William Blair

Foundation Medicine, Inc.

May 16, 2014

New Data Provides First Glimpse Into Decision Impact Data, Which Is Roughly in Line With Genomic Health Oncotype Dx

In addition to the ASCO abstracts released Wednesday, May 14, there have been two other new independent studies published in *The Oncologist* that have assessed the FoundationOne assay, based on experience in clinical practice (versus controlled studies).

In summary, one of the key ASCO abstracts released (conducted by Foundation Medicine in conjunction with U.S. Oncology) provides a first glimpse into decision impact data for the FoundationOne assay. The study is prospective, multicenter, single-arm trial in patients with refractory solid tumors of any type. A total of 128 patients were evaluated (median age 61 years, 66% female); tumor types included breast (20%), lung (16%), and colon (12%) cancers. Treatment decisions were changed based on the results of FoundationOne in 36 cases (28% switch rate). These switch rates are roughly in line with Genomic Health (GHDX $24.94; Outperform) at 30% (compared with Myriad's [MYGN $37.33; Outperform), Prolaris at 65%, and Veracyte's [VCYT $13.00; Outperform] Afirma GEC at 90%) in initial Oncotype DX studies in early-stage breast cancer.

In addition, two other noncontrolled studies were simultaneously published in *The Oncologist* in early May, which were conducted by Vanderbilt University Medical Center and The University of California San Diego. These studies provide some additional data around decision impact, more detail around "actionability" (how many alterations point to a relevant therapeutic versus a clinical trial), and some initial outcomes data. In the Vanderbilt study, for example, switching based on the FoundationOne assay was seen in 17% of total cases, or 21% of cases with actionable mutations. In addition, the Vanderbilt study suggests about one-half of actionable mutations identified a clinical trial for a targeted therapeutic versus 43%, which identified a targeted therapeutic (either approved for the tumor type or approved for another tumor type).

More details around some of the key ASCO abstracts released as well as the two independent study published in early May in the Oncologist can be found below.

To obtain coverage, diagnostic providers need to demonstrate analytical and clinical validity (around which the company has published a number of studies) as well as clinical utility (e.g., decision impact and health outcomes/economic studies). Foundation Medicine continues to build evidence around the clinical utility of the FoundationOne assay including the benefits of using FoundationOne versus hotspot panels and other approaches (e.g., FISH testing). Advantages include the identification of additional actionable alterations as well as avoidance of issues/cost associated with tissue availability (the need to obtain additional biopsies or tissue exhaustion) seen in traditional approaches.

Foundation Medicine is a CLIA-certified lab that generates revenue from its molecular information platform. Foundation leverages next-generation sequencing technology to provide genomic profiles of cancer, offering physicians individualized information about actionable alterations specific to each patient's tumor, enabling optimization of treatment.

Stock Rating:	**Market Perform**
Company Profile:	**Aggressive Growth**

Symbol:	FMI (NASDAQ)
Price:	$20.68 (52-Wk.: $20-$45)
Market Value (mil.):	$591
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

	2013A	2014E	2015E
Estimates			
EPS FY	$-1.57	$-1.92	$-1.53
CY		$-1.92	$-1.53
Sales (mil.)	29	57	105
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	28
Float (mil.)	25
Average Daily Volume	287,323

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	4.8
Return on Equity (TTM)	-32.2

Two-Year Price Performance Chart

Sources: FactSet, William Blair & Company estimates

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In addition to the decision impact data to be presented at ASCO, Foundation Medicine is in process of conducting a number of other studies with collaborators, including an ongoing sponsored trial within the U.S. Oncology network to assess the impact of FoundationOne on physician decision-making in a real world setting (enrollment began two years ago and presumably we are seeing first data at ASCO). The company is also working on studies designed for "clinical outcomes" (initiated before 2014), including the FoundationOne Registry (goal of 3,000 patients) and a prospective study with MD Anderson (300 patients).

