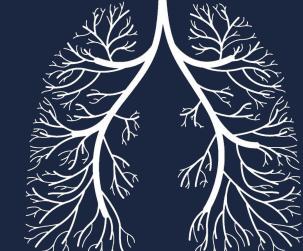


# Annual Report 2021

Vicore Pharma Holding AB (publ)



vicorepharma.com

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# Summary of the Period

### Important events during 2021

- In February, Vicore completed a directed share issue raising 336 MSEK. The share issue was approved at an Extraordinary General Meeting in March.
- In March, Vicore reported top-line data from the mechanistic phase II study in systemic sclerosis and Raynaud's phenomenon (SSc) showing that C21 increased bloodflow in fibrotic tissue.
- In May, Vicore announced that the company had entered into a collaboration agreement with Alex Therapeutics for the development of a digital therapeutic (DTx) for patients living with idiopathic pulmonary fibrosis (IPF).
- In June, Vicore announced that the company had received approval from the U.S. Food and Drug Administration (FDA) to start the pivotal phase 3 trial with C21 in COVID-19.
- In August, Vicore announced a strengthened management team with three senior recruitments; Jessica Shull, Head of Digital Therapeutics, Åsa Magnusson, Chief Commercial Officer and Mikael Nygård, VP Business Development.

- In September, Vicore announced that the first patients in the global phase 3 trial with C21 in COVID-19 (ATTRACT-3) were dosed.
- In September, Vicore announced that the company was granted a patent in the US covering the use of C21 to treat infections caused by Severe Acute Respiratory Syndrome (SARS) coronavirus (CoV), including SARS CoV-2.
- In October, Vicore announced that the results from the phase 2 trial in COVID-19 (ATTRACT) were published in EClinicalMedicine, a scientific journal published by the Lancet.
- In November, Vicore announced results from the ATTRACT phase 2 extension trial showing that C21 reduced long-term lung injury after COVID-19.

# Important events after the year-end

- In February, an interim analysis of the AIR phase 2 trial in idiopathic pulmonary fibrosis (IPF) suggests that C21 stabilizes disease and shows an unanticipated increase in lung function in IPF patients.
- In February, Vicore announced the advancement of its first new chemical entity from the VP03 program to a first in human phase 1 trial. A clinical trial application (CTA) is expected to be submitted during the second quarter 2022.
- In March, Vicore announced the plan to initiate a proof-of-concept trial with C21 in pulmonary arterial hypertension (PAH).
- In March, Vicore announced the initiation of a human forearm blood flow study with C21, planned to start in Q2 2022.
- In March, Vicore announced that Michael Wolff Jensen resigned from the board and was replaced by Jacob Gunterberg as chairman until the annual general meeting in May 2022.

#### Financial overview for 2021

Net sales amounted to 0.0 MSEK (0.0) The operating loss was -294.8 MSEK (-149.5) Loss for the period amounted to -296.5 MSEK (-146.9) Loss per share before and after dilution was -4.25 SEK (-2.71) Cash, cash equivalents and short-term investments as of December 31, 2021, amounted to 371.5 MSEK (318.7)

#### **Financial calendar**

May 5, 2022	Interim report, Q1
May 11, 2022	Annual General Meeting 2022
August 25, 2022	Interim report, Q2
November 3, 2022	Interim report, Q3
February 28, 2023	Year-end report 2022
Einanoial reporte are	available on the company's websit

Financial reports are available on the company's website www.vicorepharma.com from the day of publication.



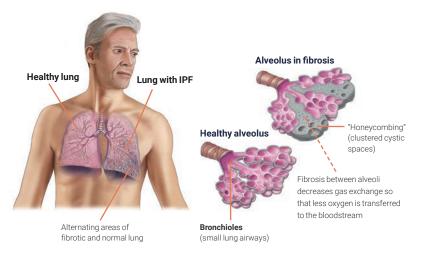
# Vicore in Brief

icore is a clinical-stage pharmaceutical company focused on developing innovative medicines in severe diseases where the Angiotensin II type 2 receptor (AT2R) plays an important role. The company currently has four development programs: VP01, VP02, VP03 and VP04. VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (IPF), COVID-19 and pulmonary arterial hypertension (PAH). VP02 is a new formulation and delivery route of thalidomide and focuses on the underlying disease and the severe cough associated with IPF. VP03 includes the development of new AT2 receptor agonists (ATRAGs). VP04 develops a clinically validated digital therapeutic for IPF patients.

The company's shares (VICO) are listed on Nasdaq Stockholm's main market.

#### Idiopathic Pulmonary Fibrosis (IPF)

Idiopathic pulmonary fibrosis ("IPF") is characterized by progressive fibrosis (scarring) in the lungs. The disease gradually causes impaired lung function leading to shortness of breath and cough. In later stages of IPF, signs of pulmonary hypertension are often seen.



"Patients with IPF have a high incidence of anxiety. The impact of untreated anxiety may synergize with the physiological burden of IPF and further decrease quality of life for these patients."

- Prof. Maureen Horton, Johns Hopkins University

# "All I know is decline, acceptance for my new reality, which is hard to do. "

- Patient with IPF

#### **Vicore pipeline**

Indication	Program	Preclinical	Phase 1	Phase 2	Phase 3	Next event
COVID-19	C21					Phase 3 read-out H2 2022
IPF	C21					Phase 2 read-out H2 2022
PAH	C21					Phase 2 start Q4/Q1 2023
IPF anxiety	DTx					Clinical trial 2022
IPF cough	Inhaled IMID					Formulation development
Multiple indications	C106					Phase 1 start estimated 2022

 Worldwide prevalence of IPF:

 133-200

 of 100 000

 Source: Source: Navaration et al. 2011 https://thorax.bmj.com/content/66/6/462 and PAH - Global drug forecast and market analysis to 2029, Global Data 2020H

# Year in Brief

2021 was a year of progress in building Vicore for the next development milestones and exploring new areas, despite the many challenges faced due to COVID-19. With a clear purpose and a highly dedicated team, Vicore is well positioned.

### Progress in preclinical and clinical development

#### Topline data from the mechanistic trial in Raynaud's phenomenon in systemic sclerosis

During the first quarter, the results from the mechanistic phase 2 trial in twelve patients with systemic sclerosis (SSc) and Raynaud's phenomenon were presented. The patients received a single-dose of C21 and the aim of the trial was to shed light on the angiotensin II type 2 receptor's (AT2R) role in acute improvement of blood flow in affected tissues.

The result from the trial showed a statistically significant temperature recovery as a result of dilation of peripheral vessels suggesting that C21 can increase blood flow in fibrotic tissue. The temperature recovery continued after the study measurement period.

This vasodilatory effect is believed to be a benefit in the treatment of IPF.

#### C21 reduced long-term lung injury after COVID-19 in the ATTRACT phase 2 extension trial

The results from the extension trial, 3-6 months after treatment, including a subset of 33 patients (ATTRACT-2)

showed that patients receiving C21 (n=17) displayed reduced pathological abnormalities compared to the placebo group (n=16). In the C21 group, on average 10.3 percent of the lung was affected compared to 19.2 percent in the placebo group meaning a nearly 50 percent reduction in lung injury in the C21 group compared with the placebo group. Radiological change was measured as ground glass opacity, a pathological characteristic following viral respiratory infection. These positive findings together with the other clinical trial results from ATTRACT suggest that C21 could accelerate recovery from COVID-19.

#### Start of FDA-approved, phase 3 trial (ATTRACT-3) in patients with COVID-19

Previously reported positive phase 2 trial results strongly supported further evaluation of C21 in COVID-19 and in June 2021, Vicore received approval from the U.S. Food and Drug Administration (FDA) to start a pivotal phase 3 trial with C21 in COVID-19 (ATTRACT-3) and in September the first patients in the trial were dosed. The study is as a randomized, double-blind, placebo-controlled, multinational, phase 3 trial that will include 600 adult patients hospitalized with COVID-19 and requiring oxygen support but not invasive mechanical ventilation. The primary objective is to evaluate the effect of C21 on recovery from COVID-19. The trial has been activated in more than 50 study centers in the US, Czech Republic, Ukraine, South Africa, India, Philippines, Argentina, Brazil, Columbia and Russia. In February 2022, the recruitment in Russia and Ukraine was stopped due to the conflict. Topline data from ATTRACT-3 is expected during the second half of 2022.

# The ongoing phase 2 AIR trial in patients with IPF presents positive interim results

The open-label, 60 patients trial in patients with IPF progressed during the year. Patients with IPF are a risk group for COVID-19, as they are particularly susceptible to respiratory diseases due to an already impaired lung function. Recruiting patients for the study, has been challenging, as regular hospital visits are required and the company has taken several measures to ensure patient safety. After year-end, an interim analysis suggested that C21 stabilized disease and increased lung function in iPF patients, results that gave Vicore confidence to prepare for the next trial.

# Highlights during 2021 and the period thereafter:

- Reported encouraging results showing an increase in lung function and stabilized disease, in patients with IPF from an interim analysis of the phase 2 AIR trial in IPF
- Results from COVID-19 extension trial showed a nearly 50% reduction in lung injury with C21 compared to placebo
- Expanded pipeline with a digital therapeutic in IPF
- Secured the companys financing through a directed share issue of 336 MSEK
- First drug candidate in the preclinical VP03 program ready to enter clinic
- PAH, decided as a new indication for clinical development
- Start of phase 3 trial in COVID-19

### New AT2R agonists (ATRAGS) developed further

Throughout 2021, Vicore efforts to develop proprietary molecules that modulate AT2R in a controlled manner was intensified. The company is in the process of establishing strong intellectual property protection around the class of AT2R stimulating drugs (ATRAGs) through patent filings.

After year-end, Vicore announced that the first compound was ready for a phase 1 trial.

### New addition to development pipeline

During the second quarter, Vicore expanded the pipeline with a digital therapeutic to treat anxiety in patients with IPF by the signing of an agreement with Alex Therapeutics for development and clinical validation.

The agreement with Alex Therapeutics, a medtech company with expertise in artificial intelligence and evidence-based psychology, marks the initiation of a new development program for Vicore; VP04 – the joint development and commercialization of a clinically validated digital therapeutic (Vicore DTx) to provide cognitive behavioural therapy (CBT) to treat anxiety for people living with IPF. Under the agreement, Vicore will own all rights to VP04 in exchange for an upfront payment to Alex Therapeutics of 8.1 MSEK (1 MUSD), plus potential milestone payments and royalties on sales.

During 2021, the main focus was on technical and software development. The first pilot phase investigation of the Vicore DTx received approval to start and a following pivotal investigation is estimated to start during H2 2022.

# Secured patent protection covering COVID-19

### Patent protection for the use of C21 in SARS CoV viruses

Vicore was granted a patent in the US covering the use of C21 to treat infections caused by Severe Acute Respiratory Syndrome (SARS) coronavirus (CoV), including SARS CoV-2(COVID-19).

#### Several important recruitments during the year

During 2021, Vicore strengthened the organization on several fronts, spanning from R&D, Quality Assurance to commercial functions. In August, Vicore announced a strenghtened management team with three senior recruitments; Jessica Shull, Head of Digital Therapeutics, Åsa Magnusson, Chief Commercial Officer and Mikael Nygård, VP Business Development. At the end of 2021, a total of 21 employees were employed in Vicore.

### Strengthened financial position

Vicore completed a successful directed share issue raising 336 MSEK during the first quarter 2021. The share issue was subscribed by Swedish and international institutional investors.



### • CEO **Comments**

2021 has been about growth and renewal. The progress we made during the year has put the company in a very optimistic position as we begin 2022. With a firm foundation in the treatment of rare lung diseases Vicore is ready to enter new therapeutic areas through the advanced development of new angiotensin II type 2 receptor agonists (ATRAGs). The first compound - C106 - from the next generation of ATRAGs, is ready to enter clinical development during 2022 and an additional three compounds are in the late stages of preclinical development. In addition, our

multi-product effort in IPF was boosted by positive interim data from the AIR trial with our lead molecule, C21, and the company will be striving to advance that program into the next phase. We also plan to launch a new clinical program for C21 in the related area of Pulmonary Arterial Hypertension during Q4/Q1 2023.

We began our Phase 3 trial (ATTRACT-3) with C21 in COVID-19

in the summer of 2021 following FDA approval in Q2 2021. With more than 50 centers in 10 countries now active, around half of the patients are enrolled in the study. A formal safety review implemented when 150 patients had been enrolled raised no safety concerns. As previously communicated, we expect to provide topline read-out of the results from the trial in the second half of 2022.

"Our aim in IPF is to address all aspects of the disease, also major advance over currently available including the associated cough and anxiety which we know are strongly affecting quality of life in this patient group"

> In February 2022, when approaching half of the patients enrolled in the IPF-trial (AIR), Vicore reported data from an interim analysis of the trial. The data showed the potential of C21 to restore lung function, widely exceeding our expectations. The AIR trial measured lung function using a standard and widely used parameter known as Forced

Vital Capacity (FVC), a measure of functional lung volume. After 24 weeks treatment with C21, FVC in the first nine patients increased on average by +250 ml: over the same period, FVC in untreated patients would be expected to decline by 120 ml. Seven of those patients received a further 12 weeks of C21 treatment and that led to further improvements in FVC.

For patients, a treatment that halted the decline in IPF would be a medicines. These interim results suggest that C21 does more than that, and actually increases lung function. We at Vicore have therefore taken the decision to begin planning the next trial with C21 in IPF. Over the next few months, we will be discussing the details of the trial design with our clinical collaborators and with regulators. We believe that it is our obligation to do our utmost to accelerate the development of C21 for IPF patients.

The past year has been an intensive year of preparation for another part of Vicore's offering in IPF, our digital ther-



apeutic (Vicore DTx) designed to help patients with anxiety and depression due to their disease through cognitive behavioral therapy. A pilot study involving around 20 patients is about to start at a number of leading centers for respiratory disease. The pilot study will help shape a much larger pivotal study in approximately 250 patients which is due to begin in H2 2022. The pivotal study is designed to provide the information needed for FDA clearance of the product which is estimated to 2024.

Based on a variety of preclinical and clinical data that the company gathered during the years, Vicore will expand its clinical program both within rare lung disease and beyond. In one initiative, the company will build a new clinical program for C21 in pulmonary arterial hypertension (PAH). PAH is a rare disease characterized by dysfunction of the arteries of the lung. In preclinical models, C21 reverses vascular damage and significantly improves blood flow; in patients, C21 can help restore blood flow in systemic sclerosis and Raynauds phenomenon. Based on this and other evidence, we plan to begin a proof-ofconcept trial with C21 in PAH in Q4 2022/ Q1 2023.

Our second new clinical initiative within the VP03 program represents a greater advancement for Vicore and recognizes the broad potential of ATRAGs. C21 is the original ATRAG and, until now, the only one tested in clinical trials. While Vicore has been working on C21 in clinical trials, the company also conducted an exhaustive discovery and preclinical development program on a series of new, proprietary ATRAGs. The first ATRAG, C106 is now ready for a phase 1 trial and Vicore expects to submit a clinical trial application in Q2 2022. An additional three ATRAGs are expected to finalize preclinical evaluation during H1 2023.

ATRAGs are about repairing. The antifibrotic, repair and regenerative effects seen in many preclinical models of diseases are reflected in human disease. The recent interim data in IPF illustrate how deep that impact could be. The emergence of a pipeline of new, proprietary small molecule agonists of AT2R and the submission of the clinical trial application represents a first step in transforming Vicore from a rare lung disease company to a clinical platform company exploring a new class of drugs, the ATRAGs, in multiple indications.

Vicore is on the threshold of change. We anticipate key clinical data on C21 in COVID-19 and reinforcement of our interim data in IPF. We are also at the start of a new era of exploration of the potential of ATRAGs with our next generation of AT2R modulators. As a company that traditionally worked closely with the academic community on C21, we are planning to establish a broad platform - the ATRAG Academy - for promoting research into the use of ATRAGs to treat human disease. The idea is to provide drug plus placebo plus documentation to groups who share our ambition to accelerate ATRAGs from model studies into humans. And to the investors who support us and the hard-working team within Vicore, and to the investigators and patients who are part of our ongoing clinical trials, we once again extend our gratitude for their continued support.

Carl-Johan Dalsgaard, CEO

"The recent interim data in IPF illustrate how deep the impact of ATRAG's antifibrotic, repair and regenerative effects can be

# Moving towards a platform company

t Vicore, we are devoted to exploiting the full potential of the angiotensin II type 2 receptor (AT2R). We are in a unique position to leverage our deep expertise in the area to bring novel therapies to patient populations with a large unmet medical need.

Clinically relevant data in COVID-19, IPF and systemic sclerosis with C21 confirm the vascular and antifibrotic effects of C21 and suggest that AT2R agonists (ATRAGs) represent an important new class of drugs and bodes well for the translation also in other diseases with similar strong preclinical support.

With increasing knowledge about AT2R agonists, and a plethora of preclinical studies pointing to the disease modifying effects in several indications, there is a multitude of opportunities to explore. To prioritize among these opportunities, Vicore conducted a strategic review during 2021. Parameters including scientific rationale, medical need and commercial potential were guiding in the process that resulted in the selection of three potential new indications for AT2R agonists, pulmonary artery hypertension (PAH), diabetic nephropathy (DN) and preeclampsia (PE).

Of these, PAH is first in line. Vicore has

generated preclinical data in pulmonary hypertension that support the decision for a proof-of-concept trial, which is planned for 2022.

In parallel with the ongoing clinical development, Vicore is running an extensive chemistry program to generate novel selective AT2R agonists with long patent life and improved properties. The aim is to generate a robust pipeline of clinical candidates, and the first new compound is planned to enter the clinic in 2022.

We strongly believe that Vicore is better positioned than anyone to pursue these opportunities and feel that it is our responsibility to do so.





#### Vicore strategic priorities

- moving towards a platform company

#### **Strategic priorities**

#### Leadership position in rare lung diseases

- Accelerate development of C21, a best-in-class IPF treatment.
- With a patient-centric approach, work closely with patient organizations and clinical experts.
- Drive innovation with digital therapeutic (DTx) addressing IPF-related anxiety.
- O Initiate a proof-of-concept trial in PAH .

#### **New indications**

- Leverage our deep expertise in AT2R to expand the clinical pipeline to new indications supported by strong preclinical data and unmet medical need.
- Attract academic partners.

#### New proprietary ATRAGs

 Continued accelerated drug discovery and chemistry approach to generate novel ATRAGs with strong IP protection.

#### Capabilities and skills

- Strengthening team capabilities to advance the clinical programs and maintain outsourced and digital working model.
- Strengthen technical capabilities to ensure product supply.
- O Continue to work with strong external partners to co-create and make progress in prioritized areas, e.g. in DTx and in the development of new ATRAGs.

#### **Partnerships**

 Increase visibility and attention for Vicore's assets and clinical programs.

# Market Overview

he most advanced clinical programs in Vicore are targeting IPF and COVID-19, two therapeutic areas that both constitute major market opportunities. As the biology around AT2R agonists (ATRAGs) is being elucidated, it is becoming evident that several additional indications beyond IPF and COVID-19 may be of relevance for this new class of drugs. With a broadened spectrum of indications, the commercial and market potential for AT2R agonists will also be expanded.

### IPF – a rare disease with large unmet need

It is estimated that between 80,000 and 111,000 people in the EU are currently living with idiopathic pulmonary fibrosis ("IPF"), with up to 35,000 new cases being diagnosed each year<sup>1</sup>. In the US, approximately 100,000 people are currently living with IPF according to the National Institute of Health (NIH), with 30,000-40,000 new cases per year. Both the incidence and prevalence of IPF are increasing worldwide<sup>2</sup>. Despite targeted treatments being available for more than ten years, mortality is still high with a median survival of approximately three years from the time of diagnosis. From the moment of diagnosis, patients will experience symptoms throughout most of their disease, with disabling dyspnea and cough that reduce quality of life. A large proportion of people

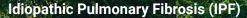
with IPF also suffer from anxiety and depression.

IPF is classified as a rare disease, and the development of drugs to treat IPF can therefore be granted orphan status. Developing an orphan drug provides several benefits, including market exclusivity for up to seven years from approval in the US and up to ten years in the EU and Japan<sup>3</sup>. Other benefits of orphan drug status can include tax credits for parts of the development costs or a discounted fee to the FDA in the US. In the EU, assistance with the development of the drug is possible and a discount on the fee to the European Medicines Agency (EMA) is also possible. For orphan drugs, which are aimed at a relatively fewer number of patients, the studies are often smaller, and the development phases are often combined, which can lead to a faster development timeline<sup>3</sup>. The orphan drug market has shown strong growth in recent years and is estimated to continue to outgrow the overall pharmaceutical market<sup>3</sup>.

There are currently two approved drugs for IPF, Esbriet (pirfenidone; Roche/Shionogi) approved since 2011/2014 and Ofev (nintedanib; Boehringer Ingelheim) approved 2014/2015 in Europe and the US. Although both drugs can slow down the progression of the deterioration of lung function, they are associated with side effects such as vomiting and diarrhea and have not yet conclusively shown that they can improve the survival or quality of life of the affected patients. The combined global sales of these drugs are estimated to approximately \$4.0 billion in 2021 of which approximately 70% in US<sup>4</sup>. The IPF market has in recent years attracted a great deal of interest from the pharmaceutical industry due to the significant unmet medical need and a number of licensing deals and acquisitions have been completed such as the acquisition of Promedior by Roche in 2019 at a value of \$1.4 billion (see table on next page).

# COVID-19 – long-term need for better treatments

The COVID-19 pandemic has impacted many aspects of society and people's lives, and in February 2022, over 354 million cases had been confirmed world-wide<sup>5</sup>. With increasing vaccine coverage in developed countries many nations are now preparing for an endemic phase of the virus, accepting that the virus is here to stay, although at a more stable level. Many factors are pointing in this direction such as viral immune escape, waning immunity, uneven global vaccine distribution<sup>6</sup>. The global effort to develop vaccines has been a scientific success, and novel treatments and approaches towards the reduction of disease mortality have also emerged. However, although



Prevalence (US and EU) : 250,000 Global market size: \$4.0 Bn Patients not on treatment in the US: 40%

There are two drugs for IPF available on the market today. Despite a limited effect and risk of severe side effects their total sales in 2021 amounted to approximately

Source: Company reports from Roche and Boehringer Ingelheim



relatively little is so far known about the long-term consequences of infection, new data hint at a "hidden pandemic" of long-term sequelae of severe Covid-19. Observational studies indicate that a significant proportion of patients experience long-term respiratory problems, decreased exercise tolerance, and lung tissue damage<sup>7,8</sup>.

Thus, there is still a need for more effective treatment to reduce long-term health consequences. In an endemic situation with new viral strains, there will be a market for effective covid-19 treatment strategies also long term. Covid therapeutics sales are forecasted to reach \$17 billion in 2021 and are expected to increase in 2022 and thereafter gradually go down and reach a more stable level of \$4 billion annual sales from 2025 and onwards<sup>9</sup>. However due to the changing nature of the disease and pandemic, it is difficult to make longer term projections.

#### Pulmonary arterial hypertension (PAH) – a rare disease with large unmet medical need

PAH is a progressive disease in which a pulmonary vascular dysfunction leads to high blood pressure in the lung arteries which ultimately leads to heart failure. The currently available treatments reduce blood pressure by dilating blood vessels but do not modify the underlying disease or improve survival. PAH is considered a rare disease and the global annual market for PAH treatment is estimated to \$4.5 billion<sup>10</sup>.

### Digital therapeutics taking off

Digital therapeutics (DTx) is a new class of medical products that has been gaining traction in the last years, to date about 35-40 DTx products have been approved by the FDA<sup>11</sup>. As the value of DTx products are becoming more evident in e.g. managing and treating

chronic conditions and acceptance with regulatory bodies and payers has increased, DTx is receiving increasing attention also from investors and the pharmaceutical industry. In the last couple of years several partnerships have been formed e.g. Sanofi partnering with Happify Health and Boehringer Ingelheim with Click Therapeutics to develop new DTx products, and several large acquisitions have also been made e.g. ResMed's acquisition of Propeller in 2019 (see table). This activity is expected to accelerate in the coming years, and so is the DTx market which is estimated to grow from \$3.4 billion in 2021 to \$13 billion in 2026<sup>12</sup>.

1. European Idiopathic Pulmonary Fibrosis and Related

2. Wakwaya et al. Idiopathic pulmonary fibrosis: Natural

 EvaluatePharma, Orphan Drug Report 2019 and 2020
 Company reports; Roche, sales in 2021 (Esbriet) and Boehringer Ingelheim, estimated sales in 2021 (Ofev)
 Coronavirus (COVID-19) - Cross-Sector Impact - Glob-

6. "COVID is here to stay: countries must decide how to

Bazdyrev, E et al. Lung Fibrosis after COVID-19: Treatment Prospects. Pharmaceuticals 2021, 14, 807
 Wu X et al. 3-month, 6-month, 9-month, and 12-month respiratory outcomes in patients following COVID-19-related hospitalisation: a prospective study. Lancet Respir

Pharmaceutical executive brief. Global data Jan 2022
 PAH - Global drug forecast and market analysis to

12. 'Digital Therapeutics (DTx) Market', Markets and

Disorders Foundation

al data, February 2022

Med. 2021. 9. 747-54

2029, Global Data 2020 11. Morning consult, June 2021

Markets, 2021

adapt", Nature 601, 165 (2022)

history; Diagnosis; Outcome. Am J Med Sci 2019; 357(5): 359–369

#### Deals in IPF, fibrosis and DTx

				Development stage		
Year	Target/Licensor	Acquiror/Licensee	Type of deal	at transaction	Area	Total deal value (MUSD)*
2021	Aptar	Voluntis	Acquisition	Marketed	DTx	79
2020	Redx Pharma	AstraZeneca	License	Preclinical	Fibrosis/IPF	377
2020	Forbius	BMS	Acquisition	Phase I	Fibrosis/IPF	Undisclosed
2020	Curzion Pharmaceuticals	Horizon Therapeutics	Acquisition	Phase II	Fibrosis/IPF	45 + milestones
2020	Enleofen	Boehringer Ingelheim	License	Preclinical	Fibrosis/IPF	>1,000 per product, subject to milestones
2019	Propeller	ResMed	Acquisition	Marketed	DTx	225
2019	Promedior	Roche	Acquisition	Phase II	Fibrosis/IPF	1,390
2019	Galapagos	Gilead Sciences	License	Phase III	IPF (part of larger portfolio)	5,000
2019	Bridge Biotherapeutics	Boehringer Ingelheim	License	Phase I	Fibrosis/IPF	1,300
2018	Morphic Therapeutic	AbbVie	License	Preclinical	Fibrosis/IPF	100 + milestones
2016	Nitto Denko	BMS	License	Phase Ib	Fibrosis/IPF	Undisclosed
2016	Afferent Pharmaceuticals	Merck	Acquisition	Phase IIb	IPF cough	1,250
2015	Promedior	BMS	Option**	Phase II	Fibrosis/IPF	1,250
2014	InterMune	Roche	Acquisition	Marketed	Fibrosis/IPF	8,300
2014	Galecto Biotech	BMS	Option**	Phase I/IIa	Fibrosis/IPF	444
2012	Stromedix	Biogen	Acquisition	Phase II	Fibrosis/IPF	563
2011	Amira Pharmaceuticals	BMS	Acquisition	Phase I	Fibrosis/IPF	475
2011	Arresto BioSciences	Gilead Sciences	Acquisition	Phase I	Fibrosis/IPF	225 + milestones

\* Total deal values including potential milestone payments

\*\* BMS decided not to exercise its option

Source: Corporate webpages

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# Angiotensin II Type 2 Receptor Agonists - ATRAGS

The renin-angiotensin system (RAS) is a hormone system that regulates several important physiological processes. The key hormone in the RAS is angiotensin II which acts via two specific receptors, the angiotensin II type 1 receptor (AT1R) and the angiotensin II type 2 receptor (AT2R).

### The renin-angiotensin system (RAS)

The AT1R (see illustration) is mainly involved in blood pressure regulation through several different mechanisms related to constriction of blood vessels and fluid retention, but also contributes to innate immunity through pro-inflammatory actions. When this system "over-shoots", it can also contribute to the pathogenesis of diseases such as hypertension, myocardial infarction and different fibrotic conditions including pulmonary fibrosis and chronic kidney disease.

The AT2R is on the other hand an inducible system that can be seen as a mechanism responsible for resolution and regeneration following immune and vascular reactions to injury. Natural ligands/agonists of AT2R such as Ang 1-9 and Ang 1-7 are fragments cleaved from Angiotensin I and II.

Vicore's candidate drug C21 and the new compounds within the VP03 program are AT2R agonists, i.e. they bind to and activate AT2R.

#### AT2R agonists (ATRAGs)

There is strong scientific evidence for an important protective role of AT2R activation in several serious diseases related to cellular senescence, fibrosis and microvascular dysfunction. In addition to IPF, these include pulmonary hypertension, chronic kidney disease, atherosclerosis, heart failure and cognitive disorders. This is based on more than 100 preclinical studies from different research laboratories around the world. Clinical evidence is now accumulating, validating the preclinical results.

In COVID-19, patients treated with the AT2R agonist C21 had a significantly lower risk of needing oxygen supplementation by the end of study, suggesting a restoration of respiratory function by the drug. In addition, at the 3-month follow-up, treated patients had fewer pathological signs on chest computer tomographies.

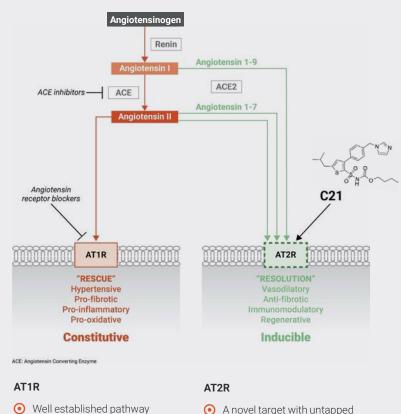
Vascular effects of C21 were demonstrated in systemic sclerosis patients with severe vasculopathy and fibrosis. The total body of evidence suggests that the AT2R is a relevant target far beyond COVID-19, systemic sclerosis and IPF.

Vicore has during the last years built a strong position in AT2R agonist chemistry and has a platform of very promising new molecules with patent protection to at least 2040 and beyond under development.

The first new AT2R agonist to follow C21 has finalized the preclinical development and is ready to enter a phase 1 trial. A clinical trial application (CTA) is expected to be submitted during the second quarter of 2022.

# "The AT2R is a repair receptor"

#### The renin-angiotensin system (RAS)

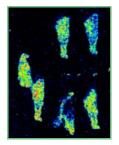


Well established pathway
 A novel ta potential
 enalapril) and angiotensin
 receptor blockers (e.g. losartan)
 C21 is a f

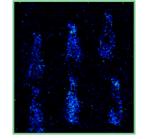
• C21 is a first-in-class selective AT2R agonist

# AT2R expression and possible mechanisms

Vicore has recently confirmed, using so-called receptor autoradiography, that human lung tissue expresses the AT2 receptor and that C21 at very low concentrations binds specifically to AT2R in the lung tissue. (see figure below).

