CELLASTRA BUSINESS PLAN

SEPTEMBER 2023

EXECUTIVE SUMMARY

Cellastra Inc., a developer of disruptive gene therapies, is a private biotech company based in the San Francisco Financial District, founded and managed by proven industry executives with a long track record of successful drug development and commercialization.

Cellastra's mission is to develop novel treatments using gene vector enabled production of anti-scarring peptides at sites of tissue injury after respiratory infections, surgery, and burns. Cellastra is currently focused on two global unmet needs: 1) prevention of pathological or excessive scarring and adhesions after surgery and burn injuries and 2) prevention and treatment of pathological tissue damage and fibrosis in lungs or other internal organs after respiratory infections such as COVID-19.

Cellastra's Proprietary Technology

Cellastra is developing a potentially revolutionary technology platform (CELLEXA^{TM}) using an encoded gene vector to turn on the production of a human natural lactoferrin-derived anti-scarring peptide (Ensereptide). These proprietary analogues contain an Fc tag enabling greater expression in vivo and prolonged systemic half-life, both major advantages. The gene vectors enable continuous long-term expression of the peptide at injury sites in the lungs after respiratory infections such as COVID-19 and Respiratory Syncytial Virus (RSV) and in the skin after surgery and burn injuries. The peptide may provide anti-scarring effects through several mechanisms:

a) Broad antimicrobial effects potentially mitigating an initial virus infection as well as secondary bacterial or fungal infections.
b) Anti-immune effects: Prevent an excessive immune response ("Cytokine storm").
c) Anti-fibrin effects: counteract excessive fibrin deposition in micro-capillaries with subsequent tissue damage and scarring/fibrosis. Fibrinolysis also helps breaking down existing thrombi and splitting fibrin and fibrinogen to degradation products with well-known viscosity reducing, ,anticoagulant and anti- platelet aggregation effects, which may improve microcirculation help prevent new thrombi.
d) Anti-fibrotic effect: the mechanisms above may facilitate smooth and rapid wound healing with less fibrin deposition and scar formation both in the interior tissues and in the skin.

The four mechanisms above may be harnessed in three areas of huge unmet medical need:

1. *Respiratory infection* such as the current COVID-19 or future pandemics or outbreaks of Respiratory Syncytial Virus (RSV), where it may prove to be an important complimentary weapon to prevent acute and long-term complications of COVID-19 ("Long COVID") by mitigating tissue damage and fibrosis in lungs and other organs when the gene vector is inhaled or injected intramuscularly.

2. *Scarless wound healing after surgery* by preventing excessive dermal scarring and adhesions with great unmet needs in women's health and aesthetic surgery in indications such as breast implant, C-section, and hysterectomy when applied in the wound area before wound closure. Intramuscular administration could potentially prevent intra-abdominal adhesions, reported in a majority of patients after abdominal or gynecological surgery.

3. *Burn injuries:* Cellastra has recently joined Center for Advanced Medical Products (CAMP), a Swedish government funded consortium exploring new treatment modalities in burn injuries. This

is a patient group where hypertrophic and stigmatizing scarring remains an unresolved problem in 70% with often life-long suffering.

Thus, scarless wound healing can be achieved using a gene vector encoding for endogenous continuous production of anti-scarring peptides at the site of injury. Three formulations of gene vectors are being developed:•

Virlexa ™ gene vector for inhalation by patients with **COVID-19**: Inhaled (once on Day 1 within 5 days of positive COVID test) into the lungs by recently exposed patients in high-risk groups to prevent severe disease with acute respiratory distress syndrome (ARDS), and pulmonary /multi-organ tissue damage, and fibrosis. The vector may also be administered as an intramuscular injection as a booster on Day 1 in patients with evidence of involvement of other organ systems than the lungs to enable long term protection for many months. Virlexa will separately also be evaluated as a potential treatment of long Covid.

Scarlexa™ gene vector for injection after Surgery: Applied (once) into or under the skin before wound closure.

Burn Injuries: Scarlexa™ gene vector for injection is mixed with a suspension of autologous skin cells from the patient. The suspension may contain cultivated keratinocytes (or cells obtained with a RECELL device) from the patient and transfected with the Scarlexa gene vector in the laboratory ("in vitro") and then sprayed back on the wound.

Proof of Concept Studies

This proprietary technology is built and expands upon a foundation of scientific Proof of Concept Studies of the anti-scarring peptide ensereptide and the novel gene vector AAV6.2FF (see below).

Ensereptide

Swedish scientists discovered that certain polypeptides derived from human lactoferrin have potent anti-scarring properties (Nilsson et al. 2009). The most potent of these was ensereptide (PXL01), a synthetic lactoferrin sub-peptide with 25 amino acid length. Laboratory studies ("in vitro") demonstrated potent anti-immune, anti-fibrin, and anti-microbial effects. Furthermore, this peptide was found to disrupt excessive scar and adhesion formation in preclinical studies in animals (Nilsson et al. 2009) and clinical Proof of Concept Studies in patients (Wiig et al. 2014).

The attempts developing ensereptide for scar prevention was hampered by rapid excretion from the kidneys making it difficult to achieve durable concentrations in blood plasma and tissues from the short exposure time after a single topical or subdermal application after surgery. Thus, the Swedish investigators used hyaluronic acid as a solvent to slowly release the peptide over several days or potentially longer, as the benefit of a single dose administration was shown up to the 6-month endpoint in a double-blind, placebo controlled Phase 2 study of 138 patients undergoing ruptured hand-tendon repair surgery. However, at 9 months follow-up, the benefit no longer reached statistical significance as many patients had dropped out.
A recent study in healthy volunteers with an artificial wound confirmed previous studies that Ensereptide is safe but failed to show clinical efficacy in terms of scar appearance compared to

placebo-treated subjects at 12 weeks follow up (Press Release Promore Pharma 20 April 2023).[1] However, the agent was formulated in hyaluronic acid and administered only once as a single dose, treatment exposure was most likely limited to only a few days, and far too short. The company therefore terminated further development of this product. As the patent for the peptide expired in 2019, Promore Pharma was relying on a patent for the hyaluronic acid formulation. The company announced on June 22 that they had terminated their Ensereptide program.

Cellastra's technology platform addresses both issues (duration of treatment exposure and patent protection). Using a proprietary gene vector to program long-term expression /synthesis of the peptide directly at the injury site for many months offers a compelling advantage to explore in well-designed clinical studies. Furthermore, Cellastra is developing an analogue of Ensereptide with longer half-life that already has demonstrated treatment exposure to measurable plasma concentrations for several months after one single intramuscular dose.

INTELLECTUAL PROPERTY

Patents

The technology of the Scarlexa™ gene vector for injection and the Virlexa™ gene vector for inhalation are described and claimed in a recent patent Continuation-in-Part (CIP) filing on May 14, 2021, which has composition of matter claims for the vector encoded for endogenous expression/production of lactoferrin and a broad range of sub-peptides of lactoferrin, including ensereptide and potentially superior analogues thereof containing IgG Fc fragment to prolong the half-life. (The original USPTO patent was filed in July 2018).

The CIP filing is based on proprietary data from an in vivo study in mice receiving intramuscular administration of a triple mutant AAV6 vector (AAV6.2FF) encoded for ensereptide demonstrating rapid and robust expression of Fc-tagged ensereptide for the duration of the study up to the time the mice were sacrificed at 11 weeks (Day 77).

