Zacks Small-Cap Research

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AmpliPhi Biosciences Corp. (APHB-NYSE MKT)

APHB: Patient Treated Under Expanded Access Protocol With AB-PA01…

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 $3.50/share. This model is highly dependent upon continued clinical and regulatory success and will be adjusted accordingly based upon future results.

Current Price (08/23/17)	$0.79
Valuation	**$3.50**

OUTLOOK

On August 14, 2017, AmpliPhi Biosciences Corp. (APHB) announced financial results for the second quarter of 2017 and provided a business update. The company exited the quarter with $9.0 million in cash and cash equivalents, which we believe will be sufficient to fund operations into mid-2018.

AmpliPhi reported that a patient in the U.S. suffering from a life-threatening multi-drug resistant *Pseudomonas aeruginosa* lung infection has been treated under an emergency IND with AB-PA01 both intravenously and by nebulizer. The treatment was well tolerated and the company was pleased with the results, which will be submitted for presentation at a future medical conference.

SUMMARY DATA

52-Week High	**$19.50**
52-Week Low	**$0.71**
One-Year Return (%)	**-95.85**
Beta	**2.74**
Average Daily Volume (sh)	**192,994**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
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 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	-$1.92 A	-$1.21 A	-$0.48 E	-$0.48 E	-$3.14 E
2018					-$1.40 E
2019					-$1.38 E

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WHAT'S NEW

Business Update

New Strategic Focus

AmpliPhi Biosciences Corp. (APHB) is developing bacteriophage therapeutics for the treatment of bacterial infections. AmpliPhi's strategy is to use single patient expanded access protocols to derive real-world data using phage therapies in patients suffering from severe, multidrug-resistant infections. In addition to offering hope to patients that have exhausted all treatment options, clinical data derived from single patient expanded access cases will help to support the utility of phage therapy when the company engages the U.S. Food and Drug Administration (FDA) in discussions for a regulatory path forward for approval of phage therapies.

- The company is looking for patients in areas of high unmet medical need, for instance in patients with prosthetic joint replacements, bacteremia, endocarditis, or difficult to treat urinary tract infections.

- AmpliPhi is hoping to collect data from approximately 10-30 patients, and the hope is that within that group of patients there will be smaller groups of 4-5 patients with similar conditions (e.g., infected joint prosthetic), thus enabling the company to design Phase 2 trials for those conditions, which may or may not end up being pivotal trials. We estimate the company could finish collecting data from a sufficient number of patients during the first half of 2018.

- The initial focus will be on patients with infections caused by *Staphylococcus aureus* (to be treated with AB-SA01) and *Pseudomonas aeruginosa* (to be treated with AB-PA01), since those are the most advanced products in the company's pipeline, and there is already an IND in place for AB-SA01.

- The company is still determining the best way to disseminate data on the single patient expanded access cases as it becomes available, and will be working closely with each institution to be sure the information that is publicly released is accurate and timely. We believe scientific meetings are the most likely venues for presenting data on the various patients that are treated, however we would not be surprised to see a few press releases over the next 6 months detailing a few of the cases, such as the case discussed below.

First Patient Treated with AB-PA01

On August 14, 2017, AmpliPhi announced that the first patient has been treated with AB-PA01 as part of the company's strategy to treat individual patients suffering from serious or life-threatening infections who have failed multiple courses of antibiotics. The patient was suffering from a multi-drug resistant *Pseudomonas aeruginosa* lung infection and received doses of AB-PA01 both intravenously and through a nebulizer. Management did not provide any additional details about the patient's health but did indicate that they were "pleased with the results so far". We anticipate the results being presented at a future medical conference.

Real World Efficacy of Personalized Phage Therapies

AmpliPhi has already shown real-world efficacy regarding the plan to develop personalized phage therapies for patients with life-threatening MDR infections.

- On August 21, 2017, AmpliPhi announced the publication of a case study reporting the successful treatment of a patient with a multidrug-resistant *Acinetobacter baumannii* infection in the journal *Antimicrobial Agents and Chemotherapy*. 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 a U.S. Naval laboratory to produce a customized phage therapy specifically targeting the *A. baumannii* strain that was infecting Dr. Patterson. Following administration of the phage 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.

- In 2011, a case report was published 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. The patient responded well to treatment and data showed that as the level of *P. aeruginosa* decreased, the level of bacteriophage subsequently decreased as the target organism disappeared.

