OUTPERFORM

Reason for report:

EARNINGS

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(NASDAQ:FMI)

FOUNDATION MEDICINE, INC.

Solid Wrap to Year with Plenty Underway in 2014

- Bottom Line: FMI's quarter was in line with the company's positive preannouncement. We increased our sales estimates to reflect the 4Q beat and 2014 guidance above our prior estimates. We maintain our Outperform rating and increase our price target to \$36 (from \$35).
- Solid FoundationOne uptake in Clinical and Biopharm during **4Q:13.** FMI's reported revenue of \$9.7M handily beat our \$8.7M estimate. FoundationOne (F1) clinical tests grew 46% q/q to 3,752, up from 2,577 in 3Q:13 and 878 in 4Q:12. The top-line beat was driven by higher Clinical test volume than we had modeled, while F1 tests by Biopharm customers also exceeded our expectations for the guarter. On the expense side, opex and cost of goods came in higher than our model, the latter due to timing of cash payments. Average reimbursement per clinical test that met revenue recognition criteria was \$3,400, up from \$3,300 in 3Q:13.
- Test adoption in the community setting continues to increase. F1 continues to gain awareness among community-based oncologists, who comprised 55% of clinical tests in the quarter. This cohort of providers should continue to comprise an increasing proportion of overall test adoption as the company builds out its U.S. sales force, in our view. We believe test adoption among all providers could receive a boost from clinical utility and perhaps decision impact data on F1 released at the American Society for Clinical Oncology (ASCO) meeting mid-year 2014.
- Coding strategy with Medicare seeks recognition of differential value. FMI indicated that it has begun to submit claims to Medicare. The company is submitting claims to Medicare under a miscellaneous (MISC) code versus code stacking, and is also working with Palmetto to establish a unique payment code (Z-Code) under Palmetto's MolDx program. We believe this strategy is consistent with FMI's efforts to achieve reimbursement for F1 that recognizes the test's value and also offers transparency to payors.
- FoundationOne Heme launched successfully; Novartis agreement extended. FMI launched FoundationOne Heme, its second clinical product developed in collaboration with Memorial Sloan-Kettering, in December. The company also extended its agreement with Novartis (OP) by three years, and increased the scope of genomic profiling services it will provide to the company for Novartis' clinical oncology programs.
- Raising revenue forecasts. We have increased our revenue forecasts to assume greater clinical test volume than we modeled previously. We have also increased our losses per share on a lower gross margin and higher expenses than modeled previously.

S&P 600 Health Care Index:	1,315.46
Price:	\$32.44
Price Target:	\$36.00 from \$35.00
Methodology:	
	DCF analysis
52 Week High:	\$41.51
52 Week Low:	\$18.00
Shares Outstanding (mil):	27.5

Key Stats:

52 Week High:	\$41.51
52 Week Low:	\$18.00
Shares Outstanding (mil):	27.5
Market Capitalization (mil):	\$892.1
Book Value/Share:	\$4.79
Cash Per Share:	\$4.52
Dividend (ann):	\$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	\$5.2	\$5.9	\$8.2	\$9.7	\$29.0	(\$2.27)	(\$3.21)	(\$3.51)	(\$0.48)	(\$4.60)	NM
2014E - New	\$10.5	\$12.6	\$15.5	\$18.2	\$56.8	(\$0.50)	(\$0.50)	(\$0.50)	(\$0.52)	(\$2.01)	NM
2014E - Old					\$50.8					(\$1.62)	NM
2015E - New					\$112.7					(\$1.74)	NM
2015E - Old					\$98.9					(\$1.05)	NM
2016E					\$205.8					(\$0.14)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in \$millions.



INVESTMENT THESIS

We rate Cambridge, Massachusetts-based Foundation Medicine (FMI) Outperform with a \$36 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 \$36 is based on a DCF analysis. This analysis includes a number of simplifying assumptions that 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 ~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 ~\$5,500 per test initially to ~\$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 achieve a healthy 70% gross margin over time. We believe it appropriate to project the margin conservatively below the 80%+ margins of GHDX and MYGN (MP), but well above ~40% gross margins of the national reference labs, which derive most of their revenue from commodity testing.

