

# **ANNUAL REPORT**

**2016**

**VICORE PHARMA HOLDING AB (PUBL)**



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# SUMMARY OF THE FINANCIAL YEAR 2016

## IMPORTANT EVENTS DURING THE FINANCIAL YEAR

- Private placement of 570,000 warrants were carried out in January
- Phase I trials began in April and was completed in November
- At the AGM in April, Leif Darner was appointed a new Board member
- The holding in the financial asset I-Tech increased by 312,500 shares in a rights issue in July
- In August, Vicore Pharma received orphan drug status in Europe for idiopathic pulmonary fibrosis (IPF)
- Klas Malmberg was recruited as Senior Medical Advisor. The position was transferred in November to Chief Medical Officer (CMO)

## IMPORTANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

- A loan agreement with Capital Recall that facilitates additional working capital was entered in January
- An additional study with the drug candidate C21 in a risk group was started in January
- A patent application for new drug molecules based on C21 was submitted in January
- Vicore Pharma received Orphan Drug Designation from the FDA for IPF in January
- On February 23, the Board took the decision of two directed issues. It was done with the authorisation from the Annual General Meeting 2016 of 2 million shares and partly provided by the Extraordinary General Meeting's subsequent approval of an additional 1.5 million shares, a total of about SEK 56 million. Both issues have now been completed and the second is under registration with the Swedish Companies Registration Office (Bolagsverket).
- C21 showed excellent properties in key markers in an in vitro study of pulmonary fibrosis that was presented on March 8

## FINANCIAL DATA

Group (KSEK)	2016	2015	2014	2013
Net turnover	852	840	851	2 585
Operating expenses	-8 782	-6 220	-6 918	-6 667
Profit/Loss for the year	-6 652	-4 570	13 687	-1 603
Cash flow from operating activities	-7 251	-3 682	- 2 825	-1 793
Cash and Cash equivalents at year end	4 266	25 175	1 710	14 025

*Vicore Pharma develops drugs targeting stimulation of the AT2 Receptor (AT2R) in the Renin-Angiotensin-System (RAS). The company vision is to establish AT2 agonists as a new and effective class of small molecule drugs. Our lead candidate, C21 is being developed for the indication idiopathic pulmonary fibrosis (IPF). For more information see: [www.vicorepharma.com](http://www.vicorepharma.com)*

# CEO'S COMMENTS

## PHASE I STUDIES CONDUCTED

2016 was a memorable year for Vicore Pharma and Vicore Pharma Holding. It was our first year as a listed company on Nasdaq First North in Stockholm and it was also the first year when our lead drug candidate C21 went into clinical trials, and we were able to initiate a Phase I trial in April. The study was performed at the Clinical Research Services Turku (CRST) in Turku, Finland. The first part of the Phase I study was a double-blind, randomized, placebo-controlled study of orally administered C21 for evaluation of safety and tolerability of escalating doses. The study included 24 healthy male volunteers.

In June, we got the first results where subjects had received C21 in increasing single doses totalling six doses from 0.3 to 100 mg, to investigate the safety and tolerability and pharmacokinetic properties of the C21. The results were convincing.

In September, the second part of the Phase I study of healthy volunteers were dosed with multiple rising doses of C21 during a period of eight days (a so called MAD study, Multiple Ascending Doses). The results showed that all objectives for the two Phase I studies have been met: C21 is well tolerated, is safe at high doses and exhibits consistent blood levels.

## CONTINUED DEVELOPMENT

The achieved safety data of C21 now allows us to initiate clinical trials in patients suffering from diseases where C21 has demonstrated strong data in animal experiments. This list is extensive, as many of our shareholders who have been with us for some time know. It is therefore with satisfaction and a measure of confidence that we approach a new stage in our development, where our focus will be - independently or together with partners - to seeking to demonstrate the clinical efficacy and safety, with idiopathic pulmonary fibrosis (IPF) as the leading indication. In parallel, however, we will initiate smaller clinical trials for other diseases, such as kidney damage caused by diabetes. This should be seen as an expression of the technology breadth and our effort to rapidly increase the value of it.



