# **COMPANY NOTE**

**Estimate Change** 

USA | Healthcare | Biotechnology

March 26, 2015

# **Jefferies**

Price target \$84.00 Price \$57.75

# Kite Pharma (KITE)

# **Q4 Update: Four Pivotal Trials On Track To** Start In 2015

## **Key Takeaway**

We believe KITE shares hold significant promise based on PI/II data, with KTE-C19 observing robust responses in ref lymphomas/leukemias, supporting a favorable outlook in its pivotal PII in 3rd-line DLBCL to start in H1'15. Three add'I trial in other leukemias/lymphomas also are planned for '15. Lastly, there are six add'l ongoing trials at NCI w/ hopefully interims from one or more this year although timelines are driven by NCI.

Awaiting Start of Pivotal PII for 3rd-line DLBCL in H1 2015: We anticipate a strong response rate in the upcoming pivotal PII third-line DLBCL trial evaluating KTE-C19 in a single-arm design, and this is supported by the NCI PI/II trial observing a strong OR in patients with relapsed/refractory DLBCL. We expect KITE to initiate this trial in H1 2015. Data from the pivotal trial in third-line DLBCL is anticipated in 2H '16, and we estimate risk-adj peak sales of \$526M in DLBCL. Additional indications may generate risk-adj peak sales of \$559M across other refractory/relapsed lymphomas and leukemias. KITE plans to initiate pivotal studies in MCL (H1'15), CLL and ALL (H2'15).

KITE Establishes European Presence: Recently, KITE announced that it is acquiring the T-Cell Factory B.V., a privately held Dutch company. Through the acquisition, KITE obtained license agreements with IBA GmbH, Sanquin Blood Supply Foundation, and the NKI that include rights to certain new intellectual property in TCR. The acquisition also provides KITE with access to European clinical manufacturing facilities, which provides them with a launching base for its CAR-T candidates to initiate clinical trials in that region. We believe this is a significant step in establishing a development plan for its candidates in the EU. We estimate risk-adj sales in the EU of \$457M and believe KITE could receive a 20% royalty on topline sales. KITE must make an upfront payment to TCF shareholders of up to €20.0M (~ \$21.0M), licensors and employees, of which €3.8M (~\$4.0M) will be paid in KITE stock. Kite must also make certain milestone payments upon the achievement of clinical, regulatory and sales milestones relating to TCR-based candidates.

Q4 Financials: KITE reported Q4 GAAP EPS of (\$0.33) v. JEF est of (\$0.13) and cons of (\$0.20) on higher expenses. Cash and equivs were \$367.0M as of end-Q4.

## Valuation/Risks

Our PT of \$84 is DCF-based. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

USD	Prev.	2013A	Prev.	2014A	Prev.	2015E	Prev.	2016E
Rev. (MM)		0.0		0.0		60.0		0.0
EV/Rev						35.8x		
EPS								
Mar				(0.66)	8.86	1.07		
Jun				(2.27)	(1.56)	(0.35)		
Sep				(0.24)	(0.41)	(0.42)		
Dec			(0.13)	(0.33)	(0.48)	(0.52)		
FY Dec		(1.18)	(3.30)	(1.91)	6.42	(0.22)	(2.44)	(1.64)
FY P/E		NM		NM		NM		NM

(\$367.0)
\$0.0
\$367.0
\$9.42
\$367.0
\$89.21 - \$21.00
,
NM \$2,512.1
NM

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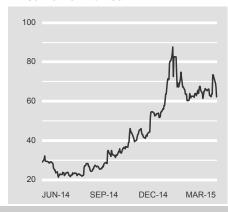
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### **Price Performance**



**Estimate Change** 

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# **Valuation**

We arrive at our \$84 PT based on a DCF valuation model, which assumes a WACC of 11%, terminal growth rate of 0% and outstanding shares of 47.6 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 \$2.7 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 \$1.6 billion by 2028.

**Exhibit 1: DCF sensitivity analysis** 

<b>Equity Value</b>	Price/Share
\$5,068.4	\$110.75
\$4,406.5	\$96.29
\$3,857.5	\$84.29
\$3,399.4	\$74.28
\$3,015.1	\$65.88

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.

