

Foundation Medicine

4Q Review: No Surprises Post Preannouncement, But Modest Positives on the Reimbursement Front

In line with the January 13th preannouncement (see our take [here](#)), Foundation Medicine reported 4Q13 revenues of ~\$9.7M, driven by higher-than-expected solid tumor test volumes, while reiterating top-line expectations of \$52-58M for 2014. In line with expectations, FMI noted that it has begun submitting claims to Medicare, although in an incremental positive, the company also noted that it has applied for a Z-code with McKesson, which could prove advantageous, should the Z-coding program go national, while it could also help in discussions with NGS, the local MAC. While 4Q performance and the 2014 outlook are both supportive of continued adoption, we look for additional progress with payors as key to a more constructive outlook, and accordingly, maintain our Neutral rating, while adjusting our December 2014 price target to \$30.

- Revenue beat led by solid test volumes in both Clinical and Pharma.** In line with the preannouncement, 4Q revenues came in at ~\$9.7M (full-year revenue of ~\$29M), above both JPMe (~\$5.9M) and the Street (\$8.2M). Clinical (\$5.3M) and Pharma (\$4.4M) both came in above our expectations of \$3.8M and \$2.1M, respectively, with the beat driven by higher test volumes. Within Clinical, FMI reported 3,752 tests to oncologists in 4Q (with the majority ordered by community-based oncologists and repeat users, bringing total clinical tests ordered to over 9,095 for 2013), while Pharma customers ordered 1,593 tests. Within Pharma, management also highlighted the participation (for patient stratification) in the Lung Cancer Master Protocol and a 3-year extension and expansion of the NVS partnership, which now includes an annual commitment to reserve testing capacity to support the targeted therapy portfolio and access to FMI's molecular information and analysis services. Moving down the P&L, gross margins of ~56% declined q/q (vs. ~65% in 3Q13), due to an increase in pharma tests reported under fixed revenue agreements and the earlier recognition of costs relative to revenue generated from cash-based payments for tests performed.
- Not surprisingly, given the recent December launch, there were few incremental details on the Heme test ramp.** Management provided few incremental details on the call regarding the hematologic malignancy panel ramp which launched ahead of schedule in December 2013, other than stating that they are pleased with validation, early results and initial adoption. Similar to the solid tumor panel, FMI intends to initially focus on late-stage patients who either lack viable treatment options or have exhausted existing options. As noted last quarter, due to the RNA sequencing component of the test, COGS will likely be higher than the solid tumor panel.

Foundation Medicine (FMI;FMI US)

FYE Dec	2013A	2014E (Prev)	2014E (Curr)	2015E (Prev)	2015E (Curr)
Revenue (\$ mn)					
Q1 (Mar)	5	9	11	19	20
Q2 (Jun)	6	10	13	20	23
Q3 (Sep)	8	14	15	26	27
Q4 (Dec)	10	12	17	25	31
FY	29	45	56	90	100

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

Neutral

FMI, FMI US

Price: \$32.44

▲ **Price Target: \$30.00**
Previous: \$28.00

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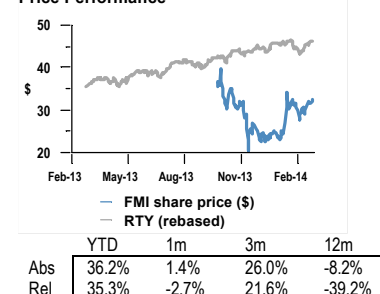
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Price Performance



Company Data

Price (\$)	32.44
Date Of Price	25 Feb 14
52-week Range (\$)	41.51-18.00
Market Cap (\$ mn)	905.23
Fiscal Year End	Dec
Shares O/S (mn)	28
Price Target (\$)	30.00
Price Target End Date	31-Dec-14

See page 8 for analyst certification and important disclosures.

