



Setting the new standard in regenerative medicine

Investor Presentation 2025

EXECUTIVE TEAM



Mark Adams
Co-Founder & Chief Executive Officer

Visionary entrepreneur with over 20+ years of CEO experience, who has founded, built, and sold or taken public several private and public companies in his career



Paul Tebbey, PhD
Chief Operating Officer

30-year veteran with deep technical, operational, and commercial experience in both pharmaceutical and biologic sectors. Multiple successful commercial launches at companies including Abbvie, Johnson & Johnson, and Wyeth/Pfizer.



John Vacalis, JD
President & Chief Legal Officer

20+ years advising start-ups and global institutions to achieve strategic initiatives across an array of legal areas including negotiations, investments, IP, and M&A



Tim Moseley, PhD
Chief Technology Officer

A leading development expert in stem cell science and extracellular vesicle (EV) technology with over 10 years of experience



Jeff Mims
Chief Financial Officer

Experienced CFO with over 25 years of experience in finance and operations across multiple different industries

3 out of 5 people are affected by overactive inflammation

1 Healthy inflammation is meant to heal and repair the body

- Infections
- Cuts & Lacerations
- Allergic Reactions
- Burns
- Chemical
- Irritants

2 But when healthy inflammation doesn't stop, it may become overactive or chronic

Chronic inflammation sends inflammatory signals to healthy tissue, causing cell death and tissue destruction

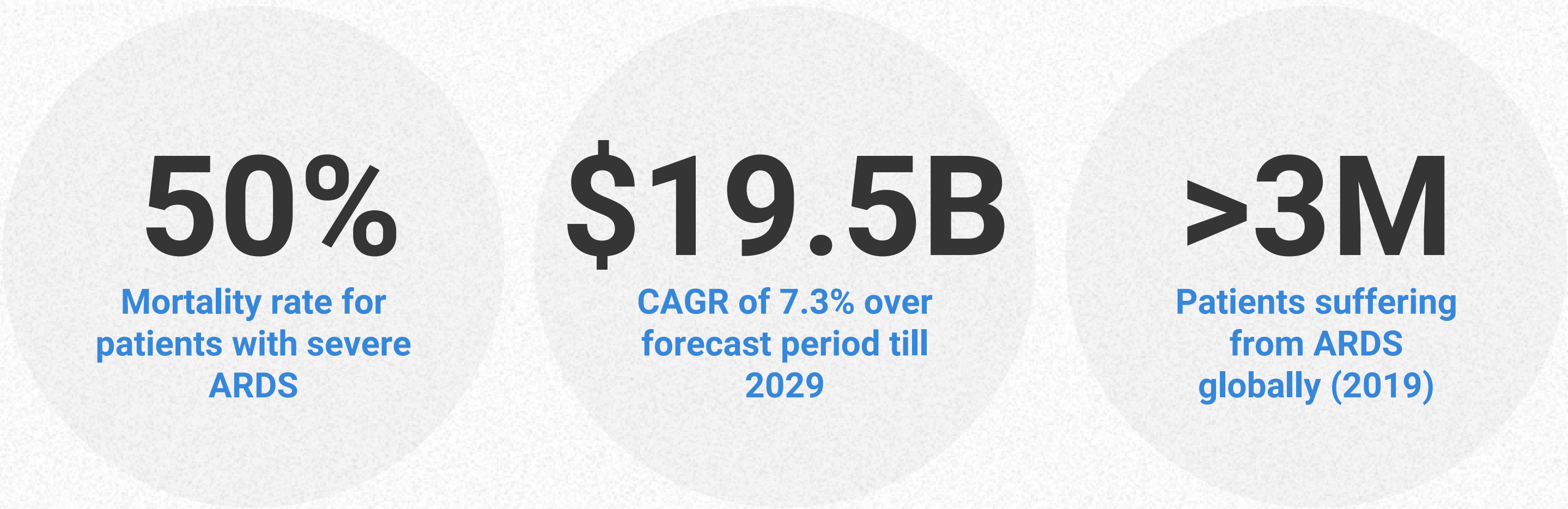
3 This may lead to a body ravaged by inflammation-based diseases

- Cardiovascular Disease
- Cancer
- Neurological Disease
- ARDS
- Rheumatoid Arthritis
- Autoimmune Disease

Acute Respiratory Distress Syndrome (ARDS) kills hundreds of thousands and costs billions every year

The cause of every ARDS related death is an inflammatory process that drives fluid into the lung and inflammatory deposits which cause scarring, or fibrosis. This fluid and fibrosis results in noncompliant lungs, meaning they can't expand to have adequate oxygenation, or breathing.

