**COMPANY NOTE**

Estimate Change

USA | Healthcare | Biotechnology

August 15, 2014

Jefferies

# Kite Pharma (KITE)

## Q2: Awaiting Start of Pivotal PII for DLBCL in H1 2015

**BUY**

Price target $35.00

Price $22.22

EQUITY RESEARCH AMERICAS

### Key Takeaway

**KITE shares hold significant promise based on PI/II data with KTE-C19 observing robust responses in patients with refractory lymphomas and leukemias and thereby supporting our favorable outlook in its pivotal PII trial in third-line DLBCL (expected to start in H1 2015) and its potential in refractory leukemia. We maintain Buy rating and a $35 PT.**

**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 enrolling >40 patients, and this is supported by the NCI PI/II trial observing an 88% objective response in eight patients with relapsed/refractory DLBCL. Data from the pivotal trial in third-line DLBCL is anticipated in mid-2016, 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 risk-adj 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.

**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.

**Q2 Financials:** KITE reported Q2 GAAP EPS of ($2.27) v. JEF est of ($0.06) and cons of ($0.06). Cash and equivs were $203.4M as of end Q2.

### Valuation/Risks

Our PT of $35 is DCF-based. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

| Financial Summary | |
|---|---|
| Net Debt (MM): | ($203.4) |
| Long-Term Debt (MM): | $0.0 |
| Cash & ST Invest. (MM): | $203.4 |
| Cash/Share: | $4.67 |
| Cash (MM): | $203.4 |

| Market Data | |
|---|---|
| 52 Week Range: | $32.65 - $21.00 |
| Total Entprs. Value (MM): | $763.2 |
| Market Cap. (MM): | $966.6 |
| Shares Out. (MM): | 43.5 |
| Float (MM): | 8.9 |
| Avg. Daily Vol.: | NA |

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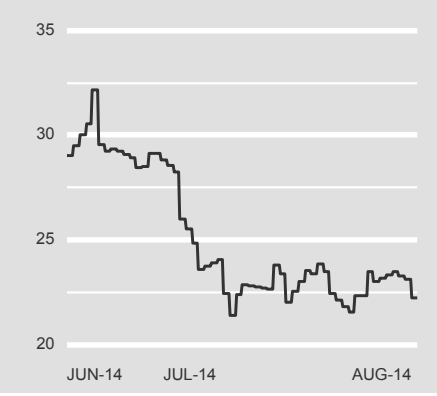
| USD | Prev. | 2013A | Prev. | 2014E | Prev. | 2015E | Prev. | 2016E |
|---|---|---|---|---|---|---|---|---|
| Rev. (MM) | -- | 0.0 | -- | 0.0 | -- | 0.0 | -- | 0.0 |
| **EPS** | | | | | | | | |
| Mar | -- | -- | *(0.56)A* | (0.66)A | -- | -- | -- | -- |
| Jun | -- | -- | *(0.06)* | (2.27)A | -- | -- | -- | -- |
| Sep | -- | -- | -- | (0.06) | -- | -- | -- | -- |
| Dec | -- | -- | *(0.08)* | (0.09) | -- | -- | -- | -- |
| FY Dec | -- | (1.18) | *(0.76)* | (3.08) | *(1.13)* | (1.21) | *(1.11)* | (1.20) |
| FY P/E | | NM | | NM | | NM | | NM |

**Price Performance**

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## Valuation

We arrive at our $35 price target 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 $1.8 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 $1.0 billion by 2028.

KITE's initial target population will be third-line relapsed/refractory diffuse large B-cell lymphoma (DLBCL). At this time, we only include the refractory DLBCL population (10%), and leave the relapsed population as upside (~30-40%). At 40% peak market penetration by 2028, we assume peak sales of $876 million (risk-unadjusted), or $526 million (risk-adjusted) using a 40% discount rate. KITE intends to expand into other lymphomas and leukemias, including PMBCL, transformed indolent NHL, FL, MCL, CLL and ALL. We estimate market expansion into FL, MCL, PMBCL, CLL and ALL in 2019 (refractory-only). We assume each reach peak market penetration of 25%, and we estimate peak sales of $214 million (FL), $39 million (MCL), and $45 million (PMBCL), $316 million (CLL) and $318 million (ALL) by 2028 (risk-unadjusted), respectively. Applying a 40% risk discount, we estimate peak sales of $128 million (FL), $24 million (MCL), and $27 million (PMBCL), $190 million (CLL) and $191 million (ALL) respectively.

