Zacks Small-Cap Research

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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

AmpliPhi Biosciences Corp. (APHB-NYSE American)

APHB: Reports Positive Interim Results for Expanded Access Program…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's personalized phage therapies, AB-SA01, and AB-PA01, APHB is valued at $5.00/share. This model is highly dependent upon continued clinical and regulatory success and will be adjusted accordingly based upon future results.

Current Price (01/05/18)	$1.42
Valuation	**$5.00**

OUTLOOK

On January 3, 2017, AmpliPhi Biosciences Corp. (APHB) announced positive interim results for the company's single-patient expanded access program. A total of seven patients with drug resistant, life-threatening infections have been treated thus far with either AB-SA01 or AB-PA01, with six of them achieving "treatment success", which was either complete resolution or significant improvement of baseline signs and symptoms.

These data are very encouraging as the patients had a wide variety of ailments including bacteremia, endocarditis, lung infection in cystic fibrosis, and ventilator-associated pneumonia. The company plans to treat up to an additional 20 patients before meeting with the FDA to map out a plan for Phase 2 studies.

SUMMARY DATA

52-Week High	**$5.40**
52-Week Low	**$0.71**
One-Year Return (%)	**-69.79**
Beta	**2.94**
Average Daily Volume (sh)	**376,253**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$13**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**2**
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 A	0.0 A	0.0 A	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	-$1.92 A	-$1.21 A	-$0.09 A	-$0.35 E	-$2.17 E
2018					-$1.17 E
2019					-$1.18 E

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WHAT'S NEW

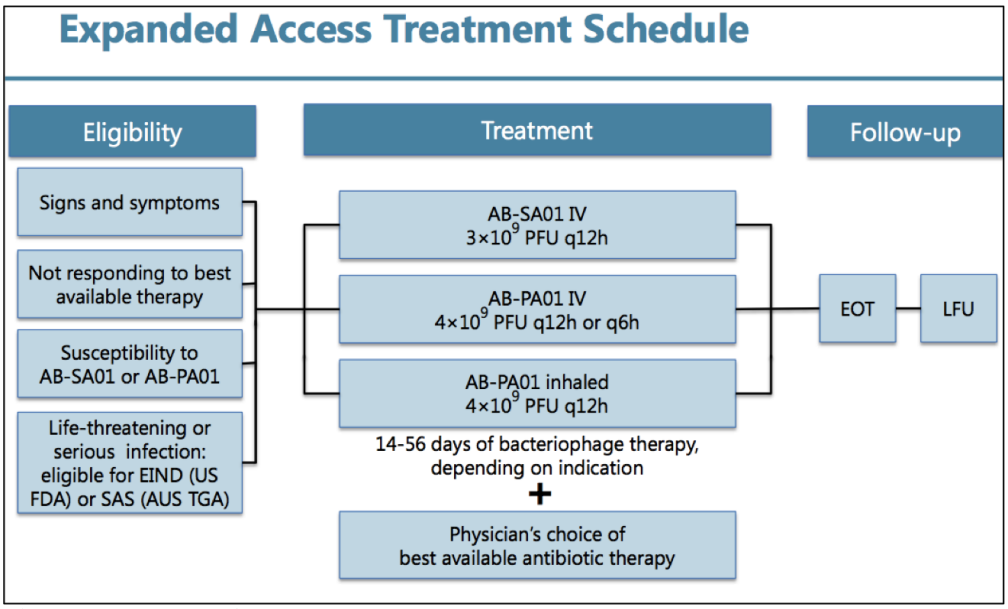
Business Update

Positive Interim Results for Single-Patient Expanded Access Program

On January 3, 2018, AmpliPhi Biosciences Corp. (APHB) announced positive interim results from the company's single-patient expanded access program. A total of seven patients with serious or life-threatening infections, which were not responding to antibiotic therapy, were treated with AB-SA01 (n=4) or AB-PA01 (n=3). Six out of the seven patients (86%) achieved "treatment success", which was defined as complete resolution or significant improvement of baseline signs and symptoms.

AmpliPhi is developing bacteriophage therapeutics for the treatment of 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. 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. AB-PA01 is being developed for the treatment of *Pseudomonas aeruginosa* infections. It contains four phage constituents that target approximately 80% of *P. aeruginosa* strains, including multi-drug resistant isolates.

The company's strategy is to use single patient expanded access protocols (Emergency IND in the U.S. and Special Access Scheme in Australia) to derive real-world data using AB-SA01 and AB-PA01 in patients suffering from severe, multidrug-resistant (MDR) infections. The following schematic shows the treatment schedule for the expanded access protocol. In order for a patient to qualify, they would need to have a serious or life-threatening infection that was not responding to antibiotics and that was also susceptible to either AB-SA01 or AB-PA01. Testing to confirm susceptibility to AB-SA01 or AB-PA01 can be performed in approximately 48 hours.



Source: AmpliPhi Biosciences Corp..

