 gene panel also enables physicians to maximize the amount of clinically relevant information they obtain from a limited sample. Finally, we believe FMI's intuitive physician report makes this information accessible to community oncologists, who see ~85% of cancer patients in the U.S.

• **Strong adoption to date with limited resources.** We can count the number of 2012 FMI sales reps on one hand with spare capacity, yet the FoundationOne test received rapid adoption in its first full year of launch. Clinical test volume exceeded 4,000 cases for the 12 months ended June 2013, following a June 2012 launch. With at least 18 sales reps today, we believe FMI should enjoy continued strong growth.

• **Several uncertainties worth monitoring, including reimbursement, competitive entry, clinical utility, and test regulation.** We do believe there are several risks associated with the FMI story worth monitoring, including the uncertain reimbursement environment (test has not yet received a positive coverage decision from a commercial payer nor has the company submitted claims to Medicare), competitive entry (hard barriers to entry are low), an evolving understanding of clinical utility, and an uncertain regulatory environment. While these risks must be taken into consideration, we don't believe their magnitude is sufficient to dampen investor enthusiasm over a large and thematic market opportunity.

Key Stats:	**(NASDAQ:FMI)**
S&P 600 Health Care Index:	**1,209.56**
Price:	**$33.99**
Price Target:	$39.00
Methodology:	~13x EV/Sept-15 TTM revenue
52 Week High:	$41.51
52 Week Low:	$18.00
Shares Outstanding (mil):	31.2
Market Capitalization (mil):	$1,060.5
Book Value/Share:	$4.63
Cash Per Share:	$4.48
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	--	--	--	--	$10.6	--	--	--	--	($1.05)	NM
2013E	$5.2A	$5.9A	$7.2	$8.2	$26.5	($0.33)A	($0.47)A	($0.49)	($0.41)	($1.71)	NM
2014E	--	--	--	--	$53.6	--	--	--	--	($1.66)	NM
2015E	--	--	--	--	$105.8	--	--	--	--	($0.86)	NM

Source: Company Information and Leerink Swann LLC Research
Revenues in $millions.

INVESTMENT THESIS

We are initiating coverage of Cambridge, Massachusetts-based Foundation Medicine (FMI) with an Outperform rating and a $39 price target. The company is the leader in bringing the benefits of next generation sequencing technology to cancer care. Its integration of next generation (i.e., nextgen) sequencing information with a clean, readily interpretable patient report helps physicians improve clinical treatment decision making and enables biopharmaceutical companies to identify and optimize the development of targeted oncology therapies. We believe this area is poised for rapid growth, and FMI's early mover advantage should enable it to be a leader in this field.

INVESTMENT POSITIVES

Large Market Opportunity, Increasing Need, Early Mover Advantage

High-content diagnostics for cancer therapeutics stratification represents a potentially large market opportunity. We believe the market opportunity for FMI's FoundationOne test is large and growing. Traditional genetic tests to determine drug sensitivity assess only one gene at a time, or a small subset of genes. This modality is becoming increasingly outdated, due to the proliferation of targeted therapeutics. FMI's FoundationOne test assesses 236 genes; the breadth of the gene panel is especially useful in determining therapeutic strategies for patients with aggressive disease, who have failed traditional lower density tests or who have rare cancers. We estimate approximately 1M patients in the U.S. would benefit from this test, a number which could grow as physicians become increasingly comfortable with the test and use it more broadly. Additionally, FMI plans to expand into the blood cancer market with the launch of FoundationOne-Heme in early 2014, and we could envision future shots on goal in recurrence monitoring and therapeutic resistance categories.

Broader panel yields information that traditional tests miss. The breadth of FMI's 236 gene panel solves many unmet needs in traditional oncology testing. These challenges include the relative limitations of small gene set, or hotspot, panel tests; tissue sample constraints; and the complexity of integrating molecular diagnostic tests into clinical practice. Of the first ~4,000 qualifying clinical specimens analyzed with FoundationOne since its commercial launch in June 2012, 82% of cases had actionable alterations, defined as those alterations directly linked to a clinically available targeted treatment option or mechanism-driven clinical trial. Only ~31% of the actionable information identified by FoundationOne would have been found by running traditional hotspot tests.

User-friendly report format. In a concise report, FMI's FoundationOne test communicates the actionable genomic alterations in a patient's cancer and matches these alterations with targeted therapies and relevant clinical trials. We believe the report format is uniquely user friendly compared to other options available, a necessary feature to gain adoption among the ~85% of U.S. oncologists who practice in a community setting. We are encouraged that FMI has already been chosen by The US Oncology Network, one of the nation's largest networks of community-based oncology physicians, as a preferred diagnostic lab.

Strong test adoption to date. FMI has experienced rapid adoption of FoundationOne. More than 1,500 physicians from large academic centers and community-based practices across more than 25 countries have ordered FoundationOne since its formal commercial launch in June 2012. As of June 2013, the company had analyzed >4,500 clinical specimens with its FoundationOne test. Also, the company has attracted partnerships with 18 biopharmaceutical customers and secured a laboratory master services agreement with Novartis (OP) for clinical research.

INVESTMENT RISKS

Reimbursement, Barriers, and Clinical Utility Are the Greatest Uncertainties

Timing of coverage decisions from commercial payers, Medicare uncertain. FMI has yet to obtain a positive coverage decision from any third-party commercial payer, nor has it begun to submit claims to Medicare. Thus, timing and magnitude of reimbursement for its FoundationOne tests are probably the greatest risk factors with the FMI story. The company has achieved some success receiving payment for FoundationOne to date, and we believe it has historically been paid on the significant majority of claims to third party payers. The average revenue per FoundationOne test for clinical use that met that company's revenue recognition criteria in 1H:13 was $3,700, which is well below the $5,800 list price but sits well above the $3,000+ level other esoteric molecular test providers have achieved. The company intends to begin submitting claims to the Centers for Medicare and Medicaid Services (CMS), which comprised 22% of 1H:13 clinical volume, prior to the end of 2013. Medicare does not contribute to our revenue forecast for 2013 and 2014, but does contribute 8% to our 2015 revenue forecast.

Hard competitive barriers are limited. The hard barriers to market entry for FMI's FoundationOne test are few and far between. Its service offering is built largely on human capital and trade-secret know-how, rather than patents or proprietary technology. Thus, we expect new entrants and existing clinical lab service providers will attempt to offer cancer sequencing tests similar to FoundationOne. However, we believe that replicating FMI's offering is not trivial, while its early mover advantage should erect several soft barriers, such as brand loyalty. Additionally, its efforts to promote and improve its Interactive Cancer Explorer could create network effects more powerful than any hard intellectual property, at least among the user base. Through Interactive Cancer Explorer, the online portal it developed in consultation with Google Ventures, physicians can currently access their FoundationOne reports and links to topical peer-reviewed literature. More than 40% of FoundationOne customers currently use this tool. We believe the company will launch in 2014 new applications on its Interactive Cancer Explorer to allow for sharing of genomic and treatment data, and the successful launch of these additional applications will be critical to creating a moat around FMI's business.

Product adoption contingent upon demonstration of clinical utility. FoundationOne is a cutting-edge, 236-gene cancer panel. In order to continue to drive adoption of its technology, FMI must persuade physicians and payers that the test provides clinical value beyond existing tests. Physicians may be reluctant to adopt FoundationOne to form their treatment decisions due to uncertainty with how to use the diagnostic information. Additionally, the clinical utility of FoundationOne is directly tied to the continued progression of targeted therapeutics through

clinical trials, a process over which FMI has no control. FMI does have several trials underway to prove the clinical utility of its test, including a study with US Oncology.

