

Foundation Medicine

2Q14 Review: Healthy Progress As Test Volumes Ramp and Pipeline Enhancements Continue, But Still No Medicare Update

Foundation Medicine reported 2Q14 revenues of ~\$14.5M, driven by solid growth in clinical test volumes and a higher-than-forecasted contribution from pharma collaborations, while reiterating top-line expectations for \$52-58M and clinical test volumes of 22-25K for 2014. In an incremental positive on the regulatory/reimbursement front, the company highlighted that it had recently received approval for both current tests from the NY State Department of Health, which should help in the ongoing dialog with payors, while average reimbursement per test increased modestly, due to the higher priced hematologic malignancy panel. That said, the company has yet to receive any payments from Medicare for claims submitted earlier in the year. While the solid 2Q performance and unchanged 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, as we roll forward our DCF to establish a December 2015 PT of \$31, which is unchanged from our prior December 2014 PT.

- **Top-line beat driven by higher than expected pharma sales and solid test volumes.** 2Q14 revenues came in at ~\$14.5M, beating JPMe and consensus (\$13.5M and \$13.4M). By segment, clinical revenues of \$9.4M were driven by strong test volumes of 5,908 tests (+26% q/q), including 4,960 solid tumor and 948 hematologic malignancy tests (both coming in modestly higher than our estimate and up sequentially vs. 3,987 solid tumor and 715 Heme tests in 1Q). Nearly two thirds (60%) of tests were from community-based physicians (vs. 54% in 1Q), with sequential volume increases across both the community and academic settings. Pharma revenues came in at \$5.1M, versus our estimate of \$4.4M driving most of the upside in revenue relative to our forecast, aided by 1,261 tests. Moving down the P&L, gross margins of ~54% increased q/q (vs. ~53.8% in 4Q13), but declined y/y due to the earlier recognition of costs relative to revenue generated from cash-based payments for tests performed.

Neutral

FMI, FMI US

Price: \$25.65

Price Target: \$31.00

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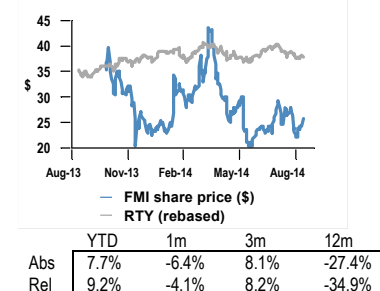
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Price Performance



Foundation Medicine (FMI;FMI US)

FYE Dec	2014E (Prev)	2014E (Curr)	2015E (Prev)	2015E (Curr)	2016E
Revenue (\$ mn)					
Q1 (Mar)	11A	11A	22	24	43
Q2 (Jun)	14A	14A	24	27	47
Q3 (Sep)	16	15	28	29	51
Q4 (Dec)	17	16	30	31	55
FY	57	57	105	111	195

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

Company Data

Price (\$)	25.65
Date Of Price	12 Aug 14
52-week Range (\$)	45.00-18.00
Market Cap (\$ mn)	726.59
Fiscal Year End	Dec
Shares O/S (mn)	28
Price Target (\$)	31.00
Price Target End Date	31-Dec-15

See page 9 for analyst certification and important disclosures.

