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Zarak Khurshid (415) 274-6823

Foundation Medicine (FMI - OUTPERFORM): Post NDR Update - Reaffirming OP on the Direction and Frequency of Payor Discussions - Greater Appreciation for Clinical Trial Master Protocol Trends

Price: \$24.75

12-Month Price Target: \$50

- **We were generally encouraged following two days of investor meetings in the Midwest.** We hosted meetings between CEO Mike Pellini, CMO Vince Miller, Sr. VP of Finance Jason Ryan and Sr. Director of IR Khaled Habayeb and high-quality investors in Minneapolis and Chicago over the last two days.
- **Encouraged by the consistent positive directionality and frequency of the large payor discussions.** Management said that they “feel good” about the payor talks and the company has daily dialogue with the large payors. Additionally, the company says that the discussions have progressed from educational to more detailed conversations and that the payors are not saying Medicare reimbursement is necessary prior to establishing coverage. As a reminder, FMI has yet to sign an in-network contract with a large payor and if they were to do this, we believe it would be very positive for the long-term story and could drive meaningful adoption from those oncologists more sensitive to payor coverage. FMI was not sure what the payors need to see at this stage to issue official coverage decisions. The company’s tone regarding reimbursement levels from the large payors appeared to be consistent with the last 12 month’s results where reimbursement per paid sample hovered in the area of \$3,400. We continue to believe that the payors would have stopped paying the company a while ago if it was their intention to not cover FoundationOne.
- **The Medicare process remains opaque. It’s unclear what exactly is happening to the claims 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. According to the company, there does not appear to be a set date for a Medicare coverage decision.
- **Greater appreciation for new trends in clinical trial design (i.e., master protocols) that could help drive awareness and adoption of FoundationOne.** The recently launched Lung Cancer Master protocol is a new approach to clinical trials that involves one clinical trial for testing multiple drugs. The trial uses genomic profiling to match patients to one of several different investigational treatments that are designed to target genomic alterations. The beauty of the approach is that the enrollment process is more efficient, drugs can be dropped or added quickly and testing is more consistent. FoundationOne is the designated profiling test for the Lung Cancer Master Protocol, which began enrolling in the last few weeks. As part of the Lung Cancer Master protocol, 200 community sites (with 5-8 oncologists each) will be screening 500-1,000 patients per year, which represents paid testing volume as well as positive exposure to roughly 10% of the total oncologist market. Additional master protocols are under foot by Genentech and others and we believe genomically driven master protocols are likely to continue to increase going forward, which can only be positive for FMI.
- **Early days for outcomes database, but still important as a long-term differentiator.** As a reminder, given FMI’s first-mover advantage, we believe the company is well positioned to establish the largest database of outcomes data from off-label use of targeted cancer therapies, which could be extremely valuable. The company appeared to talk more about building its database of clinical outcomes data and it appears that FMI will populate the database using multiple sources including electronic medical records, features of its interactive cancer explorer and customers outreach.
- **Vibes on sales force ramp not quite as positive.** The company continued to highlight that they believe it takes 18 months for sales reps to become “very effective” and six months to be selling in a confident way. That said, management stressed the quality of its newer reps, many of who are award winning (President’s Club) reps for large players in cancer diagnostics.
- **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 (5.9x vs 3.8x).

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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: 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?	??
ParadigmMdx	PCDx	>5000x	114	HiSeq	??	4-5 days	Apr-14	??

Source: Company data, Wedbush Securities, Inc.

Figure 3: 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 4: 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%
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
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 5: 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 6: 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)
Cash Flows from Financing Activities:						
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	\$174

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.

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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.

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Rating Distribution (as of June 30, 2014)	Investment Banking Relationships (as of June 30, 2014)
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Neutral: 42%	Neutral: 1%
Underperform: 4%	Underperform: 0%

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Wedbush Equity Research Disclosures as of July 11, 2014

Company	Disclosure
Foundation Medicine	1
Illumina	1

Research Disclosure Legend

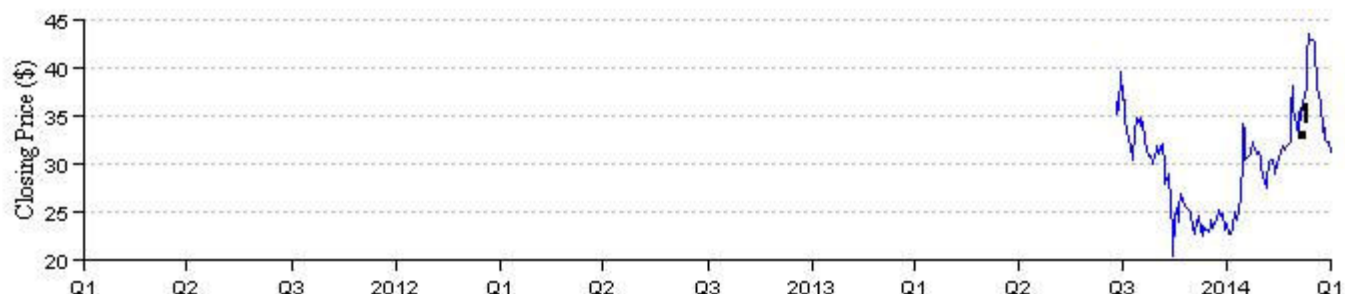
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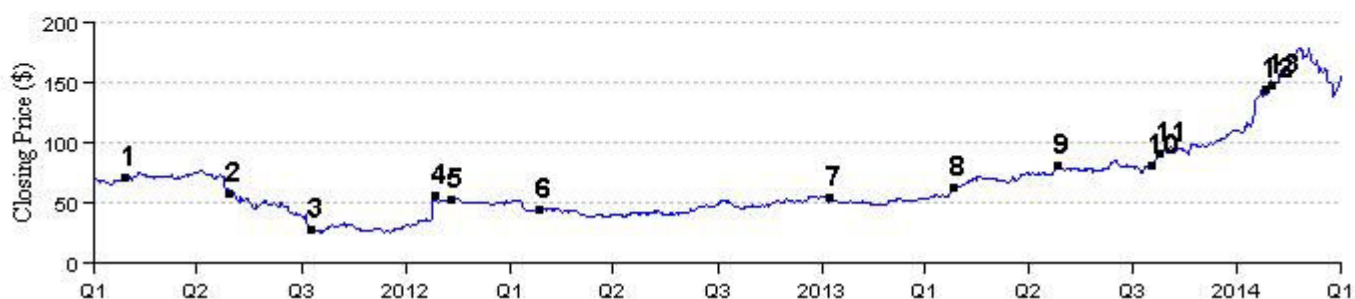
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FMI