As an early-stage company, reimbursement still remains an unknown, including whether payers will consider a 20% to 30% switching rate as enough for coverage and whether payers will consider clinical trial (versus therapeutic) recommendations as a positive cost-benefit. Moreover, we believe private payers will be focused on outcomes/health economic data—the results of the trials Foundation Medicine is conducting around patient outcomes are as yet unknown. Still, we believe there is increasing likelihood that FoundationOne (and other somatic tumor panels) could obtain coverage by Medicare at a reasonable average selling price (we view a $3,000 ASP as a win), particularly given somatic tumor panels will have their own CPT codes by 2015. The AMA MoPath committee recently made public its proposal for next-generation sequencing somatic tumor panel codes. The committee opted to split the codes into two groups (of 50 genes or less and more than 50 genes), which while somewhat arbitrary, suggests a recognition of differential levels of complexity for these assays—a positive for Foundation Medicine, in our view.

The stock is down 54% since its high reached on March 19 and is down 22% since we initiated coverage April 17, although the short interest has fallen by about 30% to 16% of the float. We continue to believe that while others can procure an Illumina (ILMN $141.63; Outperform) sequencer and launch pan-cancer panels, that given complexity of next-generation sequencing assays/workflow/bioinformatics, this type of testing will remain centralized and with specialized service providers such as Foundation Medicine for the next few years. While competition is likely to increase, we believe Foundation's alteration database represents a competitive advantage and that its workflow investments should enable it to remain a forerunner in the space as cancer genomics testing becomes more and more complex (e.g., evolving into larger panels, clinical exome sequencing, and ultimate potentially whole genome sequencing).

Our Market Perform rating was primarily driven by valuation; at the time, the stock trading at an EV-to-sales multiple of 6 times incorporated a decent amount of market share gains and already assumed some revenue benefit from potential Medicare coverage. Arguably the data has gotten incrementally better with these recent publications; there is building evidence that the test does not just work but also adds value. Valuation has gotten more compelling (now at 4.5 times EV-to-sales). We also believe there is a decent chance that Foundation Medicine obtains Medicare coverage for Foundation One in 2015, which we have projected comes mid-2015 at a $3,000 ASP. We are warming up to the story, but given recent market volatility, we would like to see a bit more valuation contraction to give some room for upside to our fair value estimate of (roughly mid-$20s).

Exhibit 1
Upside/Downside to 2016 Revenue Estimate Discounted 20%

Enterprise Value	Bear $153,612	Base $191,612	Bull $204,612
3.0x	$320,025	$399,192	$426,275
3.5x	$373,363	$465,724	$497,321
4.0x	$426,700	$532,256	$568,367
4.5x	$480,038	$598,788	$639,413
5.0x	$533,375	$665,319	$710,458

Implied Price

3.0x	$15.48	$18.33	$19.31
3.5x	$17.40	$20.73	$21.87
4.0x	$19.32	$23.13	$24.43
4.5x	$21.25	$25.53	$26.99
5.0x	$23.17	$27.93	$29.56

Bear Case: Don't get Medicare coverage which is a reduction of $38 million in revenue

Base Case: Medicare Coverage in mid 2015 at an ASP of $3,000 resulting in $38 million in revenue reduction

Bull Case: Assumes Base Case plus additional private payer coverage at 25% of current billings to commercial third party, or an additional $13 million in revenue

Additional Select Abstract and Two Independent Study Details:

- A few other abstracts (published by Foundation and its collaborators) demonstrated the benefits of using comprehensive molecular profiling assays relative to existing methods. For example, one study looked at genomic rearrangements involving ALK in non–small-cell carcinomas (NSCLC) to predict response to the ALK-targeted therapy (e.g., crizotinib). In the study, 1,070 lung carcinomas were evaluated; of these, 47 harbored ALK rearrangements (4.4%). Of those 47, 28 had been testing using traditional FISH methods; however, 9 (32%) had been classified as negative for ALK rearrangements by prior FISH testing. Of those 9 patients, 5 were given, and responded to, crizotinib, while 2 patients did not respond. (Data for 2 nonresponder patients were unavailable.)

