ReGen Factor

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EXECUTIVE SUMMARY

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INTRODUCTION AND COMPANY OVERVIEW

Based in Sydney, Australia; ReGen Factor Pty Ltd, is a disruptive biotechnology company focused on innovative science with potential life-changing applications. In 2018, The Company perfected its proprietary cost effective and exclusive bio identical Basic Fibroblast Growth Factor (bFGF). In early 2019, ReGen Factor launched its flagship product PepFactor™, achieving exceptional results with its PepFactor treatments due to product popularity and safety with no adverse reactions to-date. PepFactor has been used over 16,000 times by independent physicians across the U.S. for androgenic alopecia (male pattern baldness) traction alopecia (hair loss caused by tightly pulled hairstyles), as well as skin anti-aging, wrinkle reduction and acne treatments, —with consistent feedback from both physicians and patients that this product is vastly superior to alternative procedures in medicine and has shown positive results.

The research industry of Fibroblast Growth Factors has been growing for the past 4 decades with thousands of publications being produced on the benefits of bFGF for a multitude of cosmetic and medical applications. ReGen Factor has a distinct advantage as we are the only known company that can produce Fibroblast Growth Factors that are both bioidentical and at a fraction of the production cost of competitors. The high cost of producing Fibroblast Growth Factors has made it unfeasible for competitors to move beyond research to production. Herein alone is a huge opportunity for ReGen Factor to sell its bioidentical and cost-effective Fibroblast Growth Factors to research organizations and companies interested in bringing Fibroblast Growth Factor cosmetic and medical products to market.

Due to our disruptive biotechnology, our company has been propelled to an unparalleled position at the forefront of medicine and over the last two years have begun progressing from the preclinical to clinical stage of trials, without any institutional funding.

The acceptance of our Investigational New Drug (IND) application for PepFactor bFGF and the treatment of androgenic alopecia in men and women, will lead to the pathway to FDA approval for PepFactor Scalp as the first drug approved for the treatment of androgenic alopecia in 20 years.

The current drugs approved by the FDA for use in hair loss are Minoxidil and Finestrade. These drugs may pose some significant side effects.

The known possible Finestrade side effects are:

- Inability to have or maintain an erection
- Decreased sexual desire
- Problems with ejaculation (including decreased volume of ejaculate)
- Pain in the testicles
- Depression
- Changes in the breasts such as increased size, lumps, pain, or nipple discharge
- Rash
- Itching
- Hives
- Swelling of the lips and face
- Difficulty breathing or swallowing

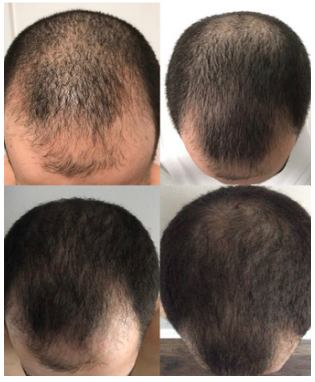
The known possible Minoxidil side effects are:

- Itching or skin rash
- Acne at site of application
- Burning of scalp
- Facial hair growth
- Increased hair loss
- Inflammation or soreness at root of hair
- Reddened skin
- Swelling of face
- Blurred vision or other changes in vision
- Chest pain
- Dizziness
- Fainting
- Fast or irregular heartbeat
- Flushing
- Headache
- Lightheadedness
- Numbness or tingling of hands, feet, or face
- Swelling of face, hands, feet, or lower legs
- Hypertrichosis (unwanted non-scalp hair including female facial hair growth)
- Weight gain (rapid)
- Chest pain
- Pruritus (including rash pruritic generalized and eye pruritus)
- Rash (including pustular, popular, generalized, vestibular, and seborrheic)
- Dry skin
- Skin exfoliation (including exfoliative rash and dermatitis exfoliative)
- Acne (acneiform rash)
- Temporary hair loss
- Changes in hair color
- Angioedema (including lip edema, lip swelling, edema mouth, oropharyngeal swelling, pharyngeal edema, swollen tongue and tongue edema)
- Hypersensitivity reactions (including face edema, generalized erythema, generalized pruritus, swelling face, pharyngeal edema, and throat tightness) Headache and Dizziness
- Nausea and Vomiting
- Eye irritation

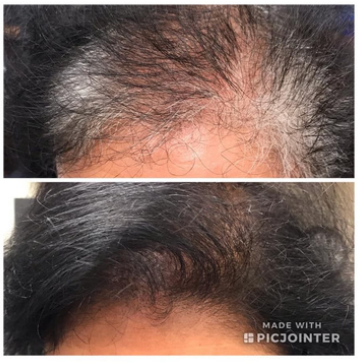
PEPFACTOR COSMETIC TRIALS

ReGen Factor has completed their initial cosmetic trials on the efficacy and safety of PepFactor Scalp treatments for the treatment of androgenic alopecia. No adverse reactions have been reported during our studies. Additional independent research of bFGF has proven bFGF to be safe and effective for the treatment of various ailments.

PepFactor™, ReGen Factors' outpatient brand of basic Fibroblast Growth product (bFGF), continues to be in high demand among physicians and advanced practitioners for hair regrowth and skin treatments across the U.S.



PepFactor™ Scalp results after 4, 6 and 8 weeks of treatment.



PepFactor™ Scalp results after 6 weeks of treatment.

REGEN FACTOR: DISRUPTIVE BIOTECHNOLOGY

Within the field of regenerative biology, researchers and clinicians increasingly understand that the therapeutic mechanism of Fibroblast Growth Factors (FGFs) is not engraftment or differentiation in the target tissue, but rather cell-to-cell communication. ReGen Factor's products contain bioidentical recombinant human basic Fibroblast Growth Factor (rh bFGF AK FGF2, bFGF), are the essential Fibroblast Growth Factor mediators of tissue inflammation, regeneration, and repair. ReGen Factor views Fibroblast Growth Factors as the future of medicine itself.

As the flagship product, PepFactor is the first product created from ReGen Factors' Fibroblast Growth Factors. PepFactor is a human recombinant basic Fibroblast Growth Factor. ReGen Factor's bio-identical and cost-effective production method is applicable to all Fibroblast Growth Factors. Fibroblast growth factors (FGFs) are a family of peptide cytokines that are important in the regulation of many tissues. To date, **23 different FGFs** have been identified, including the best-characterized acidic FGF, or FGF1; basic FGF, or FGF2; and keratinocyte growth factor, or FGF7.

Fibroblast growth factors (FGFs) that signal through FGF receptors (FGFRs) regulate a broad spectrum of biological functions, including cellular proliferation, survival, migration, and differentiation. The FGF signal pathways are the RAS/MAP kinase pathway, PI3 kinase/AKT pathway, and PLC*y* pathway, among which the RAS/MAP kinase pathway is known to be predominant. Several studies have recently implicated the *in vitro* biological functions of FGFs for tissue regeneration. ReGen factor proprietary technology is making it possible to obtain optimal outcomes *in vivo*. Current and potential applications of ReGen Factors bio-identical Fibroblast Growth Factors include applications for the regeneration of tissues, including skin, blood vessel, muscle, adipose, tendon/ligament, cartilage, bone, tooth, and nerve tissues.

PepFactor can be easily formulated for metered-dose inhalers (MDI) for the treatment of chronic obstructive pulmonary disease as well as undergo a process called lyophilization. This process transforms PepFactor from a frozen liquid into an ambient temperature powdered form for convenient storage and worldwide shipping, as well as use in a variety of health and wellness applications. This includes nutraceuticals and cosmetics for treatment of age-related skin charges, scarring, as well as alopecia (baldness) and thinning hair. For oral delivery, further encapsulation of the powder may lead to new formulations appropriate for treatment of skin ulcerations in Scleroderma, osteoarthritis, periodontal disease, diabetic ulcers and other diseases. Overall, lyophilization of PepFactor will allow ReGen Factor to access international opportunities and build a global client base more effectively.

As the clinical potential of PepFactor for treatment of COVID-19 and ARDS becomes increasingly promising, ReGen Factor continues to make great technological strides in anticipation of manufacturing scale-up requirements for global delivery.

