Zacks Small-Cap Research

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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

AmpliPhi Biosciences Corp. (APHB – NYSE MKT)

APHB: AB-SA01 On Track to Enter Clinical Trials in Q4 2015…

Current Recommendation	**Hold**
Prior Recommendation	N/A
Date of Last Change	08/04/2014
Current Price (08/26/15)	$7.40
Target Price	**$15.00**

UPDATE

On August 14, 2015, AmpliPhi Biosciences Corp. filed form 10-Q with financial results for the second quarter of 2015. The company exited the quarter with $14.4 million in cash and cash equivalents thanks to raising $13.0 million in March 2015.

Important milestones for the remainder of 2015 include: 1) IND filing and commencement of a Phase 1 clinical trial with AB-SA01; 2) cGMP manufacturing of AB-PA01; and 3) product qualification for AB-CD01.

The company recently hired M. Scott Salka as CEO, enacted a 50-for-1 reverse split, and uplisted to the NYSE MKT.

SUMMARY DATA

52-Week High	**$15.45**
52-Week Low	**$6.75**
One-Year Return (%)	**-50.67**
Beta	**0.38**
Average Daily Volume (sh)	**21,586**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$43**
Short Interest Ratio (days)	**0.01**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**1**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0.0 A	0.3 A	0.0 A	0.1 A	0.4 A
2015	0.1 A	0.1 A	0.0 E	0.0 E	0.2 E
2016					0.3 E
2017					0.3 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$2.78 A	$4.19 A	$5.15 A	-$0.70 A	$5.82 A
2015	-$3.49 A	$1.58 A	-$0.43 E	-$0.40 E	-$1.59 A
2016					-$1.40 E
2017					-$1.52 E

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WHAT'S NEW

Financial Update

On August 14, 2015, AmpliPhi Biosciences (APHB) filed its Form 10Q with financial results for the second quarter of 2015. The company had $0.1 million in revenues that were related to sublicensing agreements involving the company's former gene therapy program. Net gain for the quarter was $8.9 million, or $1.58 per share, which was due to non-cash gains of $4.6 million related to a change in the fair value of the company's warrant liability and $8.8 million related to a change in the fair value of the company's Preferred B stock derivative liability. The company had $1.6 million in G&A and $1.1 million in R&D expenses. Actual cash burn during the second quarter 2015 totaled $2.7 million.

AmpliPhi exited the second quarter of 2015 with $14.4 million in cash on the books. In March 2015, the company raised approximately $13 million in gross proceeds through the private placement of approximately 1.6 million shares of common stock at $8.25 per share (adjusted for the recent 1:50 reverse split). The offering also included approximately 0.49 million five-year warrants exercisable at $10.75 per share. Based on the company's current cash position, we now see AmpliPhi having sufficient resources to fund operations into the second half of 2016.

Uplisting Complete

On August 4, 2015, AmpliPhi announced a 1-for-50 reverse stock split effective as of August 7, 2015 in anticipation of uplisting to the NYSE MKT. This decreased the number of common shares outstanding from approximately 289 million to approximately 5.8 million. On August 18, 2015, the company announced approval for listing on the NYSE MKT and the stock would begin trading on the NYSE MKT on August 21, 2015. This is an important milestone for the company as it will both increase liquidity in the company's shares as well as enhance the company's profile among potential investors.

New CEO Hired

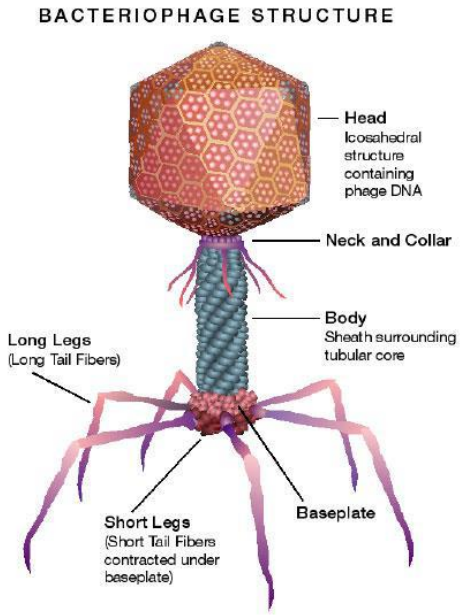
On April 30, 2015, AmpliPhi announced that M. Scott Salka has been named the new CEO, replacing Interim CEO Jeremy Curnock Cook, who will remain in his role as Chairman, effective May 18, 2015. Since 2010, Mr. Salka has served as CEO of Aspyrian Therapeutics Inc., a company focused on developing near-infrared photoimmunotherapy (PIT) therapies. Prior to this role, he was the CEO of Ambit Biosciences (acquired by Daiichi Sankyo in 2014). During Mr. Salka's tenure at Ambit, a company developing treatments for oncology, autoimmune, and inflammatory diseases, he was responsible for transforming the company from a service contract business to a fully capable drug discovery and development enterprise. Prior to joining Ambit in 2001, he served as the President and Chief Executive Officer of two privately held genomics companies, Arcaris, Inc. and 454 Corporation (sold to Roche in 2007). He also previously co-founded one of the first commercial genomics companies, Sequana Therapeutics, Inc., a pioneer in the effort to commercialize the international Human Genome Project.

