



## Interim report January-March 2023

**Stockholm, May 4, 2023 - Vicore Pharma Holding AB (publ), unlocking the potential of a new class of drugs – angiotensin II type 2 receptor agonists (ATRAgS), publishes the interim report for the first quarter 2023.**

### Important events during the first quarter

- In January, Vicore divested its entire holding of 91,829 shares in I-Tech AB (publ) amounting to approximately 4.6 MSEK after transaction costs.
- In March, Vicore was awarded Innovation Passport designation by the UK regulatory agency MHRA (Medicines and Healthcare products Regulatory Agency) for C21 for the treatment of idiopathic pulmonary fibrosis (IPF).
- In March, Vicore announced that an update regarding the AIR trial (phase 2a trial in IPF) will be presented at the ATS (American Thoracic Society) congress on May 21.

### Important events after the period

- In May, Vicore announced the first patient dosed in a proof-of-concept trial of endothelial dysfunction.

### Financial overview for the period

#### **January 1 – March 31, 2023**

- Net sales amounted to 0.0 MSEK (0.0)
- The operating loss was -66.1 MSEK (-93.2)
- Loss for the period amounted to -66.3 MSEK (-93.4)
- Loss per share, before and after dilution, was -0.81 SEK (-1.30)
- On March 31, 2023, cash, cash equivalents and short-term investments amounted to 183.6 MSEK (261.7 MSEK as of December 31, 2022)

## Financial summary of the group

Amounts in MSEK	2023 Jan-Mar	2022 Jan-Mar	2022 Jan-Dec
Net sales	0.0	0.0	0.0
Operating loss	-66.1	-93.2	-290.7
Loss for the period	-66.3	-93.4	-288.4
Loss per share, before/after dilution (SEK) <sup>1</sup>	-0.81	-1.30	-3.99
Research and development costs/ operating costs (%) <sup>2</sup>	85.4	86.0	85.5
Equity at the end of the period	224.6	291.2	289.1
Cash flow from operating activities	-77.7	-47.3	-299.9
Cash and cash equivalents and short-term investments at the end of the period	183.6	300.6	261.7

<sup>1</sup> There is no dilution effect for potential ordinary shares for periods where earnings have been negative.

<sup>2</sup> Alternative performance measure (APM). Defined on page 17 in the interim report.

## CEO Comments

During the first quarter of 2023, the company continued to make progress in the phase 2a trial (AIR) in idiopathic pulmonary fibrosis (IPF)<sup>1</sup>. More patients are completing the trial and the data set becomes more advanced. The highly promising AIR data presented in November showed a stabilization of disease up to 18 weeks of C21 treatment. What was even more exciting, in the period up to 36 weeks, was the continued improvement in lung function that was seen. Indications of an ongoing positive effect was observed in February and we hope to be able to thoroughly consolidate and verify this unprecedented effect in the upcoming interim data readout in May. If we can replicate this level of effect in larger trials it will transform the overall treatment landscape for IPF patients. The upcoming data to be presented in May will also be analyzed through 3D reconstructions of the computer tomography performed at screening to objectively confirm baseline FVC (forced vital capacity - a measure of lung capacity) as well as the amount of fibrosis in high responders. So far, we have seen that the high responders are found in the group of earlier stage IPF with less established terminal fibrosis and, in line with the mechanism of action of C21, these patients are likely more susceptible to regaining some lung function once the progressing fibrosis formation has been stopped.

<sup>1</sup> NCT0453302



Vicore is currently conducting long-term toxicology studies and a drug-drug interaction study in preparation for the next step in the development of C21 for IPF, the phase 2b trial ANDAS.

Vicore has received Innovation Passport designation for C21 in IPF by the UK regulatory authority MHRA (Medicines and Healthcare products Regulatory Agency). Like an FDA (U.S. Food and Drug Administration) breakthrough therapy designation, this is a program for additional support and guidance during product development, but also involves NICE, the price and reimbursement authority. The Innovation Passport designation is awarded to products that are believed to be innovative and important for a life-threatening and seriously debilitating condition like IPF. It aims to accelerate time to market and facilitate patient access to innovative medicines and to reduce development risks through the opportunity for extended support from regulatory and other stakeholders.