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- **In a positive on the reimbursement front, FMI announced submission of claims to Medicare and an application to establish unique z-code identifiers on the McKesson Diagnostics Exchange.** In line with expectations, FMI announced that it has now begun submitting claims to Medicare (using miscellaneous codes rather than the stacked codes it uses to bill commercial payors), as test volumes from this segment continue to grow. In addition, the company has also submitted an application to the McKesson Diagnostics Exchange to establish unique z-code identifiers for the two tests. Management noted that z-code identifiers have already been adopted by Palmetto as part of the MolDX program that determines coverage and payment for Medicare in 17 states (not including Massachusetts), with further adoption of the program by other Medicare contractors (including FMI's local administrator) and commercial payors expected in the future. Given the uncertainty around approval and timing of CPT codes that adequately represent specific NGS-based tests, we view this application for z-code identifiers as an incremental positive in obtaining reimbursement. On the call, management also noted that average reimbursement for clinical tests increased sequentially to \$3,400 (vs. \$3,300 in 3Q13 and ~\$3,650 in 1H13), while looking ahead, FMI expects realized clinical test pricing to fluctuate around these levels in 2014.
- **Solid tumor panel expansion coupled with ICE enhancements bode well for continued adoption in 2014.** FMI plans to expand its solid tumor panel to include additional genes in 1H14 (no details on the number of genes that will be added/removed were provided on the call). This is in line with prior commentary of updating their panel once a year, and management reiterated the philosophy of a fixed price point while continuing to update test content. Secondly, the company also reiterated planned enhancements to the Interactive Cancer Explorer online portal (including outcomes collection capabilities) in the second half of 2014. We believe these enhancements to the ICE portal should help drive a stronger network effect within the oncologist community, an important tenet of our FMI thesis.
- **No surprises in 2014 outlook relative to preannouncement.** In line with commentary provided in January, FMI expects to achieve \$52-58M in revenues in 2014 (vs. then-consensus forecasts of ~\$53M and our estimate of \$45M), delivering 22-25K tests (including FoundationOne Heme) over the course of the year. Operating expenses are expected to be in the \$85-92M range, driven by an increase in sales and marketing costs, as the company expects to add an incremental 20-25 reps in the U.S. by 4Q14, in addition to growing the international sales team, and investing in clinical trials, new product R&D, and the addition of new features to the Interactive Cancer Explorer online portal.
- **Modest changes to our estimates; maintain Neutral rating and adjusting December 2014 price target to \$30.** We are making modest adjustments to our model for the quarter, and now forecast 2014 sales of \$56M (vs. our prior forecast of \$45M), in line with the updated guidance range. As a result of these changes, we are also updating our DCF and revise our price target to \$30. Our Neutral rating remains unchanged, as the company's first-mover advantage in the high-growth pan-cancer panel market coupled with the operating leverage in the business model is balanced by uncertainty around reimbursement timing and evolving competitive dynamics. As such, we view the risk/reward as balanced near current valuation levels and prefer to remain on the sidelines, pending additional clarity on these key issues. Please see our [initiation](#) for additional thoughts on our investment thesis, and ASHG recap for notes from our [site visit](#) last October to FMI's new facility in Cambridge.

Figure 1: FMI – 4Q13 Variance

	4Q12A		4Q13E				4Q13A				Variance vs. JPM Est.	
	Actual		JPM Estimate		Consensus		Actual		Change y/y			
	\$ M	%	\$ M	%	\$ M	%	\$ M	%	Δ \$	Δ margin	\$ M	%
Clinical	1.6		3.8				5.3		232.1%		1	
Pharma	3.6		2.1				4.4		22.8%		2	
Total Revenue	5.2		5.9		8.2		9.7		86.6%		4	
Gross Profit	3.1	60.2%	3.4	57.3%			5.5	56.5%	75.0%	-373 bp	2	-79 bp
R&D	4.6	-88.6%	5.9	-100.0%			6.8	-70.7%	49.0%	1784 bp	1	2927 bp
Sales and Marketing	1.3		2.6				4.6					
General and Admin.	2.8	-54.3%	3.9	-65.0%			7.5	-77.7%	167.2%	-2347 bp	4	-1275 bp
Operating Income	(5.5)	-106.9%	(12.4)	-209.0%			(13.5)	-139.6%		-3271 bp	(1)	6938 bp
EBITDA	(4.8)	-92.1%	(11.7)	-196.5%			(12.4)	-128.8%		-3673 bp	(1)	6770 bp
Pretax Income	(5.6)		(12.1)				(13.1)				(1)	
Income Tax	0.0	0.0%	0.0	0.0%			0.0	0.0%		0 bp	0	0 bp
Net Income	(5.6)		(12.1)	(2.2)			(13.1)				(1)	
Diluted Shares	2.6M		28.0M				27.5M		963.2%		-0.5M	
GAAP Diluted EPS	(\$2.17)		(\$0.43)				(\$0.48)					

