ÆOLUS

PHARMACEUTICALS

protecting healthy tissue

Overview

- Over $150MM in contracts and grants from US Government
- Efficacy established in Acute Radiation Syndrome
- Near-term potential sales to US Strategic National Stockpile
- Large commercial markets driven by data from biodefense
- Two additional compounds to enter clinic in 2017
- No debt and sufficient cash for multiple years of operation

COMMERCIAL

Compound	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3
10150	Pulmonary Fibrosis	✔	2016		
10150	Radiation Therapy	✔	2016		
20415	Infectious Disease	✔	2017		
11114B	Parkinsons Disease	✔	2017		

BIODEFENSE

Compound	Indication	Model Development	CMC	Efficacy	Safety	Procurement
10150	ARS	✔	✔	✔	2016	2016-2017
10150	Chemical Gas	✔	✔	✔	2016	
10150	Nerve Gas	✔	✔		2016	
20415	Infectious Disease	✔	✔		2017	

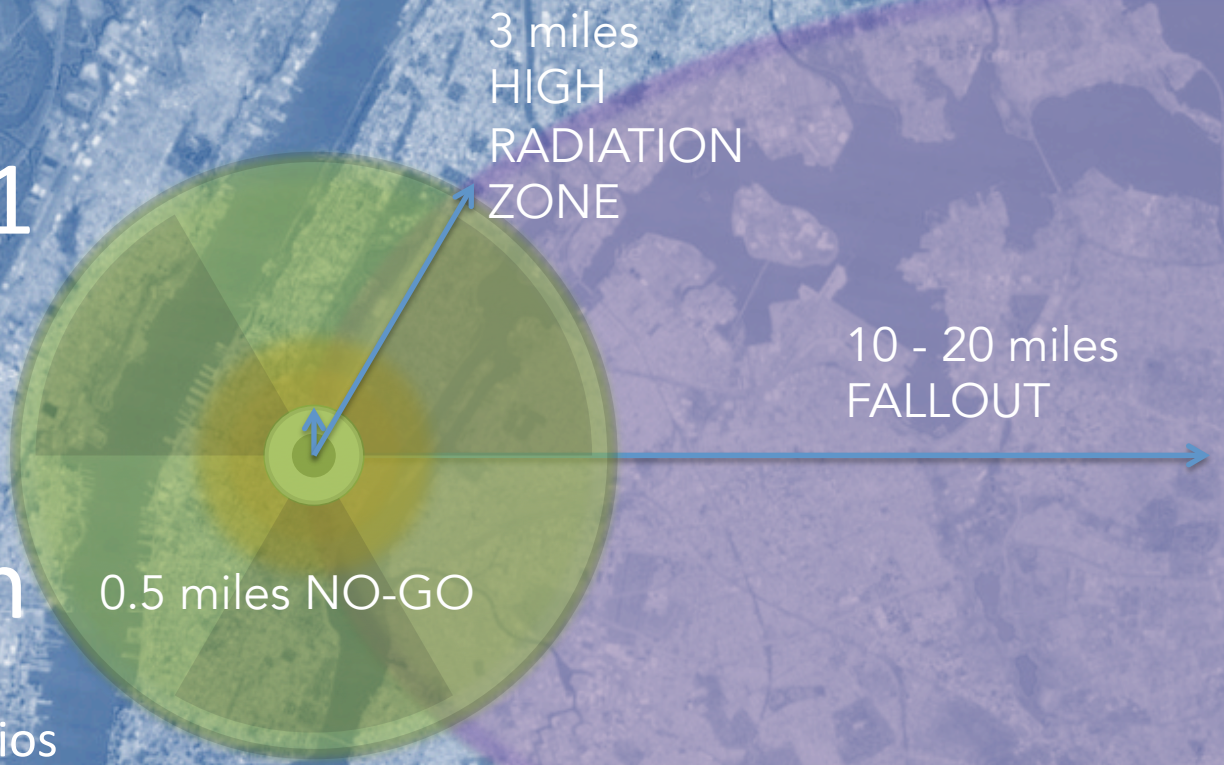
BIODEFENSE MARKETS

- Strategic National Stockpile
  - Sales prior to FDA Approval through EUA
  - Potential sales in USG FY 2017
- Foreign Governments
  - After US sales
  - Israel, Japan, South Korea
- State & Local Responders
  - ChemPaks for chemical and nerve gas