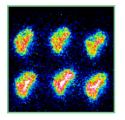


1. [<sup>3</sup>H] C21 1nM Shows binding of isotope-labeled (tritium) C21 (1 nM) to thin sections



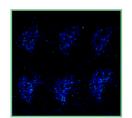
2. [<sup>3</sup>H] C21 1nM C21 0.75 µM

Shows that a higher concentration ( $0.75 \,\mu$ M) of unlabeled C21 blocks the binding of isotope-labeled C21, which shows that the binding is specific.



of human lung.

**3.** [<sup>125</sup>**I**] **Ang II 0.15 1 nM** Shows binding of isotope-labeled angiotensin II (Ang II, 0.15 nM) to human lung sections.

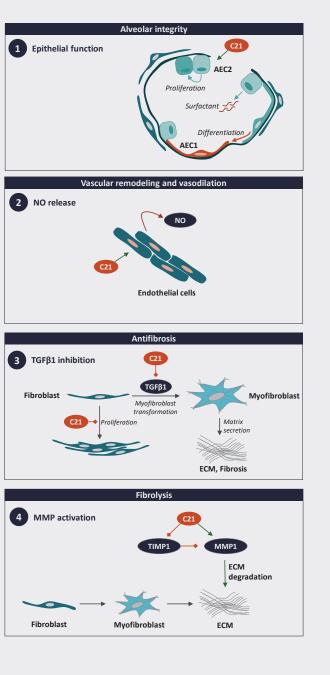


#### 4. [125] Ang II 0.15 1 nM C21 0.75 μM

Shows that unlabeled C21 blocks the binding of isotope-labeled Ang II, which illustrates that the AT2 receptor is the dominant Ang II receptor in the human lung (the binding of Ang II is not affected by valsartan which blocks the AT1 receptor - not shown in the image).

Key sources: Sumners et al. Acta Physiologica. 2019;227(1):e13280, Peluso et al. Clin Sci. 2018;132(7):777-90, Bruce et al. Br J Pharmacology 2015;172(9);2219–2231, Rathinasabapathy et al. Front Physiol. 2018;9:180. Vicore data on file.

The multimodal effects of AT2R activation are mediated by a number of possible mechanisms, including one or more of those shown in the figure to the right. (1) In the lung, the AT2R is highly expressed on alveolar epithelial cells type 2 (AEC2). These progenitor cells are involved in the repair of damaged alveoli, and they also fill a critical function in secreting surfactant which reduces alveolar surface tension and thereby makes it easier to expand the lungs. (2) AT2R activation is known to stimulate vascular endothelial cells to release nitric oxide which is a vasodilator and is an important molecule for keeping blood vessels healthy. (3) The antifibrotic effects of AT2R activation with C21 is at least in part mediated through inhibition of TGFB1 and myofibroblast activity. (4) C21 also has fibrolytic activities in that it can increase matrix metalloproteinase (MMP) enzymes that degrade fibrotic changes that has already been formed.



Abbreviations: AEC2 - Type 2 alveolar epithelial cell, NO - nitric oxide,  $TGF\beta1 - transforming growth factor beta 1, ECM - extracellular matrix, MMP1 - matrix metalloproteinase 1, TIMP1 - tissue inhibitor of metalloproteinase-1$ 

# Interview with Rohit Batta, CMO, on Vicore's new trial in PAH

In 2022, Vicore will begin a new clinical program in Pulmonary Arterial Hypertension (PAH).

#### What is the difference between Pulmonary Hypertension and Pulmonary Arterial Hypertension, and are both of interest to Vicore?

Pulmonary Hypertension (PH) is the general term for a set of conditions in which elevated pressure in the lung blood supply can lead to progressive heart failure. Pulmonary Arterial Hypertension (PAH), is a particular severe rare type of PH - such patients are likely to require intensive care unit level care at some point in their life, and over 30% of patients with PAH die within 3 years of diagnosis. Vicore's initial focus is on PAH because we believe our drugs will make a difference to patients where no disease modifying treatment options are currently available. The way our drugs work - addressing remodeling of blood vessels - means that they could also be effective more broadly in PH.

#### PAH is a severe lung disease, but is there a connection to your current work in IPF?

There is a connection. As mentioned, the general category of Pulmonary Hypertension encompasses several groups of diseases leading to heart failure. PH can also occur as a complication to many lung diseases such as IPF, where it is a strong predictor of mortality. In a World Health Organization classification, PAH is in group 1 of PH. WHO group 3 includes PH associated with already-diagnosed lung disease, which is where IPF fits.

# What drove Vicore to consider PAH as a new indication?

In short, we have evidence that our drug candidates could work in PAH, and there is a clear pathway to approval. Vicore's lead compound, C21, is a highly specific stimulator or agonist of the Angiotensin Type 2 Receptor (AT2R). A lot of animal data shows that C21 reverses vascular remodelling and improves hemodynamic pressure in the lungs. Quite recently, using a 'gold standard' animal model of Pulmonary Hypertension, we showed that C21 prevented remodelling of the blood vessels. The prevalence of PAH also means that C21 could enjoy orphan drug status protection in the US and Europe.

# How will the trial in PAH be designed?

All clinical trial designs have to be agreed with drug regulators, but we have an outline view of the study. This is based, among other factors, on Vicore's knowledge of rare lung disease, my own experience in developing medicines in PAH, and extensive inputs from Vicore's expert clinical advisors. The plan is to conduct a 'smart' proof-of-concept study generating reliable, objective data in a relatively short period of time from relatively few patients. One key element will be intensive remote monitoring of patients using a smart implantable device, making the trial pandemic-proof and providing a highly efficient, decentralized design.

"With our AT2R agonists we are addressing the vascular component of rare lung diseases."

# Digital Therapeutic for patients with IPF

Vicore is developing a digital therapeutic to treat anxiety and depression in people living with Idiopathic Pulmonary Fibrosis (IPF). Digital therapeutics (DTx) are clinically evaluated software, designed, built, and tested to treat a disease or condition. DTx are classified as medical devices and subject to that regulation.

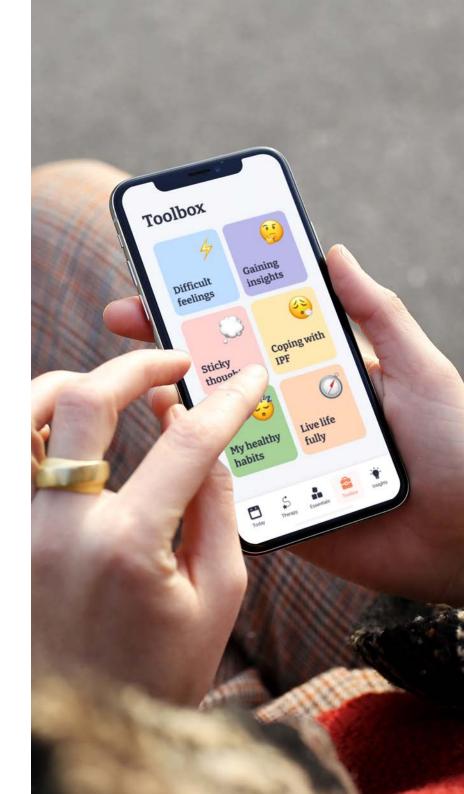
There are more than 100 companies developing DTx products, and there are more than 40 products on the market in countries like the US, Germany, Japan, Belgium, and France.

Some of these products treat type I or type II diabetes, there are products for Alzheimer's, others provide a musculoskeletal physiotherapy for pain management, and others are in the mental health space, such as the product Vicore is developing.

IPF causes scarring of the lung and difficulty in breathing which is debilitating. Activities that were once possible may become exhausting, such as walking around a grocery store or going up stairs. The diagnosis is usually unexpected, so it can negatively impact a person's state of mind. The he Vicore DTx Almee™, an investigational medical device pending FDA clearance, offers a therapy for the symptoms of anxiety and depression that patients with IPF may experience and helps patients cope.

The basic idea with Almee<sup>™</sup> is to have your own personal psychologist in your pocket: the treatment is 8 weeks of sessions of Cognitive Behavioural Therapy (CBT) built specifically for people with IPF. The sessions are made up of complex interactions and psychological tools that people can keep practicing, all which take place on a smartphone or tablet in the comfort of home rather than at a psychologist's office, whenever the patient prefers. The sessions are built by software developers, psychologists and lung disease experts and delivered through a device the patient already has.

Almee<sup>™</sup> will be validated through a Randomised Control Trial (RCT), so that potential payors and prescribers as well as patients will have evidence of its effectiveness. Throughout the design process Vicore ensured patient and physician insight was incorporated to build something that they could identify with and find useful. The ambition is that Almee<sup>™</sup> will offer support to patients who have a rare disease and an additional resource for hospital systems that can't provide daily counselling; the goal of the Almee<sup>™</sup>, as with every Vicore pipeline, is to create better patient outcomes.



# Interview with Jessica Shull, Director of Digital Therapeutics

### What background do you bring to Vicore?

In 2002 I finished a master's degree in Medical Illustration at the medical College of Georgia, which included training in Gross Anatomy, Neuropathology, and Histology as well as detailed drawing. However, my first job out of grad school was digital, done on computers with high-end 3D modeling software and coordination with a haptics team to create virtual surgery devices. Since that time, I've been working in digital health; for many years I collaborated with the WHO on projects to improve national health systems through digital advances, and I produced digital image-based protocols during the Ebola epidemic for local populations.

Now digital health has entered the personalized treatment space with digital therapeutics, and for the last four years I've been deeply involved in advocacy, national policy and now development of products under this new approach to healtcare.

#### How do you see digital therapeutics (DTx) fitting into existing healthcare practices?

I would say that a DTx needs to be conceptualized, designed, and continually evaluated for alignment with the patient and physician experience. We have been collaborating from day one with patient groups and specialists to ensure that this was a needed therapy, and that it wouldn't create an extra burden on anyone.

As for the patients, we need to ensure our design will have the desired effect, reducing symptoms of anxiety and depression in people with IPF.

#### How is a decentralized investigation for DTx different from a traditional drug trial, and what are the benefits?

With a decentralized trial for a digital therapy, we can study individual parameters which are relevant and meaningful from a patient perspective, directly from the patients.

Our decentralized trial is a randomized controlled trial (RCT) for a digital product, which is easy to deliver across a large geography. We designed the study with one central Coordinating Investigator, and we will be able to accept referrals from any eligible participant, regardless of location. Being a digital product means that collecting adverse events, documenting adherence, and even participant onboarding of how to use Almee<sup>™</sup> can be done entirely virtually.

DTx are medical devices and subject to those national regulations and standards. So while a DTx can be easily distributed and Patient Reported Outcomes (PROs) collected, there are strict requirement on the cybersecurity and privacy systems in place to protect patient data.

# Where do you see the DTx industry in 10 years?

In the last five years the DTx industry has grown rapidly; just in 2021 the industry saw deals worth \$3.4 billion. It's an impressive statement about the potential for healthcare. Countries like France are now structuring national reimbursement pathways for these kinds of products, the same way Germany did in 2019. I'm an optimist, but I see DTx continuing that global trend, especially as millennials age and personalized care becomes the norm.

"I expect to see digital therapeutics as a part of clinical guidelines in the coming years."

# Program Overview

#### **Vicore pipeline**

Indication	Program	Preclinical	Phase 1	Phase 2	Phase 3	Next event
COVID-19	C21					Phase 3 read-out in H2 2022
IPF	C21					Phase 2 read-out in H2 2022
PAH	C21					Phase 2 start Q4/Q1 2023
IPF anxiety	DTx					Clinical trial 2022
IPF cough	Inhaled IMID					Formulation development
Multiple indications	C106					Phase 1 start estimated 2022

#### VP01 (C21) – Idiopathic pulmonary fibrosis ("IPF")

- Completed phase 1 dose optimization trial in 2019, including 54 individuals. It established a safe and tolerable daily dose of 200 mg for further studies in IPF.
- The phase 2 trial is an open 6 month study in approximately 60 patients. In addition, patients will be given the opportunity to continue treatment for another three months. The study is currently active in the UK and India. Ukraine and Russia have been deactivated due to the war. The first patient was recruited in November 2020.
- An interim analysis of the trial suggests that C21 stabilizes disease and increases lung function in patients with IPF.
- Estimated read-out of the phase 2 trial is during the second half of 2022. In parallel, preparations for the next trial is ongoing.

#### VP01 (C21) - COVID-19

- Finalized phase 2 trial in 2020. The trial was a randomized, double-blind, placebo controlled study in 106 COVID-19 patients with a moderately severe disease, requiring oxygen support, but not mechanical ventilation. Summarized, the study shows that the risk for patients needing oxygen supplementation in the C21 group was decreased.
- The results from an extension trial, 3-6 months after treatment, including a subset of 33 patients (AT-TRACT-2) showed that patients receiving C21 had a nearly 50 percent reduction in lung injury compared to placebo.
- The phase 3 trial is a randomized, double-blind, placebo-controlled, multinational, phase 3 trial that will include 600 adult patients hospitalized with COVID-19 and requiring oxygen support but not invasive mechanical ventilation. The trial has currently been activated in more than 50 study centers worldwide. The first patient was recruited in September 2020 and the estimated read-out is during the second half of 2022.

#### VP01 (C21) – Pulmonary arterial hypertension ("PAH")

• A phase 2 proof-of-concept trial on patients with PAH is expected to start during 2022.

#### VP02 (IMiD) – IPF cough

• Preclinical development. Evaluation of alternative formulations to deliver thalidomide locally to the lung ongoing.

#### VP03 (multiple indications)

- Preclinical research is underway to develop new AT2R-agonists for multiple indications.
- Clinical trial application (CTA) for a phase 1 trial for the first candidate, C106, is expected to be submitted during Q2 2022.
- Three additional compounds to finalize preclinical development during H1 2023.

#### VP04 (DTx) – A digital therapeutic to treat anxiety in IPF

- Technical development of software during 2021.
- COMPANION, a randomized, controlled, parallel-group clinical investigation, in two phases, evaluating the impact of our digital cognitive behavioural therapy on psychological symptom burden, in adults diagnosed with IPF, has been initiated.
- The pilot study (first phase), on 20 patients will be followed by a pivotal study (second phase), on approximate-ly 250 patients in H2 2022. The pivotal study is estimated to be finalized in H1 2023.

# Our Programs

# VP01 – AT2 receptor agonist - first in class

Vicore's drug candidate C21 (VP01 program) originates from extensive research on the Renin-Angiotensin System (RAS) and binds specifically to and activates AT2R.

Vicore has shown pronounced effects with C21 in a gold-standard preclinical model considered predictive of human pulmonary hypertension (PH), the so called Sugen-Hypoxia-induced PH model. PH is a common and serious complication of interstitial lung disease, including IPF, and treatment options are extremely limited.

Vicore has also shown robust effects with C21 in lung tissue from patients with idiopathic pulmonary fibrosis (IPF). Treatment with clinically relevant concentrations of C21 caused a dose-dependent decrease of  $TGF\beta1$ , a key growth factor in fibrosis development.

Recently, Vicore has also shown that human lung tissue expresses the AT2 receptor and that very low concentrations of C21 bind specifically to AT2R in the lung tissue which has been shown by so-called receptor autoradiography.

C21 has previously shown very good effects in animal models with pulmonary fibrosis and is now being evaluated in a phase 2 trial in patients with IPF and a phase 3 trial in COVID-19.

Vicore has received Orphan Drug Designation for C21 in IPF from the FDA and EMA. Among other benefits, eventually receiving orphan drug status provides for up to ten years of market exclusivity (from the date of registration of an approved drug) in Europe and seven years in the United States.

#### **Program status VP01**

#### Idiopathic pulmonary fibrosis (IPF)

The phase 2 trial in IPF (AIR<sup>1</sup>) has been designed in collaboration with international clinical experts in IPF and will investigate both safety and lung function. The trial aims to support the decision to initiate a confirmatory trial and is performed in the UK, India, Ukraine and Russia. In February 2022, the recruitment in Russia and Ukraine was stopped due to the current war situation.

The study is designed as an open-label six month trial in approximately 60 patients and also offers patients the opportunity to continue treatment for an additional three months. The goal is to perform the best possible trial to answer the question if C21 can significantly slow the decline in lung function in patients with IPF.

The first patient was dosed in India in November 2020.

In February 2022, Vicore performed an interim analysis showing an initial stabilization of disease and then an increase in FVC up to the end of the study at 36 weeks. At the time of the interim analysis, there were 21 evaluable patients of which 13, 9 and 7 patients reached 12, 24 and 36 weeks of treatment, respectively. After 24 weeks, the increase in mean FVC was +251 ml, a considerable difference of 371 ml compared to the expected decline of 120 ml in 24 weeks in an untreated population<sup>2</sup>. Five of the seven patients who completed both 24 and 36 weeks of C21 treatment showed continued improvement in FVC and two remained stable. Analysis of FVC slope values at 28, 32 and 36 weeks are statistically significant (p=0.016 at 36 weeks) compared to the expected mean for untreated patients. The study drug was well tolerated with no related serious adverse events related to C21 or gastrointestinal signals.

The trial is estimated to read-out in H2 2022 at current recruiting plan and







outlook. In parallel, Vicore is preparing for the next trial in IPF.

#### COVID-19

During 2020, Vicore conducted a phase 2 trial with C21 in 106 patients with COVID-19 (ATTRACT<sup>3</sup>). In October 2020, the company reported that the trial was fully recruited. Top-line data was published in December 2020.

The study was designed as a randomized, double-blind, placebo-controlled trial in patients with moderately severe disease and signs of acute respiratory infection but not requiring mechanical ventilation. It investigated the safety and efficacy of C21 on respiratory failure and other functional outcomes. The vast majority of the patients received corticosteriod treatment as part of standard of care.

The clinical results from the trial were positive demonstrating that C21 can restore lung function in COVID-19, suggesting that C21 can prevent disease progression.

Summarized, the trial showed that the risk for patients of needing oxygen supplementation in the C21 group was decreased by 58 percent (p=0.026) at day 8 after start of treatment. At day 14 there was only one patient in the C21 group in need of oxygen supplementation compared to eleven patients in the placebo group (p=0.003), a reduction of more than 90 percent.

There was also a clear trend for C21 reducing the number of patients needing mechanical ventilation and a trend for C21 reducing mortality. The treatment was reported safe and well tolerated. There were no treatment-related side effects.

The results from an extension trial,

3-6 months after treatment, including a subset of 33 patients (ATTRACT-2<sup>4</sup>) showed that patients receiving C21 (n=17) displayed reduced pathological abnormalities compared to the placebo group (n=16). In the C21 group, on average 10.3 percent of the lung was affected compared to 19.2 percent in the placebo group. The dominating radiological change was ground glass opacity, a pathological characteristic following viral respiratory infection.

In June 2021, Vicore received approval from the U.S. Food and Drug Administration (FDA) to start a pivotal phase 3 trial with C21 in COVID-19 (ATTRACT-3<sup>5</sup>) and in September the first patients in the trial were dosed.

The study is designed as a randomized, double-blind, placebo-controlled, multinational, phase 3 trial that will include 600 adult patients hospitalized with COVID-19 and requiring oxygen support but not invasive mechanical ventilation. The primary objective is to evaluate the effect of C21 on recovery from COVID-19. The patients are randomized to receive 100 mg C21 or placebo twice daily on top of standard of care (SoC) for 14 days and patients will be followed for 60 days. The trial has currently been activated in more than 50 study centers in the US, Czech Republic, Ukraine, South Africa, India, Philippines, Argentina, Brazil, Columbia and Russia. In February 2022, the recruitment in Russia and Ukraine was stopped due to the current war situation.

According to the current recruitment plan, top-line results from ATTRACT-3 are expected during the second half of 2022.

#### Pulmonary arterial hypertension (PAH)

In March 2022, Vicore communicated plans to commence a phase 2 trial in PAH. The tentative design is an open label trial investigating the safety and efficacy of C21 in patients with PAH, with the aim of first patient screened in Q4 2022/Q1 2023. Haemodynamics will be assessed using the Abbott remote monitoring CardioMEMS device.

# VP02 – Targeting IPF and IPF-related cough

In the VP02 program, Vicore is developing a novel formulation of thalidomide, which is an existing immunomodulatory drug (IMiD), to be administered locally to the lung. It is thought that the actions of thalidomide suppress pathways involved in the cough reflex together with antifibrotic effects.

Many IPF patients suffer from a chronic intractable cough which considerably affects the patients' quality of life due to sleep disturbances, difficulties at work and stress incontinence<sup>6</sup>. Currently, there is no established therapy for IPF-related cough and standard cough medications have little or no effect on the disease. The anti-cough mechanism of VP02 in IPF is unknown, but the cough is thought to be due to structural changes in the lungs, increased sensitivity of the cough reflex, airway inflammation and/or changes in mucus production and clearance<sup>7</sup>.

Using IMiDs to treat IPF-related cough is a breakthrough finding which has been shown to have clinical validity. IMiDs have documented antifibrotic and anti-inflammatory attributes and may therefore be well suited for treatment of



a number of interstitial lung diseases. In a clinical trial, an IMiD given orally demonstrated a significant positive effect on patients with IPF, reducing the cough and dramatically improving quality of life which is not seen in other interventional clinical trials<sup>8</sup>.

However, the high risk of severe side effects such as peripheral neuropathy, constipation and sedation due to systemic IMiD exposure has limited their use. Vicore's novel VP02 program aims to eliminate the negative aspects of systemic exposure by developing thalidomide for local administration to the lungs.

#### **Program status VP02**

The inhaled formulation for local delivery of thalidomide to treat IPF-related cough is in preclinical development. Vicore continues to evaluate alternative formulations to deliver thalidomide locally to the lung. Further details on the progress in the VP02 program will be announced in coming reports.

#### VP03 – New AT2R agonists

Within this program, Vicore aims to develop new patentable AT2R agonists (ATRAGs). The objective is to develop competitive pharmaceutical products also for broader indications.

#### Program status VP03

The first drug candidate, C106, has completed preclinical development and a CTA for a phase 1 trial is expected during the second quarter of 2022. Three additional ATRAGs are expected to finalize preclinical development during H1 2023.

The preclinical work to develop additional ATRAGs continues in parallell.

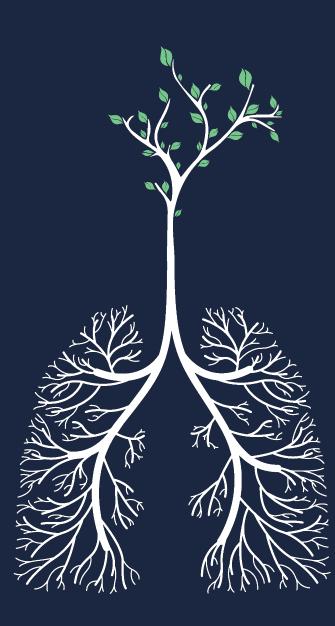
#### VP04 – Digital Therapeutics – a broader perspective

The VP04-program consists of a digital therapeutic (DTx) based on cognitive behavioral therapy (CBT) to address the psychological impact of living with IPF. DTx products are clinically evaluated software, designed, built, and tested to treat a disease or condition. DTx are medical devices and subject to medical device regulations in the country of use. DTx products can be a stand-alone software, or used with a wearable sensor, or be part of a medicinal therapy protocol, depending on the intended use and target condition. Vicore is collaborating with Alex Therapeutics for the development. Alex Therapeutics is a Swedish medtech company specializing in design and development of medical device software, with expertise in technology and clinical psychology.

The Vicore DTx will be evaluated through real-world pilots and clinical trials as well as secure regulatory approvals, according to national and international medical device development standards.

#### **Program status VP04**

Technical development of the software is nearing completion. In March 2022, COMPANION was approved; a randomized, controlled, parallel-group clinical investigation evaluating the impact of digital cognitive behavioural therapy on psychological symptom burden in adults diagnosed with IPF. The study will be conducted in two phases. The first phase is a pilot study with 20 patients. This will be followed by the second phase, a pivotal trial, with 250 patients in Q3 2022. The pivotal study is estimated to read-out during H1, 2023 and thereafter Vicore will seek FDA clearance as a medical device to be made available to patients in 2024.



1. NCT04533022 2. Richeldi et al 2014; King et al 2014 3. NCT04452435 4. NCT04878913 5. NCT04880642
 6. Saini et al 2011
 7. Vigeland et al 2017
 8. Horton et al 2012

# Interview on our commercial activities

Åsa Magnusson joined Vicore in the fall of 2021 as Chief Commercial Officer. With an ongoing phase 3 trial in COVID-19 and an advanced patient focused program in IPF, it was time to complement the R&D focused team with a strategic commercial person.

### What experiences do you bring to Vicore?

With 30 years in different commercial roles in the pharmaceutical industry, I challenge myself to stay curious, continuously learning new things and that's why Vicore is a perfect match for me. I bring my experience of launching rare disease medicines in areas with high unmet medical need, mainly by ensuring that patients get access to these orphan medicines. Beyond the scientific evidence proving that a medicine is efficacious and safe. we need to prove to payer stakeholders that the price is right. My ambition is to work closely with the highly innovative team at Vicore and focus our cross-functional collaborative forces to create value for external stakeholders

#### What is your key priority?

My first priority this year is to prepare for the commercialization of C21 in COVID-19.

In parallel I'm working with our digital expert, Jessica Shull, to ensure that our innovative digital therapy specifically designed to treat anxiety and depression with cognitive behavioral therapy (CBT) in people with IPF gets to the market as soon as possible. We have learned that there is a huge need both from the patient perspective as well as from the health care providers.

Last, but not least, the commercial perspective is needed also during the planning of next steps of our of our development programs to ensure that C21 and our next generation of ATRAGs create value for external stakeholders beyond efficacy and safety.

#### How could C21 add value to patients suffering from COVID-19?

Despite recent advances in preventing and treating COVID-19, there will be a group of patients who are hospitalized and need oxygen supplementation, and this is the patient group that we target.

C21 has a unique position in therapy by addressing the alveolar damage of COVID-19. With C21 we have a first in class selective AT2R agonist (ATRAG), targeting the angiotensin II type 2 receptor. This alternate mode of action (vs. current treatments) promotes alveolar healing and reduces the need of oxygen support. In the treatment regimen C21 is clearly positioned between antivirals/antibodies and acute respiratory distress syndrome. Our ATTRACT program aims at confirming how C21 (on top of steroids and antivirals) restores respiratory function and reduces long-term lung injury in COVID-19. C21 is, through its alternate mode of action not targeting the virus per se, expected to be effective independently of variant.

# How is the value of a new product established?

Countries have different ways of evaluating the value that a new treatment brings. In general, I would say that payers look at a variety of parameters, ranging from the severity of the disease, how many other treatments are available and how efficacious and safe they are, as well as their price. In addition, payers in many countries would also want to see that there is a patient relevant benefit when evaluating if they are willing to reimburse a new treatment. Here patient reported outcomes and quality of life evaluations play an important role.

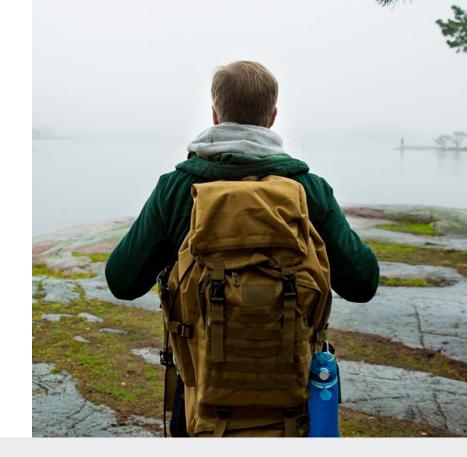
"My focus is to ensure that payers see the value of a product for patients, beyond its efficacy and safety"

# Intellectual Property

he granted original C21 patent is in force until 2024 (see Table A). In addition to this patent, C21 is expected to be protected by different types of patents, including those directed to new formulations and methods of use. In the US a patent covering the use of C21 in the treatment of COVID-19 has been granted (Product patents, See Table B). Moreover, Vicore will most likely be able to rely on the so-called orphan drug status Vicore obtained in the EU and the US for C21 regarding treatment of IPF in the VP01 program. Orphan drug designation provides for up to ten-year protection in Europe and an up to seven-year protection in the United States from the time of registration of an approved drug. If Vicore subsequently receives a market approval, the sale of C21 for the treatment of IPF will also be protected by regulatory data/ market exclusivity (ten years in Europe and five years in the US). The company also sees good opportunities to obtain orphan drug

status for C21 for certain diseases other than IPF. Overall, Vicore believes that the company has strong product protection for C21 based on the development plan being followed.

Vicore also develops new improved patentable AT2R agonists in the VP03 programme. The goal is to develop competitive pharmaceutical products for broader indications where it is not possible to obtain orphan drug status. Eight patent applications with new AT2R agonists have been filed (see Table A).



#### Table A – Substance patents VP01 (C21) and VP03

Project	Country	Application date (priority)	Status	Expiry year (planned)
VP01	US	31.05.2001	Granted	2024
VP03	National	20.09.2019	Pending	2040
VP03	International	19.03.2020	Pending	2041
VP03	International	20.03.2020	Pending	2041
VP03	International	01.09.2020	Pending	2041
VP03	International	23.03.2021	Pending	2042
VP03	International	23.03.2021	Pending	2042
VP03	International	23.03.2021	Pending	2042
VP03	International	09.07.2021	Pending	2022

#### Table B – Other pantents related to product VP01 (C21)

Project	Country	Application date (priority)	Status	Expiry year (planned)
VP01	International/US	23.03.2020	Granted in US/ Pending	2040/41
VP01	International	24.04.2020	Pending	2041
VP01	International/US	24.04.2020	Pending	2041
VP01	International/US	24.04.2020	Pending	2041
VP01	International	14.05.2020	Pending	2041
VP01	Priority	25.10.2021	Pending	2042
VP01	Priority/US	10.02.2022	Pending	2042/43

# Shareholder information

#### The share

Vicore's shares are listed on Nasdaq Stockholm with the ticker VICO and ISIN SE0007577895. As of December 31, 2021, the total number of shares amounted to 71,760,293 and the market capitalization was 999 MSEK. The number of shareholders amounted to 5,141. The company's shares are issued in one class and each share carries one vote.

#### **Capital supply**

In November 2020, Vicore acquired novel AT2R agonists from HaLaCore Pharma and decided on an issue in kind of 142,054 shares as part of the payment, which was registered at the Swedish Companies Registration Office during the first quarter of 2021.