Since August of 2020, the FDA defines the term "Advanced Manufacturing" as "new medical product manufacturing that can improve drug quality, address the shortage of medications, and speed time-to-market". ReGen Factor has since made exciting headway in the development of its proprietary advanced cost effective FGF manufacturing technology. ReGen Factor employs a bioreactor capable of producing cost-effective bioidentical to PepFactor in addition to other pipeline products in a current Good Manufacturing Practices (cGMP) environment. It can significantly increase the yield of FGF production and reduce manufacturing costs by 80%.

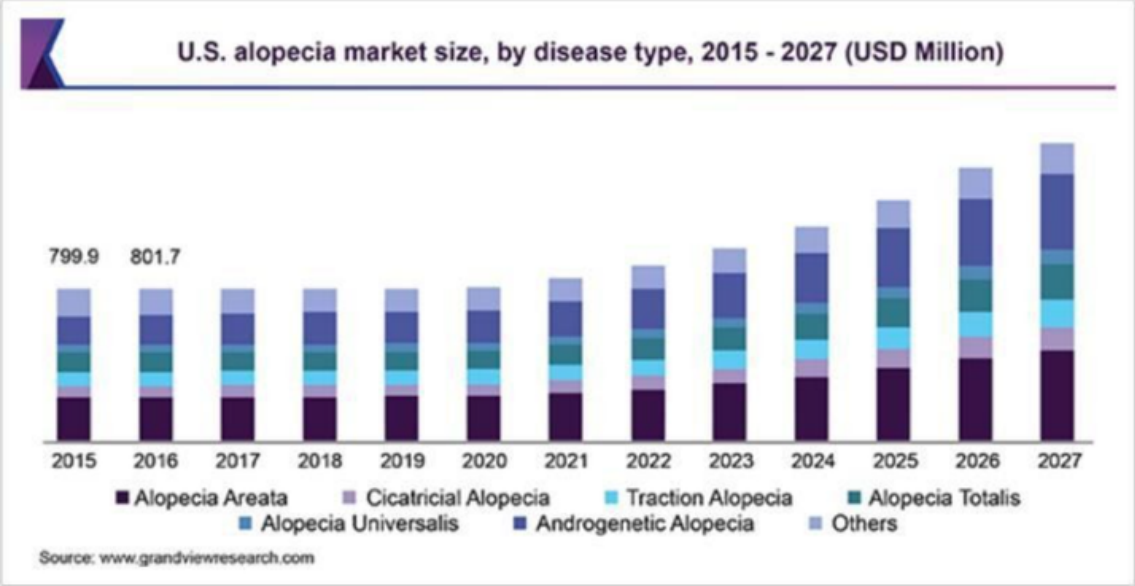
ANALYSIS OF TARGET MARKETS AND COMPETITIVE LANDSCAPE

PEPFACTOR SCALP: ANDROGENIC ALOPECIA, ALOPECIA AREATA AND TELOGEN EFFLUVIUM

Unmet Need:
Androgenic Alopecia or hair-loss/baldness is an extremely common disorder of the hair follicle that affects roughly 50% of men and perhaps just as many women over the age of 40, due to a combination of systemic androgen and genetic factors. Alopecia Areta is an immune disorder of the hair follicle with an incidence as high as 13% among premenopausal women. Telogen Effluvium is the condition of thinning hair. Any of these aforementioned conditions may be detrimental to an individual's self-esteem and cause psychological distress, prompting the search for market solutions. According to data published by the American Hair Loss Association, it was stated that over 95.0% of hair loss in men is caused due to androgenetic alopecia. The prevalence of hair follicle-based disorders is only expected to increase with the rising incidence of chronic disorders such as diabetes, hyperthyroidism, hypothyroidism, Hashimoto's Disease, acute stress disorder, and celiac disease. This is compounded by the rise in average consumption of tobacco, alcohol, and other associated products, in addition to an overall aging population. The current pharmacologic standard of care treatments including Minoxidil are fraught with side effects while surgical solutions to Alopecia may be cost prohibitive. Intermediate solutions such as multiple scalp injections with PRP over 6 to 12 months are reported to be at best 50% effective.

PepFactor's Capacity to Address the Alopecia Market:
Leading dermatologists and plastic surgeons have provided consistent feedback to ReGen Factor that PepFactor Scalp™ for alopecia is a winning clinical application and patients who have received scalp treatments with PepFactor report at least 2-3x superior hair density and new follicle growth compared to scalp injection with PRP. To date over 16 000 treatments were done in the US with PepFactor Scalp non-surgically with no adverse reactions to date and over 94-95% satisfaction rate. Independent investigators across the U.S. are currently performing investigator-initiated trials to demonstrate the safety and efficacy of PepFactor Scalp™ for Androgenic Alopecia with hair density as a clinical endpoint.

Alopecia Market Potential:
The global alopecia market is estimated at USD $2.6 billion in 2019 and is expected to reach USD 14.2 billion by 2028. The market is expected to expand at a CAGR of 8.1% from 2021 to 2028. The strong presence of pipeline products and increasing approval for laser-based therapy to treat hair loss conditions are major factors anticipated to drive growth. Moreover, rising awareness among patients about alopecia and its treatments, increasing government initiatives, supportive regulations & laws, and improvements in healthcare infrastructure are factors expected to propel market growth over the forecast period.



Competitive Landscape of Alopecia Therapeutics:

Please note that the following list is not an exclusive list of competitors with PepFactor Scalp for treatment of alopecia and are often used together in conjunction such as hair transplant with PepFactor Scalp in treatment-refractory cases for optimal results.

- Minoxidil also known as Rogaine has a market size estimated at USD $ 964.5 million in 2020 and is expected to grow at a CAGR of 4.3% through 2026. Minoxidil is a vasodilator widely used in the medical management of male pattern hair loss and can also cause dizziness, flushing, and acne at the application site.
- Finasteride also known as Propecia is a 5-alpha reductase inhibitor (5-ARI) and also known as a dihydrotestosterone (DHT) blocker, which are widely used in the medical management of male pattern hair loss. Since the main mechanism is antiandrogenic, Finasteride is associated with the side effects of erectile dysfunction, ejaculatory dysfunction, and loss of libido. The market size of Finasteride is estimated at USD $ 110 million in 2019 and is expected to grow at a CAGR of 2.5% until 2026.
- Hair Transplant is an elective procedure that is not reimbursed by most insurance companies and is paid entirely out-of-pocket by patients, ranging from USD $ 4,000 to USD $ 15,000. Recent studies show that only 39% of patients report complete satisfaction after a hair transplant. Many clients report loss of hair follicles 12 months out from a hair transplant, often proceeding with a repeat hair transplant. The hair transplant market is estimated at around USD $ 8.1 billion in 2019 and is expected to grow at a CAGR of 26% through 2026.
- Follicum AB's FOL-005 intradermal injections (2-3x/weekly) has already demonstrated safety and promising efficacy in Phase I Clinical Trial in both healthy volunteers and patients with alopecia. FOL- 005 is a modified version of the endogenous protein Osteopontin. Follicum AB is currently underway with a Phase II trial to explore the safety, efficacy, and response to FOL-005 as a once-daily topical application.

