bio superior

Our mission is to revolutionize pulmonary care and save lives by curing lung disease.

We are shifting the course of action from management, to cure and repair.

Contact Information

Russ Lehrman, PhD
Los Altos, CA 94024
650.969.0206
russ@bio-superior.com

Industry

Biotherapeutics/Respiratory Disease

Development Stage

Preclinical

Year Founded

2017 (major company pivot 2019)

Size of Team

4

Funding

NSF I-Corps Grant:
#1917312
March of Dimes Grants:
#23-FY20-221
#23-FY21-12
NSF SBIR Grant:
#2210373

Patents

US 8,420,080 'Methods For Treating Adult Respiratory Distress Syndrome.' (license)
PCTUS21/55333 'Surfactant Treatment Compositions.'
05/05/2022 Provisional filing, gene therapy

Law Firm

Morrison Foerster LLP

Website

www.bio-superior.com

Russ Lehrman
CEO

A Word From the CEO

Watching someone struggling to breathe is a harrowing thing to see. BioSuperior, a therapeutics company, is innovating new treatments for serious respiratory disease in preterm infants and adults.

Our passion is driven by personal experience. One of my nephews, Everitt, was born at 7 ½ months and because he was preterm, he developed Neonatal Respiratory Distress Syndrome (NRDS). My mother-in-law, Cindy, died in her mid-50s due to Acute Lung Injury (ALI). In both cases, a key substance called “lung surfactant” caused their illnesses. Everitt’s lungs were too young to make lung surfactant, and, in Cindy’s case, inflammation destroyed her lung surfactant.

Our team has tremendous experience in the complementary areas needed for developing new drugs and is backed up by advisors with long experience in respiratory R&D.

BioSuperior's goal is to revolutionize care, shifting the course of action from management, to cure and repair.

We invite you to join us in our endeavor to create life changing cures for lung disease.

The Problem

40%

Respiratory disease is the third leading cause of death, behind heart disease and cancer.

Each year in the United States, 200,000 adults develop Acute Respiratory Distress Syndrome (ARDS) and Acute Lung Injury (ALI). COVID has exacerbated these numbers. In addition, 60,000 preterm infants are born with Neonatal Respiratory Distress Syndrome (NRDS) and related illnesses, such as Bronchopulmonary Dysplasia (BPD).

About 40% of ARDS and ALI patients and more than 20% of babies suffering from BPD succumb to these diseases[1,2].

ARDS, ALI and NRDS are characterized by insufficient lung surfactant, a natural compound that coats lung tissue and enables proper lung function. ARDS and ALI patients have damaged, porous lung tissue, leading to loss of lung surfactant and fluid accumulation in the lungs.

Without proper treatment, patients suffocate.

1. Williams GW et al., Acute Respiratory Distress Syndrome. Anesthesiology (2021)
2. Lapcharoensap W et al., Hospitalization costs associated with Bronchopulmonary Dysplasia in the first year of life. J Perinat. (2020)

Infants with NRDS do not yet produce sufficient lung surfactant, which leads to inflammation and development of BPD.

$30B

In addition to the loss of life, **ARDS, ALI and NRDS are costing the U.S. healthcare system more than $30B**[3,4] **per year**. With COVID, the death toll and cost due to ARDS and ALI has risen exponentially. Growing exposure to smoke, smog and other environmental factors promise to compound these numbers even more.

There is no cure for these diseases, despite decades of research and serious investment.

3. Boucher PE et al., The Cost of ARDS. Chest (2021)
4. Beam AL et al., Estimates of healthcare spending for preterm and low-birthweight infants in a commercially insured population: 2008-2016. J Perinatol. (2020)

The Solution

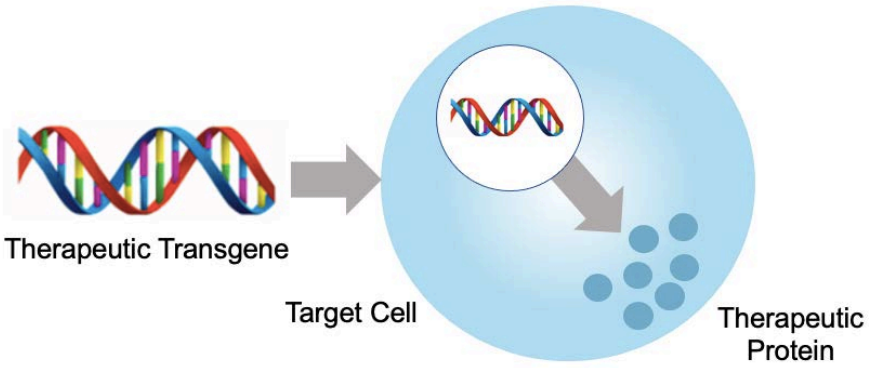
We are developing cost-effective, non-invasive, and easily accessible technologies to cure lung disease and repair damaged lung tissue.

