# **COMPANY NOTE**

Target | Estimate Change

USA | Healthcare | Biotechnology

November 17, 2014

# **Jefferies**

## BUY

Price target \$46.00 (from \$35.00)

Price \$39.34

# Kite Pharma (КІТЕ)

# Q3 Update: Awaiting Start of Pivotal PII for **DLBCL in Early 2015**

#### **Key Takeaway**

Q3 GAAP EPS loss was higher than expected on higher expenses. We believe KITE shares hold significant promise based on PI/II data, with KTE-C19 observing robust responses in refractory lymphomas and leukemias and thereby supporting our favorable outlook in its pivotal PII in 3rd-line DLBCL expected to start in H1'15. Additional PI/II data will be presented at ASH '14 in Dec. We maintain Buy rating and raise our PT to \$46 (v. \$35 prev).

Awaiting Start of Pivotal PII for 3rd-line DLBCL in Early 2015: We anticipate a strong response rate in the upcoming pivotal PII third-line DLBCL trial evaluating KTE-C19 in a single-arm design enrolling >40 patients, and this is supported by the NCI PI/II trial observing a strong objective response in patients with relapsed/refractory DLBCL. Data from the pivotal trial in third-line DLBCL is anticipated in mid-'16, and we estimate risk-adj peak sales of \$526 million in DLBCL. Additional indications may generate risk-adj peak sales of \$559 million across other refractory/relapsed lymphomas and leukemias. We estimate riskadj sales in the EU of \$457 million and believe KITE could receive a 20% royalty on topline sales. Our model does not assume potential upfront/milestone payments associated with ex-U.S. licensing agreement. Additional data on KTE-C19 will be presented at ASH '14 in Dec.

Early Stage Programs Offer Additional Upside: The company has licensed rights to a CAR-T v. EGFRvIII in glioblastoma and to TCR targeting NY-ESO-1 antigen for solid tumors. Both programs are currently in an ongoing NCI-sponsored PI/II trial with KITE-sponsored trials estimated to initiate in 2016. Clinical data with NCI's NY-ESO-1 TCR program reported a robust 67% objective response rate in fifteen patients with refractory synovial sarcoma and 53% response rate in nineteen patients with refractory metastatic melanoma. Both programs offer upside to our model, and we anticipate interim data updates from the ongoing NCI PI/II trials in the next 12-24 months.

Q3 Financials: KITE reported Q3 GAAP EPS of (\$0.24) v. JEF est of (\$0.06) and cons of (\$0.17) on higher expenses. Cash and equivs were \$195.4M as of end Q3. We have also moved our ex-DLBCL approval up by 1-yr, which increases our PT to \$46 (v. \$35 prev) given KITE believes it could initiate trials in other lymphoma/leukemia indications in 2015.

## Valuation/Risks

Our PT of \$46 (v. \$35 prev) is DCF-based. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

USD	Prev.	2013A	Prev.	2014E	Prev.	2015E	Prev.	2016E
Rev. (MM)		0.0		0.0		0.0		0.0
EPS								
Mar				(0.66)A				-
Jun				(2.27)A				-
Sep			(0.06)	(0.24)A				-
Dec			(0.09)	(0.13)				-
FY Dec		(1.18)	(3.08)	(3.30)	(1.21)	(1.32)	(1.20)	(1.31)
FY P/E		NM		NM		NM		NM

Financial Summary	
Net Debt (MM):	(\$195.4)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$195.4
Cash/Share:	\$5.10
Cash (MM):	\$195.4
Market Data	
52 Week Range:	\$48.19 - \$21.00
Total Entprs. Value (MM):	\$1,515.9
Market Cap. (MM):	\$1,711.3
Shares Out. (MM):	43.5
Float (MM):	7.4
Avg. Daily Vol.:	547,379

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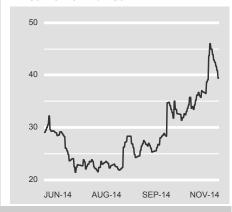
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#### **Price Performance**



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# **Kite Pharma**

# **Buy: \$46 Price Target**

#### Scenarios

#### **Target Investment Thesis**

- Positive outcome from the PII registration study of KTE-C19 in DLBCL
- We expect KTE-C19approval for DLBCL in 2017 and peak sales of \$526M by 2028 (risk-adj)
- We expect KTE-C19 approval for PMBCL, MCL, FL, ALL and CLL in 2019 and peak sales of \$559M by 2028 (risk-adj)
- We expect peak EU royalties of \$92M (riskadj by 2028 for KTE-C19.
- DCF-based PT: \$46