Whereas the composition of matter patent for ensereptide expired in July 2019, Cellastra's subsequent filings claim composition of matter for a broad range of lactoferrin sub peptides, and a range of recombinant viral vectors. To further strengthen its IP position and Freedom to Operate, Cellastra has also 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).

Freedom To Operate Analysis

An independent law firm specializing in Life Science Law was contracted to conduct a Freedom to Operate analysis. Upon review of the relevant intellectual property landscape, it is the opinion of the independent law firm that no third party patents would be an impediment to Cellastra implementing and performing their proprietary therapies within the United States and its territories. Should additional third-party intellectual property be brought to Cellastra's attention, additional and/or supplemental review of such third-party intellectual may need to be conducted.

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[1] https://www.promorepharma.com/en/promore-pharma-reports-outcome-from-clinical-phase-ii-study-with-ensereptide/

Strategic Relationships

Through its strong executive board, Cellastra has built strategic relationships with leading research institutions in North America and Europe including Professor Sara Wootton, University of Guelph in Ontario, Canada, Professor Christopher Evans, Mayo Clinic, Rochester, MN, US and Professor Folke Sjöberg, University of Linkoping, Sweden. The company has also selected a network of CMOs and CROs with global reach including those with operations in the US, Europe, and Asia.

Swedish Government funded Consortium: Scarlexa in Burn Injuries:

On the invitation from Professor Folke Sjoberg, Cellastra recently joined the Centre for Advanced Medical Products (CAMP), a Swedish consortium funded with a 48M SEK (approximately 5.6M USD) government grant to explore new treatment modalities in burn injuries. Upon funding, Cellastra would supply investigational agent for evaluation in a small Phase 1-2 clinical study, provided that regulatory approval for use of the gene vector in humans can be obtained from the Swedish Medicinal Product Agency. Upon success, Cellastra would maintain intellectual property and commercialization rights.

US Government and NIH: Virlexa in Long COVID

On June 12, 2023 Cellastra met for an hour on Zoom with NIH selection committee for the RECOVER project in Long COVID to explore the feasibility of getting funding for the Virlexa development and inclusion in government funded clinical trials. The committee members were very impressed and found Virlexa a very attractive candidate for development. However, they explained that they had no funds for manufacturing or preclinical development and that the funds for clinical trials were earmarked for 5 drug candidates with protocols under review by the FDA. None of these studies had yet started and priorities could change.

CONCLUSIONS

Compelling preclinical data for the vector and the peptide, as well as clinical data for the peptide, under the skin support the potential role for our technology in facilitating wound healing in the skin after burn injuries or surgery and in the lungs and other internal organs after respiratory infections such as COVID-19 and a subsequent syndrome named Long-Covid.

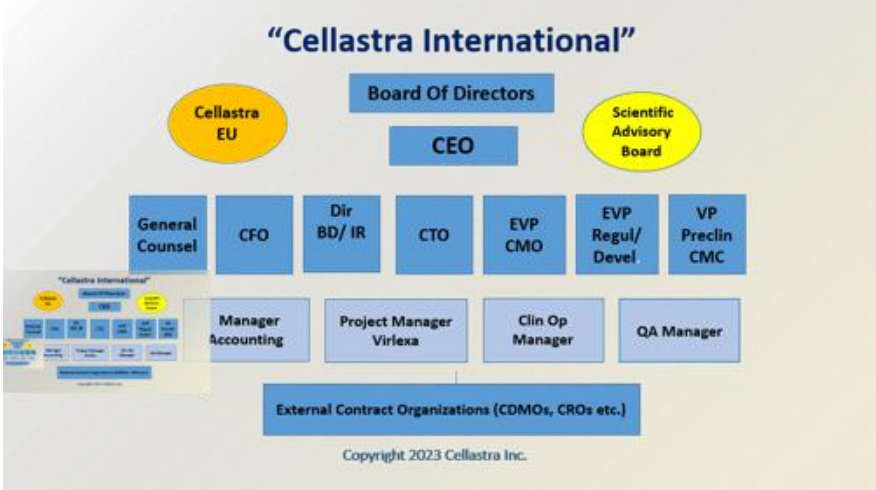
Using a proprietary gene vector to encode long-term expression /synthesis of the peptide directly at the injury site for many months offers a compelling advantage to explore in well-designed clinical studies, where the vector is applied topically under the skin before surgical wound closure, as a spray of in vitro transfected skin cells on top of a burn injury, and as an inhalation followed by an intramuscular injection in patients with Long Covid.

Furthermore, Cellastra is developing a proprietary analogue of Ensereptide with longer half-life that already has demonstrated treatment exposure to clinically meaningful plasma concentrations for several months after one single intramuscular dose.

Cellastra has immediate opportunities to advance both projects into government-funded projects in the US (American Rescue Plan funded clinical study in Long Covid) and in Sweden (Vinnova Agency funded clinical study in burn injuries). To take advantage of these unique and time sensitive opportunities, we need seed funding of 6 M USD to contract and initiate GMP manufacturing and IND-enabling pharmacology and toxicology studies in 2023 in order to enter clinical phase in Q3, 2024.

LIST OF APPENDICES

APPENDIX 1. ORGANIZATIONAL CHART AND BIOGRAPHIES



OFFICER, DIRECTOR AND EXECUTIVE TEAM BIOGRAPHIES

BRADLEY G. THOMPSON, PhD, Chairman, Director, CTO

Dr. Thompson, the CEO and Co-Founder of Kickshaw Ventures, is an experienced and highly respected biotechnology professional for more than 40 years. He is also an inventor of several patents granted or pending applications in the viral/ gene therapy area and of the proprietary technology platform assigned to Cellastra. Until recently he served as Director and the Chairman of BIOTECanada, and as Executive Chairman, CEO and President of Oncolytic Biotech Inc. He started his career in biotech as Head of Biotechnology at The Alberta Research Council where he was responsible for GMP manufacturing for biologics and held a variety of other positions from 1983 to May 1994. He served, amongst others, as a Director of Signal Gene, Paladin Labs Inc., Transition Therapeutics and Immunovaccine, Inc., and is a current Chairman of the Board of Cellastra. He was Director of Erad Therapeutics Inc. and SolAeroMed Inc. Dr Thompson is also a member of the Advisory Board of Lifeboat Foundation Biosciences Inc. He received a B.Sc. from the University of Alberta and a Ph.D. in microbiology and immunology from the University of Western Ontario.

SVEN ANDREASSON, BSc. Vice Chairman, Director

Sven Andréasson has more than 40 years' experience as an executive in the life science industry. He started his career at Kabi, Stockholm, where he became CEO for the German, UK and Belgian subsidiaries. He subsequently became head of the Biopharmaceutical division responsible for human growth hormones, blood plasma products, and LMW heparin/ thrombolytic cardiovascular products. After the acquisition of Pharmacia in 1989 he became President of Pharmacia International in Brussels, Belgium and later Pharmacia SA, Paris, France (today part of Pfizer). From 1999 he served for nine years as the President and CEO of Active Biotech, Lund Sweden, a publicly traded company developing innovative products for autoimmune diseases including

multiple sclerosis (partnered with TEVA) and for various cancers. He subsequently became CEO of Beta-Cell NV, in Brussels, a company developing cell-based treatments for diabetes. In February 2012 he became CEO of Isconova AB, a vaccine development company acquired by Novavax Inc, Rockville, MD, where he is Senior VP, Corporate Development. Sven Andréasson has an MSc in business administration and finance from the Stockholm School of Economics.

