William Blair

KaloBios Pharmaceuticals, Inc.

Initiating Coverage With an Outperform Rating

KaloBios is an antibody platform company with three agents in clinical testing. Monoclonal antibodies historically have demonstrated a 2.5-times greater development success rate than small-molecule drugs. For two of the three antibody programs, KaloBios targets orphan diseases and is creating a patient-targeted approach via a prognostic screen or diagnostic to identify persons most likely to benefit from the therapies. We believe that this will result in an enhanced treatment benefit, reduce the overall cost and risk associated with clinical development, and ultimately provide therapies that are more tailored for patients.

Prevention of ventilation-associated pneumonia (VAP) could be the company's first approved indication. Based on projections made by Hannah Wunsch et al. in "The epidemiology of mechanical ventilation use in the United States" *Critical Care Medicine* 38 (October 2010), we estimate that about 1 million cases of mechanical ventilation occur each year in the United States, with roughly 25% of these considered at high risk for bacterial colonization. KB001-A, a monoclonal antibody that targets a component of Pseudomonas aeruginosa (Pseudomonas) involved in pathogenesis, is being tested in patients at high risk for VAP as well as in patients with cystic fibrosis (a second indication that the company is pursuing). We believe this agent has the potential to address two highly unmet disease markets (VAP prevention and cystic fibrosis).

Partnership agreement with Sanofi Pasteur provides KaloBios with capital as well as developmental and commercial expertise. In 2010, KaloBios signed an agreement with Sanofi granting exclusive worldwide rights to develop and commercialize KB001-A for VAP prevention. Under the agreement, KaloBios received an up-front payment of $35 million and an additional $5 million in 2011. KaloBios is eligible for payments of up to $250 million if certain clinical, regulatory, and commercial events are achieved. In addition to providing nondilutive capital, we believe this partnership also provides validation for KB001-A in VAP prevention. We estimate the company's current cash position is $90 million; $35 million of which we expect will be used in 2013.

KB003 has a unique mechanism of action, with the potential to reach an unmet medical need in persistent/uncontrolled asthma. The American Academy of Allergy Asthma and Immunology estimates that there are about 25 million adolescent and adult asthmatics living in the United States, of whom we estimate 2 million have persistent/uncontrolled asthma. KB003 is one of the most-advanced anti-GM-CSF antibodies in clinical testing, with demonstrated efficacy in both rheumatoid arthritis and severe asthma. Based on current timelines, we believe this wholly owned asset could be further validated in 2014 with the release of positive Phase II data, leading to a potential partnership deal.

Based in South San Francisco, California, KaloBios Pharmaceuticals, Inc. is a small-cap company focused on developing patient-targeted, first-in-class monoclonal antibodies using its proprietary Humaneered technology platform, with the intent to significantly improve the lives of seriously ill patients with difficult-to-treat diseases. The company has two agents in Phase II clinical testing in three different indications.

February 26, 2013
Basic Report (13-021)

Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Symbol:	KBIO (NASDAQ)
Price:	$7.12 (52-Wk.: $7–$8)
Market Value (mil.):	$171
Fiscal Year End:	December
Dividend/Yield:	None

Estimates	**2011A**	**2012E**	**2013E**
EPS FY	-$0.09	-$0.83	-$1.62
Revenue (mil.)	$20.2	$6.1	$0

Valuation			
P/E	NM	NM	NM

Trading Data	
Shares Outstanding (mil.)	24
Float (mil.)	11
Average Daily Volume	139,635

Financial Data	
Enterprise Value (mil.)	$92

John S. Sonnier
+1 312 364 8224
jsonnier@williamblair.com

Richard M. Reznick, Ph.D.
+1 312 364 8054
rreznick@williamblair.com

Dimiter V. Tassev, Ph.D.
+1 312 364 8585
dtassev@williamblair.com

Please consult pages 26-28 of this report for all disclosures.

Portfolio Manager Summary

KaloBios Pharmaceuticals is focused on the discovery and development of monoclonal antibodies using its proprietary Humaneered technology. Based in South San Francisco, California, the company was incorporated on March 15, 2000, and its February 7, 2013, initial public offering raised $70 million. *KaloBios is one of the only pure-play antibody companies to have gone public in more than a decade*. All of the drug candidates generated by KaloBios use the company's proprietary Humaneered technology, a method that converts nonhuman antibodies (typically mouse) into engineered, human antibodies that have a high binding affinity to their target and are designed for chronic therapeutic use. In April 2007, KaloBios granted Novartis a nonexclusive license to use this technology for $30 million, which provided early validation for the antibody discovery platform, in our opinion. Furthermore, based on historical valuations involving other antibody platform companies, such as Seattle Genetics, ImmunoGen, and Micromet, we believe KaloBios shares could perform well following Phase II results over the coming 12-18 months (the aforementioned companies reached valuations of greater than $400 million after positive proof-of-concept Phase II data). In exhibit 1, we compare KaloBios to other antibody-focused companies, as well as companies that are developing drugs for rare diseases. Based on the company's current market capitalization, KaloBios shares seem to be relatively undervalued, in our view.

Currently, the company's primary clinical focus is treating infectious and respiratory diseases and cancer. KaloBios has two antibodies in Phase II clinical testing for the treatment of severe/persistent asthma and cystic fibrosis (CF), and prevention of VAP; it also has a third antibody in Phase I clinical testing for hematological malignancies (exhibit 2). In the VAP prevention setting, KaloBios partnered with infectious disease expert Sanofi Pasteur, in which Sanofi helps develop and commercialize KB001-A, a monoclonal antibody that targets *Pseudomonas* (one of the most-common pneumonia-causing bacteria), in exchange for nondilutive capital (in the form of an up-front payment and milestone payments) and royalties. KB001-A is also being investigated for the treatment of CF, a genetic disorder that leads to severe lung deterioration, due to inflammation and bacterial infection (*Pseudomonas* is considered a leading contributor to respiratory deterioration in these patients). Based on currently available clinical data, KB001 (the predecessor to KB001-A) has been shown to alleviate some of the symptoms involved with CF, and it could be a large commercial opportunity for the company. KB003, an antibody that targets GM-CSF, is in clinical testing for the treatment of severe and persistent asthma, which represents a meaningful market opportunity in a disease with few effective therapies. We believe KB003 has the potential to help patients with both allergic and non-allergic asthma, based on early published clinical data. Lastly, KB004, a monoclonal antibody that targets EphA3, is in Phase I clinical testing for hematological malignancies, which based on its mechanism of action, could provide clinical benefit for certain types of leukemia. The company's primary approach toward drug development is to: 1) identify high unmet medical needs, 2) identify patients most likely to benefit from a specific therapy, and 3) subsequently create and test antibodies that target these diseases. ***By employing patient-selection criteria and focusing on disease-specific targets, we believe KaloBios has enhanced its chances of clinical and commercial success. Moreover, by focusing on orphan indications, KaloBios may obtain premium pricing more readily (assuming regulatory approval).***

We believe KaloBios's goal is to become a leading biopharmaceutical company geared toward the development and commercialization of first-in-class, patient-targeted monoclonal antibody therapeutics that address serious medical needs. With each of the antibody programs, the company takes a patient-targeted approach by developing some type of prognostic or diagnostic tool to identify patients most likely to benefit from therapy. Overall, we believe this targeted approach will result in an enhanced treatment benefit, reduce the overall cost and risk associated with clinical trials, and ultimately provide therapies that are better tailored than existing treatments, because they target what directly contributes to the disease. While 2013 will be a building year for the company, during which several ongoing clinical trials will complete enrollment, we expect several clinical catalysts

(exhibit 3, on the following page) in 2014 to further de-risk the company's wholly owned programs (CF and severe asthma). As a result, we are initiating our coverage on KaloBios with an Outperform rating and Aggressive Growth company profile.

Exhibit 1
KaloBios Pharmaceuticals, Inc.
Biotechnology Comparative Analysis
(dollars in millions, except price and market capitalization/cash ratio)

Company	Ticker	Price	Market Cap	Shares Outstanding	Cash	EV	Market Cap/Cash
KaloBios	KBIO	$7.31	$176	24	$93	$94	1.9
Antibody Companies							
Peregrine Pharmaceuticals, Inc.	PPHM	$1.56	$222	134	$18	$157	12.3
Celldex Therapeutics Inc.	CLDX	$8.92	$702	79	$53	$465	13.2
ImmunoGen Inc.	IMGN	$14.49	$1,227	84	$161	$1,015	7.6
Immunomedics Inc.	IMMU	$2.78	$212	76	$33	$190	6.5
Xoma Ltd.	XOMA	$2.62	$213	82	$48	$159	4.4
Averages			$515		$63	$397	8.8
Rare Disease Companies							
Hyperion Therapeutics, Inc.	HPTX	$19.17	$319	17	$52	$173	6.2
Raptor Pharmaceuticals Corp.	RPTP	$5.04	$262	52	$39	$222	6.7
Synageva BioPharma Corp.	GEVA	$49.18	$1,315	27	$60	$944	21.8
Averages			$632		$50	$446	11.6

Source: FactSet

Exhibit 2
KaloBios Pharmaceuticals, Inc.
Product Development Pipeline

Drug	Type	Preclinical	Phase I	Phase II	Phase III	Market	Description
KB001/ KB001-A	VAP prevention*						Anti-PcrV antibody that targets the type three secretion system (TTSS) of *Pseudomonas aeruginosa* (PA)
	Cystic fibrosis						
KB002/ KB003	Severe asthma						Anti-GM-CSF antibody with potential in both allergic and non-allergic severe asthma
KB004	Hematology/oncology						An antibody that targets EphA3, an oncofetal antigen expressed on a variety of solid and liquid tumors

*Partnered with Sanofi Pasteur

Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 3
KaloBios Pharmaceuticals, Inc.
Timeline

Date	Drug	Indication	Event
2013	KB001-A	VAP Prevention	Initiate Phase I dose-escalation study (up to 30 mg/kg) (1H)
			Complete Phase I dose-escalation study (up to 30 mg/kg) (2H)
	KB003	Asthma	Complete enrollment of Phase II study
	KB004	Hematological Malignancies	Complete dose-escalation portion of Phase I/II study
			Begin dose-expansion portion of Phase I/II study
2014	KB001-A	Cystic Fibrosis	Top-line results from the Phase II study (2H)
		VAP Prevention	Initiate Phase IIb study (2H)*
	KB003	Asthma	Top-line results from Phase II study (1H)
			Potentially initiate Phase III study (2H)
	KB004	Hematological Malignancies	Complete enrolling dose-expansion portion of Phase I/II study
2015	KB001-A	VAP Prevention	Top-line results from Phase IIb study
		Cystic Fibrosis	Potentially initiate Phase III study
	KB004	Hematological Malignancies	Top-line results from dose-expansion portion of Phase I/II study

*Triggers a $5 million milestone payment upon initiation of the study
Sources: KaloBios Pharmaceuticals, Inc. reports

Valuation

KaloBios is one of the only pure-play antibody companies to go public in the last decade. Because human monoclonal antibodies are relatively non-immunogenic and very specific, antibody products have shown 2.5 times greater development success rates than small-molecule drugs. In addition, biologics have 12 years of exclusivity in the United States, with no clear approval pathway for biosimilars yet in this country. From a valuation standpoint, antibody platform companies historically have performed well after releasing positive proof-of-concept Phase II clinical trial data including Seattle Genetics, Human Genome Sciences, Alexion, Micromet, and ImmunoGen. Furthermore, when analyzing antibody-based companies (such as KaloBios) that have gone public over the last 27 years, we observed a compound annual return rate of 17.1%, which was due to a step-up in valuation as a result of positive Phase II proof-of-concept data and commercial success.

