Foundation Medicine

Takeaways from Meetings with Management

Neutral

FMI, FMI US
Price: $21.50
Price Target: $31.00

Yesterday, we hosted investor meetings and a group lunch with Foundation Medicine management, including CEO Mike Pellini, CMO Vince Miller and SVP of Finance Jason Ryan, in New York. Management's tone was upbeat, and we came away incrementally positive on the longer-term outlook (including FMI's differentiated offering with a non-trivial first-mover advantage in an area of rapidly growing medical need), while we continue to view additional visibility on payor and competitive dynamics as key to a more constructive near-term outlook. We maintain our Neutral rating and December 2015 PT of $31.

- **Reimbursement remains *the* most important near-term issue.** Management noted that conversations with payors continue to evolve in the right direction, and having a seat at the table early in the process is critical to shaping payor thinking on both validation and standards, thereby creating a barrier to entry for later entrants. While each payor has different requirements for coverage, there has been little pushback in terms of test price and there is a growing realization of the difference between targeted sequencing/hotspot panels (30-40 genes), such as AmpliSeq/TruSeq, which are likely to be commoditized (~$1,500-2K range) vs. comprehensive molecular profiles, such as FoundationOne, which are more expensive (>$3K), but eliminate the need for multiple tests. In terms of timing, FMI is now 1-2 years into what could be a five-year process with payors, with conversations moving from educational to tactical (timelines, indications, etc.). Importantly, initial coverage decisions are expected to be for individual indications, while there is a reasonable likelihood of little advance notice (to FMI and investors) before a major coverage decision is announced. On indications, management noted that making the point indication-by-indication has resonated well with payors, with a focus on six areas: (1) front-line NSCLC; (2) carcinoma of unknown primary; (3) the subset of rare tumors (non-melanoma skin cancer, etc.); (4) patients who have cancers where requisite markers tested negative (TNBC, etc.), have failed available therapies and are still candidates for treatment; (5) patients with aggressive cancers that have failed available therapy but have adequate functional capacity for treatment; and (6) cases where there is not enough tissue for the work up. Finally, management noted that it remains committed to maintaining current price (realized ASPs in the ~$3,500 range), while continuing to add new content (i.e. FMI is now on the 4th generation of FoundationOne, with no increases to price). The company also intends to provide payors with free access to the patient knowledge base, which is a significant incentive, as it would provide the latter with valuable data upon which to make better-informed decisions regarding future coverage.

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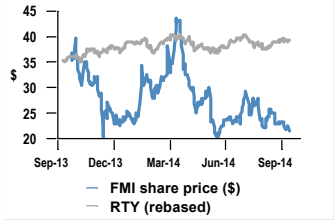
Price Performance



	YTD	1m	3m	12m
Abs	-6.1%	-11.5%	-7.0%	-39.2%
Rel	-6.8%	-14.2%	-7.5%	-50.3%

Foundation Medicine (FMI;FMI US)

FYE Dec	2014E	2015E	2016E
Revenue ($ mn)			
Q1 (Mar)	11A	24	43
Q2 (Jun)	14A	27	47
Q3 (Sep)	15	29	51
Q4 (Dec)	16	31	55
FY	57	111	195

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	21.50
Date Of Price	11 Sep 14
52-week Range ($)	45.00-18.00
Market Cap ($ mn)	609.03
Fiscal Year End	Dec
Shares O/S (mn)	28
Price Target ($)	31.00
Price Target End Date	31-Dec-15

See page 7 for analyst certification and important disclosures.

- **While the competitive landscape continues to evolve, FMI has a significant and sustainable first-mover advantage.** Despite increasing efforts at academic centers to develop broader cancer panels, and announcements from reference labs such as Quest Diagnostics to launch "competing" products (albeit more along the lines of hotspot panels) in the next 12-18 months, FMI remains confident in the sustainability of its first-mover advantage. Management cited an example of a recent study with Memorial Sloan Kettering of 31 lung cancer patients, who had undergone all relevant testing using MSK's suite of in-house targeted tests, including EGFR, ALK, KRAS, HER2, ROS, RET, map kinase and AKT. Importantly, FMI's solid tumor panel was able to detect alterations that MSK's tests missed (that were included in NCCN guidelines and for which a targeted drug existed) in eight of the patients, while matching nine patients to open clinical trials at MSK itself, with results expected to be submitted to the *Journal of Clinical Oncology* next month. Moreover, running MSK's battery of tests required larger amounts of tissue and multiple biopsies (71% of cases) relative to FMI's comprehensive panel, speaking to the economic benefits of FoundationOne. Management also noted that despite having developed an in-house 340-gene pan-cancer panel (called MSK-IMPACT), MSK continues to send solid tumor samples in which they fail to detect alterations to FMI, in addition to all the hematologic malignancy cases (MSK co-developed the heme panel with FMI). In terms of Quest's (covered by JPM analyst, Lisa Gill) June announcement regarding a collaboration with MSK, FMI noted that the first phase was only around providing interpretation and curation data for Quest's existing 34-gene OncoVantage solid tumor hotspot panel. In terms of DGX launching a jointly developed broader panel with MSK by spring 2015, FMI noted that this is not a distribution agreement for MSK-IMPACT, and management remains skeptical about development timelines, noting that even for a competing panel containing the same subset of genes, short insertions-deletions, copy-number variations, and translocations are often missed.
- **Management does *not* view ILMN's Actionable Genome Consortium (AGC) and Onco Panel efforts with biopharma, or the recent TMO/Mt. Sinai collaboration, as competitive threats.** ILMN recently announced the formation of the AGC to help drive standardization in the use of NGS to guide clinical decision making in oncology, while the company also announced partnerships with AstraZeneca, Janssen Biotech and Sanofi to develop a universal NGS-based oncology test system for panel-based companion diagnostics for use in clinical trials of targeted cancer therapies. When asked about these developments, management (which was quick to acknowledge the dominant presence of ILMN in NGS), stated that it does not view these developments as a competitive threat, noting that ILMN and TMO are focused on technology and developing panels that can be kitted to run on NGS platforms, while FMI is more focused on applications. FMI does expect companies such as ILMN, TMO and possibly QGEN to drive commoditization in the hotspot panel market, which is distinct from the comprehensive pan-cancer panel approach. Moreover, the rapidly growing knowledge base of ~21K patient cases (expected to grow to 22-25K by year-end, with a path to 100K+) and 2H14 improvements in the Interactive Cancer Explorer online portal (ICE 2.0), including outcomes collection capability and physician networking, in addition to existing features such as links to relevant abstracts and clinical trials, should drive further differentiation in terms of the FMI offering, while inducing a strong network effect and loyalty among ordering physicians.