KARL METTINGER, MD, PhD, Cofounder, President & CEO

Dr. Mettinger has more than 30 years of experience as an executive in the life science industry and has been involved with the successful development of new therapeutics, including a number of oncology, hematology, cardiovascular and CNS drugs and biologic products approved by regulatory agencies worldwide. Dr. Mettinger is the Principal and Founder of Progressive Clinical partners and helped accelerate and facilitate approvals of a novel oral breakthrough therapy in lymphoma and leukemia, leading to the USD 21B market cap and acquisition. He was also a consultant to Philanthropist /Investor Edward Bosarge (Capital Technologies, Houston) and Tissue Genesis LLC, Honolulu) helping establish a franchise in cellular therapeutics/ Regenerative Medicine. He served as Medical Director of Hematology and as Deputy General Manager of the cardiovascular business unit of Kabi (Pharmacia, acquired for USD 60B by Pfizer) in Sweden; as Medical Director/ Executive Director at IVAX Corporation (acquired for USD 7.4 B by Teva); Chief Medical Officer/Senior Vice President at SuperGen, (Astex, acquired for USD 900 M by Otsuka); Chief Medical Officer at Oncolytics Biotech Inc, AB; co-founder and past President of the Swedish Stroke Society, a 10,000-member stroke research and patient support organization. Dr. Mettinger received his M.D. from the University of Lund in Sweden and his Ph.D. in Hematology/Neurology from, and is a former Associate Professor of, the Karolinska Institutet, the home of the Nobel Prize in Medicine and Physiology in Stockholm.

VINOD KUMAR, MD, EVP, Chief Medical Officer

Dr. Vinod Kumar is a distinguished clinical scientist with more than 30 years' experience of clinical drug development in academic medicine and the biopharma industry. He joined Lilly Pharmaceuticals as a Senior Research Physician. During his 16 years tenure at Novartis, Dr. Kumar advanced to become Section Head, and Executive Global Program Medical Director Development and Medical Affairs. Under leadership of its CEO, Vasant Narasimhan, MD, Novartis is today a leader in approved cell and gene therapies. Dr Kumar has a long-standing research interest as a KOL in Aging Diseases and Regenerative Medicine. He served for more than 12 years on the NIH funded Steering Committee working with FDA on selecting and validating instruments for approval of new drugs for Alzheimer's disease. He was Editor in Chief of International Journal of Geriatric Psychopharmacology, and is co-editor of two books, most recently "Exosomes, stem cells and microRNA – Aging, Cancer and Aging Diseases. Biological and Clinical Advances." Springer 2018. He was a Professor of Neurology/Psychiatry at University of Illinois, where he also oversaw a Stem Cell Laboratory, and at University of Miami. Dr. Kumar received his medical degree from University of Lucknow, India, and post training from Leicester University, Birmingham University, UK and UCLA in US.

HENRIK (HANK) KULMALA, PhD, EVP Regulatory/Product Development

Dr. Kulmala has more than 30 years of life sciences experience. He has worked closely with FDA and international regulatory agencies as a principal on numerous marketing applications (NDAs/MAAs) and INDs, involving some 75 drugs in various therapeutic areas. He joined the

pharmaceutical industry as a medical/ regulatory writer at Marion Merrell Dow in Cincinnati. He became Manager of Technical Composition of R&D Operations at Fujisawa USA, Inc. (now Astellas) in Illinois, where he was responsible for writing and organizing the New Drug Application for Prograf (tacrolimus), a multibillion dollar drug in liver (and other solid organ) transplantation, and several other projects. Dr. Kulmala served as Director of Regulatory Affairs for Curatek Pharmaceuticals, Inc., Vice President of Regulatory Affairs at Quark Pharmaceuticals and at Genix Therapeutics, LLC. For more than 20 years he has served as a consultant in areas of Product Development/ Regulatory Affairs, writing/organizing marketing applications in numerous therapeutic areas including Regenerative Medicine, asthma, oncology, diabetes mellitus, infections, and gastrointestinal, cardiovascular, and renal disorders. Dr. Kulmala also has extensive translational experience advancing numerous drugs into human trials by preparing INDs and worked on device and drug-device combinations and biotechnology applications in early to late-stage clinical development. He received a BS degree from Northern Illinois University in Biological Sciences and was commissioned a 2LT, IN, USAR. After earning a doctorate at The University of Chicago in Pharmacological & Physiological Sciences, he underwent postdoctoral training in neurology and neuropathology. He served as an Assistant Professor of Pharmacology at Northeastern Ohio Medical University College of Medicine. His research focused on neurological disorders including Parkinson's disease, Alzheimer's disease, Huntington's disease, and Tourette syndrome. He is an author of numerous scientific publications and a few books including A Life Transplanted about his experiences with liver transplantation. He is a graduate of the US Army Command and General Staff Officer Course and attained the rank of Major, Infantry, USAR.

BRUCE PHILLIPS CPA, CFO

Bruce Phillips has had a long and distinguished career in the accounting industry for more than 30 years. After graduating from the College of William & Mary, he joined Arthur Young and became an accounting manager for Ernst & Young. In 1992 he became a Founding Partner, and later CEO of HPC (Harshman, Phillips & Company) which for decades operated as a traditional accounting firm in Atlanta. At the annual accounting convention in 2011, he met Rodney Drury, the founder of XERO, the pioneer of the cloud based accounting technology platform. Soon HPC became a Platinum Partner of XERO and a leading cloud-based accounting firm and grew to become a full-service provider working remotely all over United States, from California to Florida and New Hampshire and with an increasing number of clients all over the globe. After the merger with Aprio Cloud in 2018, Bruce became Managing Director and Partner, Head of Cloud Accounting Solutions in the merged company operating globally.

DANIEL QUINTERO Sr., Esq., General Counsel, Corporate Secretary

Daniel Quintero has a long and distinguished career in Silicon Valley and the SF Bay area. He is a Founding Partner and Managing Partner of Prometheus Partners LLP, a diverse group of accomplished former Big Law Partners and Executive In-House counsel committed to supporting innovation. Mr. Quintero was previously the General Counsel and Corporate Secretary for Sony Optiarc America Inc., where he concurrently served as Senior Managing Counsel and Director for Sony Electronics Inc. and managed Sony's Silicon Valley law department operations. His responsibilities included advising executive management and the board of directors of a multi-national corporation and negotiating and structuring multi-million and multi-billion dollar engagements. Mr. Quintero is largely well respected for his views on innovation and technology

and was named one of California's Top 20 General Counsels by the Daily Journal. Mr. Quintero received his undergraduate degree from the University of San Francisco (USF) and received his law degree from Berkeley Law (Boalt Hall), University of California at Berkeley.

KENT PERSSON, PhD, Cofounder, Director

Dr. Persson is an experienced cell and molecular biologist with more than 20 years' research expertise in genomics and molecular-cellular biology. He holds a Ph.D. in Molecular Biology from Umeå University in Sweden and did a Postdoctoral Fellowship in gene expression research at the University of California San Francisco. After postdoctoral work, Dr. Persson served as Senior Scientist in the Gene Expression Division of Bio-Rad Laboratories in California, participated in research and development of gene expression tools and led technical training in genetic analysis work. Returning to Sweden, Dr. Persson has been working for Octapharma AB in Stockholm. First as a Senior Scientist at the Biopharmaceutical Division where he oversaw Cell and Molecular Biology and manages process analysis development, introducing new molecular biology techniques including development of technologies in cell culturing, recombinant protein production, and molecular biological IND filings. Later Dr. Persson served as a Project Manager at Octapharma's Quality Unit. Within the project he oversaw development, implementation and regulatory submission for assays to serve Octapharma's recombinant production. Now Dr. Persson works as Senior Analytical Specialist working with various projects at the Octapharma Quality Unit.

