

Foundation Medicine (FMI)

Updated: Opportunity Slightly Murkier Post Doc Calls - Reimbursement & Competition Dynamics Fine - Lowering Estimates & PT to \$44 from \$48

- Recent community-based oncology checks have yielded wide-ranging data, making it difficult to fully understand the opportunity. FMI is roughly two years into its launch within the community-based oncology setting and adoption remains in the early innings. Checks with several oncologists in the last few weeks show that FoundationOne awareness is high, but product utilization trends vary widely.
- Oncologist feedback suggests significant long-term belief in deep tumor profiling. Almost every community-based oncologist we have spoken with believes tumor sequencing is "the future" of oncology. Many oncologists believe that in 3-5 years, the vast majority of solid tumors and blood-based cancers will be sequenced in some way.
- FoundationOne use frequency seems more muted than we had expected. Based on recent checks with community-based oncologists, FoundationOne ordering frequency ranged from 0-4 per month. Extrapolating these data, it's conceivable that the current effective addressable annual solid tumor market is closer to 400k (>\$800 MM) vs. our prior estimate of 800k (>\$1.2 B).
- Reimbursement trends continue to be solid and competition appears nonexistent, in our view. Based on our recent conversations, community-based oncologists ordering the test are not hearing of significant pushback from private payors (consistent with the positive 2Q14 reimbursement trend). Additionally, there appears to be minimal competition from commercial players and virtually no community outreach from academic medical centers.
- Lowering PT to \$44 from \$48 to reflect lower 2016 estimates. We arrive at our new \$44 price target through an EV/sales valuation framework, assuming a ~9x (unchanged) 2016E EV/sales multiple of our new \$158 MM sales estimate (vs \$174 previously) with no cash and 29 MM shares outstanding, discounted back at 15%. This multiple is still justified to us given FMI's hyper growth profile (~76% 3-year CAGR, ~36% in 2016), cancer focus and the very early stages of adoption (~8% share in 2016). On a 2015E EV/sales multiple basis, shares of FMI are trading at a premium to the group median (5x vs 3.3x).

September 24, 2014

Price
\$20.10

Rating
OUTPERFORM

12-Month Price Target
\$44 (from \$48)

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Company Information

Shares Outst (M)	28
Market Cap (M)	\$568
52-Wk Range	\$19.51 - \$45
Cash/sh	3
Enterprise Value	469
LT Debt/Cap	0
2015 EV/Sales	5 x
Book Value/sh	3.8

Company Description

Foundation Medicine is the leading provider of test services to oncologists for the deep analysis of genetic alterations in cancer. These test results provide clinically actionable information for rare, recurring & stubborn solid tumors and hematologic cancers.

FYE Dec	2013A	2014E			2015E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	\$5.2A	\$11.5A		\$11.5A	\$21.2E		\$22.4E
Q2 Jun	\$5.9A	\$14.5A		\$14.5A	\$24.2E		\$24.2E
Q3 Sep	\$8.2A	\$15.7E		\$15.7E	\$27.8E		\$27.5E
Q4 Dec	\$9.7A	\$18.5E		\$17.6E	\$31.2E		\$30.4E
Year*	\$29.0A	\$60.2E		\$58.8E	\$104.4E		\$109.8E
Change	172%	108%			74%		
	2013A	2014E			2015E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	(\$0.64)A	(\$0.44)A		(\$0.44)A	(\$0.40)E		(\$0.42)E
Q2 Jun	(\$0.52)A	(\$0.49)A		(\$0.49)A	(\$0.39)E		(\$0.44)E
Q3 Sep	(\$0.44)A	(\$0.44)E		(\$0.48)E	(\$0.32)E		(\$0.32)E
Q4 Dec	(\$0.48)A	(\$0.44)E		(\$0.47)E	(\$0.31)E		(\$0.43)E
Year*	(\$2.08)A	(\$1.81)E		(\$1.88)E	(\$1.42)E		(\$1.50)E
P/E	NM	NM			NM		
Change	410%	-13%			-21%		

Consensus estimates are from Thomson First Call.

* Numbers may not add up due to rounding.



Source: Thomson Reuters

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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 75% 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. That said, we believe sentiment on shares is medium-low with reimbursement pessimism and fears around meaningful competition from ILMN and the company's FDA approved oncopanel strategy represent meaningful overhangs on shares that may be difficult to overcome near term. Based on the clinical outcomes data from US oncology, early traction with the higher priced FoundationOne heme test and recent physician checks, we believe average reimbursement is likely to become easier and may manifest in an in-network contract in the next few quarters prior to clarity from Medicare.