Gene-delivered Therapeutic - Alveogene

We are developing a gene-delivered therapeutic, **Alveogene**, that halts disease progression and repairs damaged lung tissue in ARDS and ALI. Our gene therapy can be administered to the lung by itself or in combination with our bio-engineered lung surfactant.

Technology #1

Alveogene is a genetic construct that infects lung cells where a protein that repairs injured tissue is expressed.

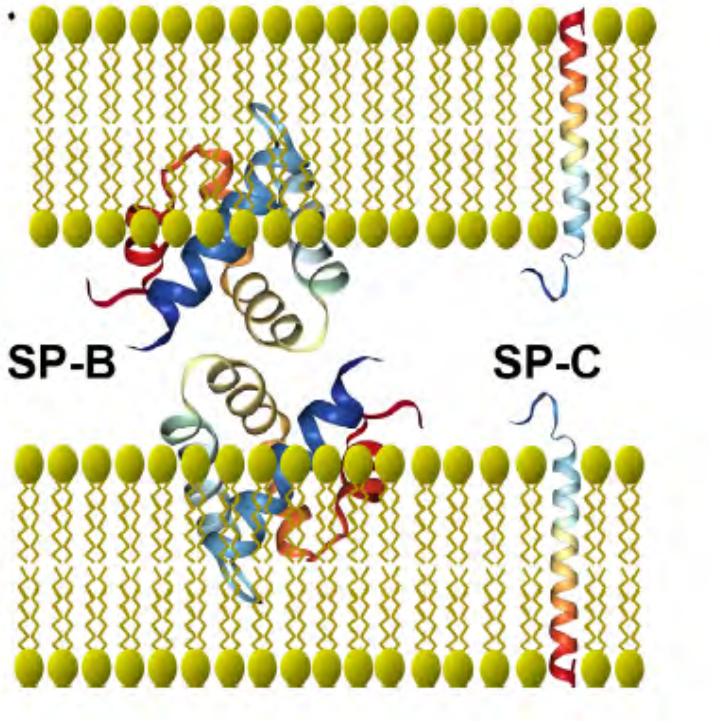


Technology #2

The composition of our synthetic lung surfactant is unique.

Bio-engineered Lung Surfactant - BioSURF™

We have bio-engineered a novel synthetic pulmonary surfactant prototype, **BioSURF™**, an essential biomaterial required for breathing. **BioSURF™** has direct therapeutic effects and will be used to deliver potent drugs that restore normal lung function. We have overcome key technical issues that have limited the efficacy of other synthetic lung surfactants.



Business Strategy

We will initiate clinical trials on our drug candidates, including Alveogene and BioSURF™. We will sublicense our candidates to strategic partners, who will help us complete clinical development and commercialize the products.

Beyond the pulmonary field, we expect that our technology platforms will be applicable to the treatment of other illnesses related to the microvasculature, including hemorrhagic stroke and chronic kidney disease. In the US, over 100,000 people die of hemorrhagic stroke[5] and 37 million are afflicted with chronic kidney disease[6] each year.

Progress to Date

Since the inception of the company, we have garnered more than $500,000 in funding, including grants from March of Dimes, NSF SBIR and I-Corps programs.

We have three patents that protect our gene therapy and synthetic pulmonary surfactant technology and have started animal model testing. We will raise additional funds to continue product development and conduct clinical trials for Alveogene, BioSURF™ and other product candidates.

5. US Department of Health and Human Services. How many people are affected by/at risk for stroke? https://www.nichd.nih.gov/health/topics/stroke/conditioninfo/risk/

6. Centers for Disease Control and Prevention. Chronic Kidney Disease in the United States, https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html2021

Our Team and Advisors

We are proud to be working with prestigious partners, key scientists and clinicians in respiratory medicine.