BIOGRAPHIES SCIENTIFIC ADVISORY BOARD MEMBERS

Professor Christopher Evans. Scientific Advisor, Gene Therapy, Tissue Repair

Professor Evans is a leading expert in the field of tissue repair and new treatment modalities, including gene therapy in arthritis. He is currently Director of the Rehabilitation Medicine Research Center, Mayo Clinic, Rochester, and Professor of Orthopedics, Physical Medicine and Rehabilitation. He previously served as Director of Center for Advanced Orthopedic Studies, Beth Israel Deaconess Medical Center, and Harvard Medical School, and is Maurice Müller Professor of Orthopedic Surgery Emeritus, Harvard Medical School. Originally from Great Britain, Dr. Evans holds a bachelor's degree in genetics and microbiology, a Ph.D. in biochemistry from the University of Wales, a master's degree in history and philosophy of science from the University of Pittsburgh, and a D.Sc. from the University of Wales. He is the author of more than 300 peer reviewed scientific publications. He served as President Orthopedic Research Society 2004 -2005, and has served as the Chair, Scientific Advisory Board, and Journal of Orthopedic Research. In 2009 he won the Marshall R Urist MD Award, Orthopedic Research Society for excellence in tissue regeneration, and in 2010 the Arthur Steidler MD Award, Orthopedic Research Society for understanding of the musculoskeletal system. In 2016 he was elected an inaugural Fellow of International Orthopaedic Research (FIOR).

Folke Sjoberg, MD, PhD, Scientific Advisor Tissue Repair Burn injuries

Professor Sjoberg is a world-renowned, leading expert in the field of burn care/wound healing/tissue repair. He is Professor of Biomedical and Clinical Sciences, Linkoping University, and Director of Burns Intensive Care Unit (National), Linköping University Hospital, Linköping, Sweden. He is President Elect of International Society for Burn Injuries. From 2007 to 2009 he served as President of the European Burns Association and since 2011 he is a board member of the Verification Committee, American Burn Association. He is coauthor of more than 200 peer

reviewed publications, eight books. He has supervised 40 PhD students, about 20 dissertations, and served as primary investigator of 150 clinical trials Phase 1-4. He received his MD in 1983, and PhD in 1990, both from Linkoping University. He is a prolific lecturer at conferences around the world and serves on the editorial board of seven International Journals.

Magda Forsberg, PhD. Scientific Advisor

Dr. Forsberg obtained her Ph.D. in animal development and epigenetics from Uppsala University in Sweden and did a Postdoctoral Fellowship in Reprogramming and Neurobiology at the Karolinska Institutet in Stockholm, Sweden, and is the author of publications exploring fundamental aspects of cell biology. Dr. Forsberg, who became an Assistant Professor at the Karolinska Institute, Stockholm, has worked in the development of cell replacement therapy for neuro-degenerative diseases, focusing on stem cell biology, cell differentiation and clinical applications. Dr. Forsberg is currently President & CEO of DVL-op MEDICO Inc., based in Valencia, CA, involved in the production and commercialization of orthopedic and medical

Employees

Cellastra has the highly qualified personnel in place to initiate the development program and potentially to submit an application (IND in the US and CTA in Europe) to be allowed to start clinical studies. The plan is to rely on contract manufacturing (CMO) and research organizations (CRO) to conduct the required activities. Oversight of CMO and CRO activities would require additional Cellastra personnel. Expansion of Cellastra staff might include 2-3 project management positions in Year 2 as shown in the org. chart.

Marketing Strategy

Cellastra has no current plans to become a fully integrated biotech company and has no plans to hire a sales force. Rather, the expectation is that Cellastra will develop the products to the stage where a more established biotech or pharma company can license the product(s) and continue the development. This could occur one product at a time or could include the entire portfolio.

We expect cost of goods for large indications may enable market introduction at price levels which are affordable for patients and health insurance providers.

Market Projections for the Scarlexa^{TM} and Virlexa^{TM} gene vectors for injection and Net Present Value Projections for both projects are available upon request

Cellastra plans to hire a full time Director or VP of Business Development to start building relationships with potential co-development partners or out licensing deals.

APPENDIX 2. MARKET ANALYSIS

COMPETITIVE LANDSCAPE

Respiratory Infections

Virlexa is not confined to use in viral infections, which include the examples below, but also could be used in bacterial and fungal infections or those of unknown etiology because of its antimicrobial properties and the general nature of its immunomodulatory activity.

COVID-19

No pharmaceutical agent today is designed to prevent or reduce the lung damage caused by pathogens such as SARS-CoV-2. Current treatment approaches are designed to prevent infection (vaccination), to treat the symptoms, or to directly (antiviral) or indirectly (spike protein binding competition) combat the coronavirus. Steroids appear to be useful in preventing some lung damage, although their use is reserved for advanced ARDS patients (Prescott and Rice 2020). Secondary infections, often bacterial, are generally treated with intravenous antibiotics (Langford et al. 2020).

A number of agents were authorized for emergency use (EUA) for the treatment of COVID-19 by the US FDA. Numerous clinical trials were initiated with agents in COVID-19 treatment, often with drugs approved for other indications. Most companies sponsored only a single clinical study and the majority of these did not show promising results. ,Numerous specific drugs were tested during the pandemic, but many had little efficacy, and most have been removed from the market in the US. Few drugs are left to fight the pandemic.

There remains a need for effective treatments for COVID-19, both in the current post-pandemic (waning) phase and in preparation for outbursts of new variants during the cooler seasons when people congregate in confined spaces with less ventilation.

Current Treatment Options

There are currently no approved drugs to prevent or treat Long-Covid.

Vaccines are highly effective for a few months and widely used to prevent infections with COVID-19 (SARS-CoV-2). They were introduced in the US based on Emergency Use Authorization and as large databases became available several have received full approval by FDA and other regulatory agencies. Monoclonal antibodies and antivirals became a treatment option for patients testing positive for the virus based on Emergency Use Authorization but are not widely used.

Vaccines

The current Omicron variants seen globally are extremely immune evasive, responding little to the original vaccines (designed against the S protein of original variants) and to prior infection. Only the bivalent vaccine is expected to have some, but limited, efficacy, as it was developed against an original Omicron variant. While the vaccine can be modified to recognize major changes in the S protein, these modifications take months under the current system to be tested for efficacy and safety and the virus keeps mutating rapidly. The current XBB.1.5 variant went from first detected to predominant in the US in just a matter of weeks. Annual vaccination with a vaccine designed against expected circulating variants likely will be needed in the future, for years to come. Even

in the best situations, a vaccine is not 100% effective and often is much less effective, as seen annually with influenza vaccines (FDA wants 50% or better efficacy), and many people don't bother getting a vaccine. A vaccine is dependent on the host immune system to generate antibodies, and elderly, immunosuppressed individuals, and people with some diseases have a weaker immune system. Vaccines are not considered to be competitive for Virlexa and prior vaccination is not a contraindication to treatment with the vector.