We also model EU sales for KTE-C19. We model $141 million in peak sales for third-line refractory DLBCL in 2028 using a 40% risk-discount. For FL, MCL, PMBCL, CLL and ALL we model market entry in 2021 and peak sales of $35 million (FL), $7 million (MCL), $8 million (PMBCL), $131 million (CLL) and $136 million (ALL) in 2028, respectively (applying a 40% risk-discount). In total, we estimate peak sales in the EU of $457 million with a 40% risk-discount. We assume a 20% royalty, which translates to $92 million in 2028 in royalty revenue.

At this time, we do not model sales for its EGFRvIII CAR-T program for glioblastoma or Kite's TCR targeting NYESO-1, and these represent upside to our current estimates. We assume R&D expenses of $9.1 million in 2014, with the pivotal Phase I/IIb trial expected to begin in H1 2015. We expect R&D expenses to grow to $67 million by 2028. We assume $3.0 million in SG&A expenses in 2014, and expect them to grow to $46 million by 2020 as it launches KTE-C19 in 2017 and expands into additional indications in 2019. We expect SG&A expenses to grow to $54 million by 2028.

**Exhibit 1: DCF sensitivity analysis**

| Equity Value | Price/Share |
|---|---|
| $2,054.7 | $47.37 |
| $1,749.8 | $40.34 |
| **$1,500.8** | **$34.60** |
| $1,296.2 | $29.88 |
| $1,127.2 | $25.99 |

**Source: Jefferies estimates**

## Risks



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**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.