#### **Upside Scenario**

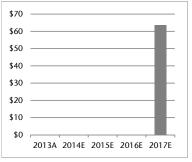
- De-risked KTE-C19 program through Phase II/III trial datasets
- DCF-based PT: \$71
- Positive proof-of-concept for EGFRvIII CAR program in GBM
- DCF-based PT: an add'l \$5
- Positive proof-of-concept for NY-ESO-1 TCR program in synovial and bladder cancer
- DCF-based PT: an add'l \$5

#### **Downside Scenario**

- Negative outcome for KTE-C19 in DLBCL
- DCF-based PT: \$13
- Negative outcome for KTE-C19 in other hem malignancies
- DCF-based PT: \$16-24
- Negative outcome for KTE-C19 in all indications
- Cash-based PT: \$5

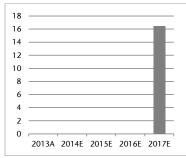
#### **Long Term Analysis**

#### Revenue (millions)



Source: Company data; Jefferies estimates

# **Enterprise Value (EV)/Sales**



Source: Company data; Jefferies estimates

#### **Other Considerations**

We consider small-cap and mid-cap biotech companies with late-stage programs to continue to be attractive targets for partnering or M&A partnering with large-cap biotech and pharma companies, which we believe will be a driving factor for performance in the biotech sector 2014-2015.

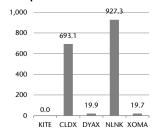
## **Peer Group**

#### **Group EV**



Source: Factset, Jefferies estimates

#### Group EV/2014E Sales



Source: Factset, Jefferies estimates

#### **Recommendation / Price Target**

Ticker	Rec.	PT		
KITE	Buy	\$46		
CLDX	Buy	\$24		
DYAX	Buy	\$13		
NLNK	Buy	\$36		
XOMA	Buy	\$9		

#### Catalysts

- Additional data on KTE-C19 at ASH December 2014
- Initiation of PI/IIb trial of KTE-C19 in DLBCL in H1 2015
- IND filing and initiation of PI trial of NY-ESO-1 TCR trial in synovial and bladder cancer in Q4 2014.
- Initiation of NCI sponsored PI trial of SSX2 TCR in solid tumors in Q4 2014.

#### **Company Description**

Kite Pharma, Inc. is a biopharmaceutical company focused on the development and commercialization of cancer immunotherapy products involving the engineering of T-cells to express chimeric antigen receptors (CARs) or T-cell receptors (TCRs) to combat cancer. Its lead candidate is KTE-C19, a CAR-T product for the treatment of heavily pre-treated relapsed/refractory DLBCL which is set to begin a pivotal Phase I/IIb trial. KITE intends to expand KTE-C19 into other difficult-to-treat hem malignancies, including FL, MCL, PMBCL, CLL and ALL. KITE's technology has been developed in part through its collaboration with the National Cancer Institute through a cooperative research agreement (CRADA).

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# **Valuation**

We arrive at our \$46 PT (v. \$35 previously) based on a DCF valuation model, which assumes a WACC of 13%, terminal growth rate of 0% and outstanding shares of 43.4 million, driven by sales of KTE-C19. We assume market entry for KTE-C19 for third-line refractory diffuse large B-cell lymphoma (DLBCL) in 2017 based on accelerated approval on a positive data package from its pivotal Phase I/IIb trial. We estimate total U.S. peak sales of KTE-C19 of \$1.9 billion (risk-unadjusted) by 2028 for multiple potential indications in hematology. Applying a 40% discount rate to reflect the risk associated with this asset, we estimate peak sales of \$1.2 billion by 2028.

**Exhibit 1: DCF sensitivity analysis** 

<b>Equity Value</b>	Price/Share
\$2,632.5	\$60.69
\$2,288.9	\$52.77
\$2,002.3	\$46.16
\$1,761.7	\$40.62
\$1,558.7	\$35.94

Source: Jefferies estimates

# Risks

**Clinical Failure:** As with all companies in biotechnology and pharmaceuticals developing treatments of the future, a clinical failure can lead to delays in approval or possibly discontinuation of programs.