Today, there is no FDA-approved drug for ARDS



You can save millions of lives and win in multiple billion-dollar markets if you can modulate inflammation

ExoFlo™ has the potential to work for other indications in multiple billion-dollar markets

\$39.5 B

Global inflammatory bowel disease market (by 2031, with a 5.8% CAGR)

Source: [Growth Market Reports](#)

\$10.3 B

Osteoarthritis therapeutics market (by 2032, with 9.1% CAGR)

Source: [Market Research Future](#)

\$10.9 B

Crohn's disease treatment market (2022)

Source: [Coherent Market Insights](#)

\$8.2 B

Alopecia global market (2022)

Source: [Grand View Research](#)

\$12.9 B

Ulcerative Colitis market 2022)

Source: [Growth Market Reports](#)

ExoFlo by Direct Biologics

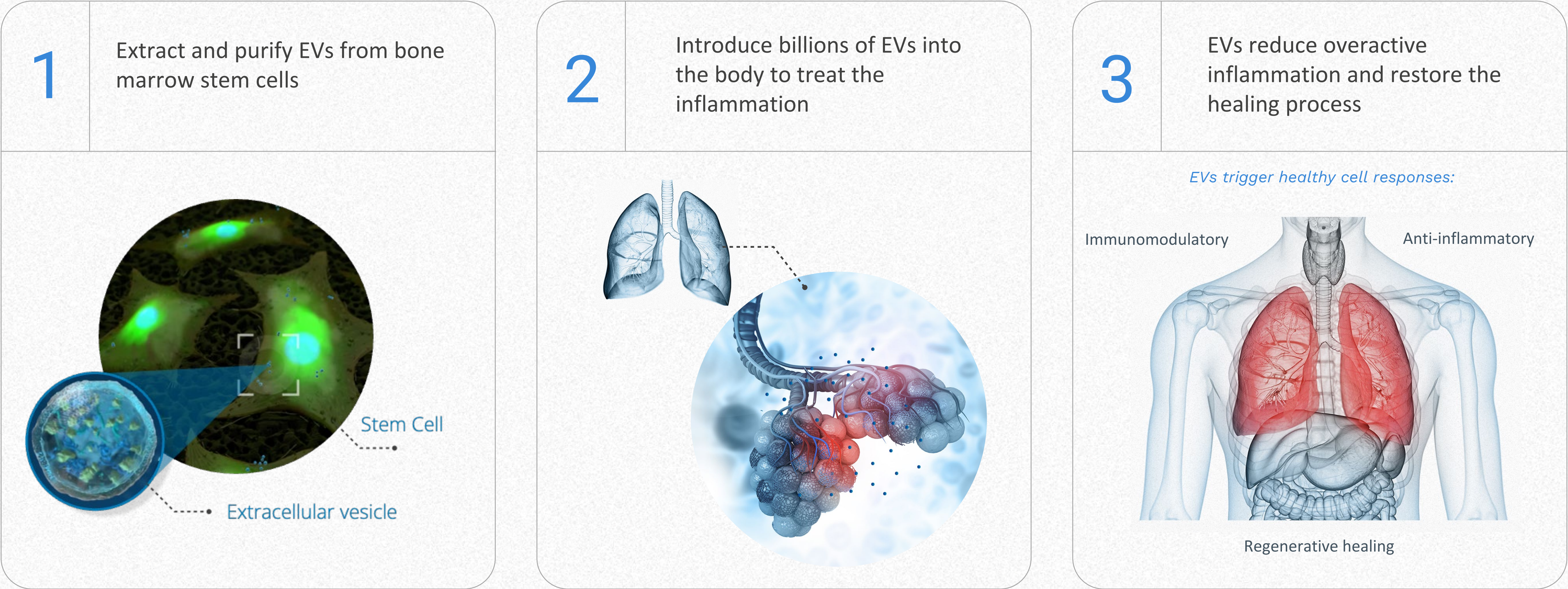
ExoFlo is an investigational product currently in clinical studies for the treatment of ARDS, IBD, and Transplant.