On February 10, 2021, Vicore completed a directed share issue of 11,200,000 shares at a subscription price of SEK 30,0 per share, raising a total amount of approximately 336 MSEK before transaction costs. The directed share issue was approved at an Extraordinary General Meeting in March 2021.

#### Analyst coverage

The following analysts cover Vicore and continuously analyze the company's development:

- DNB Bank ASA, Patrik Ling
- Pareto Securities, Dan Akschuti
- Redeye, Fredrik Thor

#### Share price development

At the end of 2021, the share price was 13.9 SEK. The highest price paid for the share during the year was 34.6 SEK on February 16 and the lowest price paid was 12.8 SEK on December 21. The share price decreased by a total of 56 percent during 2021 and the market value amounted to 999 MSEK as of December 31, 2021.

#### Share data

The number of registered shares on December 31, 2021 amounted to 71,760,293 ordinary shares.

# Financial targets and dividend policy

The target is to distribute approximately 50 percent of the company's annual net profit as dividends when Vicore has achieved the desired financial stability, taking into account present and future profit levels, investment needs, liquidity and development opportunities as well as general economic and business conditions. In accordance with the Board of Directors' dividend policy, no dividend is to be paid before the company generates significant revenue.

#### Development of the share during 2021



#### Largest shareholders

Largest shareholders in Vicore as of February 28, 2022:

Shareholder	No. of shares	%
HealthCap VII L.P.	15,834,834	22,1%
Fourth Swedish National Pension Fund	6,632,041	9,2%
HBM Healthcare Investments (Cayman) Ltd.	4,620,302	6,4%
Protem	4,030,340	5,6%
Handelsbanken Funds	3,120,425	4,3%
Unionen	2,663,990	3,7%
Swedbank Robur	2,644,165	3,7%
Third Swedish National Pension Fund	2,641,425	3,7%
Avanza Pension	2,527,370	3,5%
Kjell Stenberg	1,531,303	2,1%
Second Swedish National Pension Fund	1,050,000	1,5%
Alexander Shaps	685,108	1,0%
Nordnet Pension	502,001	0,7%
Lancelot Asset Management	500,000	0,7%
Alfred Berg Funds	484,537	0,7%
Carl-Johan Dalsgaard	477,981	0,7%
Jonas Wikström	410,000	0,6%
Mats K Andersson	390,000	0,5%
SEB Funds	376,641	0,5%
Other	20,637,830	28,8%
Total number of shares	70,760,293	100.0%

#### Share capital development

			Increase in			
Year	Event	Quota value	number of shares	Increase in share capital	Total no. of shares	Total share capital
2021	Share issue	0.5	11,200,000	5,600,000	71,760,293	35,880,147
2021	Issue in kind	0.5	142,054	71,027	60,560,293	30,280,147
2021	Share issue	0.5	10,000,000	5,000,000	60,418,239	30,209,119
2020	Share issue	0.5	243,525	121,763	50,418,239	25,209,119
2020	Share issue	0.5	7,800,000	3,900,000	50,174,714	25,087,357
2019	Share issue	0.5	9,414,706	4,707,353	42,374,714	21,187,357
2018	Share issue	0.5	8,240,002	4,120,001	32,960,008	16,480,004
2018	Issue in kind	0.5	8,851,502	4,425,751	24,720,006	12,360,003
2017	Share issue	0.5	1,500,000	750,000	15,868,504	7,934,252
2017	Share issue	0.5	2,000,000	1,000,000	14,368,504	7,184,252
2015	Share issue/Listing	0.5	3,248,144	1,624,072	12,368,504	5,684,252
2015	Reverse split,1:10	0.5	-73,083,239	-	8,120,360	4,060,180
2015	Share issue	0.05	12,639,073	631,954	81,203,599	4,060,180
2013	Share issue	0.05	34,282,263	1,714,113	68,564,526	3,428,226
2012	Offset issue	0.05	474,498	23,725	34,282,263	1,714,113
2011	Share issue	0.05	10,402,389	520,120	33,807,765	1,690,388
2010	Offset issue	0.05	1,000,000	50,000	23,405,376	1,170,269
2010	Share issue	0.05	5,601,344	280,067	22,405,376	1,120,269
2010	Share issue	0.05	5,601,344	280,067	16,804,032	840,202
2008	Share issue	0.05	688	34	11,202,688	560,134
2008	Split 1:2000	0.05	11,196,399	-	11,202,000	560,100
2008	Bonus issue	100	4,601	460,100	5,601	560,100
2005	Formation	100	1,000	100,000	1,000	100,000

#### Shareholder categories

Shareholder categories in Vicore as of February 28, 2022:

Shareholder category	Number of shares	% of capital
Swedish shareholders	60,575,144	84.4%
International shareholders	11,185,149	15.6%
Shareholder types	Number of shares	% of capital
Swedish institutional shareholders	34,523,574	48.1%
International institutional shareholders	4,650,951	6.5%
Swedish retail investors	17,406,644	24.3%
Other	9,804,694	13.7%
Anonymous holdings	5,374,430	7.5%

#### Ownership distribution by holding

Ownership distribution in Vicore as of February 28, 2022:

Number of known		
shareholders	Number of shares	% of capital
5,773	5,086,679	7.1%
188	4,237,692	5.9%
30	2,249,991	3.1%
26	6,379,482	8.9%
2	1,187,109	1.7%
9	24,829,320	34.6%
2	22,466,875	31.3%
-	5,323,145	7.4%
6,030	71,760,293	100.0%
	<b>shareholders</b> 5,773 188 30 26 2 9 2 2 9	shareholders         Number of shares           5,773         5,086,679           188         4,237,692           200         2,249,991           26         6,379,482           21         1,187,109           9         24,829,320           22         2,246,875           201         5,323,145

# Annual Report 2021 Administration Report

The Board of Directors and the CEO of Vicore Pharma Holding AB (publ.), Corp. Reg. No. 556680-3804, hereby submit the annual report and consolidated financial statements for the 2021 fiscal year.

#### Vicore's operations

Vicore is a clinical-stage pharmaceutical company focused on developing innovative medicines in severe diseases where the Angiotensin II type 2 receptor (AT2R) plays an important role. The company currently has four development programs, VP01, VP02, VP03 and VP04. VP01 aims to develop the substance C21 for the treatment of idiopathic pulmonary fibrosis (IPF), COVID-19 and pulmonary arterial hypertension (PAH). VP02 is a new formulation and delivery route of thalidomide and focuses on the underlying disease and the severe cough associated with IPF. VP03 includes the development of new AT2R-agonists. VP04 develops a clinically validated digital therapeutic for IPF patients (Vicore DTx).

The company's shares (VICO) are listed on Nasdag Stockholm's main market

In the beginning of the year, Vicore completed a directed share issue raising 336 MSEK. The issue was subscribed by Swedish and international institutional investors and the intended use of the proceeds was among others, to finance the phase 3 trial in COVID-19. The share issue was approved at an Extraordinary General Meeting in March. The results from the trial with C21 in patients with systemic sclerosis and Raynaud's phenomenon was presented in March and showed vasodilating effects with C21 on peripheral resistance vessels.

In May, Vicore entered into a collaboration agreement with Alex Therapeutics for the development of a digital therapeutic (DTx) to treat anxiety in patients living with idiopathic pulmonary fibrosis (IPF). A pilot phase study on 20 patients will be followed by a pivotal study on approximately 250 patients in H2 2022.

In September, the first patients in the global phase 3 trial in COVID-19 (ATTRACT-3) on 600 patients, were dosed.

In September, Vicore was granted a patent in the US covering the use of C21 to treat infections caused by Severe Acute Respiratory Syndrome (SARS) coronavirus (CoV), including SARS CoV-2.

In November, Vicore announced results from the phase 2 extension trial in COVID-19 (ATTRACT-2) showing that C21 reduced long-term lung injury after COVID-19.

The open-label phase 2 trial in 60 patients with IPF is progressing. After

year-end an interim analysis suggests that C21 stabilizes disease and increases lung function in patients with IPF.

Estimated read-out of the phase 2 trial is during the second half of 2022. In parallel, preparations for the next trial is ongoing.

The evaluation of alternative formulations to o deliver thalidomide locally to the lung in the VP02 program continued during 2021.

The VP03 program progressed well during 2021 and after year-end, Vicore announced that the first drug candidate, C106, is ready for clinical development and a phase 1 trial is expected to start during 2022.

After year-end, Vicore announced the plan to initiate a proof-of-concept trial with C21 in pulmonary arterial hypertension (PAH).

During 2021, Vicore strengthened the organization, spanning from R&D, Quality Assurance to commercial functions. In August, Vicore announced a strenghtened management team with three senior recruitments; Jessica Shull, Head of Digital Therapeutics, Åsa Magnusson, Chief Commercial Officer and Mikael Nygård, VP Business Development. At the end of 2021, a total of 21 employees were employed by Vicore.

### Important events during 2021

- In February, Vicore completed a directed share issue raising 336 MSEK. The share issue was approved at an Extraordinary General Meeting in March.
- In March, Vicore reported top-line data from the mechanistic phase II study in systemic sclerosis and Raynaud's phenomenon (SSc) showing that C21 increased bloodflow in fibrotic tissue.
- In May, Vicore announced that the company had entered into a collaboration agreement with Alex Therapeutics for the development of a digital therapeutic (DTx) for patients living with idiopathic pulmonary fibrosis (IPF).
- In June, Vicore announced that the company had received approval from the U.S. Food and Drug Administration (FDA) to start the pivotal phase 3 trial with C21 in COVID-19.
- In August, Vicore announced a strengthened management team with three senior recruitments; Jessica Shull, Head of Digital Therapeutics, Åsa Magnusson, Chief

Commercial Officer and Mikael Nygård, VP Business Development.

- In September, Vicore announced that the first patients in the global phase 3 trial with C21 in COVID-19 (ATTRACT-3) were dosed.
- In September, Vicore announced that the company was granted a patent in the US covering the use of C21 to treat infections caused by Severe Acute Respiratory Syndrome (SARS) coronavirus (CoV), including SARS CoV-2.
- In October, Vicore announced that the results from the phase 2 trial in COVID-19 (ATTRACT) were published in EClinicalMedicine, a scientific journal published by the Lancet.
- In November, Vicore announced results from the ATTRACT phase 2 extension trial showing that C21 reduced long-term lung injury after COVID-19.

### Important events after the year-end

 In February, an interim analysis of the AIR phase 2 trial in IPF suggests that C21 stabilizes disease and shows an unanticipated increase in lung function in IPF patients.

- In February, Vicore announced the advancement of its first new chemical entity from the VP03 program to a first in human phase 1 trial. A clinical trial application (CTA) is expected to be submitted during the second quarter 2022.
- In March, Vicore announced the plan to initiate a proof-of-concept trial with C21 in pulmonary arterial hypertension (PAH).
- In March, Vicore announced the initiation of a human forearm blood flow study with C21, planned to start in Q2 2022.
- In March, Vicore announced that Michael Wolff Jensen resigned from the board and was replaced by Jacob Gunterberg as chairman until the annual general meeting in May 2022.

#### Revenue

Net sales amounted to 0.0 MSEK (0.0) for the full year 2021.

#### **Operating expenses**

Operating expenses amounted to -295.9 MSEK (-167.7) for the full year 2021. Research and development expenses comprise a large fraction of the operating expenses. The increase in operating expenses is according to plan and is mainly attributable to increasing research and development expenses. Administrative expenses amounted to -20.2 MSEK (-25.0) for the full year 2021. The costs for share-based incentive programs related to administrative staff amounted to +2.3 MSEK (-6.9) for the full year 2021.

Marketing and distribution expenses were -1.4 MSEK (0.0) for the full year 2021. The costs for share-based incentive programs related to staff within marketing and distribution amounted to -0.1 MSEK (0.0) for the full year 2021.

Research and development expenses amounted to -271.8 MSEK (-142.0) for the full year 2021. Research and development expenses are mainly related to clinical trial costs for VP01. The costs for share-based incentive programs related to research and development staff amounted to -0.7 MSEK (-1.3) for the full year 2021.

Other operating income and expenses amounted to -1.4 MSEK (17.5) for the full year 2021. During the second quarter of 2020, Vicore received a grant of 1.5 GBP million from the British research charity LifeArc for the ATTRACT study in patients with COVID-19.

The total costs for the share-based incentive programs for the full year 2021 amounted to +1.5 MSEK (-8.2), of which +5.4 MSEK (-5.6) consisted of provisions for social security contributions and -3.9 MSEK (-2.6) were IFRS 2 classified salary costs. These costs have had no cash flow impact.

#### Result

The operating loss amounted to -294.8 MSEK (-149.5) for the full year 2021. The result after tax for the full year 2021 was -296.7 MSEK (-147.3). Tax amounted to 0.3 MSEK (0.5) for the full year 2021. Tax is mainly related to a change in deferred tax liability attributable to acquired intangible assets. The group's accumulated tax loss carryforwards as of December 31, 2021, amounted to 729.8 MSEK. The group's tax loss carryforwards have not been measured and are not recognized as a deferred tax asset. These tax loss carryforwards will be accounted for only when the group has established a level of earnings which management with confidence estimates will lead to taxable profits. The loss for the full year 2021 amounted to -296.5 MSEK (-146.9). The loss per share before and after dilution amounted to SEK -4.25 (-2.71) for the full year 2021.

### Cash flow, investments and I financial position

Cash flow from operating activities amounted to -265.2 MSEK (-119.9) for the full year 2021.

Cash flow from investing activities for the full year 2021 was -7.0 MSEK (4.0). The difference compared with the previous year is mainly attributable to the acquisition and sale of short-term interest-bearing investments.

Cash flow from financing activities amounted to 318.2 MSEK (177.0) for the full year 2021. On February 10, 2021, the company completed a directed share issue of 336 MSEK before transaction costs amounting to approximately 17.6 MSEK. The directed share issue was approved at an Extraordinary General Meeting in March 2021. The directed share issue was subscribed for by Swedish and international institutional investors. The subscription price of 30.0 SEK per share was determined through an accelerated bookbuilding process and corresponds to approximately 0.6 percent premium to the 10-day volume weighted average share price. The issue proceeds are mainly intended to finance the company's development programs.

As of December 31, 2021, cash and cash equivalents amounted to 294.2 MSEK (248.6) and short-term investments were 77.3 MSEK (70.1). Accordingly, cash, cash equivalents and short-term investments amounted in total to 371.5 MSEK (318.7). The equity ratio as of December 31, 2021, was 85.0 percent (87.2 percent) and equity amounted to 383.3 MSEK (354.5). Total equity and liabilities amounted to 451.2 MSEK (406.5).

#### Parent company

The group ("Vicore") consists of the parent company, Vicore Pharma Holding AB (publ) and the subsidiaries Vicore Pharma AB and INIM Pharma AB. The parent company's operations mainly consist of providing management and administrative services for the group's operative companies. The research and development operations are conducted in the wholly owned subsidiaries Vicore Pharma AB and INIM Pharma AB.

Net sales for the parent company amounted to 38.8 MSEK (3.7) for the full year 2020. Net sales mainly consisted of re-invoiced costs and management fees to group companies. Administrative expenses amounted to -19.9 MSEK (-24.7) for the full year 2021. The operating profit (loss) for the full year 2021 amounted to 17.1 MSEK (-22.6). The profit (loss) amounted to 17.6 MSEK (-21.8) for the full year 2021. During the full year 2021, shareholder contributions amounting to 400 MSEK were provided to the subsidiaries.

#### Personnel

As of December 31, 2021, the group had 21 employees, of whom 14 were women

and seven men. Of the employees, 15 are active within R&D. The group also engages consultants for specialist tasks and assignments on a frequent basis.

#### Shareholders and the share

At the end of 2021, Vicore had 5,141 shareholders and the number of shares was 71,760,293 with a quotient value of SEK 0.5 each. There is only one class of shares. The company's shares are issued in one class and each share carries one vote at the Annual General Meeting.

On December 31, 2021, HealthCap VII L.P. was the single largest shareholder in Vicore, with a total of 15,834,834 shares, corresponding to 22.1 percent of the votes and capital. No shareholder other than HealthCap VII L.P. has a direct or indirect shareholding that represents one tenth, or more, of the voting rights for all shares in the company. Further information on shareholders and Vicore's share is presented on pages 24-25 in the 2021 annual report.

### Share-based incentive programs

The purpose of share-based incentive programs is to promote the company's long-term interests by motivating and rewarding the company's senior management and other co-workers in line with the interests of the shareholders. As of December 31, 2021, Vicore has four active programs that include the management team, employees and certain board members.

At the Extraordinary General Meeting on August 13, 2018, it was resolved to implement two new incentive programs: a maximum of 2,000,000 options to senior leaders and key persons ("Co-worker LTIP 2018"); and a maximum of 475,000 share awards to board members ("Board LTIP 2018").

At the Annual General Meeting on May 20, 2020, it was resolved to implement a new incentive program for the new board members ("Board LTIP 2020") amounting to a maximum of 525,000 share awards

At the Annual General Meeting on May 11, 2021, it was resolved to implement two new incentive programs: a maximum of 3,000,000 employee stock options to senior leaders and key persons ("Co-worker LTIP 2021"), and a maximum of 73.000 share awards to certain board members ("Board LTIP 2021").

All these programs are performance-based programs entitling the holder to a maximum of one common share in Vicore per option or share award after three years.

For further information about these programs, see Note 8 "Share-based payments", the minutes of the Extraordinary General Meeting 2018, the minutes of the Annual General Meeting 2020 and the minutes of the Annual General Meeting 2021, which are published on the company's website, www.vicorepharma.com.

During the third guarter of 2021, Board LTIP 2018 expired. As the share price increased by less than 50 percent during the measurement period no share awards were earned. The program is now closed.

The increase in the company's share capital, assuming full utilization and maximum goal achievement of all active incentive programs (i.e. including nongranted employee stock options and warrants that may be used as hedge for social security contributions), amounts

to a maximum of SEK 2.793.387.2022 corresponding to a dilution of 7.2 percent of the total number of shares.

As of December 31, 2021, a total of 525,000 share awards have been granted in the Board LTIP 2020 program, 61,773 share awards have been granted in the Board LTIP 2021 program, employee stock options corresponding to 1,325,800 shares have been granted in the Co-worker LTIP 2018 program and employee stock options corresponding to 807,600 shares have been granted in the Co-worker LTIP 2021 program.

#### **Guidelines for executive** remuneration 2021

The board of directors, the CEO and other members of the executive management fall within the provisions of these guidelines. The guidelines are forward-looking, i.e. they are applicable to remuneration agreed, and amendments to remuneration already agreed, after adoption of the guidelines by the annual general meeting 2021. These guidelines do not apply to any remuneration already decided or approved by the general meeting.

#### The guidelines' promotion of the company's business strategy, longterm interests and sustainability

In short, the company's business strategy is the following.

Vicore Pharma is a rare disease pharmaceutical company with a focus on fibrotic lung diseases and related indications. The company currently has three drug development programs, VP01, VP02 and VP03. The VP01 program aims to develop the substance C21 for the treatment of IPF and COVID-19. The VP02 program is based on a

new formulation and delivery route of an existing immunomodulatory compound (an "IMiD"). The VP02 program focuses on the underlying disease and the severe cough associated with IPF. Both projects are also being actively evaluated for other indications within the field of fibrotic lung diseases which have a significant unmet need. The VP03 program includes follow-up molecules for C21. Vicore's long-term goal is to obtain regulatory approvals and establish the company as a pharmaceutical company specializing in fibrotic lung disease.

For more information regarding the company's business strategy, please see Vicore Pharma's company presentation at https://vicorepharma. com/investors/events-presentations/

A prerequisite for the successful implementation of the company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the company is able to recruit and retain qualified personnel. To this end, it is necessary that the company offers a competitive

These guidelines enable the company to offer the executive management a competitive total remuneration.

Variable cash remuneration covered by these guidelines shall aim at promoting the company's business strategy and long-term interests, including its

The company also has long-term share-related incentive plans in place. The plans have been resolved by the general meeting and aim to align the interests of the board members and key employees with those of the





#### Types of remuneration, etc.

The remuneration shall be on market terms and may consist of the following components: fixed cash salary, variable cash remuneration, pension benefits and other benefits. Furthermore. additional variable cash remuneration may be awarded in extraordinary circumstances. Additionally, the general meeting may - irrespectively of these guidelines - resolve on, among other things, share-related or share price-related incentive programs. The satisfaction of criteria for awarding variable cash remuneration shall be measured over a period of one to several years. The variable remuneration payable in cash may amount to a maximum of 40 percent of the annual fixed cash salary for the CEO and a maximum of 30 percent of the annual fixed cash salary to other senior executives under the measurement period for such criteria. Further variable cash remuneration may be awarded in extraordinary circumstances, provided that such extraordinary arrangements are limited in time and only made on an individual basis, either for the purpose of recruiting or retaining executives, or as remuneration for extraordinary performance beyond the individual's ordinary tasks. Such remuneration may not exceed an amount corresponding to 50 per cent of the fixed annual cash salary and may not be paid more than once per year for each individual. Any resolution on such remuneration shall be made by the board of directors based on a proposal from the remuneration committee. For the CEO, pension benefits,

For the CEU, pension benefits, including health insurance (Sw: sjukförsäkring), shall be premium defined. Variable cash remuneration shall not qualify for pension benefits. The pension premiums for premium defined pension shall amount to not more than 30 per cent of the fixed annual cash salary. For other executives, pension benefits, including health insurance, shall be premium defined unless otherwise required by for example collective agreements. The pension premiums for premium defined pension shall amount to not more than 30 per cent of the fixed annual cash salary.

Other benefits may include, for example, life insurance and medical insurance (Sw: sjukvårdsförsäkring). Such benefits may not amount to more than 10 per cent of the fixed annual cash salary.

For employments governed by rules other than Swedish, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines.

#### **Termination of employment**

For all executives the notice period may be up to six months if notice of termination of employment is made by the company. For the CEO, fixed cash salary during the notice period and severance pay may, in total, not exceed twelve months' fixed salary, and for other executives, such remuneration may not correspond to an amount which exceeds six months' fixed salary. The period of notice may be up to six months without any right to severance pay when termination is made by the executive.

Additionally, remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid in so far as the previously employed executive is not entitled to severance pay. The remuneration shall amount to not more than 60 per cent of the monthly income at the time of termination of employment and be paid during the time the non-compete undertaking applies, however not for more than 12 months following termination of employment.

### Criteria for awarding variable cash remuneration, etc.

The variable cash remuneration shall be linked to predetermined and measurable criteria. These criteria can be measurable advancements in the company's preclinical and clinical trials and other associated activities. The criteria can be financial or non-financial. They may also be individualized, guantitative or gualitative objectives. The criteria shall be designed so as to contribute to the company's business strategy and longterm interests, including its sustainability, by for example being clearly linked to the business strategy or the executive's long-term development. The board of directors shall have the possibility, under applicable law or contractual provisions, subject to the restrictions that may apply under law or contract, to in whole or in part reclaim variable remuneration paid on incorrect grounds (claw-back).

To which extent the criteria for awarding variable cash remuneration have been satisfied shall be evaluated/ determined when the measurement period has ended. The remuneration committee is responsible for the evaluation so far as it concerns variable remuneration to the CEO. For variable cash remuneration to other executives. the CEO is responsible for the evaluation, subject to approval by the board of directors for those executives who report directly to the CEO. For financial objectives, the evaluation shall be based on the latest financial information made public by the company.

#### Salary and employment conditions for employees

In the preparation of the board of directors' proposal for these remuneration guidelines, salary and employment conditions for employees of the company have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the remuneration committee's and the board of directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable

# The decision-making process to determine, review and implement the guidelines

The board of directors has established a remuneration committee. The committee's tasks include preparing the board of directors' decision to propose guidelines for executive remuneration. The board of directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the general meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting. The remuneration committee shall also monitor and evaluate programs for variable remuneration for the executive management, the application of the guidelines for executive remuneration as well as the current remuneration structures and compensation levels in the company. The members of the remuneration committee are independent of the company and its executive management. The CEO and other members of the executive management do not participate in the board of directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

#### Derogation from the guidelines

The board of directors may temporarily resolve to derogate from the guidelines, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the remuneration committee's tasks include preparing the board of directors' resolutions in remuneration-related matters. This includes any resolutions to derogate from the guidelines.

#### Description of significant changes to the guidelines for 2022 and how the shareholders' views have been taken into account

No significant changes have been made to the proposed guidelines for 2022 compared to previously adopted guidelines. No shareholders have provided any comments.

#### Nomination committee for the 2022 Annual General Meeting

Vicore's nomination committee for the 2021 Annual General Meeting consists of Staffan Lindstrand, appointed by HealthCap VII L.P., Ulrik Grönvall, appointed by Swedbank Robur, Jannis Kitsakis, appointed by Fourth Swedish National Fund AB and Michael Wolff Jensen, Chairman of the Board of Directors of Vicore.

#### **Risk factors**

Vicore's business is influenced by a number of factors, the effects of which on the company's earnings and financial position, in certain respects, cannot be controlled by the company at all or in part. In an assessment of the company's future development, it is important, alongside the possibilities for growth, to also consider these risks.

Set forth below is a description, without any internal order of priority, of the risks which are considered to have greatest significance for the company's future development. Risk factors related to Vicore's operations, industry and markets, and further include operational risks, regulatory risks and financial risks.

#### **Clinical trials in Russia and Ukraine**

Russia's invasion of Ukraine has negatively affected the availability and recruitment of potential trial participants as well as their ability to carry out non-essential hospital visits. This can lead to patients not completing a study or not returning for follow-up. There is thus a risk that the company's studies with VPO1 in IPF and COVID-19, respectively, will be delayed or need to be withdrawn, which could have a material negative impact on the company's operations, financial position and results.

#### COVID-19-pandemic

The outbreak of the COVID-19 pandemic throughout the world has led to major disruptions in the economies of many countries, including the group's ability to carry out clinical studies. The duration and expected development of the COVID-19 pandemic is unknown, and no predictions can be made in relation to the length of present and further measures that different countries and others may take in response to the crisis. However, any prolongation or worsening of the virus outbreak may lead to e.g. the following:

- the availability and recruitment of potential trial participants in clinical studies as well as their possibility of carrying out non-essential hospital visits is negatively affected. This could lead to delays of the studies, greater study costs and capital need than anticipated,
- disruptions in the operations of third-party manufacturers, clinical research organizations, and other parties on whom Vicore relies, the availability or cost of materials, which could damage Vicore's supply chain or otherwise limit its ability to obtain sufficient materials to manufacture Vicore's drug candidates to be used in clinical trials,
- regulatory approvals or opinions for programs are delayed,
- commercialization of new products is hampered, and
- disruption of financial markets, which can impact the company's refinancing abilities.

Given the evolving nature of the pandemic, the above list is by no means exhaustive, but each of these events, or any combination of them, could amplify the negative impact of the crisis on the group's financial performance and have material adverse effect on the group's business, financial development and shareholder value.

### Research and development and the dependency of four programs

Vicore's business consists mainly of four programs (VP01, VP02, VP03 and VP04). The company's main value may be attributable to the potential of the company's respective programs. The programs are in preclinical or clinical phase. There is a risk that Vicore's various programs will not develop as planned, which could have a material adverse effect on the company's value and future potential. This is especially true if any of the above would occur in the more advanced program VP01, which is currently of the greatest value to the company. For example, there is a risk that Vicore, any collaborating partners, institutional review bodies and / or regulatory authorities will discontinue clinical studies if the results of such studies do not demonstrate the intended treatment effect, fail to achieve an acceptable safety profile, or due to results from unwanted side effects. If a program or study is interrupted. in addition to a significant decline in the company's share price as a result of a reduced value of the company's program portfolio and a significantly impaired revenue potential for the specific program, it may cause an impairment of fixed assets.

#### Clinical trials and regulatory approvals

Before conducting certain clinical trials, approval must be obtained from the relevant regulatory authority and an ethics committee. The main markets for the company's future products are the United States and the EU, and the relevant regulators are the US Food and Drug Administration ("FDA") and / or the European Medicines Agency ("EMA"). There is a risk that the regulatory



authority and / or the ethics committee will not grant the necessary approvals for the company's ongoing or future programs. There is also a risk that program approvals or opinions will be delayed or withdrawn. If the necessary approvals are not obtained, delayed or withdrawn, this could delay the relevant program or mean that it needs to be cancelled. The aforementioned risks could have a material adverse effect on the company's operations, financial position and results.

#### Delays in clinical studies

There is a risk that the company's clinical studies within the framework of, for example, VP01, VP02, VP03 or VP04 will be delayed. Delays can occur for a variety of reasons, including difficulties in reaching agreements with clinics about participation under acceptable conditions, problems in identifying patients for studies, patients not completing a study, or not returning for follow-up. A pandemic and / or a war could negatively affect the availability and recruitment of potential trial participants as well as their possibility of carrying out non-essential hospital visits. Difficulties in adding new clinics or if a clinic withdraws from a study also entail a risk of delays. Furthermore, there may be delays as a result of problems in the supplier route, where a delay in the delivery of an ordered substance may cause a delay in the studies. A delay in a program usually means that the program will be more expensive, since the research and development costs will run for a longer time than planned. This may result in the company having to raise additional capital to complete the program.

### Development of further candidate drugs

In addition to the programs, VP01, VP02 and VP04, work is being performed to identify and develop new selective AT2 receptor molecules for treatment of diseases within or outside the orphan disease area in the VP03 program. This development work is performed in collaboration with external researchers.

There is a risk that Vicore's available financial resources will prove insufficient to conduct such development and that the company, as a result thereof, may be forced to discontinue development or find other sources of financing. Continuing the further development of new molecules could create a need to expand the company's organisational resources, which could incur further costs for the company. There is thus a risk that the company's work on further drug candidates will have a negative impact on its operations, financial position and results.

#### Intellectual property issues

The value of Vicore is largely dependent on its ability to obtain and defend patents and its ability to protect specific knowhow. Patent protection for pharmaceutical companies may be uncertain and involve complicated legal and technical questions. There is a risk that a patent sought will not be granted for an invention, that the patent granted will not provide sufficient protection, or that the patent granted will be circumvented or revoked.

Vicore holds three granted patents within the VP01 program. There is a risk that these patents do not constitute adequate protection. If intellectual property protection is not satisfactory, other parties can exploit this by circumventing the company's protection and conduct competing drug development. Such drug development could show higher efficacy. This may force Vicore to terminate a particular drug program for commercial reasons, or that the company's future product will not generate any revenue.

Vicore has several pending patent applications within the VP01, VP02 and VP03 programs. There is a risk that these patent applications or future patent applications by the company are not granted. If a patent application is not granted, it can lead to insufficient commercial protection which may result in termination of relevant programs due to lack of market prospects. Both insufficient commercial protection and a decision to terminate programs would have a material adverse effect on the company's program portfolio and outlook.

