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# Foundation Medicine (FMI)

Initiating with an OUTPERFORM rating & \$50 PT Pioneering Deep Molecular Analysis of Tumors Competitive Confusion Sets Shares up for a Strong 2014

- Initiating coverage of FMI with an OUTPERFORM and \$50 PT. Foundation Medicine is the leading provider of test services to oncologists for the comprehensive analysis of genetic alterations in solid tumors.
- FMI is a first-mover in the nascent market for broad-based tumor profiling. Improving analytical tools and affordability, plus the growing repertoire of targeted therapies are creating a new market for deeper genomic understanding of tumors. FMI is leveraging a three-year head start on competitors, proprietary technologies, high-quality publications, seasoned lab service and cancer-focused executives to drive rapid adoption.
- We believe solid tumors represent a large untapped market, and product extension opportunities within cancer are attractive. Solid tumors represent an addressable US opportunity worth roughly \$1.8 B annually, according to our estimates. FMI launched its second product, FoundationOne Heme, into the hematomalignancy market and is planning additional products (e.g. cancer monitoring) in the next few years.
- Controversy around competition and long-term reimbursement creates opportunity. We believe the Street is too pessimistic about the competitive environment, underappreciating the proprietary aspects of *FoundationOne*, as well as other technical and commercial expertise that is extremely difficult to replicate. Reimbursement has been strong in 2013 and we believe will continue to hold solid as payors recognize the economics of more targeted cancer treatments.
- We see opportunities for upside in the next 12 months, including better sales
  efficacy, faster sales force expansion, in-network payor contracts, new
  oncology network relationships and/or Medicare reimbursement.
- FMI represents our top pick for 2014. We arrive at our \$50 price target through EV/sales valuation framework, assuming a ~9x 2016E EV/sales multiple with \$31 MM in net cash and 29 MM shares outstanding, discounted back at 15%. This multiple is justified to us given our view of FMI's growth profile (~89% 3-year CAGR, +70% in 2016), cancer focus and very early penetration story (~10% share in 2016). On a 2015E EV/sales multiple basis, shares of FMI are trading a premium to the current group median (8.2x vs 4.3x).

March 4, 2014

Price

\$32.90

Rating

# **OUTPERFORM**

12-Month Price Target **\$50** 

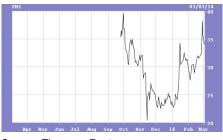
Zarak Khurshid (415) 274-6823 zarak.khurshid@wedbush.com

Company Information	
Shares Outst (M)	28
Market Cap (M)	\$921
52-Wk Range	\$20 - \$42
Cash/sh	5
Enterprise Value	846
LT Debt/Cap	0
2015 EV/Sales	8 x
Book Value/sh	5.1

# **Company Description**

Foundation Medicine is the leading provider of test services to oncologists for the deep analysis of genetic alterations in cancer. These test results provide clinically actionable information for rare, recurring & stubborn solid tumors and hematologic cancers.

FYE Dec	2013E		2014E			2015E	
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$5.2A	\$11.0E		\$11.2E	\$22.3E		\$19.6E
Q2 Jun	\$5.9A	\$13.6E		\$13.1E	\$26.6E		\$22.0E
Q3 Sep	\$8.2E	\$16.4E		\$15.9E	\$31.2E		\$24.6E
Q4 Dec	\$9.7E	\$19.5E		\$18.8E	\$35.7E		\$27.2E
Year*	\$29.0E	\$60.6E		\$58.6E	\$115.8E		\$105.1E
Change	172%	109%			91%		
	2013E		2014E			2015E	
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	(\$0.64)A	(\$0.48)E		(\$0.46)E	(\$0.38)E		N/AE
Q2 Jun	(\$0.52)A	(\$0.45)E		(\$0.46)E	(\$0.30)E		N/AE
Q3 Sep	(\$0.44)E	(\$0.43)E		(\$0.43)E	(\$0.20)E		(\$0.53)E
Q4 Dec	(\$0.48)E	(\$0.38)E		(\$0.42)E	(\$0.17)E		N/AE
Year*	(\$2.08)E	(\$1.74)E		(\$1.78)E	(\$1.04)E		(\$1.35)E
P/E	NM	NM			NM		
Change	410%	-16%			-40%		



Source: Thomson Reuters

Consensus estimates are from Thomson First Call.

\* Numbers may not add up due to rounding.

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### Investment Thesis

We are initiating coverage of Foundation Medicine (FMI) with an OUTPERFORM rating and a \$50 12-month price target. FMI is a lab services company whose test menu is focused on the genetic analysis of rare, recurring and aggressive tumors. FMI's testing platform leverages next-generation sequencing (NGS) to identify clinically actionable genetic mutations within tumor cells. The company's two tests are FoundationOne, a pan-cancer panel for solid tumors, and FoundationOne Heme, a panel for hematological malignancies (i.e., leukemia, lymphoma & myeloma). These tests are targeted for use by academic and community-based oncologists, as well as biopharmaceutical companies for use in cancer therapeutic R&D. We believe FMI's FoundationOne test represents the first mover and highest-quality test commercially available for detailed genomic workup of tumors. We estimate the company's test volumes and sales will grow north of an 85% CAGR for the next three years and we believe FMI has many years of significant growth potential ahead as the opportunity in solid tumors, blood-based cancers and future cancer monitoring products is largely untapped. We believe investors are overly concerned about potential competitive threats and potential challenges to reimbursement near term which are overhangs on the shares currently. We believe continued strong execution by the company, lack of viable competition and continued reimbursement progress with large payors will drive solid financials, thus inspiring confidence and meaningful share price appreciation in the near term. We believe the late 2013 addition of high-quality sales reps, improving sales force efficiency and recent menu expansion, combined with growing physician awareness tees up a strong case for test volume outperformance in the near term. We arrive at our \$50 price target through an EV/sales valuation framework, assuming a ~9x 2016E EV/sales multiple with \$31 MM in net cash and 29 MM shares outstanding discounted back at 15%, which is justified to us given the company's 2016 growth profile (~70% y/y estimated) and early penetration story (~10% share in 2016). On a 2015E EV/sales basis shares of FMI are trading at 8.2x representing a premium to the current group median multiple of 4.3x.

We believe the primary downside risk to our forecast and consensus estimates would be greater-than-anticipated competition in the field from large lab service companies, small private players and/or academic medical centers that enter this nascent market with either next-generation sequencing-based products or targeted cancer panel tests.

# **Company Description**

Headquartered in Cambridge, Massachusetts, Foundation Medicine (FMI) has developed cancer profiling tests, which are targeted at oncologists to help better select cancer therapy, and to drug developers as aids in the development of new cancer treatments. The company's *FoundationOne* tests leverage off-the-shelf next-generation sequencing (NGS) technology, proprietary processes and software, plus know-how to identify and report on a broad range of genetic alterations in tumors. After an oncologist orders the test, the company contacts pathology to obtain the tumor biopsy material, which is sent to the FMI's lab facility in Cambridge, MA for processing. After a detailed analysis, which takes 14-17 days, an easy-to-read interpretive report is sent back to the oncologist, matching mutations found within the tumor sample to targeted therapies that are either commercially available or accessible through enrollment in clinical trials. The *FoundationOne* test is geared for workup of stubborn, aggressive and/or rare tumor types, which impact around 1 MM patients annually in the US, according to the company.

FMI was founded in 2009 and completed its initial public offering on 9/25/13, raising roughly \$111 MM, which is expected to be used to fund expansion of the company's commercial and laboratory operations and clinical trial work as well as support technology development and working capital investment. FMI's service offering has been available to drug developers since 2010 and the company formally launched *FoundationOne* into the clinical oncology field in June 2012. FMI currently has 18 pharma and biotech partners who use *FoundationOne* to molecularly profile tumors, aiding in the development of new targeted cancer therapies. Within the clinic, over 2,100 physicians having ordered the service since launch and the business continues to grow rapidly. FMI recently expanded its test service into the hematologic malignancy setting with *FoundationOne Heme* that became officially available on December 16, 2013.

FMI is capitalizing on the growing understanding of the molecular underpinnings in cancer, and the need to define treatment around the genetic fingerprint of the tumor as opposed to its anatomical location. Molecular profiling of tumors is in the very early innings of clinical adoption and FMI appears to be the first-mover in a field with few players. The company has demonstrated solid progress obtaining reimbursement coverage from third-party payors for *FoundationOne*. Over time, we fully expect the majority of commercial payors and Medicare to recognize the value of *FoundationOne* and *FoundationOne* Heme as the financial and therapeutic benefits of effectively using targeted cancer therapies more than compensate for the cost of the test. The company is commercializing its test menu through a direct sales approach, targeting both the key academic cancer centers (~15% of the market) and community-based oncology practices (~85% of the market). FMI had 5 sales reps at the end of 2012, around 13 at the end of 3Q13 and over 26 reps today.

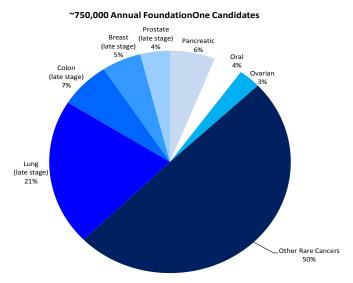
Zarak Khurshid (415) 274-6823



We conservatively estimate the number of annual *FoundationOne* candidates in the US is at least 750,000, which is based on rare, and very late-stage tumor data compiled from the National Cancer Institute's SEER database (See Figure 1). The company estimates the initial addressable US market to be around 1 MM patients annually, which FMI more broadly defines as patients with Stage III/IV solid tumors that are rare, aggressive, relapsed, or of low tissue volume. The company's addressable market estimate used custom analysis of the SEER database in addition to FMI's own market research. Over time, the company expects to see expanded use of the product in metastatic disease, which would boost the U.S. addressable market to roughly 1.8 MM annual testing opportunities. Assuming only \$2,000 per test, the total initial addressable market for *FoundationOne* is \$1.5-\$2 B heading to \$3.6 B over time. FMI is the first mover in this market and we estimate that FMI's penetration is less than 3%, based on our estimated 2013 year ending test run-rate.

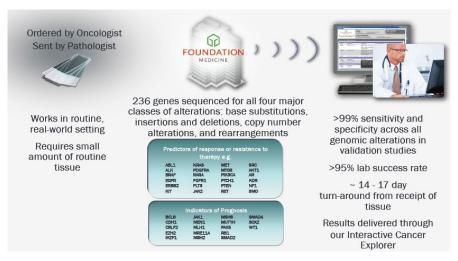
Even the most conservative addressable market assumption which excludes the academic hospital segment (15% of the market) and assumes *FoundationOne* as a reflex test following workup with traditional hotspot panel tests yields a market size of around 450,000 annual solid tumor candidates, representing at least a \$900 MM annual addressable U.S. market.

Figure 1: FoundationOne US Opportunity



Source: American Cancer Society, Wedbush Securities

Figure 2: FoundationOne Solution



Source: Foundation Medicine



#### Clinical Rationale

#### **Cancer Genetics**

Cancer is a complex disease driven by series of changes within cells at the genetic level, which leads to uncontrolled cell division and growth. Cancer is initially diagnosed with imaging (i.e., X-ray, CT scan, MRI, etc.) as well as through microscopic examination by a pathologist of abnormal cell structures in a tumor biopsy. Following cancer identification, the most common treatment strategy has involved defining tumors based on anatomical location (i.e., breast, colon, lung, pancreas, etc.) followed by treatment with broad-cytotoxic chemotherapy and radiation or drugs approved for specific tumor location. In the last 10 years there has been growing use of tests for genetic markers to better characterize cancer, however these genetic tests have tended to focus on only a few genetic mutations. The net result of the empirical (location-based) treatment approach and the focused genetic workup has proven to be inadequate as it does not fully reflect the evolving understanding of the complexities of cancer and the entire spectrum of the disease. Under the old model, after initial diagnostic workup in the hospital, tumor biopsy tissue was sent to the pathologist or reference lab for histochemistry staining (i.e., ER, PR, FISH, HER2), which was followed by focused molecular testing (i.e., KRAS, BRAF, EGFR, etc.) usually performed in another facility dedicated to esoteric testing. This paradigm is costly, time-consuming and inefficient, missing many gene alterations that could be addressed with targeted therapies. The expanding database of cancer-related genetic alterations discovered by academic and biotech /pharma supports the idea that a much deeper interrogation of a tumor's genetic fingerprint is critical to more accurately assessing and thus treating a given cancer.