Aeolus BARDA contract

- $118.4MM for Advanced Development of 10150
  - Cost plus contract
- Funds all efficacy, human safety, regulatory and manufacturing costs
- Funds portion of corporate overhead
- Benefits both fibrosis & oncology programs
  - CMC
  - Human Safety

USG Planning Scenario #1 10 KT Nuclear Detonation



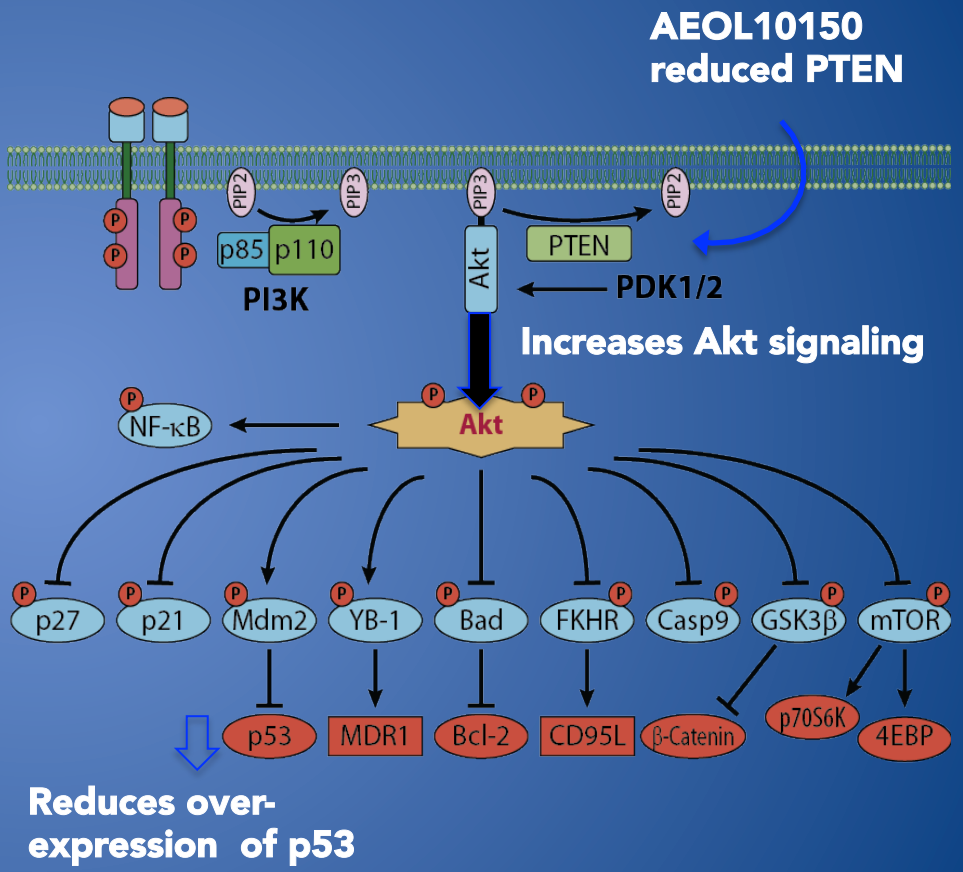
USG uses these scenarios to determine response needs for terror threats, including potential casualties and numbers to be treated

