Investor Relations

# AmpliPhi Biosciences Reports Second Quarter 2018 Financial Results and Business Highlights

*19 patients at 7 hospitals, with serious or life-threatening infections not responding to antibiotics, have been treated with AB-SA01 or AB-PA01 under single-patient expanded access program*

*AmpliPhi has scheduled meetings with the FDA in August and September to discuss the regulatory path forward for AB-SA01 and AB-PA01*

*"I'm delighted to report that we have made substantial progress with our expanded access program for AB-SA01 and AB-PA01"*

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 second quarter ended June 30, 2018. AmpliPhi Biosciences will not be conducting a conference call in conjunction with this financial release.

"I'm delighted to report that we have made substantial progress with our expanded access program for AB-SA01 and AB-PA01," said Paul C. Grint, M.D., CEO of AmpliPhi Biosciences. "As of today, we have treated a total of nineteen patients at seven different hospitals and we are encouraged by the results. We are analyzing the data and plan to share a more detailed update in the near future. We look forward to our two meetings with the FDA over the next two months, the goal of which is to obtain important clinical development feedback for Phase 2 and potentially pivotal trials in one or more indications."

Recent Business Highlights

- Two meetings are scheduled with the FDA for August and September to discuss Phase 2 trial plans and the path forward to regulatory approval for investigational drug candidates AB-SA01, targeting *Staphylococcus aureus* (*S. aureus*), and AB-PA01, targeting *Pseudomonas aeruginosa*(*P. aeruginosa*).
- North America's first Center for Innovative Phage Applications and Therapeutics (IPATH) was launched by UC San Diego (UCSD) in June 2018 with AmpliPhi as an industry partner. As part of the IPATH launch, UCSD announced the successful case of a patient treated with AmpliPhi's AB-SA01. Prior to phage therapy, the patient had a persistent *S. aureus* ventricular assist device infection that was not eradicated for three years despite antibiotic treatment.
- Presented four case studies of critically ill patients suffering from severe *S. aureus* bloodstream infections, who received treatment with AB-SA01, at the American Society for Microbiology (ASM) Microbe 2018 annual meeting in Atlanta in June 2018. In all cases, standard medical and surgical therapy was considered inadequate before starting bacteriophage therapy. AB-SA01 was well-tolerated and bacterial elimination was demonstrated in three out of four patients.
- Presented a successful case study of a patient with cystic fibrosis (CF), suffering from recurrent multi-drug resistant (MDR) *P. aeruginosa* pneumonia and multiple CF exacerbations, who received treatment with AB-PA01, at the 41st European Cystic Fibrosis Conference in Belgrade, Serbia, in June 2018. Prior to treatment with AB-PA01, the patient received multiple courses of antibiotics, including colistin, but due to renal failure, colistin administration was discontinued. Treatment with AB-PA01 was well tolerated and the patient's infection resolved. No recurrence of pneumonia or CF exacerbation was reported during the two-month follow-up period after the completion of treatment with AB-PA01. The patient's renal failure resolved.
- Presented a successful case study of a lung transplant recipient suffering from recurrent episodes of MDR *P. aeruginosa* pneumonia who received treatment with bacteriophage therapeutics, including AB-PA01, at the International Society of Heart and Lung Transplant Annual Meeting in Nice, France, in April 2018. The patient clinically responded to bacteriophage and antibiotic therapy with resolution of pneumonia and improved respiratory status.
- Utilized the Therapeutic Development Services funded by the National Institute of Allergy and Infectious Disease (NIAID), part of the National Institutes of Health (NIH), to conduct further preclinical studies of AB-SA01. The Therapeutic Development Services program funds the provision of preclinical services for selected companies and researchers in order to advance development of promising interventional agents.

Second Quarter and Six Months Ended June 30, 2018 Financial Results

- Research and development (R&D) expenses for the second quarter of 2018 were $1.7 million compared to $1.1 million for the second quarter of 2017, primarily attributable to a $0.2 million increase in professional and consulting fees and a $0.2 million increase in clinical costs.

- R&D expenses for the six months ended June 30, 2018 increased by $0.6 million to $3.2 million from $2.6 million for the six months ended June 30, 2017, primarily due to an increase in clinical costs.
- General and administrative (G&A) expenses were $1.4 million for the second quarter of 2018 compared to $2.8 million for the second quarter of 2017. The decrease was primarily due to lower payroll-related costs, lower legal and professional fees, as well as a $0.6 million decrease in non-cash stock-based compensation and other non-cash charges.
- G&A expenses for the first six months of 2018 decreased by $1.7 million to $3.0 million from $4.7 million for the first six months of 2017. The decrease was primarily attributable to a decrease in the items described above for the second quarter comparison.
- Net cash used in operating activities for the six months ended June 30, 2018 was $5.7 million compared to $6.2 million for the six months ended June 30, 2017.
- Cash and cash equivalents as of June 30, 2018 totaled $5.8 million.
- In July 2018, the Company received $1.2 million of tax rebate incentive payments in cash from the Australian tax authority. The incentive payments are based on R&D activities in Australia in 2017.
- As of August 6, 2018, there were 16.5 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 multidrug-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa,* 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.