- Another study evaluated the use of FoundationOne in 34 lung adenocarcinoma (ADC) patients with no/light smoking history (less than or equal to 15 packs per year). Patients had advanced disease and had already tested negative for ALL mutations typically found in ADC (EGFR, ERBB2, KRAS, NRAS, BRAF, MAP2K1, PIK3CA, and AKT1 by hotspot testing and/or multiplex sizing assays) and fusions (ALK, ROS1, and RET by break-apart FISH). Previous testing had already required additional biopsies in 24 cases (71%), and tissue exhaustion prevented testing in 9 patients (26%) pointing to the benefits of a comprehensive assay such as FoundationOne. As a note, additional biopsies and testing could be quite expensive; additional needle-guided lung biopsies would have cost roughly $530 (in a non-facility setting), $88.50 for the first IHC stain and $68.50 for each additional IHC stain and an additional $177.30 for each FISH probe. FoundationOne identified at least one alteration in 92% of the cases tested, with an actionable alteration tied to a targeted agent (according to NCCN guidelines) in nine (36%) patients and a targeted agent available on clinical trial in eight patients (32%).

- The Vanderbilt Ingram Cancer Center published an independent study, which evaluated the impact of comprehensive tumor profiling using a next-generation sequencing assay (FoundationOne) for 103 patients (median age of 53, 66% female, predominantly breast [26%], head and neck, [23%], and melanoma [10%], most with Stage IV disease [85%]). These independent results supported data previously published by Foundation; an actionable mutation was identified in 86 patients (83%).

The study also provided some interesting additional data around the type of actionable alterations identified. Twenty-six percent had alterations that predicted sensitivity to targeted agents already approved for the tumor type; 17% had alterations that could be targeted to drugs approved for other tumor types, and 51% were potential candidates for genotype-directed clinical trials.

The study also provided some decision impact information. Twenty-one percent of patients received genotype-directed therapy; 7 patients received clinically available therapeutics, and 11 patients were enrolled in clinical trials as a result of information provided by FoundationOne. In terms of why targeted therapy was not offered, the most common was 35% were given standard treatment (e.g., because the patient had been responding to treatment before obtaining FoundationOne, other therapeutic agents were determined to be better options, or patients could not travel to a clinical trial), 12% showed no evidence of disease after surgery, 3% demonstrated rapid progression and death, and 10% were enrolled in other clinical trials. In this case genotype-directed therapy does not include patients that would have been given a genotype-directed drug based on other standard tests that were or would have been performed on that patient anyway.

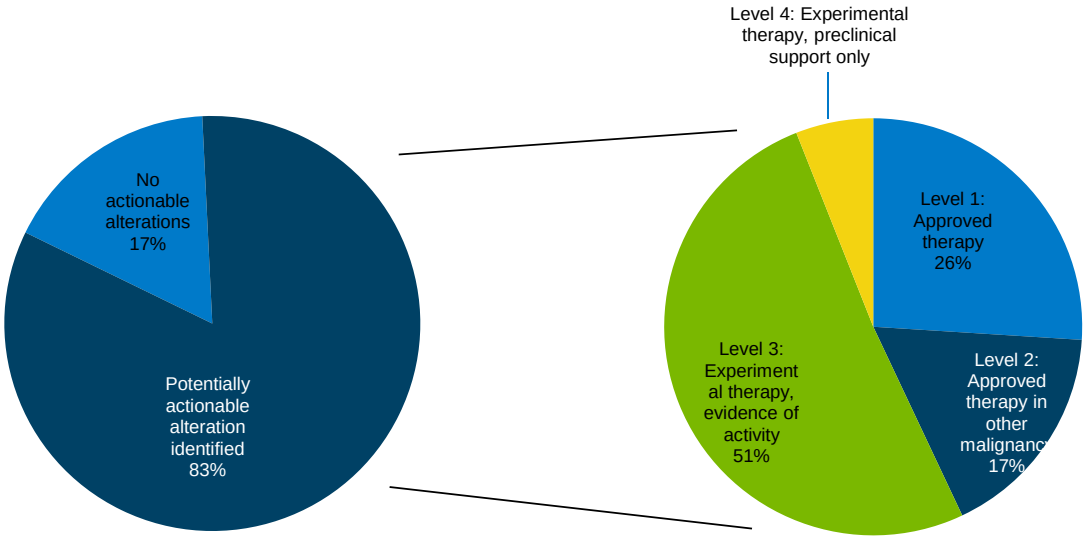
Some outcomes analysis was reported, although outcomes analysis is complex. In this case, the study had a small number of patients who received genotype-directed therapy because of FoundationOne ("n" of 18), in part because of recent therapy initiation at another facility or heterogeneous cancer types. A number of questions remain.