Monoclonal Antibodies

All of the monoclonal antibodies, designed against an S protein sequence, are now ineffective and none are currently available in the US. Convalescent serum, derived from sera of individuals who fought off an infection, is probably still somewhat effective mainly as it included antibodies against multiple regions of the viral capsid, not just the S protein. However, this is a limited option. Evusheld (tixagevimab co-packaged with cilgavimab) is not currently authorized for use in the U.S. until further notice by the Agency (26 January 2023).

Oral Antivirals

Oral antiviral treatments are in development and Pfizer's Paxlovid and Merck's Lagevrio obtained Emergency Use Authorization (EUA) by the FDA based on promising results with five-day dosing in large Phase 3 studies with about 2000 and 1400 patients, respectively, showing about 90% reduction in hospitalization and reduced death rates. Since approval, treatment with Paxlovid was reported to be followed by a viral rebound in many cases, in which patients again tested positive for the virus after negative testing. Because of probable interactions with >150 drugs at liver cytochrome P450 systems, Paxlovid must be used with caution in many patients, especially the elderly and immunocompromised subjects who likely are on many medications. Paxlovid appears to be one of the few options in patients with COVID-19 currently as the target of this drug (an enzyme) does not appear to have mutated with the viral variants. Another option for some patients who are hospitalized or at high risk of being hospitalized or having severe disease is Veklury (remdesivir), an RNA polymerase inhibitor. These agents likely could be used concomitantly with Virlexa.

Recently, it was announced that the US Government has funded placebo-controlled Phase 3 study (n=1,700 patients) to evaluate a 15-day dose regimen of Paxlovid as a potential treatment of patients with Long Covid. The study was expected to start in January 2023 and to complete enrollment in a year but, as of June 30, the study has not been initiated. If the study shows long-term effectiveness and safety with careful monitoring of potential drug-drug interactions, it seems likely that Paxlovid may be used in combination with novel and complimentary treatment modalities such as Virlexa.

Interferon Lambda

Among predominantly vaccinated outpatients with COVID-19 in Canada and Brazil, the incidence of hospitalization or an emergency department visit (observation for >6 hours) was significantly lower among those who received a single dose of pegylated interferon lambda than among those who received placebo (Reis et al., 2023). This study showed promising results for an old drug in 2022-23.

The Case for Virlexa

We propose to explore utility in COVID/ Long-Covid using inhalation, potentially combined with an intramuscular administration:

1) One inhalation of Virlexa both the gene vector itself as well as subsequently expressed ensereptide may bind to heparan sulfate (including the entry-site ACE-2 receptors) on the epithelial cells of the lung, which is the site of invasion of the SARS-COV-2 virus causing COVID-19. This will enable targeted transfection of the cells at the injury site and turn the lung epithelium into a temporary bioreactor (surface about 100 sqm = the size of a racquet ball court).

2) The inhaled dose will likely also be distributed to surrounding structures such as the epithelium of nasal cavities, the olfactory pathways for smell and taste, to the brainstem as well as to esophagus/upper gastrointestinal tract. This may help stop invasion of the CNS, the bowels. and other organ systems.

3) Ensereptide produced in close vicinity to the viral attack points seems an unprecedented advantage, particularly considering the continuous resupply of an agent with multimodal effects against the perturbations caused by the insult (anti-microbial, anti-immune, anti-fibrin, and anti-fibrotic).

4) Thus, Virlexa may become a uniquely useful tool for long-term treatment/prevention of infections, tissue damage, and fibrosis in respiratory, esophageal-upper gastrointestinal, and nasal/olfactory/CNS, which would be of paramount importance to prevent acute and long-term pathology and symptoms related to Long COVID in multiple body systems.

5) The full benefit of one inhalation will last for at least 30 days (= the life span of epithelial cells) but will decrease over the next few months as cells divide or die off. Therefore, it seems rational to combine inhalation with an intramuscular injection on Day 1 to give long-term protection of the lungs as well as other body systems.

Oral antivirals such as Paxlovid are approved for emergency use in the acute phase of COVID-19 based on evidence of reduced hospitalization and mortality, which may help prevent Long-COVID. The rational for their utility for treatment of Long-Covid is less clear. It seems counterintuitive that a 15-day course of antiviral treatment may impact chronic sequelae of tissue damage caused by blood clots and/or deranged immune system. Virlexa administered once by inhalation / intramuscular injection may not only reduce the initial tissue damage and spread of virus but also enable long term prevention / treatment of Long COVID in multiple body systems by improving micro-circulation and facilitate tissue healing.

Number of Patients with Long COVID

It is difficult to estimate the number of subjects with long-COVID in any country or in the world. Since the diagnosis is by exclusion of other etiologies in patients who have recovered from COVID-19, some studies provide an incidence rate at various times after infection. The incidence generally decreases with time since primary infection, but, so far, never reaches zero. General estimates initially were that 37% to 50% of patients recovering from COVID-19 get long-Covid, but the current incidence may be lower. Some of the reported differences in incidence may be related to whether patients were hospitalized with severe COVID-19 or not, as severe disease is

more likely to be followed by Long-Covid. The incidence of Long-Covid from the Omicron variant may be in the range of 4-5% of COVID-19 patients (37). Given the huge surge in cases globally due to the Omicron variant, the incidence of Long-Covid is expected to increase and potentially be a huge medical burden for years. Some 5% or more patients now infected are likely to get the disease, on top of the 18 million estimated cases in the US (in 2022) and over 150 million cases globally.

Respiratory Syncytial Virus (RSV) Respiratory Infection

The first two vaccines for RSV in adults were approved in 2013 in two others in late-stage clinical trials.[2] The FDA announced on 3 May 2023 that Arexvy is approved for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older. The vaccine significantly reduced the risk of developing RSV-associated LRTD by 82.6% and reduced the risk of developing severe RSV-associated LRTD by 94.1%. The FDA is requiring the company to conduct a postmarketing study to assess the signals of serious risks for Guillain-Barré syndrome (GBS) and acute disseminated encephalomyelitis (ADEM), as 2 subjects who received the RSV vaccine and concomitant influenza vaccine developed ADEM, one of which went on to develop GBS. The second vaccine from Pfizer was approved in late May 2023 based on an efficacy of 85.7% to prevent LRTD infection with 3 or more symptoms, and an efficacy of 62.1% to prevent acute respiratory infection.[3]

Moderna is finishing its Phase 3 trial of an mRNA vaccine for RSV in older adults and expects to submit results to the FDA within the next few months. Bavarian Nordic also said it will report results from a Phase 3 trial of its RSV vaccine for older adults this year. The FDA is reviewing Pfizer's maternal RSV vaccine to protect infants and is expected to make a decision by the end of August 2023.[4]

Thus, the vaccines so far approved for RSV are intended for high-risk adults, those with chronic heart or lung disease, those with weakened immune systems and those living in nursing homes or long-term care facilities. The vaccine efficacy was not 100% in clinical trials and the compliance with vaccination is generally poor in the US.

Current treatments for RSV are largely supportive (Falsey and Walsh 2005). Early therapy with ribavirin and intravenous γ-globulin appears to improve survival in immunocompromised persons. Prevention of RSV is limited to standard infection control practices, such as hand washing and the use of gowns and gloves. Masks are effective to prevent transmission by coughing, sneezing, or other respiratory means. 2.

