

AmpliPhi Biosciences Reports Third Quarter 2018 Financial Results and Business Highlights

The company intends to initiate one or more clinical trials in 2019 following positive FDA feedback

Announced positive updated results from the company's expanded access program: 21 patients with serious or life-threatening infections were treated at 7 hospitals, with 84% treatment success at the end of therapy

Raised gross proceeds of \$6.8 million through an underwritten public offering

“*AmpliPhi now intends to initiate one of the FDA agreed clinical trials for AB-SA01 in 2019, the bacteremia trial, and also to seek non-dilutive financing for our AB-PA01 program.*”

SAN DIEGO--([BUSINESS WIRE](#))--AmpliPhi Biosciences Corporation (NYSE American: APHB), a clinical-stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections, today announced financial results for the third quarter ended September 30, 2018. AmpliPhi Biosciences will not be conducting a conference call in conjunction with this financial release.

“We made significant progress in the third quarter of 2018. We announced an updated set of positive outcomes from our ongoing expanded access program for seriously ill patients, who suffer from resistant bacterial infections. Additionally, we received agreement from the FDA to proceed to randomized clinical trials for our lead product candidates, AB-SA01 and AB-PA01,” said Paul C. Grint, M.D., CEO of AmpliPhi Biosciences. “AmpliPhi now intends to initiate one of the FDA agreed clinical trials for AB-SA01 in 2019, the bacteremia trial, and also to seek non-dilutive financing for our AB-PA01 program.”

Recent Business Highlights

- Announced in September 2018 that 84% of patients achieved treatment success at the end of therapy for the company's expanded access program. Twenty-one patients at 7 hospitals, with serious or life-threatening infections not responding to antibiotics, were treated with AB-SA01 or AB-PA01. Over 1,000 doses of AmpliPhi's bacteriophage product candidates have now been administered as part of the program since mid-2017. Treatment was generally well tolerated, with no treatment-related serious adverse events.
- Received positive U.S. Food and Drug Administration (FDA) feedback for AB-SA01 in September 2018, following a Type B pre-IND meeting. AmpliPhi announced that the FDA is in general agreement with the design of two proposed randomized clinical trials of AB-SA01, for *S. aureus* bacteremia and prosthetic joint infections, and that no additional preclinical or clinical data are required to proceed with both trials. In addition, AmpliPhi continues to investigate if AB-SA01 may be eligible for approval under the limited population pathway for antibacterial and antifungal drugs (LPAD) which is intended to facilitate development of therapeutics to treat serious or life-threatening infections in a limited population of patients with unmet need.
- Received positive feedback from the FDA for AB-PA01 in September 2018. The company announced that the FDA is in general agreement with the design of two proposed randomized clinical trials of AB-PA01, hospital-acquired and ventilator-associated pneumonia (HAP/VAP) due to *P. aeruginosa* and for *P. aeruginosa* bacteremia, and no additional preclinical or clinical data are required to proceed. AmpliPhi intends to seek non-dilutive financing and explore other opportunities to conduct these clinical trials.
- Presented clinical case data from the expanded access program at the ID Week 2018 Conference in October 2018. Thirteen patients with serious and life-threatening *S. aureus* infections were treated with AB-SA01 at the Westmead Hospital in Sydney. 83% (10 out of 12) patients in the modified intent-to-treat (mITT) population achieved treatment success at the end of therapy as reported by treating physicians. Bacteriophage treatment was well tolerated, with no adverse events attributable to the therapy.
- Completed an underwritten public offering in October 2018 that raised gross proceeds of \$6.8 million, before deducting underwriting discounts and commissions and other offering expenses. AmpliPhi anticipates using the net proceeds from the offering for general corporate purposes, including manufacturing, research and development and general and administrative expenses.

Third Quarter and Nine Months Ended September 30, 2018 Financial Results

- Research and development (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 attributable to a \$1.2 million tax incentive payment received in July 2018 from the Australian tax authority, compared to a \$2.0 million tax incentive payment from the Australian tax authority received in the same quarter of 2017. Excluding any benefit from tax incentive payments, R&D expense was \$1.6 million in the third quarter versus \$1.2 million in the prior year period. The increase of \$0.4 million was primarily attributable to a \$0.3 million increase in clinical costs and a \$0.1 million increase in payroll-related costs.

- R&D expenses for the nine months ended September 30, 2018, net of incentive tax payments, were \$3.5 million, up from \$1.8 million for the nine months ended September 30, 2017. Excluding any benefit from tax incentive payments, R&D expense for the nine months ended September 30, 2018 and 2017 were \$4.7 million and \$3.8 million, respectively. The increase of \$0.9 million was primarily related to a \$0.7 million increase in clinical costs, a \$0.1 million increase in professional and consulting fees, and a \$0.1 million increase in payroll-related costs.
- General and administrative (G&A) expenses were \$1.3 million for the third quarter of 2018 compared to \$1.6 million for the third quarter of 2017. The decrease was primarily due to lower legal and professional fees, as well as a \$0.1 million decrease in certain non-cash charges.
- G&A expenses for the nine months ended September 30, 2018 decreased by \$2.1 million to \$4.2 million from \$6.3 million for the nine months ended September 30, 2017. The decrease was primarily attributable to a decrease in payroll-related costs and professional fees and the non-recurrence of a non-cash fair value adjustment charge of \$0.5 million.
- Net cash used in operating activities for the nine months ended September 30, 2018 was \$7.0 million compared to \$6.8 million for the nine months ended September 30, 2017.
- Cash and cash equivalents as of September 30, 2018 totaled \$4.5 million, which excludes the proceeds from the company's October 2018 public offering.
- As of November 5, 2018, there were approximately 32.3 million shares of common stock outstanding.