- Also in the same issue of *The Oncologist*, The University of California San Diego published an independent study evaluating use of molecular profiling at the Moore Cancer Center; the study included 34 patients, the majority of whom had breast cancer (47%), followed by gastrointestinal (23%), head and neck (12%), lung (6%), and other (12%). Median age was 56 years with patients receiving a median of three prior therapies in a metastatic setting. Thirty-three of the patients were tested with FoundationOne, two with ResponseDx (Response Genetics), three by Molecular Intelligence (Caris Diagnostics), and one with Champions Oncology (London-based, full exome sequencing).

  While the study was not a direct comparison with hotspot panels, one patient had also undergone hotspot panel based on IonAmpliSeq test. While FoundationOne had identified 14 alterations in the tumor, none where identified in the hotspot panel.

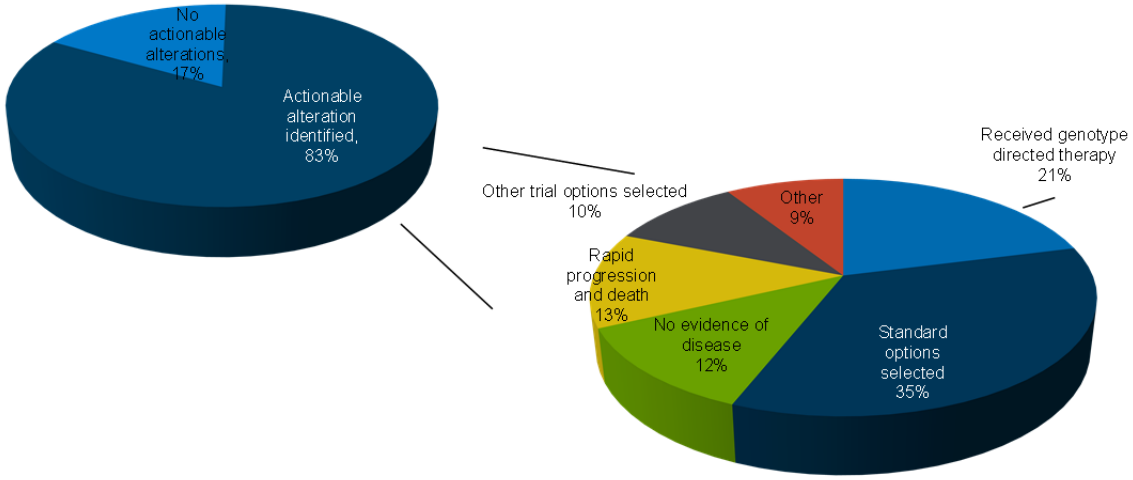
  The study also included some anecdotal outcomes data. Patients were considered in two buckets: those who were receiving a treatment (before progression) and those whose treatment had failed. At the time of publication, treatment decisions had been made in 12 of 34 patients (35%) based on results of molecular profiling. Of those 12, 11 were evaluable for outcome. Three had a partial response, four had stable disease, and four had progressive disease. Of the 22 patients where treatment was not changed, most were stable on their previous treatment (13), another decision was preferred (7) because of lack of coverage of genotype-directed therapy or patients could not travel to clinical trials sites.

