

May 16, 2016



# Aeolus Announces Second Quarter Fiscal Year 2016 Financial Results and Investor Update Call

## ***Aeolus Announces Second Quarter Fiscal Year 2016 Financial Results and Investor Update Call***

MISSION VIEJO, CA -- May 16, 2016 -- [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 March 31, 2016. The Company also announced a conference call to update investors on its development programs, including its partnership with the Biomedical Advanced Research and Development Authority ("BARDA") for the development of AEOL-10150 ("10150") as treatment for the pulmonary and delayed effects of acute radiation exposure ("Lung-ARS").

### **Investor Update Call Information:**

***Date: Thursday, May 19<sup>th</sup>, 2016***

***Time: 11:00 AM EDT/8:00 AM PDT***

***Dial-in Number: (844) 784-2549***

***International Dial-in: (661) 378-9785***

A recording of the conference call will be available on the Company's website, [www.aolsrx.com](http://www.aolsrx.com), for 28 days following the call.

The Company reported a net loss of approximately \$2,535,000, or \$0.02 per share for the three months ended March 31, 2016. This compares to a net loss of \$1,033,000, or \$0.01 per share, for the three months ended December 31, 2015. The increase in net loss was primarily attributable to a \$1,906,000 non-cash expense related to a deemed dividend for the Company's Series C Preferred Stock. The net operating loss for the period was \$629,000 or \$0.00 per share.

"During the quarter, the U.S Food and Drug Administration ("FDA") removed the clinical hold on our Investigational New Drug Application ("IND") for 10150 to treat Lung-ARS," stated John L. McManus, President and Chief Executive Officer. "We are in discussions with our development partner, BARDA, regarding the appropriate clinical studies to generate the human safety data required for a pre-Emergency Use Authorization filing and, ultimately, for an approval under the FDA's 'Animal Rule.' We are not aware of any

other compounds in advanced development for Lung-ARS or any compounds that have demonstrated efficacy when administered after radiation exposure. In addition, we are preparing to meet with the FDA to discuss the filing of INDs for human studies in Idiopathic Pulmonary Fibrosis and Cancer Radiation Therapy. We hope to initiate these studies in the second half of 2016."

#### Key Operational Accomplishments During the Quarter:

- FDA removed the clinical hold on AEOL 10150 for studies in healthy volunteers supporting the Lung-ARS program
- Preparation of IND submissions to the FDA for later this year for studies of AEOL 10150 in patients with Idiopathic Pulmonary Fibrosis and in patients receiving radiation therapy for cancer
- Patent for AEOL 11114 issued in Europe and allowed in Japan
- IND-enabling work for AEOL 11114 in Parkinson's Disease initiated with a filing expected in 2017
- Animal study of AEOL 20415 (an new, novel anti-infective) initiated as a treatment for infections in patients with Cystic Fibrosis with results expected in the second quarter
- BARDA contract modification executed to extend stability testing on AEOL 10150 bulk drug and final drug product for 3 additional years

#### ***Results of Operations for the Three Months Ended March 31, 2016***

Revenue for the three months ended March 31, 2016 was approximately \$565,000, versus revenue of \$1,189,000 for the three months ended March 31, 2015. The revenue is from the Lung ARS medical countermeasure development contract with BARDA, a division of the U.S. Department of Health and Human Services. Lower revenue in 2016 reflects the timing of the initiation of program items and revenue recognition under accounting rules.

Research and development expenses decreased to approximately \$501,000 for the three months ended March 31, 2016, from approximately \$1,297,000 for the three months ended March 31, 2015. The decrease in 2016 expenses reflects both the timing of program items under the BARDA contract and expense recognition under accounting rules.

General and administrative expenses were approximately \$693,000 for the three months ended March 31, 2016 compared to approximately \$604,000 for the three months ended March 31, 2015.

#### ***Results of Operations for the Six Months Ended March 31, 2016***

Revenue for the six months ended March 31, 2016 was approximately \$870,000, versus revenue of \$2,114,000 for the six months ended March 31, 2015. The revenue is from the Lung ARS medical countermeasure development contract with BARDA. Lower revenue in 2016 reflects the timing of the initiation of program items and revenue recognition under accounting rules.

