OUTPERFORM

Reason for report: **EARNINGS**

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FOUNDATION MEDICINE, INC.

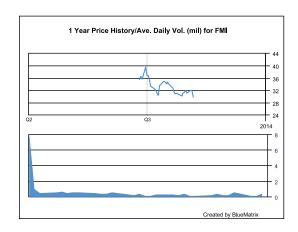
3Q:13 a Positive Start; Reimbursement Remains Key

- **Bottom Line**: FMI's first quarter as a public company exceeded Street expectations. However, we reduced our estimates to reflect lower reimbursement. We maintain our Outperform rating but have reduced our price target to \$35 (from \$39).
- FoundationOne adoption solid during 3Q:13. FMI's reported revenue of \$8.2M handily beat our and Street 3Q:13 estimates (FactSet consensus was \$7.4M). FoundationOne tests grew 58% q/q to 2,577, up from 1,626 in 2Q:13 and 494 in 3Q:12. Gross margin of 65.2% was also better vs. our 62.0% forecast and improved by 270 basis points q/q. Opex was higher than we had modeled. The upside to clinical test volume was somewhat muted by lower average reimbursement for clinical tests (\$3,300 vs our \$3,700 estimate), thus results were somewhat mixed relative to our expectations. FMI attributed the decline in reimbursement from 1H levels to the 2013 coding changes for molecular diagnostic tests, a recurrent theme in the diagnostics sector thus far in 2013. As a result, we have lowered our average clinical test payment rate.
- Test penetration in the community setting just beginning. FoundationOne continues to gain traction in the community physician setting, with ~53% of Q3 clinical tests coming from community-based oncologists. Recall that ~85% of cancer patients present in a community setting, and increasing penetration of this market confirms FMI's strength of making esoteric cancer testing readily accessible to and interpretable by community physicians. Cumulatively, more than 2,100 physicians have now ordered FoundationOne, which compares to the >1,500 number disclosed in the S1.
- Further validation studies published during the quarter. FMI recently announced the results from a 24-month analytical validation study, which further enhances the body of peer-reviewed literature in support of the FoundationOne test.
- FoundationOne Heme on track; look for physician portal enhancements in 2014. FMI remains on track to launch FoundationOne Heme in early 2014. The assay is being developed in collaboration with Memorial Sloan-Kettering and will use RNA sequencing in addition to DNA sequencing to inform the genomic profile of blood-based cancers. We also expect an update on the company's efforts to foster two-way interaction on its Interactive Cancer Explorer in 2014.

Key Stats: (NASDAQ:FMI)

HEALTHCARE EQUITY RESEARCH

S&P 600 Health Care Index: 1.197.55 Price: \$29.82 Price Target: \$35.00 from \$39.00 Methodology: ~13x EV/Sept-15 TTM revenue 52 Week High: \$41.51 52 Week Low: \$18.00 Shares Outstanding (mil): 28.1 Market Capitalization (mil): \$837.9 Book Value/Share: \$5.14 Cash Per Share: \$0.21 Dividend (ann): \$0.00 Dividend Yield: 0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A					\$10.6					(\$1.05)	NM
2013E - New	\$5.2A	\$5.9A	\$8.2A	\$8.7	\$28.0	(\$2.27)A	(\$3.21)A	(\$3.51)A	(\$0.43)	(\$4.38)	NM
2013E - Old	\$5.2A	\$5.9A	\$7.2	\$8.2	\$26.5	(\$0.33)A	(\$0.47)A	(\$0.49)	(\$0.41)	(\$1.71)	NM
2014E - New					\$50.8					(\$1.62)	NM
2014E - Old					\$53.6					(\$1.66)	NM
2015E - New					\$98.9	i				(\$1.05)	NM
2015E - Old					\$105.8					(\$0.86)	NM

Source: Company Information and Leerink Swann LLC Research Revenues in \$millions.



INVESTMENT THESIS

We are initiating coverage of Cambridge, Massachusetts-based Foundation Medicine (FMI) with an Outperform rating and a \$35 price target. The company is the leader in bringing the benefits of next generation sequencing technology to cancer care. Its integration of next generation (i.e., nextgen) sequencing information with a clean, readily interpretable patient report helps physicians improve clinical treatment decision making and enables biopharmaceutical companies to identify and optimize the development of targeted oncology therapies. We believe this area is poised for rapid growth, and FMI's early mover advantage should enable it to be a leader in this field.

