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AmpliPhi Biosciences Corp. (APHB-NYSE American)

APHB: Expecting to Meet with FDA in mid-2018 to Determine Regulatory Path Forward…

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 $4.00/share. This model is highly dependent upon continued clinical and regulatory success and will be adjusted accordingly based upon future results.

Current Price (03/26/18)	$1.10
Valuation	**$4.00**

OUTLOOK

On March 15, 2018, AmpliPhi Biosciences Corp. (APHB) announced financial results for the fourth quarter and full year 2017 and provided a business update. The most important recent news was the announcement of positive topline data from the expanded access program for AB-SA01 and AB-PA01 showing that six of seven treated patients achieved "treatment success", which was either complete resolution or significant improvement of baseline signs and symptoms.

The company is continuing to treat patients with a goal of meeting with the FDA in mid-2018 to map out a registration path forward and potentially initiate a Phase 2 or registrational clinical trial as early as the second half of 2018.

SUMMARY DATA

52-Week High	**$4.90**
52-Week Low	**$0.71**
One-Year Return (%)	**-77.55**
Beta	**2.77**
Average Daily Volume (sh)	**424,796**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$18**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5**
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 2018 Estimate	**-1.9**
P/E using 2019 Estimate	**-1.3**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0.0 A	0.0 A	0.0 A	0.0 A	0.1 A
2018	0.0 E	0.0 E	0.0 E	0.0 E	0.0 E
2019					0.0 E
2020					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$1.94 A	-$1.21 A	-$0.09 A	-$0.24 A	-$2.01 A
2018	-$0.18 E	-$0.19 E	-$0.14 E	-$0.14 E	-$0.65 E
2019					-$0.63 E
2020					-$0.66 E

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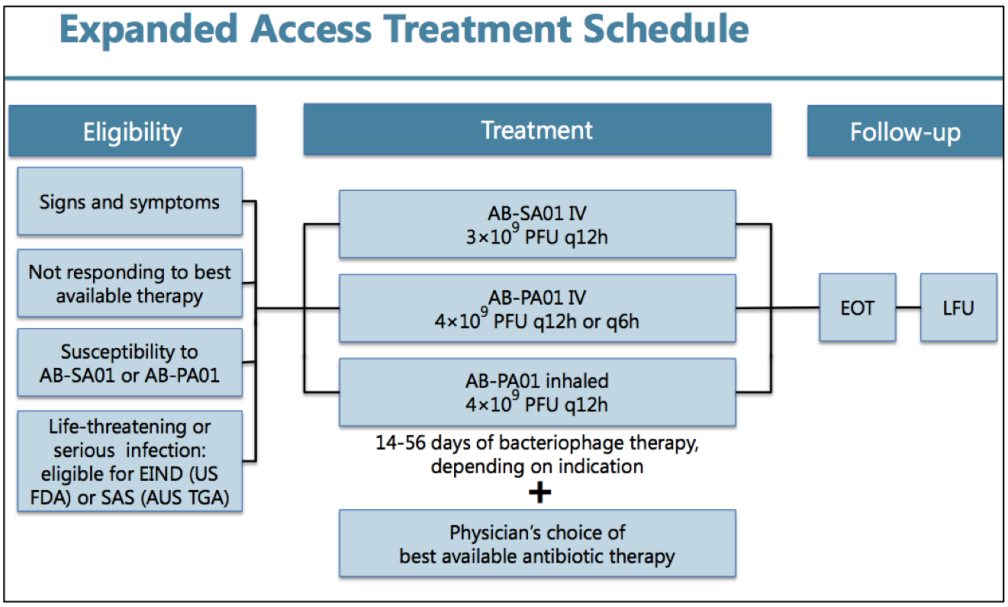
Business Update

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.

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 reported on thus far 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..

Collaborations for Expanded Access Programs

On March 13, 2018, AmpliPhi announced a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Veterans Affairs (VA) Palo Alto Health Care System in regards to expanded access to AB-SA01 and AB-PA01. The Principal Investigator for the collaboration is Mark Holodniy, MD, Professor of Medicine at Stanford University and the VA Palo Alto Health Care System. The CRADA will support the administration of AB-SA01 and AB-PA01 in patients at the VA Palo Alto Health Care System who have serious or life-threatening infections, do not respond to antibiotics, and meet the criteria for treatment under the FDA's Expanded Access program.

On March 19, 2018, AmpliPhi announced a collaboration with the Western Sydney Local Health District and the Westmead Institute for Medical Research for the compassionate use of AB-SA01 and AB-PA01 in patients with severe infections. Several patients have been treated thus far at the Westmead Hospital under the single-patient expanded access program and this collaboration will allow for additional patients with serious or life-threatening infections to receive AB-SA01 and AB-PA01.

