OUTPERFORM

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Reason for report:

EARNINGS



(NASDAQ:FMI)

\$0.00

0.0%

FOUNDATION MEDICINE, INC.

Forecast Little Changed Following 1Q Report

- Bottom Line: Our forecast for FMI is not meaningfully changed following its 1Q report. We have reduced our price target to \$33 (from \$36) to reflect a higher discount rate currently being applied to riskier assets in the market, but maintain our Outperform rating.
- 1Q largely in line, save gross margin. FMI reported 1Q revenue of \$11.5M, largely in line with the Street forecast (of \$11.4M) and ahead of our \$10.5M estimate. Clinical tests of 4,702 were roughly in line with our estimate of 4,710. We believe performance would have been even better if not for the bad weather in the U.S. that other lab companies noted, but this impact is difficult to quantify for a company at FMI's stage. Gross margin of 53.8% was meaningfully lower than our 60% estimate, due to the higher-than-anticipated number of FoundationOne (F1) Heme tests (715 vs our 150 estimate), for which costs were recorded in the period but revenue was immaterial. Lower-than-anticipated operating expenses drove a slightly lower loss per share than we had modeled (\$0.44 vs \$0.50 est).
- FMI aggressively expanding commercial infrastructure. To further the adoption of its F1 tests, FMI is aggressively expanding its commercial infrastructure. It ended the quarter with 43 U.S. sales reps, which compares to a target of 45 50 reps by year end and represents an increase from ~18 in late 2013.
- New product initiatives on track. All of FMI's major new product initiatives are on track. The company plans to launch an updated version of its F1 solid tumor test in 2Q (we assume at the American Society of Clinical Oncology [ASCO] annual meeting). The newer version improves upon the success rate of the existing test in low tumor content tissues and tissue types, has more efficient variant calling algorithms, and offers expanded content (>300 genes vs 236 genes today). Additionally, the company plans to have completely internalized its medical reporting capability by 2Q end. Finally, FMI remains on track to introduce new features to its Interactive Cancer Explorer physician portal, including outcomes collection capabilities, in 2H14.
- No update on the reimbursement. FMI continues to have some success with private payers and is submitting claims to and appealing denials from Medicare. Average revenue per test, for those tests that meet revenue recognition criteria, was ~\$3,400 in 1Q, consistent with the prior quarter.
- ASCO up next. We believe ASCO serves as the next catalyst for the FMI story.

S&P 600 Health Care Index:	1,214.38
Price:	\$27.99
Price Target:	\$33.00 from \$36.00
Methodology:	
	DCF analysis
52 Week High:	\$45.00
52 Week Low:	\$18.00
Shares Outstanding (mil):	27.7
Market Capitalization (mil):	\$775.3
Book Value/Share:	\$4.34
Cash Per Share:	\$3.98

Key Stats:

Dividend (ann):

Dividend Yield:



