Investor Relations

AmpliPhi Biosciences Reports Second Quarter 2017 Financial Results and Business Highlights

Continuing development of therapeutic candidates for multidrug-resistant (MDR) Staphylococcus aureus (S. aureus) and Pseudomonas aeruginosa (P. aeruginosa) via single-patient expanded access strategy

First patient dosed with AB-PA01, via intravenous and inhaled administration, to treat an MDR P. aeruginosa infection under an emergency IND

Conference call begins at 4:30 p.m. ET today

"The establishment of the Global Antimicrobial Resistance (AMR) Collaboration Hub at the recent G20 summit in July underscores the importance of the AMR issue for public health"

SAN DIEGO--(BUSINESS WIRE)--AmpliPhi Biosciences Corporation (NYSE MKT: APHB), a leader in the development of therapies for antibiotic-resistant infections using bacteriophage technology, announces financial results for the three and six months ended June 30, 2017 and business highlights.

“The establishment of the Global Antimicrobial Resistance (AMR) Collaboration Hub at the recent G20 summit in July underscores the importance of the AMR issue for public health,” said Paul C. Grint, M.D., CEO of AmpliPhi Biosciences. “I am excited to be at AmpliPhi where we are pioneering bacteriophage therapies for patients suffering from MDR infections and developing a promising approach to address the AMR threat.

“We are developing our lead therapeutic candidates through an approach to treat individual patients suffering from serious or life-threatening infections who have failed multiple courses of antibiotics and have few or no satisfactory treatment options,” Dr. Grint added. “We expect this strategy to validate the clinical utility of our therapies by early 2018 and position us to initiate further efficacy clinical trials later that year.”

“We are executing on the strategy to provide our therapeutic candidates AB-SA01 and AB-PA01 targeting *S. aureus* and *P. aeruginosa*, respectively, to patients under single-patient expanded access guidelines (“compassionate use”),” said Igor P. Bilinsky, Ph.D., AmpliPhi’s Chief Operating Officer. “Our goal remains to treat at least 10 patients by the end of 2017 and additional patients in early 2018. Based on this data set, we plan to define indications and optimal treatment regimens for further development and, in consultation with the FDA and other regulatory agencies, define the potential path to regulatory approval.

“We recently supplied AB-PA01 to a major U.S. teaching hospital for a patient suffering from a life-threatening MDR *P. aeruginosa* lung infection,” added Dr. Bilinsky. “Under an emergency IND allowed by the FDA, multiple doses of AB-PA01 were administered intravenously and by nebulizer. This was the first-in-human administration of AB-PA01, and the treatment was well tolerated. We expect the results to be submitted for presentation at a future medical conference.”

Second Quarter 2017 and Recent Business Highlights

- Appointed Paul C. Grint, M.D. as CEO. Dr. Grint has served as a director of AmpliPhi since November 2015 and has more than two decades of executive leadership experience in biologics and small molecule development, including the successful development and commercialization of anti-infective products.
- Achieved first-in-human dosing of AB-PA01 targeting *P. aeruginosa* under an emergency IND allowed by the FDA. Multiple doses of AB-PA01 delivered intravenously and by nebulizer were well tolerated.
- Announced positive feedback from an FDA Type B meeting in which the FDA “acknowledged that phage therapy is an exciting approach to treatment of MDR organisms and expressed a commitment to addressing the unique regulatory challenges that might arise during product development.”
- Presented at the two-day “Bacteriophage Therapy: Scientific and Regulatory Issues” workshop sponsored by the FDA and National Institutes of Health. The workshop featured presentations by government, academic, and industry opinion leaders on advancements in bacteriophage technology, clinical case studies and regulatory considerations.
- Presented on the “Adding Tools to the Toolbox: New Technology to Overcome AMR Mechanisms” panel at the 2017 BIO International Convention. Actively participated in the BIO AMR Working Group that advocates for policies to facilitate the development of novel technologies to address MDR infections.
- Announced an oral case presentation at the Centennial Celebration of Bacteriophage Research at the Institut Pasteur in Paris highlighting the successful treatment of a critically ill patient with an MDR *Acinetobacter baumannii* infection, by Dr. Biswajit Biswas of the U.S. Navy’s Medical Research Center.