Direct Biologics harnesses the healing properties of signaling molecules to reduce overactive inflammatory response and restore the body's natural healing process through extracellular vesicles (EVs)

Example: Healing ARDS with extracellular vesicles

We're activating the body's natural response to inflammation at scale



EXOFLO



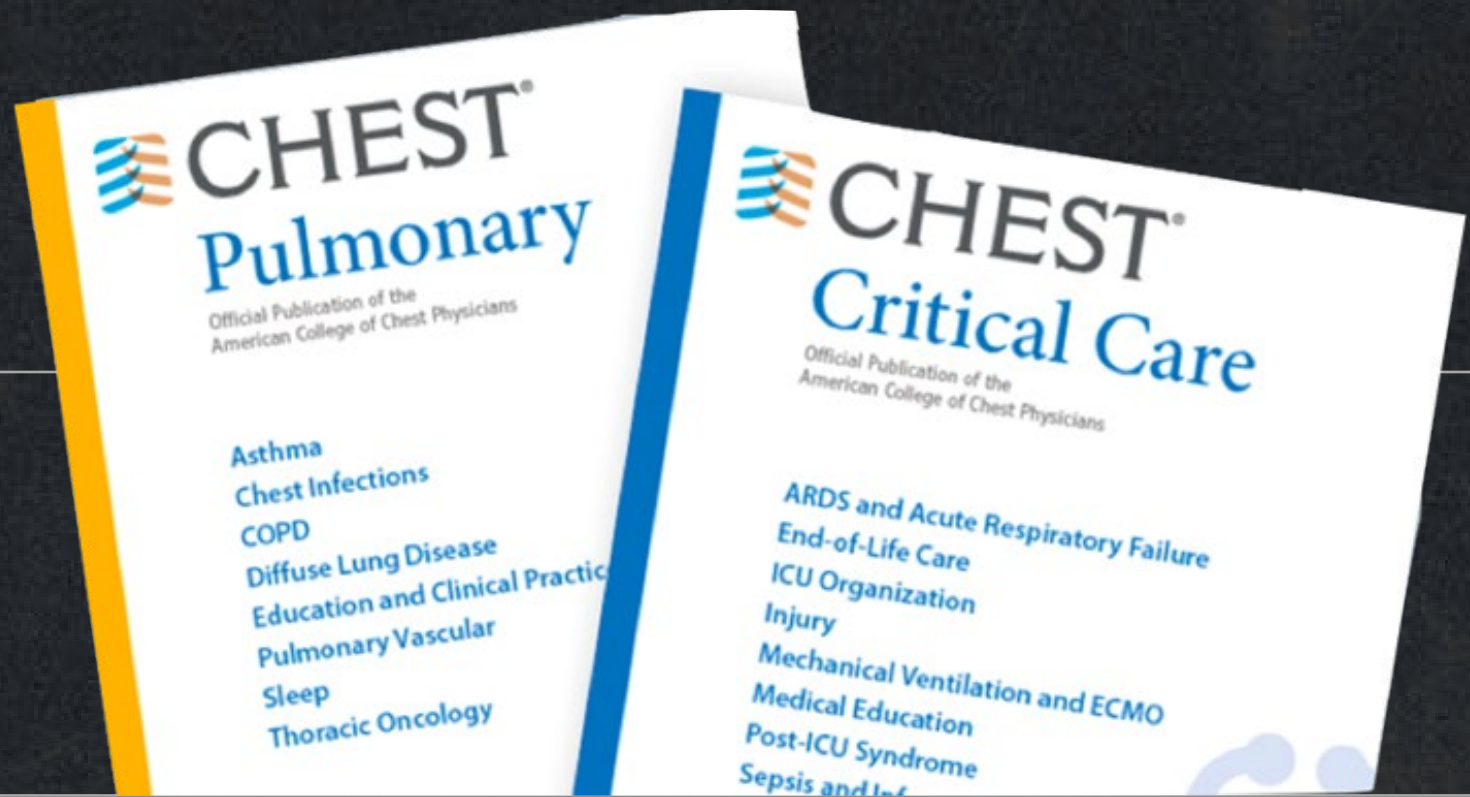
ExoFlo™ is currently being studied in clinical trials to treat All-Cause ARDS

During the COVID-19 pandemic, ExoFlo™ was designated a Regenerative Medicine Advanced Therapy (RMAT) by the FDA because of its potential as a life-saving drug for the treatment of ARDS.