#### Orphan drug status

In addition to the company's patents, Vicore has received so-called orphan drug status for C21 for the treatment of IPF in the USA and EU, which becomes particularly relevant if Vicore succeeds in developing and launching a drug. This means that Vicore will depend on other protection than patents, such as, alternative commercial protections in the form of orphan drug status or data exclusivity.

There is a risk that these protections are not adequate for Vicore's purposes, or that the market exclusivity or the orphan drug status is revoked. If Vicore's commercial and / or intellectual property protection is not adequate, other actors can take advantage of this, bypassing the company's protection, and conduct competing drug development, or launching competing products on the market. If other players develop and / or launch competing products that show higher efficiency or are sold at a lower price than Vicore's, the company could lose significant revenue.

#### Market and competition

The development and commercialization of new pharmaceutical products constitute a competitive market Vicore's competitors are mainly large pharmaceutical companies, biotech companies and academic institutions. It is possible that competitors, such as large pharmaceutical companies, have greater opportunities in terms of, for example, research and development, contacts with regulatory authorities, patient recruitment and marketing than Vicore. Therefore, there is a risk that competitors, who in many cases have greater resources than Vicore, may develop competing products more guickly and / or more efficiently, achieve broader market acceptance or succeed in obtaining market exclusivity earlier or in parallel with Vicore. This may lead to a significant weakening of the company's ability to generate revenues and the company may be forced to terminate parts of the business for commercial reasons. Furthermore, this could mean that the value of the company's program portfolio is significantly reduced.

#### Production

Since Vicore has no proprietary production facilities, the company is dependent on sub-suppliers for the production of pharmaceuticals. The manufacturing process for Vicore's drugs are made in collaboration with contract manufacturers in Europe. Vicore is dependent on the quality of the manufacturing processes as well as the availability and maintenance of the production facilities. Regulatory authorities require that all manufacturing processes and methods, as well as all equipment comply with current requirements of Good Manufacturing Practice, GMP requirements and consequences for the company in the event of deficiencies in GMP requirements may lead to delays in clinical trials or to market products.

None of the company's current manufacturers are significant in the sense that they are not replaceable, but the company is dependent on them, since changing manufacturers can be both costly and time-consuming. There is a risk that the company will not find suitable manufacturers that offer the same quality and quantity on terms acceptable to the company.

### Reliance on key individuals and employees

Vicore is highly dependent on retaining and recruiting both qualified employees and consultants as well as board members. The company's future performance is affected by its ability to attract and retain gualified key personnel. In the event that one or more key persons leave and the company fails to replace him or her, this could have a negative effect on the company's operations, financial position and earnings. In order for the company to have sufficient capacity to further develop its drug candidates and conduct phase III studies, several persons must be recruited. If the recruitment is not successful, or if Vicore fails to retain key personnel, there is a risk that the company's drug development programs cannot be developed according to plan, which would have significant negative consequences for the company's

operations and program portfolio. Such a lack of competence or resources may, in the long run, lead to delays in the company's programs, which would be associated with significant research and development costs.

#### **Financing and capital requirements**

The company currently has no approved drugs and does not generate any revenue from drug sales. It may take a long time before the company's drug candidates will be sold commercially and generate recurring cash flows. The company's ongoing and planned clinical trials entail significant costs. The company is therefore still dependent on raising capital or borrowing money to finance clinical studies. Both the extent and timing of Vicore's future capital needs will depend on a number of factors, including results from and costs for future studies. The access to, and the conditions for additional financing. for example through new share issues, licenses or partnership agreements or loans are affected by a number of factors such as Vicore's clinical study results, market conditions, general access to capital and Vicore's credit rating and credit capacity. Disruptions and uncertainty in the credit and capital markets can also limit access to additional capital. If Vicore fails to raise sufficient capital on favorable terms, or at all, it would mean that the company may have to accept a more expensive financing solution, share issues with significant discount and large dilution, or cause the company to limit its development or cease operations. For further description of the company's financial risks, see Note 19.

#### Currency risk

Assets, liabilities, income and expenses in foreign currency give rise to currency exposures. A weakening of the Swedish krona (SEK) against other currencies increases the reported amounts of Vicore's assets, liabilities, income and earnings while a strengthening of the SEK against other currencies decreases these items. The company is exposed to such changes, as parts of the company's costs are paid in EUR and other international currencies and because a part of the company's future sales revenue may be received in international currencies. A material change in such exchange rates could have a negative impact on the company's financial statements, which in turn could have negative effects on Vicore's financial position and results. To reduce currency exposure in EUR, the company exchanges SEK to EUR in the range of 60-100% of expected future cash flows. See also Note 19.

#### Tax loss carryforwards

As a result of the business having generated significant loss, Vicore has large accumulated tax loss carryforwards. As of December 31, 2021, Vicore's tax loss carryforwards amounted to 729.8 MSEK. Changes in ownership resulting in a change of controlling influence over Vicore, or certain internal transfers described above, may impose restrictions, in whole or in part, on the possibility of utilizing such losses in the future. There is also a risk that Vicore will not be able to generate enough profits to exploit such tax losses. The possibility of utilizing the losses in the future may also be adversely affected by future changes in the applicable legislation.

# Proposed appropriation of the company's profits or loss for the 2021 financial year

The following profit/loss stated in SEK is at the disposal of the Annual General Meeting:

	040 040 704
Loss of the year	17,578,105
Loss brought forward	-60,378,841
Share premium reserve	1,003,761,527

960,960,791

The Board of Directors proposes that SEK 960,960,791 are to be carried forward.

### Financial targets and dividend policy

The target is to distribute approximately 50 percent of the company's annual net profit as dividends when Vicore has achieved the desired financial stability, taking into account present and future profit levels, investment needs, liquidity and development opportunities as well as general economic and business conditions.

In accordance with the Board of Directors' dividend policy, no dividend is to be paid before the company generates significant revenue.





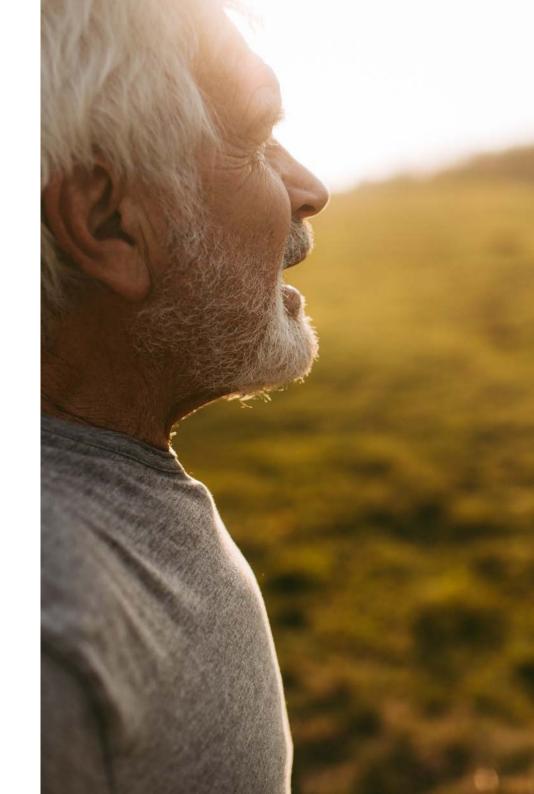
# Multi-year Overview

#### Multi-year overview, group

	2021	2020	2019	2018
Net sales (KSEK)	0	0	0	508
Loss after financial items (KSEK)	-296,735	-147,315	-93,329	-21,681
Total assets (KSEK)	451,168	406,515	341,108	301,600
Equity ratio (%)	85.0	87.2	94.3	94.6
Number of employees (average)	16	13	8	6

#### Multi-year overview, parent company

	2021	2020	2019	2018
Net sales (KSEK)	38,730	3,672	3,092	2,653
Loss after financial items (KSEK)	17,709	-21,826	-24,803	-11,100
Total assets (KSEK)	1,075,894	669,514	503,959	488,965
Equity ratio (%)	92.6	97.7	98.4	82.1
Number of employees (average)	4	4	3	3



# Financial reports Group

#### Consolidated statement of comprehensive income

KSEK	Note	2021 Jan-Dec	2020 Jan-Dec
Net sales		0	0
Gross profit		0	0
Administrative expenses	4, 5	-20,204	-24,986
Marketing and distribution expenses	4	-1,404	0
Research and development expenses	4	-271,812	-142,021
Other operating income and expenses	4, 9, 10	-1,398	17,469
Profit/loss from operations		-294,818	-149,538
Financial income	11	646	2,229
Financial expenses	12	-2,563	-6
Net financial income/expense		-1,917	2,223
Loss after financial items		-296,735	-147,315
Tax	13	254	453
Loss for the year attributable to the parent company's shareholders		-296,481	-146,862
Other comprehensive income			
Other comprehensive income		0	0
Other comprehensive income for the year, net of tax		0	0
Total comprehensive income attributable to the parent company's shareholders		-296,481	-146,862
Earnings per share, before and after dilution	14	-4.25	-2.71

#### Consolidated statement of financial position

KSEK	Note	2020 Dec 31	2019 Dec 31
ASSETS			
Fixed assets			
Patents, licenses and similar rights	15	67,427	70,755
Equipment	16	84	113
Contract asset	6	317	139
Long-term investments	17, 18	5,409	7,530
Deferred tax asset	13	0	131
Total fixed assets		73,237	78,668
Current Assets			
Other receivables		1,417	5,354
Prepaid expenses and accrued income	20	5,034	3,757
Short-term investments	21	77,281	70,118
Cash and cash equivalents	22	294,199	248,618
Total current assets		377,931	327,847
TOTAL ASSETS		451,168	406,515
EQUITY AND LIABILITIES			
EQUITY	24		
Share capital		35,880	30,209
Other contributed capital		1,021,666	702,053
Retained earnings (including profit (loss) for the period)		-674,230	-377,749
Total equity attributable to the parent company's shareholders		383,316	354,513
LIABILITIES			
Non-current liabilities			
Contract liability	6	320	0
Other provisions	25	600	2,385
Deferred tax liability	13	1,210	1,531
Total non-current liabilities		2,130	3,916
Current liabilities			
Contract liability	6	0	140
Trade payables	18, 19	23,984	10,943
Current tax liability		335	553
Other liabilities		1,112	3,132
Other provisions	25	152	3,792
Accrued expenses and deferred income	26	40,139	29,526
Total current liabilities		65,722	48,086
TOTAL LIABILITIES		67,852	52,002
TOTAL EQUITY AND LIABILITIES		451,168	406,515

#### Consolidated statement of changes in shareholders' equity

Shareholders' equity attributable to the parent company

KSEK	Share capital	Other contributed capital	Retained earnings including profit (loss) for the period	Total
Equity Jan 1, 2020	25,087	527,397	-230,887	321,597
Profit/loss for the year	0	0	-146,862	-146,862
Other comprehensive income for the year	0	0	0	0
Total comprehensive income for the year	0	0	-146,862	-146,862
Transactions with owners:				
Issue of new shares	5,122	182,428	0	187,550
Issue costs	0	-10,404	0	-10,404
Long-term incentive program	0	2,632	0	2,632
Total transactions with owners	5,122	174,656	0	179,778
Equity Dec 31, 2020	30,209	702,053	-377,749	354,513
Equity Jan 1, 2021	30,209	702,053	-377,749	354,513
Profit/loss for the year	0	0	-296,481	-296,481
Other comprehensive income for the year	0	0	0	0
Total comprehensive income for the year	0	0	-296,481	-296,481
Transactions with owners:				
Issue of new shares and issue in kind	5,671	333,329	0	339,000
Issue costs	0	-17,578	0	-17,578
Long-term incentive program	0	3,862	0	3,862
Total transactions with owners	5,671	319,613	0	325,284
Equity Dec 31, 2021	35,880	1,021,666	-674,230	383,316

#### Consolidated statement of cash flow

KSEK	Note	2021 Jan-Dec*	2020 Jan-Dec
Operating activities			
Operating profit		-294,818	-149,538
Adjustment for items not included in the cash flow	27	2,099	6,202
Interest received		483	726
Interest paid		-8	-6
Cash flow from operating activities before changes in working capital		-292,244	-142,616
Cash flow from changes in working capital			
Change in operating receivables		-340	-3,867
Change in operating payables		27,413	26,548
Cash flow from operating activities		-265,171	-119,935
Investing activities			
Acquisition of intangible assets	29	0	-3,000
Acquisition of financial assets	21	-77,000	-70,000
Sale of financial assets	21	70,000	77,000
Cash flow from investing activities		-7,000	4,000
Financing activities			
Amortization contract liability		-239	-179
Issue of new shares		336,000	187,550
Issue costs		-17,578	-10,404
Cash flow from financing activities		318,183	176,967
Cash flow for the year		46,012	61,032
Cash and cash equivalents at the beginning of the year		248,618	187,586
Foreign exchange difference in cash and cash equivalents	11, 12	-431	0
Cash and cash equivalents at year-end	22	294,199	248,618

#### \* Correction of the cash flow statement

In the year-end report for the fiscal year 2021, social security contributions for share-based incentive programs were reported in the cash flow statement as "Change in operating payables", but has been reclassified for the fiscal year 2021 to the item "Adjustments for items not included in the cash flow". The reclassification has had no cash flow impact. Historical figures have not been adjusted.

# Financial reports Parent company

#### Parent company's income statement

		2021	2020
KSEK	Note	Jan-Dec	Jan-Dec
Net sales	2	38,730	3,672
Gross profit		38,730	3,672
Administrative expenses	3, 4, 5, 6	-19,911	-24,663
Research and development expenses	3	-1,686	-1,658
Other operating income and expenses	3	-67	44
Profit/loss from operations		17,066	-22,605
Interest income and similar profit items	7	645	815
Interest expenses and similar loss items	8	-2	-36
Net financial income/expense		643	779
Profit/loss after financial items		17,709	-21,826
Tax	9	-131	68
Profit/loss for the year		17,578	-21,758

#### Parent company's statement of comprehensive income

KSEK	Note	2021 Jan-Dec	2020 Jan-Dec
Profit/loss for the year		17,578	-21,758
Other comprehensive income			
Other comprehensive income		0	0
Other comprehensive income for the year		0	0
Comprehensive income for the year		17,578	-21,758



## Parent company's balance sheet

KSEK	Note	2021 Dec 31	2020 Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets			
Patents, licenses and similar rights		0	6,000
Total intangible assets		0	6,000
Tangible assets			
Equipment		0	0
Total tangible assets		0	0
Financial assets			
Participations in group companies	10	796,389	396,303
Long-term investments	11	565	565
Deferred tax asset	9	0	131
Total financial assets		796,954	396,999
Total fixed assets		796,954	402,999
Current assets	12		
Receivables			
Receivables from group companies		32,386	0
Other receivables		65	305
Prepaid expenses and accrued income	13	812	270
		33,263	575
Short-term investments	14	77,281	70,118
Cash and cash equivalents	15	168,396	195,822
Total current assets		278,940	266,515
TOTAL ASSETS		1,075,894	669,514

## Parent company's balance sheet

KSEK Note	2021 Dec 31	2020 Dec 31
EQUITY AND LIABILITIES		
EQUITY 16		
Restricted equity		
Share capital	35,880	30,209
Total restricted equity	35,880	30,209
Non-restricted equity		
Share premium reserve	1,003,762	688,011
Accumulated profit or loss	-60,379	-42,483
Profit (loss) for the year	17,578	-21,758
Total non-restricted equity	960,961	623,770
TOTAL EQUITY	996,841	653,979
LIABILITIES		
Provisions		
Other provisions 17	507	5,312
Deferred tax liability	184	120
Total provisions	691	5,432
Non-current liabilities		
Liabilities to group companies 18	0	0
Total non-current liabilities	0	0
Current liabilities		
Trade payables	622	765
Liabilities to group companies 18	75,000	0
Current tax liability	61	385
Other liabilities	595	1,725
Accrued expenses and deferred income 19	2,084	7,228
Total current liabilities	78,362	10,103
TOTAL LIABILITIES	79,053	15,535

## The parent company's report of changes in equity

KSEK	Share capital	Share premium reserve	Loss brought forward	Loss for the year	Total
Equity Jan 1, 2020	25,087	515,988	-20,376	-24,740	495,959
Transfer of previous year's loss	0	0	-24,740	24,740	0
Profit/loss for the year	0	0	0	-21,758	-21,758
Other comprehensive income for the year	0	0	0	0	0
Total comprehensive income for the year	0	0	-24,740	2,982	-21,758
Transactions with owners:					
Issue of new shares	5,122	182,428	0	0	187,550
Issue costs	0	-10,405	0	0	-10,405
Incentive programs	0	0	2,633	0	2,633
Total transaction with owners	5,122	172,023	2,633	0	179,778
Equity Dec 31, 2020	30,209	688,011	-42,483	-21,758	653,979
Equity Jan 1, 2021	30,209	688,011	-42,483	-21,758	653,979
Transfer of previous year's loss	0	0	-21,758	21,758	0
Profit/loss for the year	0	0	0	17,578	17,578
Other comprehensive income for the year	0	0	0	0	0
Total comprehensive income for the year	0	0	-21,758	39,336	17,578
Transactions with owners:					
Issue of new shares and issue in kind	5,671	333,329	0	0	339,000
Issue costs	0	-17,578	0	0	-17,578
Incentive programs	0	0	3,862	0	3,862
Total transaction with owners	5,671	315,751	3,862	0	325,284
Equity Dec 31, 2021	35,880	1,003,762	-60,379	17,578	996,841

## The parent company's cash flow statement

KSEK	Note	2021 Jan-Dec	2020 Jan-Dec
Operating activities			
Operating profit		17,066	-22,605
Adjustments for items not included in the cash flow	20	-2,215	2,104
Interest received		482	726
Interest paid		-2	-2
Cash flow from operating activities before changes in working capita	I	15,331	-19,777
Cash flow from changes in working capital			
Change in operating receivables		-36,438	550
Change in operating payables		2,259	1,925
Cash flow from operating activities		-18,848	-17,302
Investing activities			
Sale/liquidation of group company		0	75
Shareholder contributions to group companies		-320,000	-120,000
Acquisition of financial assets	14	-77,000	-70,000
Sale of financial assets	14	70,000	77,000
Cash flow from investing activities		-327,000	-112,925
Financing activities			
Issue of new shares		336,000	187,550
Issue costs		-17,578	-10,404
Cash flow from financing activities		318,422	177,146
The cash flow for the year		-27,426	46,919
Cash and cash equivalents at the beginning of the year		195,822	148,903
Foreign exchange difference in cash and cash equivalents		0	0
Cash and cash equivalents at the end of the year	15	168,396	195,822

# Notes Group

## Note 1 Accounting principles

This Annual Report and the consolidated financial statements comprise the Swedish parent company Vicore Pharma Holding AB (publ), corporate registration number 556680-3804, and its subsidiaries. The parent company is a limited liability company with its registered office in Gothenburg, Sweden. The address of the main office is Kronhusgatan 11, 411 05 Gothenburg. The main operation of the group is research and development of pharmaceutical products.

On April 6, 2022, the Board of Directors approved this Annual Report and the consolidated financial statements, which will be presented for approval at the Annual General Meeting on May 11, 2022.

## **Applied regulations**

Vicore's consolidated accounts have been prepared in accordance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as well as the interpretations from the IFRS Interpretation Committee (IFRS IC) as adopted by the European Union (EU). Furthermore, the group also applies the Annual Accounts Act (1995: 1554) and the Swedish Financial Reporting Board's recommendation RFR 1 "Supplementary Accounting Rules for Groups".

## Basis for the consolidated accounts

Preparing financial statements in accordance with IFRS requires the company management to make estimates for accounting purposes. These assessments and estimates are based on historical experiences, as well as other factors that are considered to be reasonable during the current circumstances. The actual result can deviate from these estimates and assessments.

## New and amended standards and interpretations not yet adopted by the group

Updated standards and interpretations from IASB and IFRIC interpretations that came into force during the 2021 calendar year have had no material impact on the group.

## Valuation principles

Assets and liabilities have been recognised at their historical cost, except for certain financial assets that are stated at fair value. Financial assets valued at fair value consist of holdings in listed and non-listed shares.

#### Consolidation

## Subsidiaries

Subsidiaries are all the companies over which Vicore has a controlling influence. The group controls a company when it is exposed to, or has rights to, variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Subsidiaries are included in the consolidated accounts as of the date on which the controlling influence is transferred to the group. They are excluded from the consolidated accounts as of the date on which the controlling influence ceases.

Subsidiaries are reported according to the acquisition method. The method implies that acquiring a subsidiary is considered a transaction, whereby the group indirectly acquires the subsidiary's assets and liabilities. In the acquisition analysis, the fair value of acquired identifiable assets and assumed liabilities, as well as any holdings without controlling influence, is determined on the acquisition date. Transaction costs, excluding transaction costs attributable to the issue of equity instruments or debt instruments, which arise are reported directly in the profit/loss for the year. For business combinations where the transferred remuneration exceeds the fair value of acquired assets and assumed liabilities that are reported separately, the difference is reported as goodwill. When the difference is negative, a so-called bargain purchase, this is reported directly in the profit/loss for the year.

When acquiring an asset, the acquisition value is allocated to the individual identifiable assets and the debts, based on their relative fair values. Such a transaction does not give rise to goodwill.

## Eliminated transactions during consolidation

Intra-group receivables and liabilities, income or expenses and unrealised gains or losses which arise from intra-group transactions between group companies are eliminated in the preparation of the consolidated accounts. Unrealised gains arising from transactions with associated companies are eliminated to the extent which corresponds to the group's ownership in the company. Unrealised losses are eliminated in the same way, but only to the extent that there is no impairment of the asset.

## Currency

## Functional currency and reporting currency

Functional currency is the currency in the primary economic environments in which the companies operate. The parent company's functional currency is the Swedish kronor, which is also the reporting currency for the parent company and the group. Unless otherwise stated, all amounts are rounded to the nearest thousand (KSEK).

## Foreign currency transactions

Transactions in foreign currency are translated to the functional currency at the exchange rate as on the transaction date. Monetary assets and liabilities denominated in foreign currencies are translated to the functional currency at the exchange rate on the balance sheet date. Exchange rate differences that arise are recognized in the profit/loss for the year. Exchange gains and exchange losses on operating receivables and operating liabilities are reported in operating results, while exchange gains and exchange losses on financial receivables and liabilities are reported as financial items.

## **Operating segments**

Operating segments are reported in a way that corresponds with internal reporting structures. The profit/loss generated by a business segment is then followed up by the company's chief operating decision maker, who is responsible for assessing the profit/loss figures and allocating resources to the business segment. In the group, this function is identified as the company's CEO.

An operating segment is a component of the group that engages in business activities from which it may earn revenues and incur expenses, and for which discrete financial information is available. Vicore does not divide its business into different segments, instead it sees the entire business of the group as one segment. This follows the company's internal organization and reporting structures.

## Classification

Non-current assets and non-current liabilities consist in all essentials solely of amounts that are expected to be recovered or settled more than twelve months after the reporting period. Current assets and current liabilities consist in all essential solely of amounts that are expected to be recovered or settled within twelve months of the reporting period.

#### Revenue from contracts with customers

The group reports revenue when the group fulfils a performance obligation, i.e. when a promised product is delivered to the customer and the customer takes control of the product. Control of a performance obligation can be transferred over time or at a point in time. Revenue consists of the amount the company expects to receive as compensation for the transferred products or services. For the group to report revenue from contracts with customers, each customer contract is analyzed according to the five-step model included in the standard:

**Step 1:** Identify a contract between at least two parties that consists of enforceable rights and obligations.

**Step 2:** Identify the performance obligations in the contract.

**Step 3:** Determine the transaction price, i.e. the amount of consideration that the company is expected to receive in exchange for the promised goods or services.

**Step 4:** Allocate the transaction price over the identified performance obligations.

**Step 5:** Recognize revenue when the performance obligations are satisfied, i.e. when control is transferred to the customer.

The group's net sales are currently not a significant part of the business.

#### **Government grants**

Government grants are reported in the statement of financial position and the statement of comprehensive income when there is reasonable assurance that the entity will comply with the conditions attached to them and the grants will be received. The grant is recognised as income over the period necessary to match them with the related costs, for which they are intended to compensate, on a systematic basis.

#### Leasing agreement

The group's leasing portfolio consists of a few operating leases for premises, which are the two classes of leased assets presented by the group. The leasing agreements are reported as contract assets with a corresponding lease liability on the day that the leased asset is available for use by the group. Short-term leases and low value leases are excluded.

Each leasing payment is divided between amortization of the lease debt and financial cost. The financial cost shall be distributed over the lease period so that each accounting period is charged with an amount corresponding to a fixed interest rate for the liability reported during each period.

The leasing period is determined as the non-cancellable period together with both periods covered by an option to extend the lease if the lessee is reasonably sure to take advantage of that option, and periods covered by an opportunity to terminate the lease if the lessee is reasonably sure not to exercise that option.

The group's leasing liabilities are recognized at the present value of the group's future leasing fees. Leasing payments have been discounted with the group's marginal loan interest rate.

The group's contract assets are recognized at cost and initially include the present value of the leasing liabilities, adjusted for leasing fees paid on or before the commencement date and initial direct expenses. Recovery costs are included in the asset if a corresponding provision regarding recovery costs has been identified. The contract asset is amortized on a straight-line basis over the shorter of the asset's useful life and the duration of the lease.

## Employee benefits

#### Short-term remuneration

Short-term remuneration to employees, such as salary, social security contributions, holiday pay

and bonus, is expensed when the employees perform the services.

### Pension obligations

The group only has defined contribution pension plans. In defined contribution plans, the group pays fixed contributions to a separate entity and has no legal or constructive obligation to pay further contributions if this entity does not have sufficient assets to pay all the remuneration to employees connected with the employees' service during the current or prior periods. Therefore, the group has no additional risk. For the group's obligations regarding contributions for defined contribution plans, these are reported as an expense in the consolidated profit/loss as the benefits are earned.

#### Incentive programs

There are four types of share-based incentive programs in the group: two option programs for employees, and two share awards programs for certain board members. The option and share awards have been granted free of charge and are settled with equity instruments.

The fair value of share-based payments is accounted for as personnel costs. The fair value of the employee stock options is determined at grant date with the Black-Scholes model for pricing of options. For the share awards, the fair value is determined at the time of allocation using a Monte Carlo simulation of future stock price development. The cost is reported, along with a corresponding increase in equity, during the period in which the vesting conditions are fulfilled, up to and including the date when the persons concerned are fully entitled to the compensation.

The accumulated cost included in each reporting period shows to what extent the vesting period has been recognised with an estimate of the number of share-related instruments that eventually will be vested.

Social security contributions attributable to share-related instruments to employees as compensation for purchased services must be expensed over the periods during which the services are performed. This cost must then be calculated using the same valuation model that was used when the options were issued. The provision made shall be reassessed at each reporting date based on a calculation of the amount social charges that may be payable when the instruments are settled.

## Financial income and expenses

## Financial income

Financial income consists of capital gains on and dividend incomes from financial fixed assets. Dividend income is recognized when the right to receive a dividend has been established. Exchange rate gains and losses are reported net.

### **Financial costs**

Financial costs consist mainly of interest expenses on loans. Exchange rate gains and losses are reported net.

#### Income taxes

Income taxes consist of current tax and deferred tax. Income taxes are recognized in profit or loss for the year, except when the underlying transaction is recognized in other comprehensive income or equity, in which case the tax effect is recognized in other comprehensive income or equity.

#### Current tax

Current tax is the tax that must be paid or received for the current year, with the application of the tax rates that have been decided, or in practice decided, on the balance sheet date. Current tax also includes adjustments to the current tax attributable to previous periods.

## Deferred tax asset/tax liability

Deferred tax is reported in its entirety, according to the balance sheet method and is based on the temporary differences between the tax base value of assets and liabilities and their carrying amount. Temporary differences are not taken into account in consolidated goodwill or differences attributable to participations in subsidiaries, which are not expected to be taxed in the foreseeable future. The valuation of deferred tax is based on how underlying assets or liabilities are expected to be realized or regulated. Deferred tax amounts are calculated by applying the tax rates and tax rules that have been decided or announced as of the balance sheet date and which are expected to apply when the deferred tax asset is realized or the deferred tax liability is settled.

Deferred tax assets related to deductible temporary differences and loss carry forwards are only recognized to the extent it is probable that these will be utilized.

The value of deferred tax assets is reduced when it is no longer deemed likely that they can be utilized. Deferred tax assets and deferred tax liabilities are offset if there is a legal right to offset short-term tax assets against short-term tax liabilities and the deferred tax is attributable to the same entity in the group and the same tax authority.

#### Earnings per share

Earnings per share before dilution are calculated as profit or loss attributable to the parent company shareholders divided by the weighted average number of ordinary shares outstanding during the period.

Earnings per share after dilution are calculated as profit or loss attributable to the parent company shareholders divided, in some cases adjusted, by the sum of the weighted average number of ordinary shares and potential ordinary shares that may give rise to dilution effects. A dilution effect of potential ordinary shares is recognized only if a translation into ordinary shares would lead to a reduction of earnings per share after dilution.

#### Intangible assets

#### Acquired intangible assets

Intangible assets in the group consist of patents,

licenses and similar rights. They are valued at cost that is decreased by accumulated depreciation and any accumulated impairment losses.

An intangible asset is recognized if it is probable that the asset will generate future economic benefits for the group, the criteria for capitalization are met and the costs can be measured reliably. An intangible asset is valued at cost when it is included for the first time in the financial report. Intangible assets with finite useful lives are reported at cost less depreciation and any impairment losses. Intangible fixed assets with finite useful lives are depreciated linearly over the asset's estimated useful life. Intangible assets with indefinite useful lives are instead tested annually for impairment. Intangible assets with finite and indefinite useful lives are reviewed for impairment requirements in cases where there are indications that a writedown may be needed. The useful life of intangible assets is reviewed at each balance sheet date and adjusted if necessary.

#### Capitalization of development expenditure

The expenses that arise during the development phase are capitalized as intangible assets when, according to management's assessment, they are likely to result in future economic benefits for the group, the criteria for capitalization are met and the costs can be measured in a reliable way. Otherwise, development expenses are expensed as normal operating expenses.

The group only has acquired intangible assets.

#### **Depreciation principles**

Depreciation begins when the asset can be used, i.e. when it is in the place and in the condition required to be able to use it in the way management intends.

The estimated useful life for intangible fixed assets with a finite useful life is 5 years. Depreciation is made on a straight-line basis over the estimated useful life of the asset, which coincides with the remaining patent period for the product.

#### Tangible fixed assets

Tangible fixed assets are reported in the group at cost after deductions for accumulated depreciation and any accumulated impairment losses. The cost includes the purchase price and any costs directly attributable to the asset to bring it in place and in condition to be utilized in accordance with the purpose of the acquisition.

