Zacks Small-Cap Research

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AmpliPhi Biosciences Corp. (APHB-NYSE MKT)

APHB: Looking to Follow-up on a Successful 2016…

Based on our probability adjusted DCF model that takes into account potential future revenues from AB-SA01, AB-PA01, and AB-CD01, APHB is valued at $15/share. This model is highly dependent upon the clinical success of those products and will be adjusted accordingly based upon future clinical results.

Current Price (04/25/17)	$3.54
Valuation	**$15.00**

OUTLOOK

On March 27, 2017, AmpliPhi Biosciences Corp. (APHB) announced financial result for the fourth quarter and full year of 2016. During 2016, the company reported favorable Phase 1 results for the AB-SA01, which showed that treatment of patients with chronic rhinosinusitis (CRS) was safe and well tolerated and reduced or eliminated *Staphylococcus aureus* at the end of the study compared to baseline. In addition, endoscopy showed reductions in mucosal edema, discharge, and polyps from the beginning to the end of the trial. The company met with the FDA in February 2017 and received positive feedback regarding plans for a Phase 2 trial of AB-SA01 in patients with CRS. AmpliPhi exited 2016 with $5.7 million and is currently evaluating various funding options.

SUMMARY DATA

52-Week High	**$37.23**
52-Week Low	**$3.02**
One-Year Return (%)	**-87.77**
Beta	**2.23**
Average Daily Volume (sh)	**348,501**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**9**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0.1 A	0.1 A	0.0 A	0.0 A	0.3 A
2017	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2018					0.0 E
2019					0.0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$8.22 A	$7.26 A	-$3.23 A	-$5.55 A	-$24.68 A
2017	-$1.88 E	-$1.52 E	-$1.26 E	-$1.14 E	-$5.56 E
2018					-$4.00 E
2019					-$4.13 E

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WHAT'S NEW

Business Update

AmpliPhi Biosciences Corp. (APHB) is developing bacteriophage therapeutics for the treatment of bacterial infections. The company's pipeline consists of treatments that specifically target infections caused by *Staphylococcus aureus* (AB-SA01), *Pseudomonas aeruginosa* (AB-PA01), and *Clostridium difficile* (AB-CD01).

Bacteriophage Therapy Case Study

On April 25, 2017, AmpliPhi announced a case study reporting the successful treatment of a patient with a multidrug-resistant *Acinetobacter baumannii* infection will be featured in an oral presentation at the Centennial Celebration of Bacteriophage Research on April 26 at the Institut Pasteur in Paris, France.

The case study involved Tom Patterson, PhD, a Professor at the University of California, San Diego, who contracted an abdominal *A. baumannii* infection that became resistant to a wide range of antibiotics, including cephalosporins, amikacin, ciprofloxacin, and colistin. Unable to clear the infection, Dr. Patterson became gravely ill and fell into a coma. AmpliPhi joined a team that included several academic institutions and the U.S. Naval laboratory to produce a customized bacteriophage therapy specifically targeting the *A. baumannii* strain that was infecting Dr. Patterson. Following administration of the bacteriophage therapy, which was initiated under an emergency Investigational New Drug (IND) application approved by the U.S. FDA, Dr. Patterson awoke from the coma and continued to improve until the infection was completely cleared. There has been no recurrence of the infection.

This case study highlights the potential utility of bacteriophage therapy and the importance of its continued development to combat the rise of antibiotic resistant bacterial infections. In addition, it alludes to the potential to create personalized bacteriophage products for infections that cannot be cleared through conventional means.

AB-SA01

Favorable Final Trial Results for AB-SA01 in CRS

On December 19, 2016, AmpliPhi announced favorable final results from the Phase 1 trial of AB-SA01 in patients with chronic rhinosinusitis (CRS). Importantly, the trial met the primary endpoints of safety and tolerability and all nine patients enrolled in the trial experienced a reduction in the quantity of *S. aureus* in their sinuses while some of the patients experienced a complete eradication of bacterial infection. Results from the Phase 1 study were recently presented at two scientific meetings in Australia.