Dermal Scarring

The majority of products designed to allow for more normal healing and prevent scarring are devices, such as surgical meshes, and over the counter (OTC) products. Most topical products to date are OTC or "cosmeceutical" products with very limited clinical evidence of benefit. Yet, the global scar treatment market was valued at USD 23.5 billion in 2022 and is expected to expand at a compound annual growth rate (CAGR) of 9.9% from 2023 and to reach $54.9 B in 2030.

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[2] https://www.fda.gov/news-events/press-announcements/fda-approves-first-respiratory-syncytial-virus-rsv-vaccine
[3] https://www.urmc.rochester.edu/news/story/race-to-rsv-vaccine-approval-urmc-researchers-leading-the-way
[4] https://www.cnn.com/2023/06/29/health/rsv-vaccine-seniors-cdc-approval/index.html

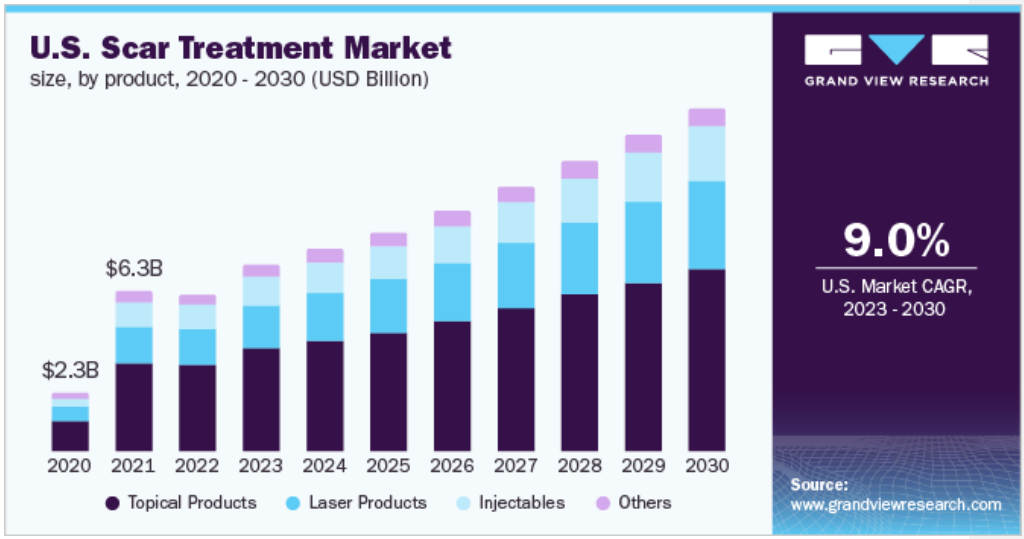
The growing concern among people regarding their aesthetic appearance is one of the major factors triggering the rise in demand for scar treatment products in the market. Treating or preventing various types of scars helps in complete skin rejuvenation, which improves the aesthetic appeal of a person. Such demand for aesthetics is mainly generated by the female population, owing to their greater concern for appearance. Thus, this population group is expected to be the largest contributor to the growing market.

Hypertrophic Scarring after Breast Augmentation

Cellastra will initially focus the development of Scarlexa on indications of concern for women's health and wellbeing. Cellastra chose scar prevention after breast augmentation surgery, in which external scars are troublesome in some patients who develop hypertrophic scarring and/or internal scars resulting in capsular contraction in some 15% to 45% of patients (El-Sheikh et al. 2008). These contractures may be severe in about 10% of subjects and require reoperation.

Hypertrophic Scarring after C-Section

Another target indication is C-section, which has become increasingly common and is currently used globally in about 30 million women every year (including 1.4 million procedures in the US and about 6 million in China). C-section may cause hypertrophic or cosmetically challenging scarring in up to a third of Caucasian women and two thirds of Chinese women. In addition, the scars may be accompanied by internal adhesions causing bowel obstruction or infertility. The growth of the US scar market is shown in the next figure.



Dermal Scar Prevention after surgery - Competitive Analysis

A few biotech agents have been in development to prevent dermal scarring and two, AZX 100 and Justiva recently failed to meet defined endpoints, as short-term improvement could not be confirmed at 12-months follow-up. One of the limitations was that these agents were only applied immediately after surgery with no maintenance treatment. Another product, RXI 109, was evaluated in a Phase 2 study, but the design using within-patient control made it difficult to interpret the results and further development is apparently on hold.

Ensereptide formulated in high molecular weight hyaluronic acid has in previous studies been applied as a single application after tendon repair surgery and treatment exposure of a few days has proven to be too short to achieve long term effect in dermal scarring. A recent study in healthy volunteers with an artificial wound confirmed previous studies that Ensereptide is safe but failed to show clinical efficacy in terms of scar appearance compared to placebo-treated patients at 12 weeks follow up (Press Release Promore Pharma 20 April 2023). However, the agent was formulated in hyaluronic acid and administered only once as a single dose, treatment exposure was most likely limited to only a few days, and far too short for long term benefit.

Thus, there do not appear to be any current competing biotech development programs. The Scarlexa^{TM} gene vector for injection, by addressing fundamental mechanisms of scar formation, may have great clinical utility and global growth potential in dermal scarring which may increase the sales potential to USD 1B or more in North America alone. Long-term expression of the peptide at the site of the wound may address the need for durable treatment to demonstrate efficacy.

THE CASE FOR SCARLEXA IN POST-SURGICAL SCAR PREVENTION

There is no doubt that the post-surgical scar prevention indication represents the largest growth opportunity but also the greatest challenge to objectively document long-term improvement at 9 and 12 months follow up.

Scarlexa gene vector for injection will be applied once under or into the skin and muscle at the surgical site prior to wound closure. Furthermore, to boost the long-term effect of Scarlexa, an intramuscular injection will be evaluated.

Whereas previous studies are hampered by lack of long term treatment exposure, Scarlexa has the advantage of long-term treatment exposure throughout the wound healing process over several months, which may be critical for long term scar prevention. To get marketing approval Regulatory agencies demand some method of analysis which arrives in a numerical score which can be compared to placebo. For exterior scars, various scales were developed to score wound healing and scar formation and reconstruction. Of these, the POSAS and VSS are the most commonly used (Jeschke et al. 2016; Karlsson et al. 2020; Li-Tsang, Lau, and Chan 2005; Fearmonti et al. 2010; DeJong et al. 2017; Thompson et al. 2015). However, using these assessment scales in clinical trials is not straightforward; as short-term improvement of time to healing (wound covering) may be valuable clinically, but a difference in scar appearance and structure over months certainly is. Of the various well-characterized surgical models to study, an assessment conducted for Cellastra by a Clinical Research Organization (CRO) specializing in dermatology suggested the best was breast augmentation surgery, where both dermal scars and internal capsule formation with visible contracture leading to replacement surgery could be end-points to evaluate.

For these reasons Cellastra will collaborate with a group of aesthetic surgeons to develop the protocol. This may not only collect data from various scales and quality of life data from a patient questionnaire, but also photographic documentation of contracture and potentially MRI or CT scan images documenting any internal capsule formation.

Thus, the initial development will focus on women's health, starting with breast implant and C-sections. Future indications may include other gynecological indications and aesthetic of abdominal and orthopedic surgery indications in both women and men. Cellastra has calculated a total potential market of more than 5 million patients in US and Canada alone. Europe, South America and Far East countries would follow rapidly once this new technology has been established in well-designed conical studies.

