#### **OUTPERFORM**

Dan Leonard (212) 277-6116 Dan.Leonard@Leerink.com

Dan.Leonard@Leenink.co

Justin.Bowers@Leerink.com

Justin Bowers, CFA (212) 277-6066

Reason for report:

**EARNINGS** 



# FOUNDATION MEDICINE, INC.

2Q Beat, but Estimates Largely Unchanged

- **Bottom Line:** Our outlook for FMI is not meaningfully changed following its 2Q report. We maintain our Outperform rating and our \$33 price target.
- Solid 2Q top-line beat. FMI's reported 2Q revenue of \$14.5M exceeded the Street forecast of \$13.4M and our forecast of \$12.8M. The top-line beat versus our model was driven equally by Biopharma and Clinical. Clinical tests of 5,908 exceeded our estimate by 6%. Gross margin of 54.3% fell short of our 55% expectation. We are modeling gross margin improvement in 2H14 but have nonetheless reduced our forecasts for gross margin following a 1H14 which tracked below our model. Lower-than-anticipated operating expenses drove a slightly lower loss per share than we had modeled (\$0.49 vs \$0.52 est). All in, a solid top-line beat with continued increasing penetration of FoundationOne tests in the community setting (60% of test volume in the quarter, vs 54% in 1Q).
- Enhanced FoundationOne launched. FMI launched an enhanced version of FoundationOne for solid tumors shortly following the New York State Department of Health's approval of FoundationOne and FoundationOne Heme. The updated design now interrogates 314 genes, up from 236, and select rearrangements in 29 genes. FoundationOne Heme continues to ramp well (948k tests in 2Q) following its 1Q launch.
- Biopharma shows upside; Lung-MAP expanded. Biopharma grew 65% y/y and 19% q/q. We believe this and the recent Clovis (OP) partnership are evidence of FMI's growing suite of solutions that it's able to offer Biopharma. FMI has received initial patient samples since the June launch of the Lung Cancer Master Protocol (Lung-MAP) trial. In July, the program expanded to an additional 169 sites and now totals 274 locations.
- No material change in reimbursement. FMI reported no material change in average reimbursement for FoundationOne. The overall average reimbursement rate for clinical tests which meet revenue recognition criteria ticked up slightly to \$3,600 (from \$3,400 in 1Q) due to the higher priced FoundationOne Heme test.
- **Updates to look for in 2H14.** FMI is on track to introduce new features to its Interactive Cancer Explorer physician portal, including outcomes collection capabilities, in 2H14.
- Estimates not materially changed. While our 2014 revenue forecast might now look conservative following 2Q results, we believe it best to adopt this stance in light of the many uncertainties surrounding the early stage adoption curve of a product such as FoundationOne, not the least of which is reimburgement.

Key Stats: (NASDAQ:FMI)

 S&P 600 Health Care Index:
 1,281.85

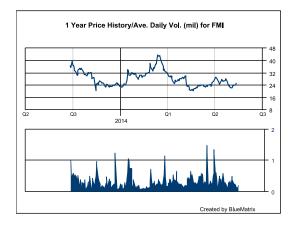
 Price:
 \$25.65

 Price Target:
 \$33.00

Methodology:

~6.5x EV/Jun-16 TTM revenue

52 Week High: \$45.00 52 Week Low: \$18.00 Shares Outstanding (mil): 27.9 Market Capitalization (mil): \$715.6 Book Value/Share: \$3.87 Cash Per Share: \$3.48 Dividend (ann): \$0.00 Dividend Yield: 0.0%



of which is reimbursement.											
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	\$14.5A	\$15.0	\$16.7	\$57.7	(\$0.44)A	(\$0.49)A	(\$0.51)	(\$0.52)	(\$1.97)	NM
2014E - Old	\$11.5A	\$12.8	\$15.4	\$17.8	\$57.4	(\$0.44)A	(\$0.52)	(\$0.49)	(\$0.49)	(\$1.94)	NM
2015E - New					\$108.9	İ				(\$1.76)	NM
2015E - Old					\$108.3					(\$1.67)	NM
2016E - New					\$203.5	İ				(\$0.26)	NM
2016E - Old					\$203.4	İ				(\$0.13)	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 reflects enterprise value, using projected levels of debt and cash, that is ~6.5x our revenue forecast for the 12 months ended June 2016. Note that we've switched our revenue methodology from DCF to a revenue multiple to be more consistent with our methodology for the rest of our emerging growth tools and diagnostics coverage. A multiple of 6.5x is a premium to the median tools/diagnostics peer group multiple of 4x, which we believe is warranted in light of FMI's stronger revenue growth prospects.

