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Foundation Medicine (FMI - OUTPERFORM): Under-the-Radar Palmetto Document Sheds Light on NGS Framework - Step in the Right Direction for Medicare Reimbursement - Reaffirm OUTPERFORM

Price: $28.00 **12-Month Price Target: $50**

- **Palmetto NGS validation guidelines were issued quietly, representing the first detailed document outlining requirements for next-generation sequencing-based tests.** Palmetto, a Medicare Administrative Contractor (MAC), is responsible for administering Medicare insurance in North Carolina, South Carolina, Virginia and West Virginia. Palmetto is a thought leader in molecular diagnostics, having initiated its MolDx program in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests, which we believe is influential across the other regional MACs. Palmetto issued an update recently (appears to have been posted on 7/11, but did not surface through the Palmetto listserv email blast and is difficult to navigate to on their website). The update included a document titled "MolDx Next Generation Sequencing (NGS) Guidelines".http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~General~8PKRZF3404?open&navmenu=Browse^By^Topic|||| . The guidelines appear to be the first detailed document from an MAC or any private insurer with transparency in terms of what they are looking for with respect to next-generation sequencing-based tests. (See Figure 2. Page 3.)

- **We believe the NGS validation guidelines are a slight positive for FMI as they represent a small first step towards developing standards which could eventually lead to Medicare reimbursement.** Prior to these guidelines we believe expectations were low for Palmetto to say anything specific related to next-gen sequencing-based tests this year.

- **The next logical step would be for Palmetto to establish performance requirements for NGS-based tests. The timing of this next step is unknown. Perhaps Palmetto wants to keep the ball rolling?** The Medicare process remains opaque. It's unclear what exactly is happening to the claims FMI submits to Medicare and there does not appear to be a drop-dead date for them to make a decision. The company continues to submit its claims to NGS, its Medicare Administrative Contractor, where there is a dialogue of denials and appeals between the two, as well as a de minimis level of revenue coming from these claims.

- **Reaffirming OUTPERFORM.** We arrive at our $50 price target through an EV/sales valuation framework, assuming a ~9x 2016E EV/sales multiple with no net cash and 29 MM shares outstanding, discounted back at 15%. This multiple is justified to us given FMI's hyper growth profile (~83% 3-year CAGR, +60% in 2016), cancer focus and the very early stages of adoption (~10% share in 2016). On a 2015E EV/sales multiple basis, shares of FMI are trading at a premium to the current group median (7x vs 4x).

Investment Thesis

FMI is a lab services company whose test menu is focused on the genetic analysis of rare, recurring and aggressive tumors. FMI's testing platform leverages next-generation sequencing (NGS) to identify clinically actionable genetic mutations within tumor cells. The company's two tests are FoundationOne, a pan-cancer panel for solid tumors, and FoundationOne Heme, a panel for hematological malignancies (i.e., leukemia, lymphoma & myeloma). These tests are targeted for use by academic and community-based oncologists, as well as biopharmaceutical companies for use in cancer therapeutic R&D. We believe FMI's FoundationOne test represents the first mover and highest-quality test commercially available for detailed genomic workup of tumors. We estimate the company's test volumes and sales will grow above an 85% CAGR for the next three years and we believe FMI has many years of significant growth potential ahead as the opportunity in solid tumors, blood-based cancers and future cancer monitoring products is largely untapped. We believe investors are overly concerned about potential competitive threats and potential challenges to reimbursement near term which are overhangs on the shares currently. We believe continued strong execution by the company, lack of viable competition and continued reimbursement progress with large payors will drive solid financials, thus inspiring confidence and meaningful share price appreciation in the near term. We believe the late 2013 addition of high-quality sales reps, improving sales force efficiency and recent menu expansion, combined with growing physician awareness tees up a strong case for test volume outperformance in the near term. Additionally, we believe sentiment on shares is medium-low and based primarily on reimbursement concerns. Based on the slightly earlier clinical outcomes data from US oncology and better traction with the higher priced FoundationOne heme test recently, we believe average reimbursement is likely to get easier, representing near-term validation for our long-term thesis.

Figure 1: Potential Catalysts

Catalyst	Timing
Earnings	Aug-14
ASCO publications	2H14/2015
FoundationOne Solid enhancements	2H14
Additional product launches/enhancements	2015
In-Network Contracts with Large Payors	??
CMS coverage decision	??

