

Research Roadmap: Accomplishments To Date & Remaining Tasks

Manufacturing

- Scalable formulation with precise PLS NP QC^{1,*}
- Lyophilization of PLS NPs while preserving original properties^{2,*}

Surface Behavior Characterization

- Effect of PLS NP size properties³
- Structure of PLS NP monolayers using scattering techniques⁴
- Effect of polymer chemistry⁵ and T_g ⁶

In Vivo Proof of Concept

- Efficacy in mouse models of lung injury^{7,8,*}
- PK in mice⁹
- Parameters affecting delivery to alveoli¹⁰

Pre-IND Preclinical Studies

- Optimize PLS formulations
- Select a lead candidate(s)

IND-Enabling Preclinical Studies

- GMP manufacturing (CMO)
- Toxicology (CRO)
- ADME (CRO)

Human Clinical Trials

- Phase I(b)
- Phase II
- Phase III

Selected Publications/Patents

1. Fesenmeier et al., “Overcoming Limitations of Conventional Solvent Exchange Methods: Achieving Monodisperse Non-Equilibrium Polymer Micelles through Equilibration-Nanoprecipitation (ENP)”, *Journal of Colloid and Interface Science* 661, 861-869, **2024**.
2. Kim et al., “Excipient-Free Lyophilization of Block Copolymer Micelles for Potential Lung Surfactant Therapy Applications”, *International Journal of Pharmaceutics* 646, 123476, **2023**.
3. Fesenmeier et al., “Surface Mechanical Behavior of Water-Spread Poly(styrene)-Poly(ethylene glycol) (PS-PEG) Micelles at the Air-Water Interface: Effect of Micelle Size and End/Linking Group Chemistry”, *Journal of Colloid and Interface Science* 617, 764-777, **2022**.
4. Kim et al., “Electrocapillary Deformation of “Glassy” Polymer Micelles at an Air-Water Interface”, *Nano Letters* 26(32), 10867-10872, **2026**.
5. Kim et al., “Surface Pressure-Area Mechanics of Water-Spread Block Copolymer Micelle Monolayers at the Air-Water Interface: Effect of Hydrophobic Block Chemistry”, *Langmuir* 39(38), 13546-13559, **2023**.
6. Fesenmeier et al., “Effect of Temperature on the Air-Water Surface Mechanical Behavior of Water-Spread Block Copolymer Micelles”, *Soft Matter* 19, 9269-9281, **2023**.
7. Kim et al., “Polymer Lung Surfactants”, *ACS Applied Bio Materials* 1(3), 581-592, **2018**.
8. Fesenmeier et al., “Polymer Lung Surfactants Attenuate Direct Lung Injury in Mice”, *ACS Biomaterials Science & Engineering* 9(5), 2716-2730, **2023**.
9. Kim et al., “Pulmonary Pharmacokinetics of Polymer Lung Surfactants Following Pharyngeal Administration in Mice”, *Biomacromolecules* 23(6), 2471-2482, **2022**.
10. Jun et al., “Intrapulmonary Spreading of Pharyngeally Instilled Liquids: Impact of Nanoparticle Concentration and PEG Lubrication in Polymer Lung Surfactant Solutions”, *Molecular Pharmaceutics* 22(10), 5975-5988, **2025**.

* World-wide patents granted or in prosecution