RMAT is intended to expedite a life-saving therapy faster than any other pathway through the FDA approval process.

CONFIDENTIAL

PHASE II RESULTS



As published in Chest, a leading, peer-reviewed journal in pulmonology

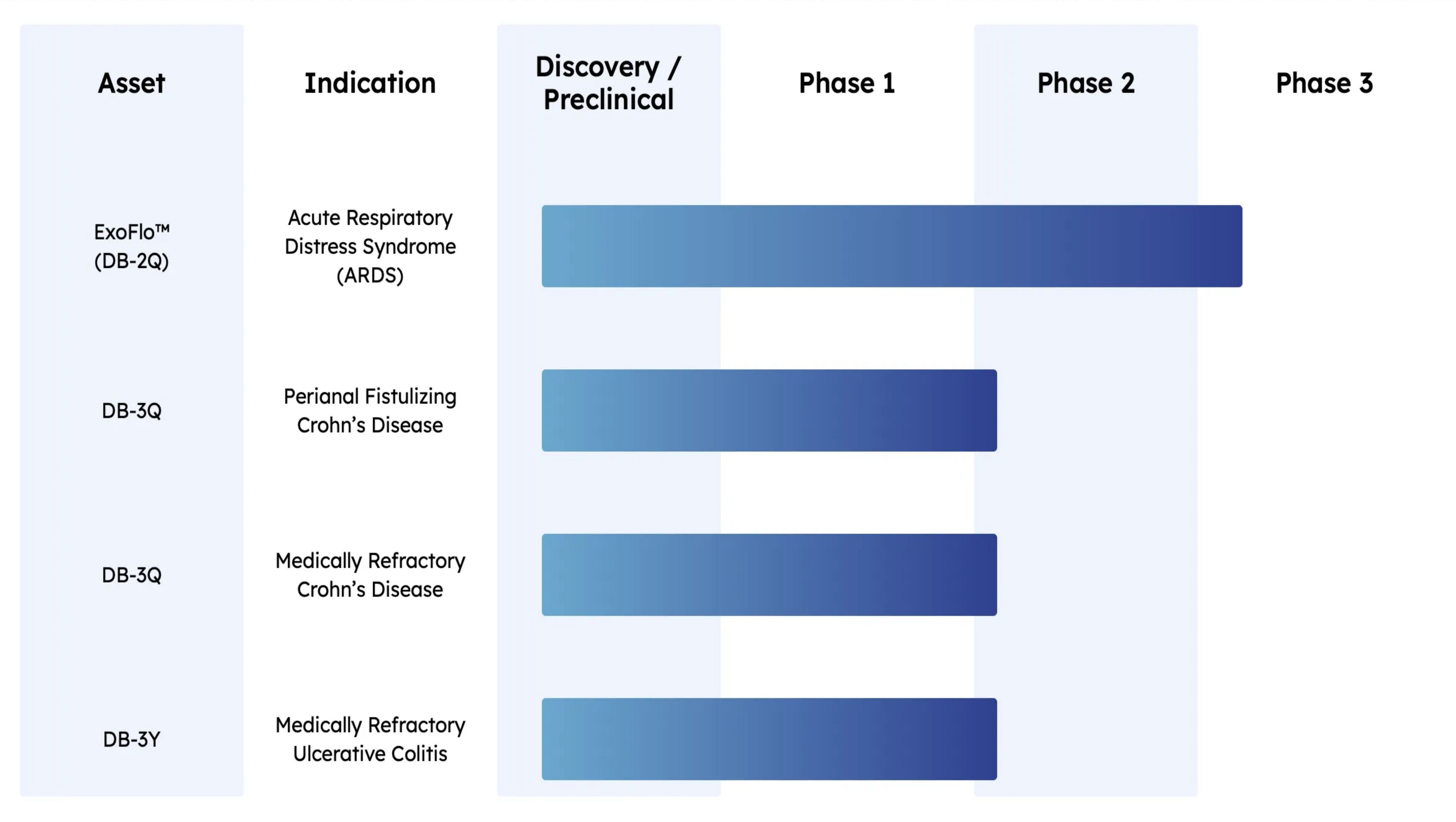
40% reduction in mortality: one of the most relevant phase II trial results in pulmonology

ARDS phase II clinical results for respiratory failure:

40%
Reduction in mortality

ExoFlo™ has demonstrated a positive benefit-to-risk profile in clinical studies performed to date.