Second Quarter Financial Overview

- On May 10, 2017, the Company completed an underwritten public offering of common stock and warrants, in which it received net proceeds of approximately $9.0 million after deducting underwriting discounts and commissions, certain incentive payments and other offering expenses paid by the Company. The Company currently has 8.7 million common shares outstanding.
- Cash and cash equivalents were $9.0 million as of June 30, 2017, compared with $5.7 million as of December 31, 2016. In 2017, the Company made operational changes in line with its strategic emphasis on precisely targeted bacteriophage therapies and believes its existing cash resources will be sufficient to fund its planned operations until mid-2018.

Second Quarter and Six Months Ended June 30, 2017 Financial Results

- Research and development (R&D) expenses for the second quarter of 2017 decreased by $0.1 million to $1.1 million from $1.2 million for the second quarter of 2016, primarily attributable to a $0.3 million decrease in costs from the completion of the CRS Phase 1 clinical trial in 2016, offset by an increase of $0.2 million in payroll-related costs.
- R&D expenses for the six months ended June 30, 2017 decreased by $0.6 million to $2.6 million from $3.2 million for the six months ended June 30, 2016, primarily due to approximately $0.4 million of expense recorded in connection with assets acquired from Novolytics Ltd. in 2016 and a decrease by $0.4 million in costs from the completion of the CRS Phase 1 clinical trial in 2016, offset by a $0.2 million increase in payroll-related costs.
- General and administrative (G&A) expenses for the three months ended June 30, 2017 increased by $0.3 million to $2.8 million from $2.5 million for the second quarter of 2016. During the three months ended June 30, 2017, we recorded a $0.4 million severance charge, a $0.3 million increase in payroll-related costs and a $0.4 million non-cash charge related to the fair value of 523,210 shares of our common stock to potentially be issued to certain shareholders, subject to shareholder approval at our 2017 annual meeting. These increases were primarily off-set by a $0.4 million decrease in legal fees and a $0.4 million decrease in non-cash stock-based compensation expense from the same period in the prior year.
- G&A expenses for the first six months of 2017 decreased by $0.4 million to $4.7 million from $5.1 million for the first six months of 2016. The decrease was primarily attributable to declines of $0.9 million in non-cash stock-based compensation expense and $0.5 million in legal and professional fees, partially offset by a $0.4 million severance charge, a $0.3 million increase in payroll-related costs and a $0.4 million non-cash charge related to the 523,210 shares of our common stock potentially issuable to certain shareholders, subject to shareholder approval at our 2017 annual meeting.
- Operating expenses included non-cash charges totaling $5.8 million for the impairment of intangible assets for the excess of book value over the computed fair value of those assets as of June 30, 2017. The impaired assets were recorded in connection with acquisitions of predecessor companies in 2011 and 2012.

Conference Call and Webcast

AmpliPhi will hold a conference call today beginning at 4:30 p.m. Eastern time (1:30 p.m. Pacific time). The conference call dial-in number is (877) 866-5534 for domestic callers and (346) 406-0930 for international callers, and the passcode is 53278337. A live webcast of the call will be available on the Investor Relations section of www.ampliphibio.com.

A recording of the call will be available for 48 hours beginning approximately two hours after the completion of the call by dialing (855) 859-2056 for domestic callers and (404) 537-3406 for international callers. Please use passcode 53278337 to access the recording. A webcast replay will be available on the Investor Relations section of www.ampliphibio.com for 30 days, beginning approximately two hours after the completion of the call.

About AmpliPhi Biosciences

AmpliPhi Biosciences Corporation is a clinical-stage biotechnology company focused on treating antibiotic-resistant infections using its proprietary bacteriophage-based technology. AmpliPhi's lead product candidates target multidrug-resistant *S. aureus* and *P. aeruginosa* that 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 selected 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.ampliphibio.com.

About Bacteriophages

Bacteriophages (phages) are naturally occurring viruses that selectively kill bacteria, including antibiotic-resistant bacteria. Phages are the most abundant organisms on Earth and have evolved to not only directly kill bacteria, but also penetrate and disrupt biofilms, and have been shown to restore antibiotic sensitivity to drug-resistant bacteria.

