#### **OUTPERFORM**

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**COMPANY UPDATE** 



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## KALOBIOS PHARMACEUTICALS, INC.

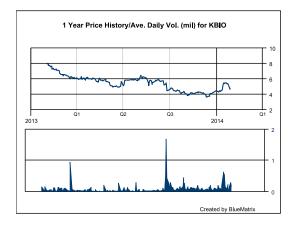
KB003 Misses Primary Endpoint, Trading Near Cash With Three More Shots on Goal

- · Bottom Line: Today after the close KBIO announced its Phase II KB003 severe asthma trial failed to hit its primary endpoint. While KBIO found encouraging, statistically significant efficacy (~8% on FEV1) in a trial subgroup (eosinophilic asthma patients demonstrating a high level of reversibility at baseline), a lack of distinction on exacerbations has led the company to discontinue development of KB003. We are removing KB003 from our model and lowering our price target to \$7 from \$15 previously. We believe that with \$2.04 in cash/share on the balance sheet, KBIO is extremely undervalued at current levels. Reiterate OP on KBIO.
- · KB003 surprisingly failed to attain statistical significance on FEV1, which could have been due to a broader patient population recruited in the Phase II. In the very promising albeit small Phase I, KBIO screened for sputum eosinophils, but the large 150-patient Phase II was not able to put in place such an academic inclusion requirement. Management noted that patients were slightly more severe but otherwise baseline criteria and trial conducted as expected.
- · KBIO expects the discontinuation of KB003 development to save the company at least ~10MM of R&D in 2014. This will allow the company to focus resources on adding more sites outside the US for the KB001-A Phase II study, advance development of KB004 in oncology, and potentially advance KB005 which is in preclinical studies against an undisclosed target.
- · Next up: KB001-A cystic fibrosis (CF) Phase II data are expected by YE14. SNY (MP) holds the rights to opt-in to KBIO's CF program and has already licensed KB001-A rights for Pseudomonas Aeruginosa in ventilator-assisted pneumonia (*Pa.* VAP). Unlike standard-of-care CF antibiotics such as NVS's (OP) Tobi, KB001-A targets the type-III secretion system of Pa bacteria, an area that can incur both inflammation and alveoli apoptosis. By hitting this target, KB001-A may be able to produce an anti-infective effect without precipitating bacterial resistance.

**Key Stats:** (Symbol:KBIO)

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ndex: 1,276.07
\$4.65
\$7.00 from \$15.00
Sum-of-the-parts DCF analysis
\$8.25
\$3.60
il): 36.3
nil): \$168.8
\$0.00
\$2.04
\$0.00
0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	\$3.0	\$3.0	\$0.1	0.0	\$6.1	\$0.57	(\$1.01)	(\$4.05)	(\$5.40)	(\$11.22)	NM
2013E	0.0A	0.0A	0.0A	0.0	0.0	(\$0.55)A	(\$0.49)A	(\$0.47)A	(\$0.36)	(\$1.79)	NM
2014E - New	0.0	0.0	0.0	0.0	0.0	(\$0.32)	(\$0.34)	(\$0.35)	(\$0.36)	(\$1.37)	NM
2014E - Old	0.0	\$12.5	0.0	0.0	\$12.5	(\$0.35)	(\$0.02)	(\$0.44)	(\$0.41)	(\$1.11)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in \$MM.

GAAP EPS; IPO 1/10/13.



### **INVESTMENT THESIS**

We believe that KBIO shares are poised to appreciate as clinical and commercial catalysts are realized for KBIO's two proprietary monoclonal antibody (mAb) therapeutics: KB001-A, and the early but intriguing KB004. We believe that KBIO's attractive clinical portfolio is differentiated by its proprietary Humaneering technology, which enables the generation of mAbs with low immunogenicity and enhanced sequence specificity. Our belief in the uniqueness of KBIO's technology has been corroborated by an investment from SNY (MP), which has agreed to fund the development and commercialization of KB001-A for ventilator-assisted patients (VAP) at risk for Pseudomonas aeruginosa (Pa) induced pneumonia. Additionally, operating by the same attractive biochemical mechanism, KB001-A is enrolled in a Phase II study examining its ability to control Pa infections in cystic fibrosis (CF) patients, with clinical data expected in late 2014. SNY has the ability to opt-in and partner with KBIO in developing KB001-A in this indication as well after Phase II data are released in 2Q:14.Our Outperform reflects our confidence that as more clinical data for KBIO's mAb therapeutics are generated and crucial partnerships are cemented, KBIO shares will appreciate on the Street's enhanced view of the company's platform and potential.

