Our Mission is to Revolutionize Pulmonary Care and Save Lives by Curing Lung Disease

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Contact Information
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Industry
Biotherapeutics

Development Stage
Preclinical

Year Founded
2017 (major company pivot in 2019)

Size of Team
4

Grant Funding: $606K
NSF I-Corps Grant: #1917312
March of Dimes Grants: #23-FY20-221, #23-FY21-12
NSF SBIR Grant: #2210373
Internal funding: $152K
Total funding: $758K

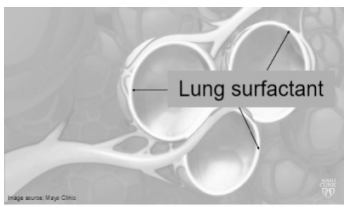
Current Raise
$2.5M for preclinical development of BioSurf leading to IND submission (mid-to-late 2024).

Patents
PCT/US21/55333 'Surfactant Treatment Compositions.'

05/05/2022 Provisional filing on a 2nd technology.

Law Firm
Brubaker Law LLC

Website
www.bio-superior.com



The Problem

Each year in the United States, 60,000 preterm infants are born with Respiratory Distress Syndrome (RDS) due to prematurity. Their lungs are underdeveloped and cannot produce a biomaterial known as lung surfactant, a critical fluid required for breathing. About 20% of infants suffering from RDS develop lung inflammation, known as Bronchopulmonary Dysplasia (BPD), which often results in death or lifelong health issues.

In addition to the human loss, BPD has a significant economic impact on Tier III/IV Hospital Neonatal Intensive Care Unit (NICU) centers. The median cost of care for BPD patients in their first year of life in NICU centers is over $377,000 and often exceeds $1,000,000[1]. These estimates do not include later hospital re-admissions, home healthcare support or disability accommodations for the survivors.

There is no cure for BPD, despite decades of research.

Animal-derived lung surfactants are currently used to treat preterm infants with RDS. These treatments do not significantly improve the health or survival chances of BPD patients and have important limitations including:

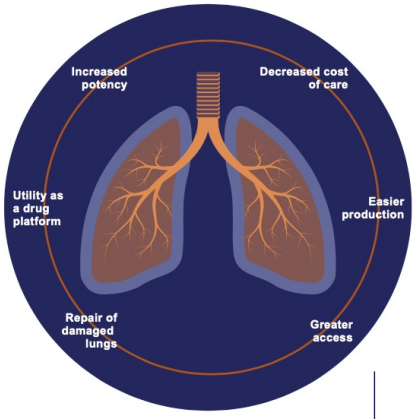
- Raising dedicated herds to harvest lung tissue is environmentally unfriendly and does not scale to meet the increasing scope of the disease.
- The current products require cold storage. This increases cost, limits distribution and therefore access to the medication.
- Animal-derived products pose an ever-present risk of contamination with dangerous pathogens.
- Although it has been clearly demonstrated that mixing lung surfactant with life-saving drugs significantly aids tissue distribution and the potency of respiratory medications, no treatments utilizing animal-derived lung surfactant have been approved.

These and other limitations have motivated a 20-year effort to replace animal-derived lung surfactants with bioengineered versions. Previous efforts have failed. The biggest roadblock has been the inability to make surfactant-specific proteins that are fully active.

BioSuperior stands alone in its ability to manufacture a scalable, stable, and safe bioengineered lung surfactant (BioSurf). We are combining BioSurf with an anti-inflammatory medication for the treatment of BPD.

Data source:

1. Hospitalization costs associated with bronchopulmonary dysplasia in the first year of life. Lapcharoensap et al., J Perinatol 2020 Vol. 40 Issue 1 Pages 130-137



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

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BioSuperior Team

Russ Lehrman
CEO & Founder
Co-founder of SnapDNA
Leadership positions at Nektar, NeXsar, and Pfizer

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

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

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

Advisors

Jeffrey Whitsett, MD
Section Chief, Division of Neonatology, Cincinnati Children's Hospital Professor, University of Cincinnati Department of Pediatrics

Elizabeth Redente, PhD
Associate Professor, National Jewish Health Division of Cell Biology

James Bridges, PhD
Associate Professor, National Jewish Health Division of Pulmonary & Critical Care

John Patton, PhD
Co-founder of Inhale/Nektar
Founder of Dance Pharma

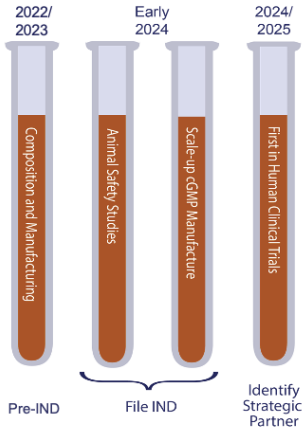
Our Solution

BioSurf is a novel synthetic pulmonary surfactant. It contains key components that closely match the structure and activity of a human natural surfactant. Due to its synthetic nature, it can be manufactured at scale, making it more accessible to a broader patient population than its animal-derived counterparts. **BioSurf** can be administered using the same protocol as products currently available on the market. No additional training is required. In addition to its core surfactant therapeutic value, a **BioSurf**-based pipeline of products can be developed to deliver potent drugs required to treat severe respiratory disease, such as IPF and adenocarcinoma.