Current Clinical Trials

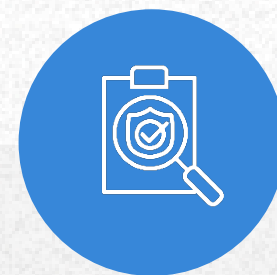


SCALABLE MANUFACTURING CAPABILITIES

Direct Biologics' proprietary EV technology is positioned to scale with global demand, including meeting the FDA's rigorous manufacturing requirements



cGMP manufacturing facilities across the US, including state-of-the-art R&D facilities and quality control labs in San Diego



Cell banks derived from healthy human donors are Good Tissue Practice compliant and have master drug files with the FDA



Treatment with cell derived EVs rather than cell therapy allows for minimal batch-to-batch variability as the product can be derived from a single donor rather than harvesting from multiple donors



Substantial progress in the development of proprietary technology capable of mass producing ExoFlo™, significantly increases the yield of EV production while simultaneously reducing manufacturing costs



Robust patent and trade secret portfolio protecting IP extensively in the US and in select jurisdictions throughout the world

Direct Biologics already has substantial cGMP manufacturing capabilities and clinical experience with ExoFlo™ in multiple diseases established during the FDA's discretionary enforcement period for certain regenerative medicines

Strong Intellectual Property Defense Strategy

Direct Biologics works to maintain its competitive position by utilizing a multilayered approach that includes filing and prosecuting US and foreign patent application and protecting proprietary know-how as trade secrets

Trade Secrets

Coupled with our patent protection, the company maintains trade secrets that further safeguard our technology and processes

Patents

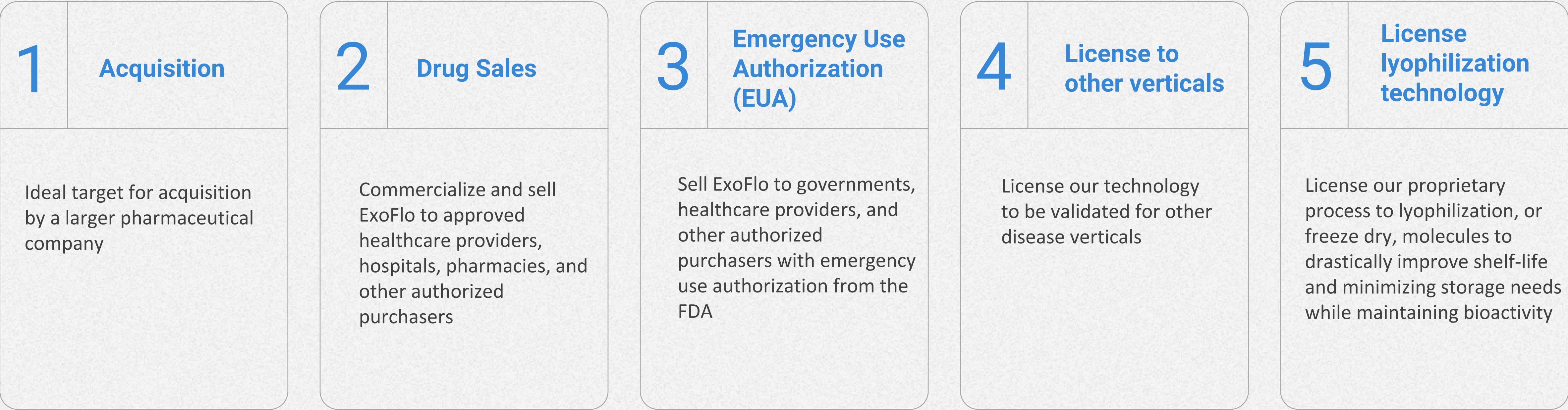
In order to protect our manufacturing process and delivery mechanisms across multiple disease states, we have a growing global portfolio of 25 different patent families which includes over 130 applications in 19 different countries.