As part of the standard of care following sinus surgery, the patients in the trial flush their sinuses twice a day with a sterile saline solution. The Phase 1 trial involved the addition of different concentrations of bacteriophage to the saline solution that the patients use to flush out their sinuses. Cohort 1 was dosed with 10^8 phage/mL in sterile saline twice daily for one week. Cohort 2 was dosed with 10^8 phage/mL in sterile saline twice daily for two weeks. Cohort 3 was dosed with 10^9 phage/mL in sterile saline twice daily for two weeks.

The most important conclusions drawn from the study were:

1) AB-SA01 was safe and well tolerated, with all patients completing the trial.
2) All patients experienced a reduction in *S. aureus* when comparing baseline to the end of the trial.
3) Endoscopy images showed symptomatic improvement, with reductions in mucosal edema, discharge, and polyps using the Lund Kennedy score, which quantifies the pathologic states of the nose and paranasal sinuses by focusing on the presence of polyps, discharge, edema, scarring, or crusting (Lund *et al*., 1995).

The most encouraging bit of data is that improvements were seen in endoscopic examinations, particularly since those were performed on day 14, or as soon as treatment ended. A previous study of a *P. aeruginosa* bacteriophage in patients with chronic otitis showed that the bacteriophage was still active in some patients up to 42 days after administration (Wright *et al*., 2009). Thus, we believe that future studies would likely include a longer

follow up time to allow for full examination of a potential therapeutic effect exerted by bacteriophage treatment, which was not done in this Phase 1 study as the primary outcome was safety.

Favorable Final Trial Results for AB-SA01 Applied Topically to Skin

In addition to treating CRS, AmpliPhi is also developing AB-SA01 in collaboration with the U.S. Army as a topical treatment for wound infections. On September 13, 2016, AmpliPhi announced topline results from a Phase 1 clinical trial designed to test the safety and tolerability of AB-SA01 administered topically to the skin. A total of 12 healthy adult volunteers were dosed in two cohorts of six participants each, with each volunteer receiving either low-dose ($1x10^8$ PFU/mL) or high-dose ($1x10^9$ PFU/mL) of AB-SA01 on the forearm under an occlusive bandage. Placebo was administered to the opposite forearm, thus allowing each participant to serve as his or her own control. AB-SA01 and placebo were administered daily for three consecutive days. Results showed that AB-SA01 was well-tolerated and that no drug-related serious adverse events were reported. This study was required before a trial involving wounds infected with *S. aureus* could get underway, and we are glad to see that it was completed successfully with no unanticipated safety signals arising.

AB-PA01

Positive Preclinical Results Seen in In Vivo and In Vitro Models

Earlier in 2016, AmpliPhi presented data on AB-PA01 showing both *in vitro* and *in vivo* activity against 87.8% of *Pseudomonas Aeruginosa* clinical isolates from a global population of cystic fibrosis (CF) patients. AB-PA01 was active against both multi-drug resistant and sensitive strains of *P. aeruginosa* and the data presents a strong rationale for moving the drug into clinical testing in CF patients.

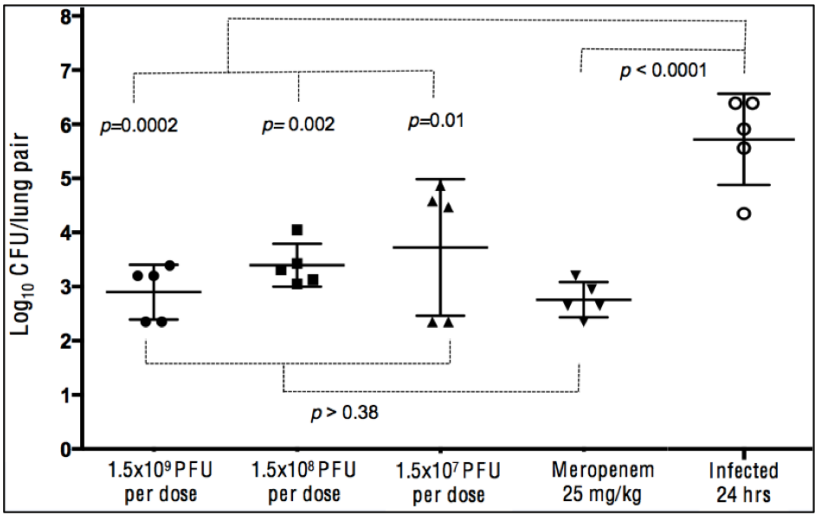
AB-PA01 is a mixture of four bacteriophages that specifically target *P. aeruginosa*. To develop this product, AmpliPhi created a global "diversity" panel of relevant *P. aeruginosa* clinical isolates from CF clinics around the globe. Clinical isolates are bacteria cultured from infected patients. This diversity panel was screened against the company's bacteriophage library that was isolated and characterized according to their proprietary discovery and development platform. The bacteriophage mix was selected to exhibit a high degree of "complementation," defined as the number of bacteria targeted by more than one bacteriophage in the product. High complementation is an important factor in preventing bacteria from developing resistance to bacteriophage products.