The characteristics of the seven patients treated thus far under the expanded access protocol are in the following slide. The APACHE II (Acute Physiology And Chronic Health Evaluation II) score is designed to measure the severity of disease of patients admitted to the intensive care unit (Knaus *et al*., 1985). The score (0-71) is calculated from the patient's age and 12 physiological measurements, with a higher score signifying more severe disease and a higher risk of death.

Patient Characteristic (ITT Population)	**Value** (N=7)
Age, years, mean (range)	52 (26-77)
Male / female	57% / 43%
Indications	Bacteremia Endocarditis (native valve) Endocarditis (prosthetic valve) Lung infection (cystic fibrosis) Lung infection (post-transplant) Ventilator-associated pneumonia
Bacterial pathogen *S. aureus* *P. aeruginosa*	 4 3
APACHE II score*, mean (range) <35 ≥35	23 (6-47) 4 patients 3 patients

Source: AmpliPhi Biosciences Corp..

Importantly, both AB-SA01 and AB-PA01 were safe and well-tolerated with no treatment-related serious adverse events (SAE). A total of 90 intravenous (IV) doses of AB-SA01 and a total of 402 IV and 92 inhaled doses of AB-PA01 were administered.

The following slide shows the clinical outcomes for the seven patients. Six of the seven were classified as "treatment success", meaning that they had a complete resolution or significant improvement of baseline signs and symptoms while one patient failed treatment. The patient who failed presented with septic shock and an APACHE II score of 47 at baseline (which equates to a predicted mortality risk of 97%). The patient was not responding to antibiotic treatment, and following three days of bacteriophage therapy they died during surgery on day 3. The treating physician deemed the death as unrelated to bacteriophage treatment.

Clinical Outcome (Physician's Assessment) (ITT Population)	**Value** (N=7)
Treatment Success	6 (86%)
Improvement	0
Failure	1 (14%)*

Physician's Assessment:

- Treatment Success: complete resolution or significant improvement of baseline signs and symptoms.
- Improvement: clinically meaningful improvement of baseline signs and symptoms.
- Failure: no resolution of baseline signs and symptoms, or death.

Source: AmpliPhi Biosciences Corp..

The following slide shows that while there was one death during the first 28 days following treatment, there were no deaths reported in the Day 28-90 period, with some follow-ups still ongoing. We believe this is indicative of the bacteriophage treatment helping to eliminate the infection, and not just delay a negative outcome. The average APACHE II predicted mortality for the seven patients was 46% (with three patients predicted mortality >85%), thus having a mortality rate of only 14% in this group is very encouraging.

Mortality (ITT Population)	**Value** (N=7)
28-day all-cause mortality	1 (14%)*
90-day all-cause mortality	No mortality between Days 28 and 90 to-date, follow-up ongoing
Mortality predicted by APACHE II scores, mean**	46% 3 patients with predicted mortality >85%

Source: AmpliPhi Biosciences Corp..

Conclusion

Based on the data shown above, AmpliPhi's strategic focus appears to be off to a successful start. While the number of patients treated thus far is small, it is very encouraging that six out of seven patients achieved treatment success. Based on these results we have adjusted our model by increasing the probability of approval to 60% for AB-SA01 and AB-PA01 in treating resistant hospital acquired infections. Our current valuation is $5.00 per share. However, we believe there is likely to be significant upside to our model once we learn more about what indications the company will be targeting later in 2018 for Phase 2 studies, at which time we may also get a better sense of timelines for approval.

PROJECTED INCOME STATEMENT

AmpliPhi Biosciences Corporation
Income Statement

AmpliPhi Bio	2016 A	Q1 A	Q2 A	Q3 A	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								
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**	**$0.1**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
General & Administration	$8.4	$1.9	$2.8	$1.6	$1.8	$8.1	$8.0	$10.0
Research & Development	$5.7	$1.5	$1.1	($0.8)	$1.5	$3.3	$6.0	$6.5
Other Operating Expenses	$9.5	$0.0	$5.8	$0.0	$0.0	$5.8	$0.0	$0.0
Operating Income	($23.4)	($3.4)	($9.7)	($0.7)	($3.3)	($17.1)	($14.0)	($16.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$4.0	$0.1	$1.9	($0.0)	$0.0	$2.0	$0.0	$0.0
Pre-Tax Income	($19.4)	($3.2)	($7.8)	($0.8)	($3.3)	($15.1)	($14.0)	($16.5)
Income Taxes Paid	($1)	$0	($1)	$0	$0	($1)	$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)	($3.2)	($6.5)	($0.8)	($3.3)	($13.8)	($14.0)	($16.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($24.68)**	**($1.94)**	**($1.21)**	**($0.09)**	**($0.35)**	**($2.17)**	**($1.17)**	**($1.18)**
YOY Growth	*24%*	-	-	-	-	*-91%*	*-46%*	*1%*
Basic Shares Outstanding	1.0	1.7	5.4	8.9	9.5	6.4	12.0	14.0

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

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HISTORICAL STOCK PRICE



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