FDA has become more vocal on regulating LDTs. The FDA has stated on several occasions its intent to more tightly regulate laboratory developed tests (LDTs). Rumblings of enhanced regulatory efforts have continued since at least 2006. More recently (June 2013), the commissioner of the FDA spent nearly a third of her address at the American Society of Clinical Oncology (ASCO) annual meeting highlighting the potential risks of LDTs and the FDA's efforts to make sure that the accuracy and clinical validity of high-risk tests are established before they come to market. FMI's FoundationOne test is an LDT, as are the commonly used hotspot tests it seeks to displace (e.g., SNaPshot, OncoCarta, OncoMap), several other well-established oncology tests (e.g., MYGN's [MP] BRACAnalysis, GHDX's [OP] Oncotype), and tests in other fields such as non-invasive prenatal testing (e.g., all of the four tests to detect trisomies via cell-free fetal DNA). While we believe enhanced regulatory oversight at some point in the future is a real possibility, we do not envision this oversight as something that impairs FMI's market opportunity.

COMPANY PROFILE

High Growth, Commercial Stage Company with Cancer Diagnostic Solution

Leaders in cancer genomics from Dana-Farber Cancer Institute, the Broad Institute, Harvard University, and MIT founded FMI in 2009 with the goal of making advanced cancer genomic analysis available to any patient in any medical center. The company is now commercial-stage, and its novel FoundationOne test for solid tumors represents an important advancement in cancer diagnostics. The company uses nextgen sequencing technology to generate actionable genomic information which helps physicians improve clinical treatment decision making and enables biopharmaceutical companies to identify and optimize the development of targeted oncology therapies. The company collaborated with key opinion leaders in the oncology community to devise its first commercial product, the FoundationOne test for solid tumors, which currently assesses 236 genes known to be altered in cancer biology. Since FoundationOne's commercial launch in June 2012, more than 1,500 physicians from 25 countries have ordered the test, and the company has analyzed >4,500 clinical specimens. The company also has 18 biopharmaceutical customers and is continually expanding its robust molecular informatics platform.

FMI had 142 full-time employees as of August 31, 2013. Its headquarters is based in Cambridge, Massachusetts, and include a clinical laboratory regulated by CMS under the Clinical Laboratory Improvement Amendments (CLIA). The majority (~86%) of the company's revenue was generated within the United States in 1H:13, though the company is expanding its marketing efforts overseas.

SERVICE OVERVIEW

Novel Offering for Cancer Analysis

FoundationOne is a next generation sequencing (NGS) based assay and the first clinical product to emerge from FMI's cancer diagnostics efforts. The company developed FoundationOne in collaboration with several key opinion leaders in oncology and cancer biology to identify a set of genes that are known to be altered in human solid tumors and are validated targets for therapy or are clear drivers of cancer. FoundationOne currently identifies genomic alterations within 236 cancer-related genes across all four classes of genomic alterations (base pair substitutions, copy number alterations, short insertions and deletions, and gene rearrangements and fusions), as well as 47 introns, which are sequences of nucleotides involved in DNA replication that do not encode for proteins, of 19 genes commonly involved in rearrangements. The following table illustrates the current list of genes, and we expect this list will expand over time.

Current Gene List for FoundationOne

CURRENT GENE LIST							
ABL1	BTK	CTNNB1	FGF23	IL7R	MLH1	PDGFRA	SMO
AKT1	CARD11	DAXX	FGF3	INHBA	MLL	PDGFRB	SOCS1
AKT2	CBFB	DDR2	FGF4	IRF4	MLL2	PDK1	SOX10
AKT3	CBL	DNMT3A	FGF6	IRS2	MPL	PIK3CA	SOX2
ALK	CCND1	DOT1L	FGFR1	JAK1	MRE11A	PIK3CG	SPEN
APC	CCND2	EGFR	FGFR2	JAK2	MSH2	PIK3R1	SPOP
AR	CCND3	EMSY (C11orf30)	FGFR3	JAK3	MSH6	PIK3R2	SRC
ARAF	CCNE1	EP300	FGFR4	JUN	MTOR	PPP2R1A	STAG2
ARFRP1	CD79A	EPHA3	FLT1	KAT6A (MYST3)	MUTYH	PRDM1	STAT4
ARID1A	CD79B	EPHA5	FLT3	KDM5A	MYC	PRKAR1A	STK11
ARID2	CDC73	EPHB1	FLT4	KDM5C	MYCL1	PRKDC	SUFU
ASXL1	CDH1	ERBB2	FOXL2	KDM6A	MYCN	PTCH1	TET2
ATM	CDK12	ERBB3	GATA1	KDR	MYD88	PTEN	TGFBR2
ATR	CDK4	ERBB4	GATA2	KEAP1	NF1	PTPN11	TNFAIP3
ATRX	CDK6	ERG	GATA3	KIT	NF2	RAD50	TNFRSF14
AURKA	CDK8	ESR1	GID4 (C17orf39)	KLHL6	NFE2L2	RAD51	TOP1
AURKB	CDKN1B	EZH2	GNA11	KRAS	NFKBIA	RAF1	TP53
AXL	CDKN2A	FAM123B (WTX)	GNA13	LRP1B	NKX2-1	RARA	TSC1
BAP1	CDKN2B	FAM46C	GNAQ	MAP2K1	NOTCH1	RB1	TSC2
BARD1	CDKN2C	FANCA	GNAS	MAP2K2	NOTCH2	RET	TSHR
BCL2	CEBPA	FANCC	GPR124	MAP2K4	NPM1	RICTOR	VHL
BCL2L2	CHEK1	FANCD2	GRIN2A	MAP3K1	NRAS	RNF43	WISP3
BCL6	CHEK2	FANCE	GSK3B	MCL1	NTRK1	RPTOR	WT1
BCOR	CIC	FANCF	HGF	MDM2	NTRK2	RUNX1	XPO1
BCORL1	CREBBP	FANCG	HRAS	MDM4	NTRK3	SETD2	ZNF217
BLM	CRKL	FANCL	IDH1	MED12	NUP93	SF3B1	ZNF703
BRAF	CRLF2	FBXW7	IDH2	MEF2B	PAK3	SMAD2	
BRCA1	CSF1R	FGF10	IGF1R	MEN1	PALB2	SMAD4	
BRCA2	CTCF	FGF14	IKBKE	MET	PAX5	SMARCA4	
BRIP1	CTNNA1	FGF19	IKZF1	MITF	PBRM1	SMARCB1	
SELECT REARRANGEMENTS							
ALK	BCR	BCL2	BRAF	EGFR	ETV1	ETV4	ETV5
ETV6	EWSR1	MLL	MYC	NTRK1	PDGFRA	RAF1	RARA
RET	ROS1	TMPRSS2					

Source: Foundation Medicine

The test includes only those genes implicated in cancers for which a targeted therapy is FDA-approved and for which targeted therapies are in current or near-term clinical development, or otherwise important in cancer biology. Thus, a clinician can identify an actionable course of treatment should the test yield a positive biomarker for cancer.

FoundationOne provides physicians with a report that empowers them to make informed treatment decisions (typically14 to 17 days after the patient's sample arrives). The FoundationOne report illustrates the test's key findings in a practice-friendly manner, and it includes genomic alterations and options for either FDA-approved therapies or open clinical trials for therapies targeting the identified alterations. The report also identifies noteworthy absences of genomic alterations typically associated with anatomical tumors of the same type; and the report incorporates analyses of peer-reviewed studies and other publicly available information. These analyses and information may include associations between a molecular alteration (or lack of alteration) and one or more drugs with potential clinical benefit (or potential lack of clinical benefit), including drug candidates that are being studied in clinical research. The following table offers an example of the first page of the FoundationOne report.

FoundationOne Report

FOUNDATIONONE

Patient Name | Report Date | Diagnosis: **Colon adenocarcinoma (CRC)**

Date of Birth	Not Given	**Client**	Sample Case	**Specimen Received**	Not Given
Gender	Male	**Physician**	Soper, Chad	**Specimen Site**	Lung
FMI Case #	TRFAAAAAI	**Additional Recipient**	Not Given	**Specimen Date**	Not Given
Medical Record #		**FMI Client #**	-1	**Specimen Type**	Block
Block ID	SAMPLE	**Pathologist**	Not Given		

ABOUT THE TEST:
FoundationOne™ is a next-generation sequencing (NGS) based assay which identifies genomic alterations within hundreds of cancer-related genes.

