

# Business Overview

Boosting the Innate Immune System in the Lungs

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Pulmotect, Inc.

## Product: PUL-042

- Inhaled therapeutic to locally boost the body's immune system
- Proprietary combination of an oligodeoxynucleotide and lipoprotein
- First inhaled product of its kind



## How It Works

- Activates the *innate* immune system to prevent multiple infections
- Causes local response – not systemic
- Kills pathogens as they land on airway surfaces
- Protection lasts ~ 5 days



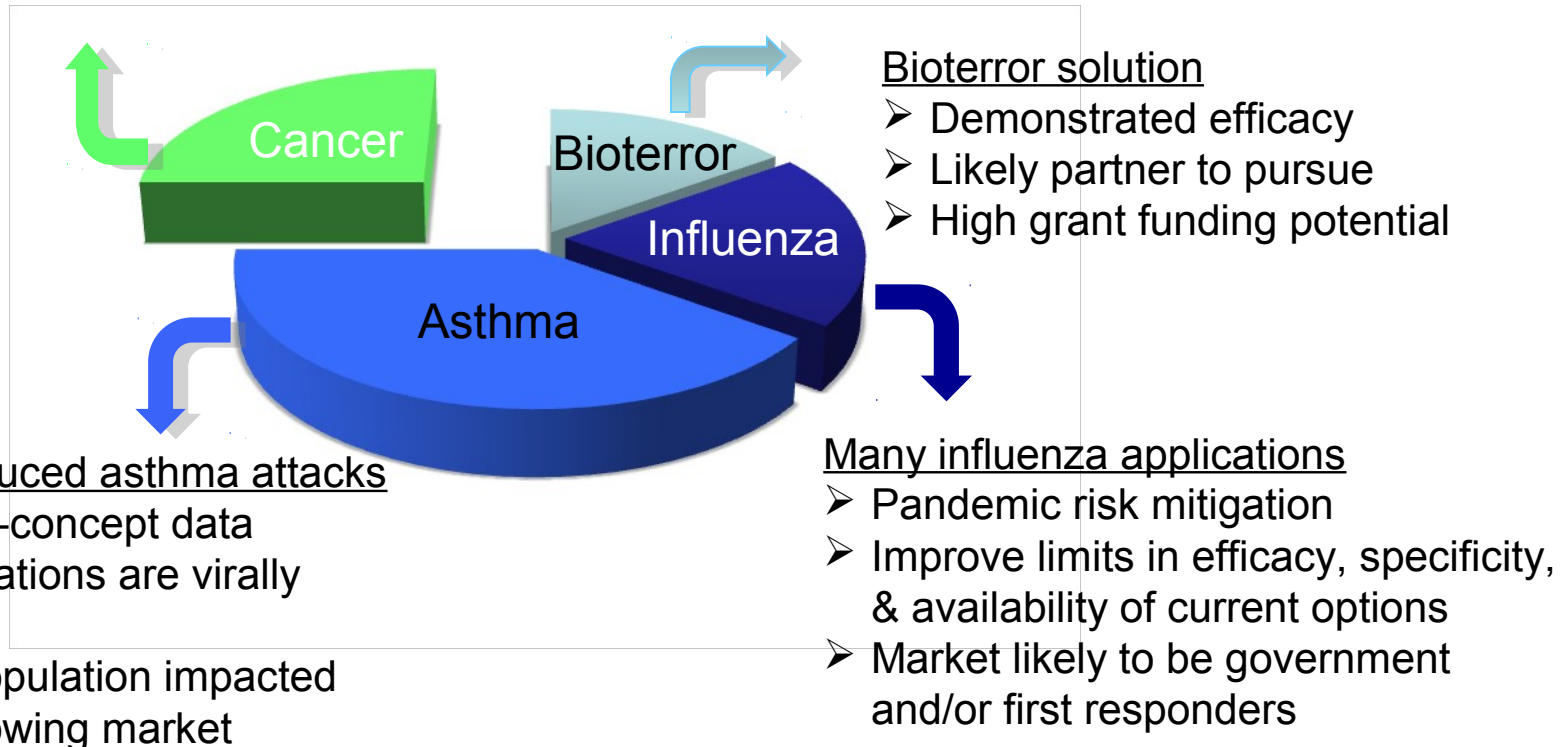
## Why It's Needed

- Current significant unmet need to prevent respiratory infections
- Single product effective against all major classes of pathogens
- Does not require the adaptive immune system
- Fast acting – immediate protection

