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AmpliPhi Biosciences Corp. (APHB-NYSE American)

APHB: Phase 2 Trial of AB-SA01 in Bacteremia to Initiate 1H19…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's personalized phage therapy AB-SA01, APHB is valued at $2.50/share. This model is highly dependent upon continued clinical and regulatory success and will be adjusted accordingly based upon future results.

Current Price (11/29/18)	$0.23
Valuation	**$2.50**

OUTLOOK

On November 8, 2018, AmpliPhi Biosciences Corp. (APHB) announced financial results for the third quarter of 2018 and provided a business update. During the quarter, the company announced positive results from the expanded access program, in which 21 patients with serious or life-threatening infections not responding to antibiotics received treatment with either AB-SA01 or AB-PA01. Results showed that 84% of those patients achieved treatment success. Following the receipt of FDA feedback, the company plans to initiate a Phase 2 clinical trial of AB-SA01 in patients with bacteremia caused by Staphylococcus aureus. We anticipate this trial initiating in the first half of 2019. To support this trial, the company recently completed a public offering that resulted in gross proceeds of $6.8 million.

SUMMARY DATA

52-Week High	**$1.87**
52-Week Low	**$0.23**
One-Year Return (%)	**-78.20**
Beta	**2.22**
Average Daily Volume (sh)	**344,069**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**4**
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	**-1.4**
P/E using 2019 Estimate	**-1.5**

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)
2017	0.0 A	0.0 A	0.0 A	0.0 A	0.1 A
2018	0.0 A	0.0 A	0.0 A	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	-$0.23 A	-$0.19 A	-$0.10 A	-$0.09 E	-$0.54 E
2019					-$0.31 E
2020					-$0.29 E

WHAT'S NEW

Business Update

Positive Data Reported for AB-SA01 in Bacteremia and Sepsis

On October 8, 2018, AmpliPhi Biosciences Corp. (APHB) announced the presentation of data on the company's expanded access program for AB-SA01 at IDWeek 2018. The presentation "Adjunctive bacteriophage therapy for sever Staphylococcal sepsis" was given by Prof. Jonathan Iredell, Senior Staff Infectious Disease Physician at the Westmead Hospital in Sydney, Australia. A total of 13 patients suffering from severe *S. aureus* infections were treated with AB-SA01. Ten of those patients also had infective endocarditis, with five of them having prosthetic valve endocarditis. 83% (10/12) of the patients in the modified intent-to-treat (mITT) population achieved treatment success, which was defined as a complete resolution or significant improvement baseline signs and symptoms and was determined by the treating physician. In addition, gene expression data showed that bacteriophage treatment was associated with a reduction in pro-inflammatory genes and an upregulation of anti-inflammatory genes, which may be an important feature that could prevent septic shock in patients suffering from sepsis.

Updated Expanded Access Data

On September 17, 2018, AmpliPhi announced updated results from the company's use of its lead bacteriophage product candidates AB-SA01 and AB-PA01 through the expanded access program. To date, a total of 21 patients with serious or life-threatening infections not responding to standard antibiotic treatments have been treated at seven hospitals. The majority of those patients (n=15) have been treated with AB-SA01 while the other six received AB-PA01. Importantly, there were no treatment-related adverse events following more than 1,000 total doses of bacteriophage.

The results showed that 84% (16/19) of patients in the mITT group achieved treatment success, which was defined as either complete resolution of the infection or significant improvement of baseline signs and symptoms. This is similar to the 86% (6/7) of patients achieving treatment success that the company reported at the beginning of 2018.

We are very encouraged by the safety profile exhibited by both AB-SA01 and AB-PA01 along with the strong efficacy in a very difficult to treat patient population. These results clearly warrant continued development of the compounds as potential weapons in the fight against antibiotic resistant infections.

Positive FDA Feedback for AB-SA01 and AB-PA01 Clinical Development Plans

On September 17 and 18, AmpliPhi announced positive FDA feedback regarding the company's clinical development plans for both AB-SA01 and AB-PA01. For AB-SA01, the FDA is in general agreement with the company's proposed clinical trials for bacteremia and prosthetic joint infections caused by *Staphylococcus aureus*. Each of these trials is anticipated to enroll approximately 100 patients. For bacteremia, patients will receive either AB-SA01 plus the best available antibiotic therapy or placebo plus the best available antibiotic therapy intravenously. For hip or knee prosthetic joint infections, patients will receive either AB-SA01 plus the best available antibiotic therapy or placebo plus the best available antibiotic therapy via intra-articular injection and then intravenously in addition to surgical treatment. We expect one of those trials to initiate in the first half of 2019. Additional details regarding which indication the first trial will target and timelines for the study are anticipated in the next few months.