## **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) Income statement

Dan Leonard, 212-277-6116 dan.leonard@leerink.com

income statement												dan.ieonard	a@ieerink.com	
Period Ended (\$ thousands)	2011	2012	Mar-13	Jun-13	Sep-13	Dec-13	2013	Mar-14	Jun-14	Sep-14e	Dec-14e	2014e	2015e	2016e
Revenues	\$2,057	\$10,645	\$5,200	\$5,920	\$8,208	\$9,662	\$28,990	\$11,455	\$14,496	\$15,039	\$16,737	\$57,727	\$108,892	\$203,516
Cost of product sales	258	5,681	2,378	2,219	2,858	4,204	11,659	5,291	6,619	6,767	7,532	26,209	45,735	75,301
Gross profit	1,799	4,964	2,822	3,701	5,350	5,458	17,331	6,164	7,877	8,271	9,205	31,518	63,158	128,215
SG&A	8,547	12,098	4,961	7,630	9,486	12,114	34,191	11,390	12,995	13,535	14,226	52,146	70,780	85,477
R&D	9,023	14,777	4,982	6,097	6,988	6,834	24,901	6,915	8,645	9,023	9,707	34,291	43,557	50,879
Operating income (loss)	(15,771)	(21,911)	(7,121)	(10,026)	(11,124)	(13,490)	(41,761)	(12,141)	(13,763)	(14,287)	(14,728)	(54,919)	(51,179)	(8,141)
Interest expense (income)	421	421	76	65	61	33	235	25	16	(7)	(5)	29	(4)	13
Other expense (income)	<u>845</u>	<u>61</u>	<u>6</u>	<u>96</u>	<u>1,278</u>	(432)	948	<u>0</u>	<u>0</u>	<u>65</u>	<u>65</u>	<u>130</u>	<u>260</u>	<u>0</u>
Pretax income	(17,037)	(22,393)	(7,203)	(10,187)	(12,463)	(13,091)	(42,944)	(12,166)	(13,779)	(14,345)	(14,788)	(55,078)	(51,436)	(8,153)
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)	(13,779)	(14,345)	(14,788)	(55,078)	(51,436)	(\$8,153)
Preferred accretion	(296)	(286)	<u>(50)</u>	(42)	<u>(47)</u>	<u>0</u>	<u>(139)</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>O</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)	(\$13,779)	(\$14,345)	(\$14,788)	(\$55,078)	(\$51,436)	(\$8,153)
Basic shares outstanding	2,331	2,395	3,190	3,190	3,565	27,505	9,363	27,734	27,877	28,077	28,277	27,991	29,277	31,127
Diluted shares outstanding	2,331	2,395	3,190	3,190	3,565	27,505	9,363	27,734	27,877	28,077	28,277	27,991	29,277	31,127
EDO III de l	(07.44)	(00.47)	(00.07)	(00.04)	(00.54)	(00.40)	(0.4.00)	(00.44)	(00.40)	(00.54)	(00.50)	(04.07)	(04.70)	(00.00)
EPS diluted	(\$7.44)	(\$9.47)	(\$2.27)	(\$3.21)	(\$3.51)	(\$0.48)	(\$4.60)	(\$0.44)	(\$0.49)	(\$0.51)	(\$0.52)	(\$1.97)	(\$1.76)	(\$0.26)
EPS growth														
Sales growth		417.5%	749.7%	225.8%	170.3%	86.6%	172.3%	120.3%	144.9%	83.2%	73.2%	99.1%	88.6%	86.9%
Clinical tests		1,753	1,140	1,626	2,577	3,752	9,095	4,702	5,908	6,591	7,444	24,644	46,704	76,135
Gross margin	87.5%	46.6%	54.3%	62.5%	65.2%	56.5%	59.8%	53.8%	54.3%	55.0%	55.0%	54.6%	58.0%	63.0%
SG&A % of revenue	415.5%	113.6%	95.4%	128.9%	115.6%	125.4%	117.9%	99.4%	89.6%	90.0%	85.0%	90.3%	65.0%	42.0%
R&D % of revenue	438.6%	138.8%	95.8%	103.0%	85.1%	70.7%	85.9%	60.4%	59.6%	60.0%	58.0%	59.4%	40.0%	25.0%
Operating margin	(766.7%)	(205.8%)	(136.9%)	(169.4%)	(135.5%)	(139.6%)	(144.1%)	(106.0%)	(94.9%)	(95.0%)	(88.0%)	(95.1%)	(47.0%)	(4.0%)
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%
Tax Tato	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070	0.070
D&A expense	\$1,520	\$2,894	\$1,030	\$1,043	\$1,086	\$1,847	\$5,006	\$1,915	\$2,200		Γ	\$8,859	\$7,597	\$9,045
EBITDA	(\$14,251)	(\$19,017)	(\$6,091)	(\$8,983)	(\$10,038)	(\$11,643)	(\$36,755)	(\$10,226)	(\$11,563)			(\$46,060)	(\$43,582)	\$905
	(\$1.1,20.7)	(4.0,0)	(40,00.)	(40,000)	(4.0,000)	(0,0.0)	(400). 00)	(4.0,220)	(4,555)		L	(4.0,000)	(4:0,002)	+000
Free cash flow														
Operating cash flow	(\$14,133)	(\$17,249)	(\$6,694)	(\$7,016)	(\$7,036)	(\$10,020)	(\$30,766)	(\$13,441)			Ī	(\$42,473)	(\$29,651)	\$18,644
Capex	(5,410)	(3,183)	(170)	(1,128)	(2,493)	(3,139)	(6,930)	(174)				(6,429)	(8,744)	(16,031)
Free cash flow	(\$19,543)	(\$20,432)	(\$6,864)	(\$8,144)	(\$9,529)	(\$13,159)	(\$37,696)	(\$13,615)				(\$48,902)	(\$38,395)	\$2,613
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Notes:
Source: Company reports and Leerink Partners estimates