Progress to Date and Milestones

We have overcome limitations in the manufacture of key lung surfactant ingredients. To date, the compounds other companies have made to address these limitations lack full functionality. We plan to file for Orphan Drug Designation (ODD) later this year, and our first IND in 2024.

Our virtual model, partnering with prominent contract labs and academia, allows us to develop our drug candidates efficiently. Once these drug candidates enter early-stage clinical development, we will sublicense them to strategic partners, who will help us complete clinical development and commercialize the products. Beyond **BioSurf**, the company plans to broaden its portfolio to Include **gene-delivered therapeutics** that will repair injured tissue, moving from managing to curing lung disease.



Funding

Since the inception of the company, we have garnered over $750,000 in funding, including grants from the March of Dimes and the National Science Foundation. We are raising an additional $2,500,000 to reach key preclinical milestones and filing of our first IND.

Prestigious Partnerships

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

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

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FAQ

Is now a good time to invest in the pulmonary care industry?
The post-COVID economic downturn has led to reduced investment in biotherapeutics. This is an opportunity for investors to reevaluate where their investments most effectively lead to the development of advanced treatments. We believe that one of the areas that will emerge from this reevaluation, and has already gathered heightened public awareness, is respiratory medicine. Lung-related deaths now rival deaths from heart disease and cancer, due in part to a significant increase in the number of lung pathogens and environmental problems (e.g., smoke inhalation from wildfires, battlefield exposure, etc.). In addition to human loss, lung disease has a significant economic impact on the healthcare system.

What is unique about BioSuperior?
BioSuperior has developed a first-in-class synthetic pulmonary surfactant - BioSurf. Our patent-pending product will be used to treat patients who cannot breathe due to surfactant deficiency. It will also be used to deliver agents to the lungs to reduce inflammation, promote lung repair and fight adenocarcinoma, pulmonary hypertension, and interstitial lung fibrosis. BioSurf can be manufactured at scale and in stable form, making it more accessible to a broader patient population than existing animal-derived products. Our first drug candidate will be be used for the treatment of Bronchopulmonary Dysplasia (BPD), an inflammatory disease that occurs in preterm infants.

What makes your team especially qualified?
Our team has the skills needed to develop innovative pharmaceutical products. Our collective efforts have resulted in products that have captured more than $1B in annual revenue. We also have a team of scientific advisors that are well-respected pulmonologists and neonatologists.

How will the funds be used and what are your immediate next steps?
Since the inception of the company, we have garnered more than $750,000 in early-stage funding, including grants from the March of Dimes and the National Science Foundation. With this money we have achieved the manufacture of our prototype surfactant. We are raising $2,500,000 to complete key preclinical milestones, which will allow us to file for Orphan Drug Designation (ODD) and an IND for our first drug candidate aimed at treating BPD.

How will BioSurf be sold and administered, how much will it cost compared to other treatments?
Following regulatory approval, our initial BioSurf-based treatments will be sold to specialty pharma and ultimately administered by pulmonologists (neonatologists, respiratory therapists, and nurses) using existing methods for administering lung surfactant. We will also work with drug device manufacturers who are adapting nebulization for the delivery of lung surfactant-based products. Specific to the treatment of BPD in infants, reduced NICU days will significantly reduce hospital costs. In addition, lower morbidity will lower the overall healthcare burden due to hospital readmissions and in-home medical support.

How will patient eligibility be determined and what will be the process?
BPD is diagnosed at 36 weeks post-menstrual age (PMA), but neonatologists can identify this developing illness within 14 days of birth. BioSuperior plans to conduct clinical trials to demonstrate that our product significantly reduces the number of preterm infants that develop BPD. We expect BioSurf to far exceed the current standard of care. Through publications in respected journals and symposia, we are confident that hospitals and insurance companies will decide to list our drug on their formularies.

What other products is BioSuperior developing?
Beyond our BioSurf-based pipeline of products, the company plans to broaden its portfolio to include a gene-delivered therapeutic that will repair injured tissue. This therapeutic, Alveogene, is an exciting new treatment modality and has tremendous potential for the treatment of lung disease. Together with BioSurf, Alveogene will allow us to move from managing to curing serious lung disease.