ACUTE RADIATION SYNDROME

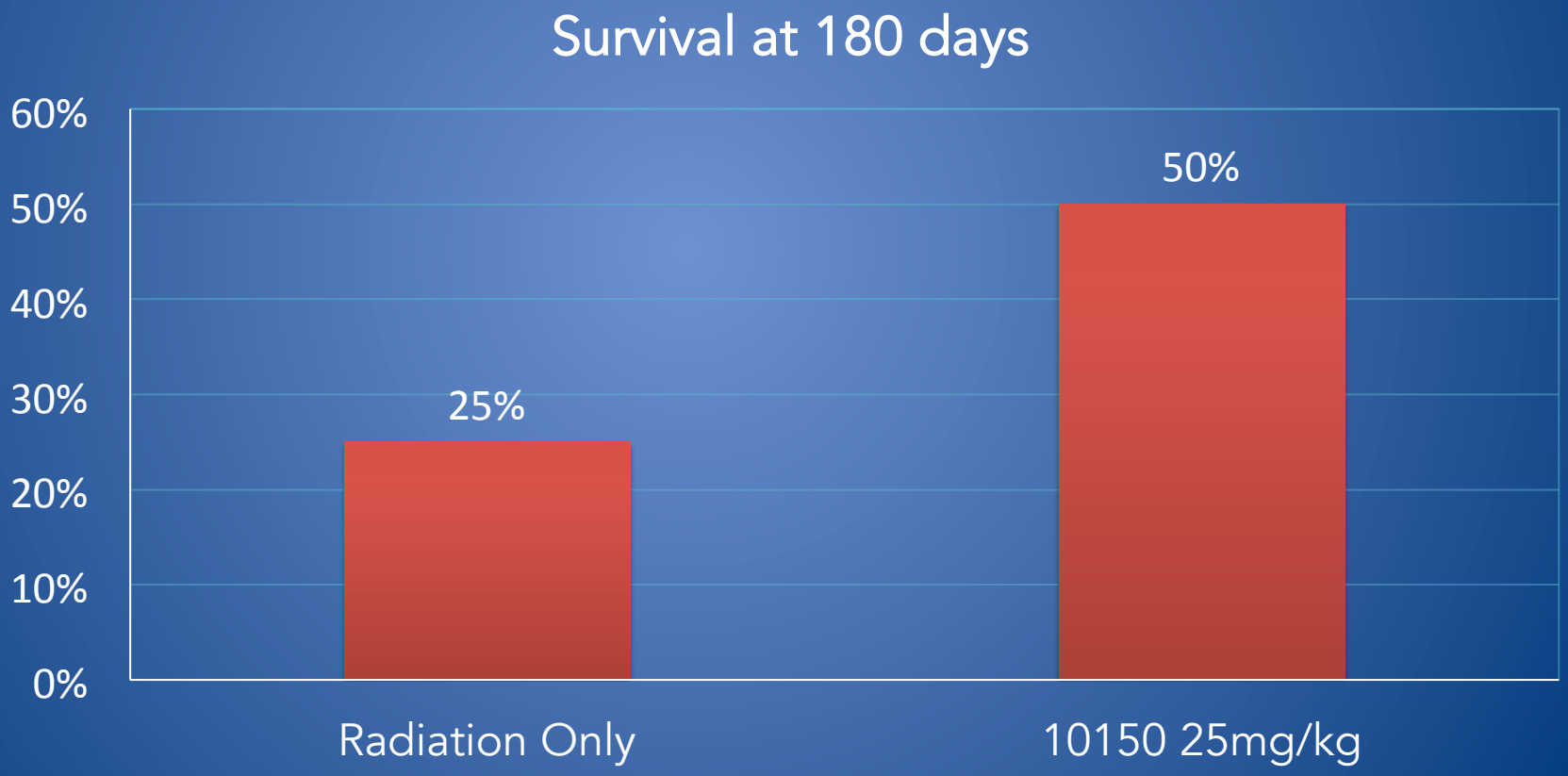
	Gastrointestinal	Hematopoietic	Lung
Onset	Acute: 1-48 Hours	Acute: 2-7 days	Long Term: 2-3 months
Effects	Damages mucosal lining of gut, infection, loss of nutrition, death 3-10 days	Severe damage to bone marrow & immune system, infection, death 3 - 4 weeks	Inflammation of lung, scarring of lung tissue, major cause of death after GI ARS & H ARS
Treatment	Supportive care only: fluids, antibiotics	Neupogen (Amgen) approved by FDA March 2015, supportive care	**NO CURRENT TREATMENT**

AEOL 10150: Catalytic Scavenger of Reactive Oxygen Species and Reactive Nitrogen Species

- **In animal models treatment with AEOL10150 after irradiation:**
- **Decreased oxidative stress**
  - Reduced 8-OHdG staining
  - Reduced Nox4
- **Decreased PTEN signaling**
  - Increased Akt signaling
  - Reduction in p53 and Bax
- **Decreased number of apoptotic cells**
  - TUNEL staining
- **Decreased TGF-b1**
- ***Reduction of oxidative stress in initial period after radiation exposure may play a role in preventing the cell death observed in delayed effects***