Mr. Salka will be based in San Diego in his role as CEO. He is currently a board member and professor of entrepreneurship at San Diego State University College of Business Administration, and will continue to serve as a board member of Aspyrian Therapeutics Inc. He also previously served as a director and chairman of the audit committee for Sorrento Therapeutics. Mr. Salka received his M.B.A. from Carnegie Mellon University and his B.S. in finance from San Diego State University.

Brief recap of the AmpliPhi story

AmpliPhi is focused on the discovery, development and commercialization of bacteriophage treatments for bacterial infections. Bacteriophages are viruses that infect, replicate in, and kill bacterial cells while not harming eukaryotic cells. This exclusivity is vital to their use in combating infectious diseases, and their unique mechanism of action compared to traditional antibiotics means they can be used in place of or in conjunction with those therapies. In addition, with the rise of antibiotic resistant bacteria, there is a pressing need for more and better treatments for bacterial infections that are resistant to the effects of antibiotics.

While bacteriophages have been known for over 100 years, up until now their use as anti-infectious agents has been restricted to limited geographic regions (mainly Eastern Europe and Russia). This is due to the rise of antibiotics during the middle part of the 20th century that proved to be cheap, plentiful, and effective therapeutics. However, the rise of antibiotic resistant organisms has resulted in a clear need for alternative treatment options, specifically for ones that no longer respond to once effective antibiotic therapies.



Bacteriophage therapies potentially hold a number of advantages over antibiotics, including:

- ✓ Multiple modes of application
- ✓ Less severe side effects
- ✓ Localized and highly specific effect
- ✓ Very low doses
- ✓ Can treat antibiotic-resistant strains
- ✓ Unique mechanism of action makes resistance less likely

Below we provide an update on each major program at AmpliPhi.

AB-PA01 (formerly AmpliPhage-001)

AB-PA01 (formerly AmpliPhage-001) is being developed for the treatment of *Pseudomonas aeruginosa* lung infections in cystic fibrosis (CF) patients. CF is an autosomal recessive genetic disorder that affects close to 30,000 individuals in the U.S. and a total of 70,000 people worldwide. The most serious complication of the disease is recurrent lung infections, with the majority of CF-related morbidity and mortality being the result of chronic pulmonary sepsis, with the major infecting pathogen in CF the lungs being *P. aeruginosa*.

AmpliPhi is developing AB-PA01 in collaboration with the Royal Brompton Hospital in London, England. During 2014, the company continued to optimize the phage mixture for treating mild to moderate CF and also conducted a productive meeting with the Medicines and Healthcare Products Regulatory Authority (MHRA) in the UK, where the company discussed the characteristics of the phage mixture being taken into the clinic as well as the study design for the clinical trial. The outcome of the meeting was extremely positive, with the authorities expressing a keen desire to see antibiotic alternatives move into the clinic.

AmpliPhi has already demonstrated that AB-PA01 can effectively kill *P. aeruginosa in vitro.* Additional preclinical animal studies will be occurring in 2015 to select the proper phage mixture, at which point the company will move on to scale up manufacturing for a GLP inhalation toxicology study. In June 2015, the company presented data showing that bacteriophages against *P. aeruginosa* retained their biological activity after nebulization. The phages were tested after nebulization through three different commercially available nebulizers, with results showing that four separate anti-Pseudomonas bacteriophages retained biological activity after nebulization with titer drops within the variability of the assay. This is important confirmation that nebulization could be a proper means of administering bacteriophages in future clinical trials.

Manufacturing of GMP product is expected to commence at the company's brand new 4,000 sq. ft. facility in Ljubljana, Slovenia before the end of 2015. The company will then perform nebulizer studies in the first half of 2016 with an IND filing likely by mid-2016 and the initiation of a Phase 1/2 clinical trial in patients with mild to moderate CF at the Royal Brompton Hospital in the second half of 2016.

