Reason for report: **EARNINGS** 

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### KALOBIOS PHARMACEUTICALS, INC.

2Q13 Recap: Pipeline Advancing, Cancer & Asthma Data in 4Q13 and 1Q14

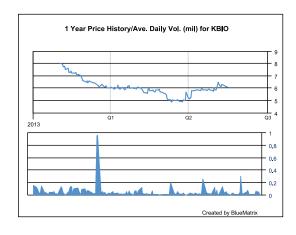
- Bottom Line: This morning KBIO reported 2Q13 EPS of (\$0.49), which was relatively in line with our estimate of (\$0.51). We continue to believe that KBIO presents an attractive portfolio of "Humaneered" monoclonal antibodies (mAbs) that could be able to confer a therapeutic benefit in inflammatory, cancer, and/or infectious disease settings. We are updating our model to reflect 2Q13 results and reiterate our Outperform rating and \$15 Price Target in 12 months.
- KBIO announced that it has completed enrollment of the KB003 severe asthma study ahead of schedule and will report top-line results in 1Q14. KB003 is an enhanced version of KB002, a mAb with specificity to granulocyte macrophage colony stimulating factor (GM-CSF). As GM-CSF is a "master" immunological of the inflammatory cascades involved in the pathogenesis of both allergic and non-allergic asthma, we believe that KB003 presents a uniquely promising clinical profile when compared to other antibodies in development. We believe that positive Phase II data could render this program very appealing to potential partners. Severe asthma presents a very attractive market opportunity as ~5-10% of the 1MM+ patients in the US fail the asthma standard of care and are in dire need of new agents. We believe that the quicker-than-expected enrollment of the KB003 Phase II trial reflects the pent-up demand for new agents from the asthma patient and physician community.
- Top-line data from the Phase I dose-escalating KB004 study in hematologic malignancies will be announced in 4Q13, and two Phase II studies will be initiated by YE13. KBIO announced testing of the 6th dose level for KB004 (190mg) and now plans to initiate the Phase II expansion phase of the study in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) when confirmatory safety and pharmacokinetic data are obtained from the Phase I trial. KB004 is an anti-EphA3 receptor tyrosine kinase monoclonal antibody, which showed activity at a relatively low dose (20mg) to an EphA3-positive patient who at the time of this announcement had been treated with KB004 for over 1 year, despite the fact that these patients generally have a life expectancy of ~3-4 months.
- KB001-A cystic fibrosis (CF) data now later than expected in 4Q14, but data from SNY's (OP) Pseudomonas aeruginosa (*Pa*) ventilator-assisted pneumonia (*PA*-VAP) study could be announced before that. The KB001-A CF study has been enrolling slower than expected, but KB001-A has also been awarded "Fast Track" designation for the treatment of *Pa* VAP which is a serious unmet need that plagues ~50k patients per year in the US.

# Kev Stats: (Symbol:KBIO)

HEALTHCARE EQUITY RESEARCH

S&P 600 Health Care Index: Price:	1,087.73 \$6.06
Price Target:	\$15.00
Methodology:	DCF analysis
52 Week High:	\$8.25
52 Week Low:	\$4.81
Shares Outstanding (mil):	27.6
Market Capitalization (mil):	\$167.3
Book Value/Share:	\$0.00
Cash Per Share:	\$1.95
Dividend (ann):	\$0.00
Dividend Yield:	0.0%

Cash Per Share: net cash



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 - New	0.0A	0.0A	0.0	0.0	0.0	(\$0.55)A	(\$0.49)A	(\$0.55)	(\$0.59)	(\$2.17)	NM
2013E - Old	0.0A	0.0A	0.0	0.0	0.0	(\$0.55)A	(\$0.51)	(\$0.55)	(\$0.59)	(\$2.20)	NM
2014E					\$25.0					(\$1.19)	NM

Source: Company Information and Leerink Swann 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 three proprietary monoclonal antibody (mAb) therapeutics: KB001-A, KB003, 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 (OP), 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 patients, with clinical data expected in mid-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 is released in 2Q:14. For KB003, KBIO is currently running a 150patient Phase II trial in patients with severe asthma. We believe that KB003 may be broadly applicable to both allergic and non-allergic asthmatics, since its epitope is an inflammatory marker integral to multiple aspects of the disease cascade. Thus far, while the trials run for KBIO's mAbs (mainly performed on its precursor antibodies) were not powered for statistical significance, they nonetheless suggested that KBIO's therapeutics are non-immunogenic and will likely be able to produce a statistically significant clinical effect by interfering with pathogenic biological processes. Thus, our rating of 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 potential.

#### VALUATION

We estimate a risk-adjusted per share value for KBIO of \$15 in 12 months. We use a sum-of-the-parts discounted cash flow (DCF) methodology, attributing ~\$4 to KB001-A in Pa VAP, ~\$4 to KB001-A in Pa CF, ~\$6 to KB003 in asthma, and ~\$2 to net cash. 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%, since KB001-A and KB003 have thus far only been examined in Phase I/II trials.