Source: Company data, Wedbush Securities, Inc.

Figure 2: Palmetto Next-Generation Sequencing Validation Guidelines (Pg. 1 of 4)

Next Generation Sequencing (NGS) Validation Guidelines

The table below represents an adaptation of analytical and clinical performance characteristics described in CTEP for NGS-based tests. (Note that "other required elements" listed as part of the CTEP AVCV guidelines remain unchanged, as does the process for evaluation of clinical utility.)

For each validation element, please provide a brief description of the experimental design (e.g., types of samples; number of samples, operators, instruments, runs, days; number of replicates; data analysis; endpoints; etc.) and a summary of the final results including any statistical analyses performed. Also indicate the location (dossier or publication) with page and section numbers for the additional detailed information.

Validation Element	Validation Element Detail*	Comments	Information Location
Accuracy	Method Comparison(s)	Specify reference method (e.g., bidirectional Sanger sequencing). Report overall, by tumor type and morphology (if applicable), and by variant type (e.g., single nucleotide variants, indels, copy number variations, translocations).** For "targeted" sequencing, include variants of each type representing a range of performance (e.g., "best", "worst", and "average" amplicons). For each type of variant (e.g., single nucleotide variants, indels, copy number variations, translocations), include range of expected alterations, including allele frequency, insertion/deletion length, amplitude of copy number changes, and variety of possible gene fusions, utilizing real-world clinical specimens, if possible, or constructed models with known properties. Include at least 2 well-characterized reference samples (e.g., HapMap DNA NA12878 and NA19240) to determine sequencing error rate.	
	Specimen Types	Include all applicable specimen types (e.g., FFPE, fresh frozen, core biopsy, cytology).	
	Matrix Comparison(s)	Include all applicable sample matrices (e.g., serum, plasma).	
Analytical Sensitivity	Analytical Sensitivity	The probability that the assay will detect a sequence variation, if present. Report overall and by variant type.	
	Limit of Detection	Lowest quantity of nucleic acid that can be sequenced reliably and distinguished from its absence with stated confidence limit Report by variant type (e.g., minimum detectable allelic fraction or minimum detectable amplitude for CNV).	
	Limits of Quantitation (Upper and Lower, if applicable)	Description of analytically measurable (AMR) and clinically reportable range for quantitative tests. Report by variant type.	
	Linearity and Reportable Range	Genomic region in which sequence of "acceptable quality" can be derived Linearity required if quantitative	
	Minimum Input Quantity and Quality	DNA, RNA, etc. Typically represents a criterion for sample rejection. Include minimum library concentration if appropriate.	
	Minimum Tumor Content (if applicable)	Evaluate in conjunction with minimum input.	
Analytical Specificity	Analytical Specificity	Probability assay will not detect a sequence variation, if absent. Report overall and by variant type.	
	Primer and Probe Specificity	Include primer and probe lists and method for determining specificity (e.g., BLAST).	
	Interfering Substances	Varies with acceptable specimen types	
Precision	Repeatability	Single operator, instrument, lot, day and run	

Link: http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~General~8PKRZF3404?open&navmenu=Browse^By^Topic||||

Source: Company data, Wedbush Securities, Inc.

Figure 3: Potential Competitors

Company/Group	Product	Genomic Coverage	# of genes	Platform	DNA sample	Turnaround Time	Launch	Price
Foundation Medicine (FMI)	FoundationOne	~590x	236	HiSeq	50-200 ng	14-17 days	Jun-12	$5,800
OncoDNA (Private, Belgium)	OncoDEEP Dx	~1000x	40	IonTorrent	10 ng	5-10 days	??	TBD
LabCorp (LH)	IntelliGEN	TBD	50 (2600 mutations)	HiSeq or MiSeq?	TBD	TBD	??	$3,200-$4,000
University of Washington	OncoPlex	>500x	194	HiSeq	5000 ng	8 weeks	??	$2,400
Memorial Sloan Kettering	MSK-IMPACT	>500x	340	HiSeq	??	??	May-14	??
Quest Diagnostics	OncoAdvantage	??	34	HiSeq	??	??	Jun-14	??
Molecular Health	TreatmentMAP	??	??	HiSeq		7-14 days	4/1/2014?	??
ParadigMdx	PCDx	>5000x	114	HiSeq	??	4-5 days	Apr-14	??