PATIENT RESULTS

- 3 genomic alterations pg - 2
- 3 therapies associated with potential clinical benefit pg - 3
- 0 therapies associated with lack of response pg - 3
- 2 clinical trials pg - 4

TUMOR TYPE: COLON ADENOCARCINOMA (CRC)

Genomic Alterations Identified
ERBB2 amplification
APC E1309*
TP53 R282W

Additional Disease-relevant Genes with No Reportable Alterations Detected
BRAF
KRAS

THERAPEUTIC IMPLICATIONS

Genomic Alterations Detected	FDA Approved Therapies (in patient's tumor type)	FDA Approved Therapies (in another tumor type)	Potential Clinical Trials
ERBB2 amplification	None	Lapatinib Pertuzumab Trastuzumab	Yes, see clinical trials section
APC E1309*	None	None	None
TP53 R282W	None	None	None

Note: Genomic alterations detected may be associated with activity of certain FDA approved drugs; however, the agents listed in this report may have varied clinical evidence in the patient's tumor type. Neither the therapeutic agents nor the trials identified are ranked in order of potential or predicted efficacy for this patient, nor are they ranked in order of level of evidence for this patient's tumor type.

Source: Foundation Medicine

FMI has also enabled ordering physicians to access their FoundationOne report through its Interactive Cancer Explorer, which is a web-based physician portal developed in consultation with Google Ventures. The Cancer Explorer also includes current information about the reported genomic alterations, associated therapies, and clinical trials. The company updates FoundationOne periodically to reflect new scientific and medical knowledge about cancer biology, including new cancer genes, available targeted therapeutics, and clinical trials. More than 40% of FoundationOne customers currently use this tool. We believe the company will launch in 2014 new applications on its Interactive Cancer Explorer to allow for sharing of genomic and treatment data. The following table offers a depiction of what such an application could look like.

Interactive Cancer Explorer (Potential Application)

Source: Foundation Medicine

FoundationOne Cancer Genome Profiling Workflow

FMI performs all FoundationOne tests in its diagnostic laboratory located in Cambridge, Massachusetts. Once a physician orders the test, FMI contacts pathology to obtain a routine tissue sample. It then prepares the sample, sequences the tissue, and analyzes the data to deliver to the order physician in the FoundationOne report. Our brief description of each of these steps follows:

- ***Specimen preparation*:** This assesses the suitability for FoundationOne testing; samples must be at least 40 microns thick and consist of at least 20% tumor cells to enable the extraction of at least 50 nanograms of DNA. About 95% of all incoming samples meet these requirements. The company uses a proprietary target enrichment method to capture the exons of 236 cancer-related genes plus 47 introns from 19 genes often rearranged or altered in cancer.
- ***Sequencing*:** Next FMI determines the content of each DNA molecule using nextgen sequencing, specifically ILMN's (OP) HiSeq 2500. The company sequences the target molecules to an average depth of coverage of greater than 250x. Thus, FoundationOne is able to detect genomic alterations that may be present in as low as 1% of all cells being tested.
- ***Data analysis*:** After sequencing, each DNA molecule that meets the tests' quality thresholds is analyzed via the company's computational algorithms in order to detect and identify all genomic alterations present in the cancer sample. The company then further distills the genomic alterations into those where there is an available FDA-approved drug or clinical trial for which the patient is eligible for therapy based on the genomic characteristics of his or her sample. The last part of the process involves synthesizing the information regarding the identified alterations into actionable information. This resultant report is then returned to the ordering physician who can use the data in conjunction with clinical assessment to form his or her treatment decisions.

Technology Addresses Challenges in Existing Cancer Analytic and Treatment Pathways

FMI's approach to cancer diagnostics offers a solution to a number of challenges clinicians face today in diagnosing and treating cancer on a molecular level. These include the relative limitations of hotspot panel tests, tissue sample constraints, and the complexity of integrating molecular diagnostic tests into clinical practice. Our brief discussion of each of these follows:

- ***Hotspot panel tests*:** Most molecular diagnostic tests in the market are single-marker or hotspot panel tests that capture only one or a limited number of targeted, well-known gene alterations. In addition, these tests generally are only able to identify base pair substitutions and specific gene rearrangements, excluding the other two classes of genomic alterations (copy number alterations and short insertions and deletions). FoundationOne employs a more comprehensive approach by including 236 target genes, many of which have actionable therapy options. Of the first ~4,000 qualifying clinical specimens analyzed with FoundationOne since its commercial launch in June 2012, 82% of cases had biologically actionable alterations, defined as those alterations directly linked

to a clinically available targeted treatment option or mechanism-driven clinical trial. Only ~31% of the actionable information identified by FoundationOne would have been found by running traditional hotspot tests (SNaPshot, OncoCarta, OncoMap, HER2, and ALK FISH [Fluorescent in Situ Hybridization]).

- The following table summarizes the uses and inherent limitations of some of the current, most commonly ordered testing methods utilized in commercially available single-marker and hotspot panel tests for cancer.

Limitations in Current Testing Methods

Name	Uses	Limitations
Polymerase chain reaction, or PCR-based tests, a technology used for amplifying DNA sequence	Enable the detection of short fragment DNA or RNA sequences.	Single-gene tests for specific and limited number of mutations. Only identify known and select base substitutions and short insertions or deletions, such as BRAF V600E.
Immunohistochemical, or IHC, stains, a process used to diagnose abnormal cells	Utilize antibody proteins to identify certain antigens that are unique to various types of cancer.	Only identify the expressed presence of a known and select protein or specific protein marker, such as HER2, related to a particular genomic alteration
FISH-based DNA probes, a mechanism for detecting DNA sequences through the use of flourescent technology	Reveal specific genomic abnormalities, including insertion/deletions and rearrangements.	Only detect select gene rearrangements, such as EML4- ALK. Difficult to test for multiple markers

Source: Foundation Medicine

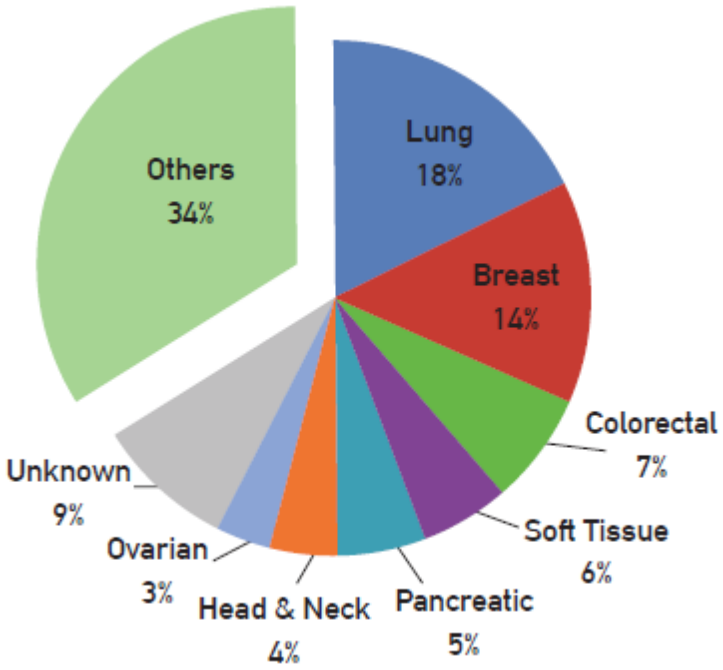
- ***Tissue constraints*:** Many clinical tumor samples yield very small tissue amounts, inherently limiting the number of diagnostic tests a physician can order. Clinical tumor specimens may also have low tumor purity, making detection of genomic alterations difficult. Also, most clinical samples are stored as formalin-fixed and paraffin-embedded (FFPE) type, which typically degrade DNA and RNA over time. FoundationOne addresses these issues since it can test for hundreds of genomic alterations in a FFPE sample with only 40 microns of tissue. This mitigates the risk of missing a genetic alteration from the lack in quantity or quality of tissue.
- ***Complexity of integrating MDx into clinical practice*:** The growing number of single-marker or hotspot molecular diagnostic (MDx) tests and common constraints with tumor samples compound the complexity of clinical decision making for physicians. In the event a physician were able to order several hotspot tests, interpreting the results from multiple labs and developing an optimal treatment protocol could prove challenging, especially if the physician is not trained in medical genetics. FoundationOne facilitates clinical practice with MDx by identifying targeted therapy options in a single, comprehensive report.