The carrying amount of an asset is derecognized from the balance sheet when disposing or divesting, or when no future economic benefits are expected from use or disposing/divesting of the asset. Gains or losses arising from the sale or disposal of an asset consist of the difference between the selling price and the asset's carrying amount with the deduction of direct sales costs. Gains and losses are reported as other operating income/expenses.

### Additional expenses

Additional expenses are added to the asset's carrying amount only if it is probable that the future economic benefits associated with the asset will be leveraged by the group and that the cost of the asset can be measured reliably. All other additional expenses are reported as an expense during the period they arise. Repairs are expensed on an ongoing basis.

#### Depreciation principles

The depreciable amount shall be allocated on a systematic basis over the asset's estimated useful life. Used depreciation methods, residual values and useful lives are reviewed at the end of each year. The estimated useful lives are:

Equipment .....5 years

#### Impairment of non-financial assets

The group's reported assets are assessed in cases where there are indications of a decline in value of tangible or intangible assets, i.e. whenever events or changes in circumstances indicate that the fair value is not recoverable. Furthermore, the group's development projects are reviewed annually for impairment requirements until they are available for use. This is done regardless of whether there are indications of a decline in value or not.

An impairment is recognized when an asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less the cost of sale on the one hand and the value in use on the other. When assessing impairment, assets are grouped at the lowest level where there are separate identifiable cash flows (cash-generating units). When the need for impairment has been identified for a cash-generating unit (group of units), the impairment amount is distributed proportionally among the assets included in the cash-generating unit (group of units). A previously recognized impairment is reversed if the recovery amount is deemed to exceed the fair value. Reversal does not occur with an amount that is greater than what the fair value would have been recorded to if the impairment had not been recognized in previous periods. Any reversals are reported in the income statement.

## Financial assets and liabilities

A financial asset or financial liability is recognized in the balance sheet when the group becomes a party according to the instrument's contractual terms. A financial asset is removed from the balance sheet when the rights in the agreement are realized, expire or when the group loses control over them. The same applies to a part of a financial asset. A financial liability is removed from the balance sheet when the obligation in the agreement is fulfilled or otherwise extinguished. The same applies to a part of a financial debt.

Acquisitions and divestments of financial assets are reported on the trade date. The trade date constitutes the day when the company undertakes to acquire or divest the asset.

Financial instruments are classified on initial recognition, including on the basis of what purpose the instrument was acquired and managed. This classification determines the valuation of the instruments.

## Classification and valuation of financial assets

The classification of financial assets that are debt instruments, is based on the group's business model for managing the asset and the nature of the asset's contractual cash flows. Assets are classified according to:

## Amortized cost

- Fair value through profit or loss, or
- Fair value through other comprehensive income

The group's financial assets that are classified at amortized cost include accounts receivable, certain other receivables, short-term investments, and cash and cash equivalents. Financial assets classified at amortised cost are initially measured at fair value with the addition of transaction costs. After initial recognition, the assets are valued at amortized cost after a deduction of a loss reserve for expected credit losses. Assets classified at amortized cost are held according to the business model to collect contractual cash flows, which are solely payments of principal and interest on the outstanding principal amount.

The group's financial assets that are classified at fair value through profit or loss relate to holdings in listed and non-listed shares.

#### Impairment of financial assets

The group's impairment model is based on expected credit losses, and takes into account prospective information. A loss reserve is made when there is an exposure to credit risk, usually at initial recognition for an asset or receivable.

## Classification and valuation of financial liabilities

The group's financial liabilities consist of accounts payable and other current liabilities, which are all classified at amortized cost. Financial liabilities recognized at amortized cost are initially measured at fair value including transaction costs. After the initial recognition, they are valued according to the effective interest method.

#### Cash and cash equivalents

Cash and cash equivalents consist of cash and balances as well as immediately available credit balances with banks and corresponding financial institutions.

## Equity

All shares in the company are ordinary shares, which are reported as equity. The share capital is reported up to its quota value and any excess part is reported as Other contributed capital. Transaction costs, directly attributable to the issue of new ordinary shares or options, are reported, net after tax, in equity as a deduction from the issue proceeds.

#### Contingent liabilities

A contingent liability is recognised when there is a possible commitment that arises from past events and whose existence is confirmed only by one or more uncertain future events, or when there is a commitment that is not reported as a liability or provision due to it being unlikely that an outflow of resources will be required.

### **Cash flow**

Cash and cash equivalents consist of available cash, bank credit balances and other liquid investments with an original maturity of less than three months, which are exposed to insignificant value fluctuation. Incoming and outgoing payments are reported in the cash flow statement. The cash flow statement has been prepared in accordance with the indirect method.

# Note 2 Judgements and accounting estimates

The preparation of the financial statements in accordance with IFRS requires company management to make judgements and accounting estimates that affect the application of the accounting policies and the carrying amounts of assets, liabilities, revenue and expenses. The actual outcome could deviate from these estimates.

The accounting estimates and assumptions are evaluated continuously. Changes to the accounting estimates are recognized in the period in which the change is made if the change only has affected the period, or in the period in which the change is made and future periods if the change affects both the current period and future periods.

## Sources of uncertainty in the accounting estimates

The sources of uncertainty in the accounting estimates, entailing a significant risk that the value of assets or liabilities might need to be adjusted to a material extent during the forthcoming fiscal year, include impairment testing of intangible assets with indefinite useful lives.

### Impairment testing of intangible assets

When impairment testing intangible assets, a number of significant assumptions and judgements must be taken into account in order to calculate a recoverable amount. These assumptions and judgements relate to, among others, future expected selling price for the company's products VP01, VP02 and VP03, expected market penetration, expected development-, sales and marketing costs and expected likelihood that the products will pass the remaining stages of development. The assumptions are based on industry- and market-specific data and are produced by the management and reviewed by the Board of Directors. For more information about impairment testing, see Note 15 "Patent, licenses and similar rights".

#### Other judgments and accounting estimates

#### Capitalization of intangible assets

Development expenditures are capitalized when they fulfill the criteria set out in IAS 38 and are expected to represent material amounts for the development initiative as a whole. Development expenditures are otherwise expensed as normal operating costs. The most important criteria for capitalization are that the end product of the development work has a demonstrable future earning capacity or cost savings and cash flow, and that there are technical and financial preconditions to finish the development work when it begins. The group only has acquired intangible assets. Since regulatory approval has not yet been obtained, no costs have been capitalized.

#### Research and development expenses

The company conducts research and development with external collaboration partners, such as clinical research organizations (CROs). The company estimate the timing of the costs when the project commences. This cost is then used as a basis for settlement with the external collaboration partner. An evaluation and update of the calculation is performed monthly and forms the basis for booking accrued costs attributable to research and development.

### Incentive programs

The group has four active share-based long-term incentive programs. The applicable accounting policies are described in Note 1 "Accounting principles". The cost for the remuneration that is recognized in a period is dependent on the original valuation that was made on the contract date of with the holder of the option/share award, the number of months of service required by the participant for becoming entitled to options (accruals are made over this period), the number of options that are expected to be vested by the participant under the terms of the programs and a continuous reassessment of the value of the tax benefits for the participants in the incentive programs (for determining provisions for social security contributions). Those estimates which affect the cost in a period and the corresponding increase in equity mainly refer to inputs for the valuation of the options. The models used for this purpose are the Black & Scholes model and a Monte Carlo simulation. Significant assumptions in these valuations are described in Note 8 "Sharebased payments".

## Tax loss carryforwards

The group's tax loss carryforwards have not been measured and are not recognized as a deferred tax asset. These tax loss carryforwards will be measured valued only when the group has established a level of earnings which management with confidence estimate will lead to taxable profits.

## Not 3 Operating segments

Vicore does not divide its business into different operating segments. Instead the group's entire business is treated as one operating segment. This reflects the company's internal organisation and reporting system. Vicore's chief operating decision maker is the CEO. Currently, Vicore is operating mainly in Sweden, where the group's tangible and intangible fixed assets are attributed.

# Note 4 Operating expenses by nature of expense

The total expenses classified by function are distributed in the following cost categories:

	2021	2020
Other external expenses	256,517	129,249
Personnel expenses	33,304	34,221
Depreciation and amortization	3,598	3,537
Other operating expenses	2,492	721
Total	295,911	167,728

## Note 5 Audit fees

Ernst & Young AB	2021	2020
Audit fees*	450	538
Other audit related services	92	47
Tax consultancy services	0	0
Other services	10	88
Total	552	673

\* Audit engagement refers to fees for the statutory audit, i.e. work that has been necessary to produce the auditor's report as well as audit advisory services provided in connection with the audit engagement.

## Note 6 Leases

	2021 Dec 31	2020 Dec 31
Contract assets		
Premises	317	139
Total	317	139
Contract liabilities		
Long-term	320	0
Short-term	0	140
Total	320	140

The following amounts related to leasing contracts are reported in the consolidated statement of comprehensive income:	2021	2020
Leasing fees, short-term	1,066	817
Depreciation		
Premises	239	175
Equipment	0	4
Interest	6	3
Total	1,311	999

The total cash flow related to leasing agreements was 245 KSEK (182 KSEK) for 2021. For information on the maturity of leases, see Note 19 "Financial risks".

## Note 7 Employees and personnel costs

Average number of employees	2021		202	20
	No. of employees	of which men/ women	No. of employees	of which men/ women
Parent company	4	50%/50%	4	50%/50%
Subsidiaries	12	30%/70%	9	67%/33%
Group total	16	36%/64%	13	62%/38%

Personnel costs for the Board of Directors, senior executives and other employees	2021	2020
Group		
The Board and other senior executives		
Salaries and other remuneration	17,898	12,273
Social security contributions	-120	7,364
Pension costs	3,046	1,690
	20,824	21,327
Group		
Other employees		
Salaries and other remuneration	9,048	9,496
Social security contributions	744	1,879
Pension costs	2,239	1,154
	12,031	12,529
Group		
Other personnel costs	449	365
	449	365
Total personnel costs	33,304	34,221
Parent company		
The Board and other senior executives		
Salaries and other remuneration	9,813	10,245
Social security contributions	-2,154	6,730
Pension costs	1,508	1,407
	9,167	18,382
Parent company	·	
Other employees		
Salaries and other remuneration	906	592
Social security contributions	277	203
Pension costs	72	90
	1,255	885
Parent company	,	
Other personnel costs	226	90
and the second second	226	90
Total personnel costs	10,648	19,357

### Senior executives include members of the Board of Directors, the CEO and other senior executives.

## Salaries and other remuneration

Costs related to the long-term incentive programs amounts to 3,862 KSEK (2,632 KSEK) of the payroll expenses and -5,425 KSEK (5,602 KSEK) of the social security contributions.

## Pensions

All pension plans in the group are defined contribution plans. The group's total cost for defined contribution plans amounted to 5,285 KSEK (2,844 KSEK).

## Gender breakdown among senior executives

	2021 Dec 31	2020 Dec 31
Group		
Proportion of women on the Board	33%	29%
Proportion of men on the Board	67%	71%
Proportion of women among other senior executives	50%	43%
Proportion of men among other senior executives	50%	57%
Parent company		
Proportion of women among other senior executives	25%	33%
Proportion of men among other senior executives	75%	67%

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## Information regarding remuneration to the Board and other senior executives

2021	Basic salary, board fee*	Pension costs	Variable remuneration	Share- based payments	Other remuneration	Total
Chairman of the Board						
Michael Wolff Jensen	450	0	0	730	50	1 230
Members of the Board						
Jacob Gunterberg	150	0	0	0	125	275
Hans Schikan	150	0	0	142	50	342
Maarten Kraan	150	0	0	142	75	367
Sara Malcus	150	0	0	108	50	308
Heidi Hunter	150	0	0	365	50	565
Senior executives						
CEO	2,753	745	261	431	0	4,190
Other senior executives**	9,484	2,301	753	1,287	0	13,825
Total	13,437	3,046	1,014	3,205	400	21,102

\* Board fees as resolved at the AGM, excluding social security contributions and remuneration of board committee work for the May 2021 to May 2022 financial year. Other remuneration include remuneration for board committee work.

\*\* For more information, see "Remuneration for senior executives" below.

	Basic salary,	Pension	Variable	Share- based	Other	
2020	board fee*	costs	remuneration	payments	remuneration	Total
Chairman of the Board						
Michael Wolff Jensen	300	0	0	692	25	1,017
Members of the Board						
Jacob Gunterberg	100	0	0	0	100	200
Hans Schikan	100	0	0	126	75	301
Maarten Kraan	100	0	0	126	75	301
Peter Ström	100	0	0	51	0	151
Sara Malcus	100	0	0	51	50	201
Heidi Hunter	100	0	0	346	50	496
Senior executives						
CEO	2,540	697	787	343	0	4,367
Other senior executives**	4,582	993	938	536	0	7,049
Total	8,022	1,690	1,725	2,272	375	14,084

\* Board fees as resolved at the AGM, excluding social security contributions and remuneration of board committee work for the May 2020 to May 2021 financial year. Other remuneration include remuneration for board committee work. \*\* For more information. see "Remuneration for senior executives" below.

\*\* For more information, see "Remuneration for senior executives" belo

#### Share-based payments

Share-based payments refer to share awards and options granted to independent directors, the CEO, other senior executives, and other employees. Each vested share award entitles the holder to receive one share in the company, provided that the holder is still a member of the Board of Directors of the company at the relevant time of vesting. Each option entitles the holder to acquire one share in the company for a predetermined exercise price. The options are subject to vesting over a three year period whereby all options shall be vested on the third anniversary of the granting date, provided that the holder, with some customary exceptions is still employed by the company. The participants in the programs have received the share awards / options free of charge. For further information about the incentive programs, see Note 8 "Share-based payments".

#### Other remuneration

Other remuneration include remuneration for board committee work.

#### **Remuneration for senior executives**

Remuneration of the CEO and other senior executives consists of, in accordance with the guidelines for remuneration decided by the shareholder's meeting in 2021, basic salary, pension benefits, bonus and share-based incentives adopted by the shareholders' meeting (e.g. employee stock options). Other senior executives refer to the individuals who, together with the CEO, constitute the group management. During the period January 1, 2020, to November 2, 2020, other senior executives refer to the Chief Financial

Officer, Head of Project Management, Investor Relations Manager, and Chief Administrative Officer. As of November 3, 2020, other senior executives refer to the Chief Financial Officer, Chief Medical Officer, Chief Scientific Officer, VP Clinical Development, Head of Preclinical Development, and Chief Administrative Officer. During 2021, the group of other senior executives was expanded as follows: Head of Digital Therapeutics (July 1, 2021), Chief Commercial Officer (October 2, 2021) and Head of Business Development (November 8, 2021).

The CEO has a period of notice of six months in the event the termination is made by the group or if the CEO resigns. Other senior executives have a period of notice of three to six months, in the event the termination is made by the group or if the senior executive resigns.

In addition to salary during the termination period, the CEO is entitled to a termination benefit corresponding of six months' salary in the event of termination by the company on a basis other than a breach of contract.

## Note 8 Share-based payments

The purpose of share-based incentive programs is to promote the company's long-term interests by motivating and rewarding the company's senior management and other co-workers in line with the interests of the shareholders. As of December 31, 2021, Vicore has four active incentive programs that include the management team, other employees and certain board members. For more information, see below.

## Long-term incentive programs 2018

The Extra General Meeting in Vicore held on August 13, 2018, resolved, in accordance with the Board of Directors' proposal, to adopt a long-term incentive program for certain of the company's senior management and key persons ("Co-worker LTIP 2018") and for certain members of the Board of Directors ("Board LTIP 2018") in Vicore. A maximum of 2,000,000 options (Co-worker LTIP 2018) or 475,000 share awards (Board LTIP 2018) may be allotted to participants under the program. Of these, a total of 1,325,800 options and 475,000 share awards have been allocated. The increase in the company's share capital in full utilization of both incentive programs amounts to a maximum of approximately SEK 1,237,500, corresponding to a dilution of approximately 3,3 percent of the total number of shares. The options and share awards have been granted to the participants of the incentive programs free of charge and the settlement is made with equity instruments.

## Board LTIP 2018

Board LTIP 2018 is a program under which the participants will be granted, free of charge, share awards subject to performance vesting ("share awards") that entitle to shares in the company to be calculated in accordance with the principles stipulated below, however a maximum of 475,000 shares.

Board LTIP 2018 is intended for members of the Board of Directors of the company independent from the main owners. The main owners believe that an equity-based incentive program is a central part of an attractive and competitive remuneration package in order to attract, retain and motivate internationally competent members of the Board of Directors of the company, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

The share awards are subject to gradual vesting gradually over approximately three years, corresponding to three terms until the day of publication of the interim report for the second quarter of 2021. The share awards shall be vested by 1/3 at the end of each term, provided that the participant is still a member of the

Board of Directors of the company on said date. In addition to the vesting conditions just stated, the share awards are subject to performance vesting based on the development of the company's share price, in accordance with the vesting conditions below.

The share awards are subject to performance vesting based on the development of the company's share price over the period from the date of 13 August, 2018, up to and including the date of the annual general meeting 2021. The development of the share price will be measured based on the volume weighted average price of the share price will be measured based on the volume weighted average price of the company's share price for the 30 trading days immediately following after 17 August, 2018, and the 30 trading days immediately preceding the date of the publication of the interim report for the second guarter 2021. In the event the price of the company's share has thereby increased by more than 150 percent, 100 percent of the share awards shall vest, and should the share price have increased by 50 percent, 25 percent of such share awards shall vest. In the event of an increase of the share price between 50 and 150 percent, vesting of the share awards will occur linearly. Should the increase of the share price be less than 50 percent, no vesting will occur. The earliest date at which accrued share awards may be exercised is the date of publication of the interim report for the second guarter of 2021.

The valuation of the share awards is based on a Monte Carlo simulation in accordance with accepted valuation theory. Volatility has been based on the expected volatility of the Vicore share and other listed companies with similar operations. The risk-free interest rate has been derived through an interpolation between a 2-year and 5-year government bond, respectively. The fair value of the share awards at the time of allocation amounts to SEK 4.70 per share award. In order to calculate the value of the share awards in relation to the current performance conditions, a starting value is used that corresponds to the volume-weighted average price paid for the Vicore share over a fixed period, which in this case corresponds to the value of the underlying share at the time of valuation.

During the third quarter of 2021, Board LTIP 2018 expired. As the share price increased by less than 50 percent during the measurement period no share awards were earned. The program is now closed.

## Co-worker LTIP 2018

Co-worker LTIP 2018 is an incentive program intended for members of senior management and key persons in the company. According to the program participants will be granted, free of charge, options subject to three year vesting that entitle to acquire a maximum of 2,000,000 shares in the company in total, in accordance with the terms stipulated below.

The Board of Directors of the company believes that an equity-based incentive program is a central part of an attractive and competitive remuneration package in order to attract, retain and motivate competent members of senior management and key persons in the company, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

Co-worker LTIP 2018 is an incentive program under which the participants will be granted options free of charge. The Board of Directors shall resolve upon the allocation of options annually or at such time as the Board of Directors can be considered as relevant to such decision (with each respective date of granting being a "granting date"). Each option entitles the holder to acquire one share in the company for a predetermined exercise price. The exercise price per share shall correspond to 150 percent of the volume weighted average price of the company's share for the five trading days preceding the granting date. The options are subject to vesting over a three year period whereby all options shall be vested on the third anniversary of the granting date, provided that the holder, with some customary exceptions is still employed by the company. The latest point in time at which vested options may be exercised shall be the fourth anniversary of the granting date.

The options are valued according to the so-called Black & Scholes model, which means that the value of the options depends, among other things, on the value of the underlying share, the options's issue price and life, risk-free interest rate and volatility. The volatility has been based on the expected volatility of the Vicore share and other listed companies with similar operations. The risk-free interest rate was equated with the interest rate for Swedish government bonds. The fair value of the options at the time of allocation during 2020 amounts to SEK 3.98 per option. No allocation within Co-worker LTIP 2018 has taken place in 2021. The following inputs have been used in the model:

	202	0
Underlying share price	18.85	SEK
Excercise price	29.25	SEK
Expected volatility	45.00	%
Option life	4	years
Expected dividends	0	SEK
Risk-free interest rate	-0.35	%

### Long-term incentive program 2020

The Annual General Meeting in Vicore Pharma Holding AB held on May 20, 2020, resolved, in accordance with the proposal from the Nomination Committee, to adopt a long-term incentive program for the new members of the Board of Directors ("Board LTIP 2020") in Vicore Pharma Holding AB. A maximum of 525,000 share awards may be allotted to participants in the program Board LTIP 2020. The increase in the company's share capital, assuming full utilization, amounts to a maximum of approximately SEK 262,500, corresponding to a dilution of 0.7% of the total number of shares. Taking into account also the shares which may be issued pursuant to previously implemented incentive programs in the company, the maximum dilution amounts to 3.4% on a fully diluted basis.

## Board LTIP 2020

Board LTIP 2020 is a program under which the participants will be granted, free of charge, share awards subject to performance vesting ("share

awards") that entitle to shares in the company to be calculated in accordance with the principles stipulated below, however a maximum of 525,000 shares.

Board LTIP 2020 is intended for the newly elected, main owner independent, members of the Board of Directors in the company. The Nomination Committee believes that an equity-based incentive program is a central part of a competitive remuneration package in order to attract, retain and motivate internationally competent members of the Board of Directors, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

The share awards shall vest gradually over approximately three years, corresponding to three terms up to the date of, whichever is earliest, (i) the Annual General Meeting 2023 or (ii) June 1, 2023 ("vesting date"), where each term equals the period from one Annual General Meeting up until the day falling immediately prior to the next Annual General Meeting or the vesting date, as applicable (each such period a "term"). The share awards shall vest by 1/3 at the end of each term, provided that the participant is still a member of the Board of Directors of the company on said date. In addition to the vesting conditions just stated, the share awards are subject to performance vesting based on the development of the company's share price, in accordance with the vesting conditions below.

The share awards are subject to performance vesting based on the development of the company's share price over the period from the date the share awards are allocated ("grant date") up to and including the vesting date. The development of the share price will be measured based on the volume weighted average price of the company's share on Nasdag Stockholm for the 30 trading days immediately following the grant date and the 30 trading days immediately preceding the vesting date, respectively. In the event the price of the company's share has thereby increased by more than 150 percent, 100 percent of the share awards shall vest, and should the share price have increased by 50 percent, 25 percent of the share awards shall vest. In the event of an increase of the share price

between 50 and 150 percent, vesting of the share awards will occur linearly. Should the increase of the share price be less than 50 percent, no vesting will occur. The earliest point in time at which vested share awards may be exercised shall be the day falling immediately after the vesting date.

The valuation of the share awards is based on a Monte Carlo simulation in accordance with accepted valuation theory. Volatility has been based on the expected volatility of the Vicore share and other listed companies with similar operations. The risk-free interest rate has been derived through an interpolation between a 2-year and 5-year government bond, respectively. The fair value of the share awards at the time of allocation amounts to SEK 5.18 per share award. In order to calculate the value of the share awards in relation to the current performance conditions, a starting value is used that corresponds to the volume-weighted average price paid for the Vicore share over a fixed period. which in this case corresponds to the value of the underlying share at the time of valuation.

#### Long-term incentive programs 2021

The Annual General Meeting in Vicore Pharma Holding AB held on May 11, 2021, resolved to implement a long-term incentive program for senior management and key persons in the company ("Co-worker LTIP 2021") and to implement a longterm performance-based incentive program for independent board members in the company who are not participants in Board LTIP 2020 ("Board LTIP 2021"). A maximum of 3,000,000 options (Co-worker LTIP 2021) and 61,773 share awards (Board LTIP 2021) may be allotted to participants in the programs. The increase in the company's share capital, assuming full utilization of both incentive programs, amounts to a maximum of approximately SEK 1,530,887, corresponding to a dilution of approximately 4.1 percent of the total number of shares. Taking into account also the shares which may be issued pursuant to previously implemented

incentive programs in the company, the maximum dilution amounts to approximately 7.2 percent on a fully diluted basis.

### Board LTIP 2021

Board LTIP 2021 is a program under which the participants will be granted, free of charge, share awards subject to performance vesting that entitle to shares in the company to be calculated in accordance with the principles stipulated below, however a maximum of 61,773 shares.

Board LTIP 2021 is intended for independent board members in the company who are not participants in Board LTIP 2020. The Nomination Committee believes that an equity-based incentive program is a central part of a competitive remuneration package in order to attract, retain and motivate internationally competent members of the Board of Directors, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders. The share awards shall vest gradually over

approximately three years, corresponding to three terms up to the date of, whichever is earliest, (i) the Annual General Meeting 2024 or (ii) June 1, 2024 ("vesting date"), where each term equals the period from one Annual General Meeting up until the day falling immediately prior to the next Annual General Meeting or the vesting date, as applicable (each such period a "term"). The share awards shall vest by 1/3 at the end of each term, provided that the participant is still a member of the Board of Directors of the company on said date. In addition to the vesting conditions just stated, the share awards are subject to performance vesting based on the development of the company's share price, in accordance with the vesting conditions below.

The share awards are subject to performance vesting based on the development of the company's share price over the period from the date the share awards are allocated ("grant date") up to and including the vesting date. The development of the share price will be measured based on the volume weighted average price of the company's share on Nasdag Stockholm for the 30 trading days immediately following the grant date and the 30 trading days immediately preceding the vesting date, respectively. In the event the price of the company's share has thereby increased by more than 80 percent, 100 percent of the share awards shall vest, and should the share price have increased by 40 percent, 25 percent of the share awards shall vest. In the event of an increase of the share price between 40 and 80 percent, vesting of the share awards will occur linearly. Should the increase of the share price be less than 40 percent, no vesting will occur. The earliest point in time at which vested share awards may be exercised shall be the day falling immediately after the vesting date.

The valuation of the share awards is based on a Monte Carlo simulation in accordance with accepted valuation theory. Volatility has been based on the expected volatility of the Vicore share and other listed companies with similar operations. The risk-free interest rate has been derived through an interpolation between a 2-year and 5-year government bond, respectively. The fair value of the share awards at the time of allocation amounts to SEK 10.99 per share award. In order to calculate the value of the share awards in relation to the current performance conditions, a starting value is used that corresponds to the volume-weighted average price paid for the Vicore share over a fixed period, which in this case corresponds to the value of the underlying share at the time of valuation.

## Co-worker LTIP 2021

Co-worker LTIP 2021 is an incentive program intended for members of senior management and key persons in the company. According to the program participants will be granted, free of charge, options subject to three-year vesting that entitle to acquire a maximum of 3,000,000 shares in the company in total. The Board of Directors of the company believes that Co-worker LTIP 2021 will create a strong alignment of the interests of the participants and the interests of the shareholders. Co-worker LTIP 2021 is adapted to the current position and needs of the company. The Board of Directors is of the opinion that Co-worker LTIP 2021 will increase and strengthen the participants' dedication to the company's operations, improve company loyalty and that Co-worker LTIP 2021 will be beneficial to both the shareholders and the company.

Co-worker LTIP 2021 is a program under which the participants will be granted, free of charge, options. The Board of Directors shall annually resolve upon the allocation of options no later than the day falling three years after the Annual General Meeting 2021 (with each respective date of granting being a "grant date"). Each Option entitles the holder to acquire one share in the company for a pre-determined exercise price. The exercise price shall correspond to 125 percent of the volume weighted average price of the company's share on Nasdag Stockholm for the five trading days preceding the grantdate. The options shall vest over a three-year period with one third each year on the anniversary of the grant day, whereby all options shall vest on the third anniversary of the grant date, provided that the holder, with some customary exceptions, still is employed by the company. The latest point in time at which vested options may be exercised shall be the fifth anniversary of the grant date.

The options are valued according to the so-called Black & Scholes model, which means that the value of the options depends, among other things, on the value of the underlying share, the options's issue price and life, risk-free interest rate and volatility. The volatility has been based on the expected volatility of the Vicore share and other listed companies with similar operations. The risk-free interest rate was equated with the interest rate for Swedish government bonds. The fair value of the options at the time of allocation during 2021 amounts to SEK 8.45 per option. The following inputs have been used in the model:

	2021	
Underlying share price	20.00	SEK
Excercise price	26.48	SEK
Expected volatility	50.00	%
Option life	5	år
Expected dividends	0	SEK
Risk-free interest rate	0.10	%

#### Summary of issued share awards and options

	2021		2020		
Issued share awards (Board LTIP 2018)	Average exercise price per share award	Number of share awards	Average exercise price per share award	Number of share awards	
At January 1	0	433,333	0	475,000	
Forfeited/expired during the year	0	-433,333	0	-41,667	
At December 31	0	0	0	433,333	

A total of 433,333 share awards have expired during the year.

	2021		2020		
Issued share awards (Board LTIP 2020)	Average exercise price per share award	Number of share awards	Average exercise price per share award	Number of share awards	
At January 1	0	525,000	0	0	
Granted during the year	0	0	0	525,000	
At December 31	0	525,000	0	525,000	

No share awards have been exercised, forfeited or expired during the year.

Issued share awards (Board LTIP 2021)	Average exercise price per share award	Number of share awards
At January 1	0	0
Granted during the year	0	61,773
At December 31	0	61,773

2021

No share awards have been exercised, forfeited or expired during the year.

	2021		2020	
Issued options (Co-worker LTIP 2018)	Average exercise price per option	Number of options	Average exercise price per option	Number of options
At January 1	27.48	1,239,600	25.81	765,800
Granted during the year	0	0	29.25	560,000
Forfeited during the year	0	0	25.99	-86,200
At December 31	27.48	1,239,600	27.48	1,239,600

No options have been exercised, forfeited or expired during the year.

	2021	
Issued options (Co-worker LTIP 2021)	Average exercise price per option	Number of options
At January 1	0	0
Granted during the year	26.26	807,600
At December 31	26.26	807,600

2021

No options have been exercised, forfeited or expired during the year.

## Outstanding share awards and options at year-end

			Dec 31, 2021		Dec 31, 20	20
Program per year	Date of expiration	Exercise price	Share awards/ options	Vested (%)	Share awards/ options	Vested (%)
Program share awards (Board LTIP 2018)	September, 2021	0	-	-	433,333	92%
Program share awards (Board LTIP 2020)	Annual Gen- eral Meeting 2023	0	525,000	78%	525,000	38%
Program share awards (Board LTIP 2021)	Annual Gen- eral Meeting 2024	0	61,773	38%	-	-
Program 2018 options (Co-worker LTIP 2018)	September 27, 2022	25.26	283,333	100%	283,333	93%
Program 2019 options (Co-worker LTIP 2018)	September 27, 2023	26.17	396,267	92%	396,267	71%
Program 2020 options (Co-worker LTIP 2018)	September 24, 2024	29.25	560,000	68%	560,000	15%
Program 2021 options (Co-worker LTIP 2021)	September 16, 2026	26.26	807,600	15%	-	-

The costs for social security contributions related to share-based incentive programs varies from quarter to quarter due to the change in the underlying share price. Related provisions are reported as non-current liabilities. Total IFRS 2-classified payroll expenses for the incentive programs for the entire duration of the programs amount to 9,779 KSEK. The total costs for the share-based incentive programs for each year is presented below. These costs have had no cash impact.

