Zacks Small-Cap Research

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AmpliPhi Biosciences Corp. (APHB-NYSE MKT)

APHB: Results from Two Phase 1 Studies of AB-SA01 to be Reported in 2H16…

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 $11/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 (08/17/16)	$1.87
Valuation	**$11.00**

OUTLOOK

On August 15, 2016, AmpliPhi Biosciences Corp. announced financial results for the second quarter of 2016 and provided a business update. The company reported a net loss of $6.4 million, or $0.73 per share, and exited the quarter with approximately $7.1 million in cash and cash equivalents following a public offering in June 2016 that resulted in net proceeds to the company of $4.2 million. We estimate this will be sufficient to fund operations into the fourth quarter of 2016.

The company announced that AB-SA01 was well tolerated in the first cohort of chronic rhinosinusitis patients in the ongoing Phase 1 safety study. Full results of that trial, along with results from a safety study of AB-SA01 on intact skin, will be released in the second half of 2016.

SUMMARY DATA

52-Week High	**$9.10**
52-Week Low	**$1.20**
One-Year Return (%)	**-78.79**
Beta	**1.76**
Average Daily Volume (sh)	**283,875**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**18**
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)
2015	0.1 A	0.1 A	0.1 A	0.1 A	0.5 A
2016	0.1 A	0.1 A	0.1 E	0.1 E	0.5 E
2017					0.5 E
2018					0.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$3.49 A	$1.58 A	-$0.30 A	-$0.40 A	-$1.99 A
2016	-$0.82 A	-$0.73 A	-$0.41 E	-$0.36 E	-$1.93 E
2017					-$1.18 E
2018					-$1.08 E

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WHAT'S NEW

Financial Update

On August 15, 2016, AmpliPhi Biosciences Corp. (APHB) announced financial results for the second quarter of 2016 and provided a business update. The company reported $0.1 million in revenue, which was received in relation to sublicensing agreements from the company's former gene therapy program. The net loss for the second quarter was $6.4 million, or $0.73 per share, and included $1.2 million in R&D expenses and $2.5 million in G&A expenses. Total cash burn for the first six months of 2016 was $6.0 million. In June 2016, the company raised approximately $4.2 million through a public offering of 2,127,660 shares of common stock sold at $2.35 per share. Included with each share was a warrant to purchase one-half of a share of common stock at an exercise price of $2.25 per share. We estimate that the company currently has sufficient capital to fund operations into the fourth quarter of 2016.

During the second quarter, AmpliPhi announced that the company converted all 7.5 million outstanding shares of Series B convertible preferred stock into approximately 1.5 million shares of common stock. The move came after more than 2/3rd of the holders of the Series B preferred stock elected for the conversion, which was in accordance with the company's articles of incorporation. As of Aug. 8, 2016 AmpliPhi had approximately 11.1 million shares of common stock outstanding and when factoring in stock options and warrants, a fully diluted share count of approximately 14.3 million.

Business Update

AmpliPhi is focused on the discovery, development, and commercialization of bacteriophage treatments for bacterial infections. Bacteriophages are viruses that infect, replicate in, and kill bacterial cells while not harming eukaryotic cells. This exclusivity is vital to their use in combating infectious diseases, and their unique mechanism of action compared to traditional antibiotics means they can be used in place of or in conjunction with those therapies.

While bacteriophages have been known for over 100 years, up until now their use as anti-infectious agents has been restricted to limited geographic regions (mainly Eastern Europe and Russia). This is due to the rise of antibiotics during the middle part of the 20th century that proved to be cheap, plentiful, and effective therapeutics. However, the rise of antibiotic resistant organisms has resulted in a clear need for alternative treatment options, specifically for ones that no longer respond to once effective antibiotic therapies.

Bacteriophage therapies potentially hold a number of advantages over antibiotics, including:

- ✓ Multiple modes of application
- ✓ Less severe side effects
- ✓ Localized and highly specific effect
- ✓ Very low doses
- ✓ Can treat antibiotic-resistant strains
- ✓ Unique mechanism of action makes resistance less likely

AB-SA01 Update

AB-SA01 is being developed for the treatment of *Staphylococcus aureus* infections, including methicillin-resistant *S. aureus* (MRSA) infections. It contains three phage constituents that target greater than 96.7% of *S. aureus* isolates from a global diversity panel.

On November 19, 2015, AmpliPhi announced a clinical trial research agreement has been entered into with the University of Adelaide for the purpose of conducting a Phase 1 clinical trial of AB-SA01. The study is titled "A Phase 1 Investigator Initiated Study to Evaluate the Safety, Tolerability and Preliminary Effectiveness of AB-SA01 in Patients with Chronic Rhinosinusitis Associated with Staphylococcus aureus infection".