# Foundation Medicine (FMI) Balance sheet

Balance sheet									
Period Ended (\$ thousands)	Dec-12	Mar-13	Jun-13	Sep-13	Dec-13	Mar-14	Jun-14	Sep-14e	Dec-14e
Assets									
Cash, equivalents, ST investments, restricted cash	\$54,838	\$45,832	\$35,965	\$138,088	\$124,293	\$110,308	\$97,054	\$92,037	\$80,716
Accounts receivable	2,195	3,127	4,114	4,437	6,262	7,960	6,067	8,240	9,171
Inventory	803	796	725	942	1,763	2,973	2,593	2,299	2,559
Prepaid expenses and other current assets	<u>550</u>	<u>953</u>	1,004	<u>950</u>	992	<u>1,256</u>	<u>1,191</u>	2,105	2,343
Total current assets	58,386	50,708	41,808	144,417	133,310	122,497	106,905	104,682	94,788
Property and equipment, net	7,465	7,560	7,260	19,480	22,104	22,277	21,696	19,097	18,858
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>	1,315	<u>54</u>	129	<u>121</u>	<u>321</u>	<u>321</u>	321
Total assets	\$66,039	\$60,180	\$52,269	\$165,676	\$157,268	\$146,620	\$130,647	\$125,825	\$115,693
Liabilities and shareholders' equity									
Notes payable - current portion	\$1,704	\$1,739	\$1,712	\$1,540	\$1,499	\$1,058	\$576	\$576	\$576
Accounts payable	1,609	2,336	2,109	3,339	7,007	5,245	5,491	5,191	5,778
Accrued expenses	3,463	3,165	3,530	5,022	5,168	7,506	4,747	7,219	8,034
Deferred revenue	1,622	2,427	2,090	1,304	918	807	693	6,016	6,695
Deferred rent, current portion	132	137	141	149	1,167	1,167	1,178	902	1,004
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	15,783	12,685	19,904	22,086
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>	<u>0</u>	226	<u> 26</u>	9,798	<u>10,502</u>	10,040	10,040	10,040
Total liabilities	\$10,778	\$11,43 <del>2</del>	\$12,380	\$23,031	\$25,557	\$26,285	\$22,725	\$29,944	\$32,126
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	\$120,335	\$107,922	\$95,881	\$83,566
Total liabilities and shareholders' equity	\$66,039	\$60,180	\$52,269	\$165,676	\$157,268	\$146,620	\$130,647	\$125,825	\$115,693