### Tumor Profiling Made Possible by Targeted Therapies and Cheaper Analytical Tools

Currently there is a limited amount of rigorous genomic interrogation of tumors taking place in clinical practice, but the market is evolving quickly as a result of more powerful and cheaper analytical tools, combined with the growing number of targeted cancer therapies. New FDA-approved targeted therapies and clinical trials for new therapies is expanding the oncologist's repertoire of treatment options and increasing treatment complexity, which is driving a greater need for tools to help guide cancer treatment. There are currently >20 FDA approved targeted cancer therapies and >950 unique clinical trials currently underway (see Figures 3-5).

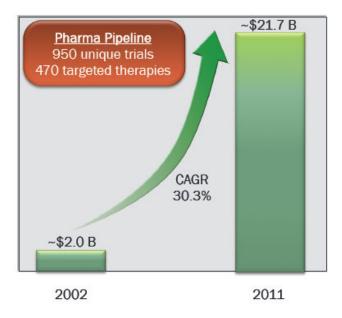
Since targeted drugs tend to have faster approval times and can be sold at higher prices, the number of gene-targeted oncology therapies is expected to continue to increase in coming years. Pharmaceutical benefits managers have estimated that a third of the cancer drugs in development could come to market with a pharmacogenomic label requiring the use of a molecular diagnostic test.

**Figure 3: FDA Approved Targeted Cancer Therapies** 

Drug	Company	Gene Target	Subgroup	Indication*
Gilotrif (afatinib)	Boehringer	EGFR	EGFR exon 19 deletion or exon 21 substitution	NSCLC
Trisenox (arsenic trioxide)	Teva	PML/RARA	PML/RAR? t(15;17) gene expression positive	ALP
Bosulif (bosutinib)	Pfizer	BCR/ABL1	Philadelphia chromosome positive	CML
busulfan	Generic	BCR/ABL	Philadelphia chromosome negative	CML
Xeloda (capecitabine)	Roche	DPYD	Dihydropyrimidine dehydrogenase (DPD)	Colorectal, Breast
Erbitux (cetuximab)	Eli Lilly	EGFR, KRAS	EGFR expression +, KRAS codon 12 & 13 mutation -	Colorectal
cisplatin	Generic	TPMT	TPMT*3B, TPMT*3C	Testicular, Ovarian, Bladder
Xalkori (crizotinib)	Pfizer	ALK	ALK gene rearrangement positive	NSCLC
Tafinlar (dabrafenib)	GSK	BRAF, G6PD	BRAF V600E mutation positive, G6PD deficiency	Melanoma
Sprycel (dasatinib)	Bristol-Myers	BCR/ABL1	Philadelphia chromosome t(9;22) positive	CML, ALL
Tarceva (erlotinib)	OSI	EGFR	EGFR exon 19 deletion or exon 21 substitution positive	NSCLC
Afinitor (everolimus)	Novartis	ERBB2, ESR1	HER2, estrogen receptor positive	Breast
fluorouracil	Generic	DPYD	DPD deficient	Multiple
Iressa (gefitinib)	AstraZeneca	EGFR	EGFR protein expression positive	Multiple
Gleevec (imatinib)	Novartis	KIT, BCR/ABL1, PDGFRB	c-KIT D816V mut. neg, Philadelphia chr. t(9;22) pos., PDGFR gene rearrangement pos.	CML, ALL
irinotecan	Generic	UGT1A1	UGT1A1*28 allele carriers	Colorectal
Tykerb (lapatinib)	GSK	ERBB2	HER2 protein	Breast
mercaptopurine	Generic	TPMT	TPMT intermediate or poor metabolizers	Leukemia
Tasigna (nilotinib)	Novartis	BCR/ABL1	Philadelphia chromosome t(9:22) positive	CML
Vectibix (panitumumab)	Amgen	KRAS	KRAS codon 12 and 13 mutation negative	Colorectal
Perjeta (pertuzumab)	Roche	ERBB2	HER2 protein overexpression positive	Breast
Iclusig (ponatinib)	Ariad	BCR/ABL1	Philadelphia chromosome t(9;22) positive, BCR-ABL T315I mutation	CML, ALL
Elitek (rasburicase)	Sanofi	G6PD	G6PD deficient	Multiple
Stivarga (regorafenib)	Bayer	KRAS	KRAS wild-type	Colorectal
thioguanine	Generic	TPMT	TPMT poor metabolizer	AML, CML
Bexxar (tositumomab)	GSK	MS4A1	CD20 positive antigen	non-Hodgkins Lymphoma
Mekinist (trametinib)	GSK	BRAF	BRAF V600E/K mutation positive	Melanoma
Zelboraf (vemurafenib)	Roche	BRAF	BRAF V600E mutation positive	Melanoma
*simplified for presentation				

Source: Simon, R. and Roychowdhury, S. "Implementing personalized cancer genomics in clinical trials". Nature Reviews. May 2013.

Figure 4: Trend in Targeted Therapy Use



Source: Foundation Medicine Inc, Tufts Center for the Study of Drug Development

Figure 5: Ongoing Clinical Trials for Targeted Therapies

Mutation	Indication	Ongoing Clinical Trials
AKT1	Breast cancer	27
	Colorectal cancer	20
	Lung cancer	21
ALK	Lung cancer	20
	Neuroblastoma	14
	Rhabdomyosarcoma	13
	Soft tissue sarcoma	13
BRAF	Colorectal cancer	19
	Gastrointestinal Stromal Tumors	13
	Lung cancer	16
	Melanoma	38
	Ovarian cancer	14
	Thyroid Cancer	18
CTNNB1	Melanoma	1
DDR2	Lung cancer	2
EGFR	Lung cancer	90
FGFR1, FGFR2	Breast cancer	12
	Lung cancer	6
GNAQ, GNA11	Melanoma	7
HER2	Breast cancer	161
	Gastric cancer	31
	Lung cancer	33
HRAS	Thyroid cancer	5
KIT	Gastrointestinal stromal tumors	9
	Melanoma	10
	Thymic carcinoma	10

Indication	Ongoing Clinical Trials
Colorectal cancer	39
Lung cancer	14
Ovarian cancer	13
Thyroid cancer	10
Lung cancer	2
	4
	31
Colorectal cancer	3
Lung cancer	3
Medulloblastoma	6
Thyroid cancer	4
Breast cancer	31
Colorectal cancer	20
Lung cancer	23
Ovarian cancer	19
Breast cancer	105
Breast cancer	22
Colorectal cancer	13
Lung cancer	13
Ovarian cancer	12
	11
	10
Bladder cancer	3
Squamous/Basal Cell skin cancer	3
Medulloblastoma	1
Bladder cancer	5
	Colorectal cancer Lung cancer Ovarian cancer Thyroid cancer Lung cancer Melanoma Lung cancer Colorectal cancer Lung cancer Medulloblastoma Thyroid cancer Breast cancer Colorectal cancer Lung cancer Golorectal cancer Eneast cancer Colorectal cancer Lung cancer Colorectal cancer Lung cancer Ovarian cancer Breast cancer Colorectal cancer Lung cancer Colorectal cancer Lung cancer Thyroid cancer Lung cancer Thyroid cancer Bladder cancer Squamous/Basal Cell skin cancer

Source: mygenome.org

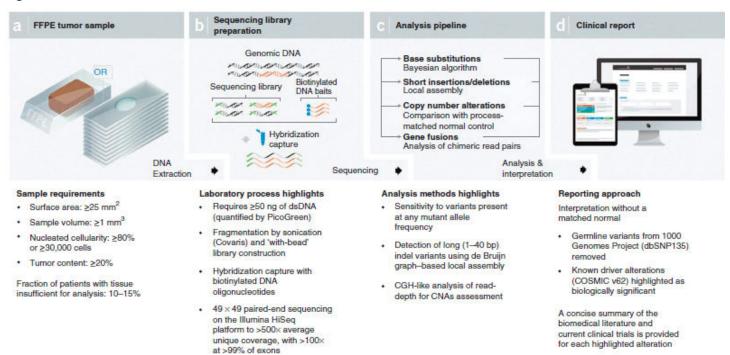


# Key Products - FoundationOne & FoundationOne Heme

### FoundationOne Solid Tumors

The company's first marketed test for the clinic, *FoundationOne* was launched in June 2012 for use with solid tumors. *FoundationOne* detects genomic alterations in the tumor and provides actionable treatment information to clinicians dealing with late stage, rare, aggressive and/or treatment resistant cancer. The test is designed to interrogate 236 genes (representing 3,769 exons) and 47 introns (from 19 genes commonly involved in genetic rearrangements) from collected tumor tissue and reports results back to the clinician in 14-17 days. The analytical backbone of *FoundationOne* is next generation sequencing, which the company leverages to identify all four major classes of alteration, which include base pair substitutions (i.e., single letter changes), insertions & deletion (missing or extra short stretches of DNA in the genome), copy number variations (i.e., extra copies of or missing genes) and translocations (rearrangement of chromosomes fusing genes together).

Figure 6: FoundationOne Workflow



Source: Foundation Medicine

Figure 7: Foundation One Performance Across Different Genomic Alterations

Genomic Alteration	Description		tion One Specificity
Base Pair Substitution	Replacement of a single nucleotide base (one letter) with another DNA or RNA molecule	99%	99%
Short insertion/deletions	Mutations in which DNA is inserted into a new place or when a section of DNA is lost.	98%	>99%
Copy number alterations	Variation in the number of copies of a section of DNA.	>95%	>99%

Source: Foundation Medicine



### Leveraging Breakthroughs in Next-Generation Sequencing

The key barriers to widespread use of gene sequencing in clinical oncology historically have been the heavy costs and performance limitations (sensitivity and specificity) associated with analyzing tumor tissue that is of varying quality. Significant advances in targeted sample preparation, sequencing throughput and speed plus better analytical software in the last several years have made deep genomic profiling of tumors practicable in clinical medicine. Consistent innovation by Illumina in its core next-generation sequencing (NGS) platform has driven over a 10-fold (~90%) reduction in the cost of gene sequencing in the last 3-4 years (see Figure 8).

Due mainly to the low purity of cancer samples and heterogeneity of cancer sub-clones in a tumor; the relevant genomic alterations of interest typically represent a low fraction of the total pool of material needed to be analyzed. Additionally, the majority of tissue samples are stored as formalin-fixed and paraffin-embedded (FFPE) specimens, a process which can damage DNA and RNA. To overcome the low frequency and poor sample quality issues in order to achieve sensitivity and specificity >99%, FMI sequences each region of interest 500-1000x. This depth of sequencing is roughly 30x what is typical in academic whole genome studies and therefore would be cost prohibitive (likely >\$50,000 per sample) in the clinical setting. In addition to the high costs associated with whole-genome sequencing, the vast majority of the alterations detected by this approach are passenger mutations whose clinical relevance is unknown. As a result, FMI uses a targeted enrichment method whereby select regions of the genome are captured prior to sequencing analysis. This enrichment step reduces the amount of DNA to be analyzed by 99.95% (3,000 Mb to ~1.5 Mb), which reduces the sequencing costs and simplifies the workflow dramatically.