10150 Survival Advantage Monkey LD 75 – 10.74Gy



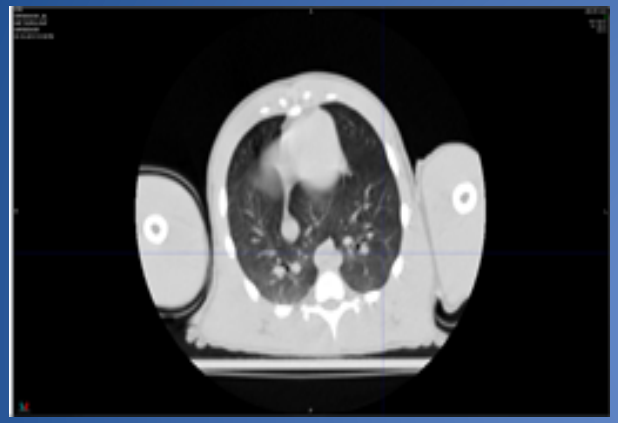
Secondary Endpoints
Monkey LD75 – 10.74 Gy

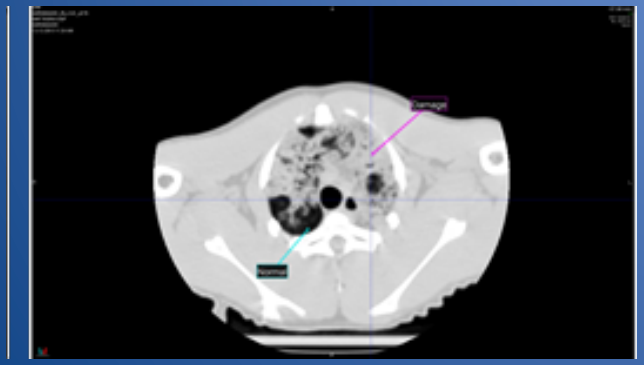
- Reduction in pneumonitis and fibrosis
  - In-life CT scan
  - Histology post-mortem
- Improved clinical measures of lung function
  - Increased p02 levels
  - Lowered breathing rates
- Treated animals showed no evidence of molecular biomarkers for lung injury

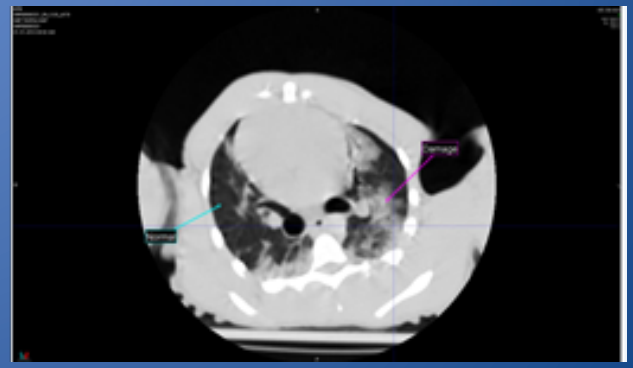
CT Scans – Monkey LD75

Control Lung – 10.74 Gy

AEOL10150 Treated Lung – 10.74 Gy



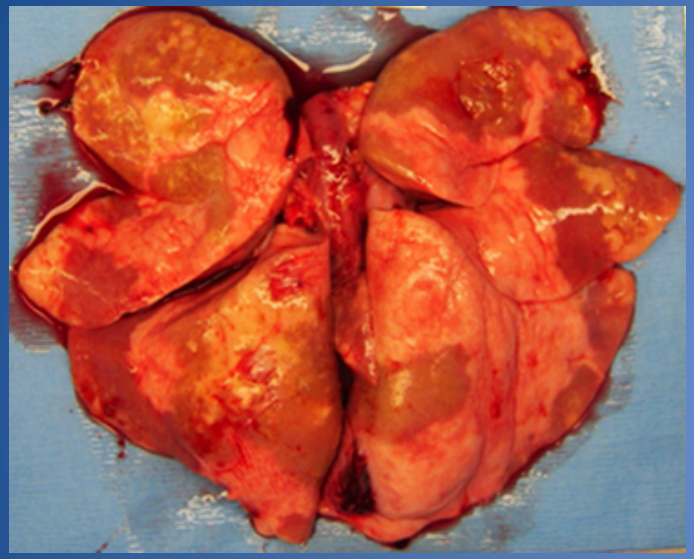




Claire L Carter, Ph.D.; Maureen A. Kane, Ph.D.; Thomas MacVittie,Ph.D.; Ann Farese, M.S.; et al.