**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 | 2013A | 2014E | | | | | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | FY | FY | 1QA | 2QA | 3QE | 4QE | FY | FY | FY | 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 | 185.1 | 393.4 | 635.5 | 805.4 | 933.7 | 964.7 | 996.5 | 1029.2 | 1055.9 | 1070.1 | 1084.6 |
| 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 | 87.2 | 89.3 | 91.5 |
| **Total revenue, net** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** | **63.4** | **$ 185.1** | **$ 393.4** | **$ 639.4** | **$ 829.7** | **$ 984.1** | **$ 1,031.0** | **$ 1,079.3** | **$ 1,114.3** | **$ 1,143.2** | **$ 1,159.5** | **$ 1,176.0** |
| **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 | 46.3 | 98.3 | 158.9 | 193.3 | 214.8 | 212.2 | 209.3 | 205.8 | 211.2 | 214.0 | 216.9 |
| Research & development | 18 | 5.1 | 2.1 | 7.4 | 2.0 | 3.0 | 14.5 | 47.0 | 47.0 | 49.4 | 51.8 | 54.4 | 56.0 | 57.7 | 59.5 | 60.6 | 61.9 | 63.1 | 64.4 | 65.6 | 67.0 |
| Selling, general & administrative | 0.8 | 1.3 | 1.1 | 3.7 | 0.8 | 0.8 | 6.4 | 6.8 | 7.2 | 26.5 | 39.8 | 43.7 | 45.9 | 46.8 | 47.8 | 48.7 | 49.7 | 50.7 | 51.7 | 52.7 | 53.8 |
| **Total operating expenses** | **2.6** | **6.4** | **3.2** | **11.1** | **2.8** | **3.8** | **20.9** | **53.8** | **54.2** | **75.9** | **137.9** | **196.5** | **260.8** | **297.9** | **322.0** | **321.6** | **320.8** | **319.6** | **327.2** | **332.4** | **337.7** |
| **Income (loss) from operations** | **(2.6)** | **(6.4)** | **(3.2)** | **(11.1)** | **(2.8)** | **(3.8)** | **(20.9)** | **(53.8)** | **(54.2)** | **(12.4)** | **47.3** | **196.9** | **378.5** | **531.9** | **662.2** | **709.4** | **758.5** | **794.7** | **815.9** | **827.1** | **838.4** |
| **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 |
| Interest income | 0.0 | 0.1 | 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 | 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 |
| Other | (0.0) | (1.4) | (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 | 0.0 | 0.0 | 0.0 |
| **Net profit (loss) before income taxes** | **(2.6)** | **(7.9)** | **(3.7)** | **(17.4)** | **(2.8)** | **(3.8)** | **(27.7)** | **(53.8)** | **(54.2)** | **(18.4)** | **47.3** | **196.9** | **368.5** | **531.9** | **662.2** | **709.4** | **758.5** | **794.7** | **815.9** | **827.1** | **838.4** |
| 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 | 19.7 | 36.9 | 186.2 | 231.8 | 248.3 | 265.5 | 278.2 | 285.6 | 289.5 | 293.4 |
| *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%* | *35.0%* | *35.0%* | *35.0%* |
| **Net Income (GAAP)** | **(2.6)** | **(7.8)** | **(3.7)** | **(17.9)** | **(2.8)** | **(3.8)** | **(28.2)** | **(53.8)** | **(54.2)** | **(18.4)** | **47.3** | **177.2** | **331.7** | **345.7** | **430.4** | **461.1** | **493.0** | **516.6** | **530.3** | **537.6** | **544.9** |
| **Adjusted Items (Non-GAAP)** | | | | | | | | | | | | | | | | | | | | | |
| Stock options | 0.0 | 0.0 | 0.0 | 7.0 | 0.3 | 0.3 | 7.6 | 3.0 | 5.0 | 5.0 | 7.0 | 10.0 | 10.0 | 10.0 | 12.0 | 12.0 | 12.0 | 15.0 | 15.0 | 20.0 | 20.0 |
| Other | 0.0 | 1.4 | 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 | 0.0 | 0.0 | 0.0 |
| **Net Income (Non-GAAP)** | **(2.6)** | **(6.4)** | **(3.1)** | **(10.9)** | **(2.5)** | **(3.5)** | **(20.0)** | **(50.8)** | **(49.2)** | **(13.4)** | **54.3** | **187.2** | **341.7** | **355.7** | **442.4** | **473.1** | **505.0** | **531.6** | **545.3** | **557.6** | **564.9** |
| **EPS, GAAP** | **(0.49)** | **(1.43)** | **(0.66)** | **(2.27)** | **(0.06)** | **(0.09)** | **(3.08)** | **(1.21)** | **(1.20)** | **(0.40)** | **1.00** | **3.68** | **6.76** | **6.91** | **8.43** | **8.86** | **9.28** | **9.54** | **9.60** | **9.54** | **9.48** |
| Basic shares | 5.3 | 5.5 | 5.6 | 7.9 | 43.5 | 43.6 | 25.1 | 44.4 | 45.3 | 46.2 | 47.2 | 48.1 | 49.1 | 50.0 | 51.0 | 52.1 | 53.1 | 54.2 | 55.3 | 56.4 | 57.5 |
| **Diluted shares** | **5.3** | **5.5** | **5.6** | **7.9** | **43.5** | **43.6** | **25.1** | **44.4** | **45.3** | **46.2** | **47.2** | **48.1** | **49.1** | **50.0** | **51.0** | **52.1** | **53.1** | **54.2** | **55.3** | **56.4** | **57.5** |
| **EPS, Non-GAAP** | (0.49) | (0.22) | (0.11) | (0.34) | (0.06) | (0.08) | (0.59) | **(1.14)** | **(1.08)** | **(0.29)** | **1.15** | **3.89** | **6.96** | **7.11** | **8.67** | **9.09** | **9.51** | **9.81** | **9.87** | **9.89** | **9.83** |
| Basic shares | 5.4 | 29.2 | 29.3 | 31.6 | 43.5 | 43.6 | 37.0 | 44.4 | 45.3 | 46.2 | 47.2 | 48.1 | 49.1 | 50.0 | 51.0 | 52.1 | 53.1 | 54.2 | 55.3 | 56.4 | 57.5 |
| **Diluted shares** | **5.4** | **29.2** | **29.3** | **31.6** | **43.5** | **43.6** | **37.0** | **44.4** | **45.3** | **46.2** | **47.2** | **48.1** | **49.1** | **50.0** | **51.0** | **52.1** | **53.1** | **54.2** | **55.3** | **56.4** | **57.5** |

