Company Overview:

Cellastra Inc. is a private biotech company specializing in gene therapies that target scarring and adhesions, particularly in conditions such as pulmonary fibrosis and post-surgical recovery. Cellastra aims to revolutionize the treatment of tissue injuries through its patented gene vector technology, enabling long-term expression of anti-scarring peptides at injury sites.

Key Information

- **HQ**: San Francisco, California.
- **Industry:** Bio-Tech/Gene Therapy/Post-Surgery Recovery.
- **Investment Ask:** $25 million (Series A); $1-6 million upfront.
- **Investment to Date**: $350,000
- **Use of Funds:** Manufacturing, formulation, preclinical studies, GMP manufacturing, IND filing, and Phase 1-2 clinical trials.

Market Opportunity

- **Pulmonary Fibrosis:** Large patient population with no effective treatments, offering significant market potential.
- **Long COVID:** 60 million global cases, including 16 million in the US, with ongoing demand for effective treatment solutions.
- **Post-Surgical Scarring:** Millions of surgical procedures annually that could benefit from scarring prevention, including C-sections and breast implants.

Revenue Model

Projected revenues are expected to reach $2.5 billion by Year 4, driven by product sales of Fibrexa and Scarlexa post-regulatory approval. Emergency Use Authorization (EUA) for Fibrexa could initiate early revenue streams within a three-year timeline.

Competitive Advantage

- **Patented Technology:** Long-term, localized expression of anti-scarring peptides encoded via a gene vector, offering the prospect of a unique and highly effective solution.
- **Proven Safety and Efficacy:** Published, peer- reviewed robust preclinical results and a uccessful double-blind, placebo-controlled Phase 2 trial (138 pts) demonstrated excellent safety and significant improvement for the peptde (ensereptide) over placebo in 4/5 anti adhesion efficacy endpoints at 6 months s follow up. Strongly support the potential of Cellastra's vectors.
- **First-Mover Advantage:** No other competitors are currently using gene vectors for scarring prevention in this manner.

Current Status

- **Preclinical Studies:** Contracts for IND enabling studies in models of adhesion and scarring prevention, and pharmacology /toxicology studies, and manufacturing ready to be signed.
- **Clinical Trials:** Preparations for Phase 1-2 trials are in progress, with funds being raised to support all these efforts.

The Challenge

Scarring and adhesions after surgery, burns, and respiratory infections represent significant unmet medical needs. Current treatments fail to provide long-term benefits, particularly in preventing severe scarring in critical conditions such as pulmonary fibrosis and burn injuries.

Our Solution

Cellastra has developed a novel gene vector that encodes production of anti-scarring peptides directly at the site of tissue injury, with a potential to significantly reduce the formation of severe scars / adhesions. Published studies have demonstrated over 75% reduction in severe scars /adhesions using ensereptide, a lactoferrin sub peptide. However, further development of ensereptide was abandoned due to the short estimated biological half-life of only 1-2 days when formulated in a classic solution (hyaluronic acid). Cellastra has overcome this s problem by using a proprietary gene vector to encode continuous synthesis (for several months) of a long half-life ensereptide - analogue directly at the injury/ injection site. This technology opens new avenues to target tissue injuries, positioning Cellastra as a leader in this innovative and potentially revolutionary treatment approach.

Accomplished Milestones

- **2020:** Cellastra announced successful transfection after intramuscular administration of recombinant gene vector with successful long-term expression of antiscarring peptide ensereptide analogue.
- **2021:** Cellastra secured patent rights to the mutant AAV6.2FF vector via a license from University of Guelph, ON, Canada, (US Patent 10,806,802B2 (granted October 30, 2020).
- **2021:** Files in vivo expression data in mice with USPTO as a Continuation In Part (CIP) application.
- **2022:** Cellastra has obtained a Freedom to Operate declaration from an independent Health Science Law firm after their review of the patent landscape.
- **2023:** Meeting with NIH leaders, who expressed interest in Cellastra's proposed gene vector for treatment / prevention of Long COVID. We will revisit upon IND filing.
- **2024:** Granted US Patent 11,891,429 B2, expanding intellectual property rights and confirming robust gene vector performance in preclinical studies. Composition of matter, Broad range of recombinant vectors expressing lactoferrin and subpeptide analogues (with expected improved biological half-life).

Exit Strategy

Potential exit opportunities include acquisition by larger pharmaceutical companies following successful clinical trials or strategic partnerships to scale the technology across additional indications.