

VP04 – Digital Therapeutic (DTx)

A rare disease company with focus on patients with fibrotic disease



Vicore-Alex launches VP04 Digital therapeutic (DTx)

Vicore Pharma - Alex Therapeutics

- Domain expertise in IPF/respiratory + Development expertise in DTx/AI/psychology

Joint development of digital CBT for IPF

- There is a need for treatments beyond drugs
- Cognitive behavioural therapy is an established therapy for mental health/conditions

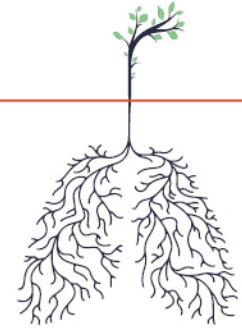
Terms

- Alex receives 8.1 MSEK (1 MUSD) upfront + milestones and royalties on sales
- Vicore owns all rights to VP04

Vicore appoints Jessica Shull as Head of Digital Therapeutics

- Specialist in requirements for digital therapeutics, EU/US market
- Led European policy for the Digital Therapeutics Alliance
- 20 years' experience in integration of digital health for international markets

Vicore's portfolio for IPF patients



Integrated healthcare for IPF

VP01

- In phase II PoC for treatment of IPF, to reduce/stop fibrosis
- Recruitment ongoing and keeping the schedule
- No safety concerns (GI) so far

VP02

- Inhaled IMiD to treat IPF related cough
- GMP synthesis ongoing
- Phase I 2022

VP03

- Novel C21 follow-on molecules for ILD and/or other indications

VP04

- Digital cognitive behavioral therapy
- Collaboration with Alex Therapeutics

Why is a DTx needed for IPF?

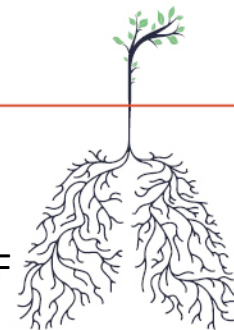
IPF diagnosis often leads to depression and anxiety

- 3-5 years of life expectancy
- Drugs are available but have poor tolerability
- Daily reminder of symptoms and the limitations on your life
- Frequent relapse or decline to the next phase of the disease
- Distancing from friends and family due to having a terminal disease

Vicore will provide an integrated care solution for IPF

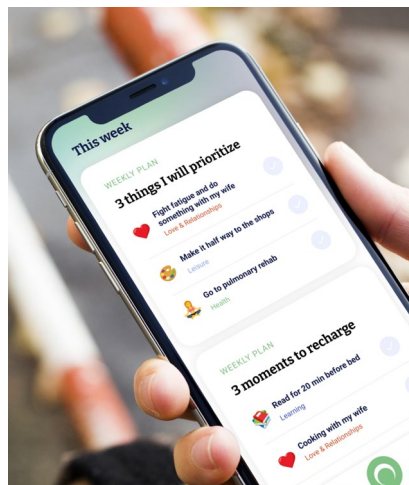
- Develop a product that aims to relieve the associated depression - 24/7
- Behaviour change, handling their situation, to avoid mental anguish
- Structure their day, learn about the condition and abilities
- Find balance in activities and recovery

The VP04 product



Mission – to improve the life for patients with IPF

- Fully autonomous and stand-alone prescription digital therapeutic (DTx) treating IPF patients with anxiety and depression
- CE certified and registered as a Software as a Medical Device
- MDR (EU) & FDA (US) Compliant
- AI engine delivering personalized therapeutic programs
- Built on evidence-based Cognitive Behavioral Therapy (CBT)
- Continuous support to maintain the positive effects of CBT over time



Digital therapeutics – Regulated medical devices

DTx - clinically proven software that treats a specific disease or condition

Require CE-mark and clinical trial to demonstrate

- Safety
- Reliability
- Efficacy

Growing evidence base for effectiveness

- Psychology
- Circulatory disease
- Neurology
- Respiratory disease (COPD, asthma)
- Endocrinology
- Oncology

Successful and ongoing DTx developments

Current examples of DTx partnerships

- Sanofi and Happify - psychological aspects of MS
- Pfizer and Alex Therapeutics – nicotine addiction
- Boehringer and Click Therapeutics - schizophrenia
- Otsuka and Click Therapeutics - MDD
- Janssen and Koa - depression
- Roche and Kaiku – cancer

Business Insider estimates that the DTx industry will be worth \$56 billion in the next 5 years.

DTx products are priced as medical products

DTx products are often described as companion products to a drug therapy but can also be used as a stand-alone-treatment.

VP04 Path to Market

Design and Development phase

- Design for needs: with patients, physicians, and healthcare systems
- Develop DTx features and interface according to relevant standards to comply with "software as a medical device" regulations
- Design and approval of clinical trial – 2022
- Run trial, publish results

Certification as a medical device – this certifies the product for sale in every EU country, opening OTC pathways in 27 markets

Obtain reimbursed prescription status and launch

- Gather real world data to indicate efficacy
- Final price negotiation after one year of prescribed use

Value of DTx for Vicore

This product development will be a paradigm shift in the way we engage, support, and collaborate with patient communities and healthcare systems

- Formalizes, extends and values what Vicore already does
- Builds a patient-facing product together

How does this benefit Vicore, in addition to revenue stream?

- Patient familiarity, trust and backing
- Engagement with physicians, patients, families
- Learn to evolve products through understanding of disease

IPF patients suffer from much more than shortness of breath

VP04 DTx addresses the mental health issues that are part of IPF



THANK YOU FOR LISTENING!

Q & A session