Figure 1: Potential Catalysts

Catalyst	Timing
Earnings	Nov-14
Additional publications (ASH meeting)	2H14/2015
Additional FoundationOne Solid enhancements	2015
Additional new product milestones	2015
In-Network Contracts with Large Payors	??
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, OUTPERFORM) 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 2: Income Statement

	2011	2012	2013	1Q14	2Q14	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Product Revenue	2,057	10,645	28,990	11,455	14,496	15,676	18,543	60,170	21,225	24,179	27,799	31,246	104,449	158,083
Total Revenues	2,057	10,645	28,990	11,455	14,496	15,676	18,543	60,170	21,225	24,179	27,799	31,246	104,449	158,083
Cost of revenues	258	5,681	11,659	5,291	6,619	7,054	8,344	27,309	8,490	9,672	11,120	12,498	41,780	59,040
COGS as % of sales			36%											
Gross profit	1,799	4,964	17,331	6,164	7,877	8,622	10,198	32,861	12,735	14,508	16,679	18,748	62,669	99,043
Gross Margins	87.5%	46.6%	59.8%	53.8%	54.3%	55.0%	55.0%	54.6%	60.0%	60.0%	60.0%	60.0%	60.0%	62.7%
Selling and Marketing	1,555	3,454	12,508	5,690	7,170	7,054	7,417	27,331	8,278	9,188	9,174	10,624	37,263	48,872
General and administrative	6,992	8,644	21,865	5,700	5,825	6,400	7,500	25,425	7,600	7,700	7,800	7,850	30,950	35,200
Research and development	9,023	14,777	24,901	6,915	8,645	7,600	7,700	30,860	8,300	8,600	8,900	9,200	35,000	36,000
Total operating expenses	17,570	26,875	59,275	18,305	21,640	21,054	22,617	83,616	24,178	25,488	25,874	27,674	103,213	120,072
Operating Income	(15,771)	(21,911)	(41,944)	(12,141)	(13,763)	(12,432)	(12,419)	(50,755)	(11,443)	(10,981)	(9,194)	(8,926)	(40,544)	(21,029)
Interest income	(421)	(421)	(1,452)	(25)	(16)	247	212	418	170	153	122	95	541	143
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)	(13,779)	(12,185)	(12,207)	(50,337)	(11,272)	(10,828)	(9,072)	(8,831)	(40,003)	(20,886)
Provision for income taxes	0	0	-	0	0	0	0	0	0	0	0	0	0	0
Tax Rate														
Net income	(17,037)	(22,393)	(43,129)	(12,166)	(13,779)	(12,185)	(12,207)	(50,337)	(11,272)	(10,828)	(9,072)	(8,831)	(40,003)	(20,886)
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)	(13,779)	(12,185)	(12,207)	(50,337)	(11,272)	(10,828)	(9,072)	(8,831)	(40,003)	(20,886)
GAAP EPS -Basic	(\$3.52)	(\$0.41)	(\$2.09)	(\$0.44)	(\$0.49)	(\$0.44)	(\$0.44)	(\$1.81)	(\$0.40)	(\$0.39)	(\$0.32)	(\$0.31)	(\$1.42)	(\$0.74)
GAAP EPS -Diluted	(\$3.52)	(\$0.41)	(\$2.08)	(\$0.44)	(\$0.49)	(\$0.44)	(\$0.44)	(\$1.81)	(\$0.40)	(\$0.39)	(\$0.32)	(\$0.31)	(\$1.42)	(\$0.74)
Non-GAAP EPS -Diluted	(\$3.52)	(\$0.41)	(\$2.08)	(\$0.44)	(\$0.49)	(\$0.44)	(\$0.44)	(\$1.81)	(\$0.40)	(\$0.39)	(\$0.32)	(\$0.31)	(\$1.42)	(\$0.74)
Weighted average shares - basic	4,930	55,642	21,577	27,734	27,877	27,919	27,961	27,872	28,017	28,059	28,101	28,143	28,143	28,326
Weighted average shares - diluted	4,930	55,642	21,778	27,734	27,877	27,919	27,961	27,873	28,017	28,059	28,101	28,143	28,143	28,326
Cash and Equivalents	10,852	54,838	124,293	112,000	98,779	84,739	68,130	68,130	61,064	48,977	38,040	22,477	22,477	(7,081)
Net Cash	10,852	54,838	124,293	112,000	98,779	84,739	68,130	68,130	61,064	48,977	38,040	22,477	22,477	(7,081)
Net Cash/share			5	4	4	3	2	2.4	2.18	1.75	1.35	0.80	1	(0)
NOLs			(52,991)	(65,157)	(78,936)	(91,121)	(103,328)	(103,328)	(114,601)	(125,429)	(134,500)	(143,331)	(143,331)	(164,218)
% of Sales	2011	2012	2013	1Q14	2Q14	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Gross Margins	87%	47%	60%	54%	54%	55%	55%	55%	60%	60%	60%	60%	60%	63%
Sales and Marketing	76%	32%	43%	50%	49%	45%	40%	45%	39%	38%	33%	34%	36%	31%
General and administrative	340%	81%	75%	50%	40%	41%	40%	42%	36%	32%	28%	25%	30%	22%
Research and development	439%	139%	86%	60%	60%	48%	42%	51%	39%	36%	32%	29%	34%	23%
Total operating expenses	854%	252%	204%	160%	149%	134%	122%	139%	114%	105%	93%	89%	99%	76%
EBIT	-767%	-206%	-145%	-106%	-95%	-79%	-67%	-84%	-54%	-45%	-33%	-29%	-39%	-13%
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net income	-843%	-213%	-149%	-106%	-95%	-78%	-66%	-84%	-53%	-45%	-33%	-28%	-38%	-13%
Free Cash Flow	-1015%	-199%	-132%	-59%	-94%	-70%	-81%	-77%	-24%	-43%	-32%	-42%	-36%	-11%
y/y Δ	2011	2012	2013	1Q14	2Q14	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Total Revenues	NA	418%	172%	120%	145%	91%	92%	108%	85%	67%	77%	69%	74%	51%
Cost of revenues	NA	2102%	105%	122%	198%	147%	98%	134%	60%	46%	58%	50%	53%	41%
Gross Margins	NA	-47%	28%	-1%	-13%	-16%	-3%	-9%	12%	10%	9%	9%	10%	4%
Sales and Marketing	NA	122%	262%	214%	135%	132%	61%	119%	45%	28%	30%	43%	36%	31%
General and administrative	NA	24%	153%	81%	23%	-1%	0%	16%	33%	32%	22%	5%	22%	14%
Research and development	NA	64%	69%	39%	42%	9%	13%	24%	20%	-1%	17%	19%	13%	3%
Total operating expenses	NA	53%	121%	84%	56%	28%	19%	41%	32%	18%	23%	22%	23%	16%
EBIT	NA	39%	91%	70%	35%	12%	-8%	21%	-6%	-20%	-26%	-28%	-20%	-48%
Tax rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net income	NA	31%	91%	68%	32%	-3%	-7%	16%	-7%	-21%	-26%	-28%	-21%	-48%