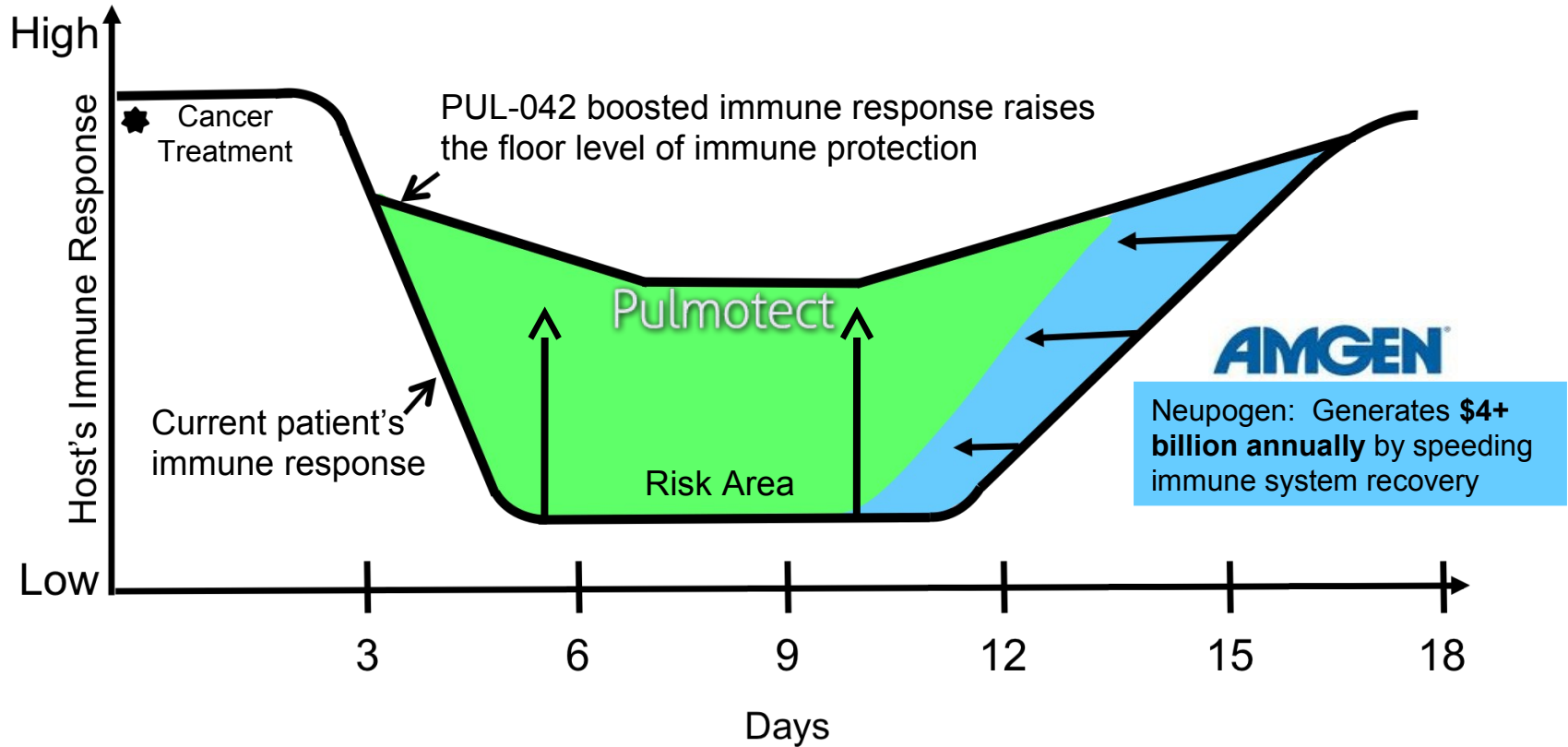


## Point of entry – Prevention of Pneumonia in Immunosuppressed Patients

- Leukemia - \$500 M primary market potential
- Multiple other cancer markets
- Significant unmet need
- Neupogen earns \$4+ billion accelerating immune system recovery
- Well-defined target – relatively low trial costs