APPLICATIONS OF FOUNDATIONONE TEST

Enhancing Clinical Treatment Decision Making: Clinical (~70% of 2014e revenue)

Cancer clinicians worldwide have rapidly adopted FMI's FoundationOne test since its commercial launch in June 2012. More than 1,500 physicians from academic medical centers and community-based practices across more than 25 countries have ordered FoundationOne. One of the unique aspects of the FoundationOne test is that physicians can use the test to gain information on any solid tumor. To date, physicians have utilized the test in a broad range of tumors, as illustrated in the following table:

Tumor Types Analyzed With FoundationOne, First ~2,200 Cases



Source: Foundation Medicine

From our discussions with physicians, including MEDACorp specialists, as well as the company, we believe usage of FoundationOne is congregating into five broadly defined situational categories, summarized in the following table:

Common Categories of Usage for FoundationOne

Patient category	Example	Impact
Aggressive disease	Pancreatic cancer, or patients late in the progression of their disease	Under these circumstances, no good options exist; physicians and payers more willing to use novel approaches
Tested negative in traditional hotspot tests	Negative results for alterations in the genes EGFR, ALK, and KRAS in non-small cell lung cancer	These diseases are known to be genomically diverse; FoundationOne reveal targets not typically looked for
Failed standard treatment regimens	Patients with breast cancer who continue to progress despite multiple lines of chemotherapy	Patients are still treatment eligible but no further standards of care exist
Insufficient tissues	Non-small cell lung cancer patients with insufficient tumor tissue in archive for multiple hotspot tests	Physicians not forced to prioritize testing; FoundationOne helps get more information out of less tissue
Rare or uncommon tumors	Certain sarcomas or non-colon/small-bowel gastrointestinal tumors, which lack standard treatment options	Under these circumstances, no good options exist; physicians and payers more willing to use novel approaches

Source: Foundation Medicine, Leerink Swann

We believe these five patient cohorts represent ~1M U.S. patients annually according to published cancer statistics and third-party research commissioned by the company. Long-term pricing assumptions between $2,500 and $4,000 per test (list of $5,800) would suggest a $2.5B – $4B market opportunity for solid tumor testing in the U.S. alone.

As previously discussed, the FoundationOne test addresses several challenges in existing cancer analytic and treatment pathways. We present three case studies which exhibit how broader molecular profiling enabled by FoundationOne can identify targeted therapy and improve clinical decision making; outcomes that would have been unlikely under alternative testing methods.

- ***Case Study 1 – Identifying an actionable alteration missed by hotspot tests***: FoundationOne detected an anaplastic lymphoma kinase (ALK) fusion in a tumor specimen from a 43 year-old man diagnosed with metastatic adenocarcinoma of the lung involving his bones and pleura. Previous traditional diagnostic tests, including a customary FISH (Fluorescence in Situ Hybridization) test failed to identify the mutation. The patient was then treated with Xalkori (crizotinib), a targeted therapy that inhibits the activity of the ALK fusion protein. The treatment shrank the tumor and the patient experienced near complete resolution of disease for 16 months. The results were published in the *Journal of Thoracic Oncology* in September 2012.
- ***Case Study 2 – Identifying an actionable mutation not tested for in breast cancer***: FoundationOne detected an epidermal growth factor receptor (EGFR) point mutation in a tumor specimen from a middle-aged woman with metastatic inflammatory breast cancer (IBC); she initially had received combination chemotherapy and targeted therapy including Herceptin (trastuzumab) though her disease progressed within 12 months. Based on the EGFR finding, the patient began Tarceva (erlotinib) therapy as part of a combination regimen and experienced durable symptomatic and radiographic benefit that lasted eight months. Since therapies are traditionally prescribed per the tumor's

anatomical location, and EGFR mutations are commonly associated with lung cancer, it is not likely that other tests would have identified this alteration. The company plans to submit these results to a peer-reviewed journal in the near future.

- ***Case Study 3 – lung cancer from rare mutation responds to off-label agent and leads to further clinical trials:*** A 66-year-old man, a never-smoker, was referred to an oncology department for stage IV non-small-cell lung cancer (NSCLC); the patient had developed progressive left thoracic pain. A subsequent chest computed tomography (CT) scan showed massive left pleural effusion and pleural thickening, mainly involving the mediastinal pleura. Traditional testing did not reveal any activating epidermal growth factor receptor (EGFR) mutation or any specific ALK rearrangement. Given the patient's never-smoker status, additional molecular analyses were performed and revealed a BRAF V600E mutation. The patient was then treated with off-label vemurafenib monotherapy which induced rapid and complete metabolic and radiologic response. The *Journal of Clinical Oncology* published this case in July 2013.

Optimizing Drug Development and Identifying Targeted Therapies: Biopharma (~30% of 2014e revenue)

Biopharmaceutical companies are leveraging FMI's molecular information platform to aid in the development of targeted oncology therapies. FMI analyzes tissue samples from clinical trials and in turn, provides its biopharmaceutical partners with genomic profiling and information relevant to targeted therapies for both retrospective and prospective clinical studies and other drug development activities. FMI's technology platform enables biopharmaceutical companies to:

- accelerate clinical development timelines and increase the likelihood of patient response by prospectively analyzing tumor specimens to identify patients with certain genomic alterations for enrollment in clinical trials for targeted cancer therapeutics;
- guide usage and inform future development opportunities for experimental and marketed therapies by retrospectively analyzing clinical trial patients to stratify them as responders or non-responders based on presence or absence of certain genomic alterations;
- create opportunities for drug combination studies or new target discovery by identifying mechanisms of primary and acquired resistance; and
- form improvements to clinical trial design by contributing to the understanding of why some clinical studies have not met their primary endpoints.

Recently, one of the company's biopharmaceutical customers revised its development strategy by employing FMI's informatics platform. After its Phase II trial failed to meet its primary endpoint, FoundationOne predicted a response to the drug in development, and the customer created new hypotheses to test in upcoming Phase III trials. Eighteen biopharmaceutical companies currently use FMI's platform; including: Agios (OP), ARIAD (OP), Array BioPharma (OP), AstraZeneca (MP), Celgene (OP), Clovis Oncology (OP), Eisai, Johnson & Johnson (OP), Novartis (OP), and Sanofi (MP). Novartis (>10% of 1H:13 total revenue) generates the majority of FMI's biopharma revenue; the laboratory master services agreement between the two companies extends through May 1, 2015.

GROWTH RUNWAY

Multi-Pronged Strategy to Deliver Growth for Several Years

FMI is well positioned to drive growth, in our view; the following discussion highlights some areas of opportunity.

Organic market expansion: Since FoundationOne is a nascent molecular diagnostic test, we believe the company could drive further adoption by increasing the scientific literature available to the medical community that validates the company's technology. The company has three clinical trials underway which could build awareness of FoundationOne. We highlight each of these here:

- ***The US Oncology Decision Impact Study.*** This study is designed to assess the impact of FoundationOne on physician decision-making in a real world setting. FoundationOne will be performed on solid tumors from 300 patients during their second or later line of therapy. When the patient progresses, the impact of FoundationOne in switching a physician's recommended next course of treatment will be evaluated. The company may evaluate other endpoints as well.
- ***The FoundationOne Registry.*** The objective of this study is to better understand the impact of FoundationOne on a clinical population including: how physicians act on the results and how the results impact care and outcomes. The study is designed to recruit 3,000 patients over three years, with the initial 500 patients drawn from all patients for whom the FoundationOne test is ordered. The study will analyze several clinical variables, including subsequent treatments and responses to those treatments.
- ***The MD Anderson Prospective Study.*** This study aims to compare the clinical outcomes of patients who are treated with targeted therapy after testing with FoundationOne compared to historical outcomes for patients treated with chemotherapy. The study is designed to enroll a group of 300 patients with advanced solid tumors who are screened at enrollment with FoundationOne. The clinical outcomes for these patients will be compared to recent historical results for patients who received treatment with conventional chemotherapy for the same tumor types and stage versus the study population treated with a targeted therapy selected on the basis of the FoundationOne test.

