

Foundation Medicine

3Q13 Review: Solid Quarter Out of the Gate; Reimbursement, Pricing and Heme Launch Remain in Focus

Foundation Medicine (FMI) reported solid F3Q results – its first quarter as a public company – with revenues of \$8.2M coming in well above JPMe (\$5.7M) and consensus (\$6.9M), aided by strong test volumes in both clinical and pharma segments, while the bottom line benefitted from healthy gross margins (65% vs. JPMe 58%). No guidance was provided on the call, although management reiterated expectations for early 2014 launch of the hematologic malignancy test. For now, we see little to change the investment thesis, as 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 competitive dynamics. We maintain a Neutral rating and December 2014 price target of \$38. Please see our [initiation](#) for more thoughts on the investment thesis, and ASHG [recap](#) for notes from our site visit to FMI's new facility in Cambridge.

- 3Q13 revenues and gross margins handily beat expectations, driven by strong test volumes.** Reported sales of \$8.2M came in above JPMe (\$5.7M) and the Street (\$6.9M), led by Clinical revenues of \$4.4M and Pharma revenues of \$3.8M, both of which came in above our expectations (\$3.6M and \$2.1M, respectively). The beat was driven by strong test volumes (2,577 clinical and 965 biopharma tests), which offset q/q weakness in pricing. Over 2,100 physicians have now ordered FoundationOne, with ~53% of 3Q test orders coming from community oncologists. Turning to other metrics, gross margins of 65% were ~720 bps above JPMe, driven by economies of scale as volumes ramp, coupled with a decrease in turnaround times (14-15 days), driven by a reduction in sequencing times and streamlining front- and back-end processes. As a reminder, increased penetration rates for FoundationOne, coupled with operating leverage, are key tenets of our thesis, and we were encouraged by outperformance in these metrics relative to our forecast in the quarter.
- Limited updates on pricing and payor dynamics.** On the call, management noted that average reimbursement for clinical tests declined to \$3,300 (vs. ~\$3,650 in 1H14), due to transitioning to the 2013 molecular pathology codes. FMI expects realized clinical test pricing to stabilize at these levels in the near term. On the pharma side, average test revenue came in at \$3,700, with a modest q/q decline driven by volume-based pricing in clinical trials. Regarding payor discussions, management offered few incremental updates, other than reiterating that they continue to build a “body of evidence”, are in discussions with large private payors and Medicare, and plan to submit claims to Medicare by year-end (in view of the steady growth in Medicare patient test volumes, which currently stand at 533 tests in 3Q).

Foundation Medicine (FMI;FMI US)

FYE Dec	2012A	2013E (Prev)	2013E (Curr)	2014E (Prev)	2014E (Curr)	2015E
Revenue (\$ mn)						
Q1 (Mar)	1	5A	5A	10	9	19
Q2 (Jun)	2	6A	6A	10	10	20
Q3 (Sep)	3	6A	8A	11	14	26
Q4 (Dec)	5	6	6	12	12	25
FY	11	23	25	43	45	90

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

Neutral

FMI, FMI US

Price: \$29.82

Price Target: \$38.00

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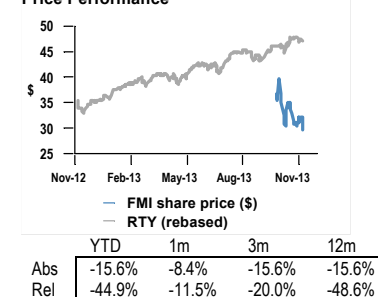
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Price Performance



Company Data

Price (\$)	29.82
Date Of Price	06 Nov 13
52-week Range (\$)	41.51-18.00
Market Cap (\$ mn)	845.33
Fiscal Year End	Dec
Shares O/S (mn)	28
Price Target (\$)	38.00
Price Target End Date	31-Dec-14

See page 8 for analyst certification and important disclosures.

