

May 19, 2014

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Foundation Medicine (FMI - OUTPERFORM): ASCO Cheatsheet - Encouraged by Flow of Good Clinical Outcomes Data - UCSF Check Jibes with Recent Positive Academic Data Points - Maintain OP

Price: \$21.24

12-Month Price Target: \$50

- **Encouraged by new clinical outcomes data being presented at ASCO. Three abstracts out of 17 stand out as the most impactful.** As a reminder, we believe additional clinical outcomes data is an important part of FMI's long term quest to achieve strong reimbursement from large private payors as well as Medicare. Late last week FMI announced its 17 abstracts which are being presented at this year's American Society for Clinical Oncology (ASCO) meeting (5/30-6/3). With this note we outline the three key abstracts which we believe are most important to the long term reimbursement and clinical adoption story.
- **US Oncology study is FMI's largest outcomes study yet and demonstrates a high rate of changing practice.** Abstract #11109 represents FMI's largest broad-based clinical outcomes study to date which was performed by the company's large partner/customer US Oncology. The prospective, multi-center study included 128 metastatic patients receiving second or third line therapy across multiple cancer types (20% breast, 16% lung, 13% colon). Results of the study showed that testing with FoundationOne led to recommendation to change treatment in roughly 28% of patients. Collection of progression free survival data is ongoing.
- **Study with Memorial Sloan Kettering demonstrates better detection in lung cancer of actionable mutations vs older technology.** Abstract #8029 described a study of 25 patients which had a strong smoking history yet were negative for genomic alterations with the current gold standard hotspot tests by PCR and FISH. After testing with FoundationOne, 9 of the 25 samples were positive for a genomic alteration associated with a targeted agent in the NCCN guidelines and 8 of the 25 samples were positive for a genomic alteration associated with a targeted agent available through a clinical trial.
- **Lung carcinoma study shows that FMI is better at detecting ALK rearrangements versus the standard FISH test.** In a study of 1,070 lung carcinomas with several collaborating cancer centers, data demonstrated that FoundationOne detected ~50% more ALK rearrangements versus the standard test and the newly discovered ALK positive patients had a 70% response rate to crizotinib.
- **UCSF check is consistent with other recent academic medical center checks. UCSF is strong proponent of tumor profiling and is likely to continue outsourcing to FMI in the medium term.** While UCSF has invested in building more molecular testing capabilities in house there does not appear to be a detailed plan in place and thus the institution appears to be at least a year away from having a comparable test to FoundationOne like. The UCSF cancer genomics core lab has three Illumina HiSeq instruments, which are primarily being used for translational research as opposed to clinical workup. Motivation at UCSF to bring more complicated testing in house is driven partially by the need for better quality and more comprehensive care, money and competition with other academic institutions, however UCSF is not looking to compete nationally. When probed more deeply about the investment in building sequencing-based tumor profiling and bioinformatics, our contacts suggested that some elements including the software and algorithms would need to be achieved through partnering and its more likely they develop a test specific to one cancer like colorectal as opposed to a broad test like FMI's FoundationOne.
- **Maintaining OUTPERFORM. Encouraged by the quantity and quality of ASCO data. Collection and reimbursement fundamentals continue to shape up solidly.** We arrive at our \$50 price target through an EV/sales valuation framework, assuming a ~9x 2016E EV/sales multiple with no net cash and 29 MM shares outstanding, discounted back at 15%. This multiple is justified to us given FMI's hyper growth profile (~83% 3-year CAGR, +60% in 2016), cancer focus and the very early stages of adoption (~10% share in 2016). On a 2015E EV/sales multiple basis, shares of FMI are trading at a premium to the current group median (5x vs 3.7x).