To test the activity of AB-PA01, 10^8 PFU/mL was spotted onto different strains of *P. aeurigonsa* cultures. Each strain was considered sensitive if more than 20 plaques (areas of bacterial cell death) were observed. The following table shows the percentage of *P. aeruginosa* isolates that were sensitive to treatment with AB-PA01. Complementation was shown by the high percentage of *P. aeruginosa* isolates that were sensitive to two or more of the phages in AB-PA01.

Number of Isolates	Area (Year of Isolation)	Type	AB-PA01 % of Activity	% of isolates sensitive to ≥2 phages in mix
67*	UK/AU/USA (2012-13)	CF	95.5%	87.5%
120	UK (2012-13)	CF	85.0%	95.0%
60	AU (2007-2013)	CF	93.3%	98.2%
40	USA (2014)	CF	87.5%	91.4%
82	UK (2015)	CF	81.7%	92.5%
60	USA/EU/AU (2013)	Non-CF	83.3%	80.0%
369	Total CF Isolates		87.8%	93.2%
429	Total isolates (CF + Non-CF)		87.2%	91.4%

Source: Lehman *et al.*, 2016

The *in vivo* activity of AB-PA01 was tested in immunocompetent CD-1 mice infected with 6.26 $\log_{10}$ CFU of *P. aeruginosa*. Two hours after infecting the mice, three different doses of AB-PA01 ($7.5x10^9$/mL, $7.5x10^8$/mL, or $7.5x10^7$/mL) were administered intranasally to three different dosage groups (n=5). A second dose of phage was administered four hours later. Meropenem, a broad spectrum antibiotic, was administered to a fourth group of animals subcutaneously two and six hours post infection, while a fifth group of animals received phage diluent as a control. The mice were euthanized 24 hours after infection and the CFU/lung pair was determined. The following graph shows that all three doses of phage resulted in a statistically significant decrease in bacterial load compared to the control group. There was also a dose response seen with higher doses of AB-PA01 resulting in decreased bacterial load. Lastly, AB-PA01 showed similar efficacy to meropenem.



Source: Lehman *et al.*, 2016

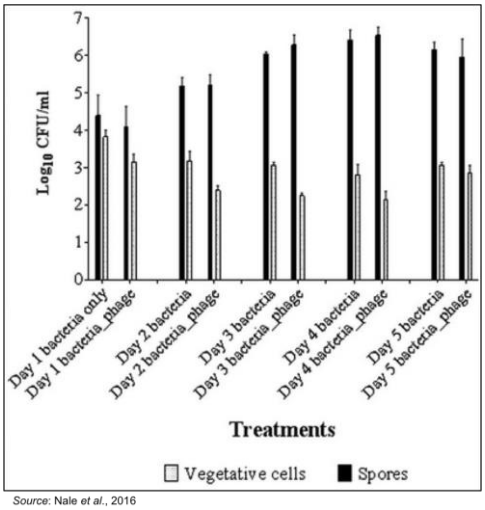
The company is currently conducting manufacturing process development and scale-up with the goal to produce initial clinical batches of AB-PA01 in mid-2017. AmpliPhi is developing AB-PA01 in collaboration with the Royal Brompton Hospital in London, England. The company met with the Medicines and Healthcare Products Regulatory Authority (MHRA) in the UK to receive feedback on plans to move AB-PA01 into the clinic. The MHRA has agreed with the company's plans to conduct a first-in-man dose ranging clinical trial in CF patients, thus bypassing the need to test AB-PA01 first in healthy volunteers.