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: the potential benefits of phage therapy; the potential use of bacteriophages to treat bacterial infections, including infections that do not respond to antibiotics or are associated with biofilms; and AmpliPhi's scheduled meetings with the FDA in August and September 2018 and the anticipated benefits therefrom. 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 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

| | June 30, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| Assets | | |
| Cash and cash equivalents | $5,798,000 | $5,132,000 |
| Prepaids and other current assets | 322,000 | 253,000 |
| Total current assets | 6,120,000 | 5,385,000 |
| Property and equipment, net | 678,000 | 816,000 |

| | | |
|---|---|---|
| Intangible assets, net | 4,922,000 | 4,937,000 |
| Total assets | $11,720,000 | $11,138,000 |
| | | |
| Liabilities and stockholders' equity | | |
| Total current liabilities | $2,049,000 | $1,968,000 |
| Derivative liabilities | 185,000 | 292,000 |
| Deferred tax liability | 1,147,000 | 1,147,000 |
| Total liabilities | 3,381,000 | 3,407,000 |
| | | |
| Stockholders' equity | 8,339,000 | 7,731,000 |
| Total liabilities and stockholders' equity | $11,720,000 | $11,138,000 |

AmpliPhi Biosciences Corporation
Condensed Consolidated Statements of Operations

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 (Unaudited) | 2017 (Unaudited) | 2018 (Unaudited) | 2017 (Unaudited) |
| Revenue | $- | $28,000 | $- | $57,000 |
| Operating expenses: | | | | |
| Research and development | 1,692,000 | 1,130,000 | 3,156,000 | 2,620,000 |
| General and administrative | 1,360,000 | 2,784,000 | 2,951,000 | 4,682,000 |
| Impairment charges | - | 5,800,000 | - | 5,800,000 |
| Total operating expenses | 3,052,000 | 9,714,000 | 6,107,000 | 13,102,000 |
| Loss from operations | (3,052,000) | (9,686,000) | (6,107,000) | (13,045,000) |
| Other income (expense): | | | | |
| Change in fair value of derivative liabilities | 2,000 | 1,920,000 | (77,000) | 2,034,000 |
| Other income, net | - | 3,000 | - | 2,000 |
| Total other income (expense), net | 2,000 | 1,923,000 | (77,000) | 2,036,000 |

| | | | | |
|---|---|---|---|---|
| Loss before income taxes | (3,050,000) | (7,763,000) | (6,184,000) | (11,009,000) |
| Income tax benefit | - | 1,302,000 | - | 1,302,000 |
| Net loss | $(3,050,000) | $(6,461,000) | $(6,184,000) | $(9,707,000) |
| Net loss per share, basic | $(0.19) | $(1.21) | $(0.42) | $(2.76) |
| Weighted average shares outstanding, basic | 16,464,675 | 5,350,930 | 14,890,164 | 3,514,181 |
| Net loss per share, diluted | $(0.19) | $(1.46) | $(0.42) | $(3.09) |
| Weighted average shares outstanding, diluted | 16,464,675 | 5,519,895 | 14,890,164 | 3,652,501 |

AmpliPhi Biosciences Corporation
Condensed Consolidated Statement of Cash Flows

| | Six Months Ended June 30, | |
|---|---|---|
| | 2018 | 2017 |
| | (Unaudited) | (Unaudited) |
| Operating activities: | | |
| Net loss | $(6,184,000) | $(9,707,000) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Change in fair value of derivative liabilities | 77,000 | (2,034,000) |
| Impairment charges | - | 5,800,000 |
| Stock-based compensation | 246,000 | 470,000 |
| Deferred taxes | - | (1,302,000) |
| Depreciation and amortization | 193,000 | 185,000 |
| Other non-cash adjustments, net | - | 18,000 |
| Changes in operating assets and liabilities, net | (41,000) | 340,000 |
| Net cash used in operating activities | (5,709,000) | (6,230,000) |
| Investing activities: | | |
| Purchases of property and equipment | (31,000) | (7,000) |
| Net cash used in investing activities | (31,000) | (7,000) |

| | | |
|---|---|---|
| Financing activities: | | |
| Proceeds from sale of common stock, net of offering costs | 6,203,000 | 9,690,000 |
| Other financing activities | 203,000 | (202,000 ) |
| Net cash provided by financing activities | 6,406,000 | 9,488,000 |
| Net increase in cash and cash equivalents | 666,000 | 3,251,000 |
| Cash and cash equivalents, beginning of period | 5,132,000 | 5,711,000 |
| Cash and cash equivalents, end of period | $5,798,000 | $8,962,000 |

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