

Foundation Medicine, Inc.

Latest Thoughts on Reimbursement, XIFIN Expert Call, and Second-Quarter Expectations

- With the recent public meeting for the new Clinical Laboratory Fee Schedule and the 2014 American Association for Clinical Chemistry meeting, there has been some noise around reimbursement for next-generation sequencing codes to be introduced next year, which has driven some volatility in the stock in recent trading. This note provides an overview of various reimbursement proposals on the table, our expectations for the second quarter, and our thoughts on the stock.
- In addition, on August 14, at 2:00 p.m. Eastern time, we are hosting a call with **Rina Wolf**, vice president of commercialization strategies, consulting, and industry affairs, and **Kyle Fetter**, associate vice president-integrated care initiatives, at XiFin. The call will focus on potential implications of the Protecting Access to Medicare Act of 2014 to lab reimbursement as well as potential outcomes for pricing of the new next-generation sequencing codes. Please see the separate invitation for call details.
- There continues to be a great deal of uncertainty about how private and public reimbursement will be determined for next-generation sequencing-based assays such as FoundationOne. CMS is working to implement 27 new next-generation sequencing-based codes (referred to as genomic sequencing procedures, or GSPs) including codes for somatic tumor panels (categorized as panels with between 5 to 50 genes and panels with 51 or greater genes). It is not clear whether CMS will choose to establish pricing via the gap-fill process (which requires local Medicare Contractor involvement in the pricing process), by applying cross-walking (which leverages existing codes to build out reimbursement), or opt to delay pricing of these codes all together.
- It is our understanding that Foundation Medicine and other labs/lab industry associations are advocating for a gap-fill approach (with unique identifiers for each test either via an HCPCS code or a Z-code) in lieu of cross-walking. This way, respective labs will be able to initiate a dialogue with the local MACs and provide more detail about the analytical validity, clinical validity, and clinical utility of each test as well as further coverage discussions.
- One presenter from the Association of Molecular Pathology (AMP) at the recent Annual Clinical Laboratory public meeting proposed using cross-walking for pricing of new next-generation sequencing codes. If CMS adopts this approach, it would still provide robust reimbursement for FoundationOne (almost \$4,600) but would provide less ability to differentiate between levels of test complexity. More specific:
 - The cross-walking would be based on comparing the number of required exons to the number of exons in the MLH1 gene. MLH1 has 21 exons and 2,271 base pairs.

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.

Amanda Murphy, CFA
+1 312 364 8951
amurphy@williamblair.com

JP McKim
+1 312 364 8991
jpmckim@williamblair.com

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August 01, 2014

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

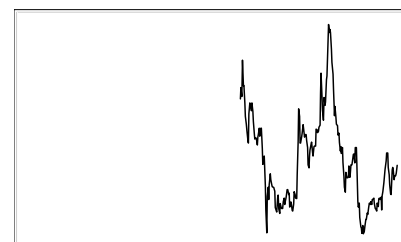
Symbol: FMI (NASDAQ)
Price: \$22.52 (52-Wk.: \$20-\$45)
Market Value (mil.): \$635
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	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.)	16
Average Daily Volume	351,284

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	4.3
Return on Equity (TTM)	-32.2