Humaneered technology provides the company with a differentiated antibody platform. We believe that the company's Humaneered antibody platform technology is differentiated from others in various ways including:

1. "Humaneering" seems to generate more germline antibody sequences, and has the potential to create less immunogenic antibodies than those that have been humanized using other methods.

2. Humaneered technology incorporates affinity maturation, which is typically a separate process before and after conventional humanization.

3. "Humaneering" selects for favorable pharmacokinetic, biochemical, and manufacturing characteristics, which are important in the downstream use of these antibodies.

Sanofi collaboration should enable developmental prowess and global commercial reach. As one of the most-experienced vaccine/infectious-disease-focused companies in the world, we believe Sanofi is an ideal partner for KaloBios with regard to KB001-A. Under an agreement between the two companies, KaloBios received an up-front payment of $35 million in January 2010, along with an additional payment of $5 million on August of 2011. KaloBios is also eligible to receive contingent

payments of up to $250 million if certain clinical, regulatory, and commercial events are achieved, including $5 million upon initiation of a Phase II clinical trial in VAP prevention (scheduled for 2014) and $20 million upon successful completion of the study. Upon commercialization, KaloBios is entitled to tiered royalties from 12% to 17% of worldwide KB001-A VAP prevention sales. ***Beyond VAP, Sanofi has the option to participate in the CF indication once the Phase II data is available in 2014; this coincides with additional up-front and milestone payments to KaloBios.***

In addition to nondilutive capital via an up-front payment, milestones and royalty payments throughout the development and commercialization KB001-A, Sanofi provides KaloBios the expertise needed to effectively and efficiently test and hopefully market the compound in the future. Furthermore, in early September, KaloBios announced that Sanofi would manufacture new KB001-A using a more-refined process at Sanofi's facility in Vitry, France, rather than using existing material that was manufactured by Lonza. We believe that this decision will increase the drug's probability of success (regulatory approval), since the material will be more "commercial ready" with less risk of clinical variability. As a result, partnering with Sanofi is a significant positive for KaloBios, in our view.

Market Potential: We Anticipate Significant Value With KB001-A and KB003 Approvals

KB001-A. VAP can develop 48 hours of longer after mechanical ventilation is given by means of an endotracheal tube or tracheostomy. Based on projections made in *Critical Care Medicine* (Wunsch et al. October 2010), we estimate that roughly 1 million cases of mechanical ventilation occur each year in the United States, with about 25% of these considered high risk for bacterial colonization and 20% done as a result of the bacteria *Pseudomonas*. At about $10,000 per dose, we estimate a U.S. market opportunity of more than $500 million, with $75 million going to KaloBios, based on the company's royalty structure with Sanofi.

According to the Cystic Fibrosis Foundation (CFF), 30,000 children and adults in the United States and 70,000 worldwide (35,000 in Europe) have CF. About 80% of adults with CF have chronic *Pseudomonas* infection. As a result, we estimate that about 24,000 patients would qualify for KB001-A therapy, which could generate a market opportunity of $1.2 billion in the United States alone, assuming $50,000 per patient per year.

KB003. The American Academy of Allergy Asthma and Immunology estimates that there are about 25 million adolescent and adult asthmatics living in the United States, with about 10 million currently on some type of treatment. Of the 10 million patients on therapy, about 4 million have moderate or severe disease. Overall, we estimate that the persistent/uncontrolled asthma population is about half of all moderate/severe asthma patients, which would result in about 2 million patients who could qualify for and benefit from KB003. With an estimated price of $10,000 per patient per year, the persistent/uncontrolled asthma market potential is sizable.

Risks

Competitive

We believe that the major competitors to KB001-A in VAP prevention are antibiotics such as azithromycin; however, these have not been widely adopted by the medical community due to a counteractive effort aimed at limiting patient exposure to antibiotics. In CF, the competitive landscape seems to be greater; however, not all of the agents that are approved or still in development target the bacterial issues associated with this disease (Kalydeco, for example). Of the agents that could directly compete with KB001-A in CF, Tobi, Zithromax, and Cayston also target the *Pseudomonas*. With respect to severe/persistent asthma, Xolair seems to be the primary competitor; however, its activity is restricted to patients with specific allergic asthma (IgE-related), which is more restrictive than the currently sought-after indication for KaloBios.

Clinical/Regulatory

As with all biotechnology and pharmaceutical companies, regulatory authorities have the power to accept or deny the use of new drugs in the marketplace, based on a combination of clinical efficacy and safety data. One of the main features differentiating KaloBios from most companies is its sole focus on developing antibodies, which historically have had a 32% success rate from investigational new drug application through approval, versus 13% for small molecules (DiMasi et al. *Clin Pharmacol Ther.* 87;272-7 2010). In addition, in VAP prevention, KaloBios is collaborating with Sanofi, one of the leading and most experienced drug companies in infectious disease.

Financial

As is the case with most small-cap drug companies, one of the primary risks for investors is whether the company has enough cash to develop its drug candidate all the way to the clinic. KaloBios's recent IPO raised $70 million. Quarter-over-quarter increases in spending (R&D and SG&A), which we expect will continue, and the company's cash position (currently about $90 million) could become critical. To continue operations, the company will likely need to generate capital in some manner, which may come from stock or debt issuance, or additional partnerships, based on the company's drug-discovery platform.

Management

KaloBios's management team comprises individuals with a broad range of backgrounds, including entrepreneurs, experienced scientists, and finance/business professionals with successful records in the biotech industry. Senior management and advisors have been instrumental in building numerous industry-leading companies, including Rinat Neuroscience Corporation, Metabolix, Inc., Triton Biosciences, BioMarin Pharmaceutical Inc., Syntex Corporation, and Celscia Therapeutics. Further information about the management team members is summarized in exhibit 4.

Exhibit 4
KaloBios Pharmaceuticals, Inc.
Management Team

Executive	Position (Start Date)	Previous Positions	Education
David W. Pritchard	President and Chief Executive Officer (2006)	Rinat Neuroscience Corporation (Chief Business Officer); Matrix Pharmaceuticals (Chief Financial Officer); Metabolex, Inc. (VP of Business Development and CFO); Triton Biosciences (one of the founding members)	Bachelor of Science in chemical engineering from Cornell University and a Master of Business Administration from Stanford University
Jeffrey H. Cooper	Chief Financial Officer (2012)	BioMarin Pharmaceuticals (CFO); Matrix Pharmaceuticals (VP of Finance); Foundation Health Systems (Corporate Controller); Syntex Corporation (Director of Business Analysis)	Bachelor of Arts in economics from the University of California, Los Angeles, and a Master of Business Administration from Santa Clara University
Néstor A. Molfino, M.D., FCCP	Chief Medical Officer (2012)	MedImmune (VP of Clinical Development and Pulmonary Therapeutic Area Head); Otsuka Maryland Research Institute (Senior Director, Clinical Development); Baxter Bioscience (Senior Director, Medical Affairs); Theratechnologies, Inc. (VP of Research and Development and Scientific Affairs); Abbott Laboratories (Director, Clinical Research)	M.D. from the Universidad Nacional de Rosario, Argentina, and a Master of Science degree from the University of Toronto/Mount Sinai Research Institute
Geoffrey T. Yarranton, Ph.D.	Chief Scientific Officer (2006)	Celscia Therapeutics (Co-founder and Chief Executive Officer); Coulter Pharmaceuticals (Senior VP of Research and Development); Corixa Corporation (Senior VP of Research and Development); Celltech Therapeutics (Director of Research)	Bachelor of Science degree from the University of Leicester in the United Kingdom and a Ph.D. from the National Institute for Medical Research, United Kingdom

Sources: KaloBios Pharmaceuticals, Inc. reports and the company website

Technology Overview

KaloBios is focused primarily on the discovery and development of monoclonal antibodies for the treatment of a variety of human diseases ranging from inflammatory, infectious, and cancer. The foundation of the company's pipeline is its antibody discovery Humaneered platform. Below, we provide a summary of the Humaneered technology as well as the company's investigational agents, targeted pathways, and disease rationale.

Humaneered

The Humaneered technology forms the basis of the company's drug discovery and development platform. The platform first uses conventional methods to identify initial antibody leads (typically in the form of a mouse antibody). Subsequently, the Humaneered process improves on the antibody's immunogenicity (replacing most of the antibody residues that are not directly involved in antigen binding with human germline , or natural, antibody sequences that are common among all humans), affinity, specificity, solubility (minimal aggregation in solution), and production ability (in cell lines). Once these physiochemical modifications are made, the Humaneered antibodies are tested in the clinic. In addition to having three Humaneered antibodies in clinical trials (with positive safety signals to date), the technology was further validated in 2007 when Novartis paid $30 million for a nonexclusive license. While it may be difficult to assess the value of this antibody platform, we believe that it is integral in allowing the company to generate new investigational agents for clinical development.

KB001/KB001-A

KB001 is a monoclonal antibody that targets and blocks the PcrV protein, an essential component of the type III secretion system that *Pseudomonas aeruginosa* (a gram-negative bacterium) uses to release toxins into the human body (exhibit 5). To date, all of the completed studies in the settings of VAP prevention and CF have used KB001. KB001-A is a Humaneered version of KB001, which only contains the antibody binding domain (Fab) linked to polyethylene glycol (PEG). As a result, KB001-A does not have immune effector functions (i.e., does not bind to immune cells and activate them), but due to its PEG component it can circulate in the human body for an extended period of time. The primary focus for the development of KB001-A is for the prevention of VAP due to *Pseudomonas* infection and for the treatment of CF in patients colonized with *Pseudomonas*. KB001 (the parent antibody of KB001-A) was obtained by KaloBios by way of an exclusive license from University of California at San Francisco and the University of Wisconsin. ***All current and future clinical studies will be conducted using KB001-A, including an ongoing dose-escalation study that we expect to be completed by the end of this year.***

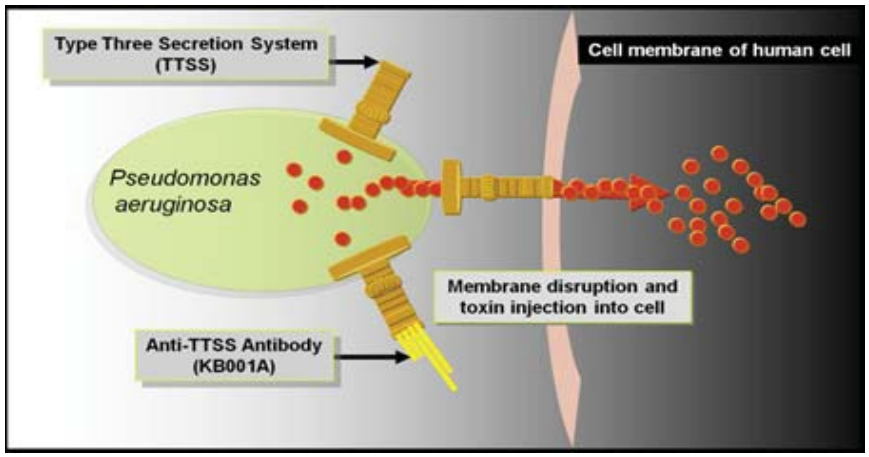
KB002/KB003

KB002, the precursor to the Humaneered KB003 (both have the same target specificity), is a chimeric monoclonal antibody licensed by KaloBios from the Ludwig Institute in 2004. KB002 and KB003 (the antibody that KaloBios is taking into future clinical testing) target granulocyte macrophage colony-stimulating factor (GM-CSF), an important cytokine protein that is known to mediate an inflammatory cascade that stimulates white blood cells. While GM-CSF is crucial for the clearance of infections, the same protein is also involved in tissue damage associated with various autoimmune diseases. KB003 is currently in Phase II clinical studies for the treatment of severe/persistent asthma. Because GM-CSF is involved in the differentiation, proliferation, and enhanced survival of both eosinophils and neutrophils (two inflammatory cell types), some believe that a reduction of excess GM-CSF could be a potentially effective treatment for both allergic and non-allergic asthma (exhibit 6, on the following page).