**Regulatory Failure:** The FDA could determine the Biologic Licensing Application is inadequate for KTE-C19 for DLBCL and could delay approval. KITE is under the assumption that an ORR >50% with a duration of response >6 months in patients from a single-arm trial will be sufficient for accelerated approval, but the FDA could decide that is inadequate. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

**Commercial Failure:** We currently assume peak sales for KTE-C19 of \$1.0 billion in the U.S. (risk adjusted) and royalty revenue of \$92 million (risk-adjusted) on EU sales by 2028. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

**Manufacturing Risks:** KITE relies on its eACT process to manufacture its CAR-T products, and involves 1) harvesting T-cells from the patient's blood, 2) genetically engineering the T-cells to express cancer-specific receptors, and 3) increasing the number of engineered T-cells and 4) infusing the modified T-cells back into the patient. Assuming approval, KITE will require reliable commercial supplies for the materials used to manufacture and process its eACT-based candidates. KITE will need a consistent and reliable process, while limiting contamination risks, for manufacturing these candidates for the approved patient population. Any supply or manufacturing disruption could negatively impact KTE-C19 supply and sales.

**Competitive Risks:** Other companies are rapidly developing CAR-T product candidates in various stages of clinical development for hematological malignancies that may compete with KTE-C19. If any of these product candidates have an improved therapeutic profile over KTE-C19 and is approved, KTE-C19's growth trajectory in the marketplace, even if approved, could be adversely impacted.

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**Financing Risks:** We expect KITE to have adequate cash to support the KTE-C19 launch in 2017, and we do not currently model any equity financing. However, KITE may need additional dilutive financing to fund the potential U.S. launch of KTE-C19 and its R&D programs in additional indications.

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# **Exhibit 2: KITE Income Statement**

# Kite Pharma, Inc.

# **Quarterly Income Statement**

(All values in \$MM except EPS and average shares)																		
	2012A	2013 A			2014E			2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY	FY	1QA	2QA	3QA	4QE	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
Revenue:																		
CD19 CAR-T U.S. Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	63.4	295.5	562.8	7319	903.7	973.7	1032.6	1065.7	1099.8
CD19 CAR-T EU Royalty	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.8	24.3	50.4	66.3	82.8	85.2
Total revenue, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	63.4	\$ 295.5	\$ 562.8	\$ 735.7	\$ 928.0	\$ 1,024.1	\$ 1,098.9	\$ 1,148.5	\$ 1,184.9
Costs and expenses:																		
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	73.9	140.7	183.0	216.9	223.9	227.2	213.1	220.0
Research & development	1.8	5.1	2.1	7.4	5.7	3.0	18.2	47.0	47.0	49.4	51.8	54.4	56.0	57.7	59.5	60.6	612	61.9
Selling, general & administrative	0.8	13	1.1	3.7	3.4	2.8	11.0	11.6	12.3	26.5	35.8	39.4	413	42.1	43.0	43.8	44.7	45.6
Total operating expenses	2.6	6.4	3.2	11.1	9.1	5.8	29.2	58.6	59.3	75.9	161.5	234.5	280.3	316.7	326.4	331.7	319.1	327.4
Income (loss) from operations	(2.6)	(6.4)	(3.2)	(11.1)	(9.1)	(5.8)	(29.2)	(58.6)	(59.3)	(12.4)	134.0	328.3	455.3	611.2	697.7	767.2	829.4	857.5
Other income (expense):																		
Miscellaneous (expense) income	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	0.0	0.0	0.0	0.0
Interest income	0.0	0.1	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest expense	(0.0)	(0.0)	0.0	(6.3)	0.0	0.0	(6.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other	(0.0)	(14)	(0.6)	0.0	(0.0)	0.0	(0.6)	0.0	0.0	(6.0)	0.0	0.0	(10.0)	0.0	0.0	0.0	0.0	0.0
Net profit (loss) before income taxes	(2.6)	(7.9)	(3.7)	(17.4)	(9.1)	(5.8)	(35.9)	(58.6)	(59.3)	(18.4)	134.0	328.3	445.3	611.2	697.7	767.2	829.4	857.5
Income tax expense (benefit)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	32.8	44.5	213.9	244.2	268.5	290.3	300.
Income tax (%)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	10.0%	10.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Net Income (GAAP)	(2.6)	(7.8)	(3.7)	(17.9)	(9.1)	(5.8)	(36.4)	(58.6)	(59.3)	(18.4)	134.0	295.5	400.8	397.3	453.5	498.7	539.1	557.4
Adjusted Items (Non-GAAP)																		
Stock options	0.0	0.0	0.0	7.0	3.4	0.3	10.7	10.0	10.0	10.0	15.0	20.0	22.0	23.0	24.0	25.0	25.0	25.0
Other	0.0	14	0.6	0.0	0.0	0.0	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Non-GAAP)	(2.6)	(6.4)	(3.1)	(10.9)	(5.7)	(5.5)	(25.2)	(48.6)	(49.3)	(8.4)	149.0	315.5	422.8	420.3	477.5	523.7	564.1	582.4
EPS, GAAP	(0.49)	(1.43)	(0.66)	(2.27)	(0.24)	(0.13)	(3.30)	(1.32)	(1.31)	(0.40)	2.84	6.14	8.17	7.94	8.88	9.58	10.15	10.29
Basic shares	5.3	5.5	5.6	7.9	38.3	43.6	23.8	44.4	45.3	46.2	47.2	48.1	49.1	50.0	51.0	52.1	53.1	54.2
Diluted shares	5.3	5.5	5.6	7.9	38.3	43.6	23.8	44.4	45.3	46.2	47.2	48.1	49.1	50.0	51.0	52.1	53.1	54.2
EPS, Non-GAAP	(0.49)	(0.22)	(0.11)	(0.34)	(0.15)	(0.13)	(0.73)	(1.09)	(1.09)	(0.18)	3.16	6.56	8.62	8.40	9.35	10.06	10.62	10.75
Basic shares	5.4	29.2	29.3	31.6	38.3	43.6	35.7	44.4	45.3	46.2	47.2	48.1	49.1	50.0	51.0	52.1	53.1	54.2
Diluted shares	5.4	29.2	29.3	31.6	38.3	43.6	35.7	44.4	45.3	46.2	47.2	48.1	49.1	50.0	51.0	52.1	53.1	54.2