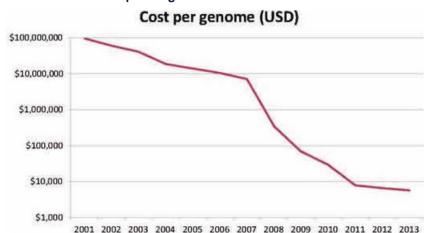


Figure 8: Declining Cost of Human Genome Sequencing

Source: National Human Genome Research Institute

# **Comparison to Other Molecular Diagnostic Methods**

The most commonly used molecular diagnostics today in the cancer field involve single marker (aka "hot spot") test panels which identify a limited number of gene alterations. These tests are also limited by the types of alterations they can detect, with most hotspot panel tests being able to detect only base pair substitutions and a limited number of specific gene rearrangements. The technologies used for single-marker tests, including PCR, Sanger sequencing, mass spectrometry-based genotyping (i.e., Sequenom MassArray), fluorescence *in situ* hybridization (FISH) and immunohistochemistry are also difficult to scale. NGS tests, like *FoundationOne*, can detect not only an increased quantity (>200 vs 1-5 marker hot spot tests), but also a higher quality of alterations, including base pair substitutions, copy number alterations, short insertions and deletions, and gene rearrangements and fusions.

#### FoundationOne Workflow

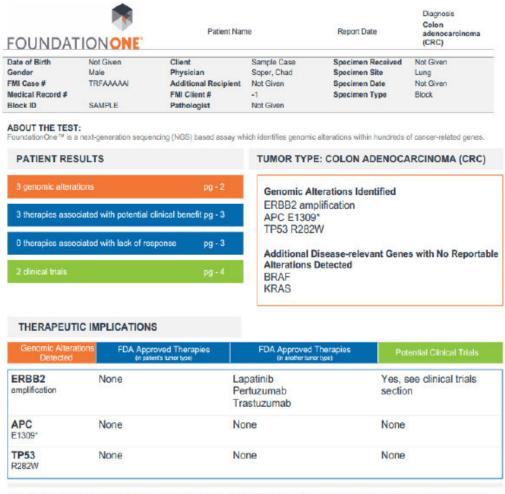
The five main steps involved in *FoundationOne* are sample extraction/specimen preparation, sequencing library preparation, target enrichment, sequencing and data analysis. Specimen preparation includes a pathology review to determine if 50-200 ng of high-quality DNA can be extracted from the tissue sample, which translates into a sample thickness of at least 40 microns consisting of at least 20% tumor cells. Typically >95% of the specimens sent to FMI by pathologists meet this minimum requirement. After the DNA is extracted from the specimen and quantified it is fragmented using sonication. The resulting DNA fragments from this shearing step need to be processed into a sequencing library, which involves the addition of adaptors (short synthetic pieces of DNA) to each end of the fragment. These adaptors allow the DNA fragments to attach to the Illumina flow cell and include sequencing primer sites which are the key initiation elements in the sequencing reaction. Next is a proprietary target enrichment step that is performed to isolate the relevant cancer genes to be analyzed. This is done in order to reduce the total amount of sample sequenced while allowing greater analytical coverage of the key cancer genes. Following target enrichment, sequencing protocols are begun using the Illumina HiSeq 2000 platform. After completion of the sequencing run, genetic variant analysis is performed using proprietary algorithms as well as some off the shelf products. The identified genomic alterations are listed on the *FoundationOne* report which is delivered to the clinician, along with actionable information about any therapies available or in development that target the specific mutations.



#### FoundationOne Report

The clinician receives a paper report as well as access to the company's Interactive Cancer Explorer which is an easy-to-use online portal for clinicians. On the paper and electronic reports are a list of the identified mutations and a list of therapies (either approved or in development) that are targeted for the specific cancer variant the patient has.

Figure 9: Example of FoundationOne Report



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

#### FoundationOne Heme

On December 9' 2013, the company announced introduction of its *FoundationOne Heme* test which is geared toward hematologic cancers (leukemia, lymphoma and myeloma plus many sarcomas and pediatric cancers). Like FMI's solid tumor product, *FoundationOne Heme* is designed to provide clinically actionable information to guide therapy based on the genomic profile of the cancer. *FoundationOne Heme* assesses 405 cancer-related genes and the selected introns of 31 genes for rearrangements with DNA sequencing and employs RNA-based sequencing across 265 genes to identify gene fusions common in hematologic malignancies. *FoundationOne Heme* became officially available to customers on 12/16/2013. Key validation data for *FoundationOne Heme* was presented on 12/9/13 at the annual meeting for the American Society of Hematology which demonstrated high sensitivity and high specificity for genetic alteration including (indels, copy number variations, base pair substitutions and gene fusions/rearrangements) in 350 clinical specimens spanning many different hematologic cancers. The company estimates there are around 100,000 new hematologic malignancies diagnosed annually in the US which equates to >\$200 MM addressable market. Additionally, pediatric tumors and sarcomas will likely add to the addressable opportunity for *FoundationOne Heme*.



#### **Pharmaceutical Services**

FMI offers unbranded versions of *FoundationOne* to drug companies for the analysis of tumor samples collected from current and historical clinical trials. Genetic profiling of tumors can be can be extremely valuable to pharmaceutical and biotech companies developing new targeted treatments as genetic information can help optimize and speed up drug discovery and development. Customers may use the service to identify within specific patient populations genetic variations that confer better response to treatment as well as drug metabolism. FMI regularly updates their test to reflect advances made in cancer research, including the addition of new genes matched to new therapeutics in development. The largest such partnership FMI has established is with Novartis, under which FMI provides genomic profiling of patient samples from clinical trials evaluating Novartis drug candidates and grants access to their molecular information and analysis services. The partnership began in 2011 and on 1/3/14 was extended and expanded through at least September 2016. Novartis has an option to extend the term for an additional three years. Additional pharmaceutical services customers of FMI include AstraZeneca, Celgene, Eisai, Sanofi, Johnson & Johnson, Clovis Oncology, Array Biopharma, Ariad and Agios. During 3Q13 pharmaceutical services test volume represented 27% of test volume and roughly 45% of revenue. We expect that pharmaceutical services revenue will decline meaningfully as a percent of total volume and sales going forward as the company focuses its efforts on the larger clinical opportunity.

Figure 10: Molecular Diagnostics used in Clinical Trials

Methods or assays (genes tested)	Technology	Platforms	Academic centres or companies	Speed; discovery opportunity	Burden <sup>‡</sup> ; CLIA certification challenges	<sup>§</sup> Cost per patient
Pre-NGS						
• Sequenom <sup>15</sup> • SnapSHOT <sup>26</sup> (20–50)	PCR     Mass     spectrometry	MassArray	Karmanos Cancer Institute     Dana-Farber Cancer Institute (DFCI)/Broad Institute of MIT and Harvard	12 weeks; limited scope	Low; medium	\$500–1,500
NGS						
Gene panel by PCR amplicon <sup>5,12</sup> (50–100)	• NGS	<ul><li>Personal Genome Machine</li><li>MiSeq</li></ul>	Oregon Health     Sciences University     Baylor College of     Medicine     Washington University     in St Louis     Fox Chase Cancer     Center	2 weeks; medium	Medium; medium	\$500–1,500
• Gene panel by targeted capture <sup>49,60</sup> (200–10,000)	• NGS	• HiSeq2000 • HiSeq2500 • Proton	Foundation Medicine     Ohio State University     University of     Washington     University of Michigan	2–8 weeks; high	High; high	\$500–1,500
• Exome and/or transcriptome (RNAseq) • Transcriptome (RNAseq) <sup>0.35</sup> (20,000)	• NGS	HiSeq2000     HiSeq2500     Proton	Baylor College of Medicine     DFCI/Broad Institute     of MIT and Harvard     Ohio State University     University of Michigan     Washington University     in St Louis	4–12 weeks; very high	Very high; very high	\$5,000-10,000
<ul> <li>Whole-genome and transcriptome (RNAseq)</li> <li>Transcriptome (RNAseq)<sup>10,76,77</sup> (20,000+)</li> </ul>	• NGS	• HiSeq2000 • HiSeq2500 • Proton	Translational Genomics Research Institute     Washington University in St Louis	4–12 weeks; very high	Very high; very high	\$5,000-20,000

Source: Simon, R. and Roychowdhury, S. "Implementing personalized cancer genomics in clinical trials". Nature Reviews. May 2013.



#### Validation Data

### FoundationOne Solid Tumor Data

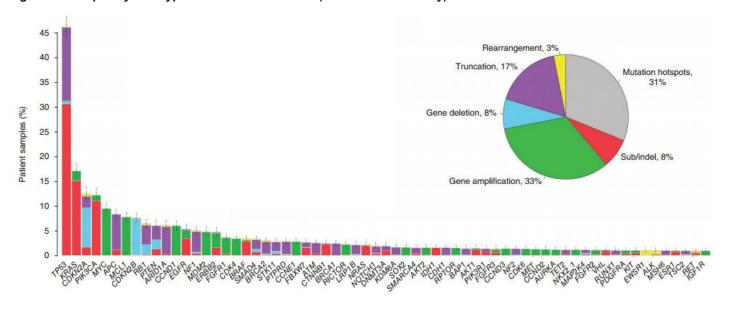
FMI's key validation study was published in Nature Biotechnology on October 20, 2013 and reported experience with *FoundationOne* on 2,221 solid tumor FFPE specimens sent from multiple cancers (see Figure 12), where test success rate was 95%. Of the 189 genes tested during the study, alterations were reported in 174 (92%) of them. There was an average of 3.06 alterations per patient sample and 1.57 clinically actionable alterations (meaning when a targeted treatment is available) per sample. At least 76% of samples contained at least one clinically actionable alteration, with 1,579 unique alterations reported. These data represent a dramatic improvement over the current gold standard "hot spot" testing which yielded actionable results in only 31% of samples (see Figure 13). Of note the study demonstrated a fairly broad distribution of the location and type of genomic alteration identified across the tumor samples (See Figure 13).

Figure 11: Key Publications

Publication	Date	Description	Sample Size	Genomic alterations (GA)/Tumor	% of samples with ≥ 1 GA
Natue Biotechnology	2013	Large validation study in multiple solid tumors	2,221	3.06 total 1.4 actionable	92% (76% actionable)
Gynecologic Oncology (130),	2013	Epithelial ovarian cancer	48	2.9 GA per tumor 1.4 actionable	69%
Clinical Cancer Research (19 (10))	2013	Invasive lobular breast cancer	22	3.4 total 1.6 actionable	86%
European Urology (5 (63))	2013	Prostate cancer	45	NA	44%
Nature Medicine (3 (18))	2012	Colorectal (CRC) and NSCLC	40 CRC 24 NSCLC	CRC: 3.1 total NSCLC: 2.1 total	CRC: 98% NSCLC: 83%
ASH 2013, Abstract #230	2013	Multiple hematologic malignancies	362	3.1 total	NA

Source: Foundation Medicine

Figure 12: Frequency and Type of Genomic Alteration (from validation study)



Source: Foundation Medicine



#### FoundationOne Heme Data

A study presented at the 2013 ASH Meeting analyzed 350 specimens from 319 patients with various hematological malignancies, including ALL (n=20), AML (n=83), CLL (n=53), DLBCL (n=57), MDS (n=48), postmyeloproliferative neoplasm (MPN, n=32), and MM (multiple myeloma, n=57). Using a very similar approach as *FoundationOne* for solid tumors, the *Heme* product uses custom target enrichment technology and deep sequencing (590x average coverage) to interrogate 374 cancer-related genes and 282 frequently rearranged genes (24 by DNA sequencing, and 258 by RNA sequencing). The main difference between the two procedures is the incorporation of RNA sequencing into *FoundationOne Heme* which adds another layer of information pertaining to the relative expression levels (on/off) of specific genes.

