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Foundation Medicine (FMI - OUTPERFORM): New Clinical Decision Data at AACR, Newly Uncovered Payor Comments and BRCA Pricing News Encouraging for the LT Reimbursement Story - Reaffirm OP

Price: $30.14 **12-Month Price Target: $50**

- **New data on clinical actionability in the latest AACR abstracts is encouraging.** FMI announced that five abstracts, including new data from three, will be presented at the annual meeting of the American Association of Cancer Research (AACR) meeting next week (4/5-4/9) in San Diego. In addition to new data demonstrating strong performance for gene fusion detection and the importance of gene fusion detection, interesting new clinical action data was released on 4/2/14 in abstract #4261. The abstract outlines a study with Rutgers demonstrating that at least one genomic alteration was detected in 95% of 72 solid tumors analyzed and led to implemented clinical action in ~15% of cases. We believe this15% level is well north of what is necessary for the large payors to recognize the clinical necessity of deep tumor profiling in rare and recurrent tumors.

- **Recently uncovered comments from UnitedHealth's Lee Newcomer shed light on how large payors may be thinking about new cancer diagnostics and willingness to pay. Hurdle seems achievable for FMI**. Summary of a workshop titled "Genome-Based Diagnostics: Demonstrating Clinical Utility in Oncology" (**http://www.nap.edu/catalog.php?record_id=18275**) was quietly published at the end of 2013. In the document, Lee Newcomer, M.D., Senior VP at UnitedHealth Group for Oncology, Genetics and Women's Health discussed views on new diagnostic tests saying that a new diagnostic would need to lower the cost of care or improve outcome by 10%. In order to help facilitate progress toward meeting this goal, Dr. Newcomer proposed that a clinically validated test could be covered by all payors for a 3-year period at a price covering some of the costs of using and continued development of the test. If the test achieved the 10% hurdle at the end of the three-year period, then it would be accepted (see detailed excerpt in Figure 1.) We believe Dr. Newcomer's comments demonstrate an open mind towards early adoption and payment for emerging new advanced diagnostics technologies.

- **Expecting additional studies by FMI, partners and third parties this year demonstrating clinical utility, which may help with coverage policies.** As a reminder, in May 2013 US Oncology Network, which encompasses more than 1,000 physicians and 350 sites of care servicing roughly 30% of US cancer cases, announced FMI as one of its preferred molecular diagnostics labs. FMI management remains optimistic about a potential publication on clinical actions within US Oncology using FoundationOne potentially this summer. Additionally, we would anticipate more clinically relevant data to be presented by the company and partners at the American Society of Clinical Oncology (ASCO) meeting (5/30/14-6/3/14).

- **CMS' recent positive revision to BRCA pricing is a positive for long-term FoundationOne reimbursement, in our view.** On 4/1/14, the Center for Medicare and Medicaid Services (CMS) surprisingly revised pricing for the Myriad BRCA 1/2 genes breast cancer test from $1,438 to $2,184, representing a ~52% increase. This improvement was surprising considering that CMS had cut pricing by 49% ($2,795 to $1,438) in December 2013 and the competition for BRCA testing has been increasing. Of note, the District Court of Utah denied Myriad's motion for preliminary injunction on March 10, 2014 leaving Ambry Genetics and other competitors with freedom to operate in the near term, yet CMS still chose to increase pricing. BRCA 1/2 is a very high-profile cancer test that represents a reasonable comparable for FoundationOne, in our view. CMS' flexibility on BRCA pricing and openness to industry feedback gives us optimism in front of a potential CMS coverage decision for FoundationOne in the next few years. As a reminder, FMI began submitting claims to Medicare (~22% of volume), but the current status or length of the total review period is unknown at this time.

