Zacks Small-Cap Research

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AmpliPhi Biosciences Corp. (APHB-NYSE MKT)

APHB: New CEO to Lead New Strategic Focus…

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 (06/28/17)	$0.85
Valuation	**$3.50**

OUTLOOK

On May 31, 2017, AmpliPhi Biosciences Corp. (APHB) announced the appointment of Dr. Paul Grint as Chief Executive Officer. Dr. Grint has served on the company's board of directors since November 2015. Previously, Dr. Grint was President and CEO of Regulus Therapeutics, Inc.

The company has a new strategic emphasis on utilizing phage technology to develop personalized precision phage therapies for patients suffering from serious or life-threatening multi-drug resistant bacterial infections. The company's goal for 2017 is to treat at least 10 patients using targeted phage therapies under compassionate-use guidelines. This clinical data will then be presented to the FDA for discussions on defining a potential path to market approval.

SUMMARY DATA

52-Week High	**$20.08**
52-Week Low	**$0.71**
One-Year Return (%)	**-94.55**
Beta	**2.76**
Average Daily Volume (sh)	**350,775**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
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 A	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	-$1.92 A	-$0.80 E	-$0.48 E	-$0.48 E	-$2.68 E
2018					-$1.40 E
2019					-$1.38 E

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WHAT'S NEW

Business Update

New CEO

On May 31, 2017, AmpliPhi Biosciences Corp. (APHB) announced the appointment of Dr. Paul Grint as Chief Executive Officer (CEO), effective immediately. Dr. Grint brings a wealth of experience that will be important as AmpliPhi moves forward with a new strategic focus on developing personalized phage therapeutics. He was previously the President and CEO of Regulus Therapeutics Inc., a company focused on the discovery and development of microRNA therapeutics. Previous to Regulus, Dr. Grint was President of Cerexa, Inc., where he was involved in the development of a portfolio of antibiotics for multidrug-resistant infections. Dr. Grint also had senior leadership roles at Forest Research Institue, Kalypsys, Inc., Pfizer Inc., and IDEC Pharmaceuticals Corp.

We recently had a chance to speak with Dr. Grint, and during the conversation he re-emphasized the company's commitment to using compassionate use protocols to derive real-world data using phage therapies in patients suffering from severe, multidrug-resistant infections. This data will then be presented to the U.S. Food and Drug Administration (FDA) as part of the discussions for a regulatory path forward for approval of phage therapies. Other notes from our conversation with Dr. Grint include:

- The company is looking for compassionate use patients in areas of high unmet medical need, for instance in patients with prosthetic joint replacements. While infections occur in only a small percentage of patients, they are usually hard to treat due to the development of biofilms (Costerton, 2005), which phage therapy may particularly well suited to treat (Azeredo *et al*., 2008).

- AmpliPhi is hoping to collect data from approximately 10-20 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 compassionate use 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.

- Following a capital raise of approximately $9.1 million in May 2017, along with an expected $1.8 million tax rebate from the Australian government, we estimate the company will have sufficient capital to fund operations through the second quarter of 2018.

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 April 25, 2017, AmpliPhi announced a case study reporting the successful treatment of a patient with a multidrug-resistant *Acinetobacter baumannii* infection. 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.

Those case studies highlight the potential for personalized phage therapies and help to validate AmpliPhi's new strategic focus.

Conclusion

AmpliPhi's new strategic focus appears to be an intriguing way to get phage therapies to patients sooner and we will be interested to hear updates about any compassionate use cases that the company is able to provide information on. 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, particularly for developing personalized phage treatments.

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 three 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 17.3 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 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	$1.9	$1.7	$1.8	$1.8	$7.2	$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)	($3.4)	($3.2)	($3.3)	($3.3)	($13.1)	($14.0)	($16.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$4.0	$0.1	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($19.4)	($3.2)	($3.2)	($3.3)	($3.3)	($13.0)	($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)	($3.2)	($3.2)	($3.3)	($3.3)	($13.0)	($14.0)	($16.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($24.68)**	**($1.94)**	**($0.80)**	**($0.48)**	**($0.48)**	**($2.69)**	**($1.40)**	**($1.38)**
YOY Growth	*24%*	-	-	-	-	*-89%*	*-48%*	*-2%*
Basic Shares Outstanding	1.0	1.7	4.0	6.8	6.9	4.8	10.0	12.0

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

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