FY14 Guidance

Revenue: \$52-58M

Clinical test volume: 22-25K tests

Operating expenses: \$85-92M

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

Other Notes

4Q Clinical test volume: 3,752 tests

4Q Pharma test volume: 1,593 tests

Investment Thesis, Valuation, and Risks

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 market gain 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 2014 price target of \$30 is derived from a 10-year DCF analysis, with a CAPM-derived WACC discount rate of 19.5% and terminal growth of 1.0% (see Figure 3).

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.

Figure 2: FMI Model

Income Statement (in millions, except per share amounts)	2012A	1QA Mar	2QA Jun	3QA Sep	4QA Dec	2013A	1QE Mar	2QE Jun	3QE Sep	4QE Dec	2014E	2015E	2016E	2017E	2018E	CAGR 13-18
Clinical	3	2	3	4	5	15	8	9	9	10	35	76	153	297	464	
Pharma	8	3	3	4	4	14	4	4	6	7	21	24	28	32	37	
Total Revenue	11	5	6	8	10	29	11	13	15	17	56	100	181	329	501	77%
Cost of goods sold	6	2	2	3	4	12	5	5	6	6	22	35	58	96	134	
Gross Profit	5	3	4	5	5	17	7	8	9	10	35	65	123	233	367	
Research and Development	15	5	6	7	7	25	8	9	9	8	34	36	37	42	50	
Sales and Marketing	3	2	3	3	5	12	6	7	8	9	30	50	81	131	175	
General and Administrative	9	3	5	6	8	22	6	7	7	7	26	27	29	49	65	
Operating Profit (Loss) - EBIT	(22)	(7)	(10)	(11)	(13)	(42)	(13)	(14)	(15)	(14)	(56)	(48)	(24)	10	77	
Depreciation & Amortization	3	1	1	1	1	4	1	1	1	1	4	4	5	7	9	
EBITDA	(19)	(6)	(9)	(10)	(12)	(38)	(12)	(13)	(14)	(13)	(52)	(44)	(19)	17	86	
Other income (expense), net	(0)	(0)	(0)	(1)	0	(1)	(0)	(0)	(0)	(0)	(0)	(0)	(2)	(2)	(2)	
Pretax Income	(22)	(7)	(10)	(12)	(13)	(43)	(13)	(14)	(15)	(14)	(56)	(48)	(26)	8	75	
Income Tax	0	0	0	0	0	0	0	0	0	0	0	0	0	3	26	
Net Income (Loss) attributable to common	(23)	(7)	(10)	(13)	(13)	(43)	(13)	(14)	(15)	(14)	(56)	(48)	(26)	5	49	
Diluted shares outstanding	2.2	2.7	3.2	3.6	27.5	9.3	27.6	27.7	27.8	27.9	27.8	28.2	28.6	29.0	29.4	
GAAP Diluted EPS	(\$10.47)	(\$2.69)	(\$3.19)	(\$3.51)	(\$0.48)	(\$4.64)	(\$0.47)	(\$0.50)	(\$0.53)	(\$0.50)	(\$2.01)	(\$1.72)	(\$0.91)	\$0.19	\$1.65	N/M
# Total tests performed (in 000s)	3.1	1.7	2.2	3.5	5.3	12.9	4.8	5.6	6.5	7.1	24.1	42.5	74.3	125.7	187.7	
Implied cost / test (\$/test)	\$1,833	\$1,369	\$987	\$807	\$787	\$906	\$936	\$913	\$908	\$903	\$913	\$829	\$781	\$762	\$712	
Gross Margin	47%	54%	63%	65%	56%	60%	60%	61%	61%	62%	61%	65%	68%	71%	73%	
R&D Margin (as % of revenue)	139%	96%	103%	85%	71%	86%	70%	65%	60%	50%	60%	37%	20%	13%	10%	
Sales & Marketing Margin (as % of revenue)	32%	35%	49%	37%	48%	43%	50%	52%	54%	55%	53%	50%	45%	40%	35%	
G&A Margin (as % of revenue)	81%	61%	80%	79%	78%	75%	55%	50%	45%	40%	47%	27%	16%	15%	13%	
Operating (EBIT) Margin	-206%	-137%	-169%	-136%	-140%	-144%	-115%	-106%	-98%	-83%	-99%	-48%	-13%	3%	15%	
Effective Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	35%	35%	
Net Margin	-213%	-139%	-173%	-152%	-135%	-149%	-115%	-106%	-98%	-83%	-99%	-48%	-14%	2%	10%	
Revenue growth (y/y)		750%	226%	170%	87%	172%	118%	122%	84%	75%	95%	77%	81%	82%	52%	
EPS growth (y/y)		-10%	9%	47%	-78%	-56%	-82%	-84%	-85%	6%	-57%	-15%	-47%	-121%	781%	