KB004

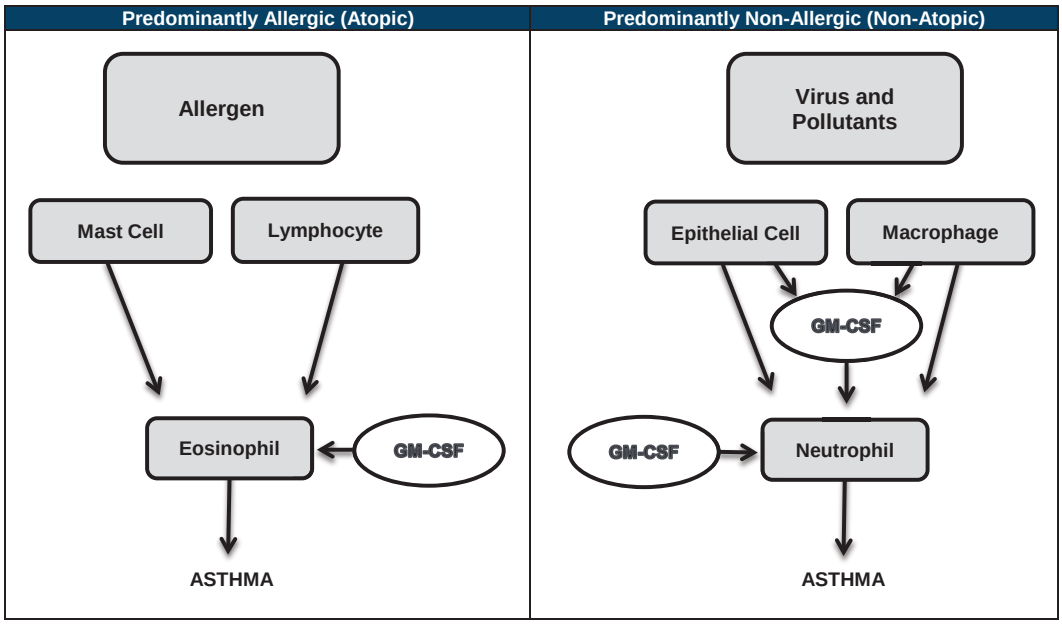
KB004 is a monoclonal antibody that targets EphA3, a receptor tyrosine kinase implicated in driving invasion and progression of numerous hematologic malignancies (leukemia and myeloma, for example). In addition to being Humaneered, KB004 has been modified to lack the sugar fucose on the Fc (effector end) portion of the antibody, resulting in enhanced antibody-dependent cell cytotoxicity (ADCC). The expression of EphA3 across multiple tumor types, tumor vasculature and on tumor stem, with restricted expression in normal tissue, makes this protein a good target for anticancer therapy. KaloBios has the exclusive license and rights to the antibody, as well as the intellectual property on the target from the Ludwig Institute (obtained in 2006).

Exhibit 5
KaloBios Pharmaceuticals, Inc.
KB001-A Mechanism of Action



Source: KaloBios Pharmaceuticals, Inc. report

Exhibit 6
Asthma and GM-CSF (Target of KB003)



Source: Douwes J, Gibson P, Pekkanen J, Pearce N. Thorax. 2002;57(7):643-648.

Market Opportunities

Ventilator-Associated Pneumonia (VAP)

Based on projections made in *Critical Care Medicine* (Wunsch et al. October 2010), we estimate that roughly 1 million cases of mechanical ventilation occur each year in the United States, with about 25% of these considered at high risk for bacterial colonization. A review of medical literature and results from the SENTRY Antimicrobial Surveillance Program (1997-2008) showed that about 80% of all VAP episodes were caused by 6 organisms: *Staphylococcus aureus* (28.0%), *Pseudomonas* (21.8%), *Klebsiella* species (9.8%), *Escherichia coli* (6.9%), *Acinetobacter* species (6.8%), and *Enterobacter* species (6.3%). Given this data, we conservatively estimate that 41,000 mechanical ventilations in the United States could qualify for treatment with KB001-A to prevent VAP. In addition, when taking into account current costs associated with VAP treatment, we believe KB001-A could be priced at about $10,000 per dose. In total, this could generate a yearly U.S. market opportunity of more than $500 million, with about $75 million going to KaloBios, based on the company's royalty structure with Sanofi. Importantly, this is a conservative estimate, based on the lower end of mechanical ventilation cases and pricing for biologics.

Cystic Fibrosis

CF is a genetic disease that causes severe lung and digestive problems, resulting in early death. Pulmonary decline is responsible for the greater share of morbidity and mortality in patients with CF. According to the Cystic Fibrosis Foundation (CFF), 30,000 children and adults in the United States and 70,000 worldwide (35,000 in Europe) have CF. The most-prevalent respiratory bacterial pathogen in patients with CF is *Pseudomonas*. Chronic *Pseudomonas* lung infection is the cause of much of the morbidity and most of the mortality in CF patients, with about 80% having chronic *Pseudomonas* infection. Based on these numbers, we estimate that 24,000 patients would qualify for KB001-A therapy. While it would be difficult to approximate the dose (relative to VAP prevention) and length of time a patient would be on therapy, we estimate about $50,000 per patient per year (based on a chronic disease model), leading to a market opportunity of $1.2 billion in the United States alone: The market size should be similar in Europe, with pricing constraints offsetting the slightly higher population of patients.

Severe/Persistent Asthma

Asthma is a respiratory condition in which pulmonary airways become inflamed and constricted, usually in response to one or more environmental triggers. Although serious and potentially fatal if left untreated, asthma is usually managed with a variety of drugs and by avoiding disease triggers. ***The American Academy of Allergy Asthma and Immunology estimates that there are about 25 million adolescent and adult asthmatics living in the United States, with roughly 10 million currently on some type of treatment.*** Of the 10 million patients on therapy, medical literature has suggested that about 40% (4 million individuals) suffer with moderate or severe disease, with half of these individuals having persistent/uncontrolled asthma that is unresponsive to standard-of-care inhaled corticosteroids and beta agonists. KaloBios is interested in targeting this persistent/uncontrolled severe asthma population as the first indication for KB003 because of the high unmet medical need, which we believe equates to roughly 2 million individuals. While pricing for this therapy is yet to be determined, a conservative estimate of $10,000 per patient per year results in a sizable market potential in the United States.

Upcoming/Ongoing Clinical Studies

KaloBios is conducting several clinical studies involving its pipeline drugs, including Phase II studies in CF and asthma, which should provide data in 2014.

Ventilator-Associated Pneumonia (VAP)
As a result of a partnership agreement between Sanofi and KaloBios, Sanofi is continuing the development of KB001-A in the *Pseudomonas*-associated VAP prevention setting. A dose-escalation Phase I study designed to assess the safety of KB001-A at increasing doses (up to 30 mg/kg) is underway, and results could be presented by year-end or the beginning of 2014. Data obtained from this Phase I trial will help to determine the dose used in a potentially pivotal randomized Phase II study (exhibit 7) where patients at high risk of *Pseudomonas* colonization during mechanical ventilation (determined using a rapid diagnostic) receive the standard of care plus KB001-A or the standard-of-care plus placebo. The primary endpoint of the study is pneumonia event-free survival.

In early September, KaloBios (along with partner Sanofi) announced that to ensure the next VAP-initiated (potentially registration-enabling) study does not require a separate bridging study, both companies decided to manufacture new lots of KB001-A using a more-refined process at Sanofi's facility in Vitry, France, rather than using existing material manufactured by Lonza. We believe this decision gives both companies the highest probability of success (regulatory approval), since the material will be more "commercial ready" with less risk of clinical variability based on CMC reasons. This decision will delay the start of the Phase IIb study until late 2014, and we estimate it should subsequently finish in 2016. Fortunately, the company believes that it could have the pivotal material from Sanofi's Vitry plant in time for the potential initiation of a Phase III study in CF (which could commence in 2015).

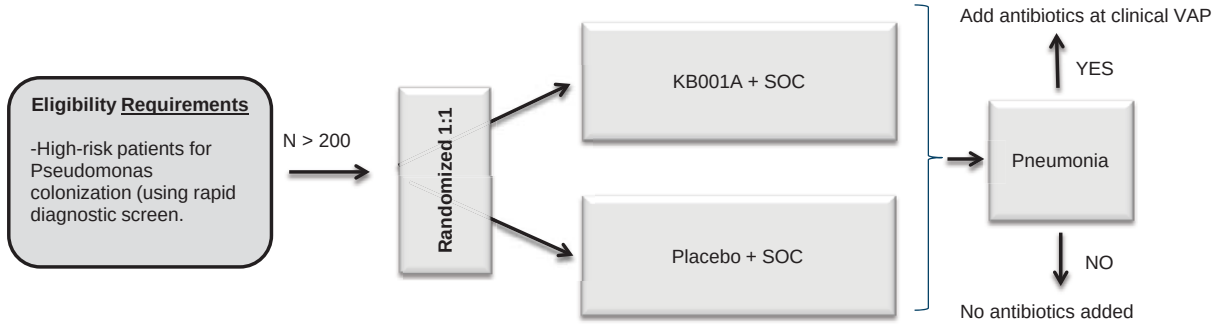
Cystic Fibrosis
At the end of last year, KaloBios initiated a proof-of-concept randomized Phase II study in patients with CF who have confirmed *Pseudomonas* infection (exhibit 8). The trial, which is being conducted in collaboration with the Cystic Fibrosis Foundation (CFF), is expected to accrue approximately 180 patients by the end of this year and randomize them to receive either placebo or KB001-A (10 mg/kg) for 16 weeks (inhaled antibiotics are given during the initial 5 weeks of study to all subjects). Following the 16-week treatment period, investigators will look at several clinical endpoints, including change in sputum-free-neutrophil elastase, time-to-need antibiotics, time-to-exacerbations, patient recorded outcome, and time-to-increase respiratory symptoms, along with safety and tolerability measurements. Data from this study is expected in the second half of 2014.

Asthma
Last year, KaloBios initiated a randomized Phase II proof-of-concept study with KB003 for the treatment of severe/persistent asthma; the first patients were treated in September in the United States (the design of the study is illustrated in exhibit 9, on page 12). In total, about 150 patients will be treated with either KB003 or placebo at multiple time points for 20 weeks. Before entering the study, patients are screened for a history of uncontrolled asthma, FEV_1 lung function, and Asthma Control Questionnaire scores. We expect the trial to be completed by the first quarter of 2014, with data soon after; the primary endpoint of the study is change in FEV_1 through week 24, with exacerbation, effect on asthma control, use of rescue therapy, and safety being important secondary endpoints. Once the trial is complete, KaloBios plans to conduct a bridging study to look at switching the intravenous formulation of the drug to a subcutaneous form. If successful, the next step would be to conduct a pivotal Phase III study using the subcutaneous form in patients with asthma who are inadequately controlled by corticosteroids.