For AB-PA01, AmpliPhi received positive written feedback from the FDA without the need for a Type B Pre-IND meeting regarding the development plan targeting *Pseudomonas aeruginosa* infections in hospital-acquired and ventilator-associated pneumonia (HAP/VAP) and bacteremia. Those trials are anticipated to enroll approximately 100 patients each. For HAP/VAP, patients will be intravenously

administered AB-PA01 plus the best available antibiotic therapy or placebo plus the best available antibiotic therapy. For bacteremia, patients will receive either AB-PA01 plus the best available antibiotic therapy or placebo plus the best available antibiotic therapy intravenously. AmpliPhi has indicated that in order to advance AB-PA01 further in the clinic it will seek non-dilutive funding or other opportunities.

S. aureus *in Bacteremia and Joint Replacement Infections*

Infections of the bloodstream (bacteremia), particularly those caused by *S. aureus*, represent a significant medical challenge. While difficult to ascertain an exact figure, most studies estimate the incidence of *S. aureus* bacteremia (SAB) ranging from 20-50 cases/100,000 population (Klevens *et al*., 2007; Benfield *et al*., 2006; El Atrouni *et al*., 2009). Prior to the advent of antibiotics, the mortality rate from SAB was close to 80% (Mendell, 1939). The introduction of antibiotics, coupled with greater standards of care, has reduced the mortality rate, which appears to have stabilized at approximately 20% (Turnidge *et al*., 2009). SAB can frequently lead to infective endocarditis (IE), an infection of the endocardial surface of the heart (Fowler *et al*., 2005). The prevalence of IE is estimated to be anywhere from 11 to 50% of patients with SAB. Development of IE leads to an increased risk of embolic event and death (Miro *et al*., 2005).

According to the American Academy of Orthopaedic Surgeons (AAOS), there are over one million joint replacement surgeries performed each year in the U.S., with the vast majority of them being hip and knee replacements. This number is expected to rise to over 4 million by the year 2030 (Kurtz *et al*., 2007). In order to minimize the risk of infection prophylactic antibiotics are typically given before and after surgery, however infections for hip and knee replacement still occur in 1-2.5% of all cases (Medline). Further complicating infected prosthetic joints is the fact that *S. aureus* can easily form biofilms (an accumulation of microorganisms surrounded by a polysaccharide mixture that adhere to a solid surface) on stainless steel and titanium orthopedic screws (Stoodley *et al*., 2005). Biofilms are typically nonresponsive to antibiotic therapy, and thus represent a significant complication of joint replacement surgery.

The treatment of choice for *S. aureus* infections is penicillin, however in most countries penicillin resistance is extremely common. Thus, first-line treatment for most *S. aureus* infections is a penicillinase-resistant β-lactam antibiotic such as oxacillin. Antibiotic resistance in *S. aureus* was uncommon when penicillin was first introduced; in fact the petri dish that Sir Alexander Fleming first observed the antibacterial activity of the *Penicillium* fungus was growing a culture of *S. aureus*. However, by 1950, 40% of *S. aureus* isolates were penicillin resistant and by 1960 the rate had grown to 80% (Chambers, 2001).

Resistance to penicillin is due to the activity of the enzyme penicillinase, which cleaves the β-lactam ring of the penicillin molecule. Penicillinase-resistant β-lactam antibiotics include methicillin, oxacillin, and flucoxacillin. *S. aureus* strains that have acquired resistance to methicillin have an altered penicillin-binding protein (PBP2a) that has lower affinity for binding β-lactam antibiotics, thus rendering them ineffective. Strains that have acquired this resistance are referred to as methicillin-resistant *S. aureus* (MRSA). *S. aureus* strains that are sensitive to the penicillinase-resistant β-lactam antibiotics are said to be methicillin-sensitive (MSSA). It is currently estimated that more than 40% of SAB are caused by MRSA (Styers *et al*., 2006).