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Investment Thesis

FMI is a lab services company whose test menu is focused on the genetic analysis of rare, recurring and aggressive tumors. FMI's testing platform leverages next-generation sequencing (NGS) to identify clinically actionable genetic mutations within tumor cells. The company's two tests are FoundationOne, a pan-cancer panel for solid tumors, and FoundationOne Heme, a panel for hematological malignancies (i.e., leukemia, lymphoma & myeloma). These tests are targeted for use by academic and community-based oncologists, as well as biopharmaceutical companies for use in cancer therapeutic R&D. We believe FMI's FoundationOne test represents the first mover and highest-quality test commercially available for detailed genomic workup of tumors. We estimate the company's test volumes and sales will grow above an 85% CAGR for the next three years and we believe FMI has many years of significant growth potential ahead as the opportunity in solid tumors, blood-based cancers and future cancer monitoring products is largely untapped. We believe investors are overly concerned about potential competitive threats and potential challenges to reimbursement near term which are overhangs on the shares currently. We believe continued strong execution by the company, lack of viable competition and continued reimbursement progress with large payors will drive solid financials, thus inspiring confidence and meaningful share price appreciation in the near term. We believe the late 2013 addition of high-quality sales reps, improving sales force efficiency and recent menu expansion, combined with growing physician awareness tees up a strong case for test volume outperformance in the near term. Additionally, we believe sentiment on shares is medium-low and based primarily on reimbursement concerns. Based on our checks, new clinical utility data expected in 2Q14 and 3Q14 and better traction with the higher priced FoundationOne heme test, we believe reimbursement is likely to get easier, representing near term validation for our long term thesis.

Figure 1: ASCO Cheatsheet/Clinical Outcomes Data History

Study/Sponsor	Description	Event	Date
Rutgers Study	72 tumors, 1 genomic alteration in 95% of cases and implemented clinical action in ~15% of cases	AACR	4/2/2014
Memorial Sloan-Kettering	Study of lung adenocarcinomas. Identified actionable alterations in 2/3rd of cases where prior molecular testing was negative.	ASCO	5/14/2014
US Oncology	Study of advanced solid tumors. FoundationOne led to an altered therapeutic choice in 28% of patients.	ASCO	5/14/2014
Several collaborating cancer centers	Study of 1,070 lung carcinomas found that FMI detects ~50% more ALK rearrangements than the standard FISH-based test. The FISH negative & FoundationOne positive patients had a 70% response rate to crizotinib.	ASCO	5/14/2014

Source: Company data, Wedbush Securities, Inc.

Figure 2: Potential Catalysts

Catalyst	Timing
Earnings	May-14
ASCO publications	Jun-14
Clinical decisions study with US Oncology	Jun-14
FoundationOne Solid tumor enhancements	2Q14
Additional product launches/enhancements	2014
CMS coverage decision	??

Source: Company data, Wedbush Securities, Inc.

Risks

Risks to attainment of our price target include a fiercely competitive diagnostics and lab service market. Additionally, clinical adoption for new paradigms of testing in diagnostics is difficult to predict and private payor as well as Medicare reimbursement for *FoundationOne* and *FoundationOne Heme* could prove to be more challenging than expected.

FMI is dependent on Illumina (ILMN, NEUTRAL) for equipment and other materials related to next-generation sequencing. If ILMN were to stop supplying the material or were to enter the space as a competitor, it could lead to an interruption in FMI's ability to perform its menu of tests. The near-term risk of this has been mitigated through a five-year supply agreement FMI signed with ILMN in July 2013.

The company operates a CLIA certified lab at their Cambridge, MA headquarters where they conduct *FoundationOne*. Operating as a CLIA lab allows the company to avoid the FDA regulatory 510(k)/PMA pathway for diagnostic devices. The FDA could more tightly regulate CLIA lab-based tests as medical devices, which would likely cause significant disruption to the business.