- **FMI is actively engaged in a dialog with the FDA and is positioned well to deal with any eventual LDT regulation.** At the end of July, the FDA announced its intention to propose a risk oversight framework for LDTs that could potentially increase the regulatory burden for test manufacturers via increased supporting clinical data requirements and a pre-market review (PMA). The draft proposal will not be published until October, at the earliest, and will be followed by a public comment period, making the timing and content of the new rules far from certain at this stage. Management highlighted that it continues to anticipate FDA oversight, and has a "good and transparent" relationship with the agency, having worked with FDA on the Lung-MAP trial and via pharma collaborations, including that with Clovis Oncology. In particular, as part of the Clovis partnership, FMI is designing and building a new lab (expected to be completed in 2015) to meet FDA Quality System Regulations (QSR), and which can be used for other future PMA approvals, should that eventuality materialize. Importantly, FDA appears to understand the problem involved in requiring approval every time a panel is updated with new genes (including multi-year delays in getting the latest technological advances to patients), and is hence unlikely to go down that path, potentially in favor of a universal diagnostic, while raising the barrier to entry for later entrants in the space. Management also highlighted the fall 2013 *Nature Biotech* paper, which laid out a roadmap to validation, and which should help set the standard for sensitivity, specificity, etc.
- **Pharmaceutical collaborations add an element of stability to the base business.** Management noted that FMI often helps pharma collaborators significantly reduce development timelines for targeted therapeutics (by 6-9 months in one case), by quickly matching them to patients with the relevant mutations, while the collaborations also provide FMI with insight on drugs in development, which can prove useful in terms of adding content, such as IDH1/2 mutations, which prior to the Agios trial, served no known purpose in the panel. The company currently has 20+ ongoing collaborations, and expects to generate $25-50M in annual pharma revenues over the medium term, lending an element of stability to the business model, while it awaits progress on the reimbursement front. Moreover, ramping new collaborations would not require any incremental capex, as there is no difference in the way pharma and clinical samples are processed in the lab.
- **Other topics:** (1) SG&A: FMI believes it needs ~100 salespeople to effectively address the U.S. market (vs. current levels of 47) and expects to expand the commercial team in 2015; (2) Margins: expected to remain lumpy in the near term, as FMI is not reimbursed on ~30% of FoundationOne test volumes, including those from Medicare patients; that said, receiving positive coverage decisions and realizing incremental scale efficiencies off increasing volumes, should drive substantial leverage in the business model; (3) R&D priorities: driving down tissue sample requirements (from 20ng to 50 cells, 20 cells, 1 cell, etc.) remains a key R&D priority and should help further reduce the number of small-volume samples that currently prove challenging; other priorities include liquid biopsy, incorporating cell-free DNA, as well as circulating tumor cells in the management of cancer, along with immunodiagnostics. As previously disclosed at ASCO 2013, in addition to driving sample input volumes down from 50ng to 20ng, FMI has already had success with fine-needle aspirates (FNA), as it showed an ability to run a full lung panel from 36 of 37 FNA samples.

- **No financial updates; maintain Neutral rating and December 2015 PT of $31.** Not surprisingly, FMI did not provide any updates to the 2014 outlook, and continues to expect $52-58M in revenues based on 22-25K tests, including FoundationOne Heme. Our Neutral rating remains unchanged, as the company's first-mover advantage in the high-growth pan-cancer panel market coupled with operating leverage in the business model is balanced by continued uncertainties around reimbursement timing and evolving competitive dynamics. Please see our initiation for additional thoughts on the investment thesis.