### **VALUATION**

We estimate a risk-adjusted per share value for KBIO of \$7 in 12 months. We use a 12% WACC as our discount rate since the risks involved with drug development and regulatory approval have already been handicapped by probability-weighting our revenues. Over the longer term, we assume a 5% terminal growth rate, which we believe is conservative, given that no generic mAbs have ever been approved and KBIO may expand its mAb pipeline and recognize revenues from therapeutics that are not yet in development. In probability weighting our projected revenue streams from each program, we risk-adjust all sales estimates at 50%.

### RISKS TO VALUATION

Risks include the potential for disappointing clinical data, regulatory setbacks, and commercial shortfalls. Since KBIO is presently unprofitable and only has products that have completed early-stage clinical trials, any of the possible aforementioned setbacks may impact the stock significantly.

KBIO P&L (\$MM)	2011	2012	1Q13	2Q13	3Q13	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E
Contract revenue (p/w)	20.3	6.1	0.0	0.0	0.0	-	0.0	-	-	-	-	-
Royalties (p/w)	-	-	-	-	-	-	-	-	-	-	-	-
Product sales (p/w)	-	-	-	-	-	-	-	-	-	-	-	-
Revenue	20.3	6.1	0.0	0.0	0.0	-	0.0	-	-	-	-	-
cogs	-	-	-	-	-	-	-	-	-	-	-	-
R&D	18.5	24.5	6.3	9.6	9.0	9.0	34.0	8.0	8.0	8.0	8.0	32.0
SG&A	4.0	5.1	2.0	1.9	2.1	2.5	8.6	2.5	3.0	3.5	4.0	13.0
Operating expenses	22.5	29.6	8.3	11.6	11.1	11.5	42.5	10.5	11.0	11.5	12.0	45.0
Operating income	(2.3)	(23.5)	(8.3)	(11.6)	(11.1)	(11.5)	(42.5)	(10.5)	(11.0)	(11.5)	(12.0)	(45.0)
Interest income	0.0	0.0	0.0	-	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.4
Interest expense	-	0.1	0.3	0.2	0.3	0.3	1.1	0.3	0.3	0.3	0.2	1.1
Other income (expense)	(0.0)	0.1	-	(0.0)	(0.0)	-	(0.0)	-	-	-	-	-
EBT	(2.2)	(23.5)	(8.6)	(11.8)	(11.3)	(11.7)	(43.4)	(10.7)	(11.2)	(11.7)	(12.1)	(45.7)
Tax expense (benefit)	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(2.2)	(23.5)	(8.6)	(11.8)	(11.3)	(11.7)	(43.4)	(10.7)	(11.2)	(11.7)	(12.1)	(45.7)
Diluted EPS	(1.15)	(11.22)	(0.55)	(0.49)	(0.47)	(0.36)	(1.79)	(0.32)	(0.34)	(0.35)	(0.36)	(1.37)
Basic shares outstanding	1.9	2.1	15.6	24.2	24.3	32.9	24.2	33.0	33.2	33.4	33.4	33.2
Diluted shares outstanding			19.0	27.6	27.7	36.3	27.6	36.3	36.5	36.7	36.7	36.6

Source: SEC filings and Leerink Partners Estimates

KBIO CFS	2011	2012	1Q13E	2Q13	3Q13	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E
Change in cash	(5.6)	(3.4)	55.2	(13.2)	(10.9)	21.2	51.8	(10.5)	(10.9)	(11.3)	(11.8)	(44.5)
Cash from operations	(15.3)	(26.8)	(8.4)	(11.4)	(10.9)	(10.8)	(41.5)	(9.6)	(10.1)	(10.5)	(10.9)	(41.2)
Net Income	(2.2)	(23.5)	(8.6)	(11.8)	(11.3)	(11.7)	(43.4)	(10.7)	(11.2)	(11.7)	(12.1)	(45.7)
Deferred revenue	(14.0)	(5.6)	-	-	-	-	-	-	-	-	-	-
SOE	0.2	0.8	0.2	0.4	0.5	0.9	1.9	1.1	1.1	1.2	1.2	4.5
	0.7	1.5	-	-	-	-	-					-
Cash from investing	9.7	(3.8)	-	(2.3)	-	-	(2.3)	-	-	-	-	-
CapEx	(0.5)	0.2	-	-	-	-	-	-	-	-	-	-
Other	10.2	(4.0)	-	(2.3)	-	-	(2.3)	-	-	-	-	-
Cash from financing	0.0	27.2	63.6	-	-	32.0	95.6	(0.8)	(0.8)	(0.8)	(0.8)	(3.3)
Issuance (buyback) shares	-	18.8	63.6	-	-	32.0	95.6	-	-	-	-	-
Issuance (repay) debt	-	9.8	-		-	-	-	(0.8)	(8.0)	(8.0)	(8.0)	(3.3)
Other	0.0	(1.5)	-	-	-	-	-	-	-	-	-	-