Of the 317 samples studied during the clinical validation study for *FoundationOne Heme*, a total of 885 genomic alterations were identified (3.1 alterations per sample), including 555 base substitutions, 213 insertion/deletions, 36 splice mutations, 51 copy number variations and 36 fusions/rearrangements. In MPN/AML samples, the test demonstrated a 97% (33/34) sensitivity in detecting known alterations for JAK2, NPM1, IDH2, FLT3 and CEBPA. The most frequent alteration across all hematological malignancies included mutations in TP53 (9%), ASXL1, and KRAS. Rearrangements in BCL2/6, MYC, MLL, MLL2, NOTCH2, ABL1 and ETV6 were identified using DNA and RNA targeted sequencing, demonstrating the ability of the platform to identify clinically relevant gene fusions as well.

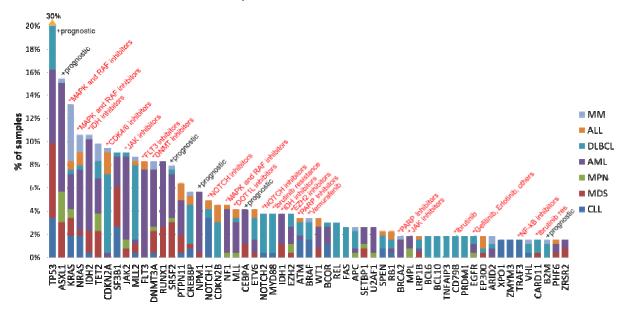


Figure 13: Gene Alterations Detected in Heme Samples

Source: Foundation Medicine

### Pricing & Reimbursement Strategy

The list price for *FoundationOne* is \$5,800 and the company has focused its billing efforts primarily on private payors. FMI appears to be achieving healthy reimbursement from private payors including solid reimbursement from many large payors throughout 2013. Despite operating out-of-network (i.e., without contracts and set pricing), FMI appears to be achieving healthy reimbursement from the large payors. The company's long-term goal is to move in-network and we believe it will make a more concerted push to ink in-network contracts in 2014. Management has been meeting with payors since it began commercialization in 2012. FMI has always expected the payor discussions to be a lengthy process of education while they were aggregating clinical and analytical data to support positive coverage decisions. Management is confident about Medicare coverage for *FoundationOne* in the long term and began submitting to Medicare for reimbursement at the end of 2013. Unlike some smaller lab service companies that outsource billing activities, FMI operates its billing activities in-house which we believe is a more effective strategy. We believe most of the large payors are reimbursing attractively and most bills are paid without a lengthy appeal process. It appears that the company was reimbursed for roughly 900 of the 2,577 tests performed (35%) in 3Q which appears to be a slight improvement versus 400 out of 1,626 (~25%) clinical tests in 2Q13. We estimate the company will gradually approach 50% reimbursement for tests performed within a given quarter over the next few years, which could be accelerated by positive coverage decisions at the national level.

FMI began discussions with Medicare in 2012 and has had active dialogue with its local Medicare administrative contractor (NGS CoreSource). We understand that Medicare asked the company to hold off on billing cases to Medicare while the agency worked to



understand and assess next-generation technology in the clinical marketplace. Since then, management has continued to communicate with them and given the significant ramp in Medicare test volume, FMI decided to submit bills to Medicare at the end of 2013. We believe that the volume of Medicare claims and clinical validation data drove FMI's decision to submit to Medicare as opposed to any expectations for a positive coverage decision near term.

Thus far, Medicare volume for FMI is slightly below 30%, which is meaningfully lower than with prior esoteric lab service companies like Clarient (owned by GE) which have tended to be closer to the 40-45% level. This positive skew is likely due to a push for a more comprehensive understanding of cancer earlier in younger patients. At this time, *FoundationOne* is not officially covered by any third party commercial or government payors. *FoundationOne* carries a list price of \$5,800, but due to typical industry practice where third-party, reimbursement comes in at a healthy discount to the list price, the recent average reimbursement per sample has been around \$3400. We are not anticipating a significant increase in average reimbursement per test at this time until the company gains more operating experience and until we better understand large payor reimbursement.

# **Barriers to Entry & Competition**

### **High Complexity**

We believe it takes a very high level of skill to make a next-generation sequencing based diagnostics test service successful clinically. From the moment a doctor orders *FoundationOne* there are roughly seven critical steps that each need to have success rates greater than 99% for the entire process to be successful. Anytime one of the steps drops to less than 80%, it could lead to failure for the entire process. As a reminder, *FoundationOne* is the most comprehensive test on the market and today there aren't any comparable offerings widely available in the marketplace.

As an illustration of the quality of *FoundationOne*, literature suggests that even sequencing-based pan-cancer tests developed by the best academic medical centers (i.e., Sanger and Broad Institutes) only have accuracy around 90% even when cherry picking the top 10% (i.e., high purity) of cancer samples. Other examples supporting the complex nature around building comprehensive sequencing based cancer tests is the fact that world class institutions like Cleveland Clinic and MD Anderson Cancer Center struggled to develop their own tests after concerted effort and investment. Additionally, Novartis announced in August of 2012 that it was launching a research group using next-generation sequencing and other technologies to stratify cancer patients in clinical trials and commercialize assays through its Genoptix diagnostics arm. Despite Novartis' significant investment and build-out of their sequencing group as well they still ended up contracting with FMI and recently extended and deepened their partnership. Additionally, Novartis had a strong economic incentive to build a test because it had the commercial channel into the community based oncologist through its Genoptix subsidiary which performs blood, bone marrow and solid tumor work up.

### **First-Mover Advantage**

FMI took several years and significant investment (>\$40 MM) to develop its tests. We believe FMI has at least at least a three-year head start and a significantly more resources and R&D productivity than its closest potential competitors. Additionally, FMI is expanding its product menu and if a competitor were to develop a comparable test, we project that FMI would have already moved on to enhanced versions of *FoundationOne* and/or a broader offering of tests which could include cancer monitoring tests using cell-free DNA. Also, lab service products tend to be quite sticky.

# **Proprietary Technical Differentiators**

### **Library Creation**

The creation of highly complex sequencing libraries is a key differentiator of the *FoundationOne* platform. According to the company, with off-the-shelf sequencing library reagents it is difficult to obtain a library with uniform coverage in the 250x-500x range. As a result, FMI developed its own proprietary approach to library creation, but is not sharing its strategy with investors at this time.

### **Target Enrichment**

Target enrichment is another key part of the *FoundationOne* assay that uses home-grown technology. Originally, the company used and optimized Agilent's SureSelect kit, however due to unevenness of coverage and lack of flexibility (i.e., difficult to add genes), FMI was not happy with the performance overall. The company ended up completely reinventing the way hybrid capture was performed in order to obtain better uniformity. According to the company, with commercially available target enrichment kits, roughly 20% of exons (protein coding regions of the genome) will have low coverage (~20x), while with their proprietary target enrichment method FMI achieves >100x coverage on 99.5% of exons.



### Computational Biology

FMI has invested heavily in the computational biological algorithms it uses to identify genomic alterations. In the recent Nature Biotech paper, *FoundationOne* was able to identify 98.2% of insertions and deletions with 99% specificity with its own algorithms, but when this data was passed through the best publically available algorithm the sensitivity and specificity dropped to around 50%. We believe that the algorithms developed by ILMN and other commercial companies are getting better, but the best algorithms to date have been developed by the large genome centers like Broad Institute, Sanger and Washington University who have large teams of computational biologists. We believe that *FoundationOne* has had an advantage over the large genome centers from day one as it built its algorithms to handle more complex data from more challenging tumor types with a focus on the clinic. Additionally, Phil Stevens FMI's Vice President, Cancer Genomics brought to the company 11 years of experience with the Sanger Institute and we believe was able to help bring the best aspects of the genome center algorithms to the company.

# **Published Large Validation Studies**

We believe recent publication of the large validation study for FoundationOne in Nature Biotechnology and the FoundationOne Heme data presented at the American Society for Hematology (ASH) meeting are key elements of the company's first mover advantage. Large scale validation studies tend to be complicated and somewhat expensive and are critical to clinical adoption as well as for establishing reimbursement with payors. FMI is continuing to invest heavily in clinical trial activity for existing products and new products.

# Competition

As the personalized genomics screening industry matures, we believe it is inevitable that other firms will enter the space and potentially drive down pricing. Several pan-cancer tests are commercially available that represent slight competition with *FoundationOne*, and it is possible that other major players with deep pockets could enter the space. To account for this, we have adjusted our model to reflect a relatively low penetration (~7% in 2016) and assume average reimbursement at a healthy discount to the list price. We also believe the market for tumor screening will grow fast enough to accommodate multiple competing products.

Today in the US there does not appear to be a nationally available test that is close to FMI's comprehensive *FoundationOne* offering. We believe over time some of the academic medical centers, such a Washington University and Memorial Sloan Kettering Cancer Center will develop tests that perform closely to *FoundationOne*, but these institutions will not likely have the infrastructure or sales channel to offer their tests broadly into the community, which represents roughly 85% of the market.

Figure 14: Comparison of Competing Pan-Cancer Tests

Company/Group	Product	Genomic Coverage	# of genes	# of genes Platform		DNA Turnaround sample Time	
Foundation Medicine (FMI)	FoundationOne	~590x	236	HiSeq 2500	50-200 ng	14-17 days	\$5,800
OncoDNA (Private, Belgium)	OncoDEEP Dx	~1000x	40	IonTorrent	10 ng	5-10 days	TBD
LabCorp (LH)	IntelliGEN	TBD	50 (2600 mutations)	HiSeq or MiSeq?	TBD	TBD	\$3,200-\$4,000
University of Washington	OncoPlex	>500x	194	HiSeq	5000 ng	8 weeks	\$2,400

Source: Company data, Wedbush Securities, Inc.

We believe there will be more targeted gene panel tests launched by multiple competitors over the next few years, but do not view them as meaningful threats as the price points will likely be comparable to *FoundationOne* and the completeness of the offerings will be lacking. For example, LabCorp recently announced introduction of its IntelliGEN test, which is a next-generation sequencing based test that targets 50 genes and is likely to be priced between \$3,200 and \$4,000. *FoundationOne*, with its ability to analyze the relevant mutations associated with 236 genes, makes it relative bargain versus LabCorp's IntelliGEN and other tests that can assess only a handful of gene at around the same cost. Additionally, if the market gravitates more towards smaller targeted gene panels, FMI has created its infrastructure in such a way that it is able to easily dial-down its test to be more targeted, which contrasts with companies like LabCorp or OncoDNA that likely do not have the technical ability to dial-up their tests.

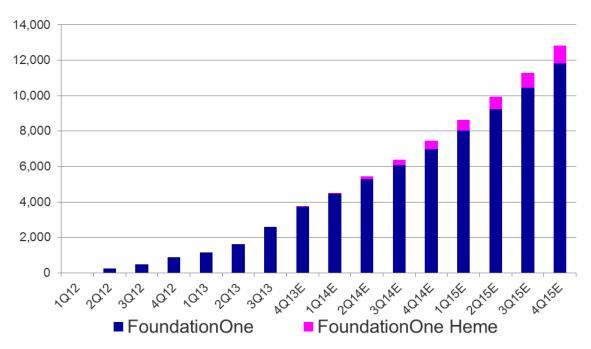


# Clinical Experience and Sales Ramp

FMI has been rapidly adopted since its 2Q12 launch, with more than 2,100 physicians having ordered over 9,000 tests from over 25 countries as of as of 2013 year end. Additionally the company has provided guidance for 2014 clinical test volume which is expected to be between 22,000 and 25,000 tests, representing 142% to 175% patient sample volume growth y/y. With a steepening adoption curve, we expect continued brisk sales for *FoundationOne* following significant 2H13 sales force expansion (~10 reps, 100% increase), greater market awareness and physician education as well as greater payor recognition (see Figure 15). Foundation is experiencing meaningful uptake within the academic cancer centers as well as with community based oncologists, which represents roughly 85% of the market.