## PRIVATE PLACEMENT

In order to accelerate the clinical development of C21 for the treatment of IPF, and to fund future clinical trials, the Board decided in February 2017 on two issues totalling SEK 56 million. The proceeds will primarily be used for the development of C21 and will take C21 until phase Ib studies for the chosen indication. The proceeds are also expected to be able to finance the capsule formulation, interaction studies, a long term study and a conceptual clinical study in diabetes.

Overall, the planned capital injections mean that the company's technology is given the potential to be evaluated in larger Phase II studies of therapeutic areas that currently lack effective treatments.

*"We achieved the milestones we determined for 2016. Now, we will continue to develop C21 into a future drug for the treatment of idiopathic pulmonary fibrosis"*

## **ORPHAN DRUG DESIGNATION**

In August we got an anticipated announcement when we received orphan drug designation for C21 in the EU. The corresponding approval for orphan drug designation for the US was obtained in January 2017 from the Food and Drug Administration (FDA). The European Medicines Agency (EMA) was very positive about C21 and especially the fact that C21 has demonstrated positive effects on blood pressure in the pulmonary circulation. This is often elevated in IPF patients and is also one prognosis worsening consequence of the disease that the registered drugs have not been able to show effects against, whether in patients or in experimental animals.

## **STRENGTHENING THE ORGANIZATION**

In order to strengthen the organisation, in October we recruited Klas Malmberg as Senior Medical Advisor. In November, the position was reassigned to Chief Medical Officer. Klas has extensive experience as a clinical cardiologist and medical director of drug development projects within large pharmaceutical companies and is therefore a welcome addition to the clinical phase we are in now.

## **POTENTIAL COLLABORATIONS**

The company's management has a continuous dialogue with the pharmaceutical industry, with the intention to

keep the industry updated on the company's development and to investigate the conditions to initiate collaborative discussions in due course. The progress made during the year- additional preclinical data in key areas, clinical safety, obtaining orphan drug status and development of a new generation of drug molecules- have collectively increased interest from industry and qualified investors.

## **I-TECH, FINANCIAL ASSET**

Vicore's financial access I-Tech continues to develop well. Sales for Selektepe in 2016 increased steadily, albeit from low levels. During autumn, the first commercial paint was launched on a large scale by the paint company Chugoku Marine Paints (CMP). Confidence in I-Tech, its development and future is great and also made us decide to uphold our ownership and subscribe to 312,500 shares at the issue that took place last summer.

In 2016, we achieved the milestones that we had set ourselves, which means we are looking forward to this year with great confidence. The company can now continue to develop C21 to a future drug for the treatment of IPF and at the same time advancing our positions with our technology in other indications.

**Per Jansson, CEO**

# **ANNUAL GENERAL MEETING AND FINANCIAL CALENDAR**

## **ANNUAL GENERAL MEETING**

AGM be held on May 10, 2017 at 15:00 in the company's premises c/o BioVentureHub (AstraZeneca), Pepparedsleden 1, 431 83 Mölndal.

Notice of the meeting is published on the company's website [www.vicorepharma.com](http://www.vicorepharma.com) and is published in Post- och Inrikes Tidningar. The notice will also be sent to shareholders who so request and provide their postal address.

Shareholders who wish to attend the Meeting must be registered in the Euroclear Sweden AB share register by Thursday, May 4, 2017, and no later than 12:00 May 5, 2017 report in writing to Nina Carlén, Vicore Pharma Holding AB, c/o BioVentureHub, Pepparedsleden 1, 431 83 Mölndal, or by telephone +46 31-78 80 560, or via email [nina.carlen@vicorepharma.com](mailto:nina.carlen@vicorepharma.com).