PEPFACTOR SKIN

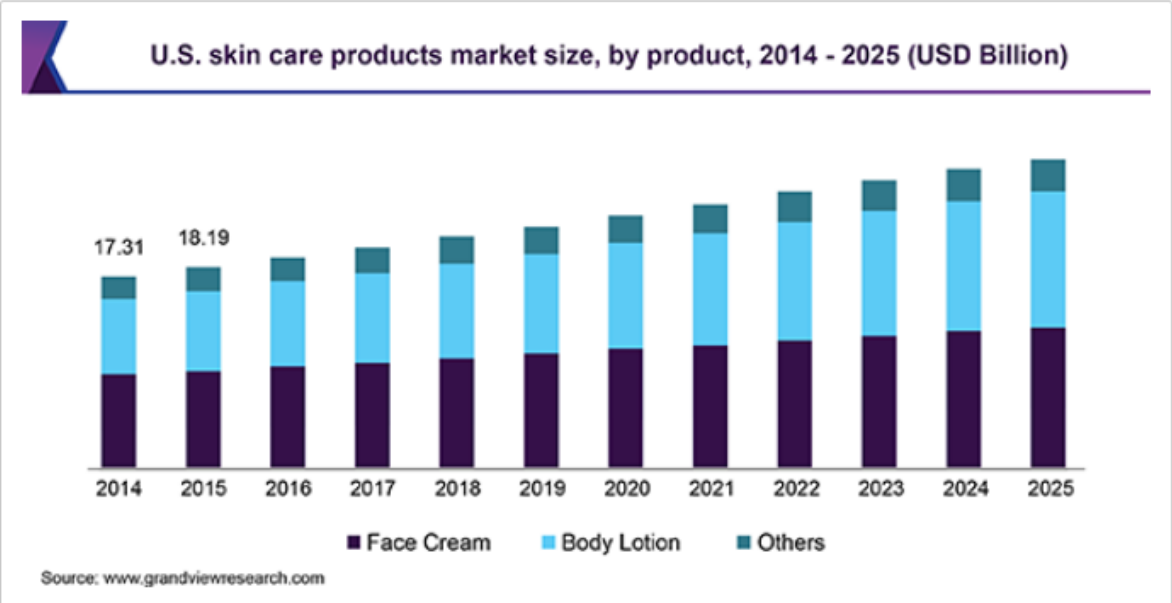
Unmet Need:
PepFactor Skin; a disruptor in this market offers “never seen before” results for anti-aging skin treatments. PepFactor Skin can be used as a stand-alone treatment, or in conjunction with most other treatments.

The skin care products market has been shaped by constantly changing customer demands. Since most of the customer base in the market has become social media savvy, awareness about anti-aging solutions has been on a rise. Hence, providing innovative and effective products & services has become imperative for market players.

Market Potential:
The global anti-aging services market size was valued at USD 23.45 billion in 2018. It is poised to expand at a CAGR of 5.3% over the forecast period - Global Market Insights. Early Onset of Ageing & Rising Adoption of minimally Invasive Procedures to drive the market; the global facial rejuvenation market will expand at a steady CAGR of 4.9% and reach US$26.5 billion market value by the end of 2021*

The global skin care products market size was valued at 134.8 billion in 2018 and is projected to expand at a CAGR of 4.4% from 2019 to 2025 on account of the rapidly expanding global cosmetics industry. There is a wide variety of products available on the market including sunscreens, anti-aging creams, body lotions, and skin brightening creams. Rising awareness regarding the various benefits of using personal care products has resulted in a rise in their demand over the last few years. This has also boosted the demand for natural and organic skincare products, making it a major sector in the cosmetics and wellness industry. An increasing need for natural quick-fix solutions for various problems that arise from pollution and other factors is projected to have a positive impact on the market over the forecast period. New product launches and the establishment of strategic partnerships are expected to remain a critical success factor for the industry participants in the years to come. **

*MarketWatch
**Grandview Research



PEPFACTOR SKIN: CONTINUED

REGENERATIVE MEDICINE

The regenerative medicine market has extraordinary potential. Operating in a market with a global CAGR of 32.3% with a projected market size of over $39 billion by 2023, we at ReGen Factor have decided to focus strategically on COVID-19 and ARDS as the first two areas of unmet need in U.S. healthcare to address through regenerative medicine solutions. This will be followed by a focus on joint and back pain, hair restoration, wound care, and burn injury. This market strategy allows our company to potentially provide our innovative and scientifically driven therapies to over 50 million patients in the U.S. alone. Competition in the regenerative medicine field is intense and subject to rapid technological changes. The following discussions will delve into the market analysis of the clinical indications for which our pipeline products have shown the strongest and most favorable preclinical and clinical evidence as well as independent feedback.

COVID-19 TREATMENTS

Unmet Need:

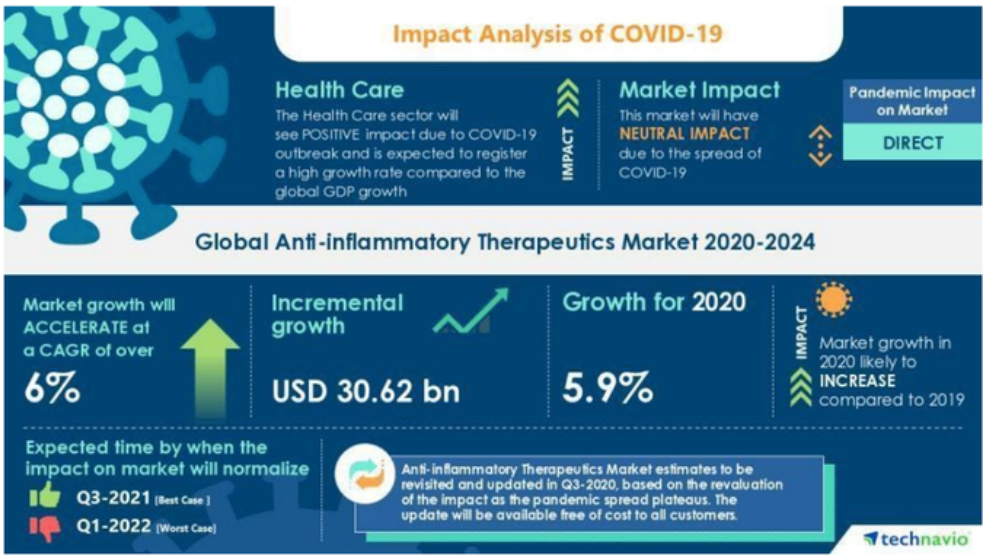
Severe COVID-19 or COVID-19 associated ARDS: With widespread availability of vaccine projected to occur in June 2021 (at the earliest), the identification of multiple, highly virulent mutant strains of SARS COV- 2 RNA virus, reports of individuals who have become repeatedly infected, and a pandemic amplifying since its inception in the U.S. in March 2020, the need for effective therapeutics agents for COVID-19 remains large and unmet. These observations would also suggest that early predictions of a high mutation rate might render ineffective vaccines, convalescent plasma, and natural host immunity developed against earlier strains of the SARS COV-2 RNA virus seem increasingly possible. Daily U.S. deaths remain in the thousands, and daily new cases in the hundreds of thousands, and 78% of ICU beds are occupied by COVID patients nationally.

Mild-Moderate COVID-19: Other clinically relevant populations who may benefit from treatment with PepFactor are patients with early (mild to moderate) COVID-19 who are at high-risk of hospitalization, intubation, and death. Largely comprised of the elderly and infirm, 20% of those infected are predicted to be "high-risk," by some estimates. Therefore roughly 20,000 high-risk patients a day are being infected based on current rates.

Post-Acute COVID-19 Syndrome: Another key population who may benefit from PepFactor are patients with post-acute COVID syndrome, otherwise known as "long-hauler" syndrome, which affects approximately 10% of those infected, therefore implying at least 2.2 million patients in 2021 in the U.S. alone.

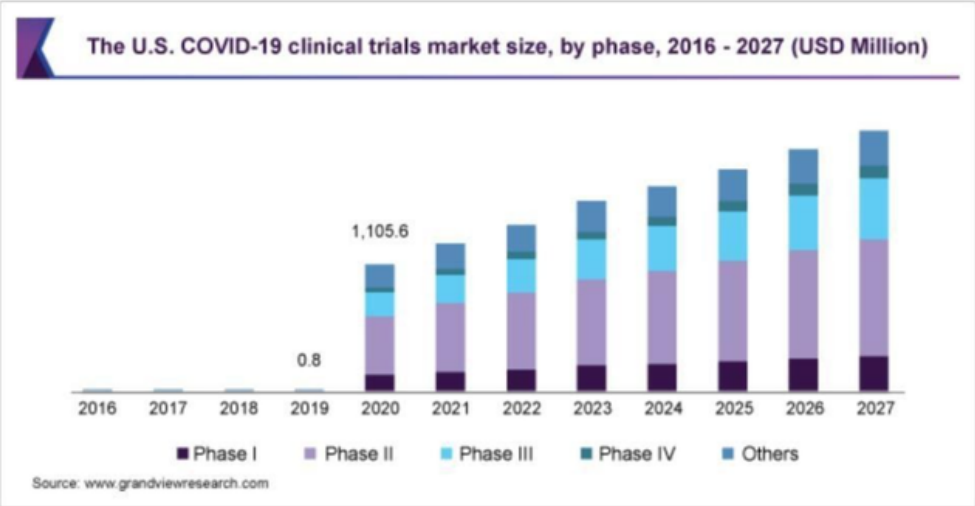
COVID-19 therapeutics market potential:

The global market value for COVID-19 anti-inflammatory therapeutics is estimated at USD $30 billion and is expected to grow at a Compound Annual Growth Rate (CAGR) of at least 6% from 2020-24.