Figure 3: Income Statement

	2011	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Product Revenue	2,057	10,645	28,990	11,455	13,534	16,099	19,000	60,088	21,772	25,760	29,807	33,692	111,032	178,510
Total Revenues	2,057	10,645	28,990	11,455	13,534	16,099	19,000	60,088	21,772	25,760	29,807	33,692	111,032	178,510
Cost of revenues	258	5,681	11,659	5,291	6,090	7,244	8,550	27,176	8,709	10,304	11,923	13,477	44,413	66,647
COGS as % of sales			36%											
Gross profit	1,799	4,964	17,331	6,164	7,444	8,854	10,450	32,912	13,063	15,456	17,884	20,215	66,619	111,862
Gross Margins	87.5%	46.6%	59.8%	53.8%	55.0%	55.0%	55.0%	54.8%	60.0%	60.0%	60.0%	60.0%	60.0%	62.7%
Selling and Marketing	1,555	3,454	12,508	5,690	7,308	7,244	7,600	27,843	8,491	9,789	9,836	11,455	39,572	55,172
General and administrative	6,992	8,644	21,865	5,700	6,000	6,400	7,500	25,600	7,600	7,700	7,800	7,850	30,950	35,200
Research and development	9,023	14,777	24,901	6,915	7,300	7,600	7,700	29,515	8,300	8,600	8,900	9,200	35,000	36,000
Total operating expenses	17,570	26,875	59,275	18,305	20,608	21,244	22,800	82,958	24,391	26,089	26,536	28,505	105,522	126,372
Operating Income	(15,771)	(21,911)	(41,944)	(12,141)	(13,165)	(12,390)	(12,350)	(50,046)	(11,328)	(10,633)	(8,652)	(8,290)	(38,903)	(14,509)
Interest income	(421)	(421)	(1,452)	(25)	280	257	225	737	183	166	135	108	593	209
Other	(845)	(61)	269	0	0	0	0	0	0	0	0	0	0	0
Income before taxes	(17,037)	(22,393)	(43,127)	(12,166)	(12,885)	(12,133)	(12,125)	(49,308)	(11,144)	(10,467)	(8,517)	(8,182)	(38,310)	(14,300)
Provision for income taxes	0	0	-	0	0	0	0	0	0	0	0	0	0	10
Tax Rate														(0)
Net income	(17,037)	(22,393)	(43,129)	(12,166)	(12,885)	(12,133)	(12,125)	(49,308)	(11,144)	(10,467)	(8,517)	(8,182)	(38,310)	(14,310)
Accretion of convertible preferred stock	(296)	(286)	(139)	0	0	0	0	0	0	0	0	0	0	0
Net Income	(17,333)	(22,679)	(43,268)	(12,166)	(12,885)	(12,133)	(12,125)	(49,308)	(11,144)	(10,467)	(8,517)	(8,182)	(38,310)	(14,310)
GAAP EPS - Basic	(\$3.52)	(\$0.41)	(\$2.09)	(\$0.44)	(\$0.46)	(\$0.44)	(\$0.44)	(\$1.77)	(\$0.40)	(\$0.37)	(\$0.30)	(\$0.29)	(\$1.37)	(\$0.51)
GAAP EPS -Diluted	(\$3.52)	(\$0.41)	(\$2.08)	(\$0.44)	(\$0.46)	(\$0.44)	(\$0.44)	(\$1.77)	(\$0.40)	(\$0.37)	(\$0.30)	(\$0.29)	(\$1.37)	(\$0.51)
Non-GAAP EPS -Diluted	(\$3.52)	(\$0.41)	(\$2.08)	(\$0.44)	(\$0.46)	(\$0.44)	(\$0.44)	(\$1.77)	(\$0.40)	(\$0.37)	(\$0.30)	(\$0.29)	(\$1.37)	(\$0.51)
Weighted average shares - basic	4,930	55,642	21,577	27,734	27,775	27,817	27,859	27,796	27,914	27,956	27,998	28,040	28,040	28,223
Weighted average shares - diluted	4,930	55,642	21,778	27,734	27,775	27,817	27,859	27,796	27,914	27,956	27,998	28,040	28,040	28,223
		proforma												
Cash and Equivalents	10,852	54,838	124,293	112,000	102,983	89,905	73,348	73,348	66,378	54,005	43,318	28,159	28,159	2,204
Net Cash	10,852	54,838	124,293	112,000	102,983	89,905	73,348	73,348	66,378	54,005	43,318	28,159	28,159	2,204
Net Cash/share			5	4	4	3	3	3	2.38	1.93	1.55	1.00	1	0
NOLs			(52,991)	(65,157)	(78,042)	(90,174)	(102,299)	(102,299)	(113,444)	(123,911)	(132,428)	(140,609)	(140,609)	(154,920)
% of Sales	2011	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Gross Margins	87%	47%	60%	54%	55%	55%	55%	55%	60%	60%	60%	60%	60%	63%
Sales and Marketing	76%	32%	43%	50%	54%	45%	40%	46%	39%	38%	33%	34%	36%	31%
General and administrative	340%	81%	75%	50%	44%	40%	39%	43%	35%	30%	26%	23%	28%	20%
Research and development	439%	139%	86%	60%	54%	47%	41%	49%	38%	33%	30%	27%	32%	20%
Total operating expenses	854%	252%	204%	160%	152%	132%	120%	138%	112%	101%	89%	85%	95%	71%
EBIT	-767%	-206%	-145%	-106%	-97%	-77%	-65%	-83%	-52%	-41%	-29%	-25%	-35%	-8%
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net income	-843%	-213%	-149%	-106%	-95%	-75%	-64%	-82%	-51%	-41%	-29%	-24%	-35%	-8%
Free Cash Flow	-1015%	-199%	-132%	-59%	-86%	-70%	-77%	-74%	-22%	-39%	-27%	-37%	-32%	-7%
y/y Δ	2011	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Total Revenues	NA	418%	172%	120%	129%	96%	97%	107%	90%	90%	85%	77%	85%	61%
Cost of revenues	NA	2102%	105%	122%	174%	153%	103%	133%	65%	69%	65%	58%	63%	50%
Gross Margins	NA	-47%	28%	-1%	-12%	-16%	-3%	-8%	12%	9%	9%	9%	10%	4%
Sales and Marketing	NA	122%	262%	214%	139%	138%	65%	123%	49%	34%	36%	51%	42%	39%
General and administrative	NA	24%	153%	81%	26%	-1%	0%	17%	33%	28%	22%	5%	21%	14%
Research and development	NA	64%	69%	39%	20%	9%	13%	19%	20%	18%	17%	19%	19%	3%
Total operating expenses	NA	53%	121%	84%	48%	29%	20%	40%	33%	27%	25%	25%	27%	20%
EBIT	NA	39%	91%	70%	29%	11%	-8%	19%	-7%	-19%	-30%	-33%	-22%	-63%
Tax rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net income	NA	31%	91%	68%	24%	-3%	-7%	14%	-8%	-19%	-30%	-33%	-22%	-63%