Exhibit 2
Potential Genotype-Directed Therapeutic Options Available Based on Genetic Profiling



Source: The Oncologists, Enabling a Genetically Informed Approach to Cancer Medicine: A Retrospective Evaluation of the Impact of Comprehensive Tumor Profiling Using a Targeted Next-Generation Sequencing Panel

Exhibit 3
Outcome and Therapy Assignment Following Genetic Profiling



Source: The Oncologists, Enabling a Genetically Informed Approach to Cancer Medicine: A Retrospective Evaluation of the Impact of Comprehensive Tumor Profiling Using a Targeted Next-Generation Sequencing Panel

Foundation Medicine, Inc. Projected Income Statement (2011 to 2017E)

	FY 2011	FY 2012	2013 Q1'13	2013 Q2'13	2013 Q3'13	2013 Q4'13	FY 2013	2014 Q1'14	2014 Q2'14E	2014 Q3'14E	2014 Q4'14E	FY 2014E	FY 2015E	FY 2016E	FY 2017E
Revenues	$2,057	$10,645	$5,200	$5,920	$8,208	$9,662	$28,990	$11,455	$13,154	$15,265	$17,396	$57,270	$105,327	$191,612	$278,879
Cost of Goods Sold	$258	$5,681	$2,378	$2,219	$2,858	$4,204	$11,659	$5,291	$5,393	$5,953	$6,436	$23,074	$34,611	$51,052	$63,281
Gross Profit	$1,799	$4,964	$2,822	$3,701	$5,350	$5,458	$17,331	$6,164	$7,761	$9,312	$10,959	$34,196	$70,715	$140,560	$215,597
Operating Expenses															
Sales & Marketing	$1,555	$3,454	$1,811	$2,875	$3,038	$4,602	$12,326	$5,690	$7,103	$7,938	$8,698	$29,429	$38,683	$51,767	$65,289
General and Administrative	$6,992	$8,644	$3,150	$4,755	$6,448	$7,512	$21,865	$5,700	$6,708	$7,175	$7,654	$27,237	$36,795	$45,303	$54,770
Research & Development	$9,023	$14,777	$4,982	$6,097	$6,988	$6,834	$24,901	$6,915	$7,366	$7,938	$8,524	$30,743	$38,133	$48,324	$62,500
Total Operating Expenses	$17,570	$26,875	$9,943	$13,727	$16,474	$18,948	$59,092	$18,305	$21,178	$23,050	$24,876	$87,409	$113,611	$145,394	$182,559
Operating Income	-$15,771	-$21,911	-$7,121	-$10,026	-$11,124	-$13,490	-$41,761	-$12,141	-$13,417	-$13,739	-$13,916	-$53,213	-$42,896	-$4,834	$33,038
Interest Expense	$421	$421	$76	$65	$61	$33	$235	$25	$27	$25	$22	$99	$61	$44	$71
Other Non-Operating Expenses	$845	$61	$6	$96	$1,278	-$432	$948	$0	$0	$0	$0	$0	$0	$0	$0
Net Income/Loss	-$17,037	-$22,393	-$7,203	-$10,187	-$12,463	-$13,091	-$42,944	-$12,166	-$13,444	-$13,764	-$13,938	-$53,312	-$42,957	-$4,878	$32,967
Taxes	$0	$0					$0					$0	$0	$816	$6,593
Convertible Preferred Stock	$296	$286	$50	$42	$47	$0	$139	$0	$0	$0	$0	$0	$0	$0	$0
Net Income Common Shareholders	-$17,333	-$22,679	-$7,253	-$10,229	-$12,510	-$13,091	-$43,083	-$12,166	-$13,444	-$13,764	-$13,938	-$53,312	-$42,957	-$5,694	$26,373
Basic & Diluted EPS	**-$0.62**	**-$0.83**	**-$0.27**	**-$0.37**	**-$0.46**	**-$0.48**	**-$1.57**	**-$0.44**	**-$0.48**	**-$0.49**	**-$0.50**	**-$1.92**	**-$1.53**	**-$0.20**	**$0.92**
Weighted Avg. Shares - Basic & Diluted	28,138	27,230	27,355	27,405	27,455	27,505	27,430	27,734	27,784	27,834	27,884	27,809	28,071	28,371	28,671
Margin Analysis:															
Gross Margin	**87%**	**47%**	**54%**	**63%**	**65%**	**56%**	**60%**	**54%**	**59%**	**61%**	**63%**	**60%**	**67%**	**73%**	**77%**
Sales & Marketing	76%	32%	35%	49%	37%	48%	43%	50%	54%	52%	50%	51%	37%	27%	23%
General and Administrative	340%	81%	61%	80%	79%	78%	75%	50%	51%	47%	44%	48%	35%	24%	20%
Research & Development	439%	139%	96%	103%	85%	71%	86%	60%	56%	52%	49%	54%	36%	25%	22%
Interest Expense	7%	0.8%	0.6%	0.6%	0.7%	0.1%	0.5%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%
Operating Income	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**12%**
Taxes	**0%**	**0%**	0%	0%	0%	0%	**0%**	0%	0%	0%	0%	**0%**	**0%**	**0%**	**20%**
Net Income/Loss	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**NM**	**13%**
Growth Metrics:															
Revenue	NM	418%	750%	226%	170%	87%	172%	120%	122%	86%	80%	98%	84%	82%	46%
Cost of Goods Sold	NM	2102%	235%	98%	60%	104%	105%	122%	143%	108%	53%	98%	50%	47%	24%
Gross Profit	NM	176%	-3009%	432%	329%	75%	249%	118%	110%	74%	101%	97%	107%	99%	53%
Sales & Marketing	NM	222%	360%	341%	358%	366%	357%	314%	247%	261%	189%	239%	131%	134%	126%
General and Administrative	NM	124%	188%	235%	302%	267%	253%	181%	141%	111%	102%	125%	135%	123%	121%
Research & Development	NM	164%	165%	169%	196%	149%	169%	139%	121%	114%	125%	123%	124%	127%	129%
Operating Income	NM	39%	35%	73%	110%	144%	91%	70%	34%	24%	3%	27%	-19%	-89%	-784%
Net Income/Loss	NM	31%	32%	73%	127%	135%	92%	69%	32%	10%	6%	24%	-19%	-89%	-776%
EPS	NM	35%	30%	70%	123%	132%	89%	65%	30%	9%	5%	22%	-20%	-87%	-558%