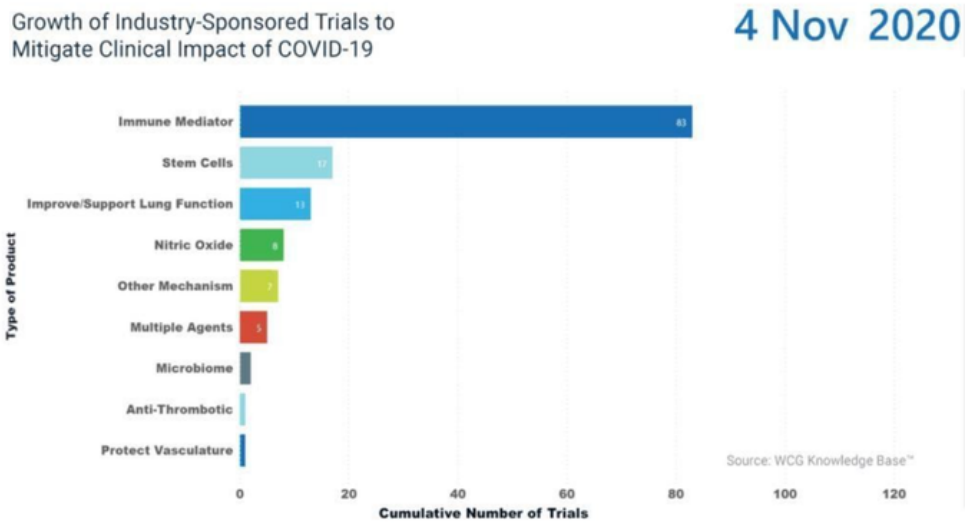


COVID-19 TREATMENTS CONTINUED

The U.S. COVID-19 clinical trial market size is estimated at USD $ 5 billion and is expected to grow at a CAGR of 9.5% from 2021-27.



Competitive landscape of COVID therapeutics:
PepFactor stands out as a treatment candidate and therapeutic for COVID-19 due to the unique strengths as (A)immune mediator that can (B) improve lung function as well as (C) directly inhibit viral activity.



COVID-19 TREATMENTS CONTINUED

- Gilead's synthetic antiviral drug Remdesivir showed that a 5-day regimen can reduce median time to recovery in Phase III trial. Remdesivir has since received FDA EUA approval and has been adopted as part of Standard of Care for Severe COVID-19. Remdesivir is expected to generate an estimated USD $ 2 billion in global sales with a CAGR of 29%, reaching $4.2 billion in 2023.

- Corticosteroid is a class of medications that includes Dexamethasone. Following over two thousand patients randomized to Standard of Care with Dexamethasone versus Standard of Care alone, the RECOVERY trial demonstrated that Dexamethasone does reduce mortality in patients who require oxygen support. Since corticosteroids are used for a variety of indications, the global market increased only subtly from USD $ 4.2 billion in 2019 to USD $ 4.5 billion in 2020 with a CAGR of 4.2% through 2023.

- Convalescent Plasma Therapy received FDA EUA approval in August 2020 for hospitalized patients with COVID-19 and is expected to grow in market size from USD $ 20.3 million in 2019 to USD $ 39.6 million in 2023 at a CAGR of 14.4%.

ARDS

Unmet Need:
Acute Respiratory Distress Syndrome (ARDS) is a life-threatening condition and one of the most common conditions facing critically ill patients in the intensive care unit (ICU). Classic ARDS, not related to COVID- 19, can be caused by pneumonia, aspiration, sepsis, pancreatitis, and trauma. Despite decades of research involving investigational products, supportive care with mechanical ventilation remains the mainstay of treatment and morbidity and mortality remain high. There is currently no FDA-approved market solution for ARDS.

PepFactor's Capacity to Address the ARDS Market:
Despite initial disagreements regarding paradoxical lung mechanics in a subset of patients during the first wave of the pandemic, scientists and physicians worldwide have since recognized COVID-19 associated ARDS as basically ARDS in peer-reviewed journals including notably JAMA.

At ReGen Factor, we believe in designing for success. Recognizing that the challenge of ARDS lies in treating a constellation of varying phenotypes, our Clinical Operations Team is currently in midst of designing a Pre IND application with our R&D Team to optimize dosing, timing of intervention, as well as potential biomarkers that can predict treatment responsive ARDS phenotypes.

ARDS Market Potential:
The Global ARDS market is estimated at USD $ 619 million in 2019 and is expected to reach USD $ 991 million by 2027, growing at a CAGR of 6% through the forecast period. Contributory factors including rising air pollution and globalization are projected to support market growth over the forecast period. Given the lack of effective market solutions thus far, the current market predictions are notably less predictive in the advent of a truly disruptive biotechnology.

ARDS: CONTINUED

Competitive Landscape of ARDS Therapeutics:

- Arthersys has completed a Phase I/II study for the treatment of ARDS using MultiStem Cell Therapy which showed higher ventilator-free days and higher ICU-free days in addition to a higher quality of life among ICU survivors; their Phase II/III study is currently underway in the US. Of note, MultiStem Cell Therapy is composed of Multipotent Adult Progenitor Cells (MAPC), rather than Fibroblast Growth Factors (FGFs). MAPCs are perceived to be a more primitive population than FGFs with a greater differentiation potential, and while FGFs are extensively studied and characterized, there are fewer studies published on MAPCs.

- Mesoblast has an ongoing Phase III trial for the treatment of classic ARDS with Remestemcel-L, an investigational product composed of mesenchymal lineage adult stem cells sourced from multiple healthy donors. Prior to the announcement of a failed Phase III trial for the treatment of COVID-19 associated ARDS Remestemcel-L, Mesoblast was offered USD $1.35 billion dollars by Novartis for the global rights to Remestemcel-L and analysts estimated that peak sales would reach USD $1.7 billion dollars once the investigational product received market approval.

General Limitations of Stem Cell Therapies:

- Stem cells need to be harvested and concentrated in high numbers prior to intravenous administration. Improvements for delivering stem cell therapy with good survival at every stage in the last few years have been marginal.
- Allogeneic (donated) stem cells need to be processed quickly and preserved before use. The primary method for preservation of these cells is by cryopreservation or freezing, which destroys the cells if they are not protected--common methods of protection include the use of chemicals such as DMSO (Dimethyl Sulfoxide) or glycerin, both of which have both been shown to contribute to additional cell death.
- Unlike exosomes, which are only 30-150 nanometers in diameter and 1/1000 the size of a cell, stem cells when intravenously administered can be trapped in the pulmonary circulation due to their large size and increase the risk for an embolic phenomenon.

OSTEOARTHRITIS

Unmet Need:
Treatment of Osteoarthritis is driven significantly by symptomatic treatment of osteoarthritic pain with NSAID and other medications. The global osteoarthritis market is divided into knee, hip, hand and other small joint osteoarthritis with knee osteoarthritis as the largest and fastest-growing segment of the market. Market-approved intra-articular treatments include corticosteroids for all joints, which is problematic as U.S. patients are more overweight and sicker on average and may not tolerate cumulative exposure to corticosteroids.

Viscosupplementation is currently the healthiest and most effective market solution for osteoarthritis, but it is only approved for knee osteoarthritis. Additionally, recent research has found viscosupplementation not to be effective at significantly reducing pain or improving function and is no longer recommended by the American Association of Orthopaedic Surgeons (AAOS). To date, there has yet to be an FDA- approved market solution for osteoarthritis that promotes healing and regeneration of cartilage. This market will continue to grow given an aging population susceptible to osteoarthritis and increased prevalence of osteoarthritis.