The current gold standard for treatment of MRSA is vancomycin. However, vancomycin is far from ideal due to poor tissue penetration, slow bactericidal activity, and a number of side effects (Gould, 2008). Additional antibiotics utilized include teicoplanin, tegecyline, linezolid, daptomycin, and televancin. Each of those medications has their own shortcomings, including the development of resistance, thus there exists a significant unmet medical need for newer therapies, particularly those that are not susceptible to the development of resistance.

Financial Update

On November 8, 2018, AmpliPhi announced financial results for the third quarter of 2018. R&D expenses for the third quarter of 2018 were $0.4 million compared to an $0.8 million benefit for the third quarter of 2017. The change was primarily due to the $1.2 million tax incentive payment the company received in July 2018 from the Australian tax authority compared to the $2.0 million tax incentive received in July 2017. Without the benefit of the tax incentive payments, R&D expenses were $1.6 million in the third quarter of 2018 compared to $1.2 million for the third quarter of 2017. The increase was primarily due to increased clinical costs. G&A expenses for the third quarter of 2018 were $1.3 million compared to to $1.6 million for the third quarter of 2017. The decrease was primarily due to lower legal and professional fees. Net loss for the third quarter of 2018 was $1.6 million, or $0.10 per share.

As of September 30, 2018, AmpliPhi had approximately $4.5 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised gross proceeds of approximately $6.8 million through the sale of 14.875 million shares of stock, 2.125 million pre-funded warrants, and common warrants to purchase 17.5 million shares of stock at a price of $0.40 per share of stock and accompanying warrant. The warrants are exercisable at a price of $.40 per share and will expire five years from the date of issuance.

Conclusion and Valuation

Now that AmpliPhi has decided upon which indications it will be targeting we have made significant changes to our model. For valuation purposes, we are only including AB-SA01 at this point as the company has indicated that they are pursuing various opportunities to fund the studies for AB-PA01 and we are uncertain when those studies will get underway.

For *S. aureus* bacteremia, based on the incidence rate cited above we estimate there are approximately 130,000 cases in the U.S. each year and that approximately 40% of those will involve MRSA. Based on obtaining approval in 2023 in the U.S. and 2024 in the E.U., peak worldwide sales of approximately $300 million, a 50% probability of approval, and a 16% discount rate leads to a net present value for AB-SA01 in SAB of $68 million.

For hip and knee replacement infections caused by *S. aureus*, we estimate there are approximately 1 million joint replacements in the U.S. and E.U. each year with that rate growing approximately 12% per year. Of those, approximately 2% result in an infection with 40% being the result of MRSA. Based on obtaining approval in this indication in 2024 in both the U.S. and E.U., peak worldwide sales of approximately $250 million, a 50% probability of approval, and a 16% discount rate leads to a net present value for AB-SA01 in joint replacement of $76 million.

Combining the net present value for each indication along with the company's current cash position, expected money from warrants, and dividing by the fully diluted share count of 70 million (current fully diluted share count of 60.0 million plus another 10.0 million shares to finance future operations) leads to a net present value for the company of approximately $2.50 per share.

PROJECTED FINANCIALS

AmpliPhi Bio	2017 A	Q1 A	Q2 A	Q3 A	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	$1.6	$1.4	$0.4	$1.6	$4.9	$7.0	$8.0
Research & Development	$2.9	$1.5	$1.7	$1.3	$1.2	$5.6	$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)	($3.0)	($3.1)	($1.6)	($2.8)	($10.5)	($12.5)	($14.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$2.0	($0.1)	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($14.1)	($3.1)	($3.1)	($1.6)	($2.8)	($10.6)	($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)	($3.1)	($3.1)	($1.6)	($2.8)	($10.6)	($12.5)	($14.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.01)**	**($0.23)**	**($0.19)**	**($0.10)**	**($0.09)**	**($0.54)**	**($0.31)**	**($0.29)**
YOY Growth	*-92%*	-	-	-	-	*-73%*	*-42%*	*-7%*
Basic Shares Outstanding	6.4	13.3	16.5	16.5	32.0	19.6	40.0	50.0

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

HISTORICAL STOCK PRICE

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