On March 31, 2015, AmpliPhi announced that the European Patent Office granted European patent No. EP 2570130 "Bacteriophage-containing Therapeutic Agents". The claims of the European patent cover various bacteriophage preparations for use in combination with antibiotics for the treatment of biofilm-related infections caused by the bacterium *Pseudomonas aeruginosa*. Examples of specific treatment regimens covered include the treatment of human and animal infections resulting from a skin burn or skin wound, lung infections such as hospital acquired pneumonia (HAP) and cystic fibrosis (CF), urinary tract infection (UTI), or an infection associated with a medical device or implant.

AB-SA01 (formerly AmpliPhage-002)

AB-SA01 (formerly AmpliPhage-002) is being developed in collaboration with the U.S. Army Medical Research and Material Command (USAMRMC) for the treatment of *Staphylococcus aureus* infections, including methicillin-resistant *S. aureus* (MRSA) infections. One of the most common MRSA infections is of the skin and soft tissue, with treatment options limited due to resistance to multiple types of antibiotics.

AmpliPhi has produced the first batch of bacteriophage in the company's new manufacturing facility in Slovenia. Final GMP certification from regulatory authorities has been achieved. The next step is to release drug product to the Walter Reed Clinical Trial Center in the next few months. As a reminder, the U.S. Army is supplying the clinical site, doctors, patients, and bacterial isolates for the study. AmpliPhi is supplying drug and regulatory oversight.

The company is collaborating with the U.S. Army on the development of a topical gel for the treatment of wound infections, an indication in which the U.S. Army has a high degree of interest due to the number of wounds suffered by armed forces personnel each year. The company is currently putting together a clinical plan with the hopes of initiating a Phase 1 clinical trial before the end of 2015.

AB-CD01 (formerly AmpliPhage-004)

AB-CD01 (formerly AmpliPhage-004) is under development for the treatment of *Clostridium difficile* infections. *C. difficile* is a gram-positive, spore-forming bacterium that is best known for causing antibiotic-associated diarrhea. According to the U.S. CDC, It is estimated to cause upwards of 300,000 infections and 30,000 deaths every year in the U.S.

There are only two antibiotics approved for the treatment of *C. difficile* infections, thus there is a need for more treatment options as relapse rates are very high. Approximately 20% of patients will have a relapse infection, and once a patient has had one recurrence the chance of having another recurrence rises to 65%.

Earlier in the year, Dr. Martha Clokie provided an update on the research currently being conducted in regards to AB-CD01 at the University of Leicester. During 2014, research showed that the panel of bacteriophages capable of targeting *C. difficile* that has been assembled thus far kills 86% of the clinically relevant ribotypes, including the most prevalent and virulent ribotypes of *C. difficile*. Dr. Clokie discussed a number of successful pre-clinical studies that have taken place in a hamster model, a standard model that is very susceptible to the toxins produced by *C. difficile*. As of today, according to the company's SEC filings, that number is now >90%, with some of the most clinically relevant strains, R014/020 and R027, on the list of ribotypes AB-CD01 kills. We also anticipate a publication highlighting the preclinical results obtained thus far before the end of 2015.

During 2015, research will continue on phage optimization, formulation development, and the potential for combination therapies with antibiotics. We believe an IND will be filed in 2016, with first in human studies to potentially start before the end of the year 2016 or early 2017.

Conclusion

AmpliPhi has taken an important step with regards to the reverse split and uplisting of the company's shares to the NYSE MKT. In addition, the company continues to make steady progress toward getting bacteriophage therapies into clinical testing. As we indicated in our initiation report on AmpliPhi, we like the AmpliPhi story and think bacteriophage therapy holds great promise.

While we have previously stated that a reverse split and uplist are necessary before we get aggressive recommending the company, we would still like to see the company show that they can get a bacteriophage product into a clinical trial before moving to a 'Buy' rating. We are hoping that the company will initiate a Phase 1 trial of AB-SA01 before the end of 2015. At this point, we recommend investors get familiar with AmpliPhi and bacteriophage technology in preparation for an entry point later in 2015.

PROJECTED INCOME STATEMENT

AmpliPhi Biosciences Corporation
Income Statement

AmpliPhi Bio	2014 A	Q1 A	Q2 A	Q3 E	Q4 E	2015 E	2016 E	2017 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	**$0.4**	**$0.1**	**$0.1**	**$0.0**	**$0.0**	**$0.3**	**$0.3**	**$0.5**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0.4**	**$0.1**	**$0.1**	**$0.0**	**$0.0**	**$0.3**	**$0.3**	**$0.3**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
General & Administration	$6.9	$1.4	$1.6	$1.6	$1.6	$6.2	$7.0	$7.5
Research & Development	$5.8	$1.0	$1.1	$1.5	$1.5	$5.0	$6.5	$10.0
Other Operating Expenses	$1.9	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($14.1)	($2.3)	($2.6)	($3.1)	($3.1)	($11.0)	($13.2)	($17.2)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$37.2	($12.2)	$13.4	$0.5	$0.5	$2.1	$2.0	$2.0
Pre-Tax Income	$23.1	($14.5)	$10.8	($2.6)	($2.6)	($8.8)	($11.2)	($15.2)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Deemed Dividends	$1.3	$0	$2	$0	$0	$0	$0	$0
Net Income	$21.8	($14.8)	$8.9	($2.6)	($2.6)	($8.8)	($11.2)	($15.2)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**$5.82**	**($3.49)**	**$1.58**	**($0.43)**	**($0.40)**	**($1.59)**	**($1.40)**	**($1.52)**
YOY Growth	*-118%*	-	-	-	-	*-127%*	*-12%*	*9%*
Basic Shares Outstanding	3.7	4.2	5.7	6.0	6.4	5.6	8.0	10.0