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	\$11.5A	\$12.8	\$15.4	\$17.8	\$57.4	(\$0.44)A	(\$0.52)	(\$0.49)	(\$0.49)	(\$1.94)	NM
2014E - Old	\$10.5	\$12.6	\$15.5	\$18.2	\$56.8	(\$0.50)	(\$0.50)	(\$0.50)	(\$0.52)	(\$2.01)	NM
2015E - New					\$108.3	l				(\$1.67)	NM
2015E - Old					\$112.7					(\$1.74)	NM
2016E - New					\$203.4	l				(\$0.13)	NM
2016E - Old					\$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 \$33 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 \$33 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 dulluation Medicine inc.	(1 1 4 11 <i>)</i>											Dan Leonard,	212-211-0110	
Income statement												dan.leonard	d@leerink.com	
Period Ended (\$ thousands)	2011	2012	Mar-13	Jun-13	Sep-13	Dec-13	2013	Mar-14	Jun-14e	Sep-14e	Dec-14e	2014e	2015e	2016e
Revenues	\$2,057	\$10,645	\$5,200	\$5,920	\$8,208	\$9,662	\$28,990	\$11,455	\$12,756	\$15,377	\$17,765	\$57,352	\$108,298	\$203,388
Cost of product sales	<u>258</u>	5,681	2,378	2,219	2,858	4,204	11,659	5,291	5,740	6,458	7,106	24,595	43,319	71,186
Gross profit	1,799	4,964	2,822	3,701	5,350	5,458	17,331	6,164	7,016	8,918	10,659	32,757	64,979	132,202
SG&A	8,547	12,098	4,961	7,630	9,486	12,114	34,191	11,390	13,394	13,839	14,212	52,835	70,394	85,423
R&D	9,023	14,777	4,982	6,097	6,988	6,834	24,901	6,915	8,036	<u>8,918</u>	10,303	34,173	43,319	50,847
Operating income (loss)	(15,771)	(21,911)	(7,121)	(10,026)	(11,124)	(13,490)	(41,761)	(12,141)	(14,415)	(13,839)	(13,856)	(54,251)	(48,734)	(4,068)
Interest expense (income)	421	421	76	65	61	33	235	25	3	4	8	40	47	60
Other expense (income)	<u>845</u>	<u>61</u>	<u>6</u>	<u>96</u>	1,278	(432)	948	<u>0</u>	<u>65</u>	<u>65</u>	<u>65</u>	195	260	<u>0</u>
Pretax income	(17,037)	(22,393)	(7,203)	(10, 187)	(12,463)	(13,091)	(42,944)	(12,166)	(14,482)	(13,908)	(13,929)	(54,485)	(49,041)	(4,128)
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)	(12,166)	(14,482)	(13,908)	(13,929)	(54,485)	(49,041)	(\$4,128)
Preferred accretion	(296)	(286)	(50)	(42)	(47)	<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)	(\$12,166)	(\$14,482)	(\$13,908)	(\$13,929)	(\$54,485)	(\$49,041)	(\$4,128)
Basic shares outstanding	2,331	2,395	3,190	3,190	3,565	27,505	9,363	27,734	27,934	28,134	28,334	28,034	29,334	31,184
Diluted shares outstanding	2,331	2,395	3,190	3,190	3,565	27,505	9,363	27,734	27,934	28,134	28,334	28,034	29,334	31,184
EPS diluted	(\$7.44)	(\$9.47)	(\$2.27)	(\$3.21)	(\$3.51)	(\$0.48)	(\$4.60)	(\$0.44)	(\$0.52)	(\$0.49)	(\$0.49)	(\$1.94)	(\$1.67)	(\$0.13)
EPS growth														
Sales growth		417.5%	749.7%	225.8%	170.3%	86.6%	172.3%	120.3%	115.5%	87.3%	83.9%	97.8%	88.8%	87.8%
Clinical tests		1,753	1,140	1,626	2,577	3,752	9,095	4,702	5,567	6,489	7,394	24,151	45,553	75,665
Gross margin	87.5%	46.6%	54.3%	62.5%	65.2%	56.5%	59.8%	53.8%	55.0%	58.0%	60.0%	57.1%	60.0%	65.0%
SG&A % of revenue	415.5%	113.6%	95.4%	128.9%	115.6%	125.4%	117.9%	99.4%	105.0%	90.0%	80.0%	92.1%	65.0%	42.0%
R&D % of revenue	438.6%	138.8%	95.8%	103.0%	85.1%	70.7%	85.9%	60.4%	63.0%	58.0%	58.0%	59.6%	40.0%	25.0%
Operating margin	(766.7%)	(205.8%)	(136.9%)	(169.4%)	(135.5%)	(139.6%)	(144.1%)	(106.0%)	(113.0%)	(90.0%)	(78.0%)	(94.6%)	(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	\$1,847	\$5,006				Г	\$8,312	\$7,556	\$9,039
EBITDA	(\$14,251)	(\$19,017)	(\$6,091)	(\$8,983)	(\$10,038)	(\$11,643)	(\$36,755)					(\$45,939)	(\$41,179)	\$4,972
Free cash flow														
Operating cash flow	(\$14,133)	(\$17,249)	(\$6,694)	(\$7,016)	(\$7,036)	(\$10,020)	(\$30,766)					(\$36,099)	(\$27,228)	\$22,467
Capex	(5,410)	(3,183)	(170)	(1,128)	(2,493)	(3,139)	(6,930)					(7,971)	(7,594)	(15,780)
Free cash flow	(\$19,543)	(\$20,432)	(\$6,864)	(\$8,144)	(\$9,529)	(\$13,159)	(\$37,696)					(\$44,071)	(\$34,821)	\$6,688
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Notes:
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

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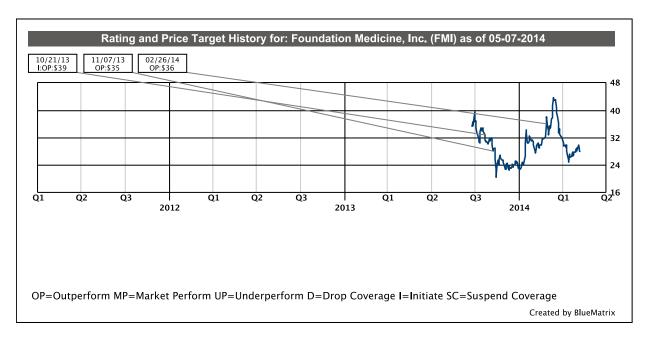
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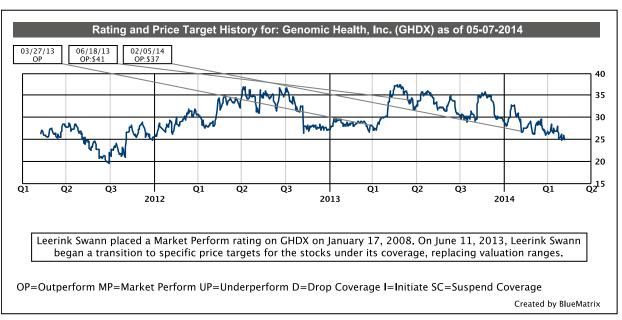
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Risks to Valuation

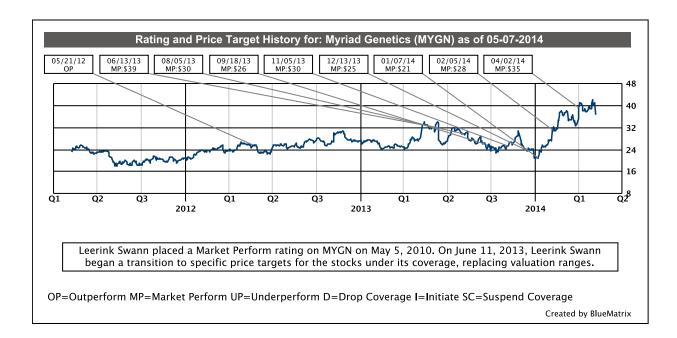
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	Distribution of Ratings/Investment Bank	ing Services (IB	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP]	131	68.23	46	35.11
HOLD [MP]	61	31.77	3	4.92
SELL [UP]	0	0.00	0	0.00

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

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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.



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

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