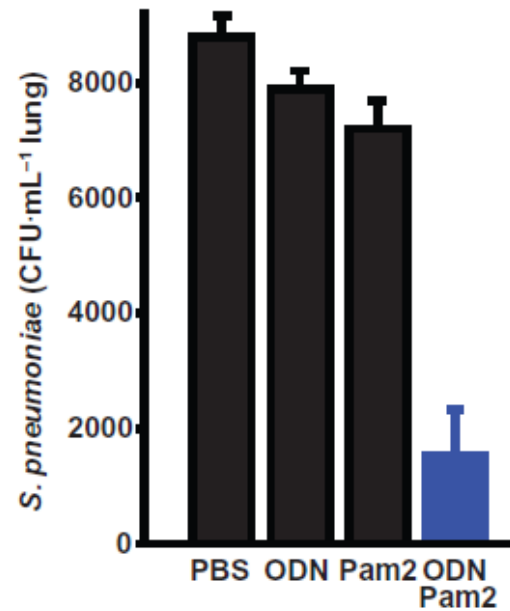
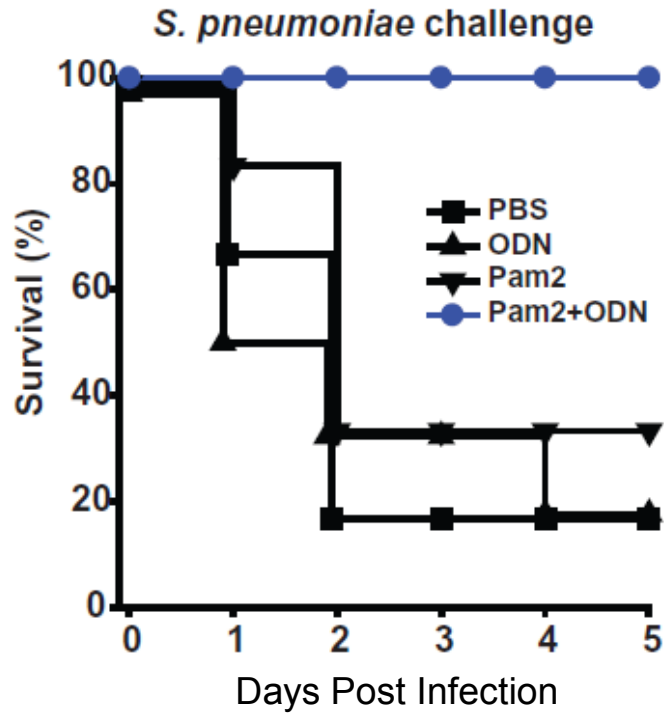


# Primary Indication to Reduce the Risk Area for Patients Undergoing Chemotherapy



Mice do not die...