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

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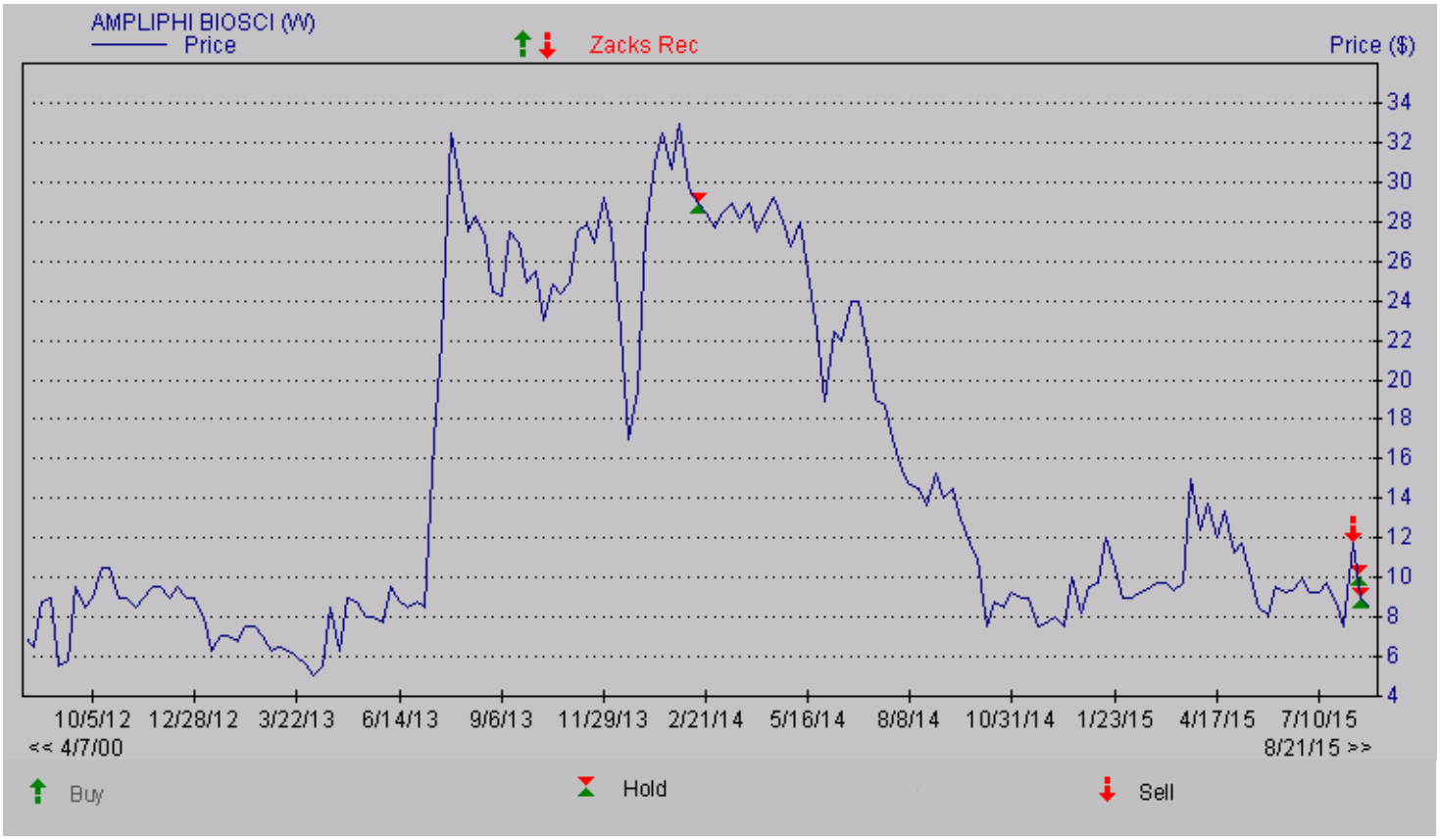

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