Broadening patient population: FoundationOne plans to make available the FoundationOne assay to all patients with solid tumors as the number of available targeted therapies expands. This includes patients who are earlier in the treatment cycle; suffer from a broader set of disease conditions; or patients diagnosed with rare and uncommon cancers regardless of stage. The potential market expansion could represent 800K total patients annually and thus nearly double the size of the solid tumor opportunity.

Growing use of targeted therapeutics: The success of FMI's FoundationOne test is tethered to the continued successful progression of targeted cancer therapeutics through clinical trials, which then increases the clinical utility of high content molecular profiling tests such as FMI's. Several signposts suggest a full pipeline of targeted oncology therapies. A survey by the Tufts Center for the Study of Drug Development found that companies increased their investment in personalized

medicine initiatives by 75% from 2005 to 2010 and expected to increase investment in personalized medicine by an additional 53% from 2010 to 2015. Several targeted therapies are available on the market while several hundred targeted therapies are in the biopharma product pipeline or undergoing clinical trials.

Today, genetic testing is guiding targeted therapy decisions for several cancers, including breast (HER2 testing), colorectal (KRAS), lung (EGFR, KRAS, and ALK), melanoma (BRAF), and leukemia (BCR/ABL). We believe the growing number of targeted cancer therapeutics will expand the market opportunity for FoundationOne. The lung cancer market, where molecular profiling is probably most widely utilized, offers a good microcosm of the diagnostic/drug progression that could proceed in every tumor type, especially as categorization of a tumor by its anatomical site of debut looks increasingly outdated. The FDA clearance of erlotinib (Tarceva) kick-started interest in molecular profiling within the lung cancer community, as mutations in EGFR and KRAS conveyed sensitivity to the drug. Thus, doctors wanted to know EGFR and KRAS status. In 2011, crizotinib (Xalkori) was approved, which added ALK to the list of information that lung cancer oncologists wanted. When we spoke with a MEDACorp lung cancer specialist in Sept 2012, he communicated that EGFR, KRAS, ALK, ROS1, and RET were now all on the standard menu of tests he wants for Stage IV lung cancer patients. In the past year, biological understanding and targeted therapeutics have advanced still further, and he now wants EGFR, KRAS, ALK, ROS1, RET, BRAF, and HER2 as standard tests for all Stage IV lung cancer patients. We believe this list will expand still further in the coming two years, as the category of fibroblast growth factor receptor (FGFR) inhibitors advances through Phase III trials toward approval, and a couple of new EGFR inhibitors as well as a MET inhibitor could be approved.

To gain a better sense of the depth of the targeted oncology pipeline, we sampled the list of targeted cancer therapeutics for common gene targets known to have a role in cancer pathology. Even isolating the list to those therapies in Phase II or later-stage clinicals, we found hundreds of trials in tens of tumor types, and this list only considered 15 of the 236 genes on the FoundationOne test. The following table summarizes these findings:

Clinical Trials and Targeted Anticancer Agents for Select Gene Targets

Gene	# of associated clinical trials, Ph II+, U.S.	Drugs/development name (1)	Cancers (2)
EGFR	153	Afatinib, canertinib, erlotinib, gefitinib, icotinib, theliatinib, vandetanib	Lung, colorectal, lymphoma, familial polyposis, thyroid
MET	61	Amuvatinib, cabozantinib, crizotinib, foretinib, tivantinib, volitinib	Breast, kidney, lung, lymphoma, thyroid
PIK3CA	45	Buparlisib, sophoretin, BYL719, GDC-0032, INK-1117	Breast, colon, glioblastomas, liver, lung, ovary, stomach
PTEN	35	Pazopanib, tivantinib, GSK2636771	Bladder, breast, glioblastoma, kidney, prostate
KRAS	35	Cetuximab, everolimus, retaspimycin, panitumumab, NKTR 102	Colorectal, lung, small bowel
VEGF/VEGFR	34	Foretinib, linifanib, orantinib, sulfatinib, vatalanib	Breast, colorectal, liver, pancreatic, renal, thyroid
ALK	28	Crizotinib, AP26113, ASP3026, CH5424802, AF802, LDK378, TSR-011	AML, lung, lymphoma
BRAF	24	Dabrafenib, vemurafenib, ARQ 736, RAF265, RO5212054, PLX3603	Melanoma, brain, colorectal, thyroid
RET	17	Amuvatinib, cabozantinib, motesanib, regorafenib, sorafenib, sunitinib	ALL, hematologic, liver, renal, thyroid
BRCA1	14	Rucaparib, veliparib	Breast, ovarian
CDK4/6	5	Palbociclib, LEE011, LY2835219	Breast, colorectal, glioblastoma, melanoma, lung
ROS1	2	Crizotinib	Breast, lung
NOTCH1	1	MK0752, PF-03084014, REGN421, RO4929097, R4733	Advanced solid, leukemia, lymphoma
MEK	1	Mekinist, cobimetinib, pimasertib, refametinib, selumetinib	Liver, lung, melanoma, pancreatic
MAP2K1	1	BVD-523, MK-8353, SCH900353	Biliary tract, colorectal, melanoma, pancreatic, thyroid
Total	**456**		

Source: mycancergenome.org, NIH, Leerink Swann. Note: (1) drugs/development name may be in trials ex-U.S. (2) may not reflect all indications (as of 10/8/13).

Thus, we feel comfortable that the therapeutic pipeline is rich enough to drive increasing interest in high content molecular profiling tests such as FoundationOne.

FoundationOne expansion for hematologic oncology: The company plans to launch its second commercial product in 1Q:14; FoundationOne for hematologic malignancies. FMI has been developing FoundationOne for hematologic malignancies in collaboration with Memorial Sloan-Kettering Cancer Center. The assay will sequence RNA and DNA to identify the genes and genomic alterations characteristic of hematologic malignancies. Hematologic malignancies account for approximately 10% of new cancer diagnoses in the United States.

International expansion: Although physicians in 25 different countries have ordered FoundationOne, approximately 85% of FMI's revenue was driven by domestic sales in 1H:13. The company has directed most of its marketing efforts domestically, and we believe it has ample opportunity for growth overseas. FMI is actively addressing market opportunities in Central and South America, Western Europe, portions of the Middle East, and is adding dedicated regional managers located outside the United States.

***Product pipeline*:** FMI has a number of projects in its active R&D pipeline. The company is exploring new products including: products utilizing circulating tumor cells and/or cell-free plasma DNA; products that expand its offerings into additional areas such as epigenetics and immune response.

REIMBURSEMENT LANDSCAPE

Third-Party Payer Contracts Critical to the Story

FMI has yet to obtain a positive coverage decision from any third-party commercial or government payer although the company has been successful in securing reimbursement for FoundationOne tests with commercial payers. Success going forward will be highly dependent on the company's ability to secure third-party reimbursement for FoundationOne. While the sticker price of $5,800 may seem high, the average commercial reimbursement of ~$3,700 for tests which have met FMI's revenue recognition criteria is consistent with approximate list or average selling prices for many other esoteric cancer tests, as illustrated in the following table:

List Price for Select Molecular Oncology Tests

Company	Test	Tumor Site	Price ($)	Source
Agendia	MammaPrint	Breast	$4,200	List
bioTheranostics	CancerTYPE ID	Unknown origin	3,600	List
Cancer Genetics	MatBA	Leukemia	3,300	List
Caris Life Sciences	Molecular Intelligence	Unknown origin	5,440	List
Foundation Medicine	FoudationOne	Any	3,700	ASP
Genomic Health	OncotypeDx	Breast, Colon	3,130	ASP
Pathwork Diagnostics	Pathwork Tissue Origin	Unknown origin	3,750	List
Rosetta Genomics	miRview mets	Unknown origin	3,650	List
XDx	AlloMap	Heart transplant	3,400	List

Source: Company reports, Leerink Swann; ASP = average selling price

FMI currently bills payers (except Medicare) via a code stack method, adding up the different codes for genes in its tests with specific reimbursement. Totaling published Medicare reimbursement amounts for only those 11 genes where we could find payment levels, illustrated in the following table, suggests that FMI can justify its $5,800 list price for FoundationOne.