Oswestry Disability Index (ODI), and 3 different functional scales of the extremities, suggesting that intra-articular treatment should be considered prior to joint replacement. The twelve-month follow-up data showed similar results and a report has been submitted for peer-reviewed publication. A Phase I/II IND application for osteoarthritis will be filed in 2021. A Phase I/II IND application for osteoarthritis will be filed in 2021.

Osteoarthritis potential market:
The global osteoarthritis market is estimated at USD
$7.3 billion and is expected to grow at a CAGR of 8.7% from 2020-25.

OSTEOARTHRITIS CONTINUED

Competitive Landscape of Osteoarthritis Therapeutics:

- Corticosteroids is a class of medications that include Kenalog, often injected intra-articularly for osteoarthritic joint pain by rheumatologists as well as pain management physicians. Although steroids serve to reduce inflammation and provide pain relief in many patients, intra-articular injection of corticosteroids do not contribute to regeneration and may exacerbate the injury with excess use for damaged or degenerative joints. Intra-articular steroids tend to provide only 30-60 day reduction in pain, which is not sustainable for chronic degenerative joint disease. The global market for corticosteroids is estimated at USD $ 4.5 billion in 2020 with a CAGR of 4.2% through 2023.
- Viscosupplementation is the injection of a series of or a single injection of hyaluronic acid for the treatment of osteoarthritis. Hyaluronic acid is found in synovial joints and is a natural lubricant to decrease friction during slow movements and absorb shock during fast movements. Viscosupplementation is primarily used for knee osteoarthritis only in the U.S. and must be repeated every 6-12 months. Globally, the viscosupplementation market is estimated at USD $ 4.2 billion in 2020 with a CAGR of 9.2% from 2020-27.
- Platelet Rich Plasma (PRP) is the most common autologous therapy and is offered by regenerative medicine and wellness clinics for the treatment of osteoarthritis and is only approved by Workers' Compensation and Personal Injury Payors in a small subset of cases in which an acute injury has been proven via imaging. Overall, the global PRP market is estimated at USD $ 414.8 in 2019 and is expected to grow at a CAGR of 12.1% from 2020 to 2027.
- Bone Marrow Aspirate Concentrate (BMAC) is the second most common autologous therapy. For this therapy, it is most common to harvest bone marrow from the patient's iliac crest as this area is one of the richest sources for FGFs. However, the harvesting of bone marrow is an invasive procedure that can be painful and carries a low risk of infection at the harvest site. Injection with BMAC is typically an elective procedure, as most insurance payers still refuse coverage for this service, and patients typically pay USD $ 3,000-5,000 for intra-articular injection of BMAC.

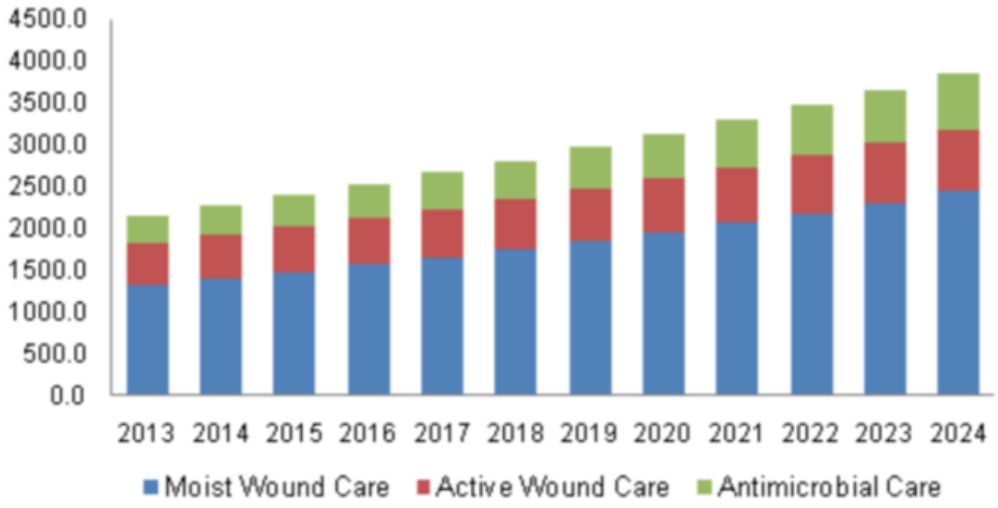
WOUND CARE

Unmet Need:
Localized injury to the skin and underlying tissue can result in pressure ulcers and bedsores that turn into chronic wounds, especially among diabetic patients. Burn injuries are also common injuries that lead to chronic wounds and account for 195,000 annual deaths globally. Chronic wounds affect over 5.7 million Americans in the U.S. and are estimated to cost an overall USD $20 billion annually. Given the rising prevalence of diabetes, the wound care market is anticipated to increase over the next 4 years.

ReGen Factor's ReGeneron's Capacity to Address the Wound Care Market:
ReGeneron is a tri-layer collagen-based skin substitute that easily conforms to irregular surfaces with many clinical applications to promote healing and regeneration in ophthalmology, wound care, burn injury, and general surgery. The innovative technology of ReGeneron prevents moving/gliding. The ability of ReGeneron to wrap around irregularities and adhere to any surface renders it an ideal skin substitute for pressure ulcers, diabetic foot, burn injuries, and other slow-healing wounds.

Wound care market potential:

The global bioactive wound care market is estimated at USD $6.9 billion in 2015 and is expected to grow at a CAGR of 6.3% until 2024. The global wound care biologics market is expected to reach USD $ 2.3 billion by 2023 at a CAGR of 9.8%.



The widespread adoption of wound care biologics for the treatment of ulcers and burn injuries in developed countries and the high incidence rate of diabetic foot ulcers attributes to the majority of the wound care biologics market growth. The end-user of the wound care market is segmented into hospitals, ASCs, burn centers, and wound clinics, with hospitals accounting for the largest end-users of wound care biologics.

Competitive Landscape of Wound Care Therapeutics:

- Moist Product Segment is a segment that already dominated more than 50% of the market share in 2015. This segment refers to foam, alginate, film, hydrogel, and hydrocolloid-based dressings that maintain a moist environment and are recommended for pressure ulcers, diabetic foot, burn injuries, and other chronic slow-healing injuries.
- Organogenesis (ORGO)'s Dermagraft is a cryopreserved human fibroblast-derived dermal substitute composed of fibroblasts, extracellular matrix, and a bioabsorbable scaffold and is FDA-approved for the indication of full-thickness diabetic foot ulcers greater than 6 weeks in duration which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.
- Organogenesis (ORGO)'s Apligraf is a bi-layered skin substitute constructed by culturing human foreskin-derived neonatal fibroblasts in a bovine type I collagen matrix over which human foreskin- derived neonatal epidermal keratinocytes are then cultured and allowed to stratify. Apligraf is FDA- approved for the indication of non-infected partial and full-thickness skin ulcers due to venous insufficiency of greater than 1-month duration and which have not adequately responded to conventional ulcer therapy and for use with standard diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than three weeks duration.
- MiMedx (MDXG) is a placental-based allograft company with annual revenue of approximately USD $300 million. MiMedx has built a foundation in the wound care space with a sales force of 250+ representatives and several brands including EpiFix, AmnioFix, EpiBurn, and AmnioFill.
- Integra (IART) is a company with revenues estimated at $1.5 billion and a market cap of $4.3 billion, Their key brands in these markets are AmnioExcel, AmnioExcel Plus, AmnioMatrix, PriMatrix, OmniGraft, and Medihoney.

OBESITY/WEIGHT LOSS

Unmet Need:
Worldwide obesity has nearly tripled since 1975 with 1.9 billion adults (39%) aged 18 and over considered overweight and 650 million of these (13%) obese in 2016. In 2020, 39 million children under the age of 5 were overweight or obese. This epidemic is preventable. According to WHO obesity and related diseases account for at least 2.8 million deaths each year and they also increase the risk of developing other serious conditions such as heart disease and stroke, diabetes, some cancers, osteoarthritis and more. Decreased physical activities in obese patients make them depressed, socially isolated, or discriminated against; resulting in poor self-esteem, body image distortions, and making them more likely to be the targets of teasing or bullying.