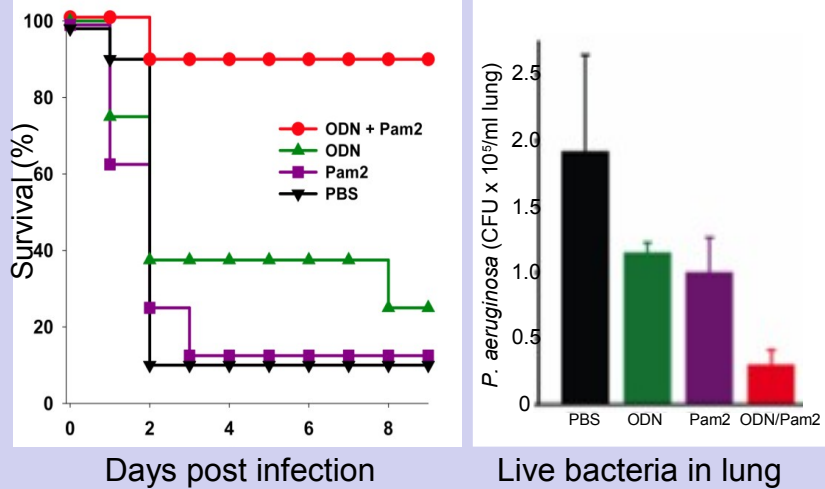
...but the pathogen does



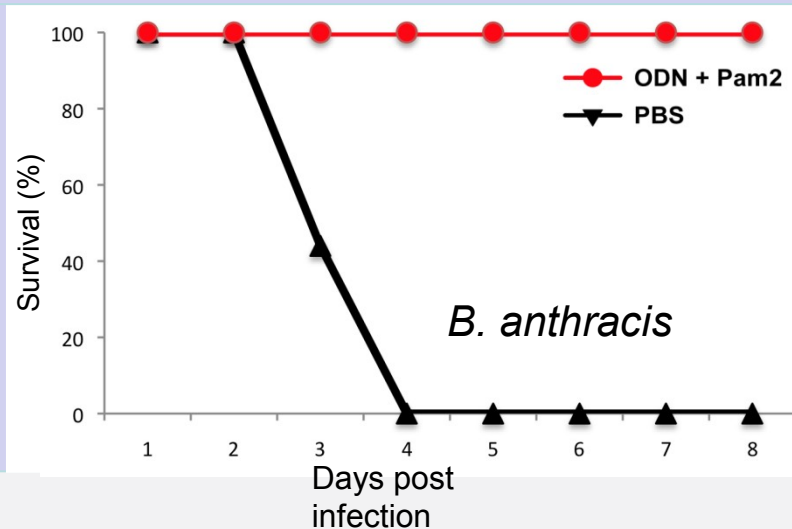
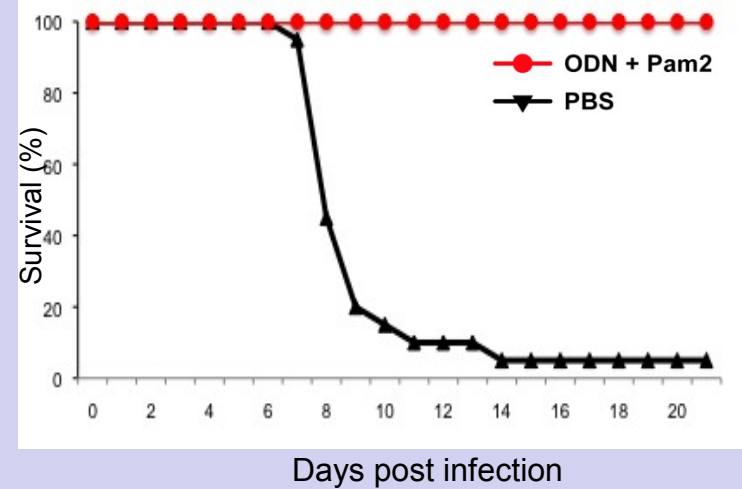
Duggan JM, *J Immunol* 186:5916, 2011