Hematologic Malignancies
Currently, KaloBios is conducting a Phase I dose-escalation study with KB004 in unscreened hematological malignancy patients. Subsequently, the company plans to conduct an expansion phase of the study in which an assay will be used to select for patients who express the target (EphA3) in their

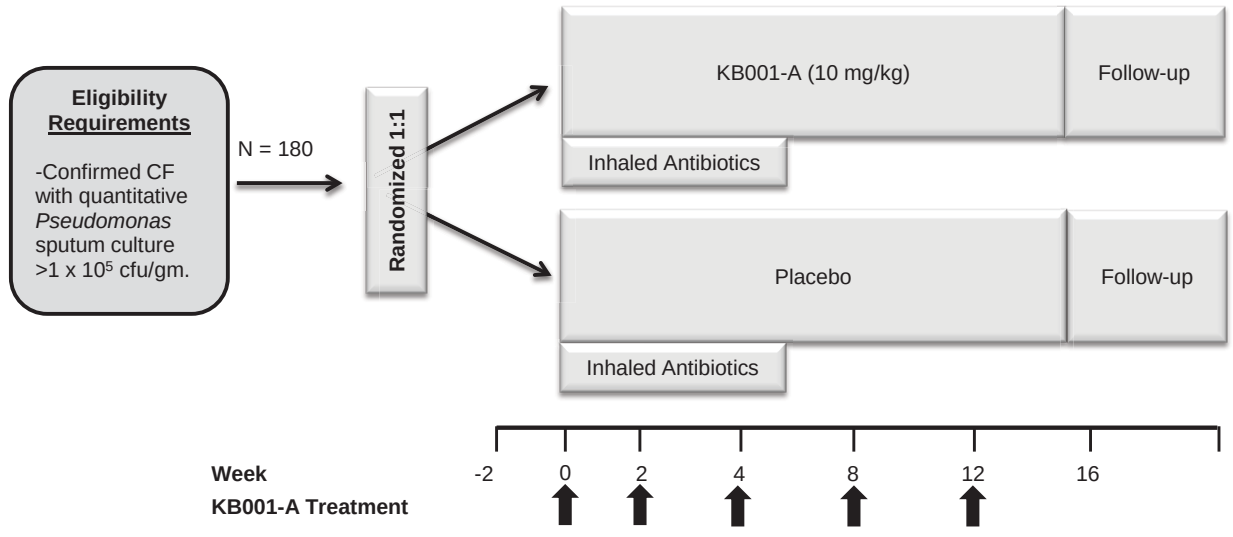
tumors (this expansion phase is expected to begin in the second half of this year). The dose-escalation phase of the study included patients with various liquid tumor types being treated at an initial dose of 20 mg and continuing up to 140 mg or beyond (until a maximum tolerated dose has been reached).

Exhibit 7
KaloBios Pharmaceuticals, Inc.
Proposed KB001-A Phase II VAP Study Design



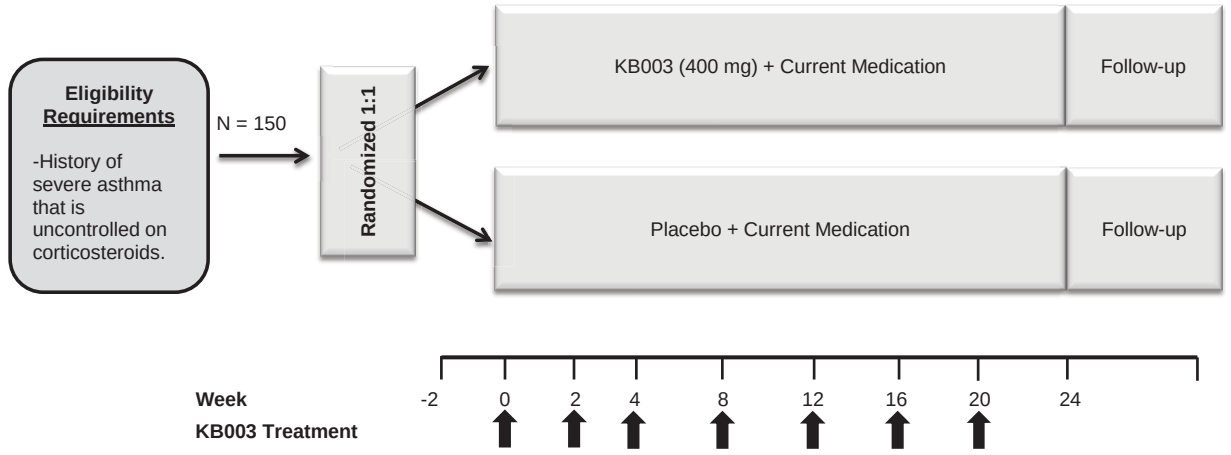
SOC=Standard of Care. VAP=Ventilator-associated pneumonia.
Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 8
KaloBios Pharmaceuticals, Inc.
KB001-A Phase II Cystic Fibrosis Study Design



Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 9
KaloBios Pharmaceuticals, Inc.
Newly Initiated KB003 Phase II Severe Inadequately Controlled Asthma Study Design



Sources: KaloBios Pharmaceuticals, Inc. reports

Completed Studies and Clinical Data

Before its IPO, KaloBios completed several Phase I and Phase II clinical trials involving a number of pipeline agents. A description of these studies is described below.

KB001/KB001-A
As mentioned earlier in this report, KB001 is the precursor to KB001-A, both of these target the PcrV protein of *Pseudomonas*. To date, KaloBios has conducted three clinical studies using KB001 (exhibit 10), the first of which was a Phase I trial in 15 healthy adult volunteers that showed the drug was well tolerated with no immunogenicity, dose-limiting toxicity, or drug-related serious adverse events. In the second and third studies (Phase I/II), KB001 was tested with mechanically ventilated patients (for the prevention of VAP) and patients with CF.

Phase I/II study in VAP prevention. In the ventilator study (for the treatment and prevention of *Pseudomonas* infections), patients were screened for colonized *Pseudomonas*. After screening, subjects were randomized to receive standard-of-care (control group), low-dose KB001 plus standard-of-care, or high-dose KB001 plus standard-of-care (exhibit 11). The results demonstrated that KB001 was well tolerated with a dose-response improvement in the prevention of *Pseudomonas*-associated pneumonia versus the standard-of-care alone (exhibit 12, on page 14).

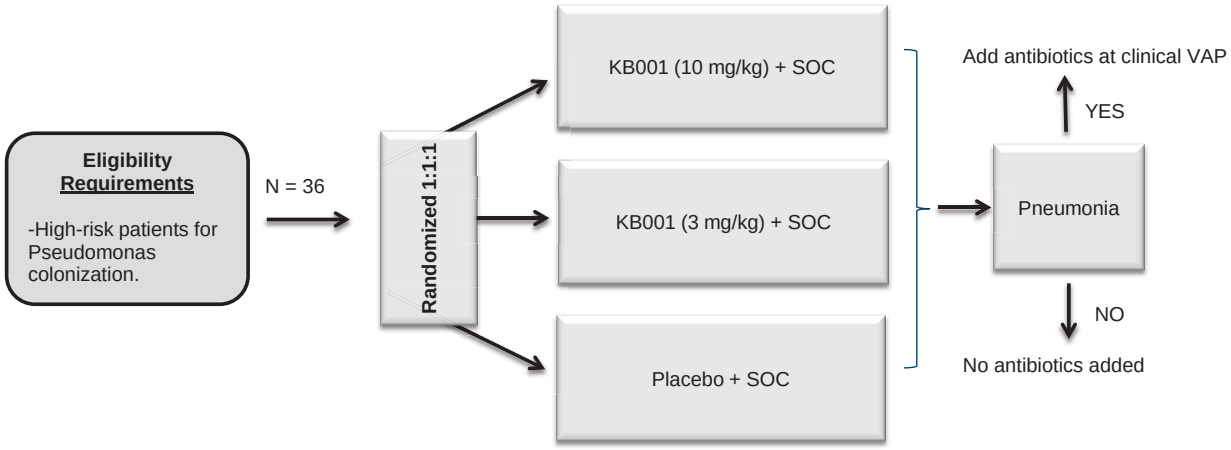
Phase I/II study in CF. In addition to VAP prevention, KaloBios also conducted a Phase I/II trial using KB001 in individuals with chronic *Pseudomonas* respiratory infection, including CF (exhibit 13, on page 14). The 10 mg/kg dose showed that KB001 is safe, with no drug-related severe adverse events. In addition, the sputum of KB001-treated patients showed a reduction in various inflammatory biomarkers relative to placebo, including statistically significant drops in neutrophil elastase and IL-1 levels (exhibit 14, on page 15). We believe this data is encouraging, given that neutrophil elastase has previously been shown to cause some of the irreversible lung damage seen in these patients. Furthermore, relative to the current standard of care, the results observed with this dose of KB001 are similar to 14 days of hospital treatment with intravenous antibiotics.

Exhibit 10
KaloBios Pharmaceuticals, Inc.
Completed KB001 Trials

Study Population	Design	Enrollment	Results
Healthy volunteers	Phase I, placebo-controlled, single-dose, dose escalation study. Arm 1: KB001 (varying doses) Arm 2: Placebo	15 Patients	No immunogenicity, dose-limiting toxicities, or severe adverse events Serum half-life: 12-14 days
Pneumonia prevention in mechanically ventilated patients	Phase I/II, randomized, double-blind, placebo-controlled, single dose study. Arm 1: KB001 (10 mg/kg) + SOC Arm 2: KB001 (3 mg/kg) + SOC Arm 3: Placebo + SOC	35 Patients	Safe and non-immunogenic Dose-dependent trend toward improved clinical outcomes
Cystic fibrosis patients	Phase I/II, randomized, double-blind, placebo-controlled, single dose study. Arm 1: KB001 (10 mg/kg) + Inhaled Antibiotics Arm 2: KB001 (3 mg/kg) + Inhaled Antibiotics Arm 3: Placebo + Inhaled Antibiotics	27 Patients	Safe and non-immunogenic Reductions in inflammatory markers Trend in reducing mucoid *Pseudomonas* burden in sputum

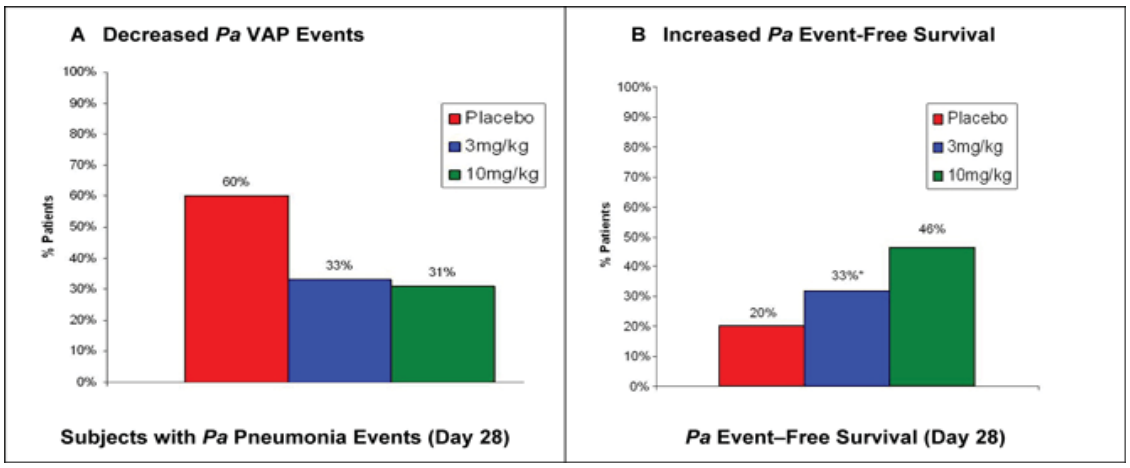
SOC=Standard of care
Sources: KaloBios Pharmaceuticals, Inc. reports, www.clinicaltrials.gov