Source: Company data, Wedbush Securities, Inc.

Figure 4: Important Clinical Outcomes Data History

Study/Sponsor	Description	Event	Date
Rutgers Study	72 tumors, 1 genomic alteration in 95% of cases and implemented clinical action in ~15% of cases	AACR	4/2/2014
Memorial Sloan-Kettering	Study of lung adenocarcinomas. Identified actionable alterations in 2/3rd of cases where prior molecular testing was negative.	ASCO	5/14/2014
US Oncology	Study of advanced solid tumors. FoundationOne led to an altered therapeutic choice in 28% of patients.	ASCO	5/14/2014
Several collaborating cancer centers	Study of 1,070 lung carcinomas found that FMI detects ~50% more ALK rearrangements than the standard FISH-based test. The FISH negative & FoundationOne positive patients had a 70% response rate to crizotinib.	ASCO	5/14/2014

Source: Company data, Wedbush Securities, Inc.

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 their Cambridge, MA headquarters where they conduct *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 5: Income Statement

	2011	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Product Revenue	2,057	10,645	28,990	11,455	13,534	16,099	19,000	60,088	21,772	25,760	29,807	33,692	111,032	178,510
Total Revenues	2,057	10,645	28,990	11,455	13,534	16,099	19,000	60,088	21,772	25,760	29,807	33,692	111,032	178,510
Cost of revenues	258	5,681	11,659	5,291	6,090	7,244	8,550	27,176	8,709	10,304	11,923	13,477	44,413	66,647
COGS as % of sales			36%											
Gross profit	1,799	4,964	17,331	6,164	7,444	8,854	10,450	32,912	13,063	15,456	17,884	20,215	66,619	111,862
Gross Margins	87.5%	46.6%	59.8%	53.8%	55.0%	55.0%	55.0%	54.8%	60.0%	60.0%	60.0%	60.0%	60.0%	62.7%
				165	166	157	158							
Selling and Marketing	1,555	3,454	12,508	5,690	7,308	7,244	7,600	27,843	8,491	9,789	9,836	11,455	39,572	55,172
General and administrative	6,992	8,644	21,865	5,700	6,000	6,400	7,500	25,600	7,600	7,700	7,800	7,850	30,950	35,200
Research and development	9,023	14,777	24,901	6,915	7,300	7,600	7,700	29,515	8,300	8,600	8,900	9,200	35,000	36,000
Total operating expenses	17,570	26,875	59,275	18,305	20,608	21,244	22,800	82,958	24,391	26,089	26,536	28,505	105,522	126,372
Operating Income	(15,771)	(21,911)	(41,944)	(12,141)	(13,165)	(12,390)	(12,350)	(50,046)	(11,328)	(10,633)	(8,652)	(8,290)	(38,903)	(14,509)
Interest income	(421)	(421)	(1,452)	(25)	280	257	225	737	183	166	135	108	593	209
Other	(845)	(61)	269	0	0	0	0	0	0	0	0	0	0	0
Income before taxes	(17,037)	(22,393)	(43,127)	(12,166)	(12,885)	(12,133)	(12,125)	(49,308)	(11,144)	(10,467)	(8,517)	(8,182)	(38,310)	(14,300)
Provision for income taxes	0	0	-	0	0	0	0	0	0	0	0	0	0	10
Tax Rate														(0)
Net income	(17,037)	(22,393)	(43,129)	(12,166)	(12,885)	(12,133)	(12,125)	(49,308)	(11,144)	(10,467)	(8,517)	(8,182)	(38,310)	(14,310)
Accretion of convertible preferred stock	(296)	(286)	(139)	0	0	0	0	0	0	0	0	0	0	0
Net Income	(17,333)	(22,679)	(43,268)	(12,166)	(12,885)	(12,133)	(12,125)	(49,308)	(11,144)	(10,467)	(8,517)	(8,182)	(38,310)	(14,310)
GAAP EPS -Basic	($3.52)	($0.41)	($2.09)	($0.44)	($0.46)	($0.44)	($0.44)	($1.77)	($0.40)	($0.37)	($0.30)	($0.29)	($1.37)	($0.51)
GAAP EPS -Diluted	($3.52)	($0.41)	($2.08)	($0.44)	($0.46)	($0.44)	($0.44)	($1.77)	($0.40)	($0.37)	($0.30)	($0.29)	($1.37)	($0.51)
Non-GAAP EPS -Diluted	**($3.52)**	**($0.41)**	**($2.08)**	**($0.44)**	**($0.46)**	**($0.44)**	**($0.44)**	**($1.77)**	**($0.40)**	**($0.37)**	**($0.30)**	**($0.29)**	**($1.37)**	**($0.51)**
Weighted average shares - basic	4,930	55,642	21,577	27,734	27,775	27,817	27,859	27,796	27,914	27,956	27,998	28,040	28,040	28,223
Weighted average shares - diluted	4,930	55,642	21,778	27,734	27,775	27,817	27,859	27,796	27,914	27,956	27,998	28,040	28,040	28,223
		proforma												
Cash and Equivalents	10,852	54,838	124,293	112,000	102,983	89,905	73,348	73,348	66,378	54,005	43,318	28,159	28,159	2,204
Net Cash	10,852	54,838	124,293	112,000	102,983	89,905	73,348	73,348	66,378	54,005	43,318	28,159	28,159	2,204
Net Cash/share			5	4	4	3	3	3	2.38	1.93	1.55	1.00	1	0
NOLs			(52,991)	(65,157)	(78,042)	(90,174)	(102,299)	(102,299)	(113,444)	(123,911)	(132,428)	(140,609)	(140,609)	(154,920)