Investment Thesis, Valuation and Risks

Foundation Medicine *(Neutral; Price Target: $31.00)*

Investment Thesis

With its first-mover advantage in NGS-based cancer diagnostics and differentiated product, we believe FMI is poised to increase its penetration and continued gain in market share as it provides a value-added improvement for oncologists and the possibility of a truly personalized treatment regimen for patients. We expect adoption rates and sales volumes to increase in the coming quarters as the company gains further traction from its Interactive Cancer Explorer online portal and launches its analogous cancer panel for hematologic malignancies in 2014. Maintain Neutral.

Valuation

Our December 2015 price target of $31 is derived from a 10-year DCF analysis, with a CAPM-derived WACC discount rate of 20.3% and terminal growth of 2.0%.

Risks to Rating and Price Target

Downside risks to our rating and price target include: (1) lack of visibility and potential delay in Medicare and commercial reimbursement; (2) competition and subsequent price erosion that could create uncertainty in the business model; (3) sole dependence on Illumina for sequencers; and (4) regulatory risk for current and future products.

Upside risks include: (1) earlier than expected Medicare reimbursement approval; and (2) faster adoption and ramp of the FoundationOne panel for both solid tumors and hematologic malignancies.

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Foundation Medicine: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14A	3Q14E	4Q14E
Revenues	29	57	111	195	Revenues	11A	14A	15	16
Cost of products sold	(12)	(24)	(39)	(63)	Cost of products sold	(5)A	(7)A	(6)	(6)
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(29)	(46)	(79)	(110)	SG&A	(9)A	(11)A	(13)	(13)
R&D	(25)	(33)	(41)	(40)	R&D	(7)A	(9)A	(9)	(9)
Operating income	(42)	(53)	(55)	(27)	Operating income	(12)A	(14)A	(14)	(13)
EBITDA	(37)	(46)	(48)	(18)	EBITDA	(10)A	(12)A	(12)	(12)
Net interest (income) / expense	(0)	(0)	0	(2)	Net interest (income) / expense	(0)A	(0)A	(0)	0
Other income / (expense)	(1)	0	0	0	Other income / (expense)	0A	0A	0	0
Income taxes	0	0	0	0	Income taxes	0A	0A	0	0
Net income	(43)	(53)	(55)	(28)	Net income	(12)A	(14)A	(14)	(13)
Diluted shares outstanding	9	28	28	29	Diluted shares outstanding	28A	28A	28	28
Diluted EPS	(4.64)	(1.90)	(1.94)	(0.99)	Diluted EPS	(0.44)A	(0.49)A	(0.49)	(0.48)
Balance Sheet and Cash Flow Data	**FY13A**	**FY14E**	**FY15E**	**FY16E**	**Ratio Analysis**	**FY13A**	**FY14E**	**FY15E**	**FY16E**
Cash and cash equivalents	124	63	22	21	Sales growth	172.3%	97.8%	94.2%	75.4%
Accounts receivable	6	10	17	28	EBIT growth	90.6%	26.7%	4.1%	(51.7%)
Inventories	2	3	4	6	EPS growth	(55.7%)	(59.1%)	2.5%	(49.2%)
Other current assets	1	2	3	5					
Current assets	133	78	47	60	Gross margin	-	-	-	-
PP&E	22	25	29	36	EBIT margin	(144.1%)	(92.3%)	(49.5%)	(13.6%)
Total assets	157	105	78	99	EBITDA margin	(126.8%)	(80.6%)	(43.0%)	(9.1%)
					Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	1	0	10	30	Net margin	(148.6%)	(92.3%)	(49.5%)	(14.5%)
Total liabilities	26	25	53	103					
Shareholders' equity	132	80	25	(4)	Net Debt / EBITDA	334.1%	136.8%	25.6%	(49.6%)
					Net Debt / Capital (book)	(1377.1%)	(386.1%)	(99.7%)	176.6%
Net income (including charges)	(43)	(53)	(55)	(28)					
D&A	5	7	7	9	Return on assets (ROA)	(38.6%)	(40.4%)	(60.4%)	(32.1%)
Change in working capital	(2)	2	6	12	Return on equity (ROE)	(46.1%)	(50.1%)	(105.8%)	(274.4%)
Other	9	(9)	1	0					
Cash flow from operations	(31)	(53)	(41)	(7)	Enterprise value / sales	20.8	11.6	6.4	3.8
					Enterprise value / EBITDA	NM	NM	NM	NM
Capex	(7)	(8)	(11)	(16)	Free cash flow yield	(18.7%)	(10.1%)	(8.5%)	(3.4%)
Free cash flow	(37)	(61)	(52)	(21)					
Cash flow from investing activities	(8)	(8)	(11)	(16)					
Cash flow from financing activities	109	(0)	11	22					
Dividends	0	0	0	0					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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Foundation Medicine (FMI, FMI US) Price Chart

Date	Rating	Share Price ($)	Price Target ($)
21-Oct-13	N	32.84	38.00
07-Jan-14	N	23.60	28.00
26-Feb-14	N	32.44	30.00
07-May-14	N	23.90	31.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Oct 21, 2013.

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IB clients*	75%	66%	54%

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