Exhibit 11
KaloBios Pharmaceuticals, Inc.
KB001 Phase I/II Ventilator-Associated Pneumonia (VAP) Study Design



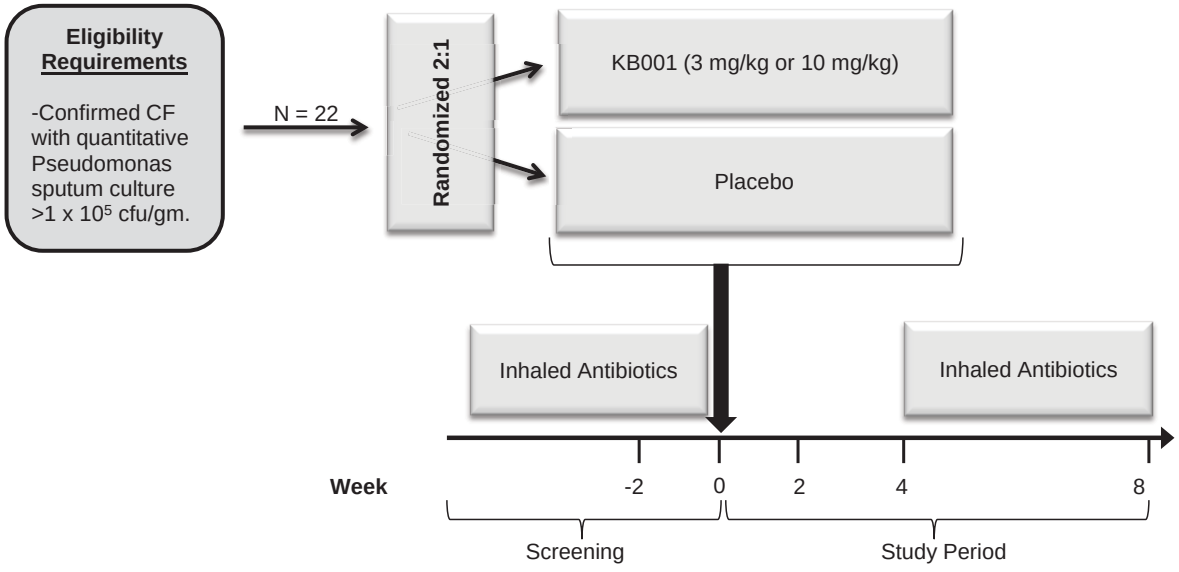
SOC=Standard of Care. VAP=Ventilator-associated pneumonia.
Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 12
KaloBios Pharmaceuticals, Inc.
KB001 Phase I/II Ventilator-Associated Pneumonia (VAP) Study Results



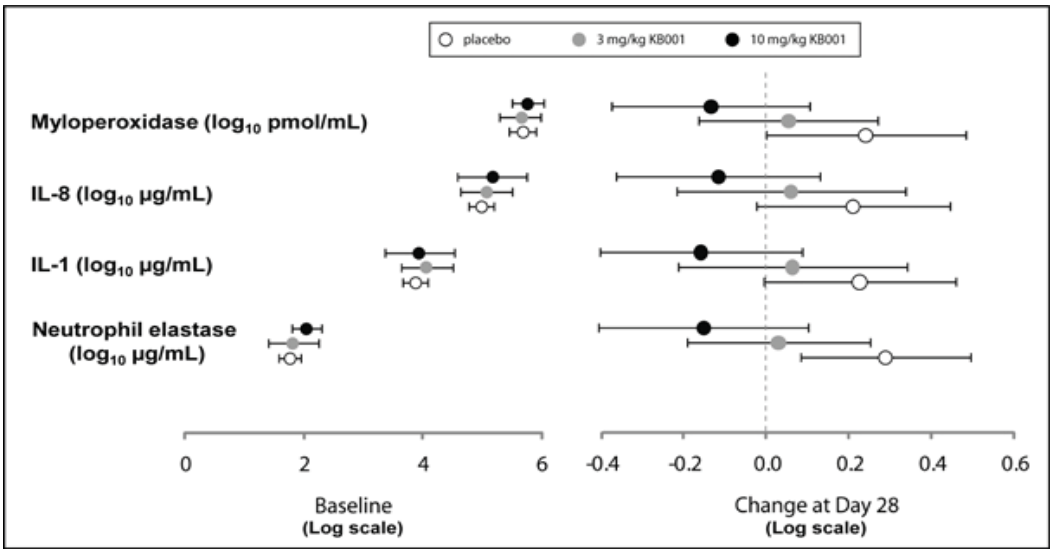
Pa=Pseudomonas. VAP=Ventilator-associated pneumonia.
*Excludes two Pseudomonas urinary tract infections
Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 13
KaloBios Pharmaceuticals, Inc.
KB001 Phase II Cystic Fibrosis (CF) Study Design



Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 14
KaloBios Pharmaceuticals, Inc.
KB001 Phase I/II Cystic Fibrosis (CF) Study Results



Sources: KaloBios Pharmaceuticals, Inc. reports

KB002/KB003

KaloBios has completed seven early-stage clinical trials with intravenous KB002, the precursor anti-GM-CSF chimeric antibody to Humaneered KB003 (exhibit 15, on the following page). Below is a brief description of the results seen in two Phase I/II studies in rheumatoid arthritis and asthma.

Phase I/II in rheumatoid arthritis. In this study, 32 patients were randomized equally to one of four KB002 doses or placebo (exhibit 16, on the following page). Results from the trial showed that KB002 was safe, well tolerated, and with no drug-related severe adverse events. At the higher-dose levels, KB002 demonstrated durable (persisted more than 90 days) and clinically meaningful reductions in the swelling of tender joints using DAS28 (Disease Activity Score at Day 28; a measure of swollen and tender joints). Overall, we believe this data (along with that seen from other anti-GM-CSF antibodies such as MOR103) added support to the safety and efficacy of targeting the GM-CSF pathway. At this point, the company has decided not to pursue additional trials in rheumatoid arthritis, but will focus further on developing KB003 for severe asthma.

Phase I/II in asthma. The KB002 Phase I/II asthma study provides us with the best look to date regarding this drug's activity for the treatment of severe asthma. This trial, which enrolled both allergic (eosinophilic) and non-allergic (neutrophilic) asthma subjects, randomized 24 patients 2:1, active versus placebo (exhibit 17). KB002 was found to be safe and well tolerated, with a measurable amount of drug in the sputum of almost half of patients after 14 and/or 28 days. In addition, KB002 showed trends of improvement in lung function (measured by FEV_1), with 59% of patients having a greater-than-100-ml FEV_1 increase at 6 weeks, versus 29% of patients on placebo. Furthermore, these responses were observed in patients with both allergic and non-allergic asthma, rarely seen with other approved and investigational therapies. With respect to the patients with allergic asthma (18 of 24), reductions in the number of eosinophils (white blood cells) were in the patients' airways were seen, which was associated with improvements in FEV_1.

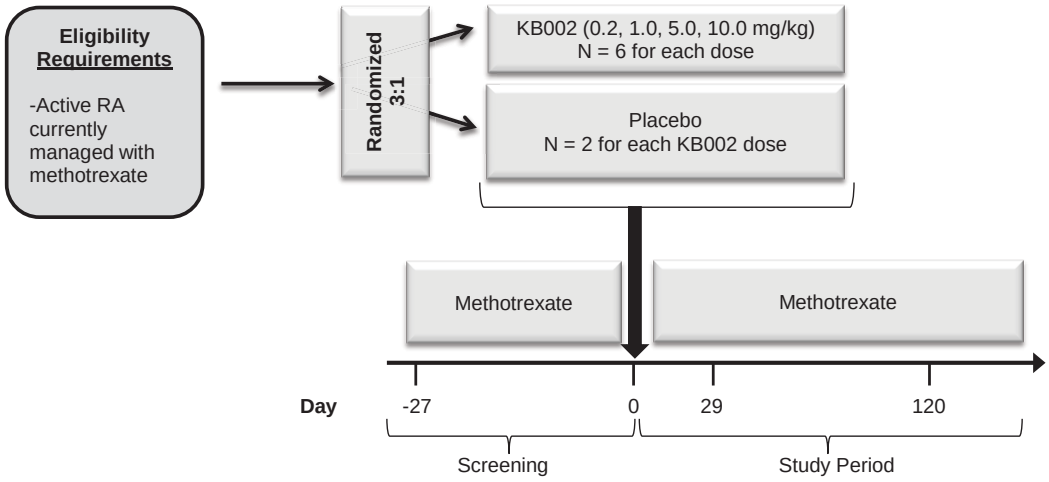
Exhibit 15
KaloBios Pharmaceuticals, Inc.
Completed KB002/3 Trials

Study Population	Drug	Design	Enrollment	Results
Healthy volunteers	KB002	Phase I, placebo-controlled, single-dose, dose-escalation study Arm 1: KB002 (varying doses) Arm 2: Placebo	12 Patients	Safe and well tolerated with no immunogenicity and dose-limiting toxicity
Persistent asthma despite treatment with corticosteroids	KB002	Phase I/II, randomized, double-blind, placebo-controlled, single-dose study Arm 1: KB002 (5 mg/kg) Arm 2: Placebo	24 Patients	Safe and well tolerated with improvement in disease measures of activity (FEV_1)
Uncontrolled RA despite stable treatment with methotrexate	KB002	Phase I/II, randomized, double-blind, placebo-controlled, single-dose study Arm 1: KB002 (varying doses) Arm 2: Placebo	32 Patients	Higher KB002 dose groups demonstrated an early, durable, and clinically meaningful reduction in swollen and tender joints
Pharmacodynamics studies	KB002	Two Phase I/II, randomized, double-blind, placebo-controlled, single-dose studies Arm 1: KB002 Arm 2: Placebo	24 Patients	Safe and well tolerated
Healthy adult volunteers	KB003	Phase I, placebo-controlled, single-dose, doseescalation study Arm 1: KB002 (varying doses) Arm 2: Placebo	12 Patients	Safe and well tolerated Nonimmunogenic No dose-limiting toxicity
RA inadequately treated with biologics	KB003	Phase I/II, randomized, double-blind, placebo-controlled, repeat-dose study Arm 1: KB002 (70, 200, or 600 mg) Arm 2: Placebo	9 Patients	Safe and well tolerated over approximately 3 months of repeat dosing Nonimmunogenic.

FEV_1=Forced expiratory volume in one second. RA=Rheumatoid arthritis.