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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i outidation medicine inc. (i	1 4 11 <i>)</i>											Dan Leonard,	212-211-0110	
Income statement												dan.leonard	l@leerink.com	
Period Ended (\$ thousands)	2011	2012	Mar-13	Jun-13	Sep-13	Dec-13	2013	Mar-14e	Jun-14e	Sep-14e	Dec-14e	2014e	2015e	2016e
Revenues	\$2,057	\$10,645	\$5,200	\$5,920	\$8,208	\$9,662	\$28,990	\$10,519	\$12,612	\$15,487	\$18,173	\$56,791	\$112,663	\$205,824
Cost of product sales	<u>258</u>	5,681	2,378	2,219	2,858	4,204	11,659	4,208	5,045	6,195	7,269	22,716	45,065	72,038
Gross profit	1,799	4,964	2,822	3,701	5,350	5,458	17,331	6,312	7,567	9,292	10,904	34,075	67,598	133,786
SG&A	8,547	12,098	4,961	7,630	9,486	12,114	34,191	12,623	13,242	13,939	14,538	54,342	73,231	86,446
R&D	9,023	14,777	4,982	6,097	6,988	6,834	24,901	7,363	8,197	9,292	10,904	35,757	45,065	51,456
Operating income (loss)	(15,771)	(21,911)	(7,121)	(10,026)	(11,124)	(13,490)	(41,761)	(13,675)	(13,873)	(13,939)	(14,538)	(56,025)	(50,698)	(4,116)
Interest expense (income)	421	421	76	65	61	33	235	12	13	17	20	62	99	113
Other expense (income)	<u>845</u>	<u>61</u>	<u>6</u>	<u>96</u>	1,278	(432)	948	<u>65</u>	<u>65</u>	<u>65</u>	<u>65</u>	260	<u>260</u>	<u>0</u>
Pretax income	(17,037)	(22,393)	(7,203)	(10, 187)	(12,463)	(13,091)	(42,944)	(13,752)	(13,951)	(14,020)	(14,624)	(56,347)	(51,057)	(4,229)
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>	<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)	(13,091)	(42,944)	(13,752)	(13,951)	(14,020)	(14,624)	(56,347)	(51,057)	(\$4,229)
Preferred accretion	(296)	(286)	<u>(50)</u>	(42)	<u>(47)</u>	<u>0</u>	(139)	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Net income to common	(\$17,333)	(\$22,679)	(\$7,253)	(\$10,229)	(\$12,510)	(\$13,091)	(\$43,083)	(\$13,752)	(\$13,951)	(\$14,020)	(\$14,624)	(\$56,347)	(\$51,057)	(\$4,229)
Basic shares outstanding	2,331	2,395	3,190	3,190	3,565	27,505	9,363	27,705	27,905	28,105	28,305	28,005	29,305	31,155
Diluted shares outstanding	2,331	2,395	3,190	3,190	3,565	27,505	9,363	27,705	27,905	28,105	28,305	28,005	29,305	31,155
EPS diluted EPS growth	(\$7.44)	(\$9.47)	(\$2.27)	(\$3.21)	(\$3.51)	(\$0.48)	(\$4.60)	(\$0.50)	(\$0.50)	(\$0.50)	(\$0.52)	(\$2.01)	(\$1.74)	(\$0.14)
Sales growth		417.5%	749.7%	225.8%	170.3%	86.6%	172.3%	102.3%	113.0%	88.7%	88.1%	95.9%	98.4%	82.7%
Clinical tests		1,753	1,140	1,626	2,577	3,752	9,095	4,710	5,566	6,485	7,404	24,164	45,854	74,567
Gross margin	87.5%	46.6%	54.3%	62.5%	65.2%	56.5%	59.8%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	65.0%
SG&A % of revenue	415.5%	113.6%	95.4%	128.9%	115.6%	125.4%	117.9%	120.0%	105.0%	90.0%	80.0%	95.7%	65.0%	42.0%
R&D % of revenue	438.6%	138.8%	95.8%	103.0%	85.1%	70.7%	85.9%	70.0%	65.0%	60.0%	60.0%	63.0%	40.0%	25.0%
Operating margin	(766.7%)	(205.8%)	(136.9%)	(169.4%)	(135.5%)	(139.6%)	(144.1%)	(130.0%)	(110.0%)	(90.0%)	(80.0%)	(98.7%)	(45.0%)	(2.0%)
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	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	\$1,086	F	\$4,159					\$8,231	\$7,860	\$9,148
EBITDA	(\$14,251)	(\$19,017)	(\$6,091)	(\$8,983)	(\$10,038)		(\$37,602)					(\$47,794)	(\$42,838)	\$5,031
Free cash flow														
Operating cash flow	(\$14,133)	(\$17,249)	(\$6,694)	(\$7,016)	(\$7,036)	Ī	(\$30,243)					(\$39,993)	(\$28,025)	\$22,297
Capex	(5,410)	(3,183)	(170)	(1,128)	(2,493)		(8,466)					(7,197)	(8,585)	(15,341)
Free cash flow	(\$19,543)	(\$20,432)	(\$6,864)	(\$8,144)	(\$9,529)		(\$38,709)					(\$47,190)	(\$36,610)	\$6,956
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Notes:
Source: Company reports and Leerink Partners estimates