- **Reaffirming OUTPERFORM.** We believe the IPO lockup on 3/24, potential financing ($150 MM S-1 filed on 3/20, mix of primary vs secondary unknown) & Aetna policy bulletin have combined to drive the 26% sell-off in FMI shares over the last three weeks (versus a 3% decline in the BTK index and 2.5% gain in the S&P 500). We arrive at our $50 price target through an EV/sales valuation framework, assuming a ~9x 2016E EV/sales multiple with $31 MM in net cash and 29 MM shares outstanding, discounted back at 15%. This multiple is justified to us given our view of FMI's growth profile (~89% 3-year CAGR, +70% in 2016), cancer focus and very early penetration story (~10% share in 2016). On a 2015E EV/sales multiple basis, shares of FMI are trading a premium to the current group median (7.1x vs 4.0x).

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 its Cambridge, MA headquarters where it conducts *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 1: Genome-Based Diagnostics Workshop Summary Excerpt

Asked if standardization might limit the potential benefits of personalized care, Dr. Newcomer responded that the two approaches to treatment are not at odds with each other. "I'd argue that standardization is highly tailored care: You are finding the best therapy for that particular patient's set of circumstances." In response to a question about the impact of the Patient Protection and Affordable Care Act (PPACA) on the rollout of new payment models, Dr. Newcomer said that new initiatives will continue to evolve with the changing landscape, with some surviving and others not. "We are looking at a period of great experimentation with innovation."

Newcomer made what he called a "blue sky" proposal at the workshop wherein a new diagnostic or drug would need to lower the cost of care by 10 percent or improve an outcome by 10 percent to demonstrate its value. That bar is high, Newcomer noted, because most advances produce an improvement on the order of only 1 percent or so.

To help facilitate the development of evidence to meet this goal, he proposed that a laboratory that has developed an analytically and clinically valid test could have the test covered by all payers for a 3-year period at a price that would cover some of the costs of using and continuing to develop the test. If the test achieves the 10 percent hurdle by the end of that 3-year period, it will be accepted. If it does not, it will not be accepted. Newcomer also emphasized that the manufacturer would still need to provide and analyze the necessary data. The payers should not be trying to determine whether a test is useful. Payers could work with physicians, for example, to identify patients who have had particular responses, and the analysis could be conducted by a neutral third party, with protections for privacy. The manufacturer would work with that group to direct the study and bring out an unidentified or de-identified result. This type of system would represent a major departure from current procedures. It would require that payers collaborate to offer provisional coverage, which would probably require an antitrust exemption. In the past, such collaboration has not been allowed, "but this may be a new world," said Newcomer. Also, the customers of the payers, most of which are self-funded businesses, would need to agree to such a system, because they would be the ultimate funders of such an approach. Finally, current health care legislation limits payers to using 15 percent of premium revenues for administrative costs, 2 and if the provisional fundi ng were considered an administrative cost rather than a medical cost, it probably would not be a viable option. These obstacles are substantial, said Newcomer, but they are all surmountable. And such a program would manage budgetary constraints while allowing biomedical advances to proceed. "We need to collaborate. We need to think about new models. I also think it is entirely possible," he said. One of the reasons Newcomer made his proposal, he noted, is that "it's going to happen no matter what." Payers, providers, and patients are going to have to find the advances of highest value if health care is to continue to progress. "The more we can begin to find those things of highest value," he said, "the better off we will all be." Newcomer concluded by stating that he is trying to bend the cost curve. "There are an awful lot of coded technologies whose value whose value is quite uncertain, yet we pay for them," he said.

Source: Company data, Wedbush Securities, Inc.

Figure 2: Potential Catalysts

Catalyst	Timing
Earnings	May-14
AACR	Apr-14
ASCO publications	Jun-14
Clinical decisions studies	3Q14
Additional product launches/enhancements	2014
CMS coverage decision	??

Source: Company data, Wedbush Securities, Inc.