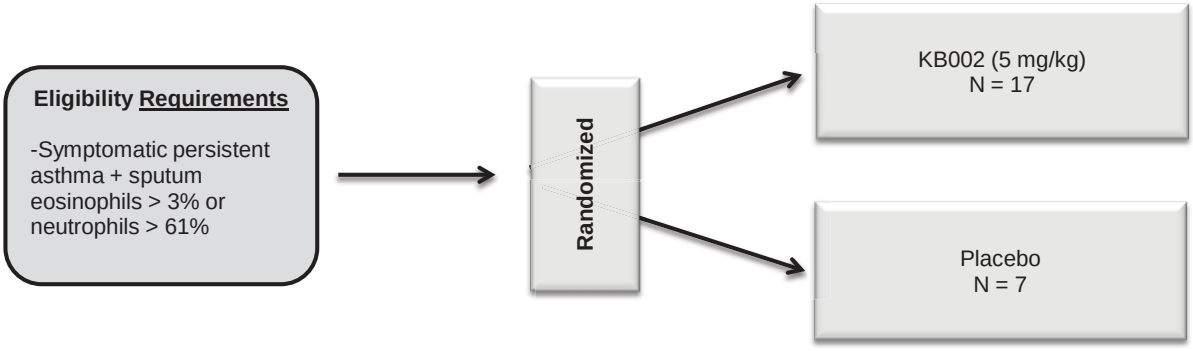
Sources: KaloBios Pharmaceuticals, Inc. reports, www.clinicaltrials.gov

Exhibit 16
KaloBios Pharmaceuticals, Inc.
KB002 Phase I/II Rheumatoid Arthritis (RA) Study Design



Sources: KaloBios Pharmaceuticals, Inc. reports

Exhibit 17
KaloBios Pharmaceuticals, Inc.
KB002 Phase II Asthma Study Design



Sources: KaloBios Pharmaceuticals, Inc. reports

Financial Analysis

Balance Sheet
At the end of third quarter 2012, the company had about $24.7 million in cash. Before February's IPO, which generated $70 million in cash for KaloBios, the company in early September closed on a $10 million debt financing, with an option to take another $5 million. The primary purpose of the financing related to the company's IPO was to allow KaloBios to have enough cash to last it into the end of 2014, by which time we expect the company to present data from its Phase II CF and severe asthma studies. We believe that the company finished 2012 with about $90 million, which we expect will fall to about $65 million by the end of 2013 as a result of the costs associated with carrying out several Phase I and Phase II clinical studies.

Income Statement
As an early-stage biotechnology company, KaloBios does not sell any products; however, it generates some revenue from partnership agreements, which may include up-front fees, funding for R&D efforts, and milestones. R&D is usually the largest expense because of fees connected with paying outside companies to manage clinical trials, the production of clinical materials, and the purchasing of supplies for conducting preclinical development activities. In the first nine months of 2012, KaloBios recognized $6 million in contract revenue, while it spent about $14.2 million on R&D and $3.4 million for general-and-administrative activities (overall, the company finished with a net loss of $11.8 million during this period).

Over the next several years (2013 and 2014), we expect KaloBios to operate at a yearly cash burn rate of approximately $37 million, which we expect should be sufficient to fund operations until the beginning of 2015. This burn rate assumes the company will draw down another $5 million from its venture debt line (through MidCap Financial) in the middle of this year as well as recognize a $5 million milestone payment due to the start of a Phase II study with KB001-A in VAP prevention toward the end of next year.

Sanofi Pasteur Partnership
In January 2010, KaloBios signed an agreement with Sanofi granting Sanofi exclusive worldwide rights to develop and commercialize KB001-A in the VAP prevention setting, with an opt-in clause for the setting of CF once the Phase II data comes out in 2014 (to exercise its option, Sanofi is required to make certain payments to KaloBios, which we estimate are in the range of $25 million to $50 million). As part of the current agreement, KaloBios received an up-front payment of $35 million and is eligible for $250 million, based on certain regulatory, clinical, and commercial events ($5 million will be paid to KaloBios upon the initiation of the VAP Phase II study in 2014, followed by $20 million upon completion of the study). If KB001-A is eventually approved, KaloBios will receive tiered royalties of between 12% and 17% of worldwide VAP prevention sales.

Conclusion

We believe that KaloBios offers investors an opportunity to invest in a pure monoclonal antibody company that has recently become publicly traded. Beginning with the antibody platform, we believe that the company's Humaneered technology is differentiated from others in the following ways. First, "Humaneering" seems to generate more germline antibody sequences, which so far have been shown to be less immunogenic than antibodies that have been humanized using other methods. Second, the technology incorporates affinity maturation, which is typically a separate process before and after typical humanization. Lastly, the Humaneered technology selects for favorable pharmacokinetic, biochemical, and manufacturing characteristics, which are important in the downstream use of these antibodies.

Along with the company's antibody platform, the three clinical programs in Phase II testing involve substantial disease indications in which there is a high unmet medical need. With regard to VAP prevention, based on the large number of mechanical ventilations in the United States every year (about 1 million) and the high rate of bacterial colonization, we believe KB001-A could play a significant role in helping reduce hospital-acquired infections, particularly in the lungs, which could lead to fewer long-term hospitalizations and mortality rates. Regarding CF, the majority of new agents are designed to address the genetic cause of the lungs' abnormal function, but not the bacterial consequences. Conversely, agents designed to target the bacteria are effective only for a short period, after which resistance arises. Based on the mechanism of action that KB001-A uses to suppress the pathogenicity of the *Pseudomonas* bacterium, resistance to this agent has yet to be observed. Lastly, in persistent/uncontrolled asthma, which about 2 million individuals in the United States suffer from, the cytokine GM-CSF seems to play an important role in the cause of the symptoms. As a result, we believe KB003 is an ideal therapeutic to be tested in this setting, with early clinical data showing improvement in several autoimmune disease measures. If eventually approved, KB003 could become a blockbuster drug in asthma alone.

Exhibit 18
KaloBios Pharmaceuticals, Inc.
Income Statement
(dollars in thousands except EPS and shares)

	2011A	2012E	Q1E	Q2E	Q3E	Q4E	2013E	2014E	2015E
Revenues									
KB001-A Sanofi Royalty									
Contract revenues	20,255	6,079	0	0	0	0	0	5,000	0
Total revenues	20,255	6,079	$0	$0	$0	$0	0	5,000	0
Operating Expenses									
R&D	18,512	21,238	7,500	8,000	8,500	9,000	33,000	37,000	38,600
SG&A	4,010	4,742	1,400	1,600	1,800	2,000	6,800	9,000	10,600
Total Operating Expenses	22,522	25,980	8,900	9,600	10,300	11,000	39,800	46,000	49,200
Income/loss from operations	(2,267)	(19,901)	(8,900)	(9,600)	(10,300)	(11,000)	(39,800)	(41,000)	(49,200)
Interest income (expense), net	43	134	90	80	70	60	300	270	150
Other income (expense), net	(8)	(306)	(2)	(2)	(2)	(2)	(8)	(8)	(8)
Other comprehensive income (loss)	0	2	0	0	0	0	0	0	0
Net income/loss	**($2,232)**	**($20,071)**	**($8,812)**	**($9,522)**	**($10,232)**	**($10,942)**	**($39,508)**	**($40,738)**	**($49,058)**
Net income/loss per common share, basic & diluted	**($0.09)**	**($0.83)**	**($0.36)**	**($0.39)**	**($0.42)**	**($0.45)**	**($1.62)**	**($1.39)**	**($1.53)**
Weighted average number of shares, basic & diluted*	24,130	24,130	24,200	24,300	24,400	24,500	24,350	29,925	32,050

*Shares after the company's IPO have been applied to all previous quarters for the purpose of comparison.
Sources: KaloBios reports and William Blair & Company, L.L.C. estimates

Appendix A: Target Disease Indications

Ventilator-Associated Pneumonia (VAP)
There are several potential reasons for acute respiratory failure, including pulmonary disease, neuromuscular disease, shock, the need for airway protection, or the need for temporary respiratory support after major surgery. For patients with acute respiratory failure, invasive mechanical ventilation can make the difference between life and death, with the vast majority of mechanically ventilated patients requiring admission to an intensive care unit (ICU).

Patients in the ICU are also at high risk of hospital-acquired infections (HAIs). According to a review of clinical data published in *Clinical Microbiology Reviews* October 2006, about 27% of critically ill patients develop hospital-acquired pneumonia—the second-most-common HAI in the ICU. Furthermore, about 86% of hospital-acquired pneumonia cases are in some way due to mechanical ventilation, termed ventilator-associated pneumonias (VAPs). VAP is defined as a pneumonia that presented more than 48 hours after a patient was initially intubated and who continues to be mechanically ventilated. VAP also has a large economic impact, including increased length of stays in the ICU (from 4 to 13 days), resulting in an estimated $5,000 and $20,000 of incremental costs per diagnosis.

The *Pseudomonas* bacteria is a frequent cause of VAP, with recent evidence suggesting that production of type III secretion proteins (by *Pseudomonas*) correlate with increased pathogenicity in both cellular and animal testing. Furthermore, a 2002 study published in *Critical Care Medicine* demonstrated that type III secreting isolates were associated with worse clinical outcomes for VAP patients, suggesting that the negative impacts of this secretion system translate over to human disease as well. These findings also supported the hypothesis that antibodies targeted against these proteins may be useful as an adjunctive therapy in intubated patients with *Pseudomonas* colonization or infection. As a result, this is the same rationale should apply to the use of KB001-A in disease settings where *Pseudomonas* is known to play a role.

Cystic Fibrosis
Cystic fibrosis (CF) is a recessively inherited disorder that affects several organs in the body, including the airways of the lungs, the small intestine, pancreas, liver, reproductive tract, and sweat glands. The cause of CF is a genetic malfunction of the chloride channel protein, which leads to decreased volume of periciliary fluid (and in turn impaired mucociliary clearance of inhaled microbes) in the lower respiratory tract. CF is characterized by the production of viscid mucus, which could eventually lead to respiratory infections, diabetes, impaired liver function, intestinal malabsorption of fat, salt loss, and male infertility. Infectious microbes known to lead to respiratory failure (and death) include *Pseudomonas*, the *Burkholderia cepacia* complex, and *Achromobacter xylosoxidans*. According to a 2011 clinical review published in the journal *BMC Medicine,* children and young adults with CF number roughly 35,000 in Europe, 30,000 in the U.S., and 3,000 in Canada. With intense therapy, the mean life expectancy can be greater than 35 years, and above 50 years in some centers; however, if left untreated, most patients die at a young age.

Much of the morbidity and most of the mortality in CF patients is caused by chronic *Pseudomonas* lung infections. Furthermore, about 80% of adults with CF have chronic *Pseudomonas* infection. During colonization, *Pseudomonas* undergoes a cellular change and begins to produce a self-protective, extracellular matrix of glycoproteins (communities of bacteria in this self-protective mucoid state are called biofilms). It is believed that the protective nature of the biofilm increases the bacterium's resistance to the host immune system and antibiotic therapy.

The type III protein secretion system (TTSS) is an important virulence determinant of *Pseudomonas*. In the setting of CF, researchers believe that most of the *Pseudomonas* bacteria reside in a dormant state within biofilms, and lack the expression of TTSS. However, "planktonic" forms of Pseudomonas (mobile forms that leave the biofilm) have been shown to express high levels of the TTSS, which

in turn makes this form highly pathogenic. Results from a recent study published in the *Journal of Clinical Microbiology* (42: 5229-5237) show that only a minority (12%) of isolates from CF patients secrete type III proteins, which decreases with duration of infection. The presumed reservoir for the majority of *Pseudomonas* strains that infect patients with CF is believed to come from the environment (about 90%); however, secreted type III proteins are found in only 4% of isolates from chronically infected adults, 18% from chronically infected children, and 49% from newly infected children. While the percentage of these isolates may be low, the frequency of isolating at least one bacterium that secretes type III proteins is present in one-third of CF patients. Furthermore, based on the inflammatory state of a CF patient's lungs (for example, during exacerbations or viral lung infections), some researchers believe that TTSS-expressing planktonic-form *Pseudomonas* isolates can be found in the majority of CF patients. As a result, we believe that KB001-A could help the immune system to clear those isolates, further limiting the proliferative nature of these isolates.