1) 03/04/14
OUTPERFORM \$50


ILMN

1) 04/27/11	2) 07/27/11	3) 10/07/11	4) 01/25/12	5) 02/08/12	6) 04/24/12
OUTPERFORM \$80	OUTPERFORM \$78	OUTPERFORM \$35	OUTPERFORM \$50	OUTPERFORM \$65	OUTPERFORM \$52
7) 01/04/13	8) 04/23/13	9) 07/24/13	10) 10/15/13	11) 10/22/13	12) 01/23/14
NEUTRAL \$52	NEUTRAL \$55	NEUTRAL \$60	NEUTRAL \$65	NEUTRAL \$72	NEUTRAL \$130
					13) 01/29/14
					NEUTRAL \$140



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EQUITY RESEARCH DEPARTMENT

(213) 688-4529

DIRECTOR OF RESEARCH

Mark D. Benson (213) 688-4435

MANAGER, RESEARCH OPERATIONS

Ellen Kang (213) 688-4529

RETAIL AND CONSUMER

Consumer Products

Rommel T. Dionisio (212) 938-9934
Alicia Reese (212) 938-9927

Footwear, Apparel and Accessories

Corinna Freedman (212) 668-9876

Healthy Lifestyles

Kurt M. Frederick, CFA CPA (415) 274-6822
Alicia Reese (212) 938-9927

Restaurants

Nick Setyan (213) 688-4519
Colin Radke (213) 688-6624

Specialty Retail: Hardlines

Joan L. Storms, CFA (213) 688-4537
John Garrett, CFA (213) 688-4523

Seth Basham, CFA (212) 938-9954

Specialty Retail: Softlines

Morry Brown (213) 688-4311
Taryn Kuida (213) 688-4505

INDUSTRIAL GROWTH TECHNOLOGY

Clean Technology

Craig Irwin (212) 938-9926

Environmental Services / Building Products

Al Kaschalk (213) 688-4539

Water and Renewable Energy Solutions

David Rose, CFA (213) 688-4319
James Kim (213) 688-4380

TECHNOLOGY, INTERNET, MEDIA & SOCIAL MEDIA

Communications and Application Software

Shyam Patil, CFA (213) 688-8062
Andy Cheng (213) 688-4548

Enterprise Security

Sanjit Singh (415) 273-7323

Computer Services: Financial Technology

Gil B. Luria (213) 688-4501
Aaron Turner (213) 688-4429

Enterprise Software

Steve Koenig (415) 274-6801
Kevin Ikeda (213) 688-4423

Entertainment: Retail

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Entertainment: Software

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Internet: Media and Gaming

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Internet: Social Media, Advertising & Technology

Shyam Patil, CFA (213) 688-8062
Andy Cheng (213) 688-4548

Media

James Dix, CFA (213) 688-4315

Movies and Entertainment

Michael Pachter (213) 688-4474
Nick McKay (213) 688-4343
Nick Citrin (213) 688-4495

Semiconductors

Betsy Van Hees (415) 274-6869
Ryan Jue, CFA (415) 263-6669

LIFE SCIENCES AND HEALTH CARE

Biotechnology/Biopharmaceuticals/BioDefense

David M. Nierengarten, Ph.D. (415) 274-6862
Dilip Joseph (415) 273-7308

Emerging Pharmaceuticals

Liana Moussatos, Ph.D. (415) 263-6626

Healthcare Services - Managed Care

Sarah James (213) 688-4503

Medical Devices

Tao Levy (212) 938-9948

Medical Diagnostics and Life Sciences Tools

Zarak Khurshid (415) 274-6823

EQUITY SALES

Los Angeles (213) 688-4470 / (800) 444-8076
San Francisco (415) 274-6800
New York (212) 938-9931
Boston (617) 832-3700

EQUITY TRADING

Los Angeles (213) 688-4470 / (800) 421-0178
San Francisco (415) 274-6811
New York (212) 344-2382
Boston (617) 832-3700

CORPORATE HEADQUARTERS

1000 Wilshire Blvd., Los Angeles, CA 90017-2465

Tel: (213) 688-8000 www.wedbush.com