Russ Lehrman, PhD
President & Founder
Co-founder of SnapDNA.
Leadership positions at Nektar, NeTar, Pfizer
LinkedIn

Hong Zhao
Senior Director of Chemistry, Manufacturing and Controls.
Dalian Inst,, Elan Pharma, American Peptide Company
LinkedIn

Lucia Mokres, DVM
VP of Clinical and Regulatory Affairs, CMO EpiBiome,
Prin. Clin. Sci. Abbott Vascular
LinkedIn

Ehud Goldin, PhD
VP of Biology, R&D,
Weismann Inst., NGHRI, SENS, Research, Angular Medicine
LinkedIn

Columbia University
Cincinnati Childrens' Hospital
March of Dimes
National Jewish Health
National Science Foundation
Stanford University

Jahar Bhattacharya, MD, DPhil

Professor of Medicine
Division of Pulmonary and Critical Care,
Columbia University Medical College
LinkedIn

Jeffrey Whitsett, MD

Section Chief, Division of Neonatology,
Cincinnati Children's Hospital Professor,
University of Cincinnati Department of Pediatrics
LinkedIn

Elizabeth Redente, PhD

Associate Professor National Jewish Health,
Division of Cell Biology
Profile

James Bridges, PhD

Associate Professor National Jewish Health,
Division of Pulmonary & Critical Care
LinkedIn

John Patton, PhD

Co-founder of Inhale/Nektar
Founder of Dance Pharma
LinkedIn

FAQs

Why is now a good time to invest in the pulmonary care industry and BioSuperior?

New lung pathogens (e.g., COVID variants) and environmental problems (e.g., smoke inhalation from wildfires, military burn pits, etc.) will continue to increase the number of patients with serious lung illness.

In 2021, the number of patients dying from lung disease rivaled deaths due to heart disease and cancer. There is heightened public awareness of these new lung pathogens and environmental problems. Gene therapy is an exciting new treatment modality and has tremendous potential for the treatment of lung disease. And the use of lung surfactant to deliver lung therapeutics is expected to enable breakthroughs in the treatment of serious lung disease.

How will the funds be used and what are your immediate next steps?

We will use the funds over the next year to establish Alveogene, our gene therapy product candidate for the repair of injured lung tissue in Acute Respiratory Distress Syndrome (ARDS) and Acute Lung Injury (ALI). This gene enables lung cells to make a protein that is a key component of the “glue” that naturally adheres neighboring cells to form intact alveoli. We will test the ability of our gene therapy to repair lungs in animal models. In parallel, we will continue working on our prototype synthetic pulmonary surfactant, BioSURF™ through our secured grants.

What is unique about BioSuperior?

Our technology is unique as Alveogene has a unique mechanism of action for the treatment of lung disease. It is not an antiviral or anti-inflammatory therapeutic. Instead, the treatment targets tissue repair as demonstrated by fundamental science and animal studies. And gene has been shown to produce protein for months, much longer than other delivery mechanisms. Since our lung surfactant drug-delivery platform is synthetic, it will be scalable and useful in a number of applications.

All of our drugs are localized to the site of action, thus limiting toxic side effects.

What makes your team especially qualified?

Each member of the BioSuperior team has deep and complementary skills in lung biology, formulation R&D of lung products and product development. We are experienced at leading and working within teams that have developed innovative pharmaceutical products. Some of these have captured more than $1B in annual revenue.

Collectively, we have strong skills in understanding how to develop early-stage biotech companies and a strong network of pulmonologists, thought leaders in respiratory biology research, pharmaceutical scientists and business leaders who provide meaningful perspective and insight.

How will the products be sold and administered, how much will they cost compared to other treatments?

Following regulatory approval, the manufactured product will be sold to specialty pharma and ultimately shipped to hospitals. The drugs will be administered by clinicians (pulmonologists, respiratory therapists, nurses, etc.) by instillation or nebulization directly to the airway. Life-saving drugs administered by gene therapy capture premium revenue. Life-saving drugs delivered with bio-engineered lung surfactant are expected to be much less expensive than the current cost of care for infants suffering from Bronchopulmonary Dysplasia (BPD).

How will eligibility be determined and what will be the process?

BioSuperior will assess safety and efficacy in different patient populations through clinical trials and will seek approval based on this data. We expect our therapeutics to far exceed the current standard of care. This will motivate hospitals and insurance companies to list our drugs on their formularies.