### 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	3Q13E	4Q13E	2013E	2014E
Contract revenue (p/w)	20.3	6.1	0.0	0.0	-	-	0.0	25.0
Royalties (p/w)	-	-	-	-	-	-	-	-
Product sales (p/w)	-	-	-	-	-	-	-	-
Revenue	20.3	6.1	0.0	0.0	-	-	0.0	25.0
COGS	-	-	-	-	-	-	-	-
R&D	18.5	24.5	6.3	9.6	8.5	9.0	33.5	40.0
SG&A	4.0	5.1	2.0	1.9	4.5	5.0	13.5	20.0
Operating expenses	22.5	29.6	8.3	11.6	13.0	14.0	46.9	60.0
Operating income	(2.3)	(23.5)	(8.3)	(11.6)	(13.0)	(14.0)	(46.9)	(35.0)
Interest income	0.0	0.0	0.0	-	0.1	0.0	0.1	0.2
Interest expense	-	0.1	0.3	0.2	0.3	0.3	1.1	1.2
Other income (expense)	(0.0)	0.1	-	(0.0)	-	-	(0.0)	-
EBT	(2.2)	(23.5)	(8.6)	(11.8)	(13.2)	(14.3)	(47.9)	(36.0)
Tax expense (benefit)	-	-	-	-	-	-	-	-
Net income (loss)	(2.2)	(23.5)	(8.6)	(11.8)	(13.2)	(14.3)	(47.9)	(36.0)
Diluted EPS	(1.15)	(11.22)	(0.55)	(0.49)	(0.55)	(0.59)	(2.17)	(1.19)
Basic shares outstanding	1.9	2.1	15.6	24.2	24.2	24.2	22.0	30.2
Diluted shares outstanding			19.0	27.6	27.6	27.6	25.4	33.6

Source: SEC filings and Leerink Swann Estimates

KBIO BS	2011	2012	1Q13	2Q13	3Q13E	4Q13E	2013E	2014E
Cash + MS	17.8	20.3	76.9	63.7	51.4	38.3	37.0	88.7
Debt	-	9.8	9.9	9.9	9.9	9.9	9.9	9.9
Term Loan (MidCap Financial)	-	9.8	9.9	9.9	9.9	9.9	9.9	9.9
Other	-	-	-	-	-	-	-	-

KBIO CFS	2011	2012	1Q13E	2Q13	3Q13E	4Q13E	2013E	2014E
Change in cash	(5.6)	(3.4)	55.2	(13.2)	(12.2)	(13.1)	16.7	51.7
Cash from operations	(15.3)	(26.8)	(8.4)	(10.9)	(12.2)	(13.1)	(44.6)	(30.0)
Net Income	(2.2)	(23.5)	(8.6)	(11.8)	(13.2)	(14.3)	(47.9)	(36.0)
Deferred revenue	(14.0)	(5.6)	-	-	-	-	-	-
SOE	0.2	0.8	0.2	0.9	1.0	1.1	3.3	6.0
	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	-	-	-	63.6	81.7
Issuance (buyback) shares	-	18.8	63.6	-	-	-	63.6	85.0
Issuance (repay) debt	-	9.8	-		-	-	-	(3.3)
Other	0.0	(1.5)	-	-	-	-	-	-

Source: SEC filings and Leerink Swann Estimates

KBIO Product Sales (P/W)	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
KB001A (CF) profit share	-	-	-	-	-	-	0.6	4.1	11.3	19.1	27.0	35.6	44.9	55.4	64.5	75.2	86.6	95.6
KB003 Asthma US Sales	-	-	-	-	-	-	-	12.5	50.0	100.0	150.0	200.0	258.5	284.4	312.8	344.1	378.5	416.3
Total product sales	-	-	-	-	-	-	0.6	16.6	61.3	119.1	177.0	235.6	303.4	339.7	377.3	419.3	465.0	511.9
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Royalties (P/W)	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Royalties (P/W) KB001A VAP (Sanofi)	2012E -	2013E	2014E -	<b>2015E</b>	<b>2016E</b>	2017E -	<b>2018E</b> 3.5	<b>2019E</b> 7.7	<b>2020E</b> 12.8	<b>2021E</b> 20.1	<b>2022E</b> 28.9	<b>2023E</b> 39.4	<b>2024E</b> 46.4	<b>2025E</b> 53.6	<b>2026E</b> 60.8	<b>2027E</b> 68.2	<b>2028E</b> 75.8	<b>2029E</b> 83.5
, , , ,	2012E - -	2013E - -	-															

Milestone Payments (P/W)	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
KB001A (VAP)	-	-	5.0	-	25.0	50.0	40.0	20.0	20.0	20.0	20.0							
probability	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
KB001A (CF)	-	-	20.0	-	10.0	10.0	-	-	_	-	-							
probability	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
KB003 (Asthma)			25.0		25.0	25.0	20.0	20.0	20.0	20.0	20.0							
probability	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total milestone payments	-	-	25.0	-	30.0	42.5	30.0	20.0	20.0	20.0	20.0	-	-	-	-	-	-	-