## Efficacy Against Every Pathogen Tested

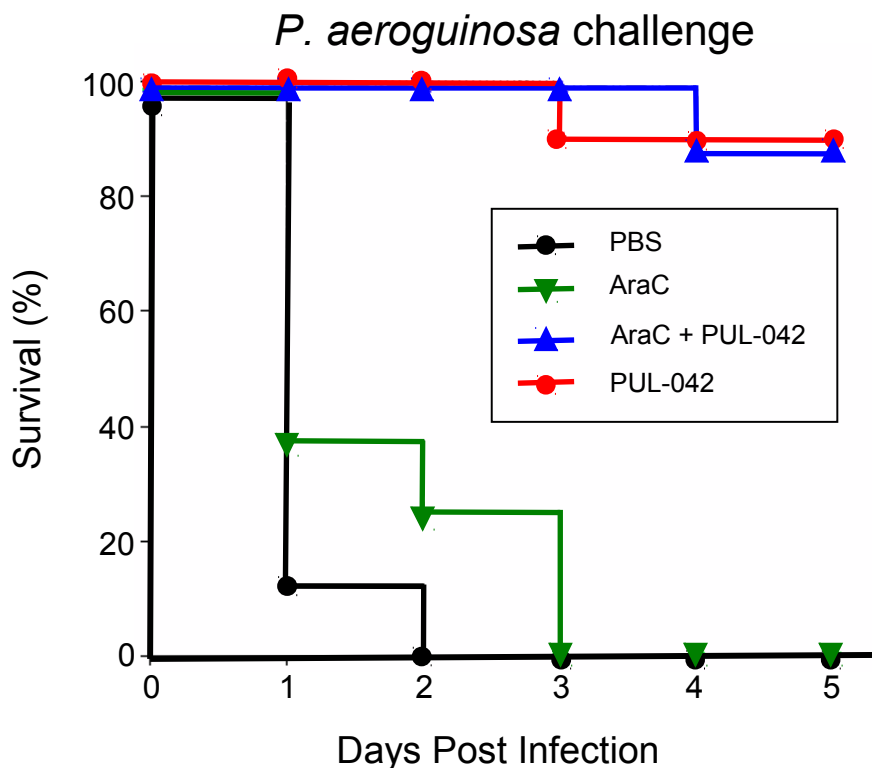
*P. aeruginosa*



Influenza A

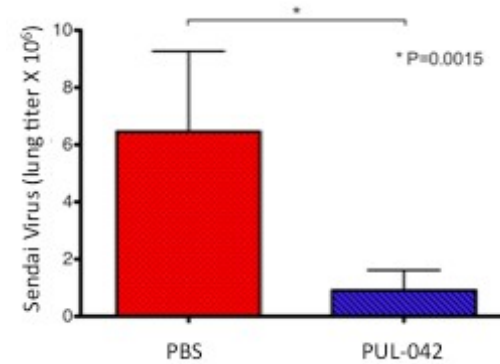


- MRSA
- Cowpox
- Smallpox
- *Y. pestis*
- *K. pneumonia*
- *S. pneumonia*
- *A. fumigatus*
- *F. tularensis*

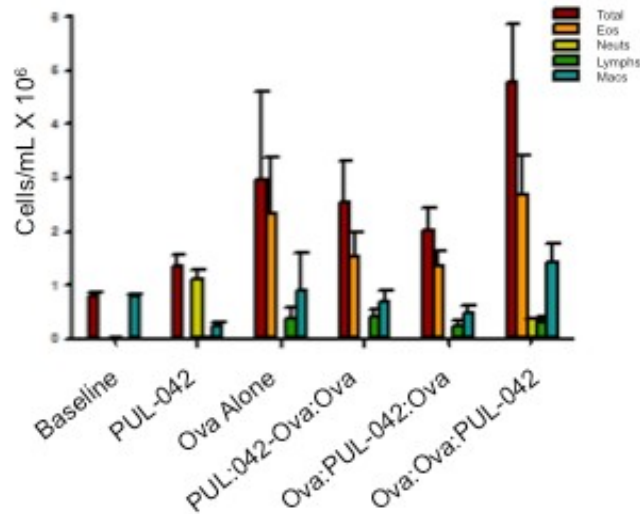
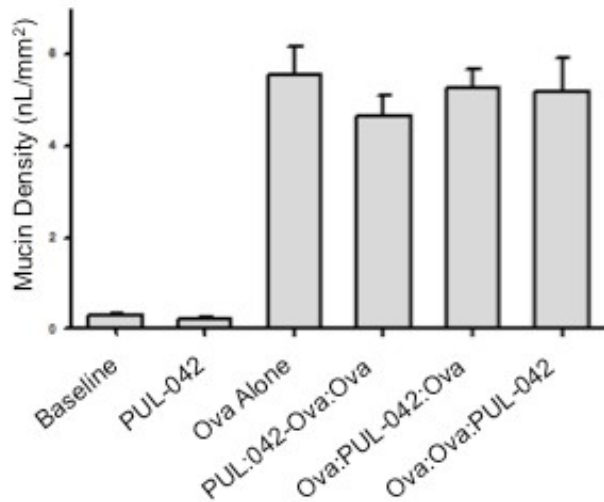