Source: Company data, Wedbush Securities, Inc.

Figure 4: Balance Sheet
Current assets:

Total Cash and Cash Equivalents
Accounts Receivable
Inventory
Prepaid expenses and other Current Assets

Total current assets

Property, Plant and Equipment
Accumulated Depreciation
Restricted cash and other non-current assets

Total assets
LIABILITIES AND STOCKHOLDERS' EQUITY
Current liabilities:

Accounts Payable and accrued expenses
Deferred revenue and Other Current Liabilities

Total current liabilities
Long-term liabilities:

Long Term Debt
Other long term liabilities

Total liabilities
Stockholders' equity:

Preferred Stock
Common Stock, APIC, RE

Total liabilities and stockholders' equity

	2011	2012	2013E	2014E	2015E	2016E
Total Cash and Cash Equivalents	10852	54,838	124,293	73,348	28,159	2,204
Accounts Receivable	278	2,195	6,262	9,500	16,846	26,412
Inventory	318	803	1,763	1,583	2,808	4,402
Prepaid expenses and other Current Assets	313	550	992	992	992	992
Total current assets	11,761	58,386	133,310	85,423	48,805	34,010
Property, Plant and Equipment	7,902	12,154	22,104	25,108	30,660	39,586
Accumulated Depreciation	(1,796)	(4,689)		(4,615)	(10,003)	(16,731)
Restricted cash and other non-current assets	198	188	1,854	1,854	1,854	1,854
Total assets	18,065	66,039	157,268	107,771	71,316	58,719
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts Payable and accrued expenses	2,408	5,072	7,007	6,818	8,673	10,387
Deferred revenue and Other Current Liabilities	1,832	3,458	8,752	8,752	8,752	8,752
Total current liabilities	4,240	8,530	15,759	15,570	17,425	19,139
Long-term liabilities:						
Long Term Debt	3,041	1,441	0	0	0	0
Other long term liabilities	632	807	9,798	9,798	9,798	9,798
Total liabilities	7,913	10,778	25,557	25,368	27,223	28,937
Stockholders' equity:						
Preferred Stock	32,455	98,658	0	0	0	0
Common Stock, APIC, RE	(22,303)	(43,397)	131,711	82,403	44,093	29,782
Total liabilities and stockholders' equity	18,065	66,039	157,268	107,771	71,316	58,719

Source: Company data, Wedbush Securities, Inc.