VALUATION

Our 12-month price target of \$35 is based on a DCF analysis. This analysis includes a number of simplifying assumptions which we think allow for a fair balance of upsides and downsides. We assume the market for FoundationOne for solid tumors in the U.S. is ~1M patients annually, this market is 60% penetrated by Foundation-like panels in 10 years (an assumption based on the 10-year penetration of the U.S. invasive breast cancer prognostic test market by GHDX (OP)and others), and FMI's early mover advantage affords it a 50% share. Any

expansion of the U.S. market beyond ~1M patients, as high content panels move earlier in treatment protocols as well as international expansion, would be upside. We assume pricing compresses from ~\$3,300 today to \$2,500 in 10 years, driven by intensifying competition and reimbursement pressure, a phenomenon we're currently seeing in the market for hereditary breast and ovarian cancer (HBOC) testing as well as hereditary colorectal cancer testing. This assumption could prove conservative as there is some opportunity for pricing to survive in this market more so than we expect it will in HBOC testing for a number of reasons, including the incremental challenge and cost associated with assessing samples from FFPE tissue as opposed to blood or saliva.

For the forthcoming FoundationOne hematology product, we assume a U.S. market opportunity of \sim 150k patients annually, 60% penetration in 10 years, and 50% share for FMI. Similar to solid tumor, international expansion would offer upside. We expect similar pricing compression from \sim \$5,500 per test initially to \sim \$4,000 in 10 years, but believe that absolute pricing will be well higher than the solid tumor test, partially to reflect what we believe will be higher costs associated with this test.

Despite expectations of price pressure and competition, we believe FMI can maintain a healthy 70% gross margin over time. We believe it appropriate to project the margin conservatively below the 80%+ margins of GHDX (OP) and MYGN (MP), but well above ~40% gross margins of the national reference labs, which derive most of their revenue from commodity testing. We believe it important to note that FMI already achieved a 65.2% gross margin in 3Q:13 on only ~\$8M of revenue, which suggests to us that 70% is reasonable if not conservative, even in the face of competition.

RISKS TO VALUATION

The primary risks to our price target for FMI include, but are not limited to: ability to obtain positive coverage decisions and contract terms with third-party payers, competitive pressures from other molecular diagnostic testing companies, an uncertain pace of drug approvals which require molecular profiling (which impacts the clinical utility of FMI's test but is outside its control), the pace of adoption of its FMI products among biopharmaceutical customers, nature and timing of FDA guidance/regulations, and policy decisions.

Foundation Medicine Inc. (FMI)

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Income statement								dan.leonard	@leerink.com
Period Ended (\$ thousands)	2011	2012	Mar-13	Jun-13	Sep-13	Dec-13e	2013e	2014e	2015e
Revenues	\$2,057	\$10,645	\$5,200	\$5,920	\$8,208	\$8,675	\$28,003	\$50,799	\$98,946
Cost of product sales	<u>258</u>	<u>5,681</u>	<u>2,378</u>	<u>2,219</u>	<u>2,858</u>	3,036	10,491	<u>17,779</u>	<u>31,663</u>
Gross profit	1,799	4,964	2,822	3,701	5,350	5,639	17,512	33,019	67,283
SG&A	8,547	12,098	4,961	7,630	9,486	10,410	32,487	46,735	64,315
R&D	<u>9,023</u>	<u>14,777</u>	<u>4,982</u>	<u>6,097</u>	<u>6,988</u>	<u>7,374</u>	<u>25,441</u>	<u>33,019</u>	<u>34,631</u>
Operating income (loss)	(15,771)	(21,911)	(7,121)	(10,026)	(11,124)	(12,146)	(40,417)	(46,735)	(31,663)
Interest expense (income)	421	421	76	65	61	87	289	358	385
Other expense (income)	<u>845</u>	<u>61</u>	<u>6</u>	<u>96</u>	<u>1,278</u>	<u>0</u>	<u>1,380</u>	<u>0</u>	<u>0</u>
Pretax income	(17,037)	(22,393)	(7,203)	(10,187)	(12,463)	(12,232)	(42,085)	(47,093)	(32,048)
Taxes	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Net income	(17,037)	(22,393)	(7,203)	(10,187)	(12,463)	(12,232)	(42,085)	(47,093)	(32,048)
Preferred accretion	(296)	<u>(286)</u>	<u>(50)</u>	<u>(42)</u>	<u>(47)</u>	<u>0</u>	<u>(139)</u>	<u>0</u>	<u>0</u>
Net income to common	(\$17,333)	(\$22,679)	(\$7,253)	(\$10,229)	(\$12,510)	(\$12,232)	(\$42,224)	(\$47,093)	(\$32,048)
Basic shares outstanding	2,331	2,331	3,190	3,190	3,565	28,657	9,651	29,157	30,457
Diluted shares outstanding	2,331	2,331	3,190	3,190	3,565	28,657	9,651	29,157	30,457
EPS diluted	(\$7.44)	(\$9.73)	(\$2.27)	(\$3.21)	(\$3.51)	(\$0.43)	(\$4.38)	(\$1.62)	(\$1.05)
EPS growth									
Sales growth		417.5%	749.7%	225.8%	170.3%		163.1%	81.4%	94.8%
Clinical tests		1,753	1,140	1,626	2,577	3,073	8,416	20,357	40,746
Gross margin	87.5%	46.6%	54.3%	62.5%	65.2%	65.0%	62.5%	65.0%	68.0%
SG&A % of revenue	415.5%	113.6%	95.4%	128.9%	115.6%	120.0%	116.0%	92.0%	65.0%
R&D % of revenue	438.6%	138.8%	95.8%	103.0%	85.1%	85.0%	90.9%	65.0%	35.0%
Operating margin	(766.7%)	(205.8%)	(136.9%)	(169.4%)	(135.5%)	(140.0%)	(144.3%)	(92.0%)	(32.0%)
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D&A expense	\$1,520	\$2,894	\$1,030	\$1,043		Г	\$5,483	\$7,362	\$6,903
EBITDA	(\$14,251)	(\$19,017)	(\$6,091)	(\$8,983)			(\$34,934)	(\$39,373)	(\$24,760)
Free cash flow									
Operating cash flow	(\$14,133)	(\$17,249)	(\$6,694)	(\$7,016)		Γ	(\$31,726)	(\$31,536)	(\$11,711)
Capex	(5,410)	(3,183)	(170)	(1,128)			(5,506)	(7,594)	(8,050)
Free cash flow	(\$19,543)	(\$20,432)	(\$6,864)	(\$8,144)			(\$37,232)	(\$39,130)	(\$19,761)
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Notes:

Source: Company reports and Leerink Swann estimates

Foundation Medicine (FMI)

Period Ended (\$ thousands)	Dec-12	Mar-13	Jun-13	Sep-13	Dec-13e
Assets				•	
Cash, equivalents, ST investments, restricted cash	\$54,838	\$45,832	\$35,965	\$138,088	\$128,264
Accounts receivable	2,195	3,127	4,114	4,437	4,754
Inventory	803	796	725	942	1,032
Prepaid expenses and other current assets	<u>550</u>	<u>953</u>	<u>1,004</u>	<u>950</u>	<u>1,388</u>
Total current assets	58,386	50,708	41,808	144,417	135,437
Property and equipment, net	7,465	7,560	7,260	19,480	19,279
Restricted cash / LT investments	161	1,886	1,886	1,725	1,725
Other assets	<u>27</u>	<u>26</u>	<u>1,315</u>	<u>54</u>	<u>54</u>
Total assets	\$66,039	\$60,180	\$52,269	\$165,676	\$156,495
Liabilities and shareholders' equity					
Notes payable - current portion	\$1,704	\$1,739	\$1,712	\$1,540	\$4,226
Accounts payable	1,609	2,336	2,109	3,339	2,662
Accrued expenses	3,463	3,165	3,530	5,022	4,164
Deferred revenue	1,622	2,427	2,090	1,304	3,470
Deferred rent, current portion	132	137	141	149	521
Other liabilities	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Total current liabilities	8,530	9,804	9,582	11,354	15,043
Notes payable - long-term portion	1,441	1,012	634	2,686	0
Deferred rent, net of current portion	287	253	1,504	6,306	6,306
Warrant to purchase preferred stock	225	232	328	1,401	1,401
Restricted stock liability	139	131	106	467	467
Other long-term liabilities	<u>156</u>	<u>0</u>	<u>226</u>	<u>817</u>	<u>817</u>
Total liabilities	\$10,778	\$11,432	\$12,380	\$23,031	\$24,034
Preferred stock	\$98,658	\$98,700	\$98,740	\$0	\$0
Shareholders' equity	(\$43,397)	(\$49,952)	(\$58,851)	\$142,645	\$132,461
Total liabilities and shareholders' equity	\$66,039	\$60,180	\$52,269	\$165,676	\$156,495