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- **Average reimbursement per test ticks up due to Heme, but no payments to date on submitted Medicare claims.** As a reminder, FMI began submitting claims to Medicare late last year (using miscellaneous codes, rather than the stacked codes used to bill commercial payors), as test volumes from this segment continue to grow. On the call, management noted that FMI has yet to receive payments based on the claims, but that this is consistent with prior expectations, and that while it is in the process of appealing the claims, it continues to have conservative expectations around associated backlog revenue. We note that last quarter, FMI also received unique Z-code identifiers for both tests, pursuant to submitting an application to the McKesson Diagnostics Exchange. As a reminder, Z-code identifiers have been adopted by Palmetto as part of the MolDX program that determines coverage and payment for Medicare in 17 states (not including Massachusetts), and further adoption of the program by other Medicare contractors (including FMI's local administrator) and commercial payors in the future would be advantageous to FMI. The company continues to submit validation and clinical utility data as part of the ongoing dialog with payors, and pointed to the recent regulatory approval for both tests from the New York State Department of Health as an important milestone, due to the rigorous levels of technical and clinical validation required for LDTs in New York. Finally, management noted that average reimbursement for clinical tests increased to \$3,600 (up from \$3,400 in 1Q14 and 4Q13, and \$3,300 in 3Q13), due to the impact of higher-priced Heme tests, with realized pricing expected to fluctuate around these levels going forward.
- **Updated solid tumor panel now launched with informatics enhancements expected in 2H.** In line with 1Q commentary, FMI announced that it launched a new version of the solid tumor panel in August (slightly delayed due to the NY State regulatory review mentioned above), which includes performance improvements and expands content to 300+ genes (including 29 fusions). In addition to the product update, management also highlighted the June launch of the FoundationOne CareLine, a personalized case management service to patients who have had either of the tests and are facing challenges gaining access to certain prescribed targeted therapies. The company also reiterated plans to release a new version of the Interactive Cancer Explorer online portal (including outcomes collection and physician networking capabilities) in 2H14.
- **Recent FDA proposal to enhance regulation of LDTs adds an element of uncertainty in the medium term, but FMI continues to engage in an active and open dialog with regulators.** 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. FMI highlighted that it continues to anticipate FDA oversight, and has a "very good and transparent" relationship with the agency, having worked with them on the Lung-MAP trial and via pharma collaborations, including that with Clovis Oncology. In particular, as part of the Clovis partnership, FMI is currently designing and building a new lab (expected to be completed in 2015) that meets FDA Quality System Regulations (QSR), and which can be used for other future PMA approvals.

- **2014 outlook unchanged, maintain Neutral rating and establish December 2015 PT of \$31.** FMI continues to expect \$52-58M in revenues, based on 22-25K tests (including FoundationOne Heme), for 2014. In terms of other metrics, gross margins are expected to be in the 55-65% range, while opex is expected to be ~\$85-92M, driven by an increase in sales and marketing costs, and investing in clinical trials, new product R&D, and informatics enhancements. We are making modest adjustments to our model for commentary from the quarter, and updating our DCF assumptions, as we roll forward our DCF to establish a December 2015 PT of \$31 (which is unchanged versus our prior December 2014 PT). Our neutral rating also 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. We view the risk reward as balanced 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.

Figure 1: FMI 2Q14 Variance

	2Q13A		2Q14E				2Q14A				Variance vs. JPM Est.		Notes
	Actual		JPM Estimate		Consensus		Actual		Change y/y				
	\$ M	%	\$ M	%	\$ M	%	\$ M	%	Δ \$	Δ margin	\$ M	%	
Clinical	2.8		9.2				9.4		232.2%		0.2		
Pharma	3.1		4.4				5.1		65.0%		0.7		
Total Revenue	5.9		13.5		13.4		14.5		144.9%		1.0		
Gross Profit	3.7	62.5%	7.6	56.0%			7.9	54.3%	112.8%	-818 bp	0	-166 bp	
R&D	6.1	-103.0%	8.1	-60.0%			8.6	-59.6%	41.8%	4336 bp	1	36 bp	
Sales and Marketing	2.9		8.1				7.2						
General and Admin.	4.8	-80.3%	6.8	-50.0%			5.8	-40.2%	22.5%	4014 bp	(1)	982 bp	
Operating Income	(10.0)	-169.4%	(15.4)	-114.0%			(13.8)	-94.9%		7442 bp	2	1906 bp	
Pretax Income	(10.2)		(15.4)				(13.8)				2		
Income Tax	0.0	0.0%	0.0	0.0%			0.0	0.0%		0 bp	0	0 bp	
Net Income	(10.2)		(15.4)				(13.8)				2		
Diluted Shares	3.1M		27.8M				27.9M		809.3%		0.0M		
GAAP Diluted EPS	(\$3.34)		(\$0.55)		(\$0.47)		(\$0.49)				\$0.06		