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

Figure 3: FMI: DCF Analysis

Projected FY Ending Dec	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Revenue (\$M)	29	56	100	181	329	501	665	826	938	1,037	1,137	1,238
growth y/y		95%	77%	81%	82%	52%	33%	24%	14%	10%	10%	9%
EBIT (\$M)	(41)	(56)	(48)	(24)	10	77	168	258	370	446	512	557
EBIT margin	-142%	-99%	-48%	-13%	3%	15%	25%	31%	39%	43%	45%	45%
Tax-affected EBIT (\$M)	(41)	(56)	(48)	(24)	7	51	110	169	241	291	333	362
Free Cash Flow	(42)	(56)	(39)	(14)	16	53	97	159	211	282	312	355
growth y/y						241%	81%	64%	33%	34%	11%	14%

Discount Rate	Discounted Cash Flows (\$M)	PV of Terminal Value (\$M) at a Perpetual Growth Rate of					Enterprise Value (\$M)					Equivalent Terminal EBITDA Multiple (forward 12 mos)				
	2015-2024	0.0%	0.5%	1.0%	1.5%	2.0%	0.0%	0.5%	1.0%	1.5%	2.0%	0.0%	0.5%	1.0%	1.5%	2.0%
18.5%	409	451	466	482	499	516	861	876	891	908	926	1.4x	1.4x	1.4x	1.4x	1.5x
19.0%	397	424	438	452	467	483	821	835	849	864	880	1.3x	1.3x	1.3x	1.4x	1.4x
19.5%	385	399	411	425	438	453	784	796	810	824	838	1.2x	1.3x	1.3x	1.3x	1.3x
20.0%	374	375	387	399	412	425	749	760	773	785	799	1.2x	1.2x	1.2x	1.2x	1.3x
20.5%	362	353	364	375	387	399	716	726	738	749	762	1.1x	1.2x	1.2x	1.2x	1.2x

Net Debt (Cash) (\$M)	Equity Value (\$M)					Equity Value per Share					Terminal Value as a % of Enterprise Value				
	0.0%	0.5%	1.0%	1.5%	2.0%	0.0%	0.5%	1.0%	1.5%	2.0%	0.0%	0.5%	1.0%	1.5%	2.0%
(30)	891	906	921	938	955	\$32.10	\$32.63	\$33.19	\$33.79	\$34.43	52%	53%	54%	55%	56%
(30)	851	865	879	894	910	\$30.66	\$31.15	\$31.67	\$32.22	\$32.80	52%	52%	53%	54%	55%
(30)	814	826	839	853	868	\$29.32	\$29.77	\$30.25	\$30.75	\$31.28	51%	52%	52%	53%	54%
(30)	779	790	802	815	829	\$28.06	\$28.47	\$28.91	\$29.37	\$29.86	50%	51%	52%	52%	53%
(30)	746	756	767	779	792	\$26.87	\$27.25	\$27.65	\$28.08	\$28.52	49%	50%	51%	52%	52%