Figure 3: Income Statement

	2011	2012	1Q13	2Q13	3Q13	4Q13	2013	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E
Product Revenue	2,057	10,645	5,200	5,920	8,208	9,662	28,990	11,021	13,599	16,421	19,547	60,589	115,838	197,057
Total Revenues	2,057	10,645	5,200	5,920	8,208	9,662	28,990	11,021	13,599	16,421	19,547	60,589	115,838	197,057
Cost of revenues	258	5,681	2,378	2,219	2,858	4,204	11,659	4,298	5,032	5,747	5,864	20,942	34,284	56,478
COGS as % of sales			46%	37%	35%	44%	36%							
Gross profit	1,799	4,964	2,822	3,701	5,350	5,458	17,331	6,723	8,568	10,673	13,683	39,647	81,554	140,580
Gross Margins	87.5%	46.6%	54.3%	62.5%	65.2%	56.5%	59.8%	61.0%	63.0%	65.0%	70.0%	65.4%	70.4%	71.3%
Selling and Marketing	1,555	3,454	1,811	3,057	3,038	4,602	12,508	5,511	6,120	6,897	7,819	26,346	41,254	60,887
General and administrative	6,992	8,644	3,150	4,755	6,448	7,512	21,865	7,700	7,900	8,200	8,500	32,300	34,950	35,200
Research and development	9,023	14,777	4,982	6,097	6,988	6,834	24,901	7,100	7,300	7,600	8,000	30,000	35,000	35,900
Total operating expenses	17,570	26,875	9,944	13,910	16,475	18,948	59,275	20,311	21,320	22,697	24,319	88,646	111,204	131,987
Operating Income	(15,771)	(21,911)	(7,122)	(10,209)	(11,125)	(13,490)	(41,944)	(13,588)	(12,752)	(12,023)	(10,636)	(48,999)	(29,650)	8,593
Interest income	(421)	(421)	(76)	(65)	(1,278)	(33)	(1,452)	311	286	251	216	1,064	570	272
Other	(845)	(61)	(6)	(96)	(61)	432	269	0	0	0	0	0	0	0
Income before taxes	(17,037)	(22,393)	(7,204)	(10,370)	(12,464)	(13,091)	(43,127)	(13,277)	(12,466)	(11,773)	(10,420)	(47,935)	(29,080)	8,865
Provision for income taxes	0	0	0	0	0	0	-	0	0	0	0	0	0	576
Tax Rate														0
Net income	(17,037)	(22,393)	(7,204)	(10,370)	(12,464)	(13,091)	(43,129)	(13,277)	(12,466)	(11,773)	(10,420)	(47,935)	(29,080)	8,288
Accretion of convertible preferred stock	(296)	(286)	(50)	(42)	(47)	0	(139)	0	0	0	0	0	0	0
Net Income	(17,333)	(22,679)	(7,254)	(10,412)	(12,511)	(13,091)	(43,268)	(13,277)	(12,466)	(11,773)	(10,420)	(47,935)	(29,080)	8,288
GAAP EPS -Basic	($3.52)	($0.41)	($0.64)	($0.52)	($0.46)	($0.48)	($2.09)	($0.48)	($0.45)	($0.43)	($0.38)	($1.74)	($1.05)	$0.30
GAAP EPS -Diluted	($3.52)	($0.41)	($0.64)	($0.52)	($0.44)	($0.48)	($2.08)	($0.48)	($0.45)	($0.43)	($0.38)	($1.74)	($1.05)	$0.30
Non-GAAP EPS -Diluted	**($3.52)**	**($0.41)**	**($0.64)**	**($0.52)**	**($0.44)**	**($0.48)**	**($2.08)**	**($0.48)**	**($0.45)**	**($0.43)**	**($0.38)**	**($1.74)**	**($1.05)**	**$0.30**