AB-CD01

AB-CD01 is under development for the treatment of *Clostridium difficile* infections. *C. difficile* is a gram-positive, spore-forming bacterium that is best known for causing antibiotic-associated diarrhea. According to the U.S. CDC, It is estimated to cause upwards of 300,000 infections and 30,000 deaths every year in the U.S.

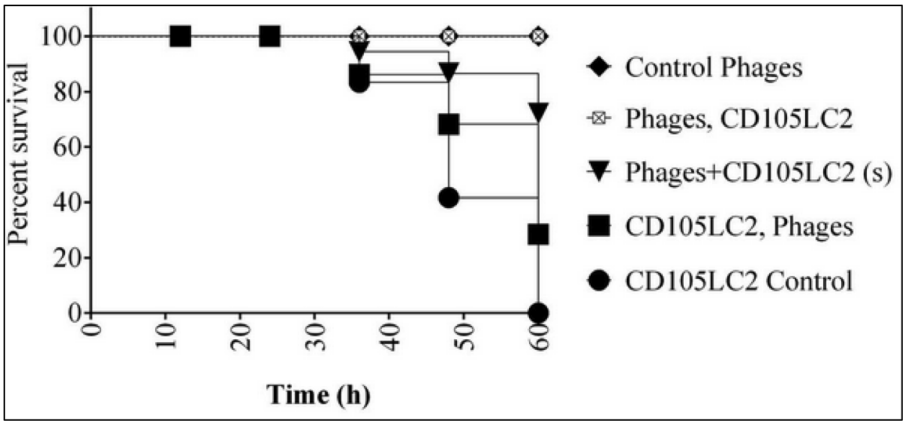
There are only three antibiotics that are utilized for the treatment of *C. difficile* infections, thus there is a need for more treatment options as relapse rates are very high. Approximately 20% of patients will have a relapse infection, and once a patient has had one recurrence the chance of having another recurrence rises to 65%.

On September 12, 2016, AmpliPhi announced the publication of data from a preclinical study in both *in vitro* and *in vivo* models of *C. difficile* infection (Nale *et al*., 2016). For the *in vitro* studies, a 4-phage cocktail was added to pre-established biofilms of *C. difficile* and live cells were quantified following treatment. The following chart shows an approximately 0.5-1.0 log reduction in vegetative cells for 1-4 day old biofilms, however there did not appear to be an effect on spore formation.



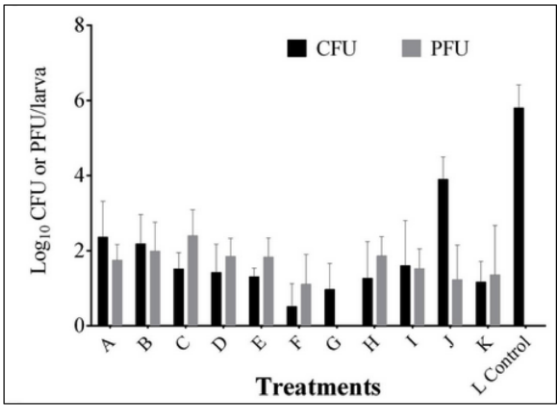
Source: Nale *et al.*, 2016

For the *in vivo* studies, the researchers used the *Galleria mellonella* larvae model, which has been used previously to study phage therapy for *P. aeruginosa* (Beeton *et al*., 2015). The following graph shows the impact of phage treatment on the larvae when phage was administered two hours before the bacterial inoculation (phages, CD105LC2), concurrently with bacterial inoculation (Phages+CD105LC2), or two hours following bacterial inoculation (CD105LC2, phages). Control groups included larvae given phage only (control phages) and those that received bacteria only (CD105L2 control). Results showed that 100% of larvae died within 60 hours following administration of *C. difficile* alone, while 100% of larvae administered phage two hours prior to bacterial inoculation survived the experiment.



Source: Nale *et al*., 2016

The phage cocktail was also tested in combination with vancomycin. The following graph shows the recovery of phage (PFU) and bacteria (CFU) following various combinations of those agents administered either prophylactically or following bacterial inoculation. Compared to larvae administered only bacteria (L), the most effective combination of agents that resulted in the lowest number of bacteria recovered was phage and vancomycin administered two hours prior to bacterial inoculation (F). These results show that phage treatment could potentially be used as an adjunct to vancomycin treatment to help prevent relapse.