Neutropenia in mice caused by administering 1 mg/kg of cytosine arabinoside on days -8, -5, -2, and -1

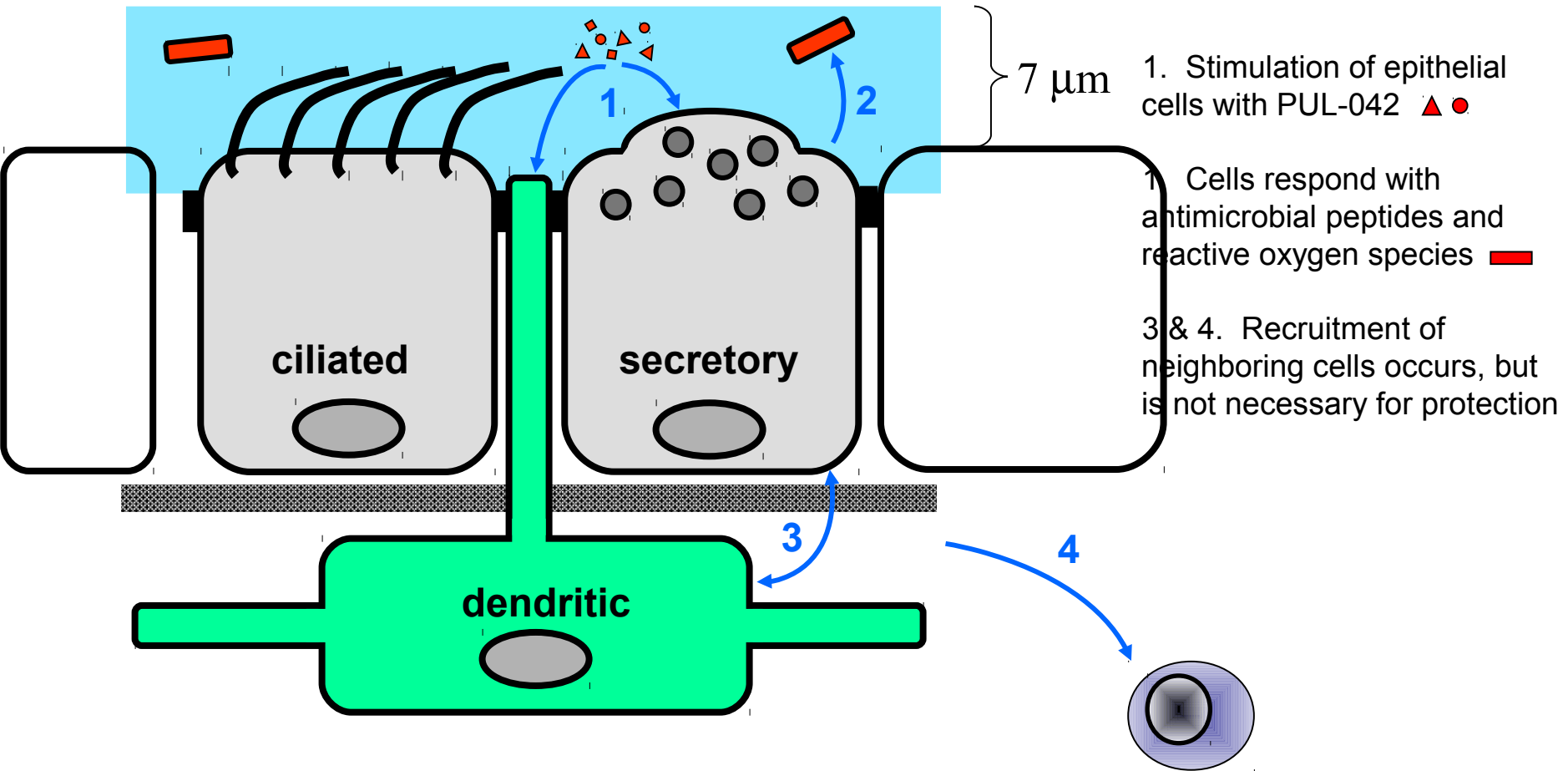
PUL-042 prevents infection of Sendai paramyxovirus in live guinea pig models...