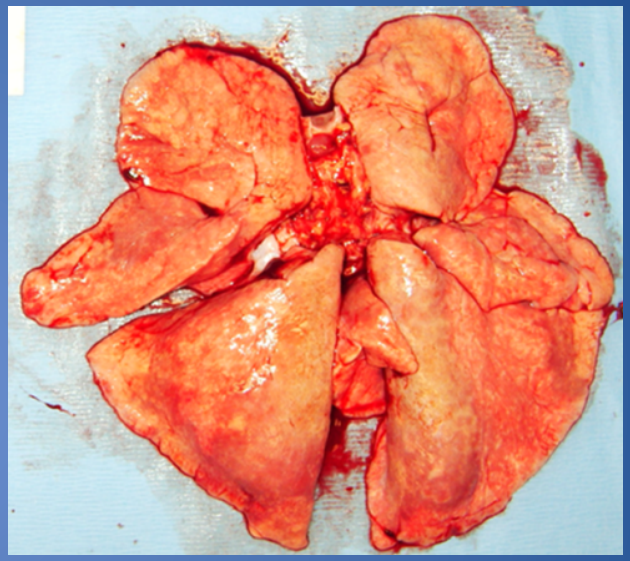
Histology – Monkey LD75

Control Lung – 10.74 Gy



Gross anatomy shows
clear signs of hemorrhage;
dark focal nodules

AEOL10150 Treated Lung – 10.74 Gy



Gross anatomy shows
areas of slight discoloration

Claire L Carter, Ph.D.; Maureen A. Kane, Ph.D.; Thomas MacVittie,Ph.D.; Ann Farese, M.S.; et al.

Emergency Use Authorization

- Allows use prior to FDA approval in declared emergency
- BARDA has made majority of procurements after pre-EUA application

	AEOL 10150
1. life threatening disease	✔
2. no adequate alternatives	✔
3. safety data in humans	
4. manufacturing capacity	✔
5. demonstrated efficacy	✔

AEOL 10150 Human Clinical Data

- Phase 1 Chronic (7 day) Dosing Study in ALS Patients Completed with No Severe or Clinical Adverse Events
  - Six patients per dose: 4 drug/2 placebo
  - Three doses: 40 mg bid (80 mg total per day), 60 mg bid (120 mg total per day), 2mg per kg (body weight) continuous infusion pump
- Phase 1 Single Dose Escalating Study in ALS Patients Completed with No Severe or Clinical Adverse Events
  - One dose per patient, 28 patients received drug
  - Doses escalated: 3 mg, 12 mg, 30 mg, 45 mg, 45 mg, 60 mg & 75 mg
- Physician-Sponsored Long Term Safety Study in ALS Patient at UCLA
  - One patient received drug for 28 days
  - 75 mg bid, subcutaneous injections
  - No serious adverse events