FY14 Guidance

Revenue: \$52-58M

- Clinical test volume: 22-25K tests
- Gross margins: 55-65%
- Operating expenses: \$85-92M
- New ICE feature including outcomes collection capabilities in 2H14
- Expecting over 31,000 patient cases in knowledgebase by year end

Other Notes

- 2Q Clinical test volume: 5,908 tests including 4,960 Solid Tumor and 948 Heme tests
- Knowledgebase of genomic data grew to over 21,000 patient cases
- Continued commercial expansion, with 60% of tests reported to community oncologists

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

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% (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	1QA Mar	2QA Jun	3QE Sep	4QE Dec	2014E	2015E	2016E	2017E	2018E	CAGR 13-18
Clinical	3	2	3	4	5	15	7	9	11	12	39	89	170	317	486	
Pharma	8	3	3	4	4	14	4	5	5	4	18	22	25	29	34	
Total Revenue	11	5	6	8	10	29	11	14	15	16	57	111	195	346	520	78%
Cost of goods sold	6	2	2	3	4	12	5	7	6	6	24	39	63	101	139	
Gross Profit	5	3	4	5	5	17	6	8	9	10	33	72	132	245	381	
Research and Development	15	5	6	7	7	25	7	9	9	9	33	41	40	44	52	
Sales and Marketing	3	2	3	3	5	12	6	7	7	7	27	56	88	139	182	
General and Administrative	9	3	5	6	8	22	6	6	7	7	26	30	31	52	68	
Operating Profit (Loss) - EBIT	(22)	(7)	(10)	(11)	(13)	(42)	(12)	(14)	(14)	(13)	(53)	(55)	(27)	11	80	
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)	(12)	(14)	(14)	(13)	(53)	(55)	(28)	9	78	
Income Tax	0	0	0	0	0	0	0	0	0	0	0	0	0	3	27	
Net Income (Loss) attributable to common	(23)	(7)	(10)	(13)	(13)	(43)	(12)	(14)	(14)	(13)	(53)	(55)	(28)	6	50	
Diluted shares outstanding	2.2	2.8	3.1	3.6	27.5	9.3	27.7	27.9	28.0	28.1	27.9	28.3	28.7	29.1	29.5	
GAAP Diluted EPS	(\$10.47)	(\$2.56)	(\$3.34)	(\$3.51)	(\$0.48)	(\$4.64)	(\$0.44)	(\$0.49)	(\$0.49)	(\$0.48)	(\$1.90)	(\$1.94)	(\$0.99)	\$0.19	\$1.71	N/M
# Total tests performed (in 000s)	3.1	1.7	2.2	3.5	5.3	12.9	5.6	7.2	7.9	8.7	29.4	49.4	80.6	132.3	194.3	
Implied cost / test (\$/test)	\$1,833	\$1,369	\$987	\$807	\$787	\$906	\$953	\$923	\$798	\$696	\$828	\$798	\$779	\$764	\$715	
Gross Margin	47%	54%	63%	65%	56%	60%	54%	54%	59%	62%	58%	65%	68%	71%	73%	
R&D Margin (as % of revenue)	139%	96%	103%	85%	71%	86%	60%	60%	55%	55%	57%	37%	21%	13%	10%	
Sales & Marketing Margin (as % of revenue)	32%	35%	49%	37%	48%	43%	50%	49%	47%	46%	48%	50%	45%	40%	35%	
G&A Margin (as % of revenue)	81%	61%	80%	79%	78%	75%	50%	40%	45%	45%	45%	27%	16%	15%	13%	
Operating (EBIT) Margin	-206%	-137%	-169%	-136%	-140%	-144%	-106%	-95%	-88%	-84%	-92%	-49%	-14%	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%	-106%	-95%	-88%	-84%	-92%	-49%	-15%	2%	10%	
Revenue growth (y/y)		750%	226%	170%	87%	172%	120%	145%	88%	65%	98%	94%	75%	77%	50%	
EPS growth (y/y)															791%	