Research and development expenses decreased to approximately \$993,000 for the six months ended March 31, 2016, from approximately \$2,270,000 for the six months ended March 31, 2015. The decrease in 2016 expenses reflects both the timing of program items under the BARDA contract and expense recognition under accounting rules.

General and administrative expenses were approximately \$1,254,000 for the six months ended March 31, 2016 compared to approximately \$1,254,000 for the six months ended March 31, 2015.

As of March 31, 2016, the Company had approximately \$4,509,000 in cash and cash equivalents and 151,559,745 common shares outstanding. The Company had accounts receivable of \$1,366,000 and accounts payable of \$1,031,000 on March 31, 2016.

Aeolus has filed today with the SEC its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016. Aeolus urges its investors to read this quarterly filing as well as its Annual Report on Form 10-K, also filed with the SEC, for further details concerning the Company. The Quarterly Report on Form 10-Q and the Annual Report on Form 10-K are also available on the Company's website, at [www.aolsrx.com](http://www.aolsrx.com).

### ***About AEOL 10150***

AEOL 10150 is a broad-spectrum catalytic antioxidant specifically designed to neutralize reactive oxygen and nitrogen species. The neutralization of these species reduces oxidative stress, inflammation, and subsequent tissue damage-signaling cascades resulting from radiation exposure. AEOL 10150 may have a profound beneficial impact on people who have been exposed, or are about to be exposed, to high-doses of radiation in the treatment of oncology.

AEOL 10150 has performed well in animal safety studies, was well tolerated in two human clinical trials and has demonstrated statistically significant survival efficacy in multiple Radiation-Induced Lung Fibrosis ("Lung ARS") studies in animals. 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. Aeolus has received "Orphan Drug" designation for the use of AEOL 10150 in treating Lung ARS and Idiopathic Pulmonary Fibrosis and has filed an IND to allow for human safety testing of the compound in healthy volunteers. AEOL 10150 is also currently in development for use in Idiopathic Pulmonary Fibrosis and as both a therapeutic and prophylactic drug in cancer patients.

### ***About Aeolus Pharmaceuticals***

Aeolus Pharmaceuticals is developing a platform of novel compounds, known as metalloporphyrins, for use in biodefense, fibrosis, oncology, infectious disease and diseases of the central nervous system. Its lead compound, AEOL 10150, is being developed, with funding from 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 to develop the compound for the treatment of lung fibrosis, including idiopathic pulmonary fibrosis ("IPF") and as a treatment to reduce side effects caused by radiation toxicity and improve local tumor control in cancer therapy. The Company is also developing AEOL 11114 as a treatment for Parkinson's Disease and AEOL 20415 as a treatment for cystic fibrosis and diseases that have developed a resistance to existing antibiotic and anti-viral therapies. For more information, please visit Aeolus's corporate website at [www.aolsrx.com](http://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 and research programs, a potential phase 1 study in healthy normal volunteers, the BARDA Contract, and the expected use of proceeds from the financing. 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, obtaining regulatory approval, 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, and competition from other biopharmaceutical companies, and whether BARDA exercises one or more additional options under the BARDA Contract. 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, 2015. 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**  
**(UNAUDITED)**  
**(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)**

	March 31, 2016	September 30, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,509	\$ 94
Accounts receivable	1,366	1,585
Deferred subcontractor cost	197	21
Prepaid expenses and other current assets	156	45
Total current assets	<u>6,228</u>	<u>1,745</u>
Investment in CPEC LLC	32	32
Total assets	<u>\$ 6,260</u>	<u>\$ 1,777</u>

**LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)**

## Current liabilities:

Accounts payable and accrued expenses	\$	1,031	\$	1,598
Deferred revenue		205		22
Note payable to shareholders, net of debt discount of \$273		-		727
Note payable to shareholders redemption liability		-		275
Total current liabilities		<u>1,236</u>		<u>2,622</u>
Total liabilities		1,236		2,622