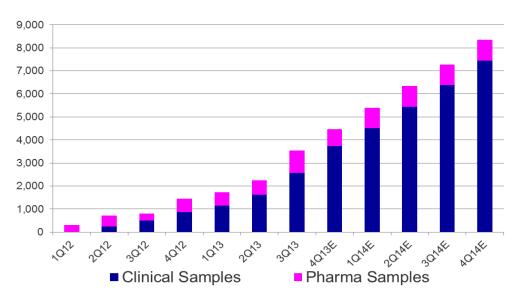
The company's significant commercial clinical experience to date suggests that roughly 82% of cases processed under *FoundationOne* resulted in clinically actionable findings which compares favorably to what is estimated to be only 31% actionability following work-up with the other commercially available multi-gene panels plus HER2 and EML4-ALK testing, which are two well established tumor mutations/signatures. As a reminder, actionability is defined as having an approved targeted therapy or an open clinical trial for a targeted therapy for said identified genomic alteration. Another encouraging sign is the diversity of cancer specimens analyzed to date, which shows a healthy distribution across multiple cancers types comparing nicely to our estimated breakdown for the *FoundationOne* addressable market by cancer type (See Figures 1 &17).

Figure 15: FoundationOne Volume Ramp



Source: Wedbush Securities, Inc.

Figure 16: Clinical vs. Pharma Samples



Source: Wedbush Securities, Inc.

**Figure 17: Clinical Diversity** 

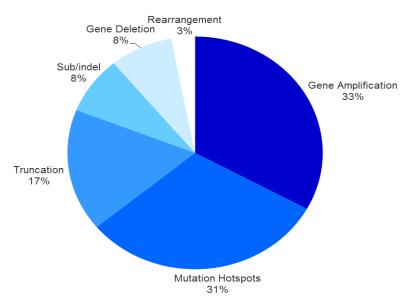
Tumor Type	Clinical Diversity					
Tumor Type	FoundationOne	Theoretical*				
Other, Unknown, Prostate, Soft Tissue	49%	54%				
Lung	17%	21%				
Breast	14%	5%				
Colorectal	8%	7%				
Pancreatic	4%	6%				
Head & Neck	4%	4%				
Ovarian	4%	3%				

\*Based on Wedbush analysis of Cancer.org data

Source: Wedbush Securities, Inc.



Figure 18: Distribution of Alterations Detected By FoundationOne in Practice



Source: Wedbush Securities, Inc.

### Management

#### Michael Pellini, MD. President and Chief Executive Officer

Prior to joining FMI in 2011 as President and CEO, Dr. Pellini served as President and COO of Clarient, a GE Healthcare Company and leading cancer lab services player. Prior to his tenure with Clarient, Dr. Pellini served as VP of Life Sciences at Safeguard Scientifics and EVP and COO at Lakewood Pathology Associates, a molecular and pathology services company. Dr. Pellini also previously served as President and CEO of Genomics Collaborative, a genomics research company acquired in 2004 by SeraCare Life Sciences. Dr. Pellini earned a MD from Thomas Jefferson University, an MBA from Drexel University and a BA from Boston College.

# Steven Kafka, PhD, Chief Operating Officer

Prior to joining the company in 2013, Dr. Kafka served as COO and CFO at Aileron Therapeutics. Dr. Kafka previously served as VP of Finance at Infinity Pharmaceuticals and senior director of finance at Millennium Pharmaceuticals. Dr. Kafka earned a PhD from Harvard University and a BA from Stanford University.

# Kevin Krenitsky, MD, Chief Commercial Officer and SVP of International Strategy

Prior to joining the company in 2011, Dr. Krenitsky served as President at Enzo Clinical Labs. Prior to that, Dr. Krenitsky served as CEO at BioServe Biotechnologies, a company specializing in processing genetic diagnostics tests. Previously Dr. Krenitsky served as CEO at Parkway Clinical Laboratories and in multiple senior roles at Genomics Collaborative. Dr. Krenitsky earned an MD from Thomas Jefferson University and a BS from the University of Scranton.

# Vincent Miller, MD, Chief Medical Officer

Prior to joining the company in 2011, Dr. Miller served as an attending physician at Memorial Sloan-Kettering Cancer Center and conducted clinical and translational research in lung cancer. Dr. Miller is considered a world's expert in lung cancer and 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 earned a MD from the University of Medicine and Dentistry of New Jersey in Newark and a BA from the University of Pennsylvania.

# Phil Stephens, PhD, VP of Cancer Genomics

Prior to joining FMI in 2011, Dr. Stephens held various senior research positions with the Cancer Genome Project at the Wellcome Trust Sanger Institute. He was a member of the team that sequenced the first two comprehensive melanoma and lung cancer genomes, and was co-lead author in the discovery of BRAF in melanoma and ERBB2 in lung cancer. Dr. Stephens earned his PhD from Oxford University.



### Financial Projections

#### **Revenue Model**

The vast majority of the company's clinical revenue is recognized on a cash basis after receiving payment for services rendered. Some of FMI's international business and revenues from pharmaceutical customers are recognized on an accrual basis. The company typically is paid by pharma customers the moment it reports study results. Payment on the clinical side of the business takes significantly longer (i.e., a few weeks to several months) due to the complicated billing and appeal process as the company operates out of network. Of note, FMI achieved solid reimbursement from large payors throughout 2013 and continues to be paid robustly by the large payors even while operating out-of-network. Reimbursement per clinical sample paid during the 18 months following launch has hovered around \$3,400. Over time we expect the company to establish in-network agreements with the top payors which could significantly improve collection efficiency. We believe the company is in the early stages of negotiations to establish in-network contracts.

FMI recently provided 2014 clinical sample and revenue guidance which calls for 22,000 to 25,000 clinical tests driving 2014 revenue quidance of \$52-\$58 MM. We are modeling 28,000 and 58,000 clinical tests delivered in 2014 and 2015 respectively driving 2014 and 2015 sales of \$61 MM and \$116 MM, respectively. Our sales estimates represent 109% and 91% organic top-line growth for 2014 and 2015, respectively versus 172% 2013 organic revenue growth. Our 2014 revenue estimate of \$61 MM (~109 % y/y growth) is above the high end of the company's guidance which calls for \$55-\$58 MM (i.e., 89%-101% y/y growth) Our model assumes \$13.5 MM in Pharma services-related revenue, representing a 19% increase y/y. Our revenue model assumes reimbursement per paid clinical sample to remain around \$3,400 per sample and we are not forecasting any meaningful in-network contracts or Medicare reimbursement achieved during 2014. We are assuming that Medicare as fraction of patient samples remains constant at around 22% for the next few years and that Medicare payment is not achieved until 3Q16 with related payments rolling in slowly. We are forecasting that during 2014 roughly 33% of clinical samples processed will be reimbursed within the quarter they are performed, which conservatively models a step down from 36% achieved in 3Q13 and we believe is a slight step up from 4Q13 levels, which we estimate were around 30% due to heavier test volume process at the end of the quarter. We are modeling this level to step up slightly in 2015 to 35% and by the end of 2016 to 38% as Medicare reimbursement starts to kick in. We are modeling 26% of total tests performed in 2014 to be reimbursed over three quarters equally and roughly 39% of tests (including 22% Medicare) to not be reimbursed at all. We are forecasting these levels to improve by around 100 BPs each in 2015 so as to continue to err on the side of caution. When subtracting Medicare samples, we are assuming the number of tests billed and paid for in the quarter increases slightly from year end 2013 levels of 38% to reach 44% in 2014 and 436% in 2015. Consistent with year-end 2013 levels, we are modeling that roughly 42% and 40% of total clinical samples performed in 2014 and 2015, respectively, will be unpaid. We model the unpaid fraction to decline to 17% by the end of 2016 following established Medicare reimbursement. Due to the company's emphasis on its clinical business we are modeling more modest growth in pharma services segment. We are modeling \$13.5 MM and \$16.8 MM in 2014E and 2015E pharmaceutical services sales representing organic y/y growth of 19% and 25%, respectively.

#### Potential Upside and Downside to Revenue Estimates

We believe the primary sources of meaningful upside to our 2014 and 2015 revenue estimates as well as consensus revenue estimates would be an improvement clinical sample volume as a result of a more effective salesforce, better physician awareness and potential acceleration sales force expansion. We are particularly encouraged by a stronger later 4Q13 push as well as the solid performance, despite the fact that several reps were added late in the quarter and likely had not reached full productivity. We believe additional upside could also be driven by new partnerships with large oncology networks. We believe 2013 sales activities were suboptimal as much of the company's energy was used to meet doctors for the first time and educate the market. Another driver of upside is the potential increase absolute reimbursement levels as a result of insurer coverage decisions, in-network contracts and/or an improvement in collection efficiency from improved billing practices. We believe expectations for Medicare reimbursement is not priced in significantly at current levels and quicker than expected Medicare recognition in 2014 or 2015 is a low probability event that would drive significant upside. We are currently forecasting Medicare reimbursement to begin in 3Q16 at around \$2,000 per patient.

The primary sources of downside to our estimates and consensus estimates would be a weaker-than-anticipated private reimbursement levels and less rapid adoption of *FoundationOne* by community based oncologists.

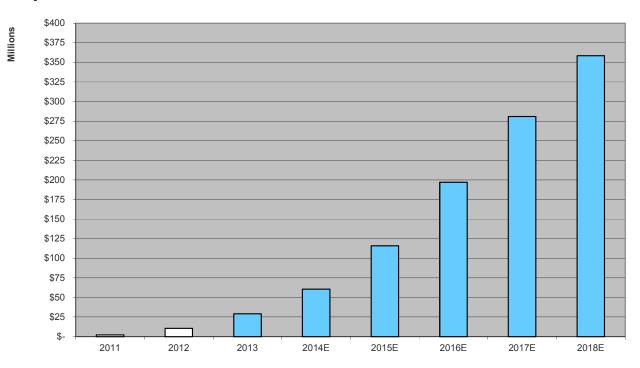
Zarak Khurshid (415) 274-6823



Figure 19: Segment Revenue Model

Revenue Streams	2011	2012	1Q13	2Q13	3Q13	4Q13	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E
FoundationOne Solid Tumors	-	2,855	2,862	3,467	4,402	5,265	15,995	7,578	10,070	12,756	15,788	46,192	94,635	165,334
FoundationOne Heme	-	-	-	-	-	1	1	77	164	299	393	933	4,372	13,211
FoundationOne Pharma	2,057	7,788	2,338	2,453	3,806	4,400	12,997	3,366	3,366	3,366	3,366	13,464	16,830	18,513
TOTAL REVENUE	2,057	10,644	5,200	5,920	8,208	9,666	28,994	11,021	13,599	16,421	19,547	60,589	115,838	197,057
		•				-					-			
Margin Analysis														
FoundationOne Solid Tumors	0%	27%	55%	59%	54%	54%	55%	69%	74%	78%	81%	76%	82%	84%
FoundationOne Heme	0%	0%	0%	0%	0%	0%	0%	1%	1%	2%	2%	2%	4%	7%
FoundationOne Pharma	100%	73%	45%	41%	46%	46%	45%	31%	25%	20%	17%	22%	15%	9%
TOTAL REVENUE	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
• 0/00		-									-			
Δ (Y/Y)		_												
FoundationOne Solid Tumors	NA	NA	NA	1448%	756%	149%	460%	165%	190%	190%	200%	189%	105%	75%
FoundationOne Heme	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	27925%	66359%	369%	202%
FoundationOne Pharma	NA	279%	282%	54%	51%	44%	67%	44%	37%	-12%	-23%	4%	25%	10%
TOTAL REVENUE	NA	418%	750%	226%	170%	87%	172%	112%	130%	100%	102%	109%	91%	70%

Figure 20: Projected Annual Revenues



Source: Wedbush Securities, Inc.