Asthma

Asthma is a condition that causes a narrowing and/or blockage of the airways to the lungs as a result of inflammation. Roughly 25 million people in the United States alone are affected by asthma, according to the American Academy of Allergy Asthma and Immunology. The disease is commonly divided into two types: allergic (atopic) asthma and non-allergic (non-atopic) asthma. While the majority of the symptoms between both allergic and non-allergic asthma are the same, allergic asthma is due to the inhalation of allergens such as pollen, mold, and dust mites. Non-allergic (non-atopic) asthma, on the other hand, is triggered by factors unrelated to allergies such as carcinogens. Both types of asthma are characterized by airway obstruction and inflammation that is at least partially reversible with medication. Non-allergic asthma can be triggered by several factors, among them cold air, smoke, stress, or anxiety.

Preclinical studies using animal models of allergic and non-allergic asthma support the use of a neutralizing antibody to inhibit the effects of GM-CSF. With respect to humans, GM-CSF has been seen in elevated levels in patients with severe, but not mild, asthma. Furthermore, lung epithelial cells have been implicated in the production of this cytokine. In fact, lung epithelial cells obtained from asthma patients have been shown to secrete high levels of GM-CSF, while similar cells from normal individuals do not. Asthma treatments currently on the market such as long-acting beta agonists, inhaled corticosteroids and Xolair are often ineffective for the most severe cases of asthma. Xolair in particular is limited to treatment of moderate to severe allergic asthma in patients with positive immunoglobulin E (IgE). Other monoclonal antibodies in clinical development also predominantly target allergic rather than non-allergic asthma. ***KB003, on the other hand, has the potential to treat both allergic and non-allergic severe asthma,*** given that anti-GM-CSF treatment reduces the activity of the eosinophils or neutrophils that predominate in both types of asthma***.***

Appendix B: Current and Future Therapeutic Landscape

Ventilator-Associated Pneumonia

VAP is associated with increased hospital costs, a greater number of days in the intensive care unit, longer duration of mechanical ventilation, and higher mortality. Despite widely accepted recommendations for interventions designed to reduce rates of VAP, few have demonstrated significant improvements. Below, we highlight results from a widely used antibiotic (azithromycin), an antimicrobial peptide (Iseganan), and a vaccine in Phase III testing (IC43). We believe there is little competition, especially one that has demonstrated significant improvements over existing treatment guidelines for prevention. ***Furthermore, based on the role that these therapies play, along with the specific inherent nature of antibodies, we believe KB001-A could be combined with most of these agents.***

Azithromycin (Zithromax by Pfizer). Azithromycin, one of the most widely used antibiotics, belongs to a class of antibacterial drugs termed macrolides (work by stopping bacterial growth) and is used to treat certain infections caused by bacteria, such as bronchitis, pneumonia, and infections of the ears, lungs, skin, and throat. Prolonged colonization of intubated patients with *Pseudomonas* isolates has been associated with VAP. In a randomized, double-blind, multicenter trial, intubated patients who were colonized received either 300 mg/day of azithromycin or placebo (details of this study were adapted from a July 2012 publication of the trial results in the journal *Intensive Care Medicine*). The study further identified patients persistently colonized by bacterial isolates that produce high levels of rhamnolipids (a quorum sensing-dependent virulence factor), who are at the highest risk to develop VAP. A total of 92 patients were enrolled in the study and the primary endpoint was the occurrence of *Pseudomonas* VAP. In the per-protocol population (43 azithromycin-treated and 42 placebo patients), the occurrence of *Pseudomonas* VAP was reduced in the azithromycin group but without reaching statistical significance (4.7% versus 14.3% developed VAP; p=0.156). Only five patients in each arm of the study were persistently colonized by high-level rhamnolipids-producing isolates. Nonetheless, in this high-risk subgroup, the incidence of VAP was dramatically reduced in azithromycin-treated patients (1/5 versus 5/5 [placebo] developed VAP; p=0.048). ***In the overall treated population, there was a trend toward a reduced incidence of VAP in colonized azithromycin-treated patients; however, the results were not statistically significant.*** Conversely, azithromycin significantly prevented VAP in those patients at high risk of rhamnolipid-dependent VAP, suggesting that virulence inhibition is a promising antimicrobial strategy. While the inhibition of virulence was the primary driver of success in this study (KB001-A also targets virulence), we believe the use of this agent in VAP prevention could become more widespread, which could affect penetration into this market with more-expensive therapies such as KB001-A.

Iseganan. Iseganan, an antimicrobial peptide, is broadly active against aerobic and anaerobic gram-positive and gram-negative bacteria, as well as fungi and yeasts. ***At present, the drug is not approved for the prevention of VAP.*** The drug has shown little resistance *in vitro* and was found to be safe and well tolerated in 800 patients with cancer treated for up to six weeks. In 2006, results from a randomized, double-blind study in which mechanically ventilated patients in the United States and Europe were randomized (1:1) to oral topical Iseganan or placebo were published in the *American Journal of Respiratory and Critical Care Medicine*. Patients were treated either six times per day with the active drug (while intubated) or with placebo for up to 14 days. A total of 709 patients were randomized and received at least one dose of study drug; the primary efficacy endpoint was the incidence of VAP in living subjects at day 14. The rate of VAP was 16% (45/282) in patients treated with Iseganan and 20% (57/284) in those treated with placebo (not statistically significant; p=0.145). Furthermore, at day 14 the mortality rate was 22.1% (80/362) in the Iseganan group and 18.2% (63/347) in the placebo group (p=0.206). No pattern of excess adverse events in the Iseganan group compared with placebo was observed, and it was determined that Iseganan is not effective in improving outcome in patients on prolonged mechanical ventilation.

IC43 (Intercell AG). IC43, initially discovered by Austria-based Intercell, is made up of a recombinant subunit vaccine that codes for two outer membrane proteins of *Pseudomonas*. In 2010, Intercell announced results from a Phase II clinical trial involving IC43, in which the study met primary immunogenicity and safety endpoints and showed a significant reduction on mortality in the vaccine groups compared with placebo (announced in an October 25, 2010, company press release). In the randomized, placebo-controlled trial, about 400 mechanically ventilated intensive care patients were vaccinated. ***No significant difference in the rate of Pseudomonas infection between any of the groups was apparent;*** however, Intercell believes that this is likely due to the relatively small sample size of the current Phase II study. In April 2011, Intercell announced that it agreed with Novartis to advance the IC43 vaccine into a confirmatory clinical efficacy trial in ventilated ICU patients. The double-blind confirmatory study is powered to show a clinically meaningful and statistically significant reduction in overall mortality between the vaccine and control group (the trial

is expected to enroll about 800 patients). Based on positive feedback from the European Medicines Agency regarding the Phase II/III efficacy trial design, Intercell initiated the confirmatory efficacy study in March 2012; interim data from this study is expected in the second half of 2013.

Cystic Fibrosis

There is no known cure for CF; however, various treatments (old and recently approved) can ease symptoms and reduce complications. In this section, we highlight the currently approved and investigational agents for the treatment of CF. Similar to the VAP setting, we believe there is little competition, especially one that has demonstrated significant improvements over existing treatment in all patients. ***Furthermore, based on the role that these therapies play, along with the specific inherent nature of antibodies, we believe KB001-A could be combined with most of these agents.***

Tobramycin (Tobi by Novartis). Tobramycin is a recently approved therapy developed by Novartis for the management of CF patients with *Pseudomonas*; it is an aminoglycoside antibiotic that disrupts bacterial protein synthesis, leading to bacterial cell death. Tobi in particular is a tobramycin solution for inhalation by a compressed air-driven reusable nebulizer; approval was granted based on two 24-week clinical studies (study 1 and study 2) in CF patients infected with *Pseudomonas*. In addition to standard-of-care treatment (oral and parenteral anti-pseudomonal therapy, β2-agonists, cromolyn, inhaled steroids, and airway clearance techniques), all patients on the study received either Tobi or placebo. Overall, Tobi-treated patients experienced significant improvement in pulmonary function in each of the two studies. Improvement was demonstrated in the Tobi group in study 1 by an average increase in FEV_1 (a common measure of lung function) of about 11% relative to baseline (week 0), compared to no average change in placebo patients. In study 2, Tobi-treated patients had an average increase of about 7%, compared to an average decrease of about 1% in placebo patients. Patients treated with Tobi were hospitalized for an average of 5.1 days, while patients on placebo were hospitalized for an average of 8.1 days. Furthermore, patients treated with Tobi required an average of 9.6 days of antibiotic, versus 14.1 days for patients in the placebo arm.

Novartis is also developing tobramycin inhalation powder (TIP), which on September 5, 2012, received support from an FDA advisory committee for patients with CF whose lungs contain *Psuedomonas* (the drug is currently approved in the European Union, Canada, and Switzerland). In contrast to Tobi, which is administered as a nebulized solution, investigational TIP is a new inhaled formulation of tobramycin consisting of dry powder in capsules delivered via a special inhaler. The new formulation was developed using proprietary Novartis PulmoSphere technology, enabling the creation of hollow porous particles of tobramycin. The panel recommendation was based on results from three Phase III clinical studies involving more than 650 CF patients; the studies found that treatment with TIP produced comparable efficacy to Tobi, while reducing administration time by about 70%.

Azithromycin (Zithromax by Pfizer). Zithromax was also tested in a randomized, placebo-controlled trial for the treatment of CF patients. In the study, of the 185 randomized patients, the active group (87 patients) received 250 mg (weighing less than 40 kg) or 500 mg (weighing more than 40 kg) of oral Zithromax 3 days a week for 168 days, while the placebo group (98 patients) received identically packaged placebo tablets. The Zithromax group had a greater mean increase in FEV_1 (a measurement of lung function) at day 168 than the placebo group (the mean difference was statistically significant; p=0.009). Patients who received Zithromax also had less risk of an exacerbation than participants in the placebo group (hazard ratio, 0.65; p=0.03) and weighed at the end of the study an average 0.7 kg more than participants receiving placebo (p=0.02). Overall, there was little difference between the two groups with regard to emergence or eradication of multidrug-resistant strains of *Pseudomonas*. However, b*acterial* density decreased by 0.3 log colony-forming units at day 168 in the active drug arm and increased by 0.2 log colony-forming units in the placebo group (mean difference, 0.5 log colony forming units; p=0.06).

Aztreonam (Cayston by Gilead Sciences). Approved by the FDA in February 2010, Cayston (aztreonam for inhalation solution) is an inhaled antibiotic for patients with CF who are colonized with *Pseudomonas*. Cayston contains aztreonam formulated with lysine, a proprietary formulation of aztreonam developed specifically for inhalation, and is administered using the Altera Nebulizer System. Through preclinical testing, Cayston has demonstrated potent activity against a variety of gram-negative aerobic pathogens. The FDA approval of Cayston was based on a randomized, placebo-controlled trial in 164 patients who received either Cayston (75 mg) or placebo administered 3 times a day for 28 days. Statistically significant improvements were seen in both adult and pediatric patients, where the treatment difference at day 28 between Cayston and placebo for percent change in FEV_1 was 10%. Subsequently, two weeks after patients stopped receiving Cayston or placebo, the difference in FEV_1 between both groups had decreased to 6%. Overall, improvements in lung function (as measured by FEV_1) were comparable between adult and pediatric patients.