About AmpliPhi Biosciences

AmpliPhi Biosciences Corporation is a clinical-stage biotechnology company focused on precisely targeted bacteriophage therapeutics for antibiotic-resistant infections using its proprietary bacteriophage-based technology. AmpliPhi's lead product candidates, AB-SA01 and AB-PA01, target *Staphylococcus aureus* and *Pseudomonas aeruginosa*, including multidrug-resistant strains, which are included on the WHO's 2017 Priority Pathogens List. Phage therapeutics are uniquely positioned to address the threat of antibiotic-resistance as they can be precisely targeted to kill select bacteria, have a differentiated mechanism of action, can penetrate and disrupt biofilms (a common bacterial defense mechanism against antibiotics), are potentially synergistic with antibiotics and have been shown to restore antibiotic sensitivity to drug-resistant bacteria. For more information visit www.ampliphio.com.

Forward-Looking Statements

Statements in this press release that are not statements of historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, statements regarding: AmpliPhi's intention to initiate a randomized clinical trial of AB-SA01 for *S. aureus* bacteremia in 2019; the potential benefits of phage therapy; and the potential use of bacteriophages to treat bacterial infections, including infections that do not respond to antibiotics or are associated with biofilms. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "may," "goal," "potential" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. Among the factors that could cause actual results to differ materially from those indicated in these forward-looking statements are the risk that AmpliPhi may not be able to obtain sufficient capital to initiate a randomized clinical trial of AB-SA01 for *S. aureus* bacteremia in 2019, risks and uncertainties associated with bacteriophage product candidate development, both generally and specifically through expanded access regulations, AmpliPhi's financial condition, and other risks and uncertainties described in AmpliPhi's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission (SEC), and AmpliPhi's subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and AmpliPhi undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

AmpliPhi Biosciences Corporation

Condensed Consolidated Balance Sheets

	September 30, 2018	December 31, 2017
	(Unaudited)	
Assets		
Cash and cash equivalents	\$ 4,499,000	\$ 5,132,000
Prepays and other current assets	615,000	253,000
Total current assets	5,114,000	5,385,000
Property and equipment, net	591,000	816,000
Intangible assets, net	4,914,000	4,937,000
Total assets	\$ 10,619,000	\$ 11,138,000

Liabilities and stockholders' equity		
Total current liabilities	\$ 2,465,000	\$ 1,968,000
Derivative liabilities	154,000	292,000
Deferred tax liability	1,147,000	1,147,000
Total liabilities	3,766,000	3,407,000
Stockholders' equity	6,853,000	7,731,000
Total liabilities and stockholders' equity	\$ 10,619,000	\$ 11,138,000

AmpliPhi Biosciences Corporation
Condensed Consolidated Statements of Operations

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue	\$-	\$38,000	\$-	\$95,000
Operating expenses:				
Research and development (benefit)	361,000	(829,000)	3,517,000	1,791,000
General and administrative	1,276,000	1,613,000	4,227,000	6,295,000
Impairment charges	-	-	-	5,800,000
Total operating expenses	1,637,000	784,000	7,744,000	13,886,000
Loss from operations	(1,637,000)	(746,000)	(7,744,000)	(13,791,000)
Other income (expense):				
Change in fair value of derivative liabilities	31,000	(37,000)	(46,000)	1,997,000
Other income, net	-	4,000	-	6,000
Total other income (expense), net	31,000	(33,000)	(46,000)	2,003,000
Loss before income taxes	(1,606,000)	(779,000)	(7,790,000)	(11,788,000)
Income tax benefit	-	-	-	1,302,000
Net loss	\$(1,606,000)	\$(779,000)	\$(7,790,000)	\$(10,486,000)
Net loss per share, basic	\$(0.10)	\$(0.09)	\$(0.51)	\$(1.97)
Weighted average shares outstanding, basic	16,468,308	8,874,813	15,418,146	5,326,139
Net loss per share, diluted	\$(0.10)	\$(0.09)	\$(0.51)	\$(2.18)
Weighted average shares outstanding, diluted	16,496,957	8,874,813	15,418,416	5,518,847

AmpliPhi Biosciences Corporation
Condensed Consolidated Statement of Cash Flows

Nine Months Ended
September 30,

	2018	2017
	(Unaudited)	(Unaudited)
Operating activities:		
Net loss	\$(7,790,000)	\$(10,486,000)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liabilities	46,000	(1,997,000)
Stock-based compensation	366,000	568,000
Charge for common stock issuance	-	519,000
Depreciation and amortization	291,000	278,000
Other non-cash adjustments, net	-	22,000
Impairment charges	-	5,800,000
Deferred taxes	-	(1,302,000)
Changes in operating assets and liabilities, net	133,000	(225,000)
Net cash used in operating activities	(6,954,000)	(6,823,000)
Investing activities:		
Purchases of property and equipment	(41,000)	(40,000)
Net cash used in investing activities	(41,000)	(40,000)
Financing activities:		
Proceeds from sale of common stock, net of offering costs	6,159,000	9,353,000
Other financing activities	203,000	(476,000)
Net cash provided by financing activities	6,362,000	8,877,000
Net increase (decrease) in cash and cash equivalents	(633,000)	2,014,000
Cash and cash equivalents, beginning of period	5,132,000	5,711,000
Cash and cash equivalents, end of period	\$4,499,000	\$7,725,000

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