\$40 \$35 \$25 \$20 \$15 \$10

Figure 21: Projected Quarterly Revenues

Source: Wedbush Securities, Inc.

#### **Gross Margins and Operating Expenses**

3Q12

2012

1Q12

4Q12

1Q13

2Q13

3Q13

FMI's cost of goods sold are reported above the gross profit line and revenue is recognized on a cash basis. The company expects to eventually achieve high (i.e., >70%) gross margins even if the average long-term reimbursement settles in below \$3,000 per case. FMI has demonstrated consistent improvement in gross margins this year with 54.3%, 62.5% and 65% gross margins reported in 1Q13, 2Q13 and 3Q13. We are modeling a 560-basis point improvement in gross margins to 65.4% in 2014 mostly as a result of better overhead absorption as clinical volumes ramp and a slight improvement in collections. We model continued volume-related benefit and drive another 310-basi- point improvement pushing gross margins to 68.5% in 2015.

4Q13

1Q14E 2Q14E 3Q14E 4Q14E

FMI's R&D spend is not solely related to investment in R&D around *FoundationOne*, but also includes investments in *FoundationOne Heme* and a series of products expected to be released in the next few years, which might include cancer therapy monitoring with cell-free DNA-based tests. FMI continues to invest significantly in clinical trials for *FoundationOne* and *FoundationOne Heme* to help drive clinical adoption and support reimbursement. Additionally, the company is investing heavily in technology, developing software tools to integrate *FoundationOne* information seamlessly in the everyday practice of medicine and to develop a knowledgebase to provide the most accurate and cutting-edge information to customers. R&D spend is more heavily weighted to new product development, but also includes laboratory costs, clinical trial work and technology development. R&D spend was \$9 MM, \$15 MM and \$25 MM in 2011, 2012 and 2013, respectively and we believe will increase to \$30 MM and \$35 MM in 2014 and 2015.

Sales and marketing expenses as well as general and administrative expenses will likely continue to be high over the next two years as a percent of sales as the company continues to invest in building out its sales channel. G&A is expected to grow much slower than the top-line as 3-5% of sales related to in-house billing activities and infrastructure scales with top-line growth. As the commercial organization stabilizes over the next few years we expect significant leverage as these expenses grow slower than the top line. We are particularly excited about the long-term sales & marketing leverage potential due to the large addressable opportunity and lack of viable competitors which can drive revenue per sales rep of 3x-5x of that achieved by the closest comps (Genoptix [acquired by Novartis] and Genomic Health). As a fraction of sales, we model 2014 sales and marketing to be 43% flat versus 2013 and we model a slight improvement to 36% in 2015. We are forecasting G&A expenses to moderate from 75% of sales in 2013 to 53% and 30% in 2014 and 2015, respectively.

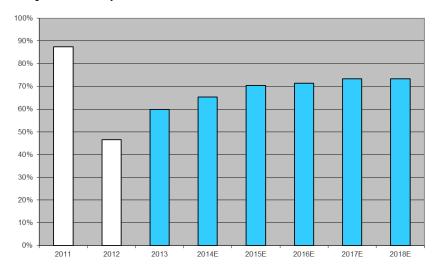


Figure 22: Margin Analysis

% of Sales	2011	2012	1Q13	2Q13	3Q13	4Q13	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E
Gross Margins	87%	47%	54%	63%	65%	56%	60%	61%	63%	65%	70%	65%	70%	71%
Sales and Marketing	76%	32%	35%	52%	37%	48%	43%	50%	45%	42%	40%	44%	36%	31%
General and administrative	340%	81%	61%	80%	79%	78%	75%	71%	60%	52%	45%	55%	30%	19%
Research and development	439%	139%	96%	103%	85%	71%	86%	65%	55%	48%	43%	51%	30%	19%
Total operating expenses	854%	252%	191%	235%	201%	196%	204%	186%	160%	142%	128%	150%	96%	69%
EBIT	-767%	-206%	-137%	-172%	-136%	-140%	-145%	-125%	-97%	-77%	-58%	-84%	-26%	2%
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	7%
Net income	-843%	-213%	-139%	-176%	-152%	-135%	-149%	-122%	-94%	-75%	-57%	-82%	-25%	2%
Free Cash Flow	-1015%	-199%	0%	0%	-89%	-95%	-122%	-78%	-95%	-76%	-75%	-80%	-28%	2%

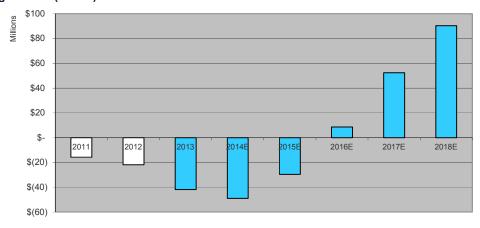
Source: Wedbush Securities, Inc.

Figure 23: Gross Margin History and Assumptions



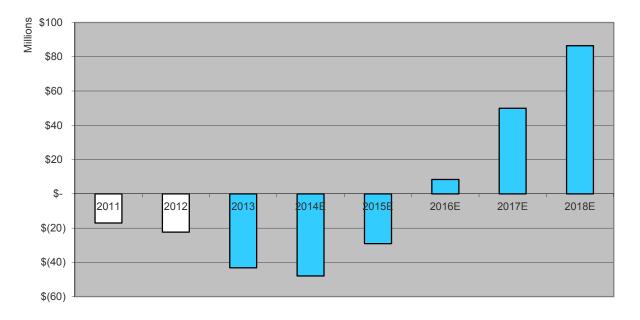
Source: Company data, Wedbush Securities, Inc.

Figure 24: Operating Income (GAAP)



Source: Company data, Wedbush Securities, Inc.

Figure 25: Net Income



### **Earnings Estimates**

We forecast revenues of \$61 MM, \$116 MM and \$197 MM with EPS losses of (\$1.74), (\$1.04) and \$0.30 in 2014, 2015 and 2016, respectively. Wall Street Consensus estimates are for sales of \$59 MM, \$105 MM and \$186 MM with EPS losses of (\$1.82), (\$1.29) and (\$0.62) in 2014, 2015 and 2016 respectively. Our 2014 sales estimates are \$2.5 MM (or 4%) above consensus estimates, while our EPS loss estimates are for (\$1.74), just above consensus EPS loss estimates. Our 2015 top-line forecast is for \$116 MM, roughly 10% above Wall Street consensus. Both our 2014 and 2015 top-line estimate are above consensus, likely due to our more optimistic view on test volumes.

Figure 26: Wedbush Estimates

	20	14	20	15	2016		
	REV (m)	REV (m) EPS		EPS	REV (m)	EPS	
Wedbush	61	(\$1.74)	116	(\$1.04)	197	\$0.30	
Consensus	59	(\$1.82)	105	(\$1.29)	186	(\$0.62)	

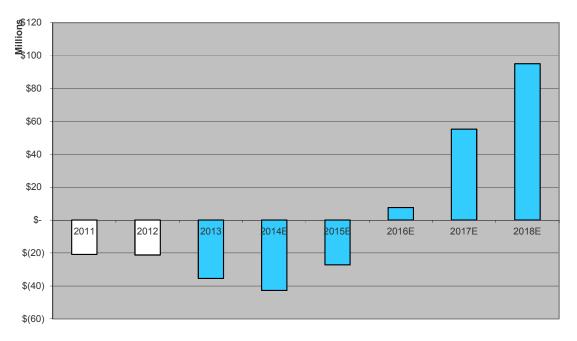
Source: First Call, Wedbush Securities, Inc.



#### **Balance Sheet and Cash Flows**

FMI exited 2013 with roughly \$75 MM in cash and no debt on its balance sheet. During 2013, the company burned around \$36 MM. We estimate the company will burn roughly \$43 MM in 2014, exiting the year with roughly \$75 MM in net cash (~\$3 net cash/share). Our cash estimates include roughly \$5 MM in capital expenditures in 2013 which drops to roughly \$3.5 MM annually in 2014 and 2015. We estimate that the company will burn \$27 MM in cash in 2015 and generate free cash flow of roughly \$7.6 MM (0.8% FCF yield) in 2016.

Figure 27: Free Cash Flows



Source: Company data, Wedbush Securities, Inc.

# Valuation & Price Target

We arrive at our 12-month \$50 price target through EV/sales valuation framework where we assume a 9x 2016E EV/sales multiple with \$31 MM in net cash and roughly 29 MM shares outstanding discounted back at 15%. This multiple is justified to us given the 2016 growth profile (~70% y/y), cancer focus and very early penetration story (~10% share in 2016). On a 2015E EV/sales basis, shares of FMI are trading at 8.2x representing a premium to the current group median multiple of 4.3x. Versus the molecular diagnostics lab service growth comps, FMI is trading at a premium on a 2015 EV/sales multiple basis (8.2x vs. 2.1x median).

### Ownership

There are roughly 28 MM shares outstanding with around 12 MM shares (or 43%) representing the current public float. Early stage investors, which include Third Rock Ventures, KPCB Holdings, Inc., Google Ventures, LabCorp, Gates Ventures LLC, and Wellington Management Company, LLP represent roughly 58% ownership of the company. Of note, LabCorp (LH, not rated), the 2<sup>nd</sup> largest lab services company, owns roughly 4% of FMI. Insiders represent roughly 5% ownership in the company. The 180-day post IPO share lock-up ends on March 24, 2014 making roughly 16 MM shares eligible for sale.

Zarak Khurshid (415) 274-6823



#### Risks

Risks to attainment of our price target include a fiercely competitive diagnostics and lab service market. Additionally, clinical adoption for new paradigms of testing in diagnostics is difficult to predict and private payor as well as Medicare reimbursement for FoundationOne and FoundationOne Heme could prove to be more challenging than expected.

FMI is dependent on Illumina (ILMN, Neutral) for equipment and other materials related to next generation sequencing. If ILMN were to stop supplying the material or were to enter the space as a competitor, it could lead to an interruption in FMI's ability to perform its menu of tests. The near-term risk of this has been mitigated through a five-year supply agreement FMI signed with ILMN in July 2013.

The company operates a CLIA certified lab at their Cambridge, MA headquarters where they conduct *FoundationOne*. Operating as a CLIA lab allows the company to avoid the FDA regulatory 510(k)/PMA pathway for diagnostic devices. The FDA could more tightly regulate CLIA lab-based tests as medical devices, which would likely cause significant disruption to the business.