Ivacaftor (Kalydeco by Vertex Pharmaceuticals). A potentiator of the CFTR protein (the chloride channel present on the surface of epithelial cells and the protein responsible for almost all of CF when damaged), Kalydeco works by facilitating chloride transport of the G551D mutant form of the CFTR protein. The efficacy of this agent was evaluated in two randomized, double-blind, placebo-controlled clinical trials in 213 CF patients who possess the G551D mutation. Patients in both trials were randomized evenly to receive placebo or 150 mg of Kalydeco every 12 hours in addition to the prescribed CF therapies they were currently taking (e.g., tobramycin). In both studies, treatment with Kalydeco resulted in a significant improvement in FEV_1 through 24 weeks of treatment. The treatment difference between the two arms of the study (mean absolute change in percent predicted FEV_1 from baseline through week 24) was 10.6% ($p<0.0001$) in the first trial and 12.5% ($p<0.0001$) in the second trial, which persisted through 48 weeks. Improvements in percent predicted FEV_1 were observed across multiple disease factors such as age, disease severity, sex, and geographic region. ***Because this agent does not address the*** Pseudomonas ***issue, we believe that KB001-A could be used in combination with Kalydeco***.

Ataluren (PTC Therapeutics). A protein restoration therapy that works similarly to Kalydeco, ataluren is designed to overcome a nonsense mutation in the CFTR gene, allowing for the production of a functional CFTR protein. A nonsense mutation creates an unwanted "stop" signal when a gene is used to produce a protein, which in this case results in the premature halt of the synthesis of CFTR. As a result, the nonsense mutation causes the CFTR protein to be short and nonfunctioning. Results from a Phase III study (presented on June 8, 2012, via a company press release) in patients with nonsense mutation CF (nmCF) were presented and demonstrated positive trends in lung function for patients treated with ataluren as measured by FEV_1 and by the rate of pulmonary exacerbations. This double-blind, placebo-controlled study compared ataluren (n=116) to placebo (n=116); the primary endpoint was change from baseline in the percentage-predicted FEV_1 at 48 weeks. In the intent-to-treat population, there was a 3% difference in the relative change from baseline in the ataluren and placebo groups; however, the results were not statistically significant. Conversely, an analysis of the relative change from baseline across all post-baseline study visits demonstrated an average difference between ataluren and placebo of 2.5%, which was statistically significant (-1.8% average change on ataluren versus -4.3% average change on placebo; $p=0.0478$). ***Similar to Kalydeco, if this agent eventually reaches the market, it targets the genetic basis behind some CF patients and would in theory be combinable with KB001-A.***

Asthma

While there are several therapies for mild and moderate asthma (inhaled corticosteroids such as Clenil/Qvar and Flovent/Flonase), few have been shown to be effective in asthma that is severe and persistent/inadequately controlled. In this section, we review therapies that target the more-severe forms of asthma.

Omalizumab (Xolair by Roche/Genentech and Novartis). As a monoclonal antibody, Xolair inhibits the binding of IgE to FcεRI (the high-affinity IgE receptor) on the surface of basophils and mast cells and is approved for the treatment of moderate to severe allergic asthma. The rationale behind Xolair's activity is the reduction in surface-bound IgE on FcεRI-bearing cells, which limits the degree of release of proteins that are responsible for potentiating an allergic response. The safety and efficacy of Xolair were evaluated in three randomized, double-blind, placebo-controlled trials where each study comprised a run-in period for patients to stably convert to common inhaled corticosteroids (beclomethasone dipropionate, for studies 1 and 2, and fluticasone propionate for study 3) followed by randomization to Xolair or placebo (details of this trial were obtained from the Xolair Label Accessdata FDA website). In study 1, an improvement in the mean number of exacerbations/patient was observed in the Xolair-treated group (0.2%), versus the placebo (0.3%; p=0.005). In study 2, the mean number of exacerbations/patient was also lower in patients who took Xolair (0.1%) versus placebo (0.4%; p<0.001). In both studies, improvements in measures of airflow (FEV_1) and asthma symptoms were also observed. In the third study, results showed that the number of exacerbations in patients treated with Xolair was similar to that in placebo-treated patients. ***While this agent will pose some competition to KB003, its activity is restricted to patients with specific allergic asthma (IgE-related), which is more restrictive than the currently sought-after indication for KaloBios.***

MOR103 (MorphoSys AG). While it is not in evaluation for the treatment of asthma, MOR103 is a monoclonal antibody against GM-CSF and on September 20, 2012, the company announced that it demonstrated some positive Phase Ib/IIa clinical trial data in rheumatoid arthritis. The randomized trial involved 96 patients with mild to moderate rheumatoid arthritis who received either placebo or MOR103; after a dose-escalation phase, one dose of MOR103 in particular met the secondary endpoint of ACR20 response rate at four weeks versus placebo (68% versus 7%; p<0.0001). Furthermore, the ACR20 response rates were 25% for low-dose MOR103 and 30% for high-dose MOR103. We believe these results validate the pathway for the treatment of autoimmune diseases, which is a positive to KB003 since these agents are being developed for different disease indications.

Mepolizumab (Bosatria; GSK). Mepolizumab is an investigational, humanized monoclonal antibody that binds specifically to interleukin-5 (a controller of eosinophils in the blood) and activates its function. Results from a multicenter Phase III study were published recently in the August 2012 issue of *The Lancet*. In the trial, patients who had a history of recurrent severe asthma exacerbations and had signs of eosinophilic inflammation were randomly assigned in equal ratios to receive one of three doses of intravenous mepolizumab (75 mg, 250 mg, or 750 mg) or matched placebo. In total, 621 patients were randomized, with 776 exacerbations defined as clinically significant. Overall, the exacerbation rate was found to be statistically higher in the placebo group over all active arms of the study—2.40 per patient per year in the placebo group, 1.24 in the 75 mg mepolizumab group (a 48% reduction versus placebo; p<0.0001), 1.46 in the 250 mg mepolizumab group (a 39% reduction versus placebo; p=0.0005), and 1.15 in the 750 mg mepolizumab group (a 52% reduction versus placebo; p<0.0001). While this data looks promising, the drug's mechanism of action and Phase III trial design will limit its use to atopic/eosinophil-related severe asthma patients, while KB003's proposed development pathway and mechanism of action will go beyond this patient population.

Appendix C: Intellectual Property

KaloBios has nine issued U.S. patents, with an exclusive license to seven U.S. patents. It also has more than 90 patent applications pending throughout the world. The patents to the Humaneered technology cover methods of producing very specific human antibodies using only a small region from mouse antibodies.

University of California at San Francisco (UCSF)
As mentioned above, KaloBios has an exclusive license for the IP relating to KB001-A from the University of California at San Francisco (UCSF) and the Medical College of Wisconsin. As a result of rights granted to KaloBios to develop antibodies for the treatment of *Pseudomonas*, a composition of matter patent was granted to the company, which provides it with protection through 2029 in the United States.

The Ludwig Institute for Cancer Research
The basis regarding the intellectual property behind the KB003 development program comes from the Ludwig Institute for Cancer Research (LICR). KaloBios has a composition of matter patent for KB003 as well as other anti-GM-CSF antibodies, which provides protection until 2029. With respect to KB004 (also obtained from the LICR), KaloBios has composition of matter patents that (if eventually issued) will provide the company with protection until 2030.

Additional information is available upon request.

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DJIA:	14,000.57
S&P 500:	1,515.60
NASDAQ:	3,161.82

The prices of the common stock of other public companies mentioned in this report follow:

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BioMarin Pharmaceutical Inc. (Outperform)	$56.10
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Peregrine Pharmaceuticals Inc.	$1.58
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Raptor Pharmaceuticals Corp.	$5.16
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Equity Research Directory

John F. O'Toole, Partner Manager and Director of Research +1 312 364 8612
Kyle Harris, CFA, Partner Operations Manager +1 312 364 8230

CONSUMER

Sharon Zackfia, CFA, Partner +1 312 364 5386
Group Head–Consumer
Apparel and Accessories, Leisure, Restaurants

Jon Andersen, CFA, Partner +1 312 364 8697
Consumer Products

Daniel Hofkin +1 312 364 8965
Hardlines, Specialty Retail

Mark Miller, CFA, Partner +1 312 364 8498
Broad Assortment and Hardlines, E-commerce, Health, Beauty, and Convenience

Amy Noblin +1 415 248 2874
Apparel and Accessories

FINANCIAL SERVICES AND TECHNOLOGY

Adam Klauber, CFA +1 312 364 8232
Co-Group Head–Financial Services and Technology
Insurance Brokers, Property & Casualty Insurance

Robert Napoli +1 312 364 8496
Co-Group Head–Financial Services and Technology
Financial Technology, Specialty Finance

Christopher Shutler, CFA +1 312 364 8197
Asset Management, Financial Technology

GLOBAL INDUSTRIAL INFRASTRUCTURE

Nick Heymann +1 212 237 2740
Co-Group Head–Global Industrial Infrastructure
Multi-industry

Larry De Maria, CFA +1 212 237 2753
Co-Group Head–Global Industrial Infrastructure
Capital Goods

Nate Brochmann, CFA +1 312 364 5385
Commercial Services, Logistics/Transportation

Brian Drab, CFA +1 312 364 8280
Filtration and Water Management, Industrial Technology

Samuel H. Eisner +1 212 237 2752
Industrial Components

Chase Jacobson +1 212 237 2748
Engineered Equipment, Engineering and Construction

Ryan Merkel, CFA +1 312 364 8603
Commercial Services, Industrial Distribution

GLOBAL SERVICES

Brandon Dobell, Partner +1 312 364 8773
Group Head–Global Services
Educational Services, Energy Services, Information Services, Marketing Services, Real Estate Services and Technology

Timothy McHugh, CFA, Partner +1 312 364 8229
Consulting, Employer Services, Information Services, Staffing

HEALTHCARE

Ben Andrew, Partner +1 312 364 8828
Group Head–Healthcare
Medical Devices

Ryan Daniels, CFA, Partner +1 312 364 8418
Healthcare Information Technology, Healthcare Services

John Kreger, Partner +1 312 364 8597
Distribution, Outsourcing, Pharmacy Benefit Management

Tim Lugo +1 415 248 2870
Therapeutics

Amanda Murphy, CFA +1 312 364 8951
Diagnostic Services, Life Sciences, Pharmacy Benefit Management

Matthew O'Brien +1 312 364 8582
Medical Devices

John Sonnier, Partner +1 312 364 8224
Biotechnology

Brian Weinstein, CFA +1 312 364 8170
Diagnostic Products

Y. Katherine Xu, Ph.D. +1 212 237 2758
Biotechnology

TECHNOLOGY, MEDIA, AND COMMUNICATIONS

Jason Ader, CFA, Partner +1 617 235 7519
Co-Group Head–Technology, Media, and Communications
Data Networking and Storage

Laura Lederman, CFA, Partner +1 312 364 8223
Co-Group Head–Technology, Media, and Communications
Business Software & Services, IT Services, Software as a Service

Jim Breen, CFA +1 617 235 7513
Internet Infrastructure and Communication Services

Anil Doradla +1 312 364 8016
Semiconductors and Wireless

Jonathan Ho +1 312 364 8276
Cybersecurity, Security Technology

Dmitry Netis +1 212 237 2714
Communications Equipment

Ralph Schackart III, CFA, Partner +1 312 364 8753
Digital Media, Internet

Bhavan Suri, Partner +1 312 364 5341
Business Software & Services, IT Services

EDITORIAL

Steve Goldsmith, Head Editor +1 312 364 8540
Maria Erdmann +1 312 364 8925
Beth Pekol Porto +1 312 364 8924
Kelsey Swanekamp +1 312 364 8174
Lisa Zurcher +44 20 7868 4549

William Blair