Number of Patients in Target Markets

The global breast implants market size was valued at USD 2.31 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 7.5% from 2023 to 2030. The number of patients receiving breast implant surgery was 287, 085 in 2019. The latest global survey (2021) by International Society of Aesthetic Plastic Surgeons reported 1,685,471 Breast Augmentation procedures, a +3.8% compared to previous year despite the pandemic.[5]

Hypertrophic Scarring after Burn Injuries

Up to 70 percent of burn victims develop hypertrophic scars which is considered the greatest unmet need after burn injuries (Finnerty et al. 2016).

Globally, burn injuries are among the most devastating of all injuries and, in many countries, are a major public health crisis and referred to as a new epidemic. Burns are the fourth most common type of trauma worldwide, following traffic accidents, falls, and interpersonal violence. According to CDC data for 2020, 359,000 Emergency Rooms visits in the US were caused by burns[6] and some 486,000 required medical treatment and 40,000 were hospitalized, three-quarters of these at 127 specialized burn centers[7] and the annual cost for special care was >$18B. An estimated 11,000 of these people die annually as a direct result of their burns.

Most wounds are superficial involving epidermis, causing redness but healing spontaneously. Full thickness skin burns involve the epidermis, dermis, with associated hair, glands, muscle, vasculature, and nerves. Repair of such burns involves the generation of a multi-tissue organ. A second degree burn injury is characterized by vesiculation of the skin surface and involves epidermis and part of dermis (also referred to as "partial thickness" burn). A third degree burn is characterized by necrosis and penetrates both epidermis and dermis ("full thickness" burn). A fourth degree burn also affects deeper tissues such as musculature and bone.

[5] https://www.isaps.org/discover/about-isaps/global-statistics/reports-and-press-releases/global-survey-2021-full-report-and-press-releases/

[6] https://www.cdc.gov/nchs/ahcd/web_tables.htm#2011

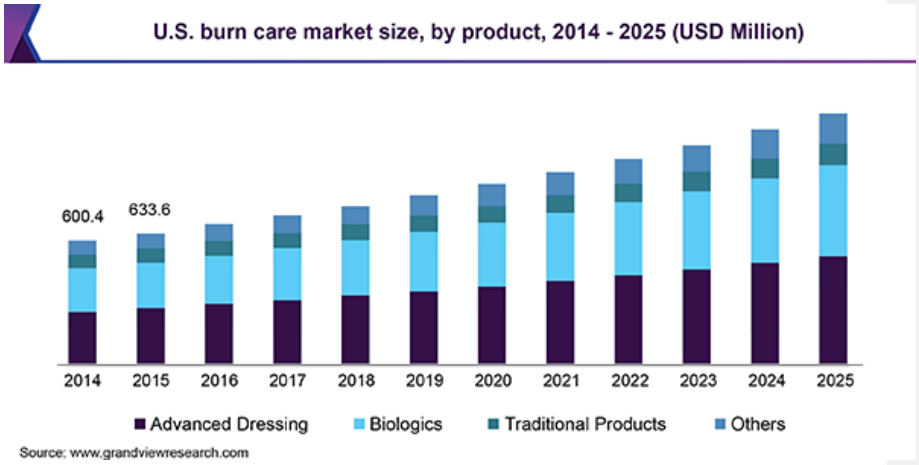
[7] https://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/

Field Code Changed

Burn injuries – market analysis

The growing incidence of burn wounds and new methods to approach the problem point to a robust market for those companies that make products to treat burns. In 2022 the global burn care market was valued at $2.49B and the market is growing with an annual growth rate of 7.2%. Most products are various wound dressings and skin grafts.

Burn Care Market Size To Reach $4.22 Billion By 2030 (grandviewresearch.com)



Thermal burns held the largest share in the global burn care market in 2017 owing to a rising incidence of fire-related burn injuries, such as the burns caused by fires, steam, flash, hot objects, and hot liquids. According to the American Burn Association (ABA), in 2017, fire burns were responsible for 43% of the total burn admissions in the U.S. Moreover, rising government efforts to create awareness through campaigns, such as the Burn Awareness Week organized by the American Burn Association and BBA National Burns Awareness Days by British Burn Association, will further fuel the segment growth.

Moreover, rising concerns regarding *aesthetic appearance* among patients are among major factors contributing to upsurge in demand for burn care products. Furthermore, advantages associated with the use of *biologics, such as accelerated and scarless wound healing*, cost efficiency, and shorter hospital stay are expected to drive the market in the near future.

North America dominated the market in 2017 attributed to the shift from traditional treatment products to advanced wound dressing products. This is due to the rising concern toward aesthetic appearance and demand for minimally invasive cosmetic surgeries in this region.

For instance, statistics published by the American Society of Plastic Surgeons indicate that in 2017, around 17.5 million minimally invasive and surgical cosmetic procedures were performed in U.S. The number is expected to increase over the forecast period. Thus, high demand of cosmetic

procedures is considered to be one of the key contributing factors for the rising demand of biologics to treat wounds, which, in turn, is projected to drive the regional market.

The presence of well-established healthcare facilities, favorable reimbursement policies, and advanced therapies are some of the key contributing factors for market growth in developing economies such as India, China, and Brazil. In addition, adoption of technologically advanced surgeries such as reconstructive burn surgery is also anticipated to propel regional market growth.

Asia Pacific is anticipated to witness lucrative CAGR in the forthcoming years. Emerging economies such as China, and India have been experiencing strong economic growth. Increasing standard of living in these countries has spurred the demand for advanced products and procedures. Rising disposable income is expected to trigger the regional demand for cosmetic procedures in the near future.

The global market is anticipated to witness intense competition over the forecast period. It is consolidated in nature, with a few players such as Johnson & Johnson, Smith & Nephew, Mölnlycke Health Care AB, ConvaTec Inc., and Acelity L.P. Inc. dominating the market. Market participants are adopting strategies to capture market share such as new product developments, geographic expansion via enhancing the distribution network, and mergers and acquisitions.

Recent developments: RECELL System

On September 21, 2018 AVITA Medical announced the Pre-Market Approval of RECELL System for severe burns by the US FDA. A small sample of skin is obtained from the patient to prepare Spray-on Skin Cells™ at the point of care and immediately immersed in the proprietary enzyme solution provided in the kit and the resultant "Regenerative Epidermal Suspension" (RES), which contains keratinocytes, fibroblasts and some melanocytes, is then sprayed directly on the prepared burn wound, providing a broad and even distribution across the entire wound bed. A skin sample approximately the size of a credit card can be expanded (without cultivation) to cover the entire back, or up to 80 times the size of the donor skin sample. According to the US product label, RECELL is indicated in patients 18 years of age or older for direct application to acute partial thickness thermal wounds or in combination with meshed autografting for acute full-thickness thermal wounds. It is not recommended for wounds > 320 cm^2 or > 30% of total body surface area (TBSA). The US approval was based on results obtained for clinical studies in 131 patients including two randomized controlled studies. The first of these was a study in partial-thickness (second degree) burn injuries comparing RECELL with conventional split-thickness autografts and the wound created by the skin sample for the RECELL group was 97.5% less than the wound created to prepare the autograft (Standard of Care) resulting in a significand reduction of pain and scar at the donor site and improved satisfaction rate in the patient's assessment. There was no difference in co-primary end point (incidence of burn wound closure). The device was approved in EU and Australia in 2006, China in 2008 and in the US in 2019.