Fibroblast Growth Factor Binding Protein 3 (FGFBP3) has been found to reduce the fat in obese mice by over a third. In a research project out of Georgetown Lombardi Comprehensive Cancer Center found that eight FGFBP3 treatments over 18 days reduced the fat in mice by over a third. FGFBP3 binds to three FGF proteins that are all involved in metabolic control and regulate the storage and use of carbohydrates and fats. The protein also cut several obesity-related disorders in the mice, including hyperglycemia (high blood sugar) and decreased the fat in their once fatty livers and microscopic and clinical examinations didn't turn up any side effects. Offering a safe alternative to dangerous surgeries in the treatment of obesity is an opportunity within the current obesity treatment market.

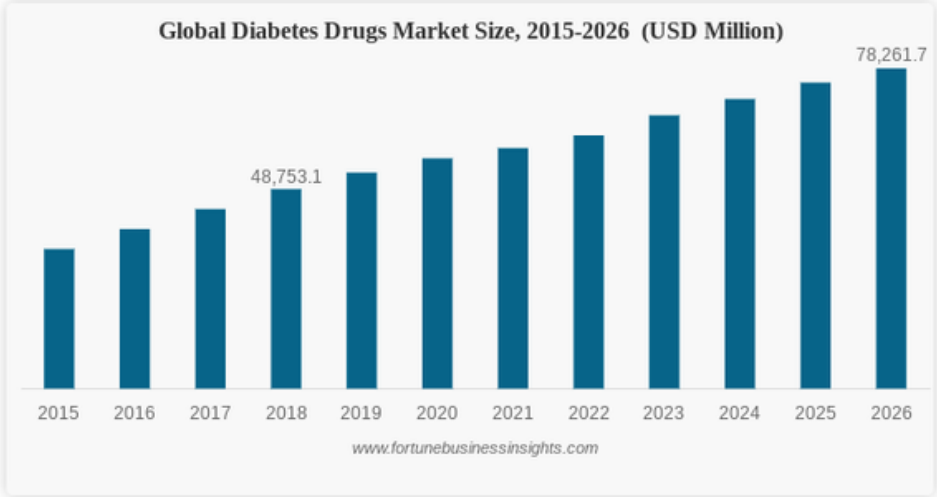
Obesity and Weight Loss market potential:
According to the current analysis of Reports and Data, the global obesity treatments market was valued at USD 6.14 Billion in 2018. The study covers in-depth analysis of obesity treatment options and upcoming innovations to cure obesity. Obesity is caused by increase in the size of fat cells in the body. Obesity is a serious medical condition that leads to high blood pressure, high cholesterols and heart diseases. The global obesity treatment market size is expected to reach USD 27.10 billion by 2028 at a CAGR of 16.7%, according to a new report by Reports and Data. The weight loss and weight management diet market size was valued at 192.2 billion in 2019, and is projected reach $295.3 billion by 2027, registering a CAGR of 7.0% from 2021 to 2027.

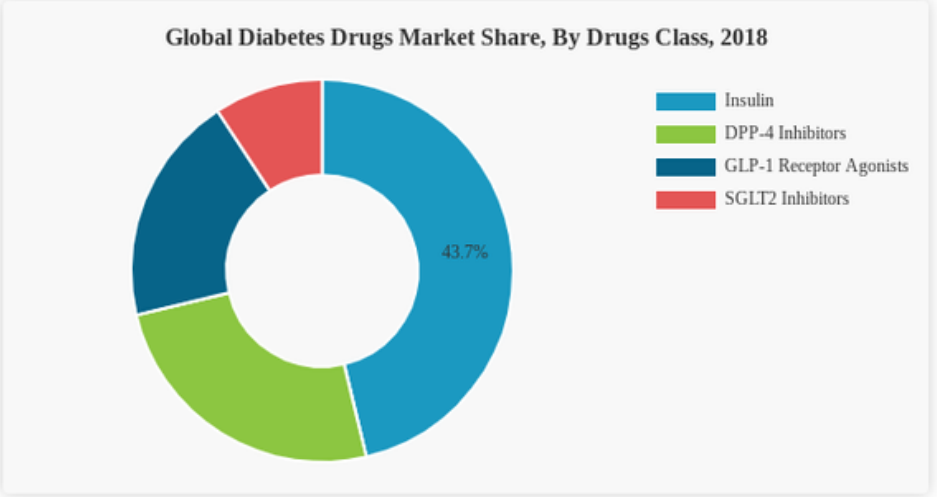
TYPE 2 DIABETES

Unmet Need:
Type 2 diabetes is an impairment in the way the body regulates and uses sugar (glucose) as a fuel. This long-term (chronic) condition results in too much sugar circulating in the bloodstream. Eventually, high blood sugar levels can lead to disorders of the circulatory, nervous and immune systems.

Recent studies have generated a great deal of interest in the insulin-independent glucose-lowering effects of fibroblast growth factor-19 (FGF19) and FGF1 in diabetic rodents and their potential application as novel anti-diabetic therapies. Standard treatment for type 2 diabetes begins with lifestyle modification, and includes oral medications and insulin therapy to compensate for progressive β-cell failure. Current pharmaceutical options are limited in that they do not maintain stable, durable glucose control without the need for treatment intensification and can be associated with adverse effects ranging from hypoglycaemia to weight gain or bone loss. Fibroblast growth factor-1 (FGF1) and FGF19 have been shown to improve glucose metabolism in diabetic rodents. FGF1 has emerged as a potentially safe candidate in restoring euglycaemia, without causing overt adverse effects.

Type 2 Diabetes market potential:
The global type 2 diabetes market is set to almost double from $31.2 billion in 2015 to $58.7 billion by 2025, representing a compound annual growth rate of 6.5%, according to research and consulting firm GlobalData.





FATTY LIVER DISEASE

Unmet Need:

The liver is a vital organ of the body performing umpteen complex functions such as fighting infections, removing toxins, bile secretion and it produces clotting factors, proteins and cholesterol among others. Malfunctioning of the liver can be life-threatening. It can cause multiple acute and chronic diseases (hepatitis, non-alcoholic fatty liver disease, liver cancer, liver tumor and liver cirrhosis).

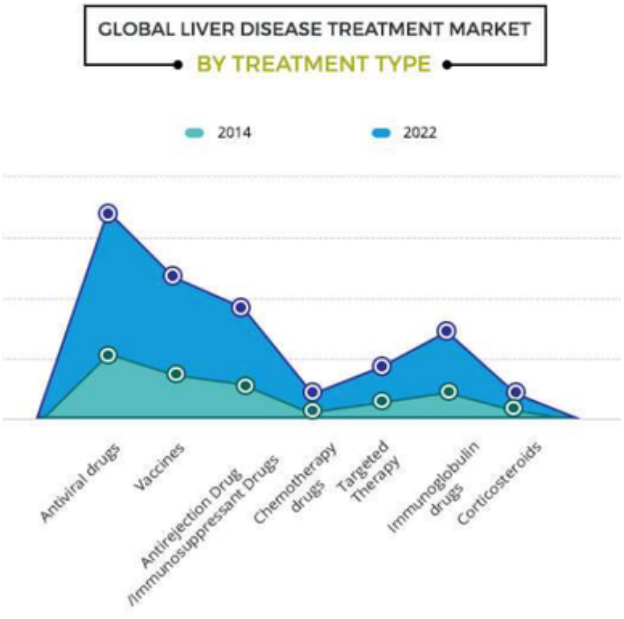
The rising global prevalence of obesity, metabolic syndrome, and type 2 diabetes has driven a sharp increase in non-alcoholic fatty liver disease (NAFLD), characterized by excessive fat accumulation in the liver.

Changing lifestyle such as increasing consumption of alcohol, unhealthy diets have increased the incidences of liver disease. Whereas, growing geriatric population has lead to significant addition in the global liver disease treatment market. There is huge market potential for this market as the occurrences of disorders have become common. The number of adults diagnosed with liver disease in the US is 4.5 million with a mortality rate of 44,358. Side effects associated with medication is the growing concern for the liver disease market.