## Summary of the total cost of the incentive programs

	2021	2020
IFRS 2-classified payroll expenses	3,862	2,632
Provisions for social security contributions	-5,425	5,602
Total	-1,563	8,234

## Summary of allotted options and share awards

•						
		2021		2020		
Program 2018 share awards (Board LTIP 2018)	Number outstanding at Jan 1, 2021	Granted/ forfeited	Number outstanding at Dec 31, 2021	Number outstanding at Jan 1, 2020	Granted/ forfeited	Number outstanding at Dec 31, 2020
Former chairman of the Board Leif Darner	83,333	-83,333	0	125,000	-41,667	83,333
Member of the Board Hans Schikan	125,000	-125,000	0	125,000	0	125,000
Member of the Board Maarten Kraan	125,000	-125,000	0	125,000	0	125,000
Member of the Board Peter Ström	50,000	-50,000	0	50,000	0	50,000
Member of the Board Sara Malcus	50,000	-50,000	0	50,000	0	50,000
Total	433,333	-433,333	0	475,000	-41,667	433,333

		2021			2020	
Program 2020 share awards (Board LTIP 2020)	Number outstanding at Jan 1, 2021	Granted/ forfeited	Number outstanding at Dec 31, 2021	Number outstanding at Jan 1, 2020	Granted/ forfeited	Number outstanding at Dec 31, 2020
Chairman of the Board Michael Wolff Jensen	350,000	0	350,000	0	350,000	350,000
Member of the Board Heidi Hunter	175,000	0	175,000	0	175,000	175,000
Total	525,000	0	525,000	0	525,000	525,000

Program 2021 share awards (Board LTIP 2021)	Number outstanding at Jan 1, 2021	Granted/ forfeited	Number outstanding at Dec 31, 2021
Member of the Board Hans Schikan	0	20,591	20,591
Member of the Board Maarten Kraan	0	20,591	20,591
Member of the Board Sara Malcus	0	20,591	20,591
Total	0	61,773	61,773

	2021		2020			
Program 2018, 2019 and 2020 options (Co-wor- ker LTIP 2018)	Number outstanding at Jan 1, 2021	Granted/ forfeited	Number outstanding at Dec 31, 2021	Number outstanding at Jan 1, 2020	Granted/ forfeited	Number outstanding at Dec 31, 2020
CEO Carl-Johan Dalsgaard	300,000	0	300,000	200,000	100,000	300,000
Other senior executives	703,750	0	703,750	337,500	366,250	703,750
Other employees	235,850	0	235,850	228,300	7,550	235,850
Total	1,239,600	0	1,239,600	765,800	473,800	1,239,600

		2021	
Program 2021 options (Co-wor- ker LTIP 2021)	Number outstanding at Jan 1, 2021	Granted/ forfeited	Number outstanding at Dec 31, 2021
CEO Carl-Johan Dalsgaard	0	100,000	100,000
Other senior executives	0	436,000	436,000
Other employees	0	271,600	271,600
Total	0	807,600	807,600

For information about other senior executives, see Note 7 "Employees and personnel costs".

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## 2021

## Note 9 Other operating income

	2021	2020
Exchange rate gains	1,094	654
Grants received	0	17,536
Total other operating income	1,094	18,190

## Note 10 Other operating expenses

	2021	2020
Exchange rate losses	2,492	721
Total other operating expenses	2,492	721

## Note 11 Financial income

	2021	2020
Financial assets measured at fair value through profit and loss		
Change in value for long-term investments	0	1,414
Total	0	1,414
Financial assets measured at amortized cost		
Interest income short-term investments	646	815
Total interest income calculated using the effective interest method	646	815
Total disclosed in net financial income/expenses	646	2,229

## **Note 12 Financial expenses**

	2021	2020
Financial assets measured at fair value through profit and loss		
Change in value for long-term investments	-2,121	0
Exchange rate losses currency accounts	-431	0
Total	-2,552	0
Financial liabilities measured at amortized cost		
Interest expenses other financial liabilities	-11	-6
Total interest expenses calculated using the effective interest method	-11	-6
Total disclosed in net financial income/expenses	-2,563	-6

## Not 13 Tax

0		2021	2020
4	Current tax	0	0
6	Change in deferred tax regarding temporary differences	254	453
0	Recognized tax	254	453

Reconciliation of effective tax rates	2021	2020
Loss before tax	-296,735	-147,315
Tax according to applicable tax rate 20.6% (21.4%)	61,127	31,525
Non-deductable expenses	-95	-1,309
Tax effect non-taxable income	1,118	0
Tax effect unrecognized tax assets	-61,896	-30,216
Change in deferred tax	254	453
Recognized tax	254	453
Effective tax rate	0%	0%

The group has no tax items that are recognized in other comprehensive income, but there are issue costs booked directly against shareholder's equity.

## Information about deferred tax assets and tax liabilities

In the table below, the tax effect of the temporary differences is specified:

Deferred tax liability	2021 Dec 31	2020 Dec 31
Intangible assets	1,026	1,411
Tax provision for pension premium	184	120
Carrying amount	1,210	1,531
Deferred tax asset		
Provision for pension premium	0	131
Carrying amount	0	131

## Tax loss carryforwards

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Tax loss carryforwards for which deferred tax assets have not been recognized in the balance sheet amounted to 729,828 KSEK (414,472 KSEK). These carryforwards have no time limit. Deferred tax assets have not been recognized for these items, as it is unlikely that the group in a foreseeable future will utilize them to offset future taxable profits. For further information about tax loss carryforwards, see Note 2 "Judgements and accounting estimates".

## Note 14 Earnings per share

Earnings per share before and after dilution	2021	2020
Profit for the year attributable to shareholders of the parent company	-296,480,577	-146,861,265
Average number of ordinary shares	69,678,461	54,249,185
Earnings per share before and after dilution	-4.25	-2.71

The average number of outstanding shares has been adjusted for bonus shares in new stock issued targeted towards existing shareholders. Diluted earnings per share is calculated by adjusting the weighted average number of ordinary shares outstanding for the dilution effect from all potential ordinary shares. These potential ordinary shares are attributable to the options and share awards allocated to senior executives, other employees and certain board members during the years 2018-2021. For further information, see Note 8 "Share-based payments". If there is a loss for the year, the options are not treated as dilutive. Neither are the options considered dilutive if the exercise rate, including the addition of the value of remaining future services to be recognized during the vesting period, exceeds the average trading price for the period. There is no dilution effect for potential ordinary shares as there was a loss for the year, as demonstrated above.

For more information about the changes of the number of outstanding shares, see Note 24 "Shareholders' equity".

## Note 15 Patents, licenses and similar rights

	2021 Dec 31	2020 Dec 31
Opening cost	75,192	69,192
Additions for the year	0	6,000
Closing accumulated cost	75,192	75,192
Opening amortizations	-4,437	-1,110
Amortizations for the year	-3,328	-3,327
Closing accumulated amortizations	-7,765	-4,437
Closing carrying amount	67,427	70,755

## Amortizations

Amortization refers to previously acquired intangible assets. This consists of a patent portfolio related to C21, whose main patent expires in the United States in September 2024. Amortization began in September 2019 and is amortized over its estimated useful life, which is the remaining patent period. Amortization has not yet begun for the group's other intangible assets.

## Impairment testing

To test the value of acquired intangible assets, Vicore uses a probability-adjusted discounted cash flow model based on fair value. The value in use for VP01, VP02 and VP02 is determined by calculating the present value of the estimated future cash flows and adjusting these in order to take the development risk into account. The valuation considers the cash flows over the projects' estimated remaining useful life, but

does not involve calculation of any residual value thereafter. The methodology used is an accepted one for impairment testing within the biopharmaceutical industry. The measurement is attributed to Level 3 in the fair value hierarchy and comprises the material assumptions specified below:

- Revenue- and cost forecasts for VP01 stretches over 7 years for the US and 10 years for the EU and Japan, that is, during the period in which the company has orphan drug protection in each market. Revenue- and cost forecasts for VP02 and VP03 stretches over 20 years.
- Revenue is calculated using estimations based on available data of different types considered indicators, e.g. forecasts of total market size, growth, anticipated market share of the product, competition from rival products and assessed price level. Market, growth, anticipated market share of the product and assessed price level is derived from secondary sources, accepted industry assumptions and assumptions made by Vicore.
- Costs comprise development expenditures as well as direct and indirect project costs based on Vicore's business plan. Operating margins are derived from secondary sources, accepted industry assumptions and assumptions made by Vicore.
- The present value of the cash flows is calculated and adjusted to reflect the probability of success for the project. This probability is based on accepted assumptions regarding the possibility for a corresponding product to go to market from the current development stage. The probability of success for VP01 is estimated at 25.6%, VP02 at 7.2% (8.9%), and VP03 at 15.3% (10.0%).
- O The weighted average pre-tax cost of capital has been estimated at 14% (15%).

The most critical assumptions mainly consist of assumptions made about market size, market share and price level. As with many pharmaceutical development projects, the results of the development work may be binary in the sense that the project can either be developed according to plan or must be cancelled altogether. Where appropriate, the valuation has been calibrated against completed share issues with external investors.

The impairment assessment for December 31, 2021, has not demonstrated a need for any impairments. No reasonable changes in the assumptions and estimates made would lead to an impairment.

## Note 16 Equipment

	2021 Dec 31	2020 Dec 31
Opening cost	147	147
Additions for the year	0	0
Sales/disposals	0	0
Closing accumulated cost	147	147
Opening depreciations	-34	-4
Depreciations for the year	-29	-30
Sales/disposals	0	0
Closing accumulated depreciations	-63	-34
Closing carrying amount	84	113

## Note 17 Long-term investments

	2021 Dec 31	2020 Dec 31
Opening carrying amount	7,530	6,116
Change in value in profit/loss	-2,121	1,414
Closing carrying amount	5,409	7,530

Vicore holds 91,829 shares in I-Tech AB (publ), which are classified as long-term investments.

## Note 18 Financial assets and liabilities

## Financial assets and liabilities at December 31, 2021

	Financial assets/ liabilities measured at fair value through profit and loss	Financial assets/ liabilities measured at amortized cost	Total carrying amount
Financial assets			
Long-term investments	5,409	0	5,409
Other current receivables	0	60	60
Accrued income	0	281	281
Short-term investments	0	77,000	77,000
Cash and cash equivalents	0	294,199	294,199
Total	5,409	371,540	376,949
Financial liablilities			
Contract liability	0	320	320
Trade payables	0	23,984	23,984
Accrued expenses	0	35,311	35,311
Total	0	59,615	59,615

The maximum credit risk of the financial assets consists of the net amounts of the reported values in the table above The group has not received any pledged assets for the financial net assets.

## Financial assets and liabilities at December 31, 2020

	Financial assets/ liabilities measured at fair value through profit and loss	Financial assets/ liabilities measured at amortized cost	Total carrying amount
Financial assets			
Long-term investments	7,530	0	7,530
Other current receivables	0	3,783	3,783
Accrued income	0	3,151	3,151
Short-term investments	0	70,118	70,118
Cash and cash equivalents	0	248,618	248,618
Total	7,530	325,670	333,200
Financial liablilities			
Contract liability	0	140	140
Trade payables	0	10,943	10,943
Accrued expenses	0	21,843	21,843
Total	0	32,926	32,926

The maximum credit risk of the financial assets consists of the net amounts of the reported values in the table above The group has not received any pledged assets for the financial net assets.

## Fair value measurement

IFRS 13, Fair Value Measurement contains a valuation hierarchy regarding inputs to the measurements. This measurement hierarchy is divided into three levels, which comprise:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities

**Level 2** - Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as price quotations) or indirectly (that is, derived from price quotations)

**Level 3** - Inputs for the asset or liability that are not based on observable market data (that is, non-observable inputs)

## Long-term investments

Investments in financial fixed assets are measured at fair value with changes in value in profit and loss. Investments in listed shares are measured at fair value according to Level 1 in the valuation hierarchy. Listed investments are measured on the basis of their share price on the closing day.

## Other financial assets and liabilities

For other current receivables and liabilities, short-term investments, cash and cash equivalents, trade payables, and accrued income and expenses with a short maturity, the carrying amount is considered a reasonable estimate of the fair value.

## Note 19 Financial risks

Through its operations, Vicore is exposed to various types of financial risk; credit risks, market risks (foreign exchange risk, interest rate risk and other price risks) and liquidity risks (including refinancing risk). The group's overall risk management objective focuses on the unpredictability of financial markets and strives to minimize potentially unfavorable consequences for the group's financial position and performance.

The Board of Directors has overall responsibility for managing financial risks and internal controls related to financial transactions. Financial risks and transactions are managed centrally by the parent company through the group's CFO and CEO. The overall objective in terms of financial risks is: to provide cost-effective financing and cash management, to ensure that all payment commitments are processed at the right time, to ensure that all financial transactions are organized in a way that supports the group in achieving the financial key ratios and ensure that risk exposures relating to credit risk, market risks and liquidity risk are reduced to an acceptable level.

The Board of Directors establishes written principles both for the overall risk management and for specific areas such as credit risks, foreign exchange risks, interest rate risks, refinancing risks, liquidity risks and the use of derivative instruments and the handling of excess liquidity. The group does not currently use derivatives, but allows hedging of currency in certain situations.

#### Credit risk

Credit risk is the risk that the group's counterparty of a financial instrument cannot fulfill its obligation and thereby causes a financial loss for the group. Given the nature of the group's business, with no foreseen revenues, credit risk is not a material issue at this stage of the company's development. However, some credit risk exists in the group's cash management, which is managed through Vicore's treasury policy.

#### **Financial credit risk**

The financial assets that are covered by provisions for expected credit losses according to the general method consist of cash and cash equivalents. Vicore applies a rating-based method in combination with other known information and forward-looking factors for assessing expected credit losses. The group has defined default as when payment of the claim is 90 days overdue or more, or if other factors indicate a suspension of payments. Significant increase in credit risk has not been considered to exist for any receivable or asset on the reporting date. Such assessment is based on whether payment is 30 days overdue or more, or if significant deterioration of the rating occurs, entailing a rating below investment grade. In cases where the amounts are not deemed to be insignificant, a provision for expected credit losses is also recognized for these financial instruments.

The assessment has been made that there has been no significant increase in credit risk for any of the group's financial assets. There counterparties do not have credit ratings, except for cash and cash equivalents where the counterparties have credit risk ratings of AA-, A+ and A.

#### Market risks

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risks are according to IFRS divided into three types: foreign exchange risk, interest rate risk and other price risks. Foreign exchange risk is the market risk with the greatest impact on the group as the financing received shall cover for research and development costs mainly in foreign currencies.

The group does not currently have any loans that expose it to interest rate risks. Interest risk may occur in short term cash management, and is regulated by maximum maturities.

The group is partly exposed to other price risks from investments in listed shares. However, the risks associated with the investments have not been considered to be significant.

#### Foreign exchange risk

Foreign exchange risk is the risk that the fair value of or future cash flow from a financial instrument may vary due to changes in foreign exchange rates. Foreign exchange risk relates to the risk that fluctuations in exchange rates will have a negative impact on the group's P&L, balance sheet or cash flow.

#### Transaction currency risk

The main exposure derives from the group's expenses in foreign currencies. This exposure is referred to as transaction exposure. The company's development costs for VP01 are mainly paid in EUR. As a result, the company is subject to exchange rate risks in relation to payment flows within Sweden and the eurozone, such as fluctuations where the exchange rate changes from the time an agreement is entered into until its payment is to be made in accordance with the agreement. Foreign exchange hedging is decided by the Board of Directors based on cash flow forecasts. In accordance with the company's policy for financial risk, the company exchanges EUR at a level of 60-100% of expected flows. See the table below for the level of exposure in each currency.

	Operating income	Operating expenses
Foreign exchange exposure 2021 (%)		
GBP	100%	7%
EUR	-	52%
DKK	-	2%
USD	-	2%
SEK	-	37%
Foreign exchange exposure 2020 (%)		
GBP	100%	21%
EUR	-	27%
DKK	-	6%
USD	-	1%
SEK	-	45%

Operating expenses in the table above are excluded from payroll expenses.

As indicated in the table above, the group's main transaction exposure consists of EUR (EUR and GBP in 2020). A 10% stronger EUR and GBP against SEK would have a negative impact on the profit after tax and shareholders' equity by approximately 14,191 KSEK (4,112 KSEK).

### **Refinancing risk**

Refinancing risk refers to the risk that cash and cash equivalents are unavailable and that financing can only be obtained partially, not at all or at an elevated cost. Currently, the group is financed by shareholders' equity and is therefore not exposed to risks related to external loan financing. The main risks therefore entail the inability to obtain further equity investments from Vicore's shareholders.

## Liquidity risk

Liquidity risk is the risk that the group will encounter difficulties in fulfilling its obligations related to financial liabilities. The Board of Directors manage liquidity risk by continuously following up the cash flow to reduce liquidity risk and ensure the solvency of the group.

Vicore uses rolling forecasts to ensure that the company has sufficient cash assets to meet its operational requirements. This monitoring takes the form of reporting to the Board, whereby outcomes and forecasts are compared with the budget that is produced and approved by the Board each year.

Surplus liquidity in Vicore, in excess of what is required to manage working capital requirements, is invested in interest-bearing current accounts. At the balance sheet date, Vicore had short-term investments in twelve-month fixed-rate accounts of 77,000 KSEK (70,000 KSEK). In addition to this, Vicore had bank deposits of 294,199 KSEK (248,618 KSEK) at the balance sheet date. The group's contractual and undiscounted interest payments and financial liability repayments are shown in the table below. Amounts in foreign currencies have been translated into SEK at the closing rate on the reporting date. Financial instruments with a variable interest rate have been calculated using the interest rate at the reporting date. Liabilities have been included in the earliest period during which repayment may be required.

	Dec 31, 2021		
	<1 month	1-3 months	>3 months
Maturity analysis			
Contract liability	21	42	257
Trade payables	23,785	198	0
Accrued expenses	0	13,934	21,377
Total	23,806	14,174	21,634

		Dec 31, 2020		
	<1 month	1-3 months	>3 months	
Maturity analysis				
Contract liability	24	72	44	
Trade payables	10,919	24	0	
Accrued expenses	28	21,815	0	
Total	10,971	21,911	44	

#### **Capital management**

The group's goals regarding the capital structure are to ensure financing of the company's development and business plan. Equity or financing related to equity is expected to be the most realistic and possible alternative in the near future.

No change occurred in the group's capital management during the year. None of the group companies are subject to external capital requirements.

## Note 20 Prepaid expenses and accrued income

	2021 Dec 31	2020 Dec 31
Prepaid rental charges	214	135
Prepaid insurances	591	0
Prepaid research and development expenses	3,123	0
Accrued income	0	3,151
Other prepaid expenses	1,106	471
Total	5,034	3,757

## Note 21 Short-term investments

	2021 Dec 31	2020 Dec 31
Fixed-rate account, SBAB	77,000	70,000
Accrued interest income	281	118
Total	77,281	70,118

Vicore has as of December 31, 2021, a total of eleven fixed-rate accounts (investment accounts) at SBAB. Each account amounts to 7 MSEK and were opened during March 2021 (fixed for 12 months). The annual interest rate per account is between 0.45% and 0.47%.

## Note 22 Cash and cash equivalents

Available balances	2021 Dec 31	2020 Dec 31
SEK	232,568	248,618
EUR	61,631	0
Total	294,199	248,618

## Note 23 Group companies

		Share of equity and votin	ig rights
Company	Principal activity	2021 Dec 31	2020 Dec 31
Vicore Pharma Holding AB	Own and manage shares in subsidiaries	Parent company	
Vicore Pharma AB	Research and development of pharmaceutical products	100%	100%
INIM Pharma AB	Research and development of pharmaceutical products	100%	100%

Sharo of aquity and voting rights

## Note 24 Shareholders' equity

Share capital and other contributed capital

	Number of		Other contributed
SEK	ordinary shares	Share capital	capital
At January 1, 2020	50,174,714	25,087,357	527,397,207
New share issue of warrants, January 8, 2020	243,525	121,762	2,427,944
New share issue, August 13, 2020	10,000,000	5,000,000	169,595,120
Share-based payments	0	0	2,632,679
At December 31, 2020	60,418,239	30,209,119	702,052,950
At January 1, 2021	60,418,239	30,209,119	702,052,950
Issue in kind, November 2, 2020, registered February 22, 2021	142,054	71,027	2,928,973
New share issue, February 22, 2021, registered March 9, 2021	11,200,000	5,600,000	312,821,895
Share-based payments	0	0	3,861,698
At December 31, 2021	71,760,293	35,880,146	1,021,665,516

## Share capital

At December 31, 2021, the registered share capital encompassed 71,760,293 ordinary shares. All shares have been fully paid and no shares are reserved for transfer. Each share carries one vote. The quotient value is SEK 0.50 (0.50). No shares are held by the company itself or its subsidiaries.

## Other contributed capital

Other contributed capital comprises capital contributed by the owners of the company, for example share premiums when subscribing for shares.

## Share-based payments

As of December 31, 2021, Vicore has four active incentive programs that include the management team, other employees and certain board members. For more information, see Note 8 "Share-based payments".

## Dividend

At the Annual General Meeting in May 2022, no dividend will be proposed for the financial year 2021.

## Note 25 Other provisions

Social security contributions related to share-based incentive programs	2021 Dec 31	2020 Dec 31
Opening amount	6,177	575
Provisions for the year	-5,425	5,602
Total	752	6,177

For more information about incentive programs, see Note 8 "Share-based payments".

## Note 26 Accrued expenses and deferred income

	2021 Dec 31	2020 Dec 31
Accrued personnel-related expenses	4,644	1,655
Accrued expenses, research and development	35,036	21,843
Accrued expenses, other	459	6,028
Total	40,139	29,526

## Note 27 Supplementary information to the cash flow statement

Adjustment for items not included in the cash flow	2021 Dec 31	2020 Dec 31
Depreciations	3,598	3,537
Loss on disposal of equipment	0	0
Incentive programs, payroll expenses	3,862	2,632
Incentive programs, social security contributions*	-5,425	0
Provision for payroll tax, pension premium	64	0
Other	0	33
Total	2,099	6,202

\* Social security contributions for share-based incentive programs were reported in the Annual Report for the fiscal year 2020 in the cash flow statement in the item "Changes in operating payables" and amounted to 5,602 KSEK, but has been reclassified to the item "Adjustments for items not included in the cash flow". The reclassification has had no cash flow impact. Historical figures have not been adjusted.

## **Note 28 Related-party transactions**

Related parties are defined as individuals with holdings of more than ten percent, members of the group's senior management, meaning the Board of Directors and senior executives, as well as their immediate family members.

For information about remuneration to senior executives and the Board of Directors, see Note 7 "Employees and personnel costs".

## **Note 29 Contingent liabilities**

Below a summary of material agreements which the company has entered into during the most recent years:

## Agreement with Emeriti Bio AB

Vicore Pharma AB ("Vicore Pharma") entered into a cooperation and development agreement with Emeriti Bio AB on August 24, 2016, which was expanded on November 1, 2017. The main purpose of the agreement is to develop new follow-on molecules based on C21 and other drug substances targeting the AT2 receptor (AT2R). On November 2, 2020, the parties expanded their cooperation and development agreement in connection with the acquisition of a number of new intellectual proporty rights as part of the development of new AT2R agonists from HaLaCore Pharma AB, where HaLaCore Pharma AB became a new party to the agreement. The agreement is valid until there is no longer any obligation to pay Emeriti Bio AB and HaLaCore Pharma AB. For Emeriti Bio AB's and HaLaCore Pharma AB's development work, Vicore Pharma pays consultancy fees, possible milestone compensation subject to achievement of predefined development goals. Vicore Pharma owns all results. The total maximum payments in the form of milestone compensation under the agreement is limited to 49.5 MSEK. In 2020, a milestone payment of 1,000 KSEK (250 KSEK) was paid to Emeriti Bio AB in connection with the filing of a patent application by Vicore Pharma. As compensation for the acquisition of intellectual propoarty rights, HaLaCore received a one-time payment of 6 MSEK in 2020, divided between 3 MSEK in cash and 142,054 newly issued shares in Vicore, corresponding to approximately 3 MSEK.

## Agreement with Nanologica AB

On May 9, 2018, INIM Pharma AB ("INIM Pharma") entered into a license agreement with Nanologica AB (publ) regarding the use of Nanologica AB's drug delivery technology, NLAB Silica® for a unique product that INIM Pharma is developing. The agreement is valid until further notice, where INIM Pharma has a unilateral right to terminate the agreement at any time without any period of notice. All results are owned by INIM Pharma. In order to fully obtain the license, INIM Pharma is required to pay a one-time payment equivalent to 2 MSEK. This payment was completed in the fourth guarter of 2018. Furthermore, INIM Pharma is obliged to pay milestone compensations equivalent to 1 MSEK per product at a defined stage of development. INIM Pharma has an obligation to develop products within a certain period of time in order not to loose the license. However, INIM Pharma is entitled to maintain its license by issuing a new one-time payment equivalent to 2 MSEK. INIM Pharma is responsible for all development.

# Note 30 Events after the balance sheet date

- In February, an interim analysis of the AIR phase 2 trial in idiopathic pulmonary fibrosis (IPF) suggests that C21 stabilizes disease and shows an unanticipated increase in lung function in IPF patients.
- In February, Vicore announced the advancement of its first new chemical entitity from the VP03 proram to a first in human phase 1 trial. A clinical trial application (CTA) is expected to be submitted during the second quarter 2022.
- In March, Vicore announced the plan to initiate a proof-of-concept trial with C21 in pulmonary arterial hypertension (PAH).
- In March, Vicore announced the initiation of a human forearm blood flow study with C21, planned to start in Q2 2022.
- In March, Vicore announced that Michael Wolff Jensen resigned from the board and was replaced by Jacob Gunterberg as chairman until the annual general meeting in May 2022.

# Notes Parent company

## Note 1 Accounting principles

## The parent company's accounting principles

The parent company has prepared its financial reports in accordance with the Annual Accounts Act and the Swedish Financial Reporting Board recommendation RFR 2 "Accounting for Legal Entities". The differences between the group's and the parent company's accounting principles are described below. The accounting policies set out below for the parent company have been consistently applied for all periods as presented in the parent company's interest otherwise stated.

## **Classification and format**

The parent company's income statement and balance sheets are prepared in accordance with the Annual Accounts Act's scheme, while the statement of comprehensive income, statement of changes in equity and the statement of cash flow are based on IAS 1 Presentation of Financial Statements and IAS 7, Statement of Cash Flow. The differences concerning the group's statements, which are relevant to the parent company's income statement and balance sheet consist mostly of the presentation of equity.

## Subsidiary and associated companies

Participations in subsidiaries and associated companies are recognized in the parent company according to the cost method less any write-downs. This means that transaction costs are included in the carrying amount of the subsidiaries.

## **Financial assets and liabilities**

Due to the relation between accounting and tax, the rules pertaining to the financial instruments in IFRS 9 are not applied in the parent company as a legal entity. Instead the parent company applies accounting at cost in accordance with the Annual Accounting Act. In the parent company, therefore, financial non-current assets are valued at cost and financial current assets according to the lowest value principle, with the application of impairments for expected credit losses according to IFRS 9 for assets that are debt instruments. For other financial assets, impairments are based on market values.

## Leasing

The parent company does not apply IFRS 16 Leases. The parent company as lessee recognizes leasing fees as a linear cost over the lease period, unless another systematic way better reflects the user's economic benefit over time. The parent company only recognizes leasing fees from leasing contracts as a linear cost over the leasing period under administrative expenses. Thus, the contract asset and the contract liability are not recognized in the balance sheet.

## Group contributions and shareholder contributions

Both received and paid group contributions are recognized as appropriations in accordance with the alternative method. Shareholder contributions are recognized directly in the receiver's equity and capitalised in shares and participations of the parent company, to the extent that impairment is not required.

## Note 2 Net sales

Net sales mainly consists of reinvoiced costs and management fees to group companies.

## Note 3 Operating expenses by nature of expense

The total expenses classified by function are distributed in the following cost categories:

	2021	2020
Other external expenses	10,947	6,970
Personnel expenses	10,648	19,357
Depreciation and amortization	0	0
Other operating expenses	69	10
Total	21,664	26,337

## Note 4 Audit fees

Ernst & Young AB	2021	2020
Audit fees	300	388
Other audit related services	92	47
Tax consultancy services	0	0
Other services	10	88
Total	402	523

For further information on audit fees, see Note 5 "Audit fees" for the group.

## Note 5 Leases

Operating leasing costs for the year concerning operating leases mainly comprise rent for premises and office equipment and amounts to 1,066 KSEK (817 KSEK).

Future payment commitments as of December 31 for operating leases are divided up as follows:

Future minimum lease payments	2021	2020
No later than 1 year	279	130
Between 1 and 5 years	0	0
Later than 5 years	0	0
Total	279	130

## Note 6 Employees and personnel costs

For salaries and remuneration to employees and senior executives as well as information on the number of employees, see Note 7 "Employees and personnel costs" for the group. For information on employee stock options, see Note 8 "Share-based payments" for the group.

## Note 7 Interest income and similar profit items

	2021	2020
Financial assets measured at amortized cost		
Interest income from other financial assets	645	815
Total interest income according to the effective interest method	645	815
Total	645	815
Total in profit or loss from financial items	645	815

## Note 8 Interest expenses and similar loss items

	2021	2020
Financial assets measured at amortized cost		
Interest expenses other financial liabilities	-2	-36
Total interest expenses calculated using the effective interest method	-2	-36
Total	-2	-36
Total in profit or loss from financial items	-2	-36

## Note 9 Tax on profit for the year

	2021	2020
Current tax	0	0
Change in deferred tax assets	-131	68
Recognized tax	-131	68
Reconciliation of effective tax rates	2021	2020
Loss before tax	17 709	-21 826
Tax according to applicable tax rate for parent company 20.6% (21.4%)	-3 648	4 671
Tax effect non-deductible expenses	-81	-1 133
Tax effect non-deductible income	990	0
Tax effect unrecognized deferred tax assets	2 608	-3 470
Recognized tax	-131	68
Effective tax rate	1%	0%

The parent company has no tax items that are recognized in other comprehensive income or directly in equity.