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- **Hematologic malignancy test on track for an early 2014 launch.** In line with prior guidance, the hematologic malignancy test remains on track for a 1Q14 commercial launch, with the test currently in the validation stage. FMI will be presenting additional details on the hematologic panel at the American Society of Hematology (ASH) meeting in December. Management noted that due to the RNA sequencing component of the test, COGS will likely be higher than the solid tumor panel.
- **No guidance... but test volumes and margins expected to fluctuate quarter-to-quarter; announcement around a novel clinical trial approach is imminent.** Management noted that it remains in the early stages of the commercialization phase of the FoundationOne test and business metrics were likely to fluctuate from quarter to quarter. In particular, they noted that test volumes were likely to be lumpy due to fewer lab days in 4Q, and unpredictability in clinical trial start timings and biopharma pipelines, while margins were also likely to fluctuate due to investments in lab infrastructure and personnel. In terms of test specifications, FMI hopes to drive further declines in turnaround time while adding additional genes to their existing panel on an annual basis. Finally (and most intriguingly), FMI noted that they were involved in discussions with partners around “a novel and important new approach to clinical trials”, with further details expected in the very near future.
- **Modest changes to our estimates; maintain Neutral rating and December 2014 price target of \$38.** We are making modest adjustments to our model for the quarter, and now forecast 2013 sales of \$25M (versus our prior forecast of \$23M). Our Neutral rating and DCF-based 2014 price target of \$38 remain 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 competitive dynamics. As such, we view the risk reward as balanced at current valuation levels and prefer to remain on the sidelines. Please see our [initiation](#) for additional thoughts on our investment thesis, and ASHG [recap](#) for notes from our recent site visit to FMI's new facility in Cambridge.

Figure 1: FMI Variance

	3Q12		3QE				3QA				Variance	
	Actual		JPM Estimate		Consensus		Actual		Change y/y		vs. JPM Est.	
	\$ M	%	\$ M	%	\$ M	%	\$ M	%	Δ \$	Δ margin	\$ M	%
Clinical	0.5		3.6				4.4		828.3%		1	
Pharma	2.6		2.1				3.8		48.3%		2	
Total Revenue	3.0		5.7		6.9		8.2		170.3%		2	
Gross Profit	1.2	41.0%	3.3	58.0%			5.4	65.2%	329.4%	2415 bp	2	718 bp
SG&A	(3.0)	98.2%	(7.4)	129.0%			(9.5)	115.6%	218.0%	1735 bp	(2)	-1343 bp
R&D	(3.6)	117.5%	(5.7)	100.0%			(7.0)	85.1%	95.9%	-3231 bp	(1)	-1486 bp
Operating Income	(5.3)	-174.6%	(9.8)	-171.0%			(11.1)	-135.5%		3912 bp	(1)	3547 bp
EBITDA	(4.5)	-149.4%	(9.2)	-160.8%			(10.1)	-123.0%		2639 bp	(1)	3781 bp
Pretax Income	(5.5)		(12.6)				(12.5)				0	
Income Tax	0.0	0.0%	0.0	0.0%			0.0	0.0%		0 bp	0	0 bp
Net Income	(5.6)	(1.8)	(12.6)	(2.2)			(12.5)				0	
Diluted Shares	2.3M		16.6M				3.6M		52.9%		-13.0M	
GAAP Diluted EPS	(\$2.39)		(\$0.76)		(\$0.76)		(\$3.51)					

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

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 \$38 is derived from a 10-year DCF analysis, with a CAPM-derived WACC discount rate of 16.7% and terminal growth of 0.5% (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; (4) Regulatory risk for current and future products.