Medicare Reimbursement for Select Gene Codes

Code	Description	Payment
81211	BRCA1 & 2 seq and com dup/del	$2,795
81210	BRAF gene	181
81235	EGFR	333
81245	FLT3 gene	167
81270	JAK2 gene	126
81275	KRAS gene	199
81292	MLH1 gene full seq	651
81295	MSH2 gene full seq	153
81298	MSH6 gene full seq	290
81310	NPM1 gene	249
81321	PTEN gene analysis, full sequence	$605
Total		**$5,749**

Source: CMS, Foundation Medicine, Leerink Swann. Note: Payment reflects the national limitation amount (NLA) for each test basted on current Medicare gapfill reimbursement. Rates for CPT codes 81201, 81209, 81242 and Tier II were not available.

Thus, we believe investors should take some comfort that FoundationOne's ASP of ~$3,700 is sustainable on its own, in our view, absent any pressures that could be exerted by competitors. We'll also note that FMI has received reimbursement on a significant majority of its commercial cases through 1H:13. Our modeling doesn't assume any positive coverage or contracting decisions until 2015. A conversation with a MEDACorp reimbursement specialist suggests to us that payment will remain a matter of hand-to-hand combat in the near term.

COMPETITIVE LANDSCAPE

List of Potential Competitors Is Vast, but FMI Has the Early Mover Advantage

FMI's list of potential competitors is vast and would include essentially include any lab services company or academic medical center which wants to offer broad nextgen sequencing oncology panels, as well as potentially even research tool suppliers who wish to expand into services. Practically, our conversions with MEDACorp specialists and other physicians reveal that FMI has a distant lead over the competition today, with many not even able to name another lab which offers a comparably broad panel. Names that do come up include Caris Life Sciences and TGEN, which launched its commercial CLIA lab earlier in the year. Additionally, FMI competes with the more targeted hotspot panels in wide use today.

VALUATION CONSIDERATIONS

Trading More Similar to a Biotech Company Than a Diagnostics Company

FMI's valuation suggests that the large market opportunity for FoundationOne is not lost on investors. The following table depicts its current revenue multiple compared to other emerging growth tools, diagnostics, and commercial stage biotech peers:

Foundation Medicine's Peer Group Valuations (dollars in millions, except share price)

Company	Ticker	Stock price	Enterprise Value	Revenue 2013e	Revenue 2014e	Revenue Growth	EV/2014E Rev. Multiple
Emerging Growth Tools/Diagnostics							
Cepheid	CPHD	$40.67	$2,675	$383	$444	16%	6.0x
Cellular Dynamics	ICEL	17.72	292	13	31	144%	9.3x
GenMark	GNMK	12.69	516	29	31	7%	16.4x
Fluidigm	FLDM	24.04	551	68	82	22%	6.7x
NanoString	NSTG	11.15	167	30	54	79%	3.1x
Illumina	ILMN	81.43	11,044	1,384	1,551	12%	7.1x
Exact Sciences	EXAS	11.26	793	4	37	792%	21.6x
Intrexon	XON	23.00	2,231	76	144	89%	15.5x
Genomic Health	GHDX	30.33	817	261	293	12%	2.8x
Pacific Biosciences	PACB	5.29	328	27	36	33%	9.0x
Emerging Growth Commercial Biotech							
ARIAD	ARIA	2.67	493	58	128	122%	3.9x
Medivation	MDVN	50.82	3,768	243	404	66%	9.3x
Orexigen Therapeutics	OREX	5.74	545	3	65	1827%	8.4x
Regeneron	REGN	303.56	33,648	1,938	2,509	29%	13.4x
Questcor	QCOR	65.80	3,945	722	908	26%	4.3x
Seattle Genetics	SGEN	40.04	4,519	245	277	13%	16.3x
Vertex	VRTX	77.06	16,010	1,164	934	(20%)	17.1x
Theravance	THRX	34.17	3,335	11	108	843%	30.9x
Arena	ARNA	4.50	903	86	69	(20%)	13.2x
BioMarin	BMRN	66.36	8,973	551	679	23%	13.2x
Isis	ISIS	32.68	3,118	134	120	(10%)	26.0x
Aegerion	AEGR	80.92	2,333	40	175	336%	13.3x
VIVUS	VVUS	$9.79	$986	$55	$184	234%	5.4x
MEDIAN -- Overall						29%	9.3x
MEDIAN -- Tools/Dx						27%	8.1x
MEDIAN -- Biotech						29%	13.2x
Foundation Medicine	FMI	$33.99	$980	$27	$54	102%	18.3x

Source: Leerink Swann, FactSet (all estimates are FactSet consensus, except FMI, which are Leerink Swann estimates)

Prices are 10/18/2013 close

Note: In calculating enterprise value (EV) for companies with material burn, we do not consider cash excess, and thus do not subtract from market cap in our EV calc; in the case of FMI, we assume ~$70M burn to breakeven, and consider rest of cash excess

VALUATION

FMI is clearly being valued as a biotech company, and thus we think it reasonable that our twelve-month price target of $39 reflects an enterprise value (using projected levels of debt and cash) that is ~13x our revenue estimate for the twelve months ended Sept. 2015, a multiple that is in line with the biotech median.

Our DCF analysis, as shown in the following table, also suggests a $39 target is reasonable.

Key assumptions/analysis in DCF model

Period Ended *($ thousands)*		2013e	2014e	2015e	2016e	2017e	2018e	2019e	2020e	2021e	2022e
Revenues		**$26,519**	**$53,641**	**$105,843**	**$215,580**	**$380,456**	**$553,257**	**$684,531**	**$778,807**	**$865,290**	**$900,527**
Volume											
FoundationOne-solid tumor		7,785	19,851	38,710	73,550	117,680	164,752	214,177	257,012	282,714	296,849
FoundationOne-heme		0	1,000	3,000	6,000	12,000	21,000	31,500	40,950	47,093	49,447
Price											
FoundationOne-solid tumor		$3,675	$3,700	$3,500	$3,300	$3,100	$2,900	$2,700	$2,500	$2,500	$2,500
FoundationOne-heme			$5,500	$5,300	$5,100	$4,900	$4,700	$4,500	$4,300	$4,100	$4,000
Gross margin		61%	63%	68%	70%	70%	70%	70%	70%	70%	70%
Free cash flow		($35,978)	($41,533)	($14,613)	$44,769	$141,522	$171,118	$211,881	$241,193	$268,018	$279,072
t		1	2	3	4	5	6	7	8	9	10
Discount factor		0.9	0.8	0.7	0.6	0.5	0.4	0.4	0.3	0.3	0.2
PV of cash		($31,285)	($31,405)	($9,608)	$25,597	$70,361	$73,979	$79,654	$78,846	$76,187	$68,982
WACC	15%										
Terminal growth	4%										
PV (thru 2022)	$401,309										
terminal value	652,197										
Enterprise value	1,053,506										
- net debt	(67,310)	*assumes ~$70M burn*									
Equity value	$1,120,816										
Diluted shares out	31,220										
Share price	$35.90										
Share price (adj ytd)	**$39.87**										

Source: Leerink Swann

This analysis includes a number of simplifying assumptions which we think allow for a fair balance of upsides and downsides. We assume the market for FoundationOne for solid tumors in the U.S. is ~1M patients annually, this market is 60% penetrated by Foundation-like panels in 10 years (an assumption based on the 10-year penetration of the U.S. invasive breast cancer prognostic test market by GHDX and others), and FMI's early mover advantage affords it a 50% share. Any expansion of the U.S. market beyond ~1M patients, as high content panels move earlier in treatment protocols as well as international expansion, would be upside. We assume pricing compresses from ~$3,700 today (average revenue per FoundationOne test for clinical use that met FMI's revenue recognition criteria during 1H:13) to $2,500 in 10 years, driven by intensifying competition and reimbursement pressure, a phenomenon we're currently seeing in the market for hereditary breast and ovarian cancer (HBOC) testing as well as hereditary colorectal cancer testing. This assumption could prove conservative as there is some opportunity for pricing to survive in this market more so than we expect it will in HBOC testing for a number of reasons, including the incremental challenge and cost associated with assessing samples from FFPE tissue as opposed to blood or saliva.

