Zacks Small-Cap Research

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AmpliPhi Biosciences Corp. (APHB-NYSE MKT)

APHB: Changing Focus to Developing Personalized Phage Therapies…

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 $4/share. This model is highly dependent upon continued clinical and regulatory success and will be adjusted accordingly based upon future results.

Current Price (05/19/17)	$0.85
Valuation	**$4.00**

OUTLOOK

On May 15, 2017, AmpliPhi Biosciences Corp. (APHB) announced financial results for the first quarter of 2017 and provided a business update. 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. The company will initially make personalized phage therapies available in Australia, which has a favorable regulatory framework with respect to treating patients under compassionate use guidelines.

SUMMARY DATA

52-Week High	**$31.30**
52-Week Low	**$1.04**
One-Year Return (%)	**-94.38**
Beta	**2.74**
Average Daily Volume (sh)	**1,406,850**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$2**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
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 Strategic Focus on Personalize Phage Therapies

AmpliPhi Biosciences Corp. (APHB) is developing bacteriophage therapeutics for the treatment of bacterial infections. On May 1, 2017, the company announced a new strategic focus on developing personalized phage therapies for patients suffering from severe, multidrug-resistant (MDR) infections who have failed prior therapies under existing compassionate-use guidelines. In addition to offering hope to patients that have exhausted all treatment options, clinical data derived from compassionate-use 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 new strategic focus will result in putting the company's two development candidates, AB-SA01 and AB-PA01, on hold as the company does not currently have sufficient capital to move AB-SA01 forward in chronic rhinosinusitis or AB-PA01 forward in adult patients with cystic fibrosis. However, as funding and/or a partnership becomes available the company will be ready to move forward with those programs.

The company is initially going to offer personalized phage therapies in Australia by working with leading hospitals and key opinion leaders to identify and select appropriate patients. In addition, Australia has a very favorable regulatory environment with the opportunity to make personalized phage therapies available under the Special Access Scheme regulations established by Australia's Therapeutics Goods Administration. The Special Access Scheme allows for the treatment of seriously ill patients using an unapproved therapeutic, and is similar to an emergency IND or extended access mechanisms in the U.S. Lastly, Australia offers a 40% R&D tax rebate, and AmpliPhi has established a research facility in Sydney with a team that has experience in phage production and purification.

AmpliPhi's plan is to isolate bacteria from a patient's infection and screen those cells against the company's phage library. According to management, the library contains several hundred different phages that cover most of the bacteria on the World Health Organization (WHO) priority list. For some infections, the company may be able to provide a targeted therapy within as little as a few days. For example, AB-SA01, the company's three phage cocktail against *Staphylococcus aureus*, has *in vitro* activity against 97% of global MRSA isolates. AB-PA01, the company's four phage cocktail against *Pseudomonas aeruginosa*, covers approximately 75% of global *Pseudomonas* isolates. For those pathogens that are not covered by the company's library, it is estimated that a customized phage therapy could be manufactured within approximately two weeks.

The company hopes to treat at least 10 patients during the rest of 2017 under compassionate use guidelines. In 2018, the plan is to meet with regulators and share the data collected from the compassionate use cases to better understand the scope of data required for eventual product approval. During a Type B meeting held on Feb. 21, 2017, the FDA acknowledged that phage therapy is an exciting approach to treating MDR infections and expressed a commitment to addressing the unique regulatory challenges that could arise during product development. We believe that a potential approval pathway was introduced by the 21st Century Cures Act, which includes a "limited population approval pathway" for antimicrobials to treat serious or life-threatening infections.

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.

Financial Update

On May 15, 2017, AmpliPhi announced financial results for the first quarter of 2017. The company reported $29,000 in revenue from the former gene therapy program, compared to $106,000 reported in the first quarter of 2016. We anticipate this revenue to be insignificant in future quarters. The company reported a net loss of $3.2 million, or $1.92 per share. R&D expenses were $1.5 million for the first quarter of 2017, compared to $2.0 million for the first quarter of 2016. The decrease was primarily due to approximately $0.4 million in expenses recorded as part of the Novolytics acquisition in 2016. G&A expenses were $1.9 million for the first quarter of 2017 compared to $2.6 million for the first quarter of 2016. The decrease was primarily attributable to a decrease in non-cash stock-based compensation.

The company exited the first quarter of 2017 with approximately $2.2 million in cash and cash equivalents. On May 10, 2016, AmpliPhi announced the closing of an underwritten public offering that resulted in net proceeds to AmpliPhi of approximately $9.1 million. We estimate that the company has sufficient capital to fund operations through the second quarter of 2018.

As of May 10, 2017, the company had approximately 6.6 million shares outstanding. When factoring in options and reasonably priced warrants (0.534 million at $7.50 and 8.0 million at $1.50), the company has a fully diluted share count of 15.3 million.

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 have been extended and we have added personalized phage therapies focused on WHO priority pathogens listed as critical (MDR *A. baumannii*, MDR *P. aeruginosa*, ESBL-producing *Enterobacteriaceae)*. We believe regulators will be most open to the development of treatments for these pathogens through non-traditional means. Based on data from the CDC, we estimate there are currently approximately 12,000 infections from those three pathogens that could be targeted for individualized phage therapies in the U.S. (all fatal cases and 25% of non-fatal but 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 $45 million from targeting just those three pathogens. Using a 15% discount rate and a 50% probability of approval leads to an NPV of $56 million. Combined with the values assigned for AB-SA01 and AB-PA01, expected additional capital requirements of $30 million, and dividing by the reasonable fully diluted share count of 15.3 million leads to a valuation of approximately $4.00 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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