The trial is being conducted at the Queen Elizabeth Hospital, Adelaide, Australia and AmpliPhi is supplying the bacteriophage drug product for the clinical study. In addition, AmpliPhi is providing scientific input, protocol

recommendation, and assisting the study's principal investigator with data management support. The trial is expected to enroll nine patients who suffer from chronic rhinosinusitis and are also positive for *S. aureus* by nasal swab. Since this is a Phase 1 study, the primary endpoint is safety, however the company will also be collecting anecdotal evidence about how bacteriophage treatment affects the patients symptoms. As part of the standard of care these patients flush their sinuses twice a day with a sterile saline solution. The trial involves 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 is currently being dosed with 10^9 phage/mL in sterile saline twice daily for two weeks.

The company recently announced that the first patient in Cohort 3 has been dosed. In addition, AmpliPhi announced that treatment with AB-SA01 in the first cohort of patients was well tolerated with no drug related adverse events. We expect that trial results will be released before the end of 2016.

In addition to treating chronic rhinosinusitis, AmpliPhi is also developing AB-SA01 in collaboration with the U.S. Army as a topical treatment for wound infections. AmpliPhi has initiated the first Phase 1 phage therapy trial under a U.S. IND to investigate the safety of topically administered AB-SA01 to intact skin on 12 healthy adult volunteers. The trial is fully enrolled, with each subject treated with phage on one arm and placebo on the other arm, thus each subject is serving as their own control. We anticipate topline data being released in the third quarter of 2016.

AB-PA01 Update

On April 12, 2016, AmpliPhi Biosciences Corp. (APHB) 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.

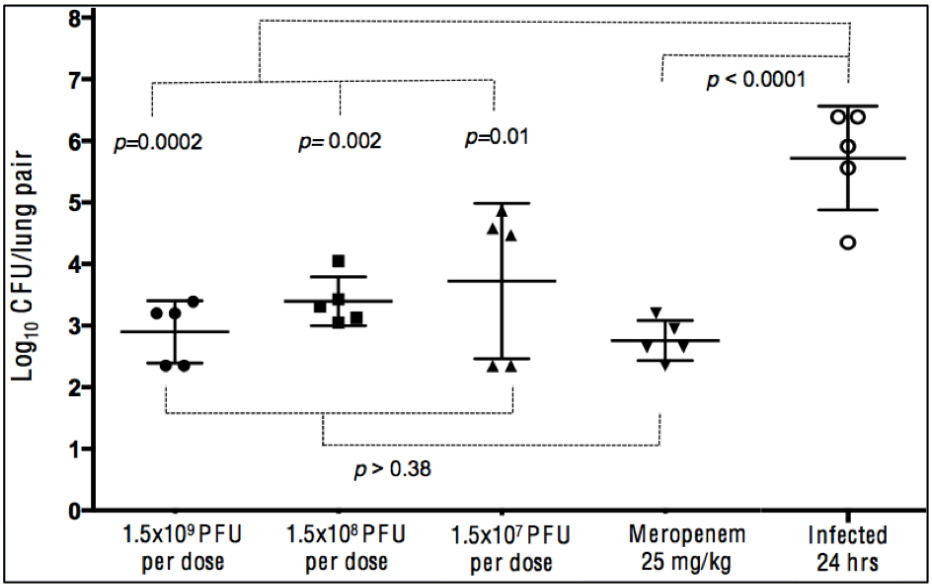
AB-PA01 is a mixture of four bacteriophages that specifically target *P. aeruginosa*. To develop this product, AmpliPhi created a global "diversity" panel of relevant *P. aeruginosa* clinical isolates from CF clinics around the globe. Clinical isolates are bacteria cultured from infected patients. This 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.