## **UPCOMING FINANCIAL REPORTS**

2017-05-10	Interim report, First quarter
2017-08-24	Interim report, Second quarter
2017-10-19	Interim report, Third quarter

Financial reports are available on the company's website [www.vicorepharma.com](http://www.vicorepharma.com) from the day of publication.

# THE STORY BEHIND C21

The year when the angiotensin AT2-receptor was first identified – 1989 - was also my first year in research. My “home lab” at that time, the group of Prof. Thomas Unger at Heidelberg University, Germany, was specialised in the renin-angiotensin system, and consequently, we got interested in this new receptor in its very early years.

The group, both on its own and in collaboration with Prof. Serge Bottari and Dr. Marc de Gasparo, both at that time working at Ciba-Geigy, Bale, Switzerland, was among the pioneering scientific teams worldwide in terms of characterisation of AT2-receptor signalling and function, which to our surprise turned out to be exactly the opposite of what was known as AT1-receptor mediated effects of angiotensin II. Incidentally, Ciba-Geigy and Du Pont were the first to have synthesised selective AT2-receptor ligands, and researchers of these companies had identified the AT2-receptor coincidentally.

Although AT2-receptor researchers at that time were struggling with non-optimal tools for studying the AT2-receptor – the only available agonist was a peptide; many studies were performed with an antagonist only – evidence accumulated in the late 90s that the AT2-receptor mediates a variety of tissue-protective actions such as anti-inflammation, anti-fibrosis and anti-apoptosis.

A further major finding was that when exposing AT2-receptor deficient mice to disease models such as myocardial infarction, stroke, or kidney disease, the course of disease was more severe in these animals compared to wildtype mice, indicating that the protective actions mediated by the AT2-receptor constitute a kind of endogenous tissue protection and repair system.

Although it would have been a logical next step to take advantage of such a protective system for therapeutic purposes, this idea only really developed with the synthesis of the first selective, non-peptide AT2-receptor agonist Compound 21 (C21) by Prof. Anders Hallberg’s group at the University of Uppsala, Sweden, in 2004. Using this agonist, the tissue protective properties of the AT2-receptor could be confirmed in a wide variety of disease models.



Moreover, availability of a selective agonist with drug-like properties changed the perception of the AT2-receptor from a receptor of academic interest to a potential future drug target.

For a basic researcher and pharmacologist like me, it is probably the most exciting thing that can happen during one’s professional life to see an idea progress from early explorative experiments in cell culture to entering of clinical drug development. C21 has successfully past the first steps of clinical development and will hopefully become a future therapeutic option for patients with devastating diseases, such as idiopathic pulmonary fibrosis, pulmonary arterial hypertension or stroke.

## **Ulrike Steckelings**

*M.D., Ph.D. Professor in Integrative Pharmacology,  
University of Southern Denmark, Odense, Denmark  
Scientific Adviser in Vicore Pharma*

***“ The most exciting thing that can happen during one’s professional life is to see an idea progress from early explorative experiments in cell culture to entering of clinical drug development”***

# VICORE PHARMA HOLDING OPERATIONS

## OPERATIONS AND FOCUS

Vicore Pharma Holding AB (publ) is since December 2015 listed on Nasdaq First North and is the parent company of a group whose main activity is the wholly owned subsidiary Vicore Pharma AB. For more than ten years, Vicore Pharma AB is engaged to develop a new type of drugs, known as AT2 agonists. Extensive preclinical studies show, among other things, the general anti-inflammatory, antifibrotic and anti-proliferative properties which counteract diseases where there is a need for organ and tissue protection.

AT2 agonists may be applied clinically in a variety of disease areas where acute or chronic diseases have caused organ damage. Together with academic researchers, Vicore Pharma has carried out an extensive preclinical work on its lead drug candidate C21, with the aim of identifying diseases where C21 can improve the condition of patients, compared with current drugs.