	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E
Total Revenue (P/W)	-	-	25.0	-	30.0	42.5	34.1	45.3	97.8	166.7	237.2	290.0	369.2	414.6	461.6	513.4	569.2	626.6

Source: Leerink Swann Estimates

DCF	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	TV
EBITDA	(45)	(30)	(65)	(46)	(41)	(68)	(88)	(50)	6	65	107	176	212	177	206	238	269	135
CapEx	-	-	-	1	1	1	1	1	1	1	1	1	1	1	-	-	-	-
FCF	(45)	(30)	(65)	(47)	(42)	(69)	(89)	(51)	5	64	106	175	211	176	206	238	269	135
Discount periods	-	0.50	1.50	2.50	3.50	4.50	5.50	6.50	7.50	8.50	9.50	10.50	11.50	12.50	13.50	14.50	15.50	16.50
Discount Rate	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%
PV FCF	(22)	(28)	(55)	(35)	(28)	(41)	(47)	(24)	2	24	36	52	56	42	44	45	45	294
NPV	358																	

TG	5%
DR	12%
Shares Outstanding 2Q13	27.6
NPV/Share	12.99

SOTP DCF	NPV	val,	/shr
KB001-A <i>Pa</i> VAP	107	\$	4
KB001-A <i>Pa</i> CF	98	\$	4
KB003 asthma	153	\$	6
Net Cash	54	\$	2
VALUATION	412	\$	15

Source: Company reports and Leerink Swann LLC estimates

Drug	Indication	Event	Timing
KB001A (SNY)	VAP	High dose Phase I ongoing (IV)	
		Phase I data	1H14
		Initiate Phase IIb	3/4Q14
		Phase IIb/III data	4Q16
		EMA/FDA approved	1Q18
		Commercial launch	2H18
KB001A	CF	Phase II ongoing since Jan. 2013 (IV)	
		Phase II data (IV)	4Q14
		SNY opt-in	4Q14
		Initiate IV-SQ bridging study	2014
		IV-SQ bridging data	2015
		Initiate 2 Phase IIIs (SQ)	4Q15
		Phase III data (SQ)	4Q16
		EU/FDA approved	4Q17
		Commercial launch	1H18
KB003	Asthma	Phase II ongoing since Aug. 2012 (IV)	
		Initiate IV-SQ bridging study	2013
		IV-SQ bridging data	2014
		Phase II data (IV)	1Q14
		Ex-US partnership	2H14
		Initiate 2 Phase IIIs (SQ)	2H15
		Phase III data (SQ)	2H17
		EU/FDA approved	2H18
		Commercial launch	1H19
KB004	Cancer	Initiate Phase I expansion phase	3Q13
	30	Initiate Phase II study	4Q13
		Complete enrolling at least one hem. malig. indication (Phase I)	4Q14

Source: Company reports and Leerink Swann LLC estimates



## Disclosures Appendix Analyst Certification

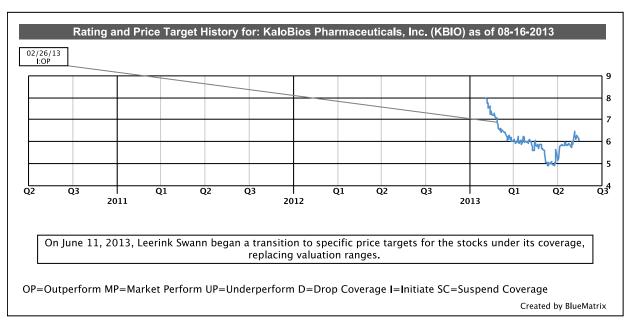
I, Joseph P. Schwartz, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### **Valuation**

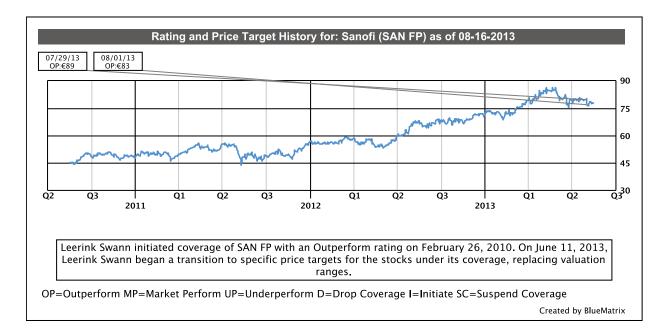
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### **Risks to Valuation**

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.









Distribu	Distribution of Ratings/Investment Banking Services (IB) as of 06/30/13 IB Serv./Past 1 Mo:					
Rating	Count	Percent	Count	Percent		
BUY [OP] HOLD [MP]	103 61	62.80 37.20	30 2	29.00 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 Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to KaloBios Pharmaceuticals, Inc.



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

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of Sanofi on a principal basis. Leerink Swann LLC has acted as the manager for a public offering of KaloBios Pharmaceuticals, Inc. in the past 12 months.

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