Figure 5: Cash Flow Statement

	2011	2012	2013	2014E	2015E	2016E
Cash Flows from Operating Activities:						
Net (loss) income	(17,037)	(22,393)	(42,944)	(49,308)	(38,310)	(14,310)
Depreciation	1,520	2,894	5,006	4,615	5,388	6,728
change in FV of investor rights obligation	1,067	0	0	0	0	0
change in FV of warrant liability	34	131	1,380	0	0	0
Stock-based compensation expense	73	1,535	7,316	0	0	0
common stock issued for services	0	0	4	0	0	0
non-cash interest expense/impairment	111	104	497	0	0	0
Change in working capital	99	480	(2,025)	(3,247)	(6,716)	(9,447)
Net cash provided by operating activities	(14,133)	(17,249)	(30,766)	(47,941)	(39,637)	(17,030)
Cash Flows from Investing Activities:						
Purchase of property and equipment	(5,410)	(3,183)	(6,930)	(3,004)	(5,552)	(8,925)
increase in restricted cash	0		(1,564)	0	0	0
Net cash used in investing activities	(5,410)	(3,183)	(8,494)	(3,004)	(5,552)	(8,925)
Cash Flows from Financing Activities:						
Proceeds from Issuance of Restricted Stock	114	70	49	0	0	0
proceeds from issuance of preferred stock	26,338	65,917	(10)	0	0	0
proceeds from issuance of common stock	0	0	110,381	0	0	0
change in notes payable	2,534	(1,569)	(1,705)	0	0	0
Net cash provided by financing activities	28,986	64,418	108,715	0	0	0
Net increase (decrease) in cash and cash equivalents	9,443	43,986	69,455	(50,945)	(45,189)	(25,955)
Cash and cash equivalents, beginning of period		10,852	54,838	124,293	73,348	28,159
Cash and cash equivalents, end of period	10,852	54,838	124,293	73,348	28,159	2,204

Source: Company data, Wedbush Securities, Inc.

Company	Ticker	Rating	Price Target	Current Price
Illumina	ILMN	NEUTRAL	\$140	\$152

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Company	Disclosure
Foundation Medicine	1

Research Disclosure Legend

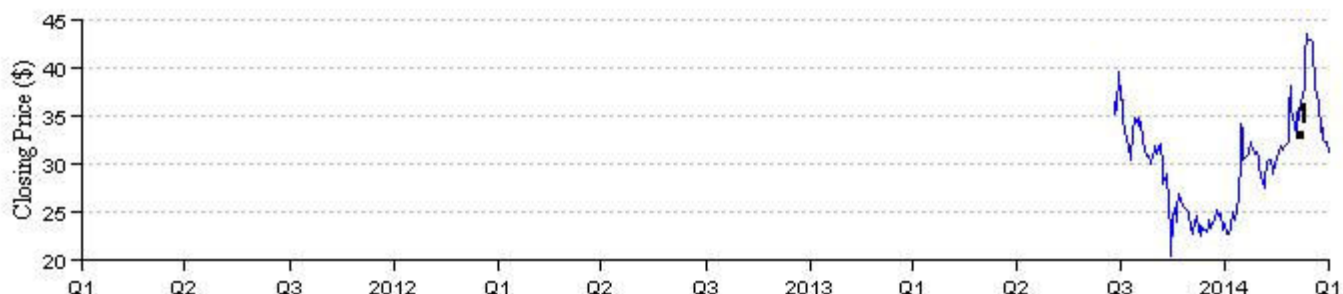
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FMI

1) 03/04/14
OUTPERFORM \$50



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Internet: Media and Gaming

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Internet: Social Media, Advertising & Technology

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LIFE SCIENCES AND HEALTH CARE

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