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- AMP recommended cross-walking to codes 81292 (paid at \$646.24 in 2014) and 87901 (\$351.22 in 2014 and to account for the bioinformatic analysis). This method was also discussed (and applauded as a logical approach) at the recent American Association for Clinical Chemistry (AACC) meeting by Dr. Charles Root, CEO of CodeMap.
 - Efficiencies gained from analysis of additional exons/genes could be accounted for by using a logarithmic function of the number of genes analyzed to calculate a multiplier of 81292 and 87901.
 - For code 81455x (targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA and RNA analysis when performed, 51 or greater genes, interrogation for sequence variants and copy number variants or rearrangements, if performed), AMP indicated that labs on average analyze 100 genes, which would suggest a multiplier of 4.6 ($\ln(100)$), which then be applied to CPT codes 81292 and 87901), yielding a rough price of \$4,600.
- Based on pricing for existing tests relative to complexity and comments made at the recent Medicare Clinical Lab meeting, we believe there is a reasonable chance that reimbursement for complex tumor panels (e.g., greater than 50 genes) could be at or above the \$3,000 break report that we believe investors are looking for whether gap-fill or cross-walking is employed.
- Establishment of CPT codes and pricing by CMS, however, does not imply coverage (the local carriers, in this case, National Government Services, would still be responsible for determining coverage based on an assessment of clinical utility). We (and we believe consensus) assume some level of Medicare reimbursement in 2015 (we assume an ASP of \$3,000 and that 75% of claims are paid) as well as some private payer coverage. Consequently, we model an increase in realized ASP of \$1,630 from 2014 to \$2,224 in 2016.
- Foundation Medicine reports second-quarter results on Tuesday, August 12, after the markets close. We model revenue of \$13.2 million (up 122%) driven by 5,515 clinical tests (239% growth), including 4,585 solid tumor tests and 930 Heme tests with a realized ASP of \$1,630. We also model biopharmaceutical revenue of \$4.2 million. We expect an in-line to slightly better-than-expected quarter given positive volume results out of labs that have recently reported as well as recent biopharma deals the company has signed.
- We continue to believe that Foundation Medicine's investments in workflow and bioinformatics provide a meaningful competitive advantage and see increased likelihood that solid tumor panels could be priced at reasonable levels by CMS. Still, although valuation has become more attractive as of late, with the stock trading at 5 times on an EV-to-2015-sales basis, expectations seem to incorporate a decent amount of market share gains and some revenue benefit from potential Medicare coverage. While we are incrementally comfortable that in the case of coverage, pricing could be in line with to above expectations, we also see an increased risk that reimbursement could come in phases (e.g., by indication) versus what could be market expectations of an all-or-nothing reimbursement decision. Thus, for now, we maintain our Market Perform rating.

Foundation Medicine, Inc. Second-Quarter Preview (\$ in thousands, Fiscal year ends December)			
	2Q 2013 Actual	2Q 2014 Estimate	Year/Year %Change
Net Sales	\$5,920	\$13,154	122.2%
Cost of Sales	\$2,219	\$5,393	143.0%
Gross Profit	\$3,701	\$7,761	109.7%
Sales & Marketing	\$2,875	\$7,103	147.1%
General & Administrative	\$4,755	\$6,708	41.1%
Research & Development	\$6,097	\$7,366	20.8%
Operating Income	-\$10,026	-\$13,417	33.8%
Interest & Other	-\$161	-\$27	-83.0%
Net Income/Loss	-\$10,187	-\$13,444	32.0%
Convertible Preferred Stock	\$42	\$0	-100.0%
Net Income Common Shareholders	-\$10,229	-\$13,444	31.4%
W. Avg. Shares (Diluted)	27,405	27,784	1.4%
EPS	-\$0.37	-\$0.48	-22.9%
Margin Analysis			
Gross Margin	62.5%	59.0%	-3.5%
Sales & Marketing	48.6%	54.0%	5.4%
General & Administrative	80.3%	51.0%	-29.3%
Research & Development	103.0%	56.0%	-47.0%
Operating Income	-169.4%	-102.0%	67.4%
Taxes	-0.4%	0.0%	0.4%
Net Income	-172.8%	-102.2%	70.6%
Clinical Revenue	\$2,820	\$8,991	218.8%
Clinical Tests	1,626	5,515	239.2%
Revenue/Tests	\$1,734	\$1,630	-6.0%

Source: Company Reports and William Blair & Company L.L.C. estimates

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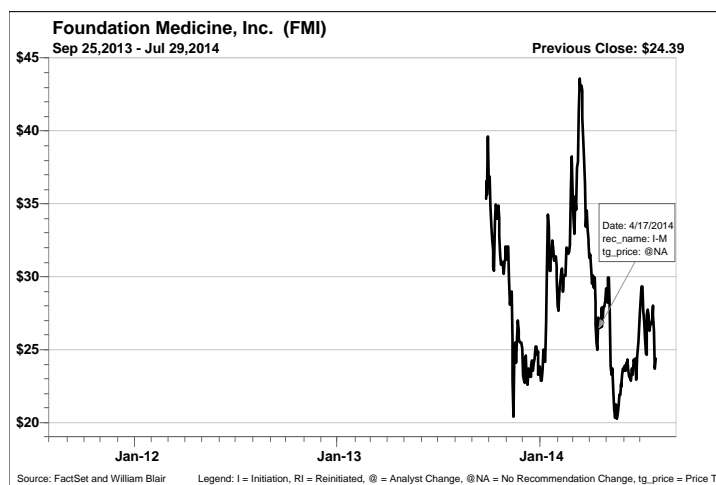
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DOW JONES: 16,563.30

S&P 500: 1,930.67

NASDAQ: 4,369.77



Current Rating Distribution (as of 07/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	66	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
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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