IMPORTANT DISCLOSURES

William Blair is a market maker in the security of Foundation Medicine, Inc. and may have a long or short position.

William Blair intends to seek investment banking compensation in the next three months from Foundation Medicine, Inc.

Additional information is available upon request.

This report is available in electronic form to registered users via R*Docs™ at www.rdocs.com or www.williamblair.com.

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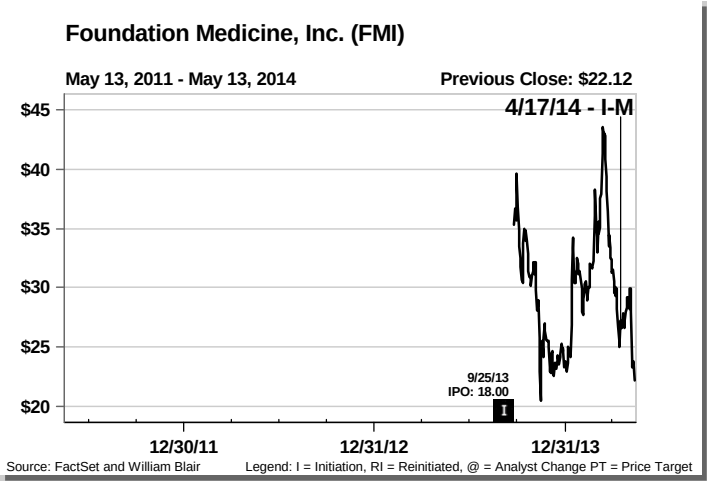
DOW JONES: 16,446.81
S&P 500: 1,870.85
NASDAQ: 4,069.29



Current Rating Distribution (as of 04/30/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	66	Outperform (Buy)	14
Market Perform (Hold)	31	Market Perform (Hold)	2
Underperform (Sell)	1	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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