Source: Nale *et al*., 2016

Financial Update

On March 27, 2017, AmpliPhi announced financial results for the fourth quarter and full year 2016. The company had revenues in the fourth quarter and full year 2016 of $29,000 and $0.3 million, respectively. These revenues were related to sublicensing agreements involving the company's former gene therapy program. We do not anticipate these revenues to be significant in the future. Net loss for the fourth quarter of 2016 was $7.6 million, or $5.55 per share, and included $1.5 million in R&D expenses, $0.8 million in G&A expenses, and a $9.6 million non-cash charge for the impairment of intangible assets for the excess of book value over the computed fair value of those assets as of Dec. 31, 2016. The impaired assets were recorded in connection with acquisitions of predecessor companies in 2011 and 2012. For the full year 2016, the company had a net loss of $24.3 million, or $24.68 per share, which included $8.4 million in R&D expenses, $5.7 million in G&A expenses. Also included in the full year results were non-cash gains of $3.0 million (based on the change in fair value on revaluation of warrant and derivative liability) and $1.5 million (related to the change in fair value of the Series B preferred stock liability, which was extinguished in April 2016). Actual cash burn in 2016 was $10.9 million and the company exited 2016 with $5.9

million in cash and cash equivalents. The company will need to raise additional capital very soon. In addition, AmpliPhi has retained H.C. Wainwright & Co. as it explores a wide range of strategic alternatives to maximize value for its shareholders following a review of its internal programs, resources, and capabilities.

On April 14, 2017, AmpliPhi announced a 1-for-10 reverse stock split that became effective at 5pm ET on April 24, 2017. Following the reverse stock split the company has approximately 1.7 million shares of common stock outstanding, and when factoring in stock options and warrants, a fully diluted share count of approximately 2.5 million.

Conclusion

AmpliPhi made substantial progress in 2016 with the results of two clinical trials reported for AB-SA01. Importantly, we believe the safety of AB-SA01 has been firmly established, and the fact that multiple CRS patients had complete eradication of *S. aureus* infections is quite promising, and certainly justifies the continued development of AB-SA01 in CRS. The case study reporting the creation of a personalized phage therapy that eliminated an antibiotic resistant infection is very encouraging, and gives a glimpse into the potential utility of bacteriophage therapy as a life-saving treatment option for those with antibiotic resistant infecitons.

We have constructed a probability adjusted discounted cash flow model that takes into account the potential market for treating CRS patients with AB-SA01, cystic fibrosis patients with AB-PA01, as well as the amount of capital that will be required to get the first product to market. Our current valuation for AmpliPhi is $15/share, and we continue to remain positive on the AmpliPhi story and believe that bacteriophage therapy has tremendous potential as a treatment for serious and life-threatening bacterial infections.

PROJECTED INCOME STATEMENT

AmpliPhi Biosciences Corporation
Income Statement

AmpliPhi Bio	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
AB-PA01 (*P. aeruginosa*)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
AB-SA01 (*S. aureus*)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
AB-CD01 (*C. difficile*)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Licensing & Royalties	**$0.3**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0.3**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
General & Administration	$8.4	$1.5	$1.7	$1.8	$1.8	$6.8	$8.0	$10.0
Research & Development	$5.7	$1.5	$1.5	$1.5	$1.5	$6.0	$6.0	$6.5
Other Operating Expenses	$9.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($23.4)	($3.0)	($3.2)	($3.3)	($3.3)	($12.8)	($14.0)	($16.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$4.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.4)	($3.0)	($3.2)	($3.3)	($3.3)	($12.8)	($14.0)	($16.5)
Income Taxes Paid	($1)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	$5	$0	$0	$0	$0	$0	$0	$0
Net Income	($24.3)	($3.0)	($3.2)	($3.3)	($3.3)	($12.8)	($14.0)	($16.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($24.68)**	**($1.88)**	**($1.52)**	**($1.26)**	**($1.14)**	**($5.56)**	**($4.00)**	**($4.13)**
YOY Growth	*24%*	-	-	-	-	*-77%*	*-28%*	*3%*
Basic Shares Outstanding	1.0	1.6	2.1	2.6	2.9	2.3	3.5	4.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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