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

Foundation Medicine: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14E	2Q14E	3Q14E	4Q14E
Revenues	29	56	100	181	Revenues	11	13	15	17
Cost of products sold	(12)	(22)	(35)	(58)	Cost of products sold	(5)	(5)	(6)	(6)
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(30)	(52)	(72)	(105)	SG&A	(11)	(12)	(14)	(15)
R&D	(25)	(34)	(36)	(37)	R&D	(8)	(9)	(9)	(8)
Operating income	(42)	(56)	(48)	(24)	Operating income	(13)	(14)	(15)	(14)
EBITDA	(38)	(52)	(44)	(19)	EBITDA	(12)	(13)	(14)	(13)
Net interest (income) / expense	(0)	(0)	(0)	(2)	Net interest (income) / expense	(0)	(0)	(0)	(0)
Other income / (expense)	(1)	0	0	0	Other income / (expense)	0	0	0	0
Income taxes	0	0	0	0	Income taxes	0	0	0	0
Net income	(43)	(56)	(48)	(26)	Net income	(13)	(14)	(15)	(14)
Diluted shares outstanding	9	28	28	29	Diluted shares outstanding	28	28	28	28
Diluted EPS	(4.64)	(2.01)	(1.72)	(0.91)	Diluted EPS	(0.47)	(0.50)	(0.53)	(0.50)
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	87	30	3	9	Sales growth	172.3%	94.9%	76.6%	81.0%
Accounts receivable	5	8	12	20	EBIT growth	90.6%	33.6%	(13.3%)	(49.9%)
Inventories	1	2	2	3	EPS growth	(55.7%)	(56.5%)	(14.7%)	(47.0%)
Other current assets	1	2	4	5	Gross margin	-	-	-	-
Current assets	95	42	21	37	EBIT margin	(144.1%)	(98.8%)	(48.5%)	(13.4%)
PP&E	12	17	16	22	EBITDA margin	(129.8%)	(91.6%)	(44.1%)	(10.6%)
Total assets	109	61	39	61	Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	1	0	10	30	Net margin	(148.6%)	(99.0%)	(48.5%)	(14.4%)
Total liabilities	17	25	52	100	Net Debt / EBITDA	227.8%	57.7%	(16.5%)	(110.4%)
Shareholders' equity	92	36	(13)	(39)	Net Debt / Capital (book)	(1433.4%)	(501.6%)	(135.6%)	(120.6%)
Net income (including charges)	(43)	(56)	(48)	(26)	Return on assets (ROA)	(49.2%)	(65.7%)	(96.2%)	(51.6%)
D&A	4	4	4	5	Return on equity (ROE)	(58.6%)	(87.7%)	(417.7%)	101.6%
Change in working capital	4	4	8	16	Enterprise value / sales	-	-	-	-
Other	2	0	1	0	Enterprise value / EBITDA	-	-	-	-
Cash flow from operations	(33)	(47)	(35)	(5)	Free cash flow yield	(13.4%)	(6.3%)	(4.2%)	(1.7%)
Capex	(8)	(9)	(3)	(11)					
Free cash flow	(41)	(56)	(38)	(16)					
Cash flow from investing activities	(10)	(9)	(3)	(11)					
Cash flow from financing activities	75	(1)	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

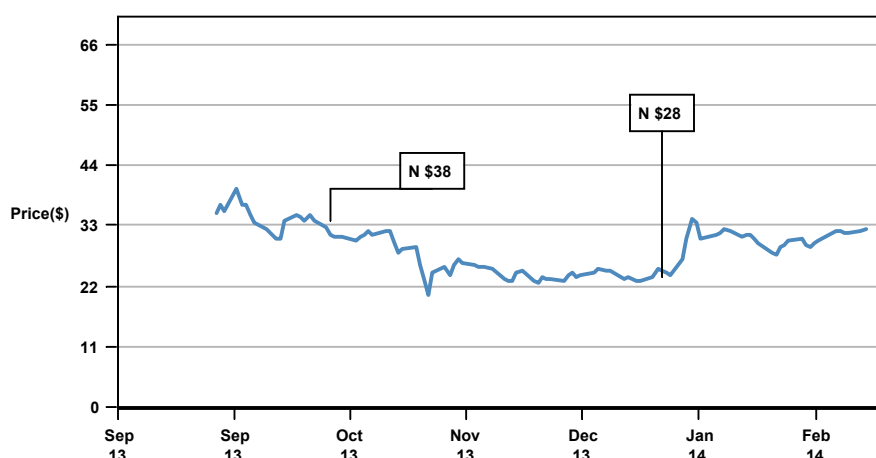
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Foundation Medicine (FMI, FMI US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
21-Oct-13	N	33.99	38.00
07-Jan-14	N	23.60	28.00

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

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