DB leverages a firm globally recognized as the #2 intellectual property law firm for emerging companies and venture capital to manage our patent portfolio. We work hand-in-hand with leading experts in cell science to develop our proprietary process and technology platform.

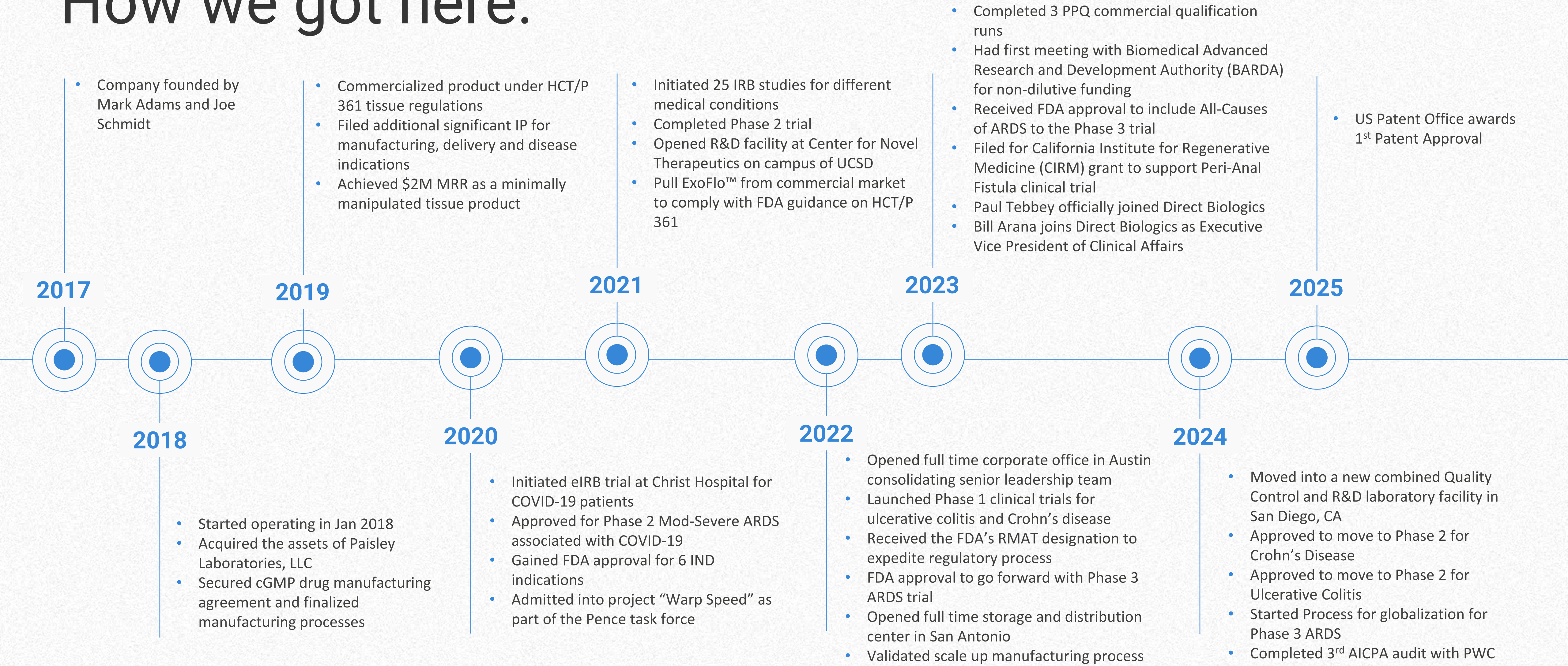
Objective is real time evaluation and patent protection of the Company's global IP position and preparation for a potential IPO or M&A transaction within the next 18 months. This includes, ongoing analysis of the company's:

- (1) Patent estate (Scope of protection, patentability, ownership, prosecution strategy)
- (2) Freedom-to-Operate / Patent Landscape Analysis regarding relevant third party patents and identification of FTO risks
- (3) Preparation of legal opinions regarding FTO, noninfringement or invalidity of third party patents identified in FTO analysis

Multiple potential paths to return shareholder value



How we got here:



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Thank you

CONTACT

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