Weighted average shares - basic	4,930	55,642	11,339	20,129	27,336	27,505	21,577	27,560	27,601	27,643	27,684	27,622	27,864	28,046
Weighted average shares - diluted	4,930	55,642	11,339	20,129	28,138	27,505	21,778	27,560	27,601	27,643	27,684	27,622	27,864	28,046
		proforma												
Cash and Equivalents	10,852	54,838	45,832	35,965	138,088	124,293	124,293	114,507	100,283	86,413	70,422	70,422	28,964	17,789
Net Cash	10,852	54,838	45,832	35,965	138,088	124,293	124,293	114,507	100,283	86,413	70,422	70,422	28,964	17,789
Net Cash/share			4	2	5	5	5	4	4	3	3	3	1	1
NOLs					(39,900)	(52,991)	(52,991)	(66,268)	(78,734)	(90,506)	(100,926)	(100,926)	(130,006)	(121,718)
% of Sales	**2011**	**2012**	**1Q13**	**2Q13**	**3Q13**	**4Q13**	**2013**	**1Q14E**	**2Q14E**	**3Q14E**	**4Q14E**	**2014E**	**2015E**	**2016E**
Gross Margins	87%	47%	54%	63%	65%	56%	60%	61%	63%	65%	70%	65%	70%	71%
Sales and Marketing	76%	32%	35%	52%	37%	48%	43%	50%	45%	42%	40%	43%	36%	31%
General and administrative	340%	81%	61%	80%	79%	78%	75%	70%	58%	50%	43%	53%	30%	18%
Research and development	439%	139%	96%	103%	85%	71%	86%	64%	54%	46%	41%	50%	30%	18%
Total operating expenses	854%	252%	191%	235%	201%	196%	204%	184%	157%	138%	124%	146%	96%	67%
EBIT	-767%	-206%	-137%	-172%	-136%	-140%	-145%	-123%	-94%	-73%	-54%	-81%	-26%	4%
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	7%
Net income	-843%	-213%	-139%	-176%	-152%	-135%	-149%	-120%	-92%	-72%	-53%	-79%	-25%	4%
Free Cash Flow	-1015%	-199%	0%	0%	-89%	-95%	-122%	-77%	-93%	-73%	-71%	-78%	-27%	2%
y/y Δ	**2011**	**2012**	**1Q13**	**2Q13**	**3Q13**	**4Q13**	**2013**	**1Q14E**	**2Q14E**	**3Q14E**	**4Q14E**	**2014E**	**2015E**	**2016E**
Total Revenues	NA	418%	750%	226%	170%	87%	172%	112%	130%	100%	102%	109%	91%	70%
Cost of revenues	NA	2102%	235%	98%	60%	104%	105%	81%	127%	101%	39%	80%	64%	65%
Gross Margins	NA	-47%	-442%	63%	59%	-6%	28%	12%	1%	0%	24%	9%	8%	1%
Sales and Marketing	NA	122%	260%	262%	258%	266%	262%	204%	100%	127%	70%	111%	57%	48%
General and administrative	NA	24%	88%	135%	202%	167%	153%	144%	66%	27%	13%	48%	8%	1%
Research and development	NA	64%	65%	69%	96%	49%	69%	43%	20%	9%	17%	20%	17%	3%
Total operating expenses	NA	53%	92%	115%	152%	119%	121%	104%	53%	38%	28%	50%	25%	19%
EBIT	NA	39%	35%	77%	110%	144%	91%	91%	25%	8%	-21%	17%	-39%	-129%
Tax rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net income	NA	31%	31%	74%	125%	134%	91%	83%	20%	-6%	-20%	11%	-39%	-129%