For the forthcoming FoundationOne hematology product, we assume a U.S. market opportunity of ~150k patients annually, 60% penetration in 10 years, and 50% share for FMI. Similar to solid tumor, international expansion would offer upside. We expect similar pricing compression from ~$5,500 per test initially to ~$4,000 in 10 years, but believe that absolute pricing will be well higher than the solid tumor test, partially to reflect what we believe will be higher costs associated with this test.

Despite expectations of price pressure and competition, we believe FMI can maintain a healthy 70% gross margin over time. We believe it appropriate to project the margin conservatively below the 80%+ margins of GHDX and MYGN, but well above ~40% gross margins of the national

reference labs, which derive most of their revenue from commodity testing. We believe it important to note that FMI already achieved a 62.5% gross margin in 2Q:13 on only ~$6M of revenue, which suggests to us that 70% is reasonable if not conservative, even in the face of competition.

RISKS TO VALUATION

The primary risks to our price target for FMI include, but are not limited to: ability to obtain positive coverage decisions and contract terms with third-party payers, competitive pressures from other molecular diagnostic testing companies, an uncertain pace of drug approvals which require molecular profiling (which impacts the clinical utility of FMI's test but is outside its control), the pace of adoption of its FMI products among biopharmaceutical customers, nature and timing of FDA guidance/regulations, and policy decisions.

MANAGEMENT

Michael Pellini, MD, President and CEO. Dr. Pellini joined Foundation Medicine as President and Chief Executive Officer in May 2011, bringing a breadth of experience in life sciences and the clinical diagnostics and laboratory industries to the company. Pellini came to Foundation Medicine from Clarient, a GE Healthcare Company, where he held the position of President and Chief Operating Officer. Pellini joined GE Healthcare through the integration of Clarient, Inc., where he worked with the company's leadership team to drive critical regulatory and reimbursement strategies in parallel with the development and commercialization of multiple diagnostic tests. Pellini's leadership was instrumental in building Clarient to the highly successful acquisition by GE Healthcare in October 2010.

Prior to his tenure with Clarient, Pellini served as Vice President, Life Sciences at Safeguard Scientifics, Inc. where he leveraged his business and medical expertise to explore new market opportunities and to support Safeguard's partner companies. Prior to Safeguard, he was Executive Vice President and Chief Operating Officer at Lakewood Pathology Associates, a national molecular and pathology services company, which was acquired by Water Street Healthcare Partners in 2006. Prior to that, Pellini was an Entrepreneur-in-Residence at BioAdvance, where he was responsible for reviewing and evaluating early-stage life science companies. He also served as President and Chief Executive Officer of Genomics Collaborative, Inc., a Boston-based biotech firm that was acquired by SeraCare Life Sciences, Inc. in 2004.

Pellini received a BA from Boston College, an MBA from Drexel University, and an MD from Jefferson Medical College of Thomas Jefferson University.

Vincent Miller, MD, SVP, Clinical Development. Dr. Miller joined Foundation Medicine in October 2011 after nearly 20 years at Memorial Sloan-Kettering Cancer Center where he served as an Attending Physician. His work in clinical and translational research in lung cancer culminated in observations and collaborative efforts critical to identification of EGFR sensitizing and resistance mutations. He is considered a world's authority in lung cancer and clinical trial

design and interpretation. Miller has authored and co-authored numerous abstracts, reviews, and peer-reviewed articles, which have appeared in such journals as *Proceedings of the National Academy of Science USA*, *Cancer Research*, *Clinical Cancer Research*, and the *Journal of Clinical Oncology*.

Dr. Miller received a BA in mathematics at the University of Pennsylvania and an MD at the University of Medicine and Dentistry of New Jersey in Newark. He completed an internship and residency, and then served as Chief Medical Resident in Internal Medicine at Thomas Jefferson University Hospital in Philadelphia, and subsequently a fellowship in Medical Oncology at Memorial Sloan-Kettering Cancer Center.

Steven Kafka, PhD, COO. Dr. Kafka joined Foundation Medicine in January 2013, bringing over 15 years of business and strategy experience in the pharmaceutical and biotechnology industries, with a focus on targeted therapies in oncology. Kafka was previously Chief Operating Officer and Chief Financial Officer at Aileron Therapeutics, where he led the company's operations, finance, and human resources functions.

Before this, Kafka was Vice President of Finance at Infinity Pharmaceuticals (NASDAQ: INFI) where he led finance, investor and public relations and business operations. While at Infinity, he worked on a number of innovative collaborations with leading pharmaceutical companies, including the company’s strategic alliance with Purdue Pharmaceuticals. Earlier in his career, Kafka was Senior Director of Finance at Millennium Pharmaceuticals.

Kafka earned his Ph.D. from Harvard University and his B.A. with Distinction and Honors from Stanford University.

Kevin Krenitsky, MD, Chief Commercial Officer and SVP International Strategy. Dr. Krenitsky joined Foundation Medicine in June 2011, bringing 15 years of experience in building and managing global diagnostic and biotechnology operations to the company. He joins Foundation Medicine from Enzo Clinical Labs where he served as President. In this role, he instituted a comprehensive operational plan that resulted in re-accreditation by the College of American Pathologists and led the introduction of numerous U.S. FDA-approved esoteric tests as well as several new laboratory developed test rollouts, all of which led to significant revenue growth during his tenure.

Prior to Enzo Clinical Labs, he was Chief Executive Officer at BioServe Biotechnologies, a global biotechnology company specializing in processing genetic diagnostic tests, and before that, he served as Chief Executive Officer at Parkway Clinical Laboratories, a clinical diagnostic lab providing comprehensive routine and esoteric testing. Before joining Parkway Clinical Laboratories, Krenitsky held multiple senior level positions within Genomics Collaborative, Inc. (a SeraCare Life Sciences Company), a full-scale clinical and genomics research company.

Krenitsky received a BS in business management from the University of Scranton and an MD from Jefferson Medical College.

Gary Palmer, MD, JD, MBA, MPH, Senior Vice President, Medical Affairs and Commercial Development. Dr. Palmer is a medical oncologist with a career spanning three decades in

oncology, initially as a clinician in both the academic and community settings and then as a biotech industry executive with diagnostic and therapeutic experience.

Palmer joined Foundation Medicine from On-Q-ity, where he was Chief Medical Officer and Head of Development for DNA repair marker development and circulating tumor cell technology. He also served as Vice President of Medical affairs at Genomic Health, Inc. Prior to Palmer's tenure with Genomic Health, he held leadership positions at Kosan Biosciences and Salmedix, Inc. He also spent five years at Amgen. Prior to joining industry, he served as Director of the Medical Breast Service at the University of California Davis Cancer Center and Chief of Medical Oncology at Mercy Health System, Sacramento.

Palmer received a BA from Yale University and an MD from the Stanford University School of Medicine. He completed his internal medicine training at the Boston City Hospital and his oncology fellowship at the Massachusetts General Hospital. He also holds an MBA from the University of California, an MPH from the University of California, Los Angeles and a JD from Concord University.