The Case for Scarlexa in Burn Injury

In initial exploratory studies, Scarlexa will be mixed with cultivated autologous keratinocytes obtained from the patient for transfection in the GMP laboratory ("in vitro"). The suspension will then be sprayed back on the patient's burn wound prior to skin grafting. Later studies will evaluate

the utility of the RECELL device to collect skin cells from the patients to prepare a skin cell suspension and mixed with Scarlexa immediately prior to spraying the suspension over the wound area.

The clinical protocols are being developed by Professor Folke Sjoberg, a world leading burn injury expert serving on the Cellastra Scientific Advisory Board.

APPENDIX 3. FOUR YEAR PROJECTED FUNDING REQUIREMENTS

MILESTONES AND FINANCIALS

Year 1: Milestone 1: File investigational new drug application (IND) in the US

Goal: Complete Manufacturing and complete IND-enabling preclinical studies of Virlexa and Scarlexa . About 12 months - $7M

The first milestone to meet is FDA filing of an IND for Virlexa, and subsequently for Scarlexa our initial application to be allowed to initiate our first clinical studies. This requires sufficient data on the chemistry, manufacturing, and controls (CMC) of the product, as well as basic nonclinical pharmacology and toxicology data. To achieve this, we need to initiate a manufacturing project at one of the vendors who have submitted bids to Cellastra and to use product from the initial engineering batch for some preclinical studies, to include proof of concept efficacy and safety studies (in vitro and in vivo). We also need to manufacture small quantities of the peptide, ensereptide, and develop an assay in biological and other fluids. The total cost for this initial phase is estimated to be $7 million, the bulk of it for manufacturing.

Year 2 and 3: Milestone 2:

Goal 1: Complete Virlexa Phase 1-2 including Phase 2-3 "bridging study" in 200 patients-obtain an EUA (Emergency Use Authorization) in Long- Covid – 18 months- $13M

The second milestone would be initiation of a Phase 1 clinical study and then completion of the Phase 1 portion of the study. We propose to conduct continuous clinical trials in which the study continues directly into Phase 2. Depending on the efficacy and safety determined in the Phase 1-2 pharmacokinetic (PK) and Dose ranging study in 30-60 patients followed by a Phase 2-3 bridging study in 200 patients, potentially followed by submission of an Emergency Use Authorization application (EUA) in Long-Covid. For full approval (see Milestone 3 below), a Phase 3 confirmatory trial and a full application (BLA) will follow.

Considering the urgency in the development of an effective treatment for Long-Covid, Cellastra has approached leaders for White House Covid Task Force as the Biden Administration has set aside $1.2B from the American Rescue Fund for research and clinical studies in Long-Covid, the RECOVER INITIATIVE. This has two components, an observational study to study the causes, mechanisms in the natural course, and epidemiology of Long-Covid, and a clinical trials component which includes both solicitation of drug candidates as well as a support center for execution and oversight of the clinical trials. We are in communication with NIH and the White House to see if we can get funding for our clinical development of Virlexa in Long-Covid. They have encouraged us to stay in touch and update them on our progress and timelines for manufacturing and IND enabling studies.

Goal 2: Complete exploratory phase 1-2 scar prevention studies of Scarlexa after burn injury and surgery (breast implant). 12 months -$6,4 M

Cellastra is a partner in the Center for Advanced Medical Products (CAMP) funded by a 50 M SEK grant which among several projects in includes a clinical study in patients with burn injuries where our vector would be used to transfect skin cells in vitro prior to them being sprayed as a suspension on top of the wound to explore scarless healing potential in a small Phase 1-2 study (10-20 patients). Our obligation is to provide GMP quality gene vector which would be taken from

the same batch as the batch used for the inhalation device for Virlexa. Only a small quantity of Scarlexa gene vector will be needed for this study.

Dermal scarring target indication 1 (breast implant): Phase 1-2 feasibility study in up to 60 patients will be initiated in Year 2.

Year 3-4: Milestone 3 File for approval /find partners

Goal 1. Complete Phase 3 studies and file marketing applications ->900 patients - 24 months – $43M

Goal 2: Find corporate partner(s) for Virlexa and / or Scarlexa

The projected costs for complete development of both projects are shown in the following table. These figures are based on estimates obtained from various vendors for specific studies.

Table. Est. Budget Year 1 – 4 (1,000 USD)

Project	Item	Year 1	Year 2	Year 3	Year 4	Total
VIR-LEXA	**CMC**	4,250*	1,200	1,200**)	(1,200**)	5,450 (2,400**)
	Preclinical	1,750*				1,750
	Clinical					
	Ph 1, 30 pts		1,200*			1,200*
	Ph 2,30-60 pts		1.900*			1,900*
	Ph 2-3 Bridging 200 pts		4,000*	4,000*		8,000*
	Phase 3			(8,000**)	(8,000**)	(16,000**)
	Regulatory			700*	(3,500**)	700* (3,500**)
	TOTAL	**6,000***	**8,300***	**4700* (9,200**)**	**(12,700**)**	**19,000* (21,900**)**
SCAR-LEXA	**CMC**		1,200	1,200	1,200	3,600
	Preclinical	950	750			
	Clinical					
	Ph 1-2 Burn: 20 pts		(1,600**)			(1,600**)
	Ph 1-2 Post op 60 pts each of 2 indications		1,700	1,700		3,400
	Ph 3 Indication 1 300 pts			3,500	3,500	7,000
	Ph 3 confirmatory 300 pts			3,500	3,500	7,000
	Phase 3 2nd Indication 300 pts			1,500	5,500	7,000
	Regulatory		250		3,500	3,750
	TOTAL	**950**	**6,400**	**11,400**	**17,200**	**41,950**
External Projects Total		6,950	14,700	16,100	17,200	54,950
Internal Operations Total		1,700	3, 500	3,900	4,100	13,200
Grand Total		***8.650***	***18,200***	***20,000***	***21,300***	***68,150***

- *Milestone 1: Seed funding
- **Milestone 2: Phase 1-3 studies, could potentially be funded by government grants

APPENDIX 4. MARKET PROJECTIONS

VIRLEXA: Prevention of Long COVID in High-Risk Patients (may be expanded to other age groups later). Assuming similar recurrence pattern as for influenza but annual growth rate (AGR) may not be meaningful to project.

US: Based on current statistics (Sept. 2022) (1), about 2 M cases / month and 24 M cases/year, and a conservative projection is that on average there are 6 M high-risk patients available annually. With a capture rate of 25% and a price tag of $1,000/patient the US market has a market value of $1.5 B/Year

Globally there would be a minimum of 240 M cases (2) and 60 M high-risk patients annually. The global market, at an average capture rate of 25% price tag of $500 per patient, would have a current value of $7.5B/Year.

SCARLEXA 6%

Indication 1. Prevent scarring /encapsulation after Breast Implant Surgery (AGR 6%)

US: 270, 00 patients /Year (3), at a capture rate of 33% and price tag of $1,500 the US current market has a value of $135M

Globally: 1.5M patients/Year (4). With a capture rate of 33% and price tag of $1,000/patient the current global market is $500 M/Year.

Indication 2. Prevention of scarring after C-section. AGR = 5.5%)

US: Currently 1.5M cases/Year (5) With a capture rate of 20 percent and a price tag of $500 the US current market would be worth $150M/ Year.

Globally: 35M cases/Year (6). With a capture rate of 20 percent and a price tag of $500/ patient the lobal current market would be worth $3.5B

Market Projection References:

1. CDC Statistics 2022
2. WHO Statistics 2022
3. American Society Plastic Surgeons, 2022
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