## 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 March 31, 2016 and September 30, 2015, respectively; no shares issued and outstanding as of March 31, 2016 and September 30, 2015, respectively

Series B nonredeemable convertible preferred stock, 1,600,000 and 1,600,000 shares authorized as of March 31, 2016 and September 30, 2015, respectively; 526,080 and 526,080 shares issued and outstanding as of March 31, 2016 and September 30, 2015, respectively

Series C nonredeemable convertible preferred stock, 5,000 and zero shares authorized as of March 31, 2016 and September 30, 2015, respectively; 4,500 and zero shares issued and outstanding as of March 31, 2016 and September 30, 2015, respectively

Common stock, \$.01 par value per share, 200,000,000 shares authorized; 151,559,745 and 135,930,068 shares issued and outstanding as of March 31, 2016 and September 30, 2015, respectively

Additional paid-in capital

Accumulated deficit

Total stockholders' equity (deficit)

Total liabilities and stockholders' equity (deficit)

	1,515	1,359
	191,797	184,421
	(188,293)	(186,630)
	<u>5,024</u>	<u>(845)</u>
	<u>\$ 6,260</u>	<u>\$ 1,777</u>

**AEOLUS PHARMACEUTICALS, INC.**

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(IN THOUSANDS, EXCEPT PER SHARE DATA)

Three months		Six Months Ended	
Ended		March 31,	
March 31,		March 31,	
<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>

Revenue:				
Contract revenue	\$ 565	\$ 1,189	\$ 870	\$ 2,114
Costs and expenses:				
Research and development	501	1,297	993	2,270
General and administrative	693	604	1,254	1,254
Total costs and expenses	<u>1,194</u>	<u>1,901</u>	<u>2,247</u>	<u>3,524</u>
Loss from operations	(629)	(712)	(1,377)	(1,410)
Interest expense	<u>-</u>	<u>-</u>	<u>(285)</u>	<u>-</u>
Net loss	(629)	(712)	(1,662)	(1,410)
Deemed dividend on Series C preferred stock	1,906	-	2,486	-
Net loss attributable to common stockholders	<u>\$ (2,535)</u>	<u>\$ (712)</u>	<u>\$ (4,148)</u>	<u>\$ (1,410)</u>
Net loss per weighted share attributable to common stockholders:				
Basic	<u>\$ (0.02)</u>	<u>\$ (0.01)</u>	<u>\$ (0.03)</u>	<u>\$ (0.01)</u>
Diluted	<u>\$ (0.02)</u>	<u>\$ (0.01)</u>	<u>\$ (0.03)</u>	<u>\$ (0.01)</u>
Weighted average common shares outstanding:				
Basic	<u>151,560</u>	<u>135,850</u>	<u>145,466</u>	<u>135,850</u>
Diluted	<u>151,560</u>	<u>135,850</u>	<u>145,466</u>	<u>135,850</u>

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

	Six Months Ended March 31,	
	<u>2016</u>	<u>2015</u>
Cash flows from operating activities:		
Net loss	\$ (1,662)	\$ (1,410)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on note payable to shareholders	273	-
Accrued interest	12	-
Non-cash compensation	74	259
Change in assets and liabilities:		
Accounts receivable	219	(248)
Deferred subcontractor cost	(176)	375
Prepaid expenses and other current assets	(111)	(64)
Accounts payable and accrued expenses	(567)	209
Deferred revenue	183	(390)
Net cash used in operating activities	<u>(1,755)</u>	<u>(1,269)</u>
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	<u>6,170</u>	<u>-</u>
Net increase (decrease) in cash and cash equivalents	4,415	(1,269)
Cash and cash equivalents at beginning of period	94	1,517
Cash and cash equivalents at end of period	<u>\$ 4,509</u>	<u>\$ 248</u>

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	\$ 2,486	\$ -

Contact:

John McManus  
President and Chief Executive Officer  
Aeolus Pharmaceuticals, Inc.  
1 (949) 481-9825

Source: Aeolus Pharmaceuticals