Source: SEC filings and Leerink Partners Estimates

DCF	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	TV
EBITDA	(42)	(41)	(30)	(39)	(15)	(32)	(38)	(26)	(11)	5	14	31	50	68	87	107	121	90
SOE	2	5	5	5	5	3	3	3	3	3	4	4	4	4	4	4	1	
FCF	(40)	(37)	(26)	(34)	(10)	(29)	(35)	(23)	(8)	9	18	35	53	72	91	111	122	90
Discount periods	-	-	1.00	2.00	3.00	4.00	5.00	6.00	7.00	8.00	9.00	10.00	11.00	12.00	13.00	14.00	15.00	16.00
Discount Rate	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%
PV FCF	-	(37)	(23)	(27)	(7)	(18)	(20)	(12)	(4)	4	6	11	15	18	21	23	22	221
NPV	195																	

TG	5%
DR	12%
Net Cash	\$ 64.11
Shares Outstanding YE13	36.3
NPV/Share	\$ 7.14

Source: Company reports and Leerink Partners LLC estimates



# **Disclosures Appendix Analyst Certification**

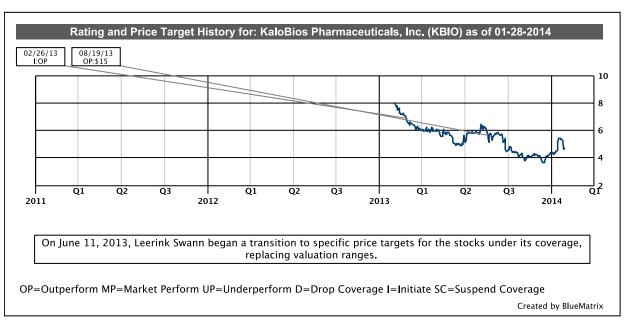
I, Joseph P. Schwartz, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### **Valuation**

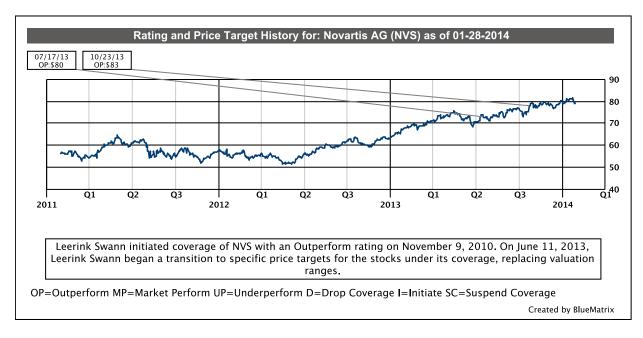
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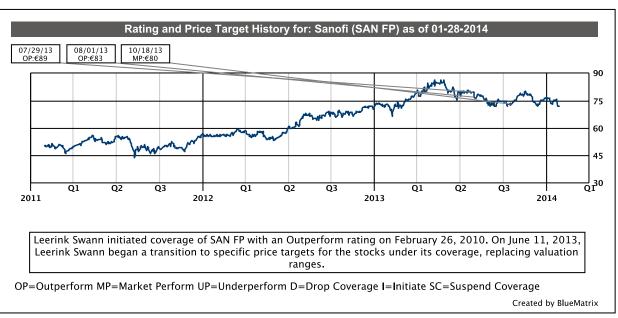
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	Distribution of Ratings/Investment Bank	ing Services (II		erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP]	118	64.50	30	25.00
HOLD [MP]	65	35.50	2	3.00
SELL [UP]	0	0.00	0	0.00

## **Explanation of Ratings**

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

<u>Market Perform (Hold/Neutral)</u>: We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.



# **Important Disclosures**

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Leerink Partners LLC makes a market in KaloBios Pharmaceuticals, Inc.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of Novartis AG and Sanofi on a principal basis.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: Novartis AG.

Leerink Partners LLC has acted as the manager for a public offering of KaloBios Pharmaceuticals, Inc. in the past 12 months.

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