**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 | 2026E | 2027E | 2028E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Sales | *0.0* | 0.0 | 0.0 | 0.0 | 0.0 | 63.4 | 185.1 | 393.4 | 639.4 | 829.7 | 984.1 | 1,031.0 | 1,079.3 | 1,114.3 | 1,143.2 | 1,159.5 | 1,176.0 |
| Operating Expenses | *7.7* | 9.4 | 20.9 | 53.8 | 54.2 | 75.9 | 137.9 | 196.5 | 260.8 | 297.9 | 322.0 | 321.6 | 320.8 | 319.6 | 327.2 | 332.4 | 337.7 |
| EBIT | (7.7) | (9.4) | (20.9) | (53.8) | (54.2) | (12.4) | 47.3 | 196.9 | 378.5 | 531.9 | 662.2 | 709.4 | 758.5 | 794.7 | 815.9 | 827.1 | 838.4 |
| (-): Taxes | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 19.7 | 36.9 | 186.2 | 231.8 | 248.3 | 265.5 | 278.2 | 285.6 | 289.5 | 293.4 |
| EBIAT | (7.7) | (9.4) | (20.9) | (53.8) | (54.2) | (12.4) | 47.3 | 177.2 | 341.7 | 345.7 | 430.4 | 461.1 | 493.0 | 516.6 | 530.3 | 537.6 | 544.9 |
| (+):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 | 0.0 | 0.0 | 0.0 |
| (+):FAS-123 Options | 0.3 | 0.3 | 7.6 | 3.0 | 5.0 | 5.0 | 7.0 | 10.0 | 10.0 | 10.0 | 12.0 | 12.0 | 12.0 | 15.0 | 15.0 | 20.0 | 20.0 |
| (-): 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 | 0.3 | 0.3 | 0.3 |
| (-): Changes in w orking 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 | 0.7 | 0.7 | 0.7 |
| **Unlevered free cash flow** | ***(7.4)*** | ***(9.1)*** | ***(16.2)*** | ***(51.7)*** | ***(50.1)*** | ***(7.9)*** | ***53.3*** | ***186.2*** | ***350.7*** | ***354.7*** | ***441.4*** | ***472.1*** | ***504.0*** | ***530.6*** | ***544.4*** | ***556.6*** | ***564.0*** |

**Source: Jefferies estimates, company data**



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Please see important disclosure information on pages 6 - 9 of this report.

## 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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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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Within the past twelve months, Kite Pharma has been a client of Jefferies LLC and investment banking services are being or have been provided.

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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.

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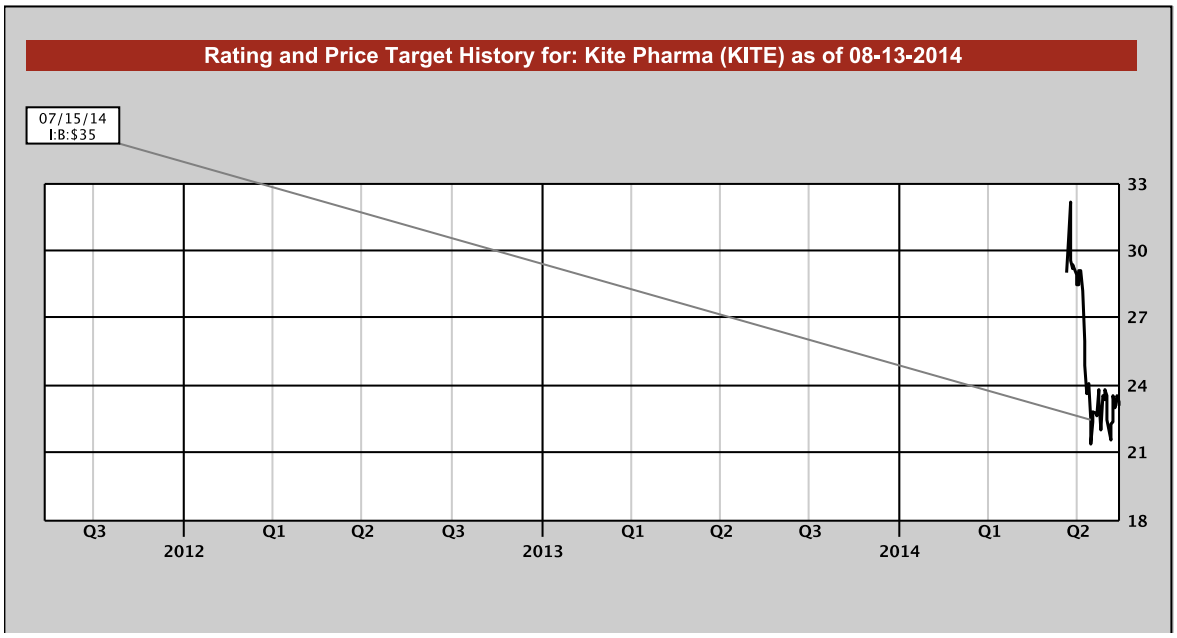


## Distribution of Ratings

| Rating | Count | Percent | IB Serv./Past 12 Mos. Count | IB Serv./Past 12 Mos. Percent |
|---|---|---|---|---|
| BUY | 969 | 51.54% | 254 | 26.21% |
| HOLD | 764 | 40.64% | 123 | 16.10% |
| UNDERPERFORM | 147 | 7.82% | 7 | 4.76% |



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