Recently, Vicore initiated a randomized, double-blind, placebo-controlled phase 1 proof-of-concept trial<sup>2</sup> investigating the effect of ATRAGs on endothelial dysfunction in 12 patients with type-2-diabetes-mellitus (T2DM). Endothelial dysfunction is a key driver of organ damage associated with many diseases and restoration of endothelial function may be both therapeutic and serve as an early efficacy biomarker in pulmonary, renal, vascular and several other diseases. The trial will be performed using EndoPAT<sup>®3</sup>, an FDA-cleared, non-invasive, simple, and robust technology to assess endothelial function. This method may serve as proof-of-principle and guidance with regards to establishing an effective dose in a range of pulmonary and vascular diseases and it has the potential to shorten the timelines and decrease the risk in early clinical development programs. The results from this study is estimated to be available in Q4 2023.

Three abstracts have been accepted for presentations at the ATS (American Thoracic Society) international congress in May. Professor Toby Maher from Keck School of Medicine at University of California will give an update of the AIR trial. There will also be an oral presentation of the pilot data with the digital therapeutic, Almee<sup>™</sup> and a poster presentation on the development of Angiotensin II type 2 receptor agonists (ATRAGs). In addition, Vicore has been selected as a Fibrosis Innovator to be showcased for an oral presentation at the ATS Respiratory Innovation Summit. This conference unites the innovators, investors, clinicians and advocacy groups who are leading the charge to create powerful new treatments for life-threatening and crippling diseases of the lungs and airways.

The COMPANION trial<sup>4</sup> of Vicore's digital cognitive behavioral therapy (dCBT) for anxiety associated with pulmonary fibrosis is progressing and the first patients have completed the trial. As a companion, this tool receives great appreciation and interest among patients, caregivers and investigators, indicating a significant medical need that could be fulfilled.

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<sup>2</sup> NCT05831644

<sup>3</sup> Registered trademark of ZOLL® Itamar®, a division of ZOLL® Medical

<sup>4</sup> NCT05330312



The first-in-human trial with the new ATRAG C106<sup>5</sup> is about to conclude, and the development of the next molecules is progressing with different indications in mind. The portfolio of new ATRAGs can serve both as back-ups in rare lung disease indications or open completely new opportunities in other areas for Vicore to pursue alone or in collaboration with other pharma companies.

Overall, Vicore has maintained momentum through the first quarter. This is an ideal moment to extend my gratitude to all involved in Vicore for their support in making our ambition, to unlock the potential of ATRAGs - a new class of drugs - and to bring a game changing medicine to patients with IPF, possible.

**Carl-Johan Dalsgaard**

Interim report January-March, 2023; <https://vicorepharma.com/investors/financial-reports/>

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**About Vicore Pharma Holding AB (publ)**

*Vicore is an innovative Swedish clinical-stage pharmaceutical company dedicated to creating life-changing treatments in diseases where the AT2 (angiotensin II type 2) receptor has a central role in stopping and reversing disease pathology. The company is establishing a portfolio in rare lung diseases including idiopathic pulmonary fibrosis (IPF) and pulmonary arterial hypertension (PAH). C21 is a first-in-class orally available small molecule angiotensin II type 2 receptor agonist (ATRAG). Almee™ (an investigational medical device in clinical development) is a digital therapeutic (DTx) based on cognitive behavioral therapy (CBT) created to address the psychological impact of living with pulmonary fibrosis. Inhaled IMID is a new formulation and delivery route of thalidomide targeting the severe cough associated with IPF. With our unique expertise in the ATRAG biology we fuel our pipeline with several new assets with long patent life for a variety of diseases, some of which could be partnered while others can be taken to the market by Vicore.*

*The company's shares (VICO) are listed on Nasdaq Stockholm's main market. For more information, see [www.vicorepharma.com](http://www.vicorepharma.com).*

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<sup>5</sup> NCT05427253