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, severe burns, or postsurgical sites. The technology uses a patented gene vector platform (Cellexa), enabling long-term expression of anti-scarring peptides mitigating scarring. Cellastra aims to revolutionize the treatment of tissue injuries by encoding long-term production of anti-scarring peptides at injury sites. Per FDA guidance, initial indications are limited to serious conditions. Initial formulations are Fibrexa (pulmonary) and Scarlexa (dermal).

Cellastra

Pioneering Targeted Scar and Adhesion Prevention at Wound Sites

Cellastra, Inc., 201 Spear Street, San Francisco, CA 94105 or visit cellastra.com

Key Information

- **HQ:** San Francisco, California
- **Industry:** Bio-Tech/Gene Therapy/Scarless Wound Healing
- **Investment Ask:** $1-6 million for proof of concept and pre-IND studies, then $25 million (Series A) for clinical trials. Investment to Date: self funded
- **Use of Funds:** Manufacturing, formulation, and proof of concept studies, followed by IND-enabling preclinical studies
- **Proposed Series A:** GMP manufacturing, IND filing, and Phase 1-2 clinical trials.

Market Opportunity

- **Pulmonary Fibrosis:** Large patient population with no effective treatments; includes patients with infections (e.g., Long- Covid, other virus), toxic insults, and idiopathic causes.
- Burns: About 400,000 fire or burn injuries with 30,000 hospitalizations in US annually including some 10,000 extensive or deep burn cases requiring surgery
- **Post-Surgical Scarring:** While not an initial indication, millions of surgical procedures annually could benefit from scarring prevention, including C-sections and breast surgery.

Revenue Model

Projected revenues could reach the billions but are restricted by indication(s) sought and need to limit patient exposure to gene therapy pending short-term and long- term safety data. FDA currently expects up to several thousand patients to be exposed annually to individual cell or gene therapies. No revenue is expected from this offering for pre-IND studies.

Competitive Advantage

- **Patented Technology:** Long-term, localized expression of proprietary anti-scarring peptides encoded via a proprietary gene vector, offering the prospect of a unique and highly effective solution.
- **Proven Safety and Efficacy:** Published, peer-reviewed preclinical results and a double-blind, placebo-controlled Phase 2 trial (138 pts) demonstrated safety and significant clinical hand improvement for the peptide (ensereptide) over placebo in 4/5 anti-adhesion efficacy endpoints at 6- month follow-up.
- **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, pharmacology-toxicology studies, and manufacturing are ready to be signed.
- **IND Preparation:** IND preparation has started; need POC and pharmacology studies completed and one GMP batch of drug to submit
- **Clinical Trials:** Preparations for Phase 1-2 trials are in progress with protocols drafted.

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 demonstrated over 75% reduction in severe scars /adhesions using ensereptide, a lactoferrin subpeptide. However, further development of ensereptide was abandoned due to the short estimated biological half-life of only 1-2 days for a hyaluronic acid formulation. Cellastra overcame this 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 (administration) 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 long-term expression of anti-scarring ensereptide analog.
- 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: Cellastra files in vivo expression data in mice with USPTO as a Continuation In Part (CIP) application.
- 2023: Cellastra meets 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 company following (1) an open IND or (2) successful Phase 1/2 clinical trials
- Strategic partnerships to Phase 2-3 trials, marketing