Source: Company data, Wedbush Securities, Inc.

Figure 3: Balance Sheet

	2011	2012	2013E	2014E	2015E	2016E
Current assets:						
Total Cash and Cash Equivalents	10852	54,838	124,293	68,130	22,477	(7,081)
Accounts Receivable	278	2,195	6,262	9,271	15,623	23,125
Inventory	318	803	1,763	1,545	2,604	3,854
Prepaid expenses and other Current Assets	313	550	992	992	992	992
Total current assets	11,761	58,386	133,310	79,938	41,695	20,890
Property, Plant and Equipment	7,902	12,154	22,104	25,113	30,335	38,239
Accumulated Depreciation	(1,796)	(4,689)		(4,618)	(9,990)	(16,590)
Restricted cash and other non-current assets	198	188	1,854	2,983	2,983	2,983
Total assets	18,065	66,039	157,268	103,415	65,023	45,522
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts Payable and accrued expenses	2,408	5,072	7,007	6,873	8,483	9,869
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	15,625	17,235	18,621
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	25,423	27,033	28,419
Stockholders' equity:						
Preferred Stock	32,455	98,658	0	0	0	0
Common Stock, APIC, RE	(22,303)	(43,397)	131,711	77,993	37,990	17,103
Total liabilities and stockholders' equity	18,065	66,039	157,268	103,415	65,023	45,522

Source: Company data, Wedbush Securities, Inc.