# **KITE**Estimate Change March 26, 2015

**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.

**Estimate Change** 

March 26, 2015

## **Exhibit 2: KITE Income Statement**

## Kite Pharma, Inc.

**Quarterly Income Statement** 

(All values in \$MM except EPS and average shares)																						
	2012A	2013A			2014A					2015E			2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue:	FY	FY	1QA	2QA	3QA	4QA	FY	1QE	2QE	3QE	4QE	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
CD19 CAR-T U.S. Sales	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	109.7	446.8	808.8	1041.2	1276.5	1368.7	1448.4	1499.0	1551.1
CD19 CAR-T G.S. Salles CD19 CAR-T EURovalty	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	11.1	52.1	99.2	128.3	158.7	163.9
Amgen collaboration revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	60.0	0.0	0.0	0.0	60.0	0.0	25.0	25.0	25.0	25.0	75.0	75.0	75.0	75.0	150.0
				0.0		0.0	0.0	60.0	0.0			60.0	0.0	134.7	471.8	833.8	1.077.2	1.403.6	1.542.9	1.651.8		
Total revenue, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	60.0	0.0	0.0	0.0	60.0	0.0	134.7	4 / 1.8	833.8	1,077.2	1,403.6	1,542.9	1,651.8	\$ 1,657.7	1,865.0
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	0.0	0.0	0.0	0.0	111.7	202.2	260.3	306.4	314.8	318.7	299.8	310.2
Research & development	1.8	5.1	2.1	7.4	5.7	7.9	23.1	8.0	9.3	12.8	17.9	48.0	50.4	52.9	55.6	58.3	60.1	619	63.8	65.7	67.0	68.3
Selling, general & administrative	0.8	13	11	3.7	3.4	5.4	13.6	5.5	5.6	6.0	6.1	23.2	24.6	26.5	39.8	43.7	45.9	48.2	49.7	511	52.2	53.2
Total operating expenses	2.6	6.4	3.2	11.1	9.1	13.3	36.7	13.5	14.9	18.8	24.0	71.2	75.0	79.4	207.0	304.3	366.3	416.5	428.2	435.5	419.0	431.7
Income (loss) from operations	(2.6)	(6.4)	(3.2)	(11.1)	(9.1)	(13.3)	(36.7)	46.5	(14.9)	(18.8)	(24.0)	(11.2)	(75.0)	55.3	264.8	529.5	710.9	987.1	1,114.7	1,216.3	1,238.7	1,433.2
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	0.0	0.0	0.0	0.0
Interest income	0.0	0.1	0.0	0.0	0.1	0.2	0.4	0.0	0.0	0.0	0.0	0.1	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	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	0.0	0.0	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)	(13.0)	(43.1)	46.5	(14.9)	(18.8)	(24.0)	(11.1)	(75.0)	49.3	264.8	529.5	700.9	987.1	1,114.7	1.216.3	1,238.7	1,433.2
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	0.0	0.0	0.0	0.0	53.0	70.1	345.5	390.1	425.7	433.6	5016
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%	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)	(13.0)	(43.7)	46.5	(15.4)	(18.8)	(24.0)	(11.7)	(75.0)	49.3	264.8	476.6	630.8	641.6	724.5	790.6	805.2	931.6
Net income (GAAF)	(2.0)	(1.0)	(3.7)	(11.5)	(3.1)	(13.0)	(43.7)	40.5	(13.4)	(10.0)	(24.0)	(11.7)	(13.0)	40.5	204.0	470.0	030.0	041.0	724.5	730.0	003.2	331.0
Adjusted Items (Non-GAAP)																						
Stock options	0.0	0.0	0.0	7.0	3.4	5.5	16.1	4.0	4.0	4.0	4.0	16.0	16.0	16.0	16.0	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	6.1	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
Net Income (Non-GAAP)	(2.6)	(6.4)	(3.1)	(10.9)	(5.7)	(7.5)	(21.4)	50.5	(11.4)	(14.8)	(20.0)	4.3	(59.0)	65.3	280.8	496.6	652.8	664.6	748.5	815.6	830.2	956.6
EPS, GAAP	(0.49)	(1.43)	(0.66)	(2.27)	(0.24)	(0.33)	(1.91)	1.07	(0.35)	(0.42)	(0.52)	(0.22)	(1.64)	1.06	5.58	9.85	12.78	12.74	14.11	15.09	15.07	17.09
Basic shares	5.3	5.5	5.6	7.9	38.3	39.0	22.8	43.6	44.4	45.1	45.8	44.7	45.6	46.5	47.4	48.4	49.4	50.3	514	52.4	53.4	54.5
Diluted shares	5.3	5.5	5.6	7.9	38.3	39.0	22.8	43.6	44.4	45.1	45.8	44.7	45.6	46.5	47.4	48.4	49.4	50.3	51.4	52.4	53.4	54.5
EPS, Non-GAAP	(0.49)	(0.22)	(0.11)	(0.34)	(0.15)	(0.19)	(0.94)	1.16	(0.26)	(0.33)	(0.44)	0.14	(1.29)	1.40	5.92	10.26	13.23	13.20	14.58	15.57	15.54	17.55
Basic shares	5.4	29.2	29.3	316	38.3	39.0	22.8	43.6	44.4	45.1	45.8	44.7	45.6	46.5	47.4	48.4	49.4	50.3	514	52.4	53.4	54.5
Diluted shares	5.4	29.2	29.3	31.6	38.3	39.0	22.8	43.6	44.4	45.1	45.8	44.7	45.6	46.5	47.4	48.4	49.4	50.3	51.4	52.4	53.4	54.5