Source: Company data and Jefferies estimate

Source: Jefferies estimates, company data

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**Exhibit 3: KITE DCF Analysis** 

# Kite Pharma, Inc.

# **Discounted Cash Flow Analysis**

(All values in \$MM)	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Sales	0.0	0.0	0.0	0.0	0.0	63.4	295.5	562.8	735.7	928.0	1,024.1	1,098.9	1,148.5	1,184.9
Operating Expenses	7.7	9.4	29.2	58.6	59.3	75.9	161.5	234.5	280.3	316.7	326.4	331.7	319.1	327.4
ЕВІТ	(7.7)	(9.4)	(29.2)	(58.6)	(59.3)	(12.4)	134.0	328.3	455.3	611.2	697.7	767.2	829.4	857.5
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	32.8	44.5	213.9	244.2	268.5	290.3	300.1
EBIAT	(7.7)	(9.4)	(29.2)	(58.6)	(59.3)	(12.4)	134.0	295.5	410.8	397.3	453.5	498.7	539.1	557.4
(+):Depreciation	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
(+):FAS-123 Options	3.4	0.3	10.7	10.0	10.0	10.0	15.0	20.0	22.0	23.0	24.0	25.0	25.0	25.0
(-): Capital expenditures	0.0	0.0	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
(-): Changes in working capital	0.0	0.0	2.7	0.7	0.7	0.3	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
Unlevered free cash flow	(4.3)	(9.1)	(21.4)	(49.6)	(50.3)	(2.9)	148.1	314.5	431.8	419.3	476.5	522.7	563.1	581.4

Source: Jefferies estimates, company data

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# **Company Description**

Kite Pharma, Inc. operates as a clinical stage biotechnology company which engages in the development of novel cancer immunotherapeutic products with focus on engineered autologous T cell therapeutics targeted to different tumor types. In addition, the company is advancing a novel therapeutic cancer vaccine aimed to trigger potent and specific immunity against multiple epithelial cancers, which has the potential to complement its eACT programs.

# **Analyst Certification:**

I, Biren Amin, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

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Buy - Describes stocks that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period. Hold - Describes stocks that we expect to provide a total return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period. Underperform - Describes stocks that we expect to provide a total negative return (price appreciation plus yield) of 10% or more within a 12-month period.

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The expected total return (price appreciation plus yield) for Buy rated stocks with an average stock price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% within a 12-month period.

NR - The investment rating and price target have been temporarily suspended. Such suspensions are in compliance with applicable regulations and/or Jefferies policies.

