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Aeolus Announces First Quarter 2017 Financial Results

MISSION VIEJO, CA / ACCESSWIRE / February 17, 2017 /Aeolus Pharmaceuticals, Inc. (OTCQB: AOLS), a biotechnology company developing compounds to protect against fibrosis, inflammation, nerve damage and infection announced today financial results for the three months ended December 31, 2016.

Key Operational Accomplishments for Quarter

1. Entered into a contract with a Clinical Research Organization to initiate a phase 1 study in Healthy Subjects during the first quarter of calendar 2017
2. Submitted final protocol to the FDA Division of Medical Imaging Products to initiate the phase 1 study in Healthy Subjects consistent with the division's guidance

"During the quarter we made the necessary filings to initiate a phase 1 single dose study in healthy subjects, which we plan to initiate shortly. FDA clearance to allow testing of AEOL 10150 in healthy subjects is a tremendous step forward for the Company and is yet another example of the valuable public-private partnership between Aeolus and the Biomedical Advanced Research and Development Authority ("BARDA")," stated John L McManus, President and Chief Executive Officer of Aeolus Pharmaceuticals, Inc. "Upon completion of the single dose study, we plan to move into multiple dose studies in Idiopathic Pulmonary Fibrosis and non-small cell lung cancer, which will provide the human safety data for the Lung Acute Radiation Syndrome indication as well as advance two significant commercial programs for the Company."

Financial Results

The Company reported a net loss of $1,087,000 for the three months ended December 31, 2016, versus a net loss of $1,260,000 for the three months ended December 31, 2015. Revenue for the three months ended December 31, 2016 was approximately $83,000, compared to $305,000 revenue for the three months ended December 31, 2015. The revenue is from the cost-plus contract with BARDA for the development of AEOL 10150 as a medical countermeasure for the pulmonary and delayed effects of acute radiation exposure. Since being awarded the BARDA Contract, we generate contract revenue from a cost-plus fee arrangement. Revenues on reimbursable contracts are recognized as costs are incurred, based on allowable costs incurred during the period, plus any recognizable earned fee. We consider fixed fees under cost-plus fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. Revenue was higher in the prior year primarily due to the timing of work related to the BARDA contract.

Research and development expenses decreased by $3,000, or 1%, to approximately $489,000 for the three months ended December 31, 2016 from approximately $492,000 for the fiscal year ended December 31, 2015. R&D expenses were lower during the three months ended December 31, 2016 versus December 31, 2015 due to the timing of work related to the BARDA Contract.

G&A expenses increased approximately $120,000, or 21%, to approximately $681,000 for the three months ended December 31, 2016 from about $561,000 for the three months ended December 31, 2015. The increase is primarily attributable to higher accounting and legal fees related to SEC filing requirements.

Net loss for the three months ended December 31, 2016 was $1,087,000 or ($0.01/share) as compared to $1,613,000 or ($0.01/share) for the three months ended December 31, 2015.

Aeolus has filed today with the SEC its quarterly report on Form 10-Q for the three months ended December 31, 2016. Aeolus urges its investors to read this quarterly filing as well as its amended Annual Report on Form 10-K/A, also filed with the SEC, for further details concerning the Company. The Quarterly Report on Form 10-Q and the amended Annual Report on Form 10-K/A are also available on the Company's website, at www.aolsrx.com.

About AEOL 10150

AEOL 10150 protects tissue from damage and increases survival in animal models of lung damage after exposure to radiation, toxic chemicals, disease and trauma by mitigating and/or preventing cell death, inflammation and fibrosis through its action on oxidative stress and regulation of growth factors and chemokines, as well as impacting subsequent signaling pathways of reactive oxygen species production, apoptosis and fibrosis. We are developing 10150 as a MCM for national defense and for use in oncology and treating lung fibrosis.

AEOL 10150 has performed well in preclinical and non-clinical studies, demonstrating statistically significant survival efficacy in an acute radiation-induced lung injury model, and was well-tolerated in two human clinical trials. The Company believes it could have a profound beneficial impact on people who have been exposed, or are about to be exposed, to high-doses of radiation, whether from cancer therapy or a nuclear event, and potentially reduce tissue damage in patients with idiopathic pulmonary fibrosis.