% of Sales	**2011**	**2012**	**2013**	**1Q14**	**2Q14E**	**3Q14E**	**4Q14E**	**2014E**	**1Q15E**	**2Q15E**	**3Q15E**	**4Q15E**	**2015E**	**2016E**
Gross Margins	87%	47%	60%	54%	55%	55%	55%	55%	60%	60%	60%	60%	60%	63%
Sales and Marketing	76%	32%	43%	50%	54%	45%	40%	46%	39%	38%	33%	34%	36%	31%
General and administrative	340%	81%	75%	50%	44%	40%	39%	43%	35%	30%	26%	23%	28%	20%
Research and development	439%	139%	86%	60%	54%	47%	41%	49%	38%	33%	30%	27%	32%	20%
Total operating expenses	854%	252%	204%	160%	152%	132%	120%	138%	112%	101%	89%	85%	95%	71%
EBIT	-767%	-206%	-145%	-106%	-97%	-77%	-65%	-83%	-52%	-41%	-29%	-25%	-35%	-8%
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net income	-843%	-213%	-149%	-106%	-95%	-75%	-64%	-82%	-51%	-41%	-29%	-24%	-35%	-8%
Free Cash Flow	-1015%	-199%	-132%	-59%	-86%	-70%	-77%	-74%	-22%	-39%	-27%	-37%	-32%	-7%

y/y Δ	**2011**	**2012**	**2013**	**1Q14**	**2Q14E**	**3Q14E**	**4Q14E**	**2014E**	**1Q15E**	**2Q15E**	**3Q15E**	**4Q15E**	**2015E**	**2016E**
Total Revenues	NA	418%	172%	120%	129%	96%	97%	107%	90%	90%	85%	77%	85%	61%
Cost of revenues	NA	2102%	105%	122%	174%	153%	103%	133%	65%	69%	65%	58%	63%	50%
Gross Margins	NA	-47%	28%	-1%	-12%	-16%	-3%	-8%	12%	9%	9%	9%	10%	4%
Sales and Marketing	NA	122%	262%	214%	139%	138%	65%	123%	49%	34%	36%	51%	42%	39%
General and administrative	NA	24%	153%	81%	26%	-1%	0%	17%	33%	28%	22%	5%	21%	14%
Research and development	NA	64%	69%	39%	20%	9%	13%	19%	20%	18%	17%	19%	19%	3%
Total operating expenses	NA	53%	121%	84%	48%	29%	20%	40%	33%	27%	25%	25%	27%	20%
EBIT	NA	39%	91%	70%	29%	11%	-8%	19%	-7%	-19%	-30%	-33%	-22%	-63%
Tax rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Net income	NA	31%	91%	68%	24%	-3%	-7%	14%	-8%	-19%	-30%	-33%	-22%	-63%

Source: Company data, Wedbush Securities, Inc.