## Information about deferred tax assets and tax liabilities

The following table specifies the tax effect of the temporary differences:

Deferred tax asset:	2021 Dec 31	2020 Dec 31
Provision for pension premium	0	131
Carrying amount	0	131

Specification of change in deferred tax assets:

	2021 Dec 31	2020 Dec 31
Opening carrying amount	131	63
Change of temporary differences	-131	68
Carrying amount deferred tax asset	0	131

Tax loss carryforwards for which deferred tax assets have not been recognized in the balance sheet amounted to 109,689 KSEK (105,521 KSEK). These carryforwards have no time limit. Deferred tax assets have not been recognized for these items, as it is unlikely that the group in a foreseeable future will utilize them to offset future taxable profits.

## Note 10 Participations in group companies

			Carrying amount		
Company	No. of shares	Proportion of equity	Share of voting power	2021 Dec 31	2020 Dec 31
Vicore Pharma AB	10,000	100%	100%	665,577	295,491
INIM Pharma AB	50,000	100%	100%	130,812	100,812
				796,389	396,303

	Corp. Reg. No.	Domicile of the entity	Equity	Loss for the year
Vicore Pharma AB	556607-0743	Göteborg	95,362	-291,864
INIM Pharma AB	559156-8471	Stockholm	28,337	-18,658
			2021	2020
			Dec 31	Dec 31
Opening cost			396,303	276,274
Acquisitions for the ye	ear		400,086	120,529
This year's sales / liqu	idations		0	-500
Closing accumulated	cost		796,389	396,303
Closing carrying amount		796,389	396,303	

## Note 11 Long-term investments

	2021 Dec 31	2020 Dec 31
Opening cost	565	565
Closing carrying amount	565	565

## Note 12 Financial assets and liabilities

### Financial assets and liabilities at December 31, 2021

	Financial assets/liabilities measured at fair value through profit and loss	Financial assets/ liabilities measured at amortized cost	Total carrying amount
Financial assets			
Receivables from group companies	0	32,386	32,386
Other current receivables	0	65	65
Short-term investments	0	77,281	77,281
Cash and cash equivalents	0	168,396	168,396
Total	0	278,128	278,128
Financial liablilities			
Liabilities to group companies	0	75,000	75,000
Trade payables	0	622	622
Accrued expenses	0	1,145	1,145
Total	0	76,767	76,767

The maximum credit risk of the financial assets consists of the net amounts of the reported values in the table above. The parent company has not received any pledged assets for the financial net assets.

## Financial assets and liabilities at December 31, 2020

	Financial assets/liabilities measured at fair value through profit and loss	Financial assets/ liabilities measured at amortized cost	Total carrying amount
Financial assets			
Other current receivables	0	15	15
Short-term investments	0	70,118	70,118
Cash and cash equivalents	0	195,822	195,822
Total	0	265,955	265,955
Financial liablilities			
Trade payables	0	765	765
Accrued expenses	0	241	241
Total	0	1,006	1,006

The maximum credit risk of the financial assets consists of the net amounts of the reported values in the table above. The parent company has not received any pledged assets for the financial net assets. For fair value measurement of long-term investments see Note 18 "Financial assets and liabilities" for the group.

For other current receivables and liabilities, short-term investments, cash and cash equivalents, trade payables, and accrued expenses and income with a short maturity, the carrying amount is considered a reasonable estimate of the fair value.

Based on the parent company's assessment, taking into account other known information and forward-looking factors, expected credit losses for any of the parent company's financial assets are deemed to be non-significant and no provision has therefore been recognized. The counterparties do not have credit ratings, except for cash and cash equivalents where counterparties have credit risk ratings of AA-, A+ and A. For a description of the expected credit loss for the cash and cash equivalents according to the general method, see Note 19 "Financial risks" for the group.

## Note 13 Prepaid expenses and accrued income

	2021 Dec 31	2020 Dec 31
Prepaid rental charges	181	126
Prepaid insurances	120	0
Other prepaid expenses	511	144
Total	812	270

## Note 14 Short-term investments

	2021 Dec 31	2020 Dec 31
Fixed-rate account, SBAB	77,000	70,000
Accrued interest income	281	118
Total	77,281	70,118

Vicore has as of December 31, 2021, a total of eleven fixed-rate accounts (investment accounts) at SBAB. Each account amounts to 7 MSEK and were opened during March 2021 (fixed for 12 months). The annual interest rate per account is between 0.45% and 0.47%.

## Not 15 Cash and cash equivalents

	2021 Dec 31	2020 Dec 31
Available balances	168,396	195,822
Total	168,396	195,822

## Note 16 Shareholders' equity

At December 31, 2021, the registered share capital comprised 71,760,293 ordinary shares. All shares are fully paid and no shares are reserved for transfer. Each share carries one vote. The quota value amounts to 0.5 SEK (0.5 SEK). No shares are held by the company itself or its subsidiaries.

The share premium reserve refers to capital from new share issues that have been issued at a price that exceeds the quotient value and includes deductions of expenditures for new share issues.

## Note 17 Other provisions

Social security contributions related to share-based incentive programs	2021 Dec 31	2020 Dec 31
Opening amount	5,312	500
Provisions for the year	-4,805	4,812
Total	507	5,312

For more information about incentive programs, see Note 8 "Share-based payments" for the group.

## Note 18 Non-current liabilities to group companies

Non-current liabilities	2021 Dec 31	2020 Dec 31
Opening cost	0	400
Reclassifications	0	-400
Additions	75,000	0
Closing carrying amount	75,000	0

## Note 19 Accrued expenses and deferred income

	2021 Dec 31	2020 Dec 31
Accrued personnel-related expenses	1,799	962
Accrued consulting fees	150	241
Accrued expense for patents	0	6,000
Other	135	25
Total	2,084	7,228

## Note 20 Supplementary information to the cash flow statement

Adjustment for items not included in the cash flow	2021 Dec 31	2020 Dec 31
Incentive programs, salary costs	2,526	2,104
Incentive programs, social security contributions*	-4,805	0
Provision payroll tax, pension premium	64	0
Total	-2,215	2,104

\* In the year-end report for the fiscal year 2021, social security contributions for share-based incentive programs were reported in the cash flow statement as "Change in operating payables" and amounted to 4,805 KSEK, but has for the fiscal year 2021 been reclassified to the item "Adjustments for items not included in the cash flow". The reclassification has had no cash flow impact. Historical figures have not been adjusted.

## Note 21 Pledged assets and contingent liabilities

For information about pledged assets and contingent liabilities in the parent company, see to the group's Note 29 "Pledged assets and contingent liabilities".

## Note 22 Related-party transactions

	Sales of goods or services	Purchase of goods or services	Other	Receivables on closing day	Payables on closing day
Transactions with subsidiaries					
2021	37,866	0	859	32,386	75,000
2020	3,672	0	56	0	0

Sales of goods or services relate to reinvoiced costs and management fee.

For information about salaries and remuneration to employees and senior executives, see Note 7 "Employees and personnel costs" for the group.

For further information on related-party transactions, see Note 28 "Related-party transactions" for the group.

# Board of Directors and Management

## **Board of Directors**



Michael Wolff Jensen Chairman of the Board since 2020 (Resigned from the board on March 23, 2022)

Michael Wolff Jensen has 20 years of experience from strategic leadership from Pharma/Biotech – as CFO, Chairman of the Board, responsible partner and as Chief Legal Officer. Michael has been responsible for four IPOs and has been responsible for several funding rounds. Michael has more than 15 years of experience as board member and as chairman, both in private and publicly traded companies.

## Born: 1971

Education: Law degree from the University of Copenhagen.

**Other assignments:** SVP / Chief Legal Officer of Ascendis Pharma AB (publ). Chairman of Visen Pharmaceuticals and MIWO Invest ApS.

**Previous assignments for the past five years:** Chairman of Ascendis Pharma A/S, XSPRAY PHARMA (publ), VANX ApS and Eurocine Vaccines AB (PUBL).

**Holdings in the company:** 350,000 share awards in the framework of the company's incentive program.

Michael is chairman of Vicore's remuneration committee.

Independent of the company and its senior management and independent of major shareholders of the company.



Hans Schikan Board member since 2018

Hans Schikan is the former CEO of Prosensa (acquired by BioMarin). His previous assignments include leading roles at Genzyme (acquired by Sanofi) and Organon (acquired by Schering Plough). He has served on the Board of Directors of Wilson Therapeutics (acquired by Alexion) and Therachon (acquired by Pfizer). He is a co-founder of Pharvaris NV.

## Born: 1958

Education: PharmD from the University of Utrecht.

**Other assignments:** Chairman of Microbiotica Ltd, InteRNA Technologies BV and Complix NV. Board member of VectivBio AG, Pharvaris NV and the Dutch Top Sector Life Sciences & Health. Advisor to various organisations in Life Sciences & Health.

**Previous assignments for the past five years:** Board member of Asceneuron, Hansa Medical, Sobi, Therachon and Wilson Therapeutics.

**Holdings in the company:** 20,591 share awards in the framework of the company's incentive program.

Hans is member of Vicore's remuneration committee and scientific committee.

Independent of the company and its senior management and independent of major shareholders of the company.



Jacob Gunterberg Board member since 2018 (New chairman of the board since March 23, 2022)

Jacob Gunterberg is a former partner at HealthCap and has extensive experience in venture capital investment operations and corporate finance in life science. Jacob Gunterberg has long experience as board member in both private and publicly traded companies.

## Born: 1967

**Education:** M.Sc. in Business Administration and Economics from Lund University.

**Other assignments:** Board member in EllAug AB, Tova Skrenen Stockholm AB, Aurelia Invest AB.

**Previous assignments for the past five years:** Board member in MIPS Helmet AB, MIPS AB, Trimb Holding AB, Trimb Healthcare AB, HealthCap Holdings GP AB, HealthCap Annex Fund I-II Bis GP AB and HealthCap Aero Holdings GP AB (which were merged in 2016), Carisma Therapeutics Inc, SynOx Therapeutics Ltd and Cenova AB. Deputy board member in BONESUPPORT AB, BONESUPPORT HOLDING AB and Wilson Therapeutics AB.

## Holdings in the company: None.

Jacob is chairman of Vicore's audit committee and a member of the scientific committee.

Independent of the company and its senior management and independent of major shareholders of the company.



Heidi Hunter Board member since 2020

Heidi Hunter (born 1958) has more than 25 years of experience from leading positions in different roles within pharmaceutical development and commercialization. She has worked strategically and operationally from clinical and commercial development to launch execution. Her leadership experience spans alliance management, investment risk mitigation, global clinical and commercial management, new business strategy development, product launch, and business sustainability.

## **Born:** 1958

**Education:** M.B.A., Marketing and International Business, The University of Chicago. B.A., Economics and German, Magna cum laude, The University of Michigan

Other assignments: President, Cardinal Health Specialty Solutions.

#### Previous assignments for the past five years:

SVP, Global immunology business unit i UCB, Belgien

**Holdings in the company:** 175,000 shares in the framework of the company's incentive program.

Heidi is a member of Vicore's audit committee.

Independent of the company and its senior management and independent of major shareholders of the company.



## Sara Malcus Board member since 2018

Sara Malcus has more than ten years of experience from operational management and board work through her work with developing early drug projects at GU Ventures, Astra Zeneca AB and in smaller start-up companies.

## Born: 1975

**Education:** Doctor's degree in immunology and inflammatory medicine at the University of Gothenburg.

**Other assignments:** Sara Malcus is the Managing Director of MetaboGen AB.

**Previous assignments for the past five years:** Board member of Oncorena AB, Oncorena Holding AB, Cereno Scientific AB and MetaboGen AB.

**Holdings in the company:** 20,591 share awards in the framework of the company's incentive program.

Sara is a member of Vicore's audit committee.

Independent of the company and its senior management and independent of major shareholders of the company.



#### Maarten Kraan Board member since 2018

Maarten Kraan has extensive experience in biomedicine and has, among others, held a senior position at AstraZeneca AB where he was responsible for the research and development of medicines for respiratory, inflammatory and autoimmune symptoms.

## Born: 1961

**Education:** Doctor's degree in rheumatology at the University of Leiden.

**Other assignments:** CMO at AM-Pharma. Maarten Kraan is a board member of Toleranzia AB and CDS Gmbh.

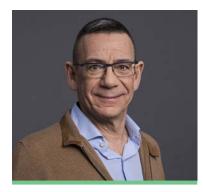
#### Previous assignments for the past five years: None.

**Holdings in the company:** 20,591 share awards in the framework of the company's incentive program.

Maarten is chairman of Vicore's scientific committee and a member of the remuneration committee

Independent of the company and its senior management and independent of major shareholders of the company.

## Management



#### Carl-Johan Dalsgaard Chief Executive Officer since 2018

Carl-Johan Dalsgaard has been a Venture Partner at HealthCap since 2000, thereby he has served as CEO of several companies in which HealthCap has invested. Prior to that, he has ten years of experience from senior positions within the AstraZeneca Group, such as pre-clinical research director, therapeutic area manager of pain and anesthesia, CEO of Astra Pain Control AB and part of the Group's research management team.

#### Born: 1956

**Education:** MD from the Karolinska Institute. Ph.D. in neurobiology and postdoc experience from Harvard Medical School. Carl-Johan has also completed a specialist training in plastic surgery.

**Other assignments:** Board member and CEO of INIM Pharma AB and Vicore Pharma AB.

Holdings in the company: 477,981 shares and 400,000 options within the framework of the company's incentive program.



#### Hans Jeppsson Chief Financial Officer since 2017

Hans Jeppsson has a cross-disciplinary background in finance and medicine. He has previously worked as a biotechnology analyst at Danske Bank as well as within preclinical research at AstraZeneca R&D.

**Education:** Ph.D. in Strategic Financial Management from the University of Gothenburg. After he obtained his Ph.D.-degree he conducted postdoctoral studies at the Haas School of Business at the UC Berkeley in the US. He also has a background in chemical engineering with a focus on biotechnology from Chalmers University of Technology.

Other assignments: Deputy board member of Vicore Pharma AB and INIM Pharma AB.

## Holdings in the company: 5,000

shares and 250,000 options within the framework of the company's incentive program.



### Elin Rosendahl VP Clinical Development since 2020

Elin Rosendahl has more than 20 years' experience of managing global biopharmaceutical development programs and leading cross-functional teams. Solid experience of all phases of clinical drug development with focus on design of innovative and patient-focused paths to market, effective management of global, cross-functional teams and optimized collaborations with contract research organizations (CROs)

**Education:** M.Sc., Pharmacy from Uppsala University.

Other assignments: None.

Holdings in the company: 100,000 options within the framework of the company's incentive program.



#### Johanna Gräns Head of Preclinical Development since 2015

Johanna has a Ph.D and expertise in pharmaceutical metabolism. She has extensive experience in preclinical interpretation and is responsible for drug development projects.

**Education:** Ph.D. in biology with a focus on toxicology from the University of Gothenburg.

Other assignments: None.

Holdings in the company: 7,004 shares and 143,750 options within the framework of the company's incentive program.



## Åsa Magnusson Chief Commercial Officer since 2021

Åsa has more than 20 years of experience as a commercial executive in the pharmaceutical industry with focus on securing market access and launching rare disease medicines. Her previous roles include leading cross-functional teams as General Manager at Arvelle and in different senior commercial roles at Alexion, expanding innovative antibody products and heading the commercial launch of Actelion's pulmonary arterial hypertension (PAH) pharmaceuticals.

**Education:** BBA and B2B marketing from Lund University.

**Other assignments:** Board member of Think Brand Direction.

Holdings in the company: 50,000 options within the framework of the company's incentive program.



## Rohit Batta Chief Medical Officer since 2018

Rohit Batta has over 20 years of experience as a medical doctor with an extensive background leading medical and clinical development teams whilst developing drugs for rare diseases. His previous roles include senior level positions within Cell and Gene Therapy at GlaxoSmithKline leading the clinical development and defining the clinical strategy for haemoglobinopathy gene therapy medicines. He also led the global medical and late stage clinical development teams to launch the world's first gene therapy for patients with a paediatric rare disease.

**Education:** MBBS from Kings College London, a fellow of the Faculty of Pharmaceutical Medicine and a member of the Royal College of General Practitioners.

**Other assignments:** Visiting Senior Lecturer at Kings College London.

Holdings in the company: 200,000 options within the framework of the company's incentive program.



## Johan Raud Chief Scientific Officer since 2018

Johan Raud has many years of experience from drug research and managing industrial drug discovery projects.

**Education:** MD Ph.D. from the Karolinska Institute and Vanderbilt university, USA.

Other assignments: None.

Holdings in the company: 238,991 shares and 130,000 options within the framework of the company's incentive program.

Karolinska Institutet.

Other assignments: None.

University. PhD Neurobiology,

Mikael Nvgård

Group.

Holdings in the company: 4,031 shares and 41,000 options within the framework of the company's incentive program.

VP Business Development since 2021

Mikael has extensive experience from

Business Development in the healthcare

industry. He has led M&A and Corporate

Humana AB and has also worked in the

global healthcare team at the strategy

consulting firm Boston Consulting

Education: MSc Pharmacy, Uppsala

Development at the care provider



## Jessica Shull Head of Digital Therapeutics since 2021

Jessica has more than 20 years' experience in the field of digital technologies for healthcare including development of virtual surgical devices. She is considered an authority in HTA requirements for patient-facing software and innovation adoption in Europe and internationally. In previous roles she worked on digital health best practices for the WHO and with the Digital Therapeutics Alliance she focused on digital therapeutic product integration, regulation, and policy.

**Education:** MA, M.Sc., Ph.D. candidate in Biomedicine.

Other assignments: None.

Holdings in the company: 50,000 options within the framework of the company's incentive program.



## Nina Carlén Chief Administrative Officer since 2009

Nina has more than 20 years of experience working with marketing and communication in the pharmaceutical industry.

**Education:** Completed training in project management, PR, communication and graphic design at, among others, Bergh's School of Communication.

**Other assignments:** Deputy board member of North River AB and North River Maintenance AB.

Holdings in the company: 24,480 shares and 125,000 options within the framework of the company's incentive program.

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# **Signatures**

The undersigned give their assurance that the annual accounts have been prepared in accordance with generally accepted accounting standards in Sweden and that the consolidated financial statements have been prepared in accordance with international accounting standards, IFRS, as adopted by the EU. The annual accounts and the consolidated financial statements each provide a fair and accurate impression of the parent company's and the group's position and earnings. The Administration Report for the parent company and the group provides a fair and accurate overview of the parent company's and the group's operations, position and earnings, and describes material risks and uncertainties faced by the parent company and the group.

#### Gothenburg April 6, 2022

Jacob Gunterberg	Hans Schikan	Sara Malcus
Chairman	Board member	Board member
Maarten Kraan	Heidi Hunter	Carl-Johan Dalsgaard
Board member	Board member	CEO
Board member	Board member	CEO

Our audit report was submitted on April 6, 2022 Ernst & Young AB

## Andreas Mast

Authorized Public Accountant

# Auditors-Report

To the general meeting of the shareholders of Vicore Pharma Holding AB (publ), corporate identity number 556680-3804.

# Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Vicore Pharma Holding AB (publ) for the year 2021. The annual accounts and consolidated accounts of the company are included on pages 26-65 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company as of 31 December 2021 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit

committee in accordance with the Audit Regulation (537/2014) Article 11.

## Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the Auditor's responsibilities for the audit of the financial statements section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying financial statements.

## the decompanying in

## Key Audit Matter 1

## Reporting of development costs

The costs of the Group's development activities amounted to a total of SEK 271,8 million during the financial year 2021, corresponding to 92% of Vicore Pharma's total operating expenses.

Most of these costs relate to the development of the product candidates VP01, VP02 and VP03 and mainly consists of costs for the clinical studies conducted.

For further information, please refer to the Group's accounting policies in Note 1 and operating expenses per cost type in Note 4.

In our audit, we have focused on this area as the expenses amount to a significant amount, and there are significant elements of assessments involved to be able to decide whether the expense should be expensed or reported as an asset, and a difficulty of distinguishing development expenses from other expenses in the income statement

## Key Audit Matter 2

## Valuation of intangible assets

As of 31st December 2021, a substantial portion (15% or SEK 67,4 m) of the Group's total assets consists of patents and goodwill (hereinafter referred to as the assets). The company examines the assets for impairment annually and when events or changes in circumstances indicate that the carrying amount of the assets may be less than the recoverable amount. Impairment assessment involves a number of material estimates and assessments, including estimating the value in use by assessing the likelihood of future product launch, estimating expected future discounted cash flows, and calculating weighted average cost of capital ("WACC").

For further information, please refer to the Group's accounting policies in Note 1, assessments and estimates in Note 2, as well as information on patents, licenses and similar rights in Note 15.

We focused on this area as the carrying value of the assets is material and impairment testing is sensitive to changes in assumptions and is therefore a particularly important area in our audit.

## Other information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-25 and 69-78. The Board of Directors and the Managing Director

## How our audit addressed this key audit matter

Our review of the development costs has included, but is not limited to the following measures:

- Evaluation of the company's procedures and internal control related to financial reporting.
- Testing of internal controls for approval and payment of invoices.
- Reconciled and performed detailed testing to invoice documents, contracts and other financial statements documentation.
- Analysis of costs based on our knowledge of the business and follow-up to internal project reports.
- We have also assessed the company's information in the annual report.

## How our audit addressed this key audit matter

 Evaluation of the company's probability-adjusted cash flow model for impairment testing.

 Examination of the assumptions made by the company when assessing impairment requirements with a focus on the assumptions for which the result of the impairment test is most sensitive.

 We have also assessed the company's information in the annual report are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to

the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

## Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the

Managing Director.

Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion. based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified. We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and

other matters that may reasonably be thought to

bear on our independence, and where applicable, actions taken to eliminate threats or related safeguards applied.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter

# Report on other legal and regulatory requirements

Report on the audit of the administration and the proposed appropriations of the company's profit or loss

## Opinions

Iln addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Vicore Pharma Holding AB (publ) for the year 2021 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

## **Basis for opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit

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conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

The auditor's examination of the ESEF report Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Vicore Pharma Holding AB for the financial year 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the ESEF report #(checksum) has been prepared in a format that, in all material respects, enables uniform electronic reporting.

#### **Basis for opinion**

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the ESEF report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Vicore Pharma Holding AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the Esef report in accordance with Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

Ernst & Young AB, with Andreas Mast au auditor in charge, Box 7850, 103 99 Stockholm, was appointed auditor of Vicore Pharma Holding by the general meeting of the shareholders on the 11th of May, 2021 and has been the company's auditor since the 10th of October 2018.

Gothenburg the 6th of April Ernst & Young AB

Andreas Mast Authorized Public Accountant

# Corporate Governance Report

## Introduction

The Board of Directors of Vicore Pharma Holding AB (publ), company reg. no. 556680-3804 ("Vicore" or the "company") hereby submits the 2021 corporate governance report in accordance with the requirements of the Swedish Annual Accounts Act) (Sw. årsredovisningslagen) and the Swedish Code of Corporate Governance (the "Code": see the Swedish Corporate Governance Board website at www.bolagsstyrning.se). The company's shares have been listed on Nasdag Stockholm since September 27, 2019. The company's shares were previously, since December 2015. listed on the Nasdag First North Growth Market. The company's corporate governance is mainly regulated by the provisions of the company's articles of association, the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and other Swedish legislation, the Nasdaq Stockholm Rulebook for issuers and the Code.

The corporate governance report has been reviewed by the company's auditors in accordance with the Swedish Annual Accounts Act. It does not constitute a part of the formal annual report documents.

The group comprises the parent company Vicore Pharma Holding AB ("Vicore") and the subsidiaries Vicore Pharma AB ("Vicore Pharma") and INIM Pharma AB ("INIM Pharma"). The company's research and development operations are conducted in Vicore Pharma and INIM Pharma.

There are no deviations from the Swedish Corporate Governance Code (the "Code") to report for the financial year of 2021. No infringements of Nasdaq Stockholm's rules and no breach of good practice on the securities market was reported by the stock exchange's disciplinary committee or the Swedish Securities Council during the financial year.

## Corporate governance within Vicore

The purpose of Vicore's corporate governance is to create a clear allocation of roles and responsibilities among the shareholders, the Board of Directors and management. Corporate governance, management and control of Vicore are allotted among the general meeting, the Board of Directors, its elected committees and the CEO.



Important external and internal regulations and policies that affect corporate governance:

## Signficant external regulations:

- Swedish Companies Act
- Swedish Accounting Act
- Swedish Annual Accounts Act
- International standards for audits and financial reporting (IFRS)
- Nasdaq Stockholm Rulebook for issuers
- Swedish Code of Corporate Governance
- Other applicable rules and recommendations

# Significant internal regulations and policies:

- Articles of association
- Rules of procedure for the Board of Directors
- Instruction for the CEO, including the financial reporting instruction
- Finance policy
- Financial handbook
- Internal control policy
- Risk management policy
- Information policy

## • Insider policy

IT policy

## Shareholders and the share

At the end of 2021, Vicore had 5,140 shareholders and the number of shares was 71,760,293 with a quotient value of SEK 0.5 each. There is only one class of shares. The company's shares are issued in one class and each share carries one vote at the AGM.

On December 31, 2021, HealthCap VII L.P. was the single largest shareholder in Vicore, with a total of 15,834,834 shares, corresponding to 22.1 percent of the votes and capital. No shareholder other than HealthCap VII L.P. has a direct or indirect shareholding that represents one tenth, or more, of the voting rights for all shares in the company. Further information on shareholders and Vicore's share is presented on pages 24-25 in the 2021 annual report.

## General meetings of shareholders

According to the Companies Act (2005: 551), the General Meetings of shareholders is the company's highest decision-making body. At the General Meetings, the shareholders exercise their voting rights in the company. The Annual General Meeting shall be held within six (6) months from the end of the financial year. At the Annual General Meeting, the shareholders decide, among other things, on the Board of Directors and, where applicable, auditors, how the Nomination Committee is to be appointed and on discharge from liability for the Board of Directors and the CEO for the past year. Decisions are also made on the adoption of Annual Report, the appropriation of profit or loss, fees for the Board of Directors and auditors, guidelines for remuneration to the CEO and other senior executives as well as the remuneration report.

The Articles of Association stipulate that the Annual General Meeting shall be held in Stockholm or Gothenburg. Shareholders who wish to attend General Meetings, in person or through a representative, must be included in the share book kept by Euroclear Sweden AB six (6) banking days before the General Meeting and make a notification to the company in accordance with the notice. Notice of General Meetings is made through advertising and via the company's website (www.vicorepharma.com).

## 2021 AGM

The Annual General Meeting 2021 was held through advance voting (postal voting), pursuant to temporary legislation, on May 11, 2021. At the AGM, approximately 52.1 percent of the total votes were represented. Michael Wolff Jensen was elected chairman of the meeting. At the AGM the following principal resolutions were passed:

- Jacob Gunterberg, Maarten Kraan, Sara Malcus, Hans Schikan, Michael Wolff Jensen and Heidi Hunter were re-elected as board members. Michael Wolff Jensen was elected Chairman of the Board.
- EY AB with principal auditor Andreas Mast was re-elected as auditor.
- Remuneration to the Chairman of the Board and the Board's members elected by the Annual General Meeting and the auditor were established.
- Resolution on adoption of a longterm performance-based incentive program (Board LTIP 2021) of a maximum 73,000 options to three board members.
- Resolution on adoption of a longterm performance-based incentive program (Co-worker LTIP 2021) of a maximum 3.000.000 options to senior management and key persons.
- Proposed guidelines for remuneration to senior executives were approved.
- Resolution on adoption of remuneration report 2020.
- Resolution on adoption of articles of association with increased margins in number of shares and share capital.
- Resolution on adoption of balance sheet and income statement.
- No dividend will be paid for 2020 and the company's earnings shall be carried forward.

• Discharge from liability of the Board of Directors and CEO for the financial year 2020.

Full minutes and information from the AGM are available on Vicore's website (www.vicorepharma.com).

## AGM 2022

The 2022 Annual General Meeting will be held on Wednesday, May 11, 2022. The meeting will held through postal voting and with no opportunity to attend in person or by proxy. Information on the decisions made at the Annual General Meeting will be published on 11 May 2022 as soon as the outcome of the voting is finally compiled. For the right to participate and more information, see Vicore's website (www. vicorepharma.com). The minutes of the Annual General Meeting will be available on Vicore's website (www. vicorepharma.com).

#### **Nomination Committee**

The Nomination Committee for the AGM 2022 consists of Staffan Lindstrand (Chairman) appointed by HealthCap VII L.P., Jannis Kitsakis appointed by Fjärde AP-fonden and Ulrik Grönvall appointed by Swedbank Robur. Staffan Lindstrand is chairman of the Nomination Committee. The Committee also includes the Chairman of the Board, Michael Wolff Jensen, as convenor.

The task of the Nomination Committee is to prepare and present proposals for the number of board members to be elected by the AGM, the election of a Chairman and other members of the Board of Directors, board fees and, if any, remuneration for committee work, election of a Chairman to the Annual General Meeting, election of auditors (if applicable) and auditors fees (if applicable) and proposals for rules for the appointment of a Nomination Committee for the next annual general meeting. The proposals will be published at the latest in conjunction with the notice of the AGM 2022.

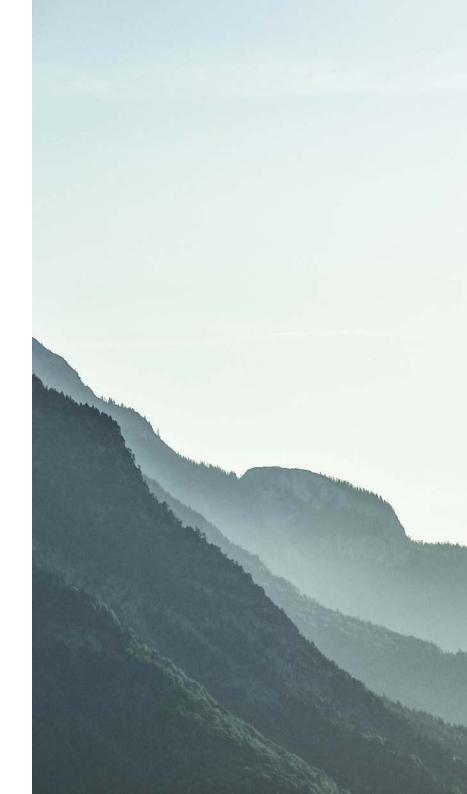
## **External auditors**

The external audit of the accounts of the parent company and the group, as well as of the management by the Board of Directors and the CEO, is carried out in accordance with generally accepted accounting standards in Sweden. The auditor participates in at least one board meeting per year, going through the accounts for the year and leading a discussion with the Board of Directors without the CEO or any other senior executive present.

Pursuant to the articles of association, Vicore must have an authorized public accountant or a registered accounting firm as its external auditor. Since the AGM 2010, the accounting firm EY AB has been auditor of the company. As of the 2019 AGM, certified public accountant Andreas Mast is the auditor in charge. Andreas Mast is member of the Swedish Institute of Authorized Public Accountants. For information regarding fees paid to the auditors, please refer to Note 5 of the 2021 Annual Report.