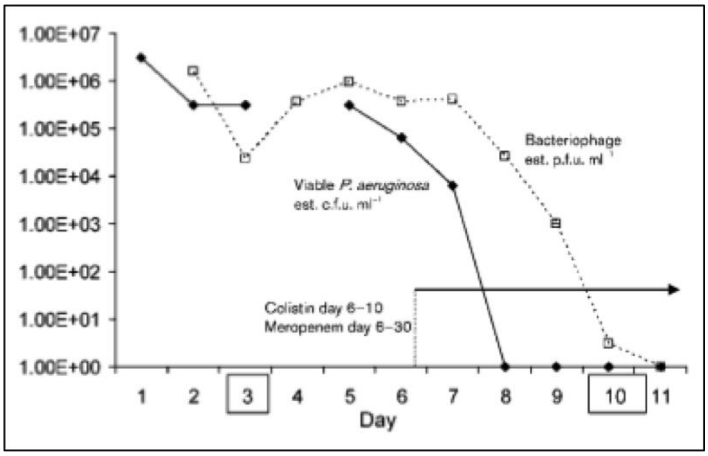


Source: Lehman *et al*., 2016

AmpliPhi is developing AB-PA01 in collaboration with the Royal Brompton Hospital in London, England. The company is continuing formulation work on AB-PA01 through the rest of 2016, and we anticipate a Clinical Trial Application (CTA) being submitted to the Medicines and Healthcare Products Regulatory Authority (MHRA) in the UK in the first half of 2017, with the first clinical trial likely to commence shortly thereafter. 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.

Bacteriophage Therapy Case Study

To show the potential for bacteriophage therapy, we identified a case report of a 67 year old female with recurrent bladder infections caused by *P. aeruginosa* that was refractory to multiple rounds of different antibiotic treatments (Khawaldeh *et al*., 2011). Following identification of multiple anti-*P. aeruginosa* lytic bacteriophages, the patient was treated directly in the bladder every 12 hours for 10 days with ~2 x 10^7 PFU of bacteriophage. As the following chart shows, the patient responded well to treatment and as the level of *P. aeruginosa* decreased (black line), the level of bacteriophage subsequently decreased (dotted line) as the target organism disappeared.



Source: Khawaldeh *et al*., 2011

Intellectual Property Update

Over the past two months AmpliPhi has been awarded two patents that have helped shore up the company's intellectual property. On June 2, 2016, the company announced that the European Patent Office issued patent No. 2136826 for the "Beneficial effects of bacteriophage treatments." The claims of the patent discuss the treatment of antibiotic-resistant infections through the use of bacteriophage treatment followed by antibiotic treatment using an antibiotic to which the bacteria were initially resistant. The initial bacteriophage treatment results in killing of a

majority of the bacteria cells, however some bacteria do survive. Those that survive typically lose factors that contributed to antibiotic resistance, thus the bacteria are now vulnerable to antibiotic treatment. This phenomenon has been observed both *in vitro* and *in vivo*, and is an important attribute of bacteriophage therapy. A similar patent was recently granted by the Japanese Patent Office for bacteriophage treatment specifically targeting *P. aeruginosa* infections.

Conclusion

We look forward to seeing the topline data from the company's two Phase 1 clinical trials and will be providing an analysis of the data after it is released. The fact that the initial cohort of patients in the chronic rhinosinusitis study tolerated bacteriophage treatment well is encouraging, and we believe that safety will not be an issue in these studies. What will be most interesting is if any anecdotal data is seen in terms of efficacy among any of the nine chronic rhinosinusitis patients.

We have constructed a probability adjusted discounted cash flow model that takes into account the potential market for treating chronic rhinosinusitis patients with AB-SA01, CF 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 $11/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	2015 A	Q1 A	Q2 A	Q3 E	Q4 E	2016 E	2017 E	2018 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	**$0.5**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.5**	**$0.5**	**$0.5**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0.5**	**$0.1**	**$0.1**	**$0.1**	**$0.1**	**$0.5**	**$0.5**	**$0.5**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
General & Administration	$6.4	$2.6	$2.5	$2.5	$2.5	$10.1	$11.0	$11.5
Research & Development	$4.0	$2.0	$1.2	$2.0	$2.2	$7.4	$10.0	$12.0
Other Operating Expenses	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($10.2)	($4.5)	($3.6)	($4.4)	($4.6)	($17.1)	($20.5)	($23.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$9.6	$1.4	($2.8)	($0.1)	($0.1)	($1.6)	($0.8)	($0.8)
Pre-Tax Income	($0.6)	($3.1)	($6.4)	($4.5)	($4.7)	($18.6)	($21.3)	($23.8)
Income Taxes Paid	($0)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	$10	$2	$0	$0	$0	$0	$0	$0
Net Income	($10.8)	($4.8)	($6.4)	($4.5)	($4.7)	($18.6)	($21.3)	($23.8)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.99)**	**($0.82)**	**($0.73)**	**($0.41)**	**($0.36)**	**($1.93)**	**($1.18)**	**($1.08)**
YOY Growth	*-134%*	-	-	-	-	*-3%*	*-39%*	*-9%*
Basic Shares Outstanding	5.4	5.9	8.7	11.0	13.0	9.7	18.0	22.0

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

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