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 about the potential benefits of phage therapy and the potential use of bacteriophages to treat bacterial infections, including

infections that do not respond to antibiotics; AmpliPhi's development of bacteriophage-based therapies; AmpliPhi's strategy for developing its lead therapeutic candidates through treatment of individual patients under compassionate-use guidelines, including the target number of patients to be treated in 2017, the expected validation of the clinical utility of AmpliPhi's therapies by early 2018, the ability to potentially initiate efficacy clinical trials in 2018 and other potential benefits expected from this strategy; the expected receipt of funds from an Australian R&D tax rebate; and the anticipated sufficiency of AmpliPhi's existing cash resources to fund its planned operations until mid-2018. 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 risks and uncertainties associated with AmpliPhi's business and financial condition and the other risks and uncertainties described in AmpliPhi's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the 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

	June 30, 2017 (Unaudited)	December 31, 2016
Assets		
Cash and cash equivalents	$8,962,000	$ 5,711,000
Prepaids and other current assets	282,000	602,000
Total current assets	9,244,000	6,313,000
Property and equipment, net	909,000	1,072,000
Intangible assets, net	4,953,000	10,768,000
Total assets	$15,106,000	$ 18,153,000
Liabilities and stockholders' equity		
Total current liabilities	$3,711,000	$ 3,538,000
Derivative liabilities	387,000	2,443,000
Deferred tax liability	1,147,000	2,449,000
Total liabilities	5,245,000	8,430,000
Stockholders' equity	9,861,000	9,723,000
Total liabilities and stockholders' equity	$15,106,000	$ 18,153,000

AmpliPhi Biosciences Corporation

Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017 (Unaudited)	2016 (Unaudited)	2017 (Unaudited)	2016 (Unaudited)
Revenue	$28,000	$103,000	$57,000	$209,000
Operating expenses:				

Research and development	1,130,000	1,241,000	2,620,000	3,221,000
General and administrative	2,784,000	2,451,000	4,682,000	5,095,000
Impairment charges	5,800,000	-	5,800,000	-
Total operating expenses	9,714,000	3,692,000	13,102,000	8,316,000
Loss from operations	(9,686,000)	(3,589,000)	(13,045,000)	(8,107,000)
Other income (expense):				
Change in fair value of derivative liabilities	1,920,000	(35,000)	2,034,000	1,371,000
Other income (expense), net	3,000	(227,000)	2,000	(227,000)
Total other income (expense), net	1,923,000	(262,000)	2,036,000	1,144,000
Loss before income taxes	(7,763,000)	(3,851,000)	(11,009,000)	(6,963,000)
Income tax benefit	1,302,000	-	1,302,000	-
Net loss	(6,461,000)	(3,851,000)	(9,707,000)	(6,963,000)
Excess of fair value of consideration transferred on conversion of Series B preferred stock	-	(2,366,000)	-	(2,366,000)
Accretion of Series B preferred stock	-	(133,000)	-	(1,858,000)
Net loss attributable to common stockholders	$(6,461,000)	$(6,350,000)	$(9,707,000)	$(11,187,000)
Net loss per share of common stock - basic	$(1.21)	$(7.26)	$(2.76)	$(15.30)
Weighted average number of shares of common stock outstanding - basic	5,350,930	874,062	3,514,181	731,206
Net loss per share of common stock - diluted	$(1.46)	$(7.82)	$(3.09)	$(15.96)
Weighted average number of shares of common stock outstanding - diluted	5,519,895	876,806	3,652,501	732,578

AmpliPhi Biosciences Corporation

Condensed Consolidated Statement of Cash Flows

	Six Months Ended June 30,	
	2017	2016

	(Unaudited)	(Unaudited)
Operating activities:		
Net loss	$(9,707,000)	$(6,963,000)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Change in fair value of derivative liabilities	(2,034,000)	(1,371,000)
Impairment charges	5,800,000	-
Stock-based compensation	470,000	1,364,000
Deferred taxes	(1,302,000)	-
Warrants and other allocable expenses	-	431,000
Depreciation and amortization	170,000	158,000
Other non-cash adjustments, net	33,000	15,000
Changes in operating assets and liabilities, net	340,000	389,000
Net cash used in operating activities	(6,230,000)	(5,977,000)
Investing activities:		
Purchases of property and equipment	(7,000)	(237,000)
Net cash used in investing activities	(7,000)	(237,000)
Financing activities:		
Proceeds from sale of common stock and related warrants, net of offering costs	9,690,000	4,224,000
Other financing activities, net	(202,000)	(236,000)
Net cash provided by financing activities	9,488,000	3,988,000
Net increase (decrease) in cash and cash equivalents	3,251,000	(2,226,000)
Cash and cash equivalents, beginning of period	5,711,000	9,370,000
Cash and cash equivalents, end of period	$8,962,000	$7,144,000

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