# Comparables

Figure 28: Small-Cap Diagnostics Comps

						FY	2013	FY	2014	FY	2015	2014	2015	
Company	Ticker	Price (\$) 3/4/2014	FYE	Shares Out. (MM)	Market Cap. (\$MM)	Projected Rev. (\$MM)	Market Cap./ Rev.	Projected Rev. (\$MM)	Market Cap./ Rev.	Projected Rev. (\$MM)	Market Cap./ Rev.	EV/ Rev.	EV/ Rev.	Ratino
Cepheid	CPHD	54.04	Dec	69	3,751	380	9.9 X	442	8.5 X	530	7.1 X	6.8 X	6.8 X	0
Cerus	CERS	6.61	Dec	70	466	40	11.7 X	39	11.9 X	57	8.2 X	10.7 X	7.3 X	0
Clarient	CLRT	NA	Dec	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NR
Exact Sciences	EXAS	13.96	Dec	71	994	4	NA	11	90.4 X	89	11.2 X	NA	10.6 X	0
Foundation Medicine	FMI	34.98	Dec	28	984	29	NA	61	16.1 X	116	8.5 X	15.5 X	8.2 X	0
Genomic Health	GHDX	26.86	Dec	31	826	262	3.2 X	288	2.9 X	323	2.6 X	2.7 X	2.4 X	NR
GenMark	GNMK	12.74	Dec	41	528	27	19.6 X	27	19.6 X	42	12.6 X	18.4 X	11.8 X	NR
Gen-Probe (acquired)	GPRO	82.75	Dec	45	3,740	712	5.3 X	NA	NA	NA	NA	NA	NA	NR
Meridian	VIVO	20.58	Sep	42	855	189	4.5 X	201	4.3 X	216	4.0 X	4.0 X	3.8 X	N
Myriad Genetics	MYGN	37.27	Dec	73	2,720	553	4.9 X	630	4.3 X	730	3.7 X	3.6 X	3.1 X	NR
Nanosphere	NSPH	2.47	Dec	77	190	13	14.6 X	20	9.5 X	36	5.3 X	7.0 X	3.9 X	NR
Nanostring	NSTG	20.33	Dec	18	365	31	11.8 X	47	7.8 X	71	5.1 X	6.5 X	4.3 X	NR
Neogenomics	NEO	3.76	Dec	49	185	66	2.8 X	73	2.5 X	85	2.2 X	2.5 X	2.1 X	NR
Orasure	OSUR	7.31	Dec	56	406	99	4.1 X	105	3.9 X	120	3.4 X	3.3 X	2.9 X	NR
Ovascience	OVAS	10.65	Dec	19	198	0	NA	1	NA	20	9.9 X	NA	7.2 X	0
Oxford Immunotec	OXFD	22.06	Dec	16	361	38	9.5 X	49	7.4 X	67	5.4 X	6.7 X	4.9 X	NR
Response Genetics	RGDX	1.44	Dec	34	49	22	2.2 X	27	1.8 X	27	1.8 X	NA	NA	NR
Qiagen	QGEN	21.85	Dec	235	5,125	1,318	3.9 X	1,352	3.8 X	1,463	3.5 X	3.9 X	3.6 X	N
Quidel	QDEL	29.20	Dec	34	995	175	5.7 X	190	5.2 X	220	4.5 X	5.0 X	4.3 X	U
Sequenom	SQNM	2.35	Dec	116	273	162	1.7 X	185	1.5 X	198	1.4 X	1.8 X	1.7 X	0
Veracyte	VCYT	17.61	Dec	21	370	22	16.8 X	40	9.3 X	72	5.1 X	9.3 X	5.1 X	NR
Vermillion	VRML	3.42	Dec	36	123	6	20.4 X	8	15.3 X	9	13.6 X	14.1 X	12.5 X	NR
Molecular Dx Subgroup	Median						8.6 X		7.0 X		NA	3.6 X	3.6 X	
					Group Mean		7.2 X		6.9 X		5.4 X	6.3 X	5.3 X	
				G	roup Median		5.1 X		4.8 X		4.5 X	5.0 X	4.3 X	

<sup>\*</sup>O = OUTPERFORM, N = NEUTRAL, U = UNDERPERFORM Blue highlight = coverage by Wedbush Securities

Source: Company data, Wedbush Securities, Inc.

Figure 29: Lab Service Comps

						FY 2	2013	FY	2014	FY	2015							
		Closing price (\$)		Shares Out.	Market Cap.	Proje	ected	Proj	ected	Proj	ected	FC EPS	2013	2013	2014	2015		
Company	Ticker	3/4/2014	FYE	(mln.)	(\$ mln.)	EPS	P/E	EPS	P/E	EPS	P/E	Growth Rate	PE/GR	EV/Sales	EV/Sales	EV/Sales	FCF Yield	Rating
Bio-Reference	BRLI	25.85	Oct	28	716	\$1.79	14.4	\$2.08	12.4	\$2.08	12.4	15%	1.2 X	1.0 X	0.9 X	0.8 X	2.7%	NR
Foundation Medicine	FMI	34.80	Dec	28	979	NA	NA	NA	NA	NA	NA	NA	NM	32.5 X	15.4 X	8.1 X	NA	0
Genomic Health	GHDX	26.85	Dec	31	825	(\$0.09)	NA	\$0.23	116.7	\$0.23	116.7	40%	NM	2.7 X	2.5 X	2.2 X	2.0%	NR
Labcorp	LH	93.45	Dec	85	7,971	\$7.02	13.3	\$7.59	12.3	\$7.59	12.3	8%	1.7 X	1.8 X	1.7 X	1.7 X	7.2%	NR
Myriad Genetics	MYGN	37.32	Jun	73	2,723	\$1.80	20.7	\$2.05	18.2	\$2.05	18.2	12%	2.1 X	3.1 X	3.0 X	3.0 X	9.1%	NR
Neogenomics	NEO	3.76	Dec	49	185	\$0.04	94.0	\$0.08	47.0	\$0.08	47.0	30%	6.3 X	2.8 X	2.4 X	2.1 X	0.5%	NR
Quest Diagnostics	DGX	52.79	Dec	144	7,618	\$3.90	13.5	\$4.30	12.3	\$4.30	12.3	9%	1.3 X	1.5 X	1.5 X	1.5 X	4.7%	NR
Veracyte	VCYT	17.77	Dec	21	374	\$3.90	4.6	\$4.30	4.1	\$4.30	4.1	9%	0.4 X	14.9 X	8.0 X	4.5 X	NA	NR
					Group mean		33.7		38.9		38.9		3.0 X	6.5 X	3.9 X	3.0 X	4.9%	
				(	Group median		20.7		22.6		22.6		1.9 X	2.7 X	2.4 X	2.2 X	4.7%	
O = OUTPERFOM, N =	O = OUTPERFOM, N = NEUTRAL , U = UNDERPERFORM																	

Blue highlight = coverage by Wedbush Securities

Source: Company data, Wedbush Securities, Inc.



ure 30: Income Statemen	t													
	2011	2012	1Q13	2Q13	3Q13	4Q13	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E
Product Revenue Total Revenues	2,057 2.057	10,645 10,645	5,200 5,200	5,920 5,920	8,208 8,208	9,662 9,662	28,990 28,990	11,021 11.021	13,599 13,599	16,421 16.421	19,547 19,547	60,589 60,589	115,838 115.838	197,05 197.05
Cost of revenues	258	5,681	2,378	2,219	2,858	4,204	11,659	4,298	5,032	5,747	5,864	20,942	34,284	56,478
COGS as % of sales Gross profit	1.799	4.964	46% 2.822	37% 3.701	35% 5,350	44% 5,458	36% 17,331	6,723	8.568	10,673	13,683	39,647	81,554	140.580
Gross Margins	87.5%	46.6%	54.3%	62.5%	65.2%	56.5%	59.8%	61.0%	63.0%	65.0%	70.0%	65.4%	70.4%	71.3%
Selling and Marketing	1,555	3,454	1,811	3,057	3,038	4,602	12,508	5,511	6,120	6,897	7,819	26,346	41,254	60,88
General and administrative Research and development	6,992 9,023	8,644 14,777	3,150 4,982	4,755 6,097	6,448 6,988	7,512 6,834	21,865 24,901	7,700 7.100	7,900 7.300	8,200 7,600	8,500 8,000	32,300 30,000	34,950 35,000	35,20 35,90
Total operating expenses	17,570	26,875	9,944	13,910	16,475	18,948	59,275	20,311	21,320	22,697	24,319	88,646	111,204	131,98
Operating Income	(15,771)	(21,911)	(7,122)	(10,209)	(11,125)	(13,490)	(41,944)	(13,588)	(12,752)	(12,023)	(10,636)	(48,999)	(29,650)	8,59
Interest income	(421)	(421)	(76)	(65)	(1,278)	(33)	(1,452)	311	286	251	216	1,064	570	27
Other	(845)	(61)	(6)	(96)	(61)	432	269	0	0	0	0	0	0	
Income before taxes Provision for income taxes	(17,037) 0	(22,393) 0	(7,204) 0	(10,370) 0	(12,464) 0	(13,091) 0	(43,127) -	(13,277) 0	(12,466) 0	(11,773) 0	(10,420) 0	(47,935) 0	(29,080) 0	8,86 57
Tax Rate Net income	(17,037)	(22,393)	(7,204)	(10,370)	(12,464)	(13,091)	(43,129)	(13.277)	(12,466)	(11,773)	(10,420)	(47.935)	(29,080)	8,28
Accretion of convertible preferred stock	(296)	(286)	(50)	(42)	(47)	(13,091)	(43, 129)	(13,277)	(12,400)	0	(10,420)	(47,933)	(29,000)	0,20
Net Income	(17,333)	(22,679)	(7,254)	(10,412)	(12,511)	(13,091)	(43,268)	(13,277)	(12,466)	(11,773)	(10,420)	(47,935)	(29,080)	8,28
GAAP EPS -Basic	(\$3.52)	(\$0.41)	(\$0.64)	(\$0.52)	(\$0.46)	(\$0.48)	(\$2.09)	(\$0.48)	(\$0.45)	(\$0.43)	(\$0.38)	(\$1.74)	(\$1.05)	\$0.3
GAAP EPS -Diluted	(\$3.52)	(\$0.41)	(\$0.64)	(\$0.52)	(\$0.44)	(\$0.48)	(\$2.08)	(\$0.48)	(\$0.45)	(\$0.43)	(\$0.38)	(\$1.74)	(\$1.05)	\$0.3
Non-GAAP EPS -Diluted	(\$3.52)	(\$0.41)	(\$0.64)	(\$0.52)	(\$0.44)	(\$0.48)	(\$2.08)	(\$0.48)	(\$0.45)	(\$0.43)	(\$0.38)	(\$1.74)	(\$1.05)	\$0.3
Weighted average shares - basic	4,930	55,642	11,339	20,129	27,336	27,505	21,577	27,560	27,601	27,643	27,684	27,622	27,864	28,04
Weighted average shares - diluted	4,930	55,642 proforma	11,339	20,129	28,138	27,505	21,778	27,560	27,601	27,643	27,684	27,622	27,864	28,04
Cash and Equivalents	10,852	54,838	45,832	35,965	138,088	124,293	124,293	114,507	100,283	86,413	70,422	70,422	28,964	17,78
Net Cash	10,852	54,838	45,832	35,965	138,088	124,293	124,293	114,507	100,283	86,413	70,422	70,422	28,964	17,78
Net Cash/share			4	2	5	5	5	4	4	3	3	3	1	
NOLs					(39,900)	(52,991)	(52,991)	(66,268)	(78,734)	(90,506)	(100,926)	(100,926)	(130,006)	(121,71
% of Sales	2011	2012	1Q13	2Q13	3Q13	4Q13	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E
Gross Margins	87% 76%	47% 32%	54% 35%	63% 52%	65% 37%	56% 48%	60% 43%	61% 50%	63% 45%	65% 42%	70% 40%	65% 43%	70% 36%	71% 31%
Sales and Marketing General and administrative	76% 340%	32% 81%	61%	52% 80%	37% 79%	48% 78%	43% 75%	70%	45% 58%	42% 50%	40% 43%	43% 53%	30%	18%
Research and development	439%	139%	96%	103%	85%	71%	86%	64%	54%	46%	41%	50%	30%	18%
Total operating expenses	854%	252%	191%	235%	201%	196%	204%	184%	157%	138%	124%	146%	96%	67%
EBIT	-767%	-206%	-137%	-172%	-136%	-140%	-145%	-123%	-94%	-73%	-54%	-81%	-26%	4%
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	7%
Net income	-843%	-213%	-139%	-176%	-152%	-135%	-149%	-120%	-92%	-72%	-53%	-79%	-25%	4%
Free Cash Flow	-1015%	-199%	0%	0%	-89%	-95%	-122%	-77%	-93%	-73%	-71%	-78%	-27%	2%
у/у Δ	2011	2012	1Q13	2Q13	3Q13	4Q13	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E
Total Revenues	NA	418%	750%	226%	170%	87%	172%	112%	130%	100%	102%	109%	91%	70%
Cost of revenues	NA	2102%	235%	98%	60%	104%	105%	81%	127%	101%	39%	80%	64%	65%
Gross Margins	NA	-47%	-442%	63%	59%	-6%	28%	12%	1%	0%	24%	9%	8%	1%
Sales and Marketing General and administrative	NA NA	122% 24%	260% 88%	262% 135%	258% 202%	266% 167%	262% 153%	204% 144%	100% 66%	127% 27%	70% 13%	111% 48%	57% 8%	48% 1%
Research and development	NA NA	64%	88% 65%	135% 69%	96%	167% 49%	153% 69%	144% 43%	20%	9%	13% 17%	48% 20%	8% 17%	1% 3%
Total operating expenses	NA NA	53%	92%	115%	96% 152%	49% 119%	121%	43% 104%	53%	9% 38%	28%	20% 50%	25%	19%
FBIT	NA NA	39%	35%	77%	110%	144%	91%	91%	25%	8%	-21%	17%	-39%	-129%
Tax rate	NA NA	NA	NA	NA	NA	NA	91% NA	91% NA	NA	NA	-21% NA	NA	-39% NA	-129% NA
	NA.	31%	31%	74%	125%	134%	91%	83%	20%	-6%	-20%	11%	-39%	-129%



