



About Aeolus

www.aeoluspharma.com

Aeolus Pharmaceuticals has over \$150M of government funding supporting its development programs. It is developing a novel platform technology that not only protects healthy tissue from the damaging effects of radiation, but has significant anticancer activity as well.

Aeolus' strategy is to leverage the substantial investment by the US Government in developing its lead compound as a medical countermeasure to pulmonary effects of Acute Radiation Syndromes (Lung-ARS) to develop it in oncology, where it would be used in combination with radiation and chemotherapy. This research work can be used to support and accelerate the Company's clinical development program for AEOL 10150 in oncology, thus reducing the company's need for dilutive financing from outside investors.

Following the filing of an Emergency Use Authorization, expected in the 2H 2013, the government program will position Aeolus for a large potential procurement for the Strategic National Stockpile (potential several hundred million dollars in annual sales, with no associated sales and marketing expenses).

#### HIGHLIGHTS

Aeolus is the only company with funding from Biomedical Advanced Research & Development Authority (BARDA) developing a medical countermeasure for Lung-ARS that has shown effectiveness when given post-exposure.

<u>Potential Profitability w/in 2 Years:</u> Once an Emergency Use Authorization is filed (scheduled for 2H 2013) the Government may begin buying the drug for the Strategic National Stockpile. Management expects sales to range from \$100M to \$400M annually.

<u>Gov't Funding Results In Low Cash Burn</u>: More than \$150M in government funding results in very low cash burn rate

- > Research work under the BARDA contract can be used to support clinical development program in oncology.
- > Less capital needed from investors = less potential dilution.

# Multiple Large Market Opportunities: 1) Biodefense, and 2) oncology.

- <u>Biodefense</u>: Potential for large procurement by BARDA (annual sales ∼\$100M-\$400M) and possible Aeolus profitability within ~24 months.
  - i. Human efficacy studies are NOT required for this sale
  - ii. FDA approval is NOT required for this sale
  - iii. No dilution from financing for product launch or sales & marketing
  - iv. No market risk
- Oncology: Potential broad applicability in multiple, large oncology indications
  - Damage to healthy tissue limits radiation dose Drug may allow higher radiation doses leading to better survival.
  - ii. Data to date show that AEOL 10150 does not interfere with the therapeutic benefit of radiation therapy, and helps <u>increase</u> tumor control when used in combination with radiation and chemotherapy

<u>Reduced Scientific Risk</u>: BARDA studies are, essentially, replications of studies Aeolus has already run, but at lower radiation doses. All prior studies succeeded in demonstrating efficacy or safety at higher radiation doses.

Approx. 50% of all cancer patients will receive radiation therapy<sup>1</sup>

- Effectiveness of radiation therapy is largely determined by the dose of radiation delivered to the tumor
- Radiation-induced toxicity to healthy tissue remains a major factor limiting radiation dose
- Increasing the effective dose of radiation by just 10% would increase tumor control rates by  $5\text{--}30\%^2$
- Delaney, G., et al. The role of radiotherapy in cancer treatment: estimating optimal utilization from a review of evidence-based clinical guidelines. Cancer 104, 1129–1137 (2005).
- Begg AC., et al. Strategies to improve radiotherapy with targeted drugs. Nat Rev Cancer. 2011 Apr;11(4):239-53. Review.

# **COMPANY QUICK FACTS**

Founded 1994

# **Contact Details**

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Stock Listing OTCQB: AOLS

#### **EXECUTIVE MANAGEMENT**

**John L. McManus,** *Chief Executive Officer Spectrum Pharmaceuticals, MFC Financial* 

**Brian Day, Ph.D.,** Chief Scientific Officer & coinventor of technology National Jewish Health, Duke University,

**Russell Skibsted,** Chief Financial Officer Spectrum Pharmaceuticals, Hana Biosciences, Asset Management Company; GE Capital