Source: Company data, Wedbush Securities, Inc.

Figure 4: Balance Sheet

	2011	2012	2013E	2014E	2015E	2016E
Current assets:						
Total Cash and Cash Equivalents	10852	54,838	124,293	74,859	37,883	31,232
Accounts Receivable	278	2,195	6,262	9,774	17,852	29,623
Inventory	318	803	1,763	1,629	2,975	4,937
Prepaid expenses and other Current Assets	313	550	992	992	992	992
Total current assets	**11,761**	**58,386**	133,310	87,254	59,702	66,785
Property, Plant and Equipment	7,902	12,154	22,104	25,133	30,925	40,778
Accumulated Depreciation	(1,796)	(4,689)		(4,613)	(10,018)	(16,853)
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	109,629	82,464	92,563
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts Payable and accrued expenses	2,408	5,072	7,007	7,286	9,140	10,848
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	16,038	17,892	19,600
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	25,836	27,690	29,398
Stockholders' equity:						
Preferred Stock	32,455	98,658	0	0	0	0
Common Stock, APIC, RE	(22,303)	(43,397)	131,711	83,793	54,774	63,165
Total liabilities and stockholders' equity	**18,065**	**66,039**	157,268	109,629	82,464	92,563

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)	(47,918)	(29,019)	8,391
Depreciation	1,520	2,894	5,006	4,613	5,405	6,836
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)	(3,099)	(7,570)	(12,025)
Net cash provided by operating activities	**(14,133)**	**(17,249)**	**(30,766)**	**(46,405)**	**(31,184)**	**3,202**
Cash Flows from Investing Activities:						
Purchase of property and equipment	(5,410)	(3,183)	(6,930)	(3,029)	(5,792)	(9,853)
increase in restricted cash	0		(1,564)	0	0	0
Net cash used in investing activities	**(5,410)**	**(3,183)**	**(8,494)**	**(3,029)**	**(5,792)**	**(9,853)**
				0	0	0
Cash Flows from Financing Activities:				0	0	0
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	(49,434)	(36,976)	(6,651)
Cash and cash equivalents, beginning of period		10,852	54,838	124,293	74,859	37,883
Cash and cash equivalents, end of period	**10,852**	**54,838**	**124,293**	**74,859**	**37,883**	**31,232**

Source: Company data, Wedbush Securities, Inc.

Company	Ticker	Rating	Price Target	Current Price
Illumina	ILMN	NEUTRAL	$140	$148
UnitedHealth Group	UNH	OUTPERFORM	$89	$75

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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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of December 31, 2013)	**Investment Banking Relationships (as of December 31, 2013)**
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Wedbush Equity Research Disclosures as of April 4, 2014

Company	Disclosure
Foundation Medicine	1
Illumina	1
Unitedhealth Group	1

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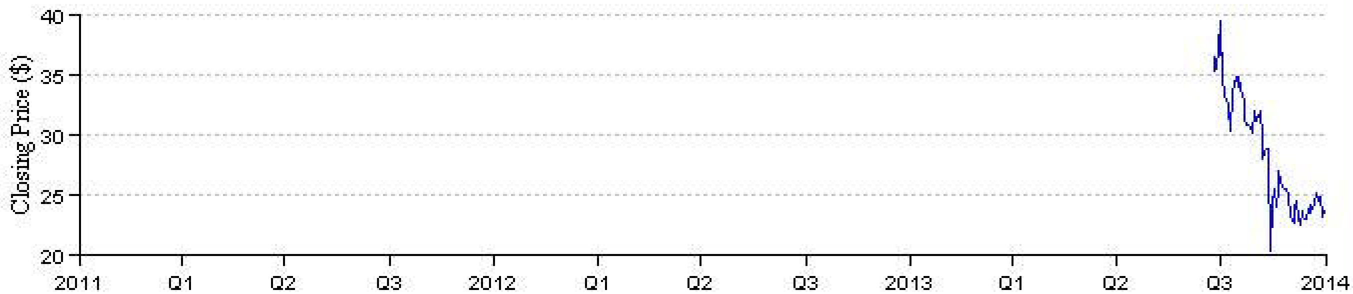
FMI



ILMN

1) 02/04/11 OUTPERFORM $75	2) 04/27/11 OUTPERFORM $80	3) 07/27/11 OUTPERFORM $78	4) 10/07/11 OUTPERFORM $35	5) 01/25/12 OUTPERFORM $50	6) 02/08/12 OUTPERFORM $65
7) 04/24/12 OUTPERFORM $52	8) 01/04/13 NEUTRAL $52	9) 04/23/13 NEUTRAL $55	10) 07/24/13 NEUTRAL $60	11) 10/15/13 NEUTRAL $65	12) 10/22/13 NEUTRAL $72

UNH

1) 01/13/11 OUTPERFORM $48	2) 04/12/11 OUTPERFORM $51	3) 04/21/11 OUTPERFORM $54	4) 07/14/11 OUTPERFORM $57	5) 07/19/11 OUTPERFORM $54	6) 01/19/12 OUTPERFORM $60
7) 04/08/12 OUTPERFORM $66	8) 07/04/12 OUTPERFORM $70	9) 07/19/13 OUTPERFORM $79	10) 10/17/13 OUTPERFORM $85	11) 12/05/13 OUTPERFORM $89	

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

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Medical Devices
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Medical Diagnostics and Life Sciences Tools
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