Figure 31: Balance Sheet

	2011	2012	2013E	2014E	2015E	2016E
Current assets:						
Total Cash and Cash Equivalents	10852	54,838	124,293	74,859	37,883	31,232
Accounts Receivable	278	2,195	6,262	9,774	17,852	29,623
Inventory	318	803	1,763	1,629	2,975	4,937
Prepaid expenses and other Current Assets	313	550	992	992	992	992
Total current assets	11,761	58,386	133,310	87,254	59,702	66,785
B	7.000	10.151	00.404	05.400	00.005	40.770
Property, Plant and Equipment	7,902	12,154	22,104	25,133	30,925	40,778
Accumulated Depreciation	(1,796)	(4,689)		(4,613)		(16,853)
Restricted cash and other non-current assets	198	188	1,854	1,854	1,854	1,854
Total assets	18,065	66,039	157,268	109,629	82,464	92,563
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts Payable and accrued expenses	2,408	5,072	7,007	7,286	9,140	10,848
Deferred revenue and Other Current Liabilities	1,832	3,458	8,752	8,752	8,752	8,752
Total current liabilities	4,240	8,530	15,759	16,038	17,892	19,600
Long-term liabilities:						
Long Term Debt	3,041	1,441	0	0	0	0
Other long term liabilities	632	807	9,798	9,798	9,798	9,798
Total liabilities	7,913	10,778	25,557	25,836	27,690	29,398
Stockholders' equity:						
Preferred Stock	32,455	98,658	0	0	0	0
Common Stock, APIC, RE	(22,303)	(43,397)	131,711	83,793	54,774	63,165
Total liabilities and stockholders' equity	18,065	66,039	157,268	109,629	82,464	92,563

Figure 32: Cash Flow Statement

	2011	2012	2013E	2014E	2015E	2016E
Cash Flows from Operating Activities:						
Net (loss) income	(17,037)	(22,393)	(42,944)	(47,918)	(29,019)	8,391
Depreciation	1,520	2,894	4,525	4,613	5,405	6,836
change in FV of investor rights obligation	1,067	0	0	0	0	0
change in FV of warrant liability	34	131	1,380	0	0	0
Stock-based compensation expense	73	1,535	4,980	0	0	0
common stock issued for services	0	0	4	0	0	0
non-cash interest expense	111	104	57	0	0	0
Change in working capital	99	480	1,244	(3,099)	(7,570)	(12,025)
Net cash provided by operating activities	(14,133)	(17,249)	(30,754)	(46,405)	(31,184)	3,202
Cash Flows from Investing Activities:						
Purchase of property and equipment	(5,410)	(3,183)	1,433	(3,029)	(5,792)	(9,853)
increase in restricted cash	0		(1,725)	0	0	0
Net cash used in investing activities	(5,410)	(3,183)	(292)	(3,029)	(5,792)	(9,853)
				0	0	0
Cash Flows from Financing Activities:				0	0	0
Proceeds from Issuance of Restricted Stock	114	70	30	0	0	0
proceeds from issuance of preferred stock	26,338	65,917	(10)	0	0	0
proceeds from issuance of common stock	0	0	110,596	0	0	0
change in notes payable	2,534	(1,569)	(1,265)	0	0	0
Net cash provided by financing activities	28,986	64,418	109,351	0	0	0
Net increase (decrease) in cash and cash equivalents	9,443	43,986	78,305	(49,434)	(36,976)	(6,651)
Cash and cash equivalents, beginning of period		10,852	54,838	124,293	74,859	37,883
Cash and cash equivalents, end of period	10,852	54,838	133,143	74,859	37,883	31,232

Company	Ticker	Rating	Price Target	Current Price
Illumina	ILMN	NEUTRAL	\$140	\$182
Sequenom	SQNM	OUTPERFORM	\$4	\$2.4
Exact Sciences	EXAS	NEUTRAL	\$15	\$14.0
Cerus	CERS	OUTPERFORM	\$8	\$6.6
Meridian Bioscience	VIVO	NEUTRAL	\$23	\$21
Quidel	QDEL	UNDERPERFORM	\$20	\$29
Cepheid	CPHD	OUTPERFORM	\$58	\$54.0
Qiagen	QGEN	NEUTRAL	\$18	\$22.0
OvaScience	OVAS	OUTPERFORM	\$20	\$11



### Analyst Biography

Zarak Khurshid is a senior equity research analyst covering the Medical Diagnostics and Life Science Tools sectors. Prior to joining Wedbush in January 2010, Mr. Khurshid was Vice President and senior equity research analyst with Caris & Company where he covered the Medical diagnostics and Life Sciences Tools sectors from 2006 to 2010. Mr. Khurshid's aggressive risk/reward focused investment style is supported by data points from a diverse network of contacts from industry, hospitals, clinical labs, and academia. Mr. Khurshid was ranked #1 in the Life Science Tools and Services sectors and #4 on Wall Street for earnings accuracy in 2012 by Starmine. Prior to his start on Wall Street with Pacific Growth Equities in 2004, Mr. Khurshid was a Research Associate with Cytokinetics and an Associate Bioengineer with Aurora Biosciences. Mr. Khurshid received a BS in Bioengineering and a BA in Economics from the University of California, San Diego.

# **Analyst Certification**

I, Zarak Khurshid, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ413.pdf

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).\*

Rating Distribution (as of December 31, 2013)	Investment Banking Relationships (as of December 31, 2013)
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Company	Disclosure	
Foundation Medicine	1	
Illumina	1	
Sequenom	1	
Exact Sciences Corp.	1	
Cerus Corp.	1,3,4,5	
Meridian Bioscience	1	
Quidel Corp.	1	
Cepheid	1	
Qiagen N.V.	1	
OvaScience	1	

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Zarak Khurshid (415) 274-6823



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### **OTHER DISCLOSURES**

# RESEARCH DEPT. \* (213) 688-4505 \* www.wedbush.com

EQUITY TRADING Los Angeles (213) 688-4470 / (800) 421-0178 \* EQUITY SALES Los Angeles (800) 444-8076 CORPORATE HEADQUARTERS (213) 688-8000

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### **EQUITY RESEARCH DEPARTMENT**

(213) 688-4529

#### **DIRECTOR OF RESEARCH**

Mark D. Benson (213) 688-4435

#### MANAGER, RESEARCH OPERATIONS

Ellen Kang (213) 688-4529

			COL		

**Consumer Products** 

Rommel T. Dionisio (212) 938-9934 Kurt M. Frederick, CFA CPA (415) 274-6822

Footwear, Apparel and Accessories

Corinna Freedman (212) 668-9876 Alicia Reese (212) 938-9927

**Healthy Lifestyles** 

Kurt M. Frederick, CFA CPA (415) 274-6822

Restaurants

Nick Setyan (213) 688-4519 Colin Radke (213) 688-6624

Specialty Retail: Hardlines

Joan L. Storms, CFA (213) 688-4537 John Garrett, CFA (213) 688-4523

Seth Basham, CFA (212) 938-9954

#### RETAIL/CONSUMER MARKET RESEARCH

Gabriella Santaniello (213) 688-4557

# INDUSTRIAL GROWTH TECHNOLOGY

Clean Technology

Craig Irwin (212) 938-9926 Min Xu (212) 938-9925

Environmental Services / Building Products

Al Kaschalk (213) 688-4539 Taryn Kuida (213) 688-4505

Water and Renewable Energy Solutions

David Rose, CFA (213) 688-4319 James Kim (213) 688-4380 TECHNOLOGY, INTERNET, MEDIA & SOCIAL MEDIA

**Communications and Application Software** 

Shyam Patil, CFA (213) 688-8062

**Communications Equipment** 

Rohit Chopra (212) 668-9871 Sanjit Singh (212) 938-9922 Ryan Flanagan (212) 938-9942

**Computer Services: Financial Technology** 

Gil B. Luria (213) 688-4501 Aaron Turner (213) 688-4429

**Enterprise Software** 

Steve Koenig (415) 274-6801 Kevin Ikeda (213) 688-4423

Entertainment: Retail

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

**Entertainment: Software** 

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Internet: Media and Gaming

Michael Pachter (213) 688-4474 Nick McKay (213) 688-4343 Nick Citrin (213) 688-4495

Internet: Social Media, Advertising & Technology

Shyam Patil, CFA (213) 688-8062

Media

James Dix, CFA (213) 688-4315

**Movies and Entertainment** 

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Semiconductors

Betsy Van Hees (415) 274-6869 Ryan Jue, CFA (415) 263-6669 LIFE SCIENCES AND HEALTH CARE

Biotechnology/Biopharmaceuticals/BioDefense

Gregory R. Wade, Ph.D. (415) 274-6863 David M. Nierengarten, Ph.D. (415) 274-6862 Christopher N. Marai, Ph.D. (415) 274-6861

**Emerging Pharmaceuticals** 

Liana Moussatos, Ph.D. (415) 263-6626 Richard Lau, CFA (415) 274-6851

Healthcare Services - Managed Care

Sarah James (213) 688-4503

**Medical Devices** 

Tao Lew (212) 938-9948

Medical Diagnostics and Life Sciences Tools

Zarak Khurshid (415) 274-6823

EQUITY SALES EQUITY TRADING

(213) 688-4470 / (800) 444-8076 (213) 688-4470 / (800) 421-0178 Los Angeles Los Angeles San Francisco (415) 274-6800 San Francisco (415) 274-6811 (212) 938-9931 (212) 344-2382 New York New York Boston (617) 832-3700 Boston (617) 832-3700

CORPORATE HEADQUARTERS

1000 Wilshire Blvd., Los Angeles, CA 90017-2465
Tel: (213) 688-8000 www.wedbush.com