FDA Workshop on Bacteriophage Therapy

AmpliPhi recently participated in a workshop organized by the U.S. Food and Drug Administration (FDA) titled "Bacteriophage Therapy: Scientific and Regulatory Issues". The workshop brought together an international group of individuals from government agencies, academia, and industry to discuss the various scientific and regulatory considerations for bacteriophage therapies. This is the second workshop on bacteriophages conducted by the FDA, and shows the agency is increasing its interest in the potential use of bacteriophage therapies.

Financial Update

On August 14, 2017, AmpliPhi announced financial results for the second quarter of 2017. The company reported $28,000 in revenue from the former gene therapy program, compared to $103,000 reported in the second quarter of 2016. We anticipate this revenue to be insignificant in future quarters. The company reported a net loss of $6.5 million, or $1.21 per share. R&D expenses were $1.1 million for the second quarter of 2017, compared to $1.2 million for the second quarter of 2016. The decrease was primarily due to a decrease in costs from the completion of the chronic rhinosinusitis Phase 1 clinical trial in 2016 partially offset by an increase in payroll-related costs. G&A expenses were $2.8 million for the second quarter of 2017 compared to $2.5 million for the second quarter of 2016. The increase was primarily attributable to a severance charge and increased payroll costs partially offset by a decrease in legal fees and non-cash stock-based compensation.

The company exited the second quarter of 2017 with approximately $9.0 million in cash and cash equivalents. In addition, the company has filed an Australian tax return for the year 2016 and currently expects the receipt of approximately $1.8 million in tax rebate incentive payments from the Australian tax authority in the third quarter of 2017. We estimate that the company has sufficient capital to fund operations through the second quarter of 2018.

As of August 9, 2017, the company had approximately 8.7 million shares outstanding. When factoring in options and reasonably priced warrants (8.0 million at $1.50), the company has a fully diluted share count of 17.1 million.

Conclusion

AmpliPhi's new strategic focus appears to be an intriguing way to get phage therapies to patients sooner and we will be very interested to hear updates on the most recent case disclosed by the company with the use of AB-PA01. It is encouraging that the FDA understands the unique situation that phage therapies are in from a regulatory standpoint, and it will be vital for the FDA to be willing to work with the company since the traditional means of product approval are not likely to be applicable to phage therapies.

We have adjusted our discounted cash flow model based on the company's new strategic focus. The timelines for AB-SA01 and AB-PA01 in the treatment of chronic rhinosinusitis and cystic fibrosis have been extended and we have added the use of AB-SA01 and AB-PA01 to treat resistant hospital acquired infections, which total approximately 72,000 for *S. aureus* and 7,000 for *P. aeruginosa* (CDC). Based on the data from the CDC, we estimate there are currently approximately 18,000 infections from those two pathogens that could be targeted for individualized phage therapies in the U.S. (all potential fatal cases and 10% of non-fatal but potentially life-threatening cases). We estimate that AmpliPhi could achieve regulatory approval in 2021, and with an estimated $8,000 cost per treatment, we believe the company could achieve peak sales of $60 million from targeting just *S. aureus* and *P. aeruginosa*. Using a 20% discount rate and a 50% probability of approval leads to an NPV of $54 million. Combined with the values assigned for the treatment of chronic rhinosinusits and cystic fibrosis, expected additional capital requirements of $30 million, and dividing by the reasonable fully diluted share count of 17.1 million leads to a valuation of approximately $3.50 per share.

PROJECTED INCOME STATEMENT

AmpliPhi Biosciences Corporation
Income Statement

AmpliPhi Bio	2016 A	Q1 A	Q2 A	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								
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	$1.8	$1.8	$8.3	$8.0	$10.0
Research & Development	$5.7	$1.5	$1.1	$1.5	$1.5	$5.6	$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)	($3.3)	($3.3)	($19.6)	($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)	($3.3)	($3.3)	($17.6)	($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)	($3.3)	($3.3)	($16.3)	($14.0)	($16.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($24.68)**	**($1.94)**	**($1.21)**	**($0.48)**	**($0.48)**	**($3.14)**	**($1.40)**	**($1.38)**
YOY Growth	*24%*	-	-	-	-	*-87%*	*-55%*	*-2%*
Basic Shares Outstanding	1.0	1.7	5.4	6.8	6.9	5.2	10.0	12.0

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

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