**Estimate Change** 

March 26, 2015

# **Exhibit 3: KITE Balance Sheet**

# Kite Pharma, Inc.

## **Balance Sheet**

(All values in \$MM)													
	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY	FY	FY	FY	FY	FY	FY						
Current assets:													
Cash and cash equivalents	22.4	209.3	215.2	157.3	223.3	504.2	996.4	1,642.4	2,298.6	3,037.8	3,843.0	4,662.8	5,609.0
Marketable securities		157.7	157.7	157.7	157.7	157.7	157.7	157.7	157.7	157.7	157.7	157.7	157.7
Cash and investments	22.4	367.0	373.0	315.1	381.0	661.9	1,154.1	1,800.1	2,456.4	3,195.5	4,000.7	4,820.6	5,766.8
Prepaid expenses and other current assets	0.2	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
Total current assets	22.6	368.4	374.3	316.4	382.4	663.3	1,155.5	1,801.4	2,457.7	3,196.8	4,002.1	4,821.9	5,768.1
Property and equipment, net		2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
Other	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Total assets	23.0	370.8	376.7	318.8	384.8	665.7	1,157.8	1,803.8	2,460.1	3,199.2	4,004.5	4,824.3	5,770.5
Current liabilities:													
Accounts payable	0.4	2.3	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Accrued expenses	0.9	3.1	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Other (Options early exercise liability)	0.1	1.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total current liabilities	1.4	6.7	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6
Other non-current liabilities		0.0											
Deferred rent, excluding current portion	0.0	0.1	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Options early exercise noncurrent liability		1.3											
Total Liability	1.4	8.2	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1
Total stockholders' equity	21.6	362.6	371.5	313.7	379.6	660.5	1,152.7	1,798.7	2,454.9	3,194.1	3,999.3	4,819.1	5,765.3
Total liabilities and stockholders' equity	23.0	370.8	376.7	318.8	384.8	665.7	1157.8	1803.8	2460.1	3199.2	4004.5	4824.3	5770.5

**Estimate Change** 

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## **Exhibit 4: KITE Cash Flow Statement**