**David C. Cavalier,** Chairman Xmark Opportunity Partners, Tiger Management Corporation, Goldman Sachs

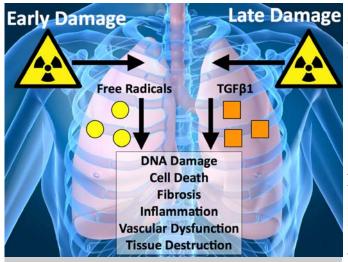
#### **INVESTIGATORS AND ADVISORS**

Thomas MacVittie, Ph.D. – University of Maryland School of Medicine. W.H.O. Collaborating Centers in Radiation Emergency Medical Preparedness & Assistance; International Council on Radiation Protection; NATO Radiation Research Study Groups. CDC Strategic National Stockpile Radiation Working Group; Medical Countermeasures against Radiation Threats (MCART)" consortium

**Zeljko Vujaskovic, MD, Ph.D.** – University of Maryland School of Medicine; MCART Duke University

#### **INVESTOR CONTACT**

Russell Skibsted Tel: (949) 481-9821 Email: info@aolsrx.com



#### **FINANCIAL HIGHLIGHTS**

• 12-month Stock Price Range: \$0.21 to \$0.48

• Common Shares Outstanding: 62.7 million

• Cash and Equivalents (6/30/12): \$0.2 million

• Market Capitalization: ~\$20 million

#### CORPORATE MILESTONES

✓ Awarded contract fully valued at \$118 million from BARDA to develop treatment for lung-ARS

✓ Announced positive results from AEOL10150 combination study with Neupogen

✓ Announced Positive Data on AEOL 11207 in Pre-Clinical Epilepsy Model

Peer-reviewed publication of mechanism of action data in cancer and radiation

✓ Awarded options scheduled for the second year under the current BARDA contract

• Data from murine dosing study

- File INDs for ARS and radiation oncology
- Data from 2<sup>nd</sup> murine dosing study
- Initiate Human safety study
- Data from NHP dosing study

### **ANALYST COVERAGE**

**Ladenburg Thalmann** - Kevin DeGeeter **Roth Capital** - *Joseph Pantginis* 

#### **MAJOR SHAREHOLDERS**

Xmark Capital Efficacy Capital

BVF Great Point Partners

SDS Capital Clear Harbor Asset Mgmt

# Late Damage CATALYTIC ANTIOXIDANT PLATFORM

Aeolus is developing a platform of a new class of broad-spectrum catalytic antioxidant compounds based on technology discovered at Duke University and National Jewish Health. These compounds, known as metalloporphyrins, scavenge reactive oxygen species ("ROS") at the cellular level, mimicking the effect of the body's own natural antioxidant enzyme superoxide dismutase ("SOD").

# **LEAD PROGRAM - AEOL 10150**

AEOL 10150 has demonstrated safety in animal studies, been well-tolerated in two human clinical trials, demonstrated efficacy in two species in acute radiation syndrome (ARS) studies, and demonstrated statistically significant survival efficacy in an acute radiation-induced lung injury model. AEOL 10150 has also demonstrated efficacy in validated animal models for GI-ARS, chlorine gas exposure, and sulfur mustard gas exposure.

# **ACUTE RADIATION SYNDROME (ARS)**

ARS is caused by exposure to high levels of radiation. There are three relevant sub-syndromes of ARS: 1) Hematopoietic and Bone Marrow (Heme), 2) Gastrointestinal (GI) and 3) Pulmonary/Lung-ARS. The CNS/Cardio sub-syndrome is not considered relevant because anyone receiving high enough levels of radiation to trigger this syndrome would not survive the blast from the nuclear event. The Heme and GI sub-syndromes are generally considered treatable in small exposed populations to exposures up to about 7-8 Gy with filgrastim, IV fluids and antibiotics. Current need in GI is a treatment for exposures >7-8Gy.

There are currently no treatments available to treat Lung-ARS, which has been a leading and significant cause of death in industrial radiological accidents over past 20 years.

AEOL 10150 has already performed well in animal safety and efficacy studies in Lung-ARS, demonstrating significantly reduced weight loss, inflammation, oxidative stress, lung damage, and most important, mortality.

# **ONCOLOGY**

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 efficiently develop the compound for use in oncology.

Data have been published showing that AEOL 10150 not only does not interfere with the therapeutic benefit of radiation therapy in prostate and lung cancer preclinical studies, but also helps increase tumor control when used in combination with radiation and chemotherapy.

The statements in this document 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. 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,