Source: Company reports and Leerink Partners estimates



# **Disclosures Appendix Analyst Certification**

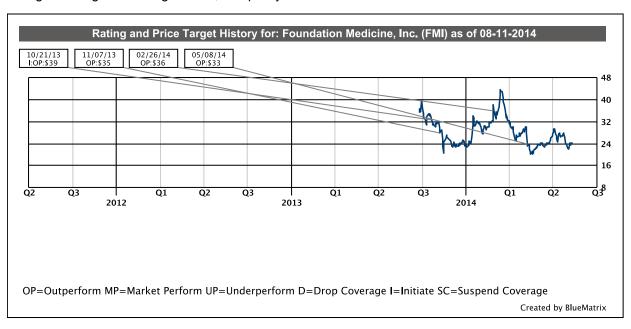
I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

# **Valuation**

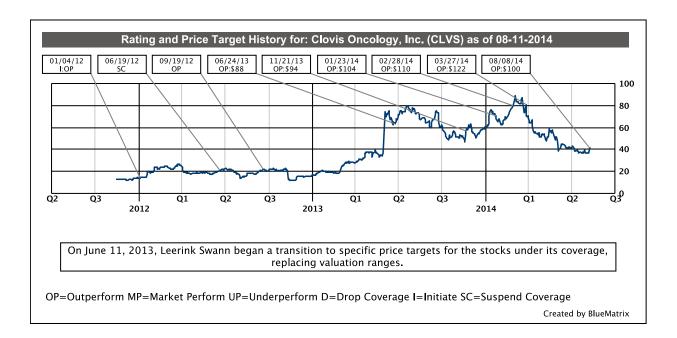
Our 12-month price target of \$33 reflects enterprise value, using projected levels of debt and cash, that is ~6.5x our revenue forecast for the 12 months ended June 2016. Note that we've switched our revenue methodology from DCF to a revenue multiple to be more consistent with our methodology for the rest of our emerging growth tools and diagnostics coverage. A multiple of 6.5x is a premium to the median tools/diagnostics peer group multiple of 4x, which we believe is warranted in light of FMI's stronger revenue growth prospects.

## **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.









	Distribution of Ratings/Investment Bankin	g Services (IB) a		rv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
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. and Clovis Oncology, Inc.

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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	Leerink Partners L	LC Equity Researc	ch					
Director of English Dance 1	Jahra I. Ossillisson OFA	(047) 040 4077						
Director of Equity Research	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com					
Associate Director of Research	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com					
Healthcare Strategy	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com					
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com					
Biotechnology	Howard Liang, Ph.D.	(617) 918-4857	howard.liang@leerink.com					
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com					
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com					
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com					
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com					
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com					
	Richard Goss	(617) 918-4059	richard.goss@leerink.com					
Life Science Tools	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com					
and Diagnostics	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com					
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com					
That madeuticals/inajor	Ario Arabi	(617) 918-4568	ario.arabi@leerink.com					
		(617) 918-4576	aneesh.kapur@leerink.com					
	Aneesh Kapur	(617) 916-4576	aneesn.kapur@ieennk.com					
Specialty Pharmaceuticals	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com					
Medical Devices, Cardiology	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com					
3,	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com					
& Orthopedics	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com					
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com					
		(= :=) =: : : : : :						
Healthcare Services	Ana Gupte, Ph.D.	(212) 277-6040	ana.gupte@leerink.com					
Healthcare Technology	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com					
& Distribution	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com					
Sr. Editor/Supervisory Analyst	Mary Ellen Eagan, CFA	(617) 918-4837	maryellen.eagan@leerink.com					
Supervisory Analysts	Robert Egan	(2.1.) 2.0 .001	bob.egan@leerink.com					
Capel visory / trialysts	Amy N. Sonne		amy.sonne@leerink.com					
Editorial	· · · · ·	(647) 040 4540	-					
Editorial	Cristina Diaz-Dickson	(617) 918-4548	cristina.diaz-dickson@leerink.com					
Research Assistant	Carmen Augustine	(212) 277-6012	carmen.augustine@leerink.com					
1.000aioii / 100i3taiit	Carrion Augustine	(212) 211-0012	Samen.aagastine @iseniik.com					

**New York** 299 Park Avenue, 21<sup>st</sup> floor New York, NY 10171 (888) 778-1653 Boston One Federal Street, 37<sup>th</sup> Floor Boston, MA 02110 (800) 808-7525

San Francisco 201 Spear Street, 16<sup>th</sup> Floor San Francisco, CA 94105 (800) 778-1164