Several indications have been evaluated in order to identify an area where there is significant commercial potential and preconditions to conduct clinical trials at a manageable cost. Vicore Pharma selected idiopathic pulmonary fibrosis (IPF) as the first indication for the clinical development of C21.

IPF is a fatal lung disease for which, at present, there are no healing treatments. IPF falls within the framework of so-called orphan drugs, which means among other aspects that the technology will receive exclusive marketing rights for a number of years, regardless of patents; the company is supported by the authorities for the development of clinical protocols; and allows it only needed limited clinical studies to be able to demonstrate clinical effectiveness. Vicore Pharma has received Orphan Drug Designation (ODD) for IPF in the EU and the US.

## BUSINESS STRATEGY

The company's main strategy is to use C21 for diseases with orphan drug status. In parallel with the clinical study, Vicore Pharma will seek additional development partners for C21 for other indications. One possibility for the company is at an early phase to enter into a license agreement with specialist pharma companies for smaller indications where orphan drug status can be obtained. A license may consist of a lump sum payment, payments based on clinical and regulatory development stage, as well as compensation when a finished product reaches certain sales. In addition, a royalty payment follows when the substance reaches the market.

## SELECTED PUBLISHED STUDIES WITH C21 DURING THE YEAR

- Sumners et al; Stroke in aged rats: <https://www.ncbi.nlm.nih.gov/pubmed/27754218>
- Chow et al; Diabetes-associated atherosclerosis: <https://www.ncbi.nlm.nih.gov/pubmed/27168137%20>
- Liu et al; Activation of Angiotensin Type 2 receptors protects pancreatic islet function in obese rats induced by high-fat diet. Poster ADA June 2016
- Ermis et al; Heart protection during chemotherapy; European Heart Journal (2016) 37 (abstract supplement), 1318, Abstract P6347
- Mateos et al; VEGF synthesis after cerebral ischemia: <https://www.ncbi.nlm.nih.gov/pubmed/27045356>
- Gallego-Delgado et al; AT-receptors in malaria: <https://www.ncbi.nlm.nih.gov/pubmed/27643439>
- Nakaoka et al; Vascular remodeling: <https://www.ncbi.nlm.nih.gov/pubmed/27597242>
- Bai et al; Synergistic effects with rosuvastatin: <https://www.ncbi.nlm.nih.gov/pubmed/27225894>
- Castoldi et al; Reduction of cyclosporine nephropathy: <https://www.ncbi.nlm.nih.gov/pubmed/27679859>
- Patel et al; Nephroprotection in rats on high salt diet: <https://www.ncbi.nlm.nih.gov/pubmed/27021008>
- Kemp et al; Prevention of sodium retention in Ang-II dependent hypertension: <https://www.ncbi.nlm.nih.gov/pubmed/27323774>
- De Kloet et al; AT2-receptors and vasopressin neurons: <https://www.ncbi.nlm.nih.gov/pubmed/27267713>
- Sampson et al; Effects on endothelial inflammation: <https://www.ncbi.nlm.nih.gov/pubmed/25560767>
- Balia et al; Effects on tissue factor in vitro: <https://www.ncbi.nlm.nih.gov/pubmed/27152091>
- Kukida et al; Effects on intima proliferation: <https://www.ncbi.nlm.nih.gov/pubmed/26471325>
- Dai SY et al; Attenuation of DOCA/NaCl-induced hypertension ; <https://www.hindawi.com/journals/omcl/2016/3981790/>
- Caillon et al; AT2-receptors, outward remodeling and IL-17 production: <https://www.ncbi.nlm.nih.gov/pubmed/27328880>

## THE RENIN-ANGIOTENSIN-SYSTEM (RAS)

Vicore Pharma owns patented pharmaceutical substances with effects of the so-called Renin-Angiotensin System (RAS). RAS is a central system of the body to regulate blood pressure and salt balance. More recently, it has also been observed that RAS affects the immunological response in the body. Pharmaceutical substances that in different ways interfere in the system have been around since the mid-1980s and are today a cornerstone in the treatment of cardiovascular diseases.