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

Figure 3: FMI DCF Analysis

Target Period: **Dec 2015**

Projected FY Ending Dec	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Revenue (\$M)	57	111	195	346	520	686	847	958	1,056	1,156	1,255	1,353
growth y/y		94%	75%	77%	50%	32%	23%	13%	10%	9%	9%	8%
EBIT (\$M)	(53)	(55)	(27)	11	80	173	265	378	454	520	565	609
EBIT margin	-92%	-49%	-14%	3%	15%	25%	31%	39%	43%	45%	45%	45%
Tax-affected EBIT (\$M)	(53)	(55)	(27)	8	52	113	173	246	296	338	367	396
Free Cash Flow	(51)	(53)	(21)	3	40	87	148	204	275	306	348	377
growth y/y					1392%	120%	70%	37%	35%	11%	14%	8%

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)				
		1.0%	1.5%	2.0%	2.5%	3.0%	1.0%	1.5%	2.0%	2.5%	3.0%	1.0%	1.5%	2.0%	2.5%	3.0%
19.3%	526	391	404	418	433	448	918	931	945	959	975	1.4x	1.4x	1.4x	1.5x	1.5x
19.8%	512	366	378	391	404	418	878	890	903	916	930	1.3x	1.4x	1.4x	1.4x	1.4x
20.3%	498	343	354	365	377	390	841	852	863	875	888	1.3x	1.3x	1.3x	1.3x	1.4x
20.8%	485	321	331	342	353	364	806	816	826	838	849	1.2x	1.2x	1.3x	1.3x	1.3x
21.3%	472	301	310	320	330	341	773	782	792	802	813	1.2x	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				
		1.0%	1.5%	2.0%	2.5%	3.0%	1.0%	1.5%	2.0%	2.5%	3.0%	1.0%	1.5%	2.0%	2.5%	3.0%
	(12)	930	943	957	971	987	\$32.83	\$33.29	\$33.78	\$34.29	\$34.84	43%	43%	44%	45%	46%
	(12)	890	902	915	928	942	\$31.43	\$31.85	\$32.30	\$32.76	\$33.26	42%	42%	43%	44%	45%
	(12)	853	864	876	888	900	\$30.12	\$30.50	\$30.91	\$31.34	\$31.79	41%	42%	42%	43%	44%
	(12)	818	828	839	850	861	\$28.88	\$29.24	\$29.61	\$30.00	\$30.41	40%	41%	41%	42%	43%
	(12)	785	794	804	814	825	\$27.72	\$28.05	\$28.39	\$28.74	\$29.12	39%	40%	40%	41%	42%

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

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	Gross margin	-	-	-	-
Current assets	133	78	47	60	EBIT margin	(144.1%)	(92.3%)	(49.5%)	(13.6%)
PP&E	22	25	29	36	EBITDA margin	(126.8%)	(80.6%)	(43.0%)	(9.1%)
Total assets	157	105	78	99	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	Net Debt / EBITDA	334.1%	136.8%	25.6%	(49.6%)
Shareholders' equity	132	80	25	(4)	Net Debt / Capital (book)	(1377.1%)	(386.1%)	(99.7%)	176.6%
Net income (including charges)	(43)	(53)	(55)	(28)	Return on assets (ROA)	(38.6%)	(40.4%)	(60.4%)	(32.1%)
D&A	5	7	7	9	Return on equity (ROE)	(46.1%)	(50.1%)	(105.8%)	(274.4%)
Change in working capital	(2)	2	6	12	Enterprise value / sales	20.8	11.6	6.4	3.8
Other	9	(9)	1	0	Enterprise value / EBITDA	NM	NM	NM	NM
Cash flow from operations	(31)	(53)	(41)	(7)	Free cash flow yield	(15.7%)	(8.5%)	(7.2%)	(2.9%)
Capex	(7)	(8)	(11)	(16)					
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	36.07	30.00
07-May-14	N	27.99	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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