Figure 6: Balance Sheet

	2011	2012	2013E	2014E	2015E	2016E
Current assets:						
Total Cash and Cash Equivalents	10852	54,838	124,293	73,348	28,159	2,204
Accounts Receivable	278	2,195	6,262	9,500	16,846	26,412
Inventory	318	803	1,763	1,583	2,808	4,402
Prepaid expenses and other Current Assets	313	550	992	992	992	992
Total current assets	**11,761**	**58,386**	133,310	85,423	48,805	34,010
Property, Plant and Equipment	7,902	12,154	22,104	25,108	30,660	39,586
Accumulated Depreciation	(1,796)	(4,689)		(4,615)	(10,003)	(16,731)
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	107,771	71,316	58,719
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts Payable and accrued expenses	2,408	5,072	7,007	6,818	8,673	10,387
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	15,570	17,425	19,139
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	25,368	27,223	28,937
Stockholders' equity:						
Preferred Stock	32,455	98,658	0	0	0	0
Common Stock, APIC, RE	(22,303)	(43,397)	131,711	82,403	44,093	29,782
Total liabilities and stockholders' equity	**18,065**	**66,039**	157,268	107,771	71,316	58,719

Source: Company data, Wedbush Securities, Inc.

Figure 7: Cash Flow Statement

	2011	2012	2013	2014E	2015E	2016E
Cash Flows from Operating Activities:						
Net (loss) income	(17,037)	(22,393)	(42,944)	(49,308)	(38,310)	(14,310)
Depreciation	1,520	2,894	5,006	4,615	5,388	6,728
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)	(3,247)	(6,716)	(9,447)
Net cash provided by operating activities	**(14,133)**	**(17,249)**	**(30,766)**	**(47,941)**	**(39,637)**	**(17,030)**
Cash Flows from Investing Activities:						
Purchase of property and equipment	(5,410)	(3,183)	(6,930)	(3,004)	(5,552)	(8,925)
increase in restricted cash	0		(1,564)	0	0	0
Net cash used in investing activities	**(5,410)**	**(3,183)**	**(8,494)**	**(3,004)**	**(5,552)**	**(8,925)**
				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	(50,945)	(45,189)	(25,955)
Cash and cash equivalents, beginning of period		10,852	54,838	124,293	73,348	28,159
Cash and cash equivalents, end of period	**10,852**	**54,838**	**124,293**	**73,348**	**28,159**	**2,204**

Source: Company data, Wedbush Securities, Inc.

Company	Ticker	Rating	Price Target	Current Price
Illumina	ILMN	NEUTRAL	$155	$181

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.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ214.pdf

Investment Rating System:
Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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 June 30, 2014)	**Investment Banking Relationships (as of June 30, 2014)**
Outperform:54% Neutral: 42% Underperform: 4%	Outperform:25% Neutral: 1% Underperform: 0%

The Distribution of Ratings is required by FINRA rules; however, WS' stock ratings of Outperform, Neutral, and Underperform most closely conform to Buy, Hold, and Sell, respectively. Please note, however, the definitions are not the same as WS' stock ratings are on a relative basis.

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Wedbush Equity Research Disclosures as of July 23, 2014