Source: Company reports and Leerink Swann estimates

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DCF Model									dan.leonar	d@leerink.com
Period Ended (\$ thousands)	2013e	2014e	2015e	2016e	2017e	2018e	2019e	2020e	2021e	2022e
Revenues	\$28,003	\$50,799	\$98,946	\$207,264	\$373,502	\$543,148	\$672,219	\$765,233	\$850,454	\$885,320
Volume										
FoundationOne-solid tumor	8,416	19,357	37,746	71,717	114,747	160,646	208,840	250,608	275,668	289,452
FoundationOne-heme	0	1,000	3,000	6,000	12,000	21,000	31,500	40,950	47,093	49,447
Price										
FoundationOne-solid tumor	\$3,475	\$3,300	\$3,200	\$3,200	\$3,100	\$2,900	\$2,700	\$2,500	\$2,500	\$2,500
FoundationOne-heme		\$5,500	\$5,300	\$5,100	\$4,900	\$4,700	\$4,500	\$4,300	\$4,100	\$4,000
Gross margin	63%	65%	68%	70%	70%	70%	70%	70%	70%	70%
-										
Free cash flow	(\$36,943)	(\$38,772)	(\$19,376)	\$37,841	\$133,206	\$165,217	\$212,471	\$234,704	\$261,275	\$273,472
t	1	2	3	4	5	6	7	8	9	10
Discount factor	0.9	0.7	0.6	0.6	0.5	0.4	0.4	0.3	0.3	0.2
PV of cash	(\$31,848)	(\$28,814)	(\$12,414)	\$20,899	\$63,421	\$67,812	\$75,178	\$71,591	\$68,703	\$61,992

16% WACC Terminal growth 4%

PV (thru 2022) \$356,521 terminal value 537,260 Enterprise value 893,782

- net debt (63,862) assumes ~\$70M burn

\$957,644 Equity value

31,220 Diluted shares out

Share price \$30.67

Share price (adj ytd) \$34.71



Disclosures Appendix Analyst Certification

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

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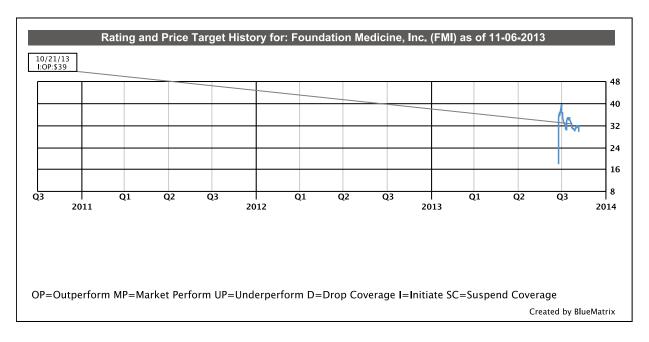
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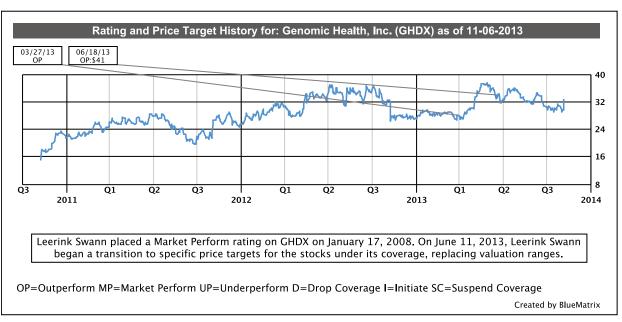
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Risks to Valuation

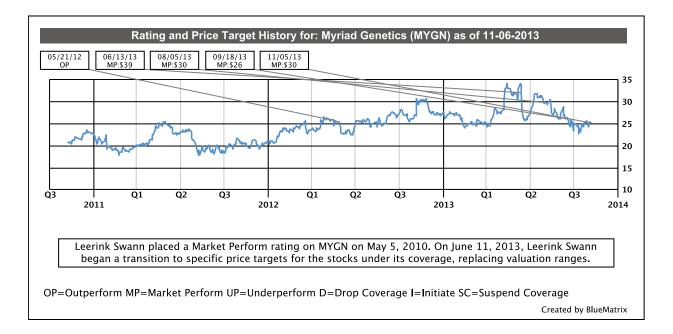
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	Distribution of Ratings/Investment Bank	ing Services (IB	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

Important Disclosures

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's asset management group and proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Publishing Department at One Federal Street, 37th Floor, Boston, MA 02110.

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Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Foundation Medicine, Inc.



Leerink Swann LLC makes a market in Foundation Medicine, Inc., Genomic Health, Inc. and Myriad Genetics. Leerink Swann LLC has acted as a co-manager for a public offering of Foundation Medicine, Inc. in the past 12 months.

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