Figure 2: FMI Model

Income Statement (in millions, except per share amounts)	2011A	1QA Mar	2QA Jun	3QA Sep	4QA Dec	2012A	1QA Mar	2QA Jun	3QA Sep	4QE Dec	2013E	2014E	2015E	2016E	2017E	2018E	CAGR 13-18
Clinical	2	0	0	0	2	3	2	3	4	4	13	30	72	149	292	459	
Pharma	0	0	1	3	4	8	3	3	4	2	12	15	17	20	23	27	
Total Revenue	2	1	2	3	5	11	5	6	8	6	25	45	90	169	316	486	81%
Cost of goods sold	0	1	1	2	2	6	2	2	3	2	10	18	32	54	92	130	
Gross Profit	2	(0)	1	1	3	5	3	4	5	3	15	27	58	115	224	356	
Research and Development	9	3	4	4	5	15	5	6	7	6	24	30	33	35	40	49	
Sales and Marketing	2	1	1	1	1	4	2	3	3	3	10	25	45	76	126	170	
General and Administrative	7	2	2	2	3	9	3	5	6	4	18	21	24	27	47	63	
Operating Profit (Loss) - EBIT	(16)	(5)	(6)	(5)	(6)	(22)	(7)	(10)	(11)	(9)	(37)	(48)	(44)	(23)	10	74	
Depreciation & Amortization	2	1	1	1	1	3	1	1	1	1	4	4	5	6	7	9	
EBITDA	(14)	(5)	(5)	(5)	(5)	(20)	(6)	(9)	(10)	(8)	(33)	(45)	(40)	(17)	17	83	
Other income (expense), net	(1)	(0)	(0)	(0)	(0)	(1)	(0)	(0)	(1)	0	(1)	(0)	(0)	(0)	(0)	(0)	
Pretax Income	(17)	(5)	(6)	(5)	(6)	(23)	(7)	(10)	(12)	(9)	(38)	(48)	(44)	(23)	10	74	
Income Tax	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	26	
Net Income (Loss) attributable to common	(17)	(6)	(6)	(6)	(6)	(23)	(7)	(10)	(13)	(9)	(39)	(48)	(44)	(23)	6	48	
Diluted shares outstanding	4.9	1.7	2.0	2.3	2.5	8.7	2.7	3.2	3.6	28.0	9.4	28.3	28.7	29.1	29.5	29.9	
GAAP Diluted EPS	(\$3.52)	(\$3.25)	(\$2.92)	(\$2.39)	(\$2.48)	(\$2.68)	(\$2.69)	(\$3.19)	(\$3.51)	(\$0.31)	(\$4.12)	(\$1.70)	(\$1.54)	(\$0.79)	\$0.22	\$1.62	N/M
# Total tests performed (in 000s)		0.3	0.6	0.8	1.4	3.1	1.7	2.2	3.5	2.6	10.1	20.1	39.8	71.3	122.4	183.9	
Implied cost / test (\$/test)		\$2,355	\$1,977	\$2,236	\$1,440	\$1,833	\$1,369	\$987	\$807	\$966	\$984	\$878	\$799	\$764	\$752	\$705	
Gross Margin	87%	-16%	38%	41%	60%	47%	54%	63%	65%	58%	61%	61%	65%	68%	71%	73%	
R&D Margin (as % of revenue)	439%	492%	199%	117%	91%	140%	96%	103%	85%	100%	95%	66%	37%	21%	13%	10%	
Sales & Marketing Margin (as % of revenue)	76%	82%	46%	28%	25%	33%	35%	49%	37%	44%	41%	55%	50%	45%	40%	35%	
G&A Margin (as % of revenue)	340%	274%	111%	70%	60%	84%	61%	80%	79%	65%	72%	47%	27%	16%	15%	13%	
Operating (EBIT) Margin	-767%	-864%	-318%	-175%	-116%	-210%	-137%	-169%	-136%	-151%	-147%	-107%	-49%	-14%	3%	15%	
Effective Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	35%	35%	
Net Margin	-843%	-902%	-329%	-183%	-120%	-219%	-139%	-173%	-152%	-145%	-153%	-107%	-49%	-14%	2%	10%	
Revenue growth (y/y)							750%	226%	170%	15%	137%	78%	100%	88%	86%	54%	
EPS growth (y/y)							-17%	9%	47%	-88%	53%	-59%	-10%	-49%	-127%	651%	