## **The Board of Directors**

The Board of Directors is the company's highest decision-making body after the Annual General Meeting. According to the Companies Act, the Board of Directors is responsible for the company's



management and organization, which means that the Board of Directors is responsible for, among other things, setting goals and strategies, ensuring routines and systems for evaluating established goals, continuously evaluating the company's results and financial position and evaluating the operational management. The Board of Directors is also responsible for ensuring that the annual accounts and interim reports are prepared in a timely manner. In addition, the Board of Directors appoints the company's CEO. Board members are normally elected by the AGM for the period until the end of the next AGM.

According to the Code, the Chairman of the Board must be elected by the Annual General Meeting and have a special responsibility for the management of the Board of Directors' work and for the Board of Directors' work being well organized and implemented in an

efficient manner. The Board of Directors adheres to written rules of procedure that are reviewed annually and are determined at the statutory board meeting each year. The rules of procedure govern, among other things, the practices and tasks of the Board of Directors, decision-making within the company, the Board of Directors' meeting agenda, the Chairman's duties and the allocation of responsibilities between the Board of Directors and the CEO. Instructions for financial reporting and instructions for the CEO are also determined in connection with the statutory board meeting. The Board of Directors meets in

accordance with a yearly schedule and essentially follows an annual cycle determined by the Board of Directors, which is decided at the statutory board meeting in conjunction with the Annual General Meeting. If necessary, special decisions are made such as acquisitions or divestments, other investment decisions, financing decisions and decisions on structural or organizational issues. In 2021, the Board of Directors held 13 board meetings, of which 6 were ordinary meetings. At the board meetings, the company's CEO and CFO were also present when needed.

#### **Board of Directors**

According to the Articles of Association, Vicore's Board of Directors shall consist of a minimum of three and a maximum of nine members. The Company's Board of directors currently consists of seven people without deputies. The assignment for all members runs until the end of the upcoming AGM.

On page 61-62 is a presentation of the Board of Directors with information on year of birth, year of inclusion in the Board, education, work experience, assignments in the company, other significant assignments and their respective direct and indirect holdings in the company as of March 31, 2021. Ownership in the company includes personal and / or related parties' holding.

#### Board of Directors' work 2021

During 2021, the Board of Directors held 13 board meetings, including the inaugural meeting, of which 13 through digital channels. In addition, the Board of Directors has made decisions per capsulam on 2 occasions during 2021. The issues that the Board of Directors dealt with in 2021 are mainly: decision to carry out a new share issue, preclinical, clinical studies and organizational issues. At the board meetings held during the financial year 2021, the members have been present as shown below.

## Evaluation of the Board of Directors' work

Pursuant to the Code, the Board of Directors is to evaluate its work annually, using a systematic and structured process, with the aim of developing the Board of Directors working methods and efficiency. The work of the Board of Directors has been evaluated by having the board members anonymously answer a number of questions about the Board of Directors' activities. The results of the evaluation have been compiled and reported orally to the members of the Board of Directors and the Nomination Committee.

#### Reporting period January 1 - December 31, 2021

	Independent in rela				ation to Remuneration, KSEK <sup>1)</sup>				Attendance <sup>2)</sup>				
Board member	Function	Elected	The company and its management	Major shareholders	Board fees	Remuneration Committee	Audit Committee	Scientific committee	Total	Board of Directors <sup>3)</sup>	Remuneration Committee	Audit Committee	Scientific committee
Michael Wolff Jensen	Chairman	2020	Yes	Yes	450	50	-	-	500	12/13	4/4	-	-
Heidi Hunter	Board member	2020	Yes	Yes	150		50		200	10/13	-	6/6	-
Hans Schikan	Board member	2018	Yes	Yes	150	25	-	25	200	13/13	4/4	-	3/3
Jacob Gunterberg	Board member	2018	Yes	No	150	-	100	25	275	124)/13	-	6/6	3/3
Maarten Kraan	Board member	2018	Yes	Yes	150	25	-	50	225	12/13	4/4	-	3/3
Sara Malcus	Board member	2018	Yes	Yes	150	-	50	-	200	12/13	-	5/6	-
Peter Ström <sup>5)</sup>	Board member	2015	Yes	Yes	-	-	-	-	-	7/13	-	-	-

1) Fee set by the AGM, excluding social security contributions, for the May 2021 to May 2022 financial year

2) Figures in table show the total number of meetings attended/total number of meetings

3) Excluding per capsulam meetings

4) Absence due to conflict of interest on one occasion

5) Peter Ström announced at the AGM on May 11, 2021 that he had declined re-election as a member of the Board of Directors

#### **Board committees**

#### **Remuneration Committee**

The Remuneration Committee is appointed by the company's Board of Directors and consists of three members: Michael Wolff Jensen (Chairman), Hans Schikan and Maarten Kraan. The Remuneration Committee shall fulfill the tasks specified in the Code. The Remuneration Committee shall keep minutes at its meetings and make the minutes available to the Board of Directors.

The Remuneration Committee's main tasks are as follows:

- Prepare decisions for the Board of Directors regarding remuneration principles, remuneration and other employment terms and conditions for senior management.
- Monitor and evaluate any programs pending or adopted during the year for variable compensation for senior management.
- monitor and evaluate the application of the guidelines for remuneration adopted by the annual general meeting, as well as applicable remuneration structures and levels for the company.

In 2021, the Remuneration Committee held four meetings.

#### Audit Committee

The Audit Committee is appointed by the Board of Directors and consists of Jacob Gunterberg (Chairman), Heidi Hunter and Sara Malcus. Primary duties of the Audit Committee:

 The Audit Committee shall, without impact on the responsibilities and duties of the Board of Directors in monitor the company's financial reporting, monitor the effectiveness of the company's internal control, internal audit and risk management, keep informed of the audit of the annual accounts and the consolidated accounts, review and monitor the auditor's impartiality and independence and in this case pay special attention to whether the auditor provides the company with services other than audit services, and assist in the preparation of proposals for the general meeting's election of auditor

other respects, among other things,

In 2021, the Audit Committee held six meetings.

### Scientific Committee

The Scientific Committee shall consist of at least three non-employed board members with a broad scientific and medical understanding and experience in the field concerned. The Board of Directors shall appoint the members of the Scientific Committee, including the Chairman. Vicore's Scientific Committee consists of Maarten Kraan (chairman), Jacob Gunterberg and Hans Schikan.

The main tasks and responsibilities of the Committee are:

- Reviewing and discussing the company's preclinical and clinical product portfolio, including its commercial attractiveness and ranking.
- Reviewing and discussing the company's R&D strategy and reviewing scientific and technological trends that the company considers are of great importance.
- Providing strategic advice and recommendations for the company's ongoing R&D program.

 To review the (quality of) R&D capacity of the company and its organization, including the product development process.

 To review and discuss the company's intellectual property strategies.
 In 2021, the Scientific Committee held three meetings.

## Remuneration

## **Remuneration to the Board of Directors**

At the Annual General Meeting on May 11.2021, it was resolved that the remuneration to the members of the Board of Directors for the period up to the end of the 2022 Annual General Meeting shall be paid with SEK 450,000 to the Chairman of the Board and SEK 150,000 to each of the other board members. As remuneration for committee work. it was decided that the Chairman of the Audit Committee should receive SEK 100,000 and the other members of the Audit Committee SEK 50,000 each. Furthermore, it was decided that the Chairman of the Remuneration Committee should receive SEK 50.000 and the other members of the Remuneration Committee SEK 25.000 each. The Chairman of the Scientific Committee shall receive SEK 50.000 and the other members of the Scientific Committee SEK 25,000 each. The table on page 4, shows the fees paid to members elected by the AGM in 2021.

### **Remuneration to management**

Remuneration issues for senior executives are dealt with by the Board of Directors Remuneration Committee. The Board of Directors decides on the CEO's remuneration on a proposal from the Remuneration Committee. Remuneration and terms for senior executives must be based on market conditions and consist of a balanced mix of fixed salary, variable remuneration, pension benefits and terms of notice. Salaries and other remuneration for the 2021 financial year were paid to the CEO and other senior executives in accordance with what is stated in note 7 "Employees and Personnel costs" in the Annual Report 2021.

## Guidelines on remuneration to senior executives and Board of Directors 2021

This is a summary of the guidelines for executive remuneration. The complete guidelines are available in the annual report 2021 and on the company's website.

At the 2021 AGM, guidelines were adopted that are valid up to the 2025 AGM as follows. Vicore shall offer remuneration in accordance with market practice which enables the recruitment and retention of internationally qualified senior executives. Remunerations within Vicore shall be based on principles of performance, competitiveness and fairness.

Senior executives refer to the CEO and the other members of the executive management. The guidelines shall apply to employment agreements concluded after the annual general meeting's resolution to adopt these guidelines, as well as when changes are made to existing agreements thereafter. The remuneration to senior executives consists of fixed remuneration, variable remuneration, share and share-price related incentive programs, pension and other benefits.

The Board of Directors is entitled to deviate from the guidelines if the Board

of Directors, in a certain case, deems that there are good reasons for the deviation.

#### Fixed salary

The fixed remuneration shall take into account the individual's responsibilities and experience. The fixed salary should be reviewed annually.

#### Variable salary

Variable remuneration paid in cash may amount to a maximum of 40 per cent of the annual fixed remuneration of the CEO and a maximum of 30 per cent of the annual fixed remuneration to other senior executives. Variable remuneration must be linked to predetermined and measurable criteria, designed to promote the company's long-term value creation.

## Share- and share price-based remuneration

Share- and share price-based incentive programs shall, if applicable, be decided by the AGM. Already decided incentive programs are described on page 74-75.

#### Pension

Pension should, where possible, be premium-based. For the CEO and other senior executives, the premium, in cases where a premium-based pension is applicable, can amount to up to 30 percent of the fixed salary. The Board of Directors has the right, without prejudice to the above, to offer other solutions that are equivalent in cost to the above.

#### Severance pay etc.

A notice period of up to six months between the company and the CEO shall apply if notice is given by the company. If notice is given by the company, the Board of Directors may decide that the CEO shall be entitled to severance pay of up to twelve months' salary. In the event of termination by the CEO, a notice period of up to six months shall apply. Other senior executives shall have a notice period of three to six months. During the notice period, normal salary shall be paid.

#### Other benefits

Senior executives may be awarded customary other benefits such as occupational health care, etc. Such other benefits shall not constitute a significant part of the total remuneration.

### Vetting and decision processes

The CEO's remuneration shall be vetted by the Remuneration Committee and decided by the Board of Directors. The remuneration of other senior executives shall be vetted by the CEO and the Remuneration Committee, which shall submit a proposal for approval to the Board of Directors. The Board of Directors has the right to deviate from the above guidelines if there are special reasons that justify it in an individual case.

At the end of 2021, Vicore has four active programs that include the company's management and staff, and certain board members. In 2018, two long-term incentive programs were set up: "Co-worker LTIP 2018" and "Board LTIP 2018" (expired in 2021). In 2020, a long-term incentive program, "Board LTIP 2020", for the two new board members was introduced. In 2021, two long-term incentive programs were set up: "Co-worker LTIP 2021" and "Board LTIP 2021".

The increase in the company's share capital, assuming full utilization and maximum goal achievement of all active incentive programs (i.e. including non-granted employee stock options and warrants that may be used as hedge for social security contributions), amounts to a maximum of SEK 2,793,387, corresponding to a dilution of 7.2 percent of the total number of shares.

Below is a description of the various programs. For other information about the incentive programs, see Note 8 in the Annual Report 2021.

#### Long-term incentive program 2018

The Extraordinary General Meeting of Vicore Pharma Holding AB on August 13.2018 resolved, in accordance with the Board of Directors proposal to adopt a long-term incentive program for senior executives and key employees ("Co-worker LTIP 2018") and to introduce a performance-based long-term incentive plan for certain directors ("Board LTIP 2018") in Vicore Pharma Holding AB. A maximum of 2,000,000 options (Co-worker LTIP 2018) and 475,000 share rights (Board LTIP 2018) may be granted to participants in the programs. The increase in the company's share capital upon full utilization of both incentive programs amounts to a maximum of around SEK 1.237.500. which corresponds to a dilution of approximately 3.3 percent with respect to the total number of shares. The participants in the programs have received the share rights / options free of charge and settlements is made with equity instruments.

#### Board LTIP 2018

Board LTIP 2018 is a program under which the participants will be granted, free of charge, share awards subject to performance vesting that entitle to shares in the company to be calculated in accordance with the principles stipulated below, however a maximum of 475,000 shares.

Board LTIP 2018 is intended for members of the Board of Directors of the company independent from the main owners. The main owners believe that an equity-based incentive program is a central part of an attractive and competitive remuneration package in order to attract, retain and motivate internationally competent members of the Board of Directors of the company, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

The share awards shall vest gradually over approximately three years and are subject to performance vesting based on the development of the company's share price over the period from the date the share awards are allocated up to and including the vesting date.

The development of the share price will be measured based on the volume weighted average price of the company's share price for the 30 trading days immediately following after 17 August, 2018, and the 30 trading days immediately preceding the date of the publication of the Q2 report 2021. In the event the price of the company's share has thereby increased by more than 150 percent, 100 percent of the share awards shall vest, and should the share price have increased by 50 percent, 25 percent of such share awards shall vest. In the event of an increase of the share price between 50 and 150 percent. vesting of the share awards will occur linearly. Should the increase of the share price be less than 50 percent, no vesting will occur. The earliest date at which accrued share rights may be exercised is the date of publication of the Q2 report 2021.

During the third quarter of 2021, Board

LTIP 2018 expired. As the share price increased by less than 50 percent during the measurement period no share awards were earned. The program is now closed.

#### Co-worker LTIP 2018

Co-worker LTIP 2018 is an incentive program intended for members of senior management and key persons in the company. According to the program, participants will be granted, free of charge, options subject to a three-year vesting that entitle to acquire a maximum of 2.000.000 shares in the company in total. The exercise price per share shall correspond to 150 percent of the volume weighted average price of the company's share for the five trading days preceding the granting date. The latest point in time at which vested options may be exercised shall be the fourth anniversary of the granting date.

The Board of Directors of the company believes that an equity-based incentive program is a central part of an attractive and competitive remuneration package in order to attract, retain and motivate competent members of senior management and key persons in the company, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

As of December 31, 2021, options corresponding to 1,325,800 shares have been granted in Co-worker LTIP 2018.

## Long-term incentive program 2020

The Annual General Meeting in Vicore Pharma Holding AB held on May 20, 2020, resolved, in accordance with the proposal from the Nomination Committee, to adopt a long-term incentive program for the new members of the Board of Directors ("Board LTIP 2020") in Vicore Pharma Holding AB. A maximum of 525,000 share awards may be allotted to participants in the program Board LTIP 2020. The increase in the company's share capital, assuming full utilization, amounts to a maximum of approximately SEK 262,500, corresponding to a dilution of 0.7 percent of the total number of shares.

## Board LTIP 2020

Board LTIP 2020 is a program under which the participants will be granted, free of charge, share awards subject to performance vesting that entitle to shares in the company to be calculated in accordance with the principles stipulated below, however a maximum of 525,000 shares. The share awards shall vest gradually over approximately three years and are subject to performance vesting based on the development of the company's share price over the period from the date the share awards are allocated up to and including the vesting date.

Board LTIP 2020 is intended for the newly elected, main owner independent, members of the Board of Directors in the company. The Nomination Committee believes that an equity-based incentive program is a central part of a competitive remuneration package in order to attract, retain and motivate internationally competent members of the Board of Directors, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

As of December 31, 2021, a total of 525,000 share awards have been granted in Board LTIP 2020.

## Long-term incentive program 2021

The Annual General Meeting in Vicore Pharma Holding AB held on May 11, 2021, resolved to implement a long-term incentive program for senior management and key persons in the company ("Co-worker LTIP 2021") and to implement a long-term performance-based incentive program for independent board members in the company who are not participants in Board LTIP 2020 ("Board LTIP 2021"). A maximum of 3,000,000 options (Co-worker LTIP 2021) and 61,773 share awards (Board LTIP 2021) may be allotted to participants in the programs. The increase in the company's share capital, assuming full utilization of both incentive programs, amounts to a maximum of approximately SEK 1,530,887, corresponding to a dilution of approximately 4.1 percent of the total number of shares. Taking into account also the shares which may be issued pursuant to previously implemented incentive programs in the company, the maximum dilution amounts to approximately 7.2 percent on a fully diluted basis.

## Board LTIP 2021

Board LTIP 2021 is a program under which the participants will be granted, free of charge, share awards subject to performance vesting that entitle to shares in the company to be calculated in accordance with the principles stipulated below, however a maximum of 61,773 shares. The share awards are subject to performance vesting based on the development of the company's share price over the period from the date the share awards are allocated up to and including the vesting date. Board LTIP 2021 is intended for independent board members in the company who are not participants in Board LTIP 2020. The Nomination Committee believes that an equity-based incentive program is a central part of a competitive remuneration package in order to attract, retain and motivate internationally competent members of the Board of Directors, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders.

As of December 31, 2021, a total of 61,773 share awards have been granted in Board LTIP 2021.

#### Co-worker LTIP 2018

Co-worker LTIP 2021 is an incentive program intended for members of senior management and key persons in the company. According to the program, participants will be granted, free of charge, options subject to three-year vesting that entitle to acquire a maximum of 3,000,000 shares in the company in total. The exercise price per share shall correspond to 125 percent of the volume weighted average price of the company's share for the five trading days preceding the granting date. The latest point in time at which vested options may be exercised shall be the fifth anniversary of the granting date. The Board of Directors of the

company believes that an equity-based incentive program is a central part of an attractive and competitive remuneration package in order to attract, retain and motivate competent members of senior management and key persons in the company, and to focus the participants on delivering exceptional performance which contributes to value creation for all shareholders. As of December 31, 2021, options corresponding to 807,600 shares have been granted in Co-worker LTIP 2021.

## Internal control and risk management regarding the financial reporting

#### Introduction

According to the Companies Act and the Annual Accounts Act, the Board of Directors are responsible for internal control. The purpose of internal control is to achieve efficient and effective operations, to ensure reliable financial reporting and information about the business, and to comply with applicable laws, regulations, policies and guidelines. Vicore's internal control is based on principles developed by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) which consists of five consecutive components:

- 1. Control environment
- 2. Risk assessment
- 3. Control activities
- 4. Information and communication
- 5. Monitoring including monitoring and evaluation

#### Internal control of financial reporting

Internal control over financial reporting aims to provide reasonable reliability and security in financial reporting and to ensure that financial external reporting is conducted in accordance with applicable laws and accounting standards. The Board of Directors are ultimately responsible for internal control and continuously evaluates, via the Audit Committee, Vicore's risk management and internal control.

Vicore ensures internal control of financial reporting through a qualitative and quantitative analysis of the balance sheet and income statement for the Group. The purpose of the quantitative analysis is to identify risks linked to significant and transaction-intensive items. The qualitative analysis aims to identify risks linked to complexity and irregularities. Based on the results of the analysis, significant financial processes and risks have been identified.

Vicore has designed procedures and activities to follow up on financial reporting and to ensure that any errors are detected and corrected. Key controls have been designed and followed up as part of the effort to maintain good internal control.

#### Internal audit

The Board of Directors has evaluated the need for an internal audit function and concluded that it is not justified in Vicore in view of the scope of the business and that the Board's follow-up of internal control is deemed sufficient to ensure that internal control is effective. The Board reexamines the need, when changes occur that can lead to re-examination and at least once a year.

## Control environment and risk assessment

The control environment within Vicore is part the framework for the orientation and culture that the Company's Board and management communicate to the organization. In order to ensure appropriate risk management and good internal control, the Company has adopted a series of internal guidelines, work processes and routines, in addition to governing documents such as the Board's rules of procedure, instructions for the CEO with associated instructions for delegation and attestation.

The Board has also established an Audit Committee whose main task is to monitor the Company's financial position, the effectiveness of the Company's internal control, internal audit and risk management to be informed of the audit of the annual accounts and the consolidated accounts, and to review and monitor the auditor's impartiality and independence. Responsibility for ongoing work regarding the internal control of the financial reporting has been delegated to the Company's CEO and CFO.

In addition to the abovementioned controls, the company has standardized procedures that govern the control and quality of drug development.

Vicore's group management shall annually conduct a risk assessment of strategic, operational, legal and financial risks with the aim of identifying potential problem areas and assessing the risk exposure in the company. The risk assessment includes identifying risks that may arise that may prevent the company from achieving its vision and goals, for example if the basic requirements for financial reporting in the company are not met. Within the scope of each risk area, the responsible person identifies risks and their potential consequences and probabilities, and proposes measures. The Audit Committee is responsible for continuously evaluating the company's risk situation and shall assist the Board of Directors with proposals regarding the management

of the company's financial risk exposure and risk management.

## **Control activities**

To identify and manage the risks associated with the company's operations, the Board of Directors has adopted a risk management policy. Risk management is a high priority within Vicore. Ultimately, it is the Board of Directors that is responsible for risk management. The company's risk situation must be evaluated annually, after which an action plan will be drawn up. Vicore base its control environment on the risks identified during the risk assessment process. The company has also appointed process owners who are responsible for individual processes. The CEO and other senior executives are all involved in the ongoing work to manage the risks associated with the business.

Vicore has designed procedures and activities to follow up on financial reporting and to ensure that any errors are detected and corrected. These activities include, among other things, follow-up and comparison of earnings performance or items, account reconciliations and balance sheet specifications, as well as approval of bank transactions and cooperation agreements, proxy and authorization instructions, and accounting and valuation principles. The company's CFO has a key role in analyzing and following up the company's financial reporting and results. Authorizations to IT systems are limited according to powers, responsibilities and roles.

#### Information and communication

The company also has internal control functions for information and commu-

nication that aim to ensure that correct financial and other company information is communicated to employees and other stakeholders.

The company's internal instructions and policies are available to all employees and provide detailed information on current routines in all parts of the company and describe the control functions and how they are implemented.

## Monitoring including follow-up and evaluation

Compliance and effectiveness regarding internal controls are regularly monitored. The CEO ensures that the Board of Directors receives regular reports on the development of the company's operations, including the development of the company's earnings and financial position and information on important events, such as research results and important agreements and contracts. The CEO reports on these issues at each board meeting. The company's compliance with applicable policies and governance documents and the effectiveness of internal control are subject to annual evaluation. The results of these evaluations are compiled by the company's CEO and reported to the Board of Directors annually. The Board of Directors handles all interim reports and annual reports before they are published and follows up the audit of the internal control via the Audit Committee. The Audit Committee supports the Board of Directors by preparing questions and provides the Board of Directors with support in its work to fulfill its responsibilities in the areas of internal control and accounting and to assure the quality of Vicore's financial reporting.

## Management

The Board of Directors appoints the CEO to lead the company. The management team consists of 10 people:

- CEO
- Chief Financial Officer
- Chief Medical Offier
- Chief Scientific Officer
- VP Clinical Development
- Head of Preclinical Development
- Chief Administrative Officer
- Chief Commercial Officer
- VP Business Development
- Director of Digital Therapeutics

The management team holds monthly meetings to discuss the group's results and financial position, follow-up of budgets and forecasts, status in research and development projects, administration, HR and organization, IR and strategy.

#### The CEO's responsibility

The CEO is subordinate to the Board of Directors and is responsible for the company's day-to-day management and operations of the company. The division of duties between the Board of Directors and CEO is specified in the rules of procedure for the Board of Directors and the CEO's instructions. The CEO shall ensure that the company's accounting is in order and that the business is conducted in accordance with relevant regulations, including Nasdaq Stockholm's Rule Book for Issuers.

The CEO shall keep the Board of Directors continuously informed of

the development of the company's operations, the company's earnings and financial position, liquidity and credit situation, important business events and any other event, circumstances or conditions that may be of material importance to the company's shareholders.

The CEO is also responsible for producing reports and necessary documentation to facilitate decisions for board meetings and is the main presenter of the material at board meetings.

#### Management team

Vicore's management team currently consist of ten individuals; CEO Carl-Johan Dalsgaard; Chief Financial Officer Hans Jeppsson; CMO Rohit Batta, CSO Johan Raud, VP Clinical Development Elin Rosendahl, Head of Preclinical Development Johanna Gräns and Chief Administrative Officer Nina Carlén, Chief Commercial Officer Åsa Magnusson, VP Business Development Mikael Nygård and Director of Digital Therapeutics Jessica Shull.

For further information about Vicore's management team, including name, position, year of employment, education, work experience, significant assignments outside the company and holdings (own and / or related parties) in Vicore on March 31, 2022, see page 63-64.

# Glossary

## Agonist

A drug that has affinity for, and stimulates physiological activity, via cellular receptors that are normally stimulated by naturally occurring substances.

## Antagonist

A substance that tends to nullify the action of another; in pharmaceutical terms, a drug that binds to a receptor without eliciting a biological response.

## Angiotensin

Peptides and hormonal substances within the renin-angiotensin system. The most potent form known as Angiotensin II, which may bind to two different receptors; the AT1 receptor and the AT2 receptor. Stimulation of the AT1 receptor via Angiotensin II provides inter alia a contraction of the blood vessels and increases the blood pressure.

## AT1 receptor

Stimulation of the AT1 receptor (AT1R) via Angiotensin II provides, among other things, a contraction of the blood vessels and raised blood pressure

## AT2 receptor (AT2R)

The Angiotensin II type 2 receptor or AT2 receptor is regarded as the "protective" receptor of the Renin-Angiotensin system. Many effects seen after stimulation of the AT2 receptor counteracts effects mediated via the AT1 receptor thus counteracting cytokines and growth factors. The AT2 receptor belongs to a family of G protein-coupled receptors. In contrast to the ubiquitous AT1 receptor, the AT2 receptor is predominantly expressed during embryonic development. In adults, however, it is mainly expressed after injury and in different disease states.

## **Clinical studies**

Phase 1 is the first time that the drug is tested on humans. This is usually done on a small group (10-30) of healthy volunteers with normal weight who are men. This is because women's reproductive capacity is more sensitive if it should prove that the substance is toxic. In the phase I study the safety of the drug is investigated, how it is broken down in the body and its effects. In the phase I study the subject is only given a small fraction of the amount that is given to experimental animals, because the effect on people is completely unknown. **Phase 2** is carried out on a larger group of patients suffering from a disease (20-3,000) to study how effective the drug is to treat the disease. During phase II, dose studies are also usually conducted to arrive at the right dose to be given to patients in the future. This dose is used later in the phase III studies. Phase II studies can be divided into early phase (IIa) and late phase (IIb).

Phase 3 is carried out in a large population (300-30,000) to conclusively define how suitable the drug is to treat the disease. This patient group should as far as possible mimic the population of which the finished product is to be used on, e.g. weight, age, gender, etc. Comparisons are made to the current standard treatment or placebo (sugar pill) if there is no standard treatment for the disease. Phase III may also be divided into two subgroups phase IIIa and phase IIIb. In phase IIIa, the drug has not come out in the market yet and during phase IIIb the drug is on the market, but new areas of use for it are tested.

**Phase 4** comes after the drug has started to be sold in the market, when new unusual side effects can be discovered. Phase IV can be seen as a monitoring of what is happening. Interstitiell lungsjukdom.



## Interstitial lung disease (ILD)

Term used for a group of lung diseases.

## Idiopathic pulmonary fibrosis (IPF)

IPF is a chronic and ultimately fatal disease characterized by a progressive decline in lung function. The term pulmonary fibrosis means scarring of lung tissue and is the cause of worsening dyspnoea (shortness of breath). Fibrosis is usually associated with a poor prognosis. IPF usually occurs in adult individuals of between 50 and 70 years of age, and affects more men than women.

## IMiD (Immunomodulatory drugs)

Is a class of drugs that affect the immune response and contains an imide group. The IMiD class includes thalidomide.

## **Preclinical research**

Preclinical research is a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected. The main goals of pre-clinical studies are to determine the safe dose for first-in-man study and assess a product's safety profile.

# Pulmonary arterial hypertension (PAH)

Pulmonary arterial hypertension (PAH) is a progressive disease characterized by high blood pressure in the lung arteries caused by narrowing and obstruction in the arteries of the lung.

## RAS or Renin-Angiotensin System

The Renin-Angiotensin System (RAS) or the Renin-Angiotensin-Aldosterone System (RAAS) is a hormone system that regulates blood pressure and water (fluid) balance. Drugs that block the ras, e.g. ACE inhibitors and Angiotensin receptor blockers, have been widely used clinically to treat high blood pressure, and for reducing mortality of patients with myocardial infarction and heart failure patients. With these drugs, the negative effects of Angiotensin II are blocked, which occurs when AT1r stimulated.

## Receptor

A specific molecule on the surface or within the cytoplasm of a cell that recognizes and binds with other specific molecules, such as the cell molecules that bind with hormone or neurotransmitter molecules and react with other molecules that respond in a specific way.

## Regulatory

Summary term for the work done to meet the authorities' formal requirements regarding, for example, pharmaceutical registration.

## Raynaud's phenomenom

Expresses itself in that fingers or toes whitens. This is due to decreased blood flow due to temporary cramps in the blood vessels of the fingers.

You distinguish between primary form, which arises without known cause, and secondary form. The secondary form is often caused by damage from working with vibrating tools, but also occurs in connection with arteriosclerosis, SLE, previous cold injuries etc. White fingers often arise in connection with cold. It is a side effect that occurs with treatment with beta blockers. The cause of the primary form is not known, but it is known that there are some hereditary relationships.

## Systemic sclerosis (SSc)

Systemic sclerosis (SSc) is a rheumatic disease and connective tissue disease where the skin first becomes thick and hardens through increased collagen formation, later the skin becomes thin and tight. The cause is unknown. The first symptom is usually attacks of frostiness and paleness in the fingers and toes (Raynaud's phenomenon). Often, muscles, joints and various internal organs (systemic sclerosis) are also affected. Systemic sclerosis is a so-called chronic autoimmune disease, which means that the body responds to its own tissues in a similar way that the immune system attacks other viruses. The disease usually debuts in the ages between 30 and 50 years. There are two types of the disease. One is called diffuse cutaneous systemic sclerosis (dcSSc) and the other type is limited cutaneous systemic sclerosis (lcSSc).

## **Orphan drugs**

The regulatory authorities can grant a drug candidate Orphan Drug Designation (ODD). Orphan drug status is a way of encouraging research and development of drugs for the treatment of rare diseases. The market for orphan drugs is growing faster than other pharmaceuticals market.

In the US and Europe, about 60 million people are estimated to suffer from one of the 7,000 identified rare diseases. In total, some 350 million people around the world are estimated to suffer from one of the rare diseases identified.

## The definition of rare disease for different markets:

USA: <200,000 patients per indication Japan: <50,000 patients per indication Europe: <5 per 10,000 inhabitants (approximately 250,000 patients per indication)

# Contact Information

## Adress

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