Jeffrey Ross, MD, Medical Director, Interim Head of Pathology and Molecular Diagnostics. Dr. Ross is a leader in the field of molecular diagnostics, having received a number of academic awards, been awarded three patents and authored more than 600 peer-reviewed scientific articles and abstracts, four textbooks and numerous book chapters in the fields of pathology, molecular diagnostics, oncology and translational cancer research.

Ross is the Cyrus Strong Merrill Professor and Chair of the Department of Pathology and Laboratory Medicine at Albany Medical College, where he directs an extramurally funded research laboratory in molecular pathology. Between 1999 and 2004, Ross served as Scientific Fellow and Head of Molecular Pathology at Millennium Pharmaceuticals before co-founding Syfr, Inc. an RFID Specimen Management and IHC/ISH/FISH autostainer company. Prior to that Ross served as Medical Director for Managed Care for Roche Biomedical Laboratories and Laboratory Corporation of America.

He is a graduate of Oberlin College, Oberlin, Ohio and The State University of New York at Buffalo School of Medicine in Buffalo, New York.

Phil Stephens, PhD, VP, Cancer Genomics. Dr. Stephens joined Foundation Medicine in March 2011, bringing more than a decade of experience in cancer genomics to the company. Stephens is a world-renowned authority in next-generation sequencing and cancer genome analysis and has authored numerous publications in *Nature*, *Nature Genetics*, *Nature Medicine*, *Cell* and other high-profile journals.

Prior to joining Foundation Medicine, Stephens held various senior research positions during his 11-year tenure with the Cancer Genome Project at the Wellcome Trust Sanger Institute under the direction of Professor Michael Stratton.

Dr. Stephens received a PhD from Oxford University.

Jason Ryan, VP, Finance. Mr. Ryan joined Foundation Medicine in May 2011 and brings over 12 years of financial and operations experience in emerging life science companies. Prior to joining Foundation Medicine, Ryan led the finance and strategic planning functions of Taligen

Therapeutics (acquired by Alexion Pharmaceuticals), Codon Devices, and Genomics Collaborative (acquired by SeraCare Life Sciences).

Ryan holds a BS in economics from Bates College and an MBA from Babson College, and earned his CPA in Massachusetts.

Foundation Medicine Inc. (FMI)

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Income statement

Period Ended *($ thousands)*	2011	2012	Mar-13	Jun-13	Sep-13e	Dec-13e	2013e	2014e	2015e
Revenues	**$2,057**	**$10,645**	**$5,200**	**$5,920**	**$7,161**	**$8,239**	**$26,519**	**$53,641**	**$105,843**
Cost of product sales	258	5,681	2,378	2,219	2,721	3,131	10,449	19,847	33,870
Gross profit	1,799	4,964	2,822	3,701	4,440	5,108	16,071	33,794	71,974
SG&A	8,547	12,098	4,961	7,630	8,593	9,063	30,246	47,740	63,506
R&D	9,023	14,777	4,982	6,097	6,800	7,800	25,679	34,330	34,399
Operating income (loss)	**(15,771)**	**(21,911)**	**(7,121)**	**(10,026)**	**(10,953)**	**(11,755)**	**(39,855)**	**(48,277)**	**(25,932)**
Interest expense (income)	421	421	76	65	31	32	204	150	176
Other expense (income)	845	61	6	96	0	0	102	0	0
Pretax income	(17,037)	(22,393)	(7,203)	(10,187)	(10,984)	(11,787)	(40,161)	(48,427)	(26,107)
Taxes	0	0	0	0	0	0	0	0	0
Net income	(17,037)	(22,393)	(7,203)	(10,187)	(10,984)	(11,787)	(40,161)	(48,427)	(26,107)
Preferred accretion	(296)	(286)	(50)	(42)	0	0	(92)	0	0
Net income to common	($17,333)	($22,679)	($7,253)	($10,229)	($10,984)	($11,787)	($40,253)	($48,427)	($26,107)
Basic shares outstanding	21,700	21,700	21,700	21,700	22,321	28,657	23,594	29,157	30,457
Diluted shares outstanding	21,700	21,700	21,700	21,700	22,321	28,657	23,594	29,157	30,457
EPS diluted	**($0.80)**	**($1.05)**	**($0.33)**	**($0.47)**	**($0.49)**	**($0.41)**	**($1.71)**	**($1.66)**	**($0.86)**
EPS growth									
Sales growth		417.5%	749.7%	225.8%			149.1%	102.3%	97.3%
Clinical tests		1,753	1,140	1,626	2,297	2,722	7,785	20,851	41,710
Gross margin	87.5%	46.6%	54.3%	62.5%	62.0%	62.0%	60.6%	63.0%	68.0%
SG&A % of revenue	415.5%	113.6%	95.4%	128.9%	120.0%	110.0%	114.1%	89.0%	60.0%
R&D % of revenue	438.6%	138.8%	95.8%	103.0%	95.0%	94.7%	96.8%	64.0%	32.5%
Operating margin	**(766.7%)**	**(205.8%)**	**(136.9%)**	**(169.4%)**	**(153.0%)**	**(142.7%)**	**(150.3%)**	**(90.0%)**	**(24.5%)**
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D&A expense	$1,520	$2,894	$1,030	$1,043			$4,591	$4,789	$5,234
EBITDA	**($14,251)**	**($19,017)**	**($6,091)**	**($8,983)**			**($35,264)**	**($43,487)**	**($20,698)**
Free cash flow									
Operating cash flow	($14,133)	($17,249)	($6,694)	($7,016)			($29,328)	($34,682)	($6,749)
Capex	(5,410)	(3,183)	(170)	(1,128)			(6,854)	(7,001)	(8,040)
Free cash flow	($19,543)	($20,432)	($6,864)	($8,144)			($36,182)	($41,683)	($14,788)

Notes:

Source: Company reports and Leerink Swann estimates

Foundation Medicine (FMI)

Balance sheet

Period Ended *($ thousands)*	Dec-12	Mar-13	Jun-13	Sep-13e	Dec-13e
Assets					
Cash, equivalents, ST investments, restricted cash	$54,838	$45,832	$35,965	$139,656	$128,957
Accounts receivable	2,195	3,127	4,114	3,924	4,514
Inventory	803	796	725	924	1,064
Prepaid expenses and other current assets	550	953	1,004	1,146	1,318
Total current assets	58,386	50,708	41,808	145,650	135,854
Property and equipment, net	7,465	7,560	7,260	8,951	10,298
Restricted cash / LT investments	161	1,886	1,886	1,886	1,886
Other assets	27	26	1,315	1,315	1,315
Total assets	$66,039	$60,180	$52,269	$157,802	$149,353
Liabilities and shareholders' equity					
Notes payable - current portion	$1,704	$1,739	$1,712	$2,346	$2,346
Accounts payable	1,609	2,336	2,109	2,386	2,745
Accrued expenses	3,463	3,165	3,530	3,437	3,955
Deferred revenue	1,622	2,427	2,090	2,864	3,295
Deferred rent, current portion	132	137	141	430	494
Other liabilities	0	0	0	0	0
Total current liabilities	8,530	9,804	9,582	11,463	12,835
Notes payable - long-term portion	1,441	1,012	634	0	0
Deferred rent, net of current portion	287	253	1,504	1,504	1,504
Warrant to purchase preferred stock	225	232	328	0	0
Restricted stock liability	139	131	106	106	106
Other long-term liabilities	156	0	226	226	226
Total liabilities	$10,778	$11,432	$12,380	$13,299	$14,671
Preferred stock	$98,658	$98,700	$98,740	$0	$0
Shareholders' equity	($43,397)	($49,952)	($58,851)	$144,503	$134,682
Total liabilities and shareholders' equity	$66,039	$60,180	$52,269	$157,802	$149,353

Source: Company reports and Leerink Swann estimates

Disclosures Appendix

Analyst Certification

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Distribution of Ratings/Investment Banking Services (IB) as of 09/30/13				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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