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NC - Not covered. Jefferies does not cover this company.

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Monitor - Describes stocks whose company fundamentals and financials are being monitored, and for which no financial projections or opinions on the investment merits of the company are provided.

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Jefferies' methodology for assigning ratings may include the following: market capitalization, maturity, growth/value, volatility and expected total return over the next 12 months. The price targets are based on several methodologies, which may include, but are not restricted to, analyses of market risk, growth rate, revenue stream, discounted cash flow (DCF), EBITDA, EPS, cash flow (CF), free cash flow (FCF), EV/EBITDA, P/E, PE/growth, P/CF, P/FCF, premium (discount)/average group EV/EBITDA, premium (discount)/average group P/E, sum of the parts, net asset value, dividend returns, and return on equity (ROE) over the next 12 months.

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# Risk which may impede the achievement of our Price Target

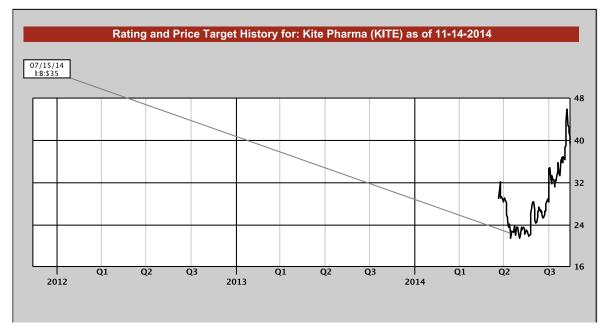
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# Other Companies Mentioned in This Report

- Celldex Therapeutics, Inc. (CLDX: \$14.16, BUY)
- Dyax (DYAX: \$12.83, BUY)
- Newlink Genetics Corp. (NLNK: \$30.54, BUY)
- XOMA Ltd. (XOMA: \$3.92, BUY)

Target | Estimate Change

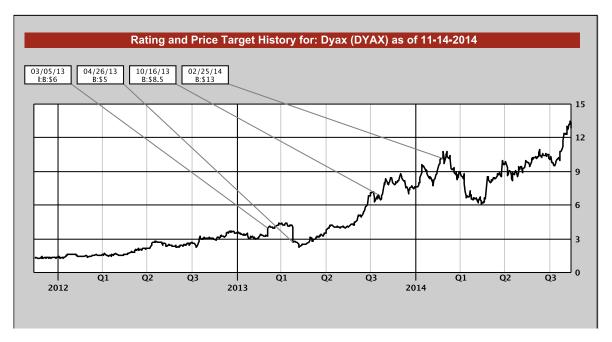
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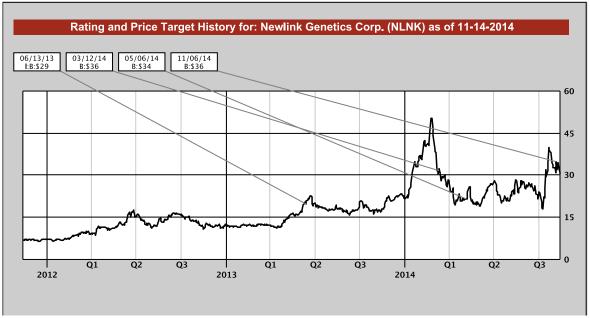




Target | Estimate Change

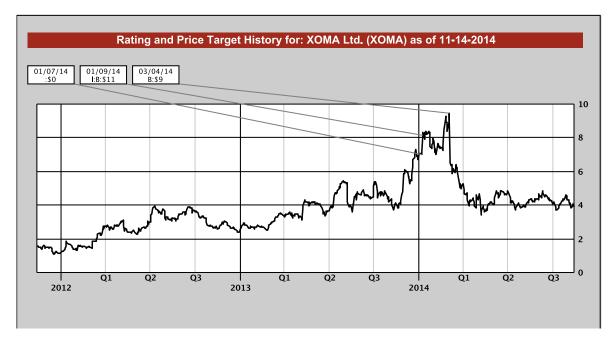
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Target | Estimate Change

November 17, 2014



# **Distribution of Ratings**

IB	Serv.	/Past	12	Mos.

			10 001 4.71	131 12 11103.
Rating	Count	Percent	Count	Percent
BUY	1018	51.94%	268	26.33%
HOLD	801	40.87%	144	17.98%
UNDERPERFORM	141	7.19%	4	2.84%

Target | Estimate Change

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