Preclinical Data of AB-PA01 in Rhinosinusitis Model

On March 9, 2018, AmpliPhi announced that *in vivo* preclinical data on the use of AB-PA01 in a model of rhinosinusitis was presented at the Australian Society of Otolaryngology Head and Neck Surgery 68th Annual Meeting. The data showed that AB-PA01 is effective in reducing biofilm formation *in vivo*, which is a common complication of *Pseudomonas aeruginosa* infections. The model involved infecting sheep with *P. aeruginosa* and after seven days flushing their sinuses twice-daily with AB-PA01 or saline. The results showed a statistically significant reduction in biofilm biomass with AB-PA01 compared to placebo ($P<0.05$) with no safety issues noted.

Financial Update

On March 15, 2018, AmpliPhi announced financial results for the fourth quarter and full year 2017. The company reported revenue of $0.02 and $0.1 million for the fourth quarter and full year 2017. All revenue was related to sub-licensing agreements from the company's former gene therapy program. We do not anticipate any significant revenues from this program in the future.

Net loss for the fourth quarter of 2017 was $2.4 million, or $0.24 per share. R&D expenses for the fourth quarter of 2017 were $1.1 million compared to $0.8 million in the fourth quarter of 2016. G&A expenses were $1.3 million in the fourth quarter of 2017 compared to $1.5 million in the fourth quarter of 2016. The decrease was mostly due to a decrease in non-cash stock-based compensation.

The company reported a net loss for 2017 of $12.8 million, or $2.01 per share. R&D expenses for 2017 were $2.9 million compared to $5.7 million for 2016. During the third quarter of 2017 and fourth quarter of 2016 the company received approximately $2.0 million and $0.9 million in tax incentive payments from the Australian tax authority based on eligible R&D expenditures incurred by the company's Australian subsidiary. Without those tax incentive payments, R&D expenses for 2017 and 2016 were $4.9 million and $6.6 million, respectively. The decrease was primarily due to decreased professional and consulting fees, a $0.4 million expense recorded in 2016 in connection with the assets acquired from Novolytics Ltd, and decreased clinical expenses.

G&A expenses for 2017 were $7.6 million compared to $8.4 million in 2016. The decrease was primarily due to decreases in non-cash stock-based compensation and legal and professional fees partially offset by increased salaries and payroll costs along with a $0.5 million non-cash charge related to the issuance of approximately 0.5 million shares of stock.

Actual cash burn during 2017 was approximately $9.3 million. AmpliPhi exited 2017 with approximately $5.1 million in cash and cash equivalents. In January 2018 the company raised net proceeds of approximately $3.5 million through the sale of 4 million shares of stock at $1.00 per share. On March 20, 2018, the company announced a registered direct offering of approximately 2.7 million shares of common stock at a price of $1.10 per share, which will result in gross proceeds of approximately $3.0 million. Following the direct offering the company has approximately 16.5 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 25.9 million.

Conclusion

We believe the data that AmpliPhi has compiled thus far from the expanded access program has been very encouraging. The addition of the VA Palo Alto Health Care System adds an additional site to the company's network of expanded access treatment centers. We continue to believe that the company will have compiled sufficient data by mid-2018 to approach the FDA about a registration pathway for AB-SA01 and AB-PA01 with a Phase 2 trial possibly starting in the second half of 2018. Our current valuation is $4.00 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 FINANCIALS

AmpliPhi Bio	2017 A	Q1 E	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 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**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0.1**	**$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	$7.6	$1.4	$1.5	$1.5	$1.6	$6.0	$7.0	$8.0
Research & Development	$2.9	$1.1	$1.2	$1.2	$1.2	$4.7	$5.5	$6.5
Other Operating Expenses	$5.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($16.2)	($2.5)	($2.7)	($2.7)	($2.8)	($10.7)	($12.5)	($14.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$2.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($14.1)	($2.5)	($2.7)	($2.7)	($2.8)	($10.7)	($12.5)	($14.5)
Income Taxes Paid	($1)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($12.8)	($2.5)	($2.7)	($2.7)	($2.8)	($10.7)	($12.5)	($14.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.01)**	**($0.18)**	**($0.19)**	**($0.14)**	**($0.14)**	**($0.65)**	**($0.63)**	**($0.66)**
YOY Growth	*-92%*	-	-	-	-	*-68%*	*-4%*	*5%*
Basic Shares Outstanding	6.4	13.5	14.0	19.0	19.5	16.5	20.0	22.0

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

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