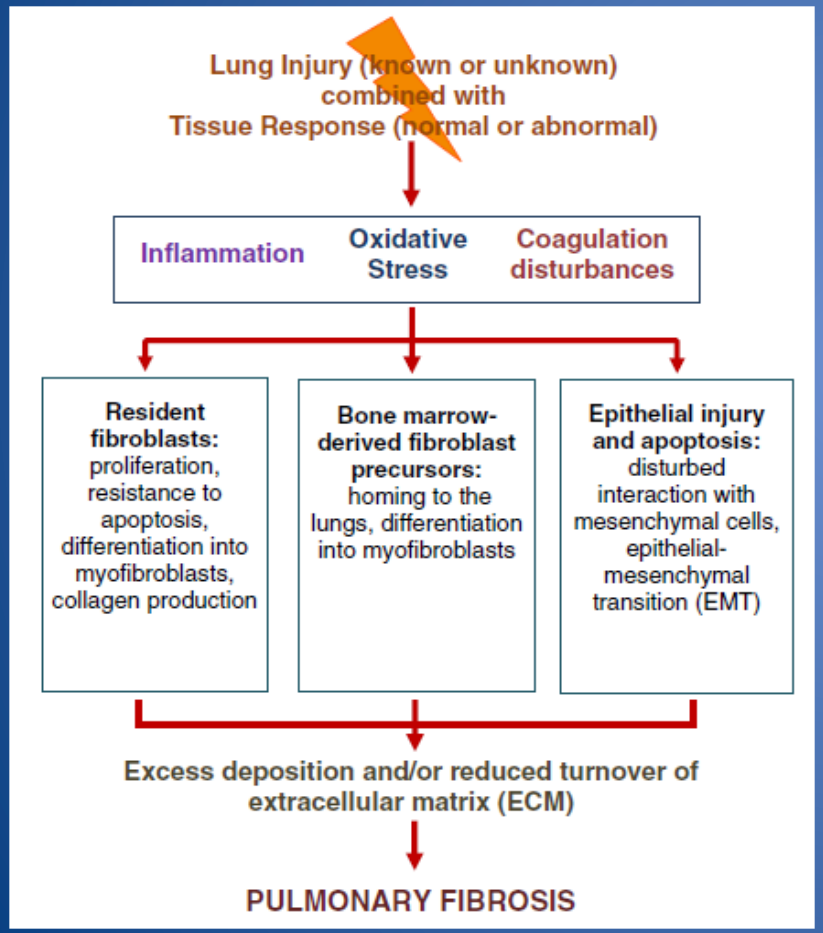
BARDA Procurement

- pre-EUA filing after completion of Phase 1 study
- BARDA would issue RFP for Lung-ARS after pre-EUA filing
  - 10150 only compound in advanced development for Lung-ARS
  - 10150 only compound to have demonstrated efficacy when administered after exposure to radiation.
- USG total requirement estimated at 100,000 to 300,000 courses of treatment based on RFP for G-CSF to treat H-ARS.
- Funding for procurement comes from Special Reserve Fund
  - Managed by BARDA
  - Successor to Project BioShield
- Projected pricing for full course of treatment for 10150 - $3,000

Manufacturing

- BARDA Contract funds all CMC work necessary for New Drug Application for for Lung-ARS and commercial applications
- Johnson-Matthey Pharma Services is manufacturing partner
  - Reduced cost of producing 10150 by >85%
  - New formulation work generated new patent for 10150
  - Completion of large-scale GMP production by 2017
- Pilot scale batches have been manufactured with stability out to 3 years

Commercial Development Idiopathic Pulmonary Fibrosis



- IPF is a chronic, progressive fibrosing interstitial pneumonia of unknown cause.
- Median survival after diagnosis is 3 to 4 years.
- Pathologically characterized by accumulations of extracellular matrix (ECM) and remodeling of the lung architecture resulting in a scarring fibrosis.
- Alteration to the lung is due to three mechanisms, inflammation, oxidative stress and coagulation disturbances