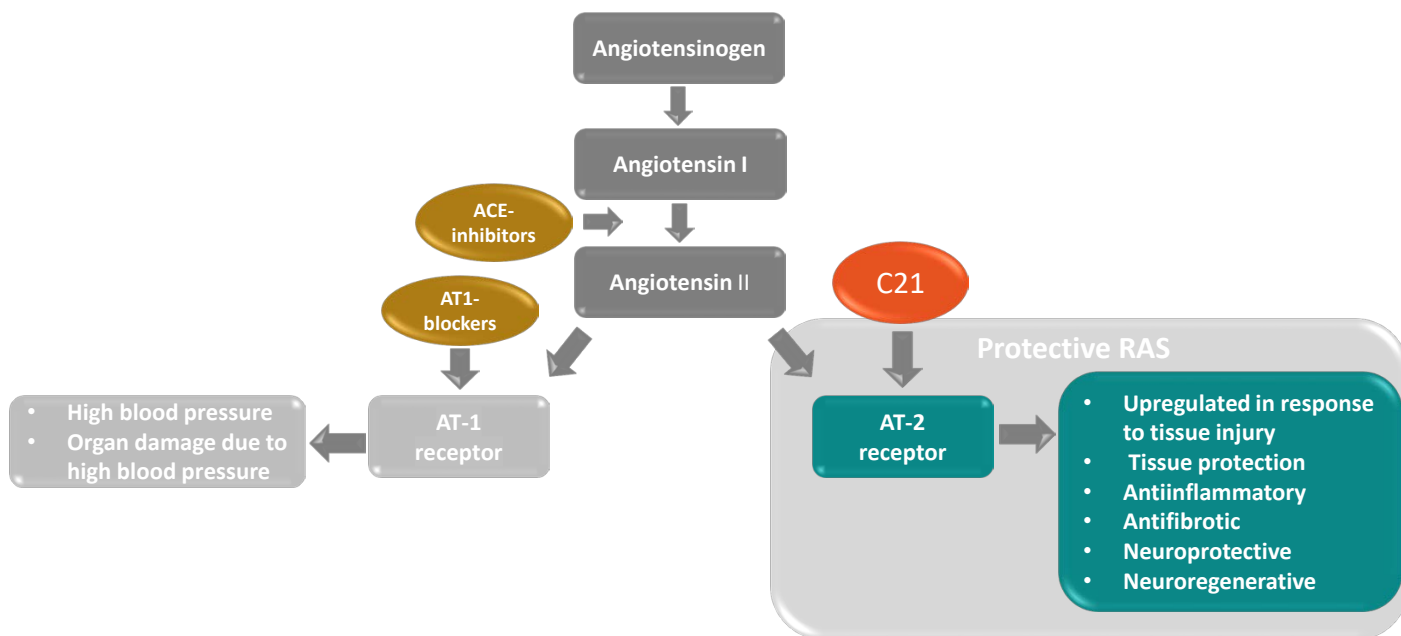
Since the late 1980s, researchers know that angiotensin II affects two different types of receptors on the cells, where the type 1 receptor mediates the negative effects for humans of angiotensin II effects (hypertension). Medications that block the AT1 receptor have proven very effective as blood pressure depressants and are relatively free of side effects. Some of the drugs that block the AT1 receptor was among the most profitable drugs in the world before they went out of patent a few years ago.

When stimulated, the Type 2 receptor can strongly contribute to beneficial effects in conditions where inflammation and/or fibrosis are essential features of pathology. Re-

searchers have therefore long since been looking for substances that can stimulate the type 2 receptor and act as a drug for oral use. With C21, Vicore Pharma is the first company such drug. C21 stimulates the AT2 receptor and thereby initiates a series of processes that contribute to inhibiting the disease process. With IPF, there is a continuous remodelling of lung tissue to tissue fibrosis.