...and mice show no augmentation of mucous metaplasia or eosinophilic infiltration when PUL-042 is given before, between, or after the asthma phenotype is induced.







Evans SE, *Annu Rev Physiol* 72:413, 2010

- Broad patent coverage (filed)
- Patent application No. PCT/US2010/028658
- Provisional converted in March, 2010; Nationalization September, 2011; Positive Office Action received Q3, 2012.
- Freedom-to-Operate analysis conducted by Fulbright & Jaworski
- Council provided by Fulbright & Jaworski, Bracewell & Giuliani, and George Gould (experienced/independent council)

Licensed from Texas A&M and the  
University of Texas M. D. Anderson Cancer Center

## Science Achievements

- Reproduced in three animal species, multiple infection models, and seven labs
- Efficacy against every pathogen tested
- Well-published peer-reviewed science
- Formulation developed for human use
- Non GLP toxicity studies completed

## Financial Achievements

- Successful grant and equity fund raising track record
- Funding available through Phase II clinical trial for cancer indication

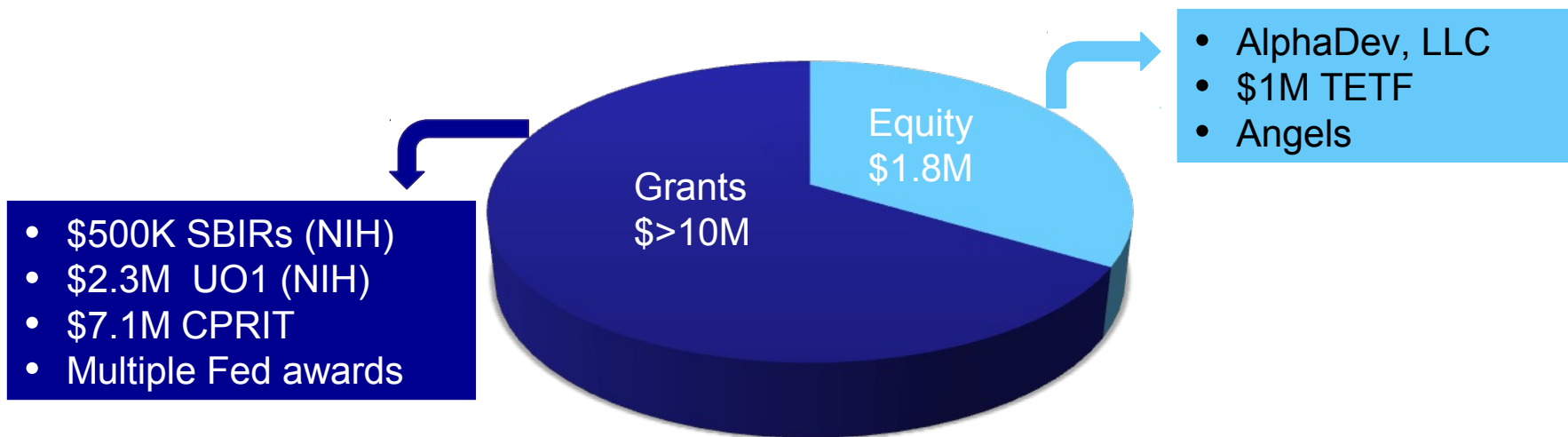
## Market Achievements

- Strong ongoing strategic partner interest (details available under CDA)
- Identified and validated unmet need
- Clear point of entry validated

## Regulatory Achievements

- Favorable Pre-IND dialogue with the FDA
- Remaining IND-enabling studies noted as “acceptable” by the FDA