# Kite Pharma, Inc.

### **Cash Flow Statement**

(All values in \$MM)	2013 A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
	<u> </u>												
Cash flows from operating activities:													
Net income	(6.4)	(42.6)	(11.7)	(75.0)	49.3	264.8	476.6	630.8	6416	724.5	790.6	805.2	9316
Adjustments to reconcile cash by operating activities:													
Depreciation and amortization expense	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
Stock-based compensation expense	0.1	16.1	16.1	16.1	16.1	16.1	16.1	16.1	16.1	16.1	16.1	16.1	16.1
Change in fair value of derivative liability		0.0											
Noncash interest expense		6.1											
Deferred rent		0.1											
Loss on disposal of assets/Other	(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
Changes in operating assets and liabilities:													
Prepaid expenses	(0.0)	(1.1)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Due to related party	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
Other assets	(0.1)	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accounts payable	0.3	19	1.9	1.9	1.9	19	1.9	1.9	1.9	1.9	1.9	1.9	19
Accrued expenses and deferred rent	0.5	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
Net cash provided by operating activities	(5.7)	(17.1)	9.0	(54.4)	70.0	285.4	497.2	651.5	662.3	745.2	811.2	825.8	952.2
Cash flows from investing activities:													
Capital expenditures		(2.1)											
Purchases of marketable securities		(1,194.9)											
Sales and maturities of marketable securities		1,036.9											
Short-term investments		0.0	(3.0)	(3.5)	(4.0)	(4.5)	(5.0)	(5.5)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)
Purchase of property and equipment	(0.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net cash (used in) provided by investing activities	(0.3)	(160.1)	(3.0)	(3.5)	(4.0)	(4.5)	(5.0)	(5.5)	(6.0)	(6.0)	(6.0)	(6.0)	(6.0)
Cash flows from financing activities:													
Principal payments on capital lease obligations		(0.0)											
		(0.0)											
Initial public offering costs		(23.6)											
Proceeds from issuance of common stock	0.0	334.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance of preferred stock, net	19.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Proceeds from exercise of stock options		2.9											
Proceeds from issuance of convertible notes		50.0											
Other	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
Net cash (used in) provided by financing activities	19.6	364.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Effect if exchange rate changes on cash/equivalents													
Increase (decrease) in cash and cash equivalents	13.6	186.9	6.0	(57.9)	66.0	280.9	492.2	646.0	656.3	739.2	805.2	819.8	946.2
Cash and cash equivalents at beginning of period	8.7	22.3	209.2	215.2	157.3	223.3	504.2	996.4	1,642.4	2,298.6	3,037.8	3,843.0	4,662.8
Cash and cash equivalents at end of period	22.3	209.2	215.2	157.3	223.3	504.2	996.4	1,642.4	2,298.6	3,037.8	3,843.0	4,662.8	5,609.0

**Estimate Change** 

March 26, 2015

**Exhibit 5: KITE DCF Analysis** 

# Kite Pharma, Inc.

# **Discounted Cash Flow Analysis**

(All values in \$MM)	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Sales	0.0	0.0	0.0	60.0	0.0	134.7	471.8	833.8	1,077.2	1,403.6	1,542.9	1,651.8	1,657.7	1,865.0
Operating Expenses	7.7	9.4	36.7	71.2	75.0	79.4	207.0	304.3	366.3	416.5	428.2	435.5	419.0	431.7
ЕВІТ	(7.7)	(9.4)	(36.7)	(11.2)	(75.0)	55.3	264.8	529.5	710.9	987.1	1114.7	1216.3	1238.7	1433.2
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	53.0	70.1	345.5	390.1	425.7	433.6	501.6
EBIAT	(7.7)	(9.4)	(36.7)	(11.2)	(75.0)	55.3	264.8	476.6	640.8	641.6	724.5	790.6	805.2	931.6
(+):Depreciation	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
(+):FAS-123 Options	3.4	5.5	16.1	16.0	16.0	16.0	16.0	20.0	22.0	23.0	24.0	25.0	25.0	25.0
(-): Capital expenditures	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
(-): Changes in working capital	0.0	0.0	2.9	4.3	4.2	1.9	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2
Unlevered free cash flow	(4.3)	(3.9)	(23.1)	0.8	(63.0)	69.6	276.8	492.6	658.9	660.7	744.6	811.6	826.2	952.6

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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.

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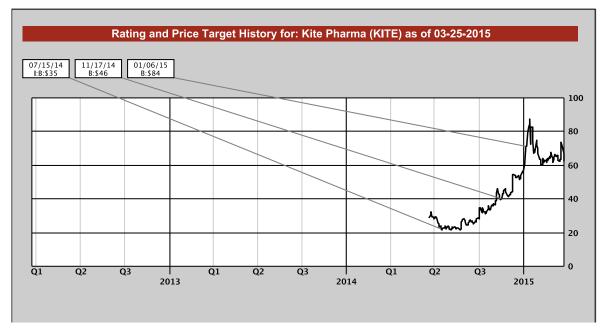
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			IB Serv./Pa	ast 12 Mos.
Rating	Count	Percent	Count	Percent
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