Company	Disclosure
Foundation Medicine Illumina	1 1

Research Disclosure Legend
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2. WS managed a public offering of securities within the last 12 months.
3. WS co-managed a public offering of securities within the last 12 months.
4. WS has received compensation for investment banking services within the last 12 months.
5. WS provided investment banking services within the last 12 months.
6. WS is acting as financial advisor.
7. WS expects to receive compensation for investment banking services within the next 3 months.
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9. WS has received compensation for products and services other than investment banking services within the past 12 months.
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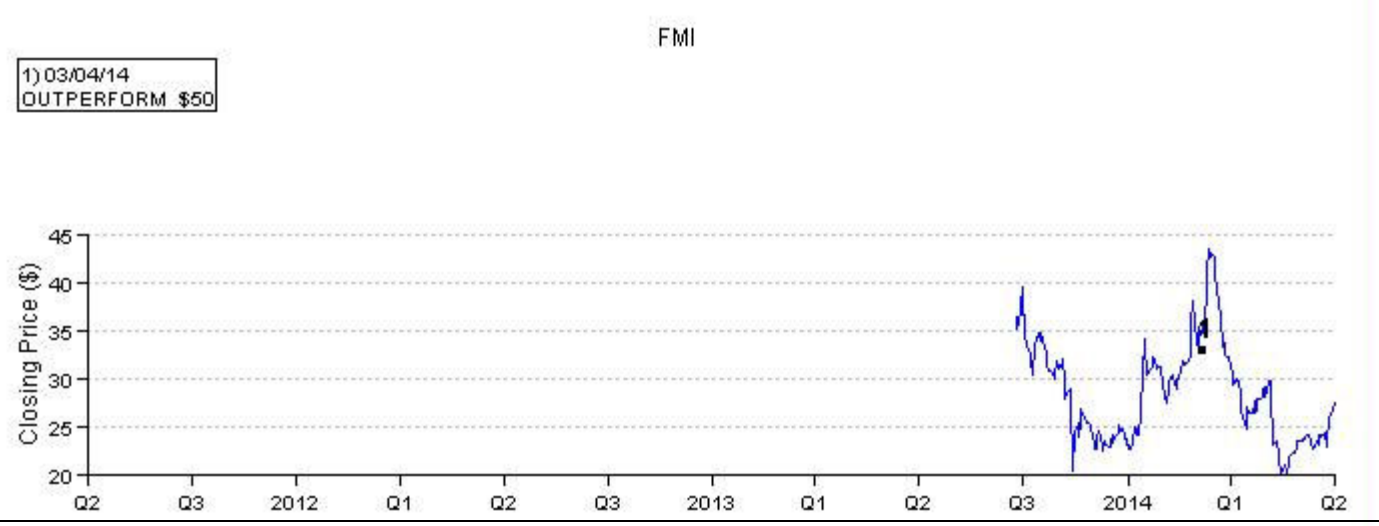
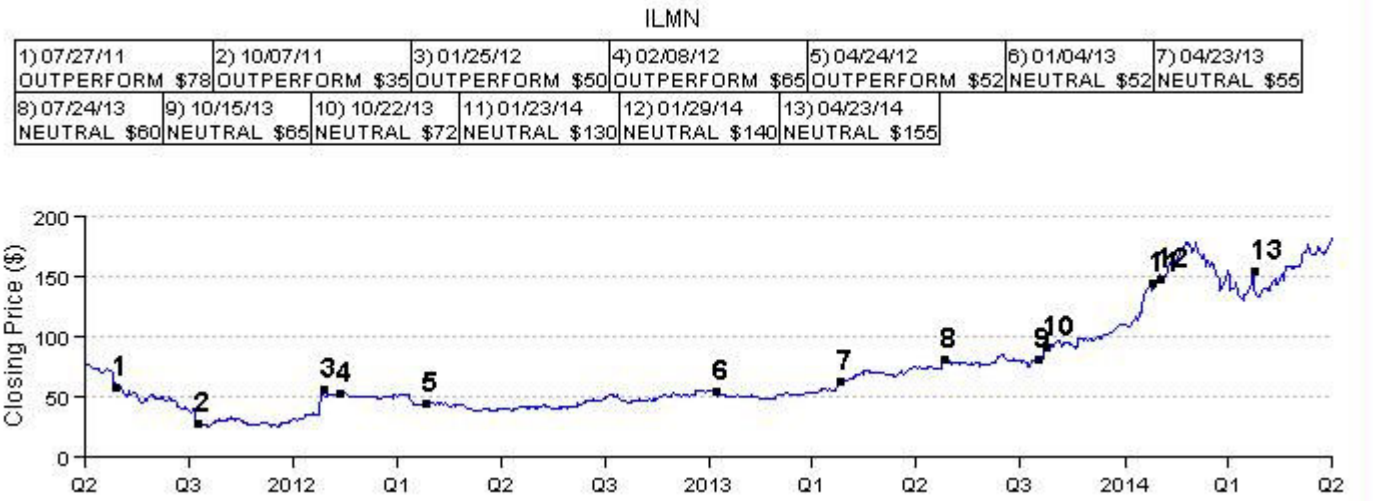
Wedbush disclosure price charts are updated within the first fifteen days of each new calendar quarter per FINRA regulations. Price charts for companies initiated upon in the current quarter, and rating and target price changes occurring in the current quarter, will not be displayed until the following quarter. Additional information on recommended securities is available on request.





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