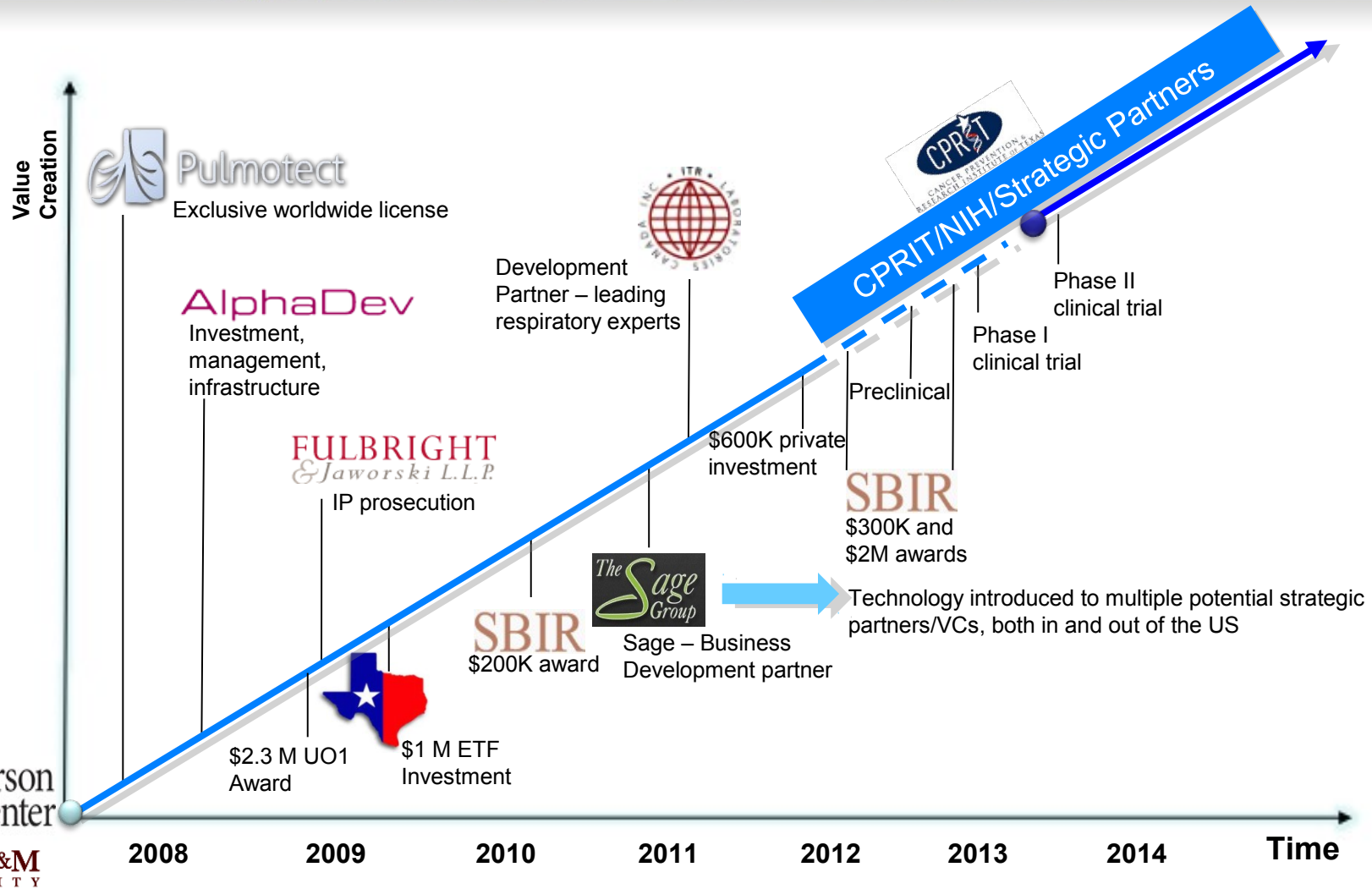
Total Funding: >\$12 M



\* Leveraging equity investments over 80%

Submitted/Planned Proposals:

- \$2M Phase II SBIR favorably reviewed and scored an 18 (cancer)
- \$5 M tPPG (asthma)



# Contact Information

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