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)	25	45	90	169	316	486	648	807	917	1,013	1,111	1,207
growth y/y		78%	100%	88%	86%	54%	33%	24%	14%	10%	10%	9%
EBIT (\$M)	(37)	(48)	(44)	(23)	10	74	164	252	362	436	500	543
EBIT margin	-146%	-107%	-49%	-14%	3%	15%	25%	31%	39%	43%	45%	45%
Tax-affected EBIT (\$M)	(37)	(48)	(44)	(23)	6	48	107	164	235	283	325	353
Free Cash Flow	(40)	(48)	(40)	(12)	16	52	94	155	206	274	304	345
growth y/y						227%	82%	64%	33%	33%	11%	14%

	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)				
Discount Rate	2015-2024		-0.5%	0.0%	0.5%	1.0%	1.5%		-0.5%	0.0%	0.5%	1.0%	1.5%		-0.5%	0.0%	0.5%	1.0%	1.5%
15.7%	477		616	638	663	689	716		1,093	1,116	1,140	1,166	1,194		1.8x	1.8x	1.9x	1.9x	1.9x
16.2%	463		576	596	618	642	667		1,038	1,059	1,081	1,105	1,130		1.7x	1.7x	1.8x	1.8x	1.8x
16.7%	448	+	539	558	578	599	622	=	987	1,006	1,026	1,047	1,070		1.6x	1.6x	1.7x	1.7x	1.7x
17.2%	434		505	522	541	560	581		939	957	975	994	1,015		1.5x	1.6x	1.6x	1.6x	1.7x
17.7%	421		474	489	506	524	543		895	910	927	945	964		1.5x	1.5x	1.5x	1.5x	1.6x
	Net Debt (Cash) (\$M)		Equity Value (\$M)						Equity Value per Share						Terminal Value as a % of Enterprise Value				
			-0.5%	0.0%	0.5%	1.0%	1.5%		-0.5%	0.0%	0.5%	1.0%	1.5%		-0.5%	0.0%	0.5%	1.0%	1.5%
	(40)		1,133	1,155	1,180	1,206	1,234		\$40.03	\$40.83	\$41.69	\$42.61	\$43.59		56%	57%	58%	59%	60%
	(40)		1,078	1,099	1,121	1,144	1,169		\$38.09	\$38.82	\$39.60	\$40.44	\$41.32		55%	56%	57%	58%	59%
-	(40)	=	1,027	1,046	1,066	1,087	1,110	=	\$36.28	\$36.95	\$37.66	\$38.42	\$39.22		55%	55%	56%	57%	58%
	(40)		979	996	1,015	1,034	1,055		\$34.60	\$35.21	\$35.86	\$36.54	\$37.28		54%	55%	55%	56%	57%
	(40)		934	950	967	985	1,004		\$33.02	\$33.58	\$34.17	\$34.80	\$35.46		53%	54%	55%	55%	56%