Figure 4: Cash Flow Statement

	2011	2012	2013	2014E	2015E	2016E
Cash Flows from Operating Activities:						
Net (loss) income	(17,037)	(22,393)	(42,944)	(50,337)	(40,003)	(20,886)
Depreciation	1,520	2,894	5,006	4,618	5,372	6,600
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)	(2,926)	(5,800)	(7,366)
Net cash provided by operating activities	(14,133)	(17,249)	(30,766)	(48,645)	(40,431)	(21,653)
Cash Flows from Investing Activities:						
Purchase of property and equipment	(5,410)	(3,183)	(6,930)	(3,009)	(5,222)	(7,904)
increase in restricted cash	0		(1,564)	(4,510)	0	0
Net cash used in investing activities	(5,410)	(3,183)	(8,494)	(7,519)	(5,222)	(7,904)
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	(56,163)	(45,653)	(29,557)
Cash and cash equivalents, beginning of period		10,852	54,838	124,293	68,130	22,477
Cash and cash equivalents, end of period	10,852	54,838	124,293	68,130	22,477	(7,081)

Source: Company data, Wedbush Securities, Inc.

Company	Ticker	Rating	Price Target	Current Price
Illumina	ILMN	NEUTRAL	\$200	\$169

Analyst Biography

Zarak Khurshid is a senior equity research analyst covering the Medical Diagnostics and Life Science Tools sectors. Prior to joining Wedbush in January 2010, Mr. Khurshid was Vice President and senior equity research analyst with Caris & Company where he covered the Medical diagnostics and Life Sciences Tools sectors from 2006 to 2010. Mr. Khurshid's aggressive risk/reward focused investment style is supported by data points from a diverse network of contacts from industry, hospitals, clinical labs, and academia. Mr. Khurshid was ranked #1 in the Life Science Tools and Services sectors and #4 on Wall Street for earnings accuracy in 2012 by *Starmine*. Prior to his start on Wall Street with Pacific Growth Equities in 2004, Mr. Khurshid was a Research Associate with Cytokinetics and an Associate Bioengineer with Aurora Biosciences. Mr. Khurshid received a BS in Bioengineering and a BA in Economics from the University of California, San Diego.

Analyst Certification

I, Zarak Khurshid, certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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Rating Distribution (as of June 30, 2014)	Investment Banking Relationships (as of June 30, 2014)
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Neutral: 42%	Neutral: 1%
Underperform: 4%	Underperform: 0%

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Company	Disclosure
Foundation Medicine	1
Illumina	1

Research Disclosure Legend

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3. WS co-managed a public offering of securities within the last 12 months.
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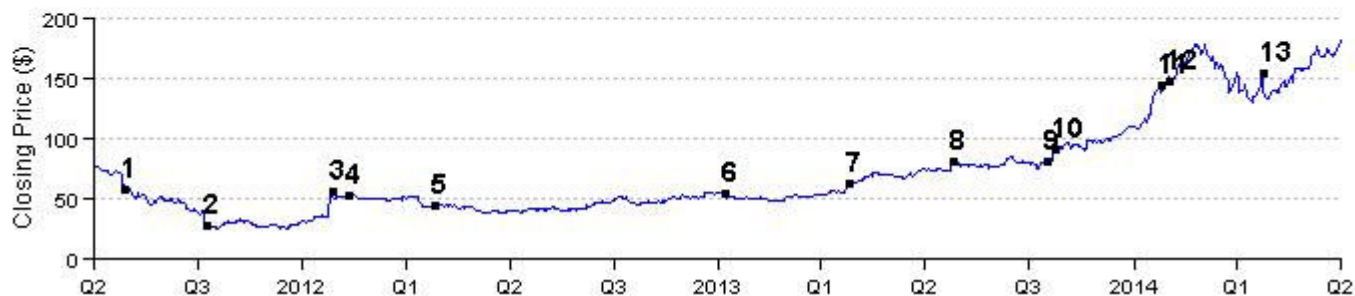
FMI

1) 03/04/14
OUTPERFORM \$50



ILMN

1) 07/27/11 OUTPERFORM \$78	2) 10/07/11 OUTPERFORM \$35	3) 01/25/12 OUTPERFORM \$50	4) 02/08/12 OUTPERFORM \$65	5) 04/24/12 OUTPERFORM \$52	6) 01/04/13 NEUTRAL \$52	7) 04/23/13 NEUTRAL \$55
8) 07/24/13 NEUTRAL \$60	9) 10/15/13 NEUTRAL \$65	10) 10/22/13 NEUTRAL \$72	11) 01/23/14 NEUTRAL \$130	12) 01/29/14 NEUTRAL \$140	13) 04/23/14 NEUTRAL \$155	



* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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