FGF21 has been recognized as a possible pathway for the treatment of nonalcoholic fatty liver disease (NAFLD). Targeting of the FGF21/FGFR/β-Klotho pathway may halt or reverse hepatic fat infiltration, inflammation, and fibrosis. Fibroblast growth factor 21 (FGF21) holds considerable promise in targeting the underlying pathogenesis as it decreases liver fat and hepatocyte injury while suppressing inflammation and fibrosis across multiple preclinical studies.

Fatty Liver Disease market potential:

The Global non-alcoholic fatty liver disease & NAFLD market is estimated to be valued at US$17.43 billion in 2021 and is projected to reach at a market value of US$62.06 billion by 2031. Non-alcoholic fatty liver disease & NAFLD are both attracting a lot of investment and research activity. Geographically, the North American market is forecasted to dominate the global liver disease treatment market in the forecast period. The growth of this regional market is majorly driven by the rising liver diseases such as hepatitis and escalating healthcare expenditure.



BEYOND BFGF - VIVOVAC

ReGen Factor Pty Ltd has entered into a partnership with VivoVac Pty Ltd (VivoVac), a Sydney headquartered, Australian vaccines research company who is strategically focusing on addressing specific areas of unmet need in Australian and U.S. healthcare systems, through potential market solutions for COVID-19 and acute respiratory distress syndrome (ARDS).

VivoVac is confident in the safety and efficacy results for the VivoVac oral COVID-19 vaccine that VivoVac is developing. VivoVac is expecting to apply for a pre-IND meeting with the US FDA by the end of November 2021. It is expected that the animal and safety studies for the VivoVac COVID-19 oral vaccine will be completed by the end of December 2021. The acceptance of our Investigational New Drug (IND) application will elevate VivoVac to the only known company to commence a Phase 1 trial for an AAV based oral COVID-19 vaccine.

VIVOVAC COVID VACCINES

Oral Vaccines for Covid 19 and other human to human transmitted viruses and ReGen Factor's Capacity to Address the COVID-19 Market

VivoVac is involved in research and development of vaccines for Covid 19. Our platform will also allow us to develop vaccines for viruses like HPV, STD's and Tuberculosis. Our current products in development are Vivo Vac oral vaccine for Covid 19. We are also developing a new drug to treat lung fibrosis caused by Covid 19 infections.

Vivo Vac is an oral vaccine being designed to use the science of (AAV) to allow for a thermally stable vaccine for COVID-19. The simplicity and ease of distribution of an oral vaccine that does not require refrigeration, will mean increases in vaccination rates in rural and remote regions of the globe, as well as reduced costs in vaccination administration due to the lack of healthcare staff needed for its administration.

COVID-19 Vaccine Prevalence - Oral Vaccine or injection?

Injections have historically been an effective way of treating disease and creating immunity. However, there are limitations that have become even more apparent with the latest pandemic & global shutdowns.

The oral COVID-19 vaccination is thermally stable, meaning transportation is simple. It requires no needles and little to no healthcare workers to administer the vaccine, meaning a country-wide and even global roll out of the vaccine can be as simple as sending them out in the post.

Vaccines are the most promising means of controlling the global pandemic, and thus far 7 different vaccines across 3 platforms have been rolled out around the globe. The stability, safety and efficacy of these potential vaccines are not yet clear.

Given the global impact of COVID-19 and the tremendous demand for vaccines worldwide, there is a huge need for a novel, cost-effective, safe and convenient COVID-19 vaccine

VIVOVAC COVID VACCINES

Vivo Vac's Difference is the first known Oral Vaccination for COVID-19.
Vivo Vac has been designed with quality, stability and efficiency in mind. Allowing for rapid deployment and fast formulation to cope with new strains, the oral Covid vaccine requires no refrigeration or injections to ensure safe and effective administration of the vaccine globally.

AAV has long been used by scientists to deliver genes into living organisms for applications like gene therapy and vaccination. Clinical trials have been done with AAV in preventing HIV, Influenza and many other infectious diseases. AAV's are not associated with human diseases and will not integrate into the human genome. Hence are a safe vector for gene delivery. AAV have low inflammatory potential, with a long-lasting gene expression, providing long-lasting and safe virus protection.

Vivo Vac Use Cases & Projections
Given the tremendous need for vaccines worldwide, there is a huge demand for a novel, cost-effective, safe and convenient COVID-19 vaccine. Oral vaccination has socioeconomic benefits and provides the possibility of stimulating both humoral and cellular immune responses at systemic and mucosal sites.

The oral COVID-19 vaccination is thermally stable, meaning transportation is simple. It requires no needles and little to no healthcare workers to administer the vaccine, meaning a country-wide and even global roll out of the vaccine can be as simple as sending them out in the post.

Study Preparations:
The next steps in moving towards clinical trials & FDA approval:

- To test the efficacy of the vaccine on in vitro study (pre-clinical study)
- To test the toxicity of the vaccine on human patients (clinical trial, phase 1)

NOTE: Our unofficial animal studies to date have shown:
- No adverse effects on animals.
- No adverse effects on humans expected.
- 100 percent of animals and humans in the study developed Covid 19 antibodies after the VivoVac Oral Covid 19 Vaccination.

The Vivo Vac Covid Vaccines requires no cold chain or medical staff to deliver the VivoVac Vaccines and the VivoVac Vaccine Platform can also be employed to create vaccines for human-to-human transmitted viruses like HPV, TB and many more.

Outcome Measures

1 Primary Outcome

Title	Number of Participants with Serious Adverse Events and Severe Adverse Events Throughout the Study
Description	Serious adverse events are medical events that resulted in death, were life-threatening, required admission to hospital, or resulted in notable incapacity of the individual. Adverse events were also graded from mild to severe. Severe adverse events are medical events that prevent normal everyday activities or fever > 39°C; this category does not include serious adverse events. Serious adverse events and severe adverse events include both solicited and unsolicited events. Solicited events comprised signs and symptoms that were reported by the participant using a predefined checklist in a diary card, or a fever, as determined by the participant's measurement of their body temperature, for up to 7 days after vaccination. Unsolicited events comprised other signs and symptoms recorded through the end of the study. Adverse events were assessed by the investigator for causality as unrelated, unlikely, possibly, or probably related to the vaccination.
Time Frame	From Day 0 up to 42 days

Outcome Measure Data

Analysis Population Description

All randomized participants who received a dose of study vaccine.

Arm/Group Title	[redacted]	[redacted]
Arm/Group Description:	[redacted] Day 0, administered orally as 1 single solution (0.5 mL total; 10^{11} viral genomic copies by qPCR).	[redacted] one vaccination with simulated solution on study Day 0, administered orally as 1 single solution (0.5 mL total).
Overall Number of Participants Analyzed	25	25
Measure Type: Count of Participants Unit of Measure: Participants		
≥1 serious adverse event	0 0.0%	0 0.0%
≥1 severe adverse event (AE)	0 0.0%	0 0.0%
≥1 severe AE probably related to vaccine	0 0.0%	0 0.0%
≥1 severe AE possibly related to vaccine	0 0.0%	0 0.0%
≥1 severe AE unlikely related to vaccine	0 0.0%	0 0.0%
≥1 severe AE unrelated	0 0.0%	0 0.0%

CRITICAL STRATEGIC INITIATIVES

In summary, ReGen Factor believes it is well-positioned to focus its proprietary technology on numerous medical markets. The result is expected unparalleled revenue growth and profitability. Revenue growth will come from three primary areas:

1. Increased sales of PepFactor, PepFactor Scalp, and ReGeneron due to expansion of pertinent indications.
2. Increased demand of the flagship product PepFactor Scalp due to the significant need for safer treatments of androgenic alopecia with less side effects in men and women and
3. International marketing of our regenerative medicine products, which will be formulated for nonmedical use including cosmetics.

In order to address these opportunities, the company has undertaken a number of critical growth initiatives, summarized as follows:

- Continue to build out critical departments within the company. Primarily:
  - Clinical Operations
  - Medical Affairs
  - Information Technology
- Technology Patents
  - Complete the groundwork to continue to convert Provisionals to permanent.
  - Continue to develop international patent protection.
- Complete the evolution to enhanced manufacturing.
- Complete the testing and approval process for the manufacturing and distribution of the lyophilized “powdered” product.
- Invest heavily in market development activities to increase product knowledge.