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

Foundation Medicine: Summary of Financials

Income Statement - Annual	FY12A	FY13E	FY14E	FY15E	Income Statement - Quarterly	1Q13A	2Q13A	3Q13A	4Q13E
Revenues	11	25	45	90	Revenues	5A	6A	8A	6
Cost of products sold	(6)	(10)	(18)	(32)	Cost of products sold	(2)A	(2)A	(3)A	(2)
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(10)	(25)	(42)	(65)	SG&A	(4)A	(7)A	(8)A	(6)
R&D	(15)	(24)	(30)	(33)	R&D	(5)A	(6)A	(7)A	(6)
Operating income	(22)	(37)	(48)	(44)	Operating income	(7)A	(10)A	(11)A	(9)
EBITDA	(20)	(33)	(45)	(40)	EBITDA	(6)A	(9)A	(10)A	(8)
Net interest (income) / expense	(0)	(0)	(0)	(0)	Net interest (income) / expense	(0)A	(0)A	(0)A	(0)
Other income / (expense)	(0)	(1)	0	0	Other income / (expense)	(0)A	(0)A	(1)A	0
Income taxes	0	0	0	0	Income taxes	0A	0A	0A	0
Net income	(23)	(39)	(48)	(44)	Net income	(7)A	(10)A	(13)A	(9)
Diluted shares outstanding	9	9	28	29	Diluted shares outstanding	3A	3A	4A	28
Diluted EPS	(2.68)	(4.12)	(1.70)	(1.54)	Diluted EPS	(2.69)A	(3.19)A	(3.51)A	(0.31)
Balance Sheet and Cash Flow Data	FY12A	FY13E	FY14E	FY15E	Ratio Analysis	FY12A	FY13E	FY14E	FY15E
Cash and cash equivalents	55	89	40	1	Sales growth	-	137.3%	77.7%	100.4%
Accounts receivable	2	3	5	10	EBIT growth	-	66.3%	29.3%	(8.4%)
Inventories	1	1	1	2	EPS growth	-	53.4%	(58.6%)	(9.8%)
Other current assets	1	1	2	4	Gross margin	-	-	-	-
Current assets	58	94	49	17	EBIT margin	(210.4%)	(147.5%)	(107.3%)	(49.1%)
PP&E	7	11	15	19	EBITDA margin	(184.2%)	(132.2%)	(99.4%)	(44.0%)
Total assets	66	107	65	38	Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	3	1	0	0	Net margin	(218.6%)	(153.0%)	(107.5%)	(49.1%)
Total liabilities	11	11	18	34	Net Debt / EBITDA	263.7%	262.8%	88.9%	2.8%
Shareholders' equity	55	96	48	4	Net Debt / Capital (book)	(1448.8%)	(1047.4%)	(481.7%)	(40.8%)
Net income (including charges)	(22)	(38)	(48)	(44)	Return on assets (ROA)	(70.5%)	(44.6%)	(55.8%)	(85.6%)
D&A	3	3	4	5	Return on equity (ROE)	(84.2%)	(51.0%)	(67.0%)	(170.7%)
Change in working capital	0	1	3	8	Enterprise value / sales	-	-	-	-
Other	2	2	0	1	Enterprise value / EBITDA	-	-	-	-
Cash flow from operations	(17)	(32)	(41)	(31)	Free cash flow yield	(7.9%)	(13.7%)	(5.7%)	(4.6%)
Capex	(3)	(7)	(7)	(9)					
Free cash flow	(20)	(38)	(48)	(39)					
Cash flow from investing activities	(3)	(8)	(7)	(9)					
Cash flow from financing activities	64	74	(1)	1					
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

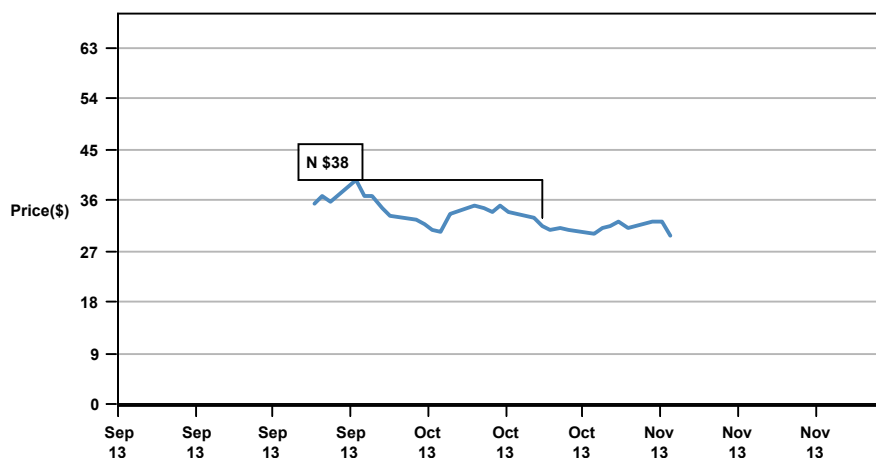
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Foundation Medicine (FMI, FMI US) Price Chart



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

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