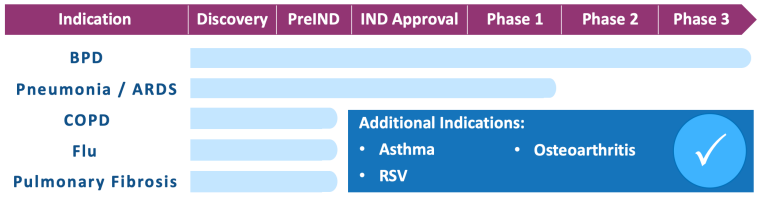
Airway Therapeutics, based in Marietta, GA, is a clinical-stage biopharmaceutical company advancing a new class of biologic therapies to drive a step change in the prevention and treatment of respiratory, inflammatory, and infectious diseases, across all age groups.

Our Platform:

Zepultide alfa is a first-in-class recombinant protein that replicates the structural and functional biology of native SP-D, a protein that modulates the immune response, regulates inflammation and aids in pathogen clearance.

- **Immunomodulation:** Regulates TLR4 signaling and cytokine release to reduce inflammation and prevent tissue damage.
- **Immune Defense:** Facilitates the recognition of bacteria, viruses, and fungi through pathogen associated molecular patterns (PAMPs), promoting opsonization and rapid clearance by immune cells before infectious diseases can spread.
- **Surfactant homeostasis**: Recycles alveolar lipids to maintain lung compliance.

Pipeline:



**BPD= Bronchopulmonary Dysplasia; ARDS = Acute Respiratory Distress Syndrome; COPD = Chronic Obstructive Pulmonary Disease; RSV = Respiratory Syncytial Virus*

Our Lead Indication:

Bronchopulmonary Dysplasia (BPD) is a chronic lung disease in very preterm infants requiring prolonged respiratory support. It results from lung immaturity, low SP-D expression, ventilator and oxygen injury, inflammation, and infections, leading to impaired lung development, poor gas exchange, and long-term complications including neurodevelopmental delays.

BPD Key Facts and Market Opportunity:

- **Epidemiology:** Affects ~50% of neonates <28 weeks gestational age (~600,000 neonates at risk annually).
- **Unmet Need:** No approved therapies; current treatments unsuccessfully, prevent, manage symptoms or complications.
- **Economic Burden:** Mean hospitalization costs of ~$700,000 in the first year; prolonged stays drive billions in annual costs.
- **Regulatory and Clinical Progress:** Zelpultide alfa has Orphan Drug Designation in the U.S. and EU and is advancing into a pivotal seamless two-part **Phase 2b/3** trial.
- **Investor Opportunity:** Peak global sales for zelpultide alfa in BPD alone are estimated at $6B. Well-positioned to rapidly penetrate NICUs through established clinical networks and lack of competitors.

Clinical Data:

Phase 1B Trial in Very Preterm Infants with BPD: Randomized, blinded, air-sham controlled study across 20 sites in the U.S. and Spain. Dosing initiated within 96 hours of birth and no later than 48 hours following intubation.

- **Cohorts:** Three gestational age cohorts in the 25–<29 weeks range and one in the 23–<29 weeks range, including three dose-escalation cohorts.
- **Safety:** Well tolerated; no dose-limiting toxicities. Mortality consistent with historical norms.
- **Efficacy Signals:**
  - 30% relative risk reduction in grade 2 or grade 3 BPD or death; no grade 3 BPD in treatment group.
  - Exploratory: 55% risk reduction among infants surviving >14 days.
  - Mechanical ventilation was reduced by 31% (8 fewer days) at 36 weeks postmenstrual age.
  - Hospitalization averaged 96 days in the first year versus 127 days for control.

Upcoming Milestones:

- Multinational, two-part pivotal seamless **Phase 2b/3** study for zelpultide alfa set to begin in Q4 2025.
- The **Phase 2b/3** trial will evaluate zelpultide alfa in two parts. In the first part (**Phase 2b**), dose optimization will be conducted in 150 patients to assess efficacy and safety across two dose levels versus placebo. The optimal dose will continue seamlessly into the second part of the trial (**Phase 3**), enrolling ~216 additional patients to confirm efficacy.

Leadership Team:

Marc Salzberg, M.D.
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