Beyond these core initiatives, which are largely management’s focus for 2021, ReGen Factor is working toward an initial set of initiatives. These will help set the stage for further expansion of the product line: The R&D department is currently exploring the following for stability, bioactivity, and characterization, including:

- PepFactor Metered-dose inhaler (MDI) Formulation for Outpatient Pulmonary Indications, Including Pulmonary Fibrosis and COPD
- Lyophilized PepFactor for International Distribution and improved logistics
- Oral formulations of PepFactor in combination with other compounds as nutraceutical products
- Cosmetic formulations of PepFactor as a facial cream, serum, ointment, and shampoo.
- Oral formulations of PepFactor for treatment of gastrointestinal disorders as well as improvement of gut health.
- Oral formulations of PepFactor to combat gum disease.
- Oral Vaccine development and production to combat Covid 19 and the formulation and production of vaccines for person to person viruses including Tuberculosis and HPV viruses.

USE OF FUNDS

- ReGen Factors core goals over the next twelve months revolve around FDA approvals, opening new markets, branding and marketing, as well as scaling manufacturing capabilities. Uses of funds are directed toward the strategic initiatives described previously. The proceeds raised through the completion of the $4 million (expandable by the Company in its discretion up to $6 million) equity offering estimated to occur during the fourth quarter of 2021 will be primarily directed toward the following areas:

1. Completion of Phase I clinical product trials
2. Manufacturing initiatives, Inventory of product, supplies, etc.
3. Other growth initiatives.

However, the company believes it is likely that in order to complete the initiatives, as outlined, additional capital will be required.

Estimated Use of Proceeds: 2021 Series Equity Raise	ESTIMATED COSTS (USD)
Pre-IND and IND (Androgenic Alopecia) Phase 1	$3,000,000
Manufacturing Initiative, Product supplies, Equipment and Testing	$500,000
Other growth initiatives	$500,000
Total Use of proceeds	$4,000,000

CAPITALIZATION

ReGen Factor is currently conducting an equity raise of $4 million (expandable up to $6 million at the Company's discretion) via a private placement at a pre-money implied valuation of $48,000,000.

The offering consists of Shares at an initial offering price of $0.20 per Share. This offering is expected to be concluded early in the fourth quarter of 2021. The Company has attained its implied pre-money valuation of $46,000,000 for the current offering, primarily by reference to information obtained from individuals with knowledge of current market capitalization information regarding privately held competitors of the Company at similar stages of development and the Company's continued success in clinical outcomes and progress towards required regulatory approvals.

To properly scale the business and capitalize on its potential market dominating technology, ReGen Factor anticipates it will require additional capital subsequent to the Class A-1 round. The Company anticipates it will obtain such capital via a strategic transaction, recapitalization or exchange listing. Any such efforts will be dependent on then-current market conditions.

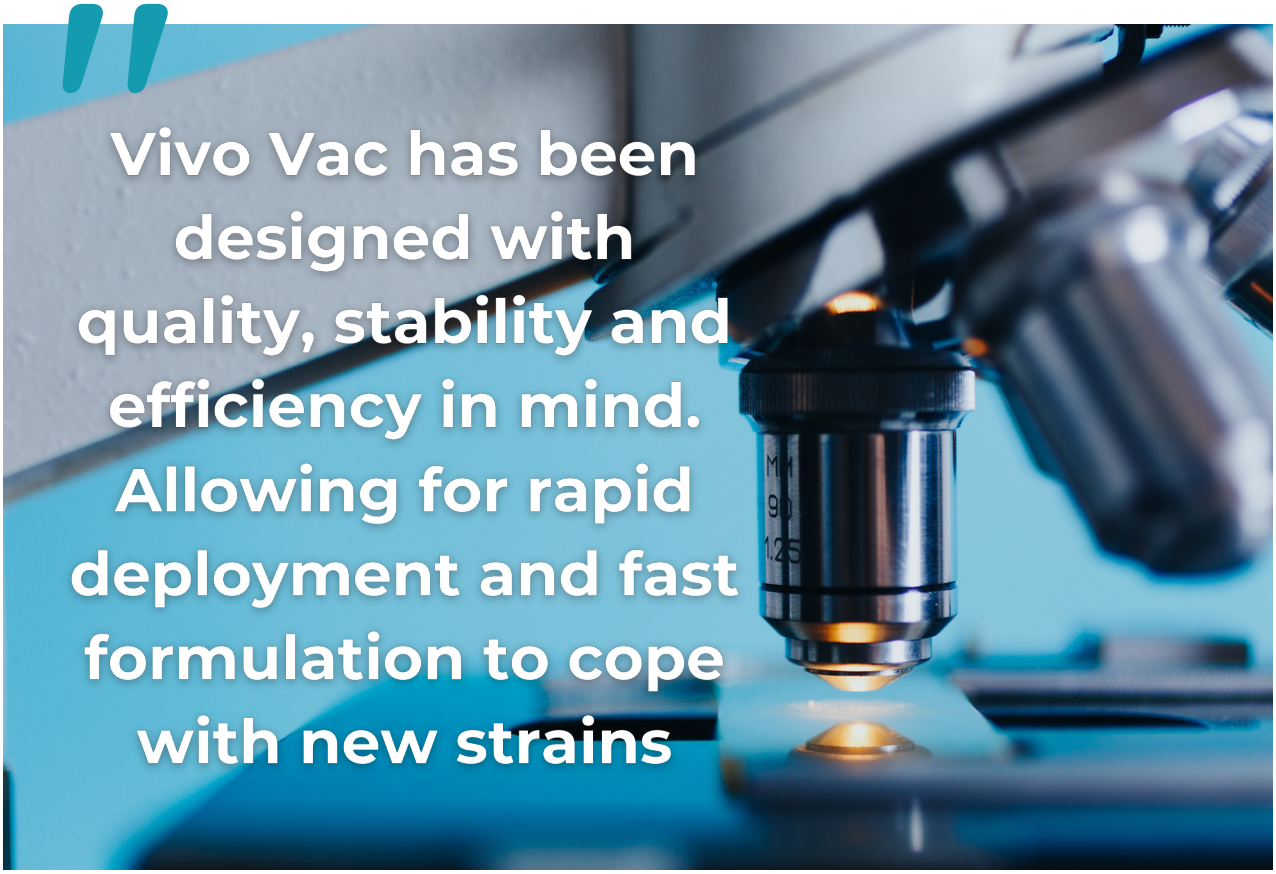
INDICATIVE FINANCIAL INFORMATION

ReGen Factor commenced sales in the United States during mid-2019, and the company has been able to nearly double sales year over year. Notably, COVID-19 greatly disrupted sales as the primary consumers of PepFactor Skin and PepFactor Scalp were associated with elective surgery and procedures which were restrained due to COVID for much of the year.

As shown in the discussion above, 2021 is a critical year for the company. If its Phase 1 and subsequent Phase 2 trials of PepFactor Scalp show its ability to help regrow hair in men and women suffering from androgenetic alopecia, the company will obviously experience a sharp rise in revenue. Additionally, the completion of other INDs will open new markets as well. To be able to seize these opportunities, ReGen Factor must invest in the initiatives previously discussed. These initiatives come with a substantial cost. Additionally, there is no guarantee of success. As such, any forward-looking estimates of sales as well costs are highly speculative.

The following financials should be viewed as indicative of potential only as well as presented in the draft, non- GAAP form. ReGen Factor has engaged an independent third-party financial audit firm to complete an inception-to-date financial audit through 2020. The audit report is expected to be completed by the end of December 2021. Looking forward, the revenue estimates shown in the following table assume that sales of its existing products will continue to double each year, that PepFactor Scalp will be adopted as an important treatment for androgenetic alopecia, that the company's additional INDs will lead to new markets.

The attached P&L summary assumes only the receipt of up to $15.0 million proceeds of the Series A-1 equity raise, it is likely that an additional larger equity raise will be required to achieve this level of revenue growth.



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