About Aeolus Pharmaceuticals

Aeolus Pharmaceuticals is developing a platform of novel compounds for use in biodefense, fibrosis, oncology, infectious diseases and diseases of the central nervous system. Its most advanced compound, AEOL 10150, is being developed, with funding by the US Department of Health and Human Services, as a medical countermeasure against chemical and radiological weapons, where its initial target indications are as a protective agent against the effects of acute radiation syndrome and delayed effects of acute radiation exposure. Aeolus' strategy is to leverage the substantial investment in toxicology, manufacturing, and preclinical and clinical studies made by US Government agencies in AEOL 10150, including the contract with BARDA valued, with options, at up to $118.4

million, to efficiently develop the compound for use in oncology. For more information, please visit Aeolus's corporate website at www.aolsrx.com

Forward-Looking Statements

The statements in this press release that are not purely statements of historical fact are forward-looking statements. Such statements include, but are not limited to, those relating to Aeolus' product candidates, as well as its proprietary technologies, development strategies and research programs, including the Company's initiation or potential initiation of pre-clinical development as well as clinical trials, including a phase 1 study in pulmonary fibrosis patients. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aeolus' actual results to be materially different from historical results or from any results expressed or implied by such forward-looking statements. Important factors that could cause results to differ include risks associated with uncertainties of progress and timing of clinical trials, scientific research and product development activities; difficulties or delays in development, testing and obtaining regulatory approval; the imposition or continuation of clinical holds on development projects; the need to obtain funding for pre-clinical and clinical trials and operations; the scope and validity of intellectual property protection for Aeolus' product candidates, proprietary technologies and their uses; competition from other biopharmaceutical companies; and whether BARDA exercises one or more additional options under the its contract with Aeolus. Certain of these factors and others are more fully described in Aeolus' filings with the Securities and Exchange Commission, including, but not limited to, Aeolus' Annual Report on Form 10-K for the year ended September 30, 2016. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof.

AEOLUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(DOLLARS IN THOUSANDS)

	December 31, 2016	September 30, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,895	$ 3,155
Accounts receivable	544	750
Prepaid expenses and other current assets	178	230
Total current assets	2,617	4,135
Investment in CPEC LLC	32	32
Total assets	$ 2,649	$ 4,167
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 514	$ 972
Total current liabilities	514	972
Total liabilities	514	972
Commitments and contingencies (Note H)		
Stockholders' equity:		
Preferred stock, $.01 par value per share, 10,000,000 shares authorized: Series A nonredeemable convertible preferred stock, 1,250,000 shares authorized as of December 31, 2016 and September 30, 2016, respectively; no shares issued and outstanding as of December 31, 2016		

and September 30, 2016, respectively	—	—
Series B nonredeemable convertible preferred stock, 1,600,000 shares authorized as of December 31, 2016 and September 30, 2016, respectively; no shares issued and outstanding as of December 31, 2016 and September 30, 2016, respectively	—	—
Series C nonredeemable convertible preferred stock, 5,000 shares authorized as of December 31, 2016 and September 30, 2016, respectively; 4,500 shares issued and outstanding as of December 31, 2016 and September 30, 2016, respectively	—	—
Common stock, $.01 par value per share, 200,000,000 shares authorized; 152,085,825 shares issued and outstanding as of December 31, 2016 and September 30, 2016, respectively	1,520	1,520
Additional paid-in capital	191,890	191,863
Accumulated deficit	(191,275)	(190,188)
Total stockholders' equity	2,135	3,195
Total liabilities and stockholders' equity	$ 2,649	$ 4,167

AEOLUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Three Months Ended December 31,	
	2016	2015
Revenue:		
Contract revenue	$ 83	$ 305
Costs and expenses:		
Research and development	489	492
General and administrative	681	561
Total costs and expenses	1,170	1,053
Loss from operations	(1,087)	(748)
Interest expense	—	248
Net loss	(1,087)	(1,033)
Deemed dividend on Series C preferred stock	—	580
Net loss attributable to common stockholders	$ (1,087)	$ (1,613)
Net loss per weighted share attributable to common stockholders:		
Basic net loss per common share	$ (0.01)	$ (0.01)
Diluted net loss per common share	$ (0.01)	$ (0.01)
Weighted average common shares outstanding:		
Basic	152,086	139,439
Diluted	152,086	139,439

AEOLUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Three Months Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$ (1,087)	$ (1,033)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on note payable to shareholders	—	273
Accrued interest	—	12
Noncash compensation	27	38

Change in assets and liabilities:		
Accounts receivable	206	714
Deferred subcontractor cost	—	21
Prepaid expenses and other current assets	52	(21)
Accounts payable and accrued expenses	(458)	(802)
Deferred revenue	—	(22)
Net cash used in operating activities	(1,260)	(820)
Cash flows from financing activities:		
Proceeds from issuance of common stock and common stock warrants, net	—	2,005
Proceeds from issuance of preferred stock and common stock warrants, net	—	4,165
Net cash provided by financing activities	—	6,170
Net (decrease) increase in cash and cash equivalents	(1,260)	5,350
Cash and cash equivalents at beginning of period	3,155	94
Cash and cash equivalents at end of period	$ 1,895	$ 5,444
Supplemental disclosure of non-cash financing activities:		
Conversion of note payable to shareholders for common stock and warrants	$ —	$ 1,000
Conversion of accrued interest on note payable to shareholders for common stock and warrants	$ —	$ 12
Issuance of warrants for financing costs	$ —	$ 266
Deemed dividend on Series C preferred stock	$ —	$ 580

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SOURCE: Aeolus Pharmaceuticals, Inc.