Foundation Medicine (FMI) Balance sheet

Balance Sneet									
Period Ended (\$ thousands)	Dec-12	Mar-13	Jun-13	Sep-13	Dec-13	Mar-14e	Jun-14e	Sep-14e	Dec-14e
Assets									
Cash, equivalents, ST investments, restricted cash	\$54,838	\$45,832	\$35,965	\$138,088	\$124,293	\$121,508	\$108,077	\$94,287	\$80,303
Accounts receivable	2,195	3,127	4,114	4,437	6,262	5,764	6,910	8,486	9,958
Inventory	803	796	725	942	1,763	1,429	1,714	2,105	2,470
Prepaid expenses and other current assets	<u>550</u>	<u>953</u>	1,004	<u>950</u>	992	<u>1,473</u>	1,766	2,168	2,544
Total current assets	58,386	50,708	41,808	144,417	133,310	130,174	118,467	107,046	95,275
Property and equipment, net	7,465	7,560	7,260	19,480	22,104	12,196	14,622	17,956	21,070
Restricted cash / LT investments	161	1,886	1,886	1,725	1,725	1,725	1,725	1,725	1,725
Other assets	<u>27</u>	<u>26</u>	<u>1,315</u>	<u>54</u>	129	<u>129</u>	<u>129</u>	<u>129</u>	<u>129</u>
Total assets	\$66,039	\$60,180	\$52,269	\$165,676	\$157,268	\$144,224	\$134,943	\$126,857	\$118,199
Liabilities and shareholders' equity									
Notes payable - current portion	\$1,704	\$1,739	\$1,712	\$1,540	\$1,499	\$1,499	\$1,499	\$1,499	\$1,499
Accounts payable	1,609	2,336	2,109	3,339	7,007	3,228	3,870	4,752	5,576
Accrued expenses	3,463	3,165	3,530	5,022	5,168	5,049	6,054	7,434	8,723
Deferred revenue	1,622	2,427	2,090	1,304	918	4,208	5,045	6,195	7,269
Deferred rent, current portion	132	137	141	149	1,167	631	757	929	1,090
Other liabilities	<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>
Total current liabilities	8,530	9,804	9,582	11,354	15,759	14,615	17,224	20,809	24,158
Notes payable - long-term portion	1,441	1,012	634	397	0	0	0	0	0
Deferred rent, net of current portion	287	253	1,504	11,147	0	0	0	0	0
Warrant to purchase preferred stock	225	232	328	0	0	0	0	0	0
Restricted stock liability	139	131	106	107	0	0	0	0	0
Other long-term liabilities	<u>156</u>	0	<u>226</u>	<u>26</u>	9,798	9,798	9,798	9,798	9,798
Total liabilities	\$10, 778	\$11,43 2	\$12,380	\$23,031	\$25,557	\$24,413	\$27,022	\$30,607	\$33,956
Preferred stock	\$98,658	\$98,700	\$98,740	\$0	\$0	\$0	\$0	\$0	\$0
Shareholders' equity	(\$43,397)	(\$49,952)	(\$58,851)	\$142,645	\$131,711	\$119,811	\$107,921	\$96,249	\$84,243
Total liabilities and shareholders' equity	\$66,039	\$60,180	\$52,269	\$165,676	\$157,268	\$144,224	\$134,943	\$126,857	\$118,199

Source: Company reports and Leerink Partners estimates



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

Our 12-month price target of \$36 is based on a DCF analysis. This analysis includes a number of simplifying assumptions that 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.