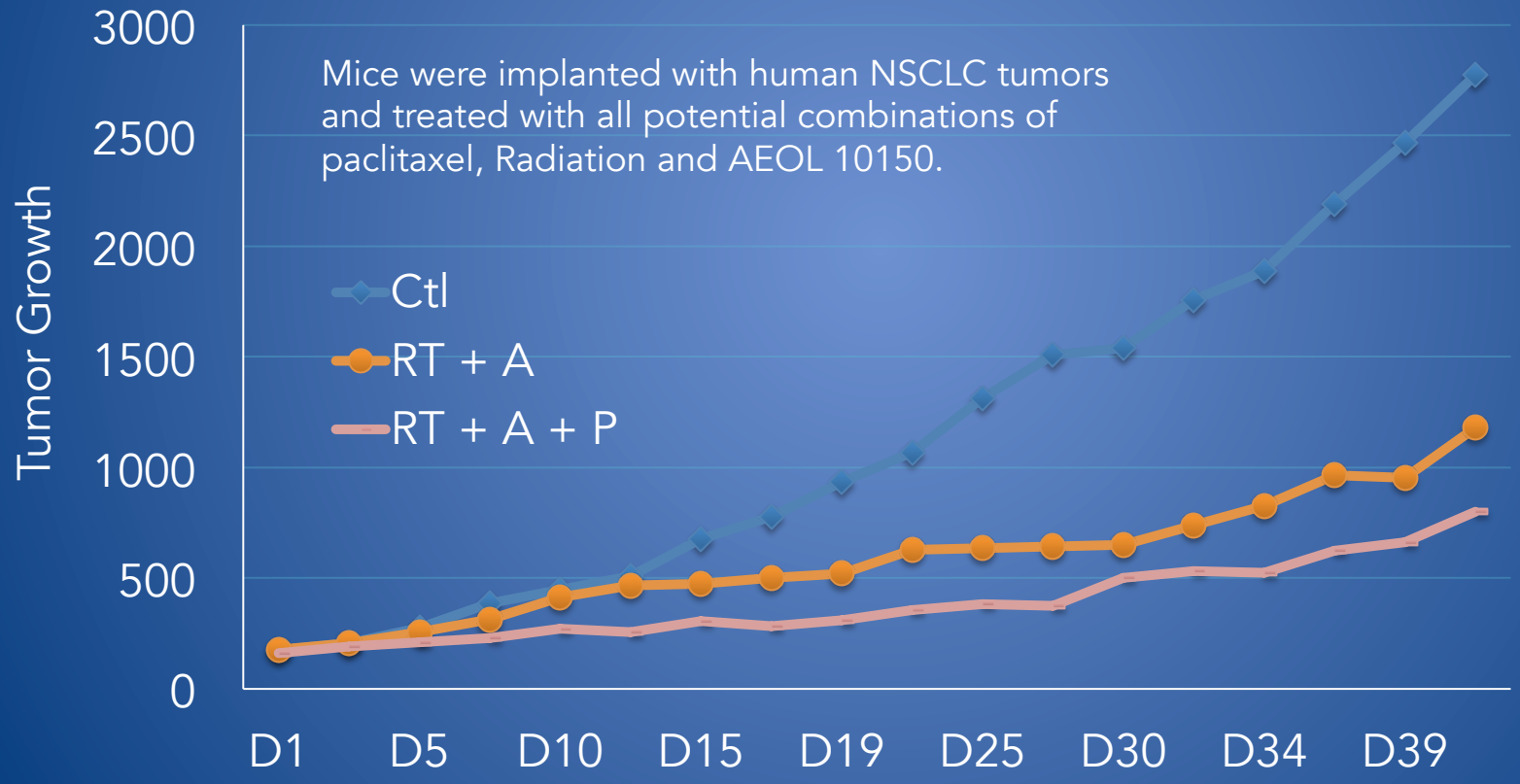
Commercial Development Idiopathic Pulmonary Fibrosis

- Animal models for Lung-ARS are also excellent models for lung fibrosis
- Consistent data from both mouse and monkey radiation studies showing anti-fibrotic effect
  - Efficacy also demonstrated in bleomycin rodent studies
- FDA granted Orphan Drug designation for use in IPF in early 2015
- Scientific Advisory Board with experience in successful drug development in IPF (Esbriet) to be announced in October
- Pre-IND meeting and IND filing expected in 2016 – phase 1 clinical study to follow

Commercial Development Radiation Therapy

- 10150 did not interfere with lung tumor kill when administered with radiation and/or chemo
  - Data in multiple pre-clinical studies at FDA request
- Two potential development pathways
  - Reduction in side effects from radiotherapy
  - Increased tumor control as a third agent with chemo

Commercial Development
Radiation Therapy



Pipeline

- AEOL 11114 – Parkinson's Disease
  - Developed with Michael J. Fox Foundation
  - IND-enabling work underway
  - Explore partnering opportunities
- AEOL 20415 – Infectious Disease
  - Novel approach to anti-microbial therapy
  - IND-enabling work underway
  - Biodefense applications

Financial Information

Balance Sheet at 6/30/2016	
Cash	$3.8MM
Debt	-
Capitalization	
Common Shares Outstanding	152.1MM
Warrants	53.1MM
Options	12.7MM
Series C Preferred Shares	20.5MM
Fully Diluted Shares	238.4MM

MILESTONES

- File IND for IPF
  H2 2016
- File IND for Radiation Oncology
  H2 2016
- Additional Option Exercise from BARDA
  H2 2016
- Initiate IPF Study
  H2 2016

MILESTONES

- Initiate Radiation Oncology Study
  H2 2016
- File Pre-EUA Application
  H1 2017
- File IND for Parkinson's Disease
  H1 2017
- File IND for Infectious Disease
  H2 2017
- Potential RFP from US Government for 10150
  mid-2017