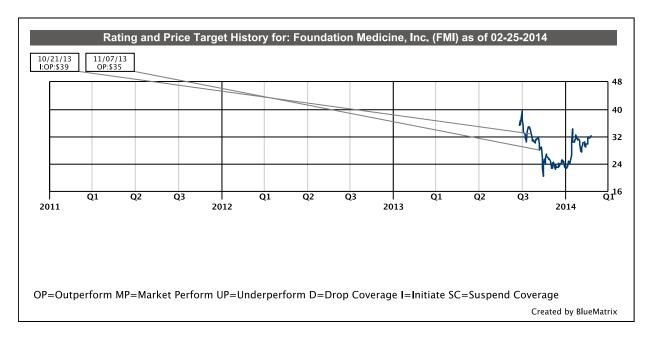
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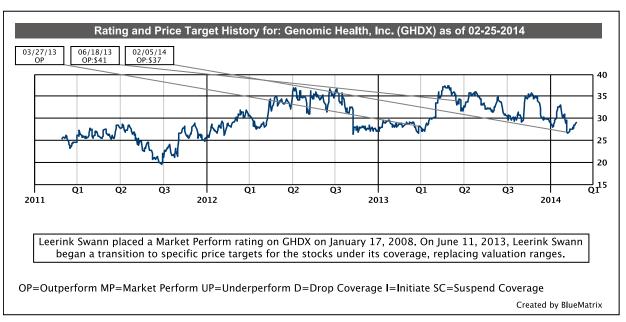
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Risks to Valuation

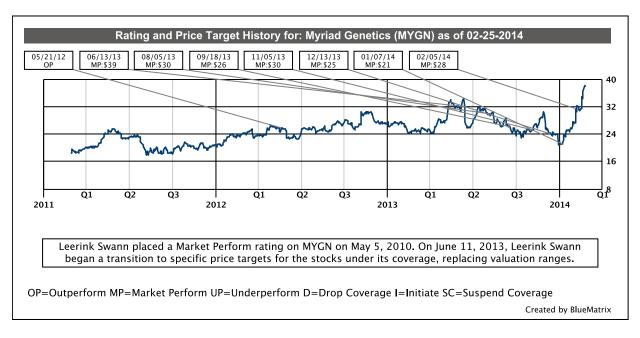
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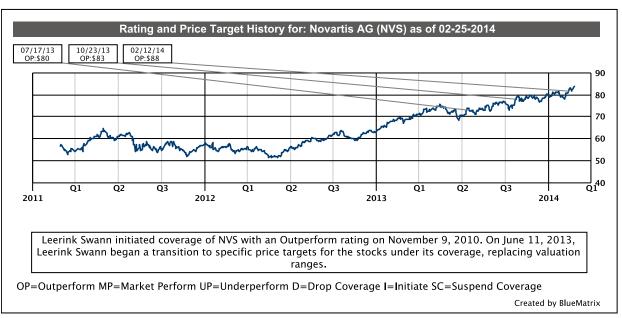














	Distribution of Ratings/Investment Bank	ing Services (IB	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP] HOLD [MP]	118 65	64.50 35.50	30 2	25.00 3.00
SELL [UP]	0	0.00	ō	0.00

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

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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

Leerink Consulting LLC, an affiliate of Leerink Partners, 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 Partners LLC makes a market in Foundation Medicine, Inc., Genomic Health, Inc. and Myriad Genetics. Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of Novartis AG on a principal basis.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: Novartis AG.

Leerink Partners LLC has acted as a co-manager for a public offering of Foundation Medicine, Inc. in the past 12 months.

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