Doctors have tried to treat the disease with many types of drugs that, for instance, inhibit inflammation or the increased blood pressure in the heart-lung circulation. These attempts have not been able to improve the situation for patients. The strength of AT2 stimulation and thus C21 is to attack the disease from several different directions at once; the inflammation is inhibited, the fibrotisation is inhibited, the elasticity of the surrounding blood vessels is improved and premature cell death is inhibited. The combined effect of the concept thus offers a much stronger response to the disease than narrow concepts that affect limited parts of the disease panorama. It is scientifically proven that the expression of the AT2 receptor is significantly increased in the lungs affected by IPF. All of this taken together, Vicore Pharma therefore views this disease as an appropriate first indication of C21.

### THE RAS-SYSTEM



*Angiotensinogen* is a plasma protein that is produced in the liver. During the catalysis of the renin released from the kidneys when the perfusion of the renal tissue decreases, angiotensinogen splits into *angiotensin I*. This is part of the body's blood pressure regulation. Angiotensin I proceeds to split into the biologically active *angiotensin II* that controls blood pressure and volume in the cardiovascular system. *ACE inhibitors* are drugs that lower blood pressure and reduce morbidity and mortality during heart failure by inhibiting the enzymatic conversion of angiotensin I to angiotensin II. *AT1 receptor* is known as the receptor that regulates blood pressure. *AT1 blockers* are, in recent years well-known drugs for lowering of blood pressure. *AT1-blockers* also reduces morbidity and mortality during heart failure. *AT2 receptor* is highly expressed in the embryonic stage. In adults, the receptor is active only for various conditions. *C21* effects the AT2 receptor by enhancing the healing effect when incurred medical conditions where AT2 receptor is activated



## IDIOPATHIC PULMONARY FIBROSIS (IPF)

This relatively rare disease is characterized that the alveoli (the small air bubbles in the lungs) and lung tissue adjacent the alveoli are damaged. The disease is aggravated by an incorrect healing process, causing thickening and damage to the walls of the alveoli, and that fibrosis (scarring) of the alveoli and lung tissue occurs. Scarring occurs progressively and gradually impairs lung function. The disease is fatal and the survival is 2-3 years from diagnosis.

IPF usually affects people aged 60 to 70 years. According to US statistics, the prevalence is up to 40 cases per 100,000. More men than women are affected, and the disease is increasing. Until a few years ago, there were no specific drugs for IPF registered, but in 2010 Pirfenidone was registered in Europe and four years later in the US. Also in 2014, Nintedanib was registered in the EU and the US. Both drugs have shown that they can slow the progression of the deterioration of lung function compared with untreated patients. They have not yet been able to show that they have improved survival or quality of life of affected patients.

In 2016, these drugs sold for a total of about 1.2 billion US dollars, and they increase in sales. The market for IPF preparations in recent years has attracted quite a lot of interest from the pharmaceutical industry due to the large treatment need and that there have been several successful licensing deals in the area.

## OTHER PROJECTS

The company's focus is on the further development of C21 against IPF. However, there are several other areas of orphan drug indications that are interesting and in which pre-clinical studies have demonstrated promising results. These include pulmonary arterial hypertension (PAH), spinal cord injury and renal failure in sickle cell anaemia. These are

very serious diseases and conditions that currently lack effective treatments. Today Vicore Pharma supports some preclinical research in these areas, particularly with regulatory support and access to substance.

Vicore Pharma's new generation of molecules that potentially results in new substance patents means that the company can also consider diseases that are much more resource and time consuming than orphan drug diseases, which today is the focus of the company's development towards a finished drug. These potential diseases include diabetes, rheumatoid arthritis and heart failure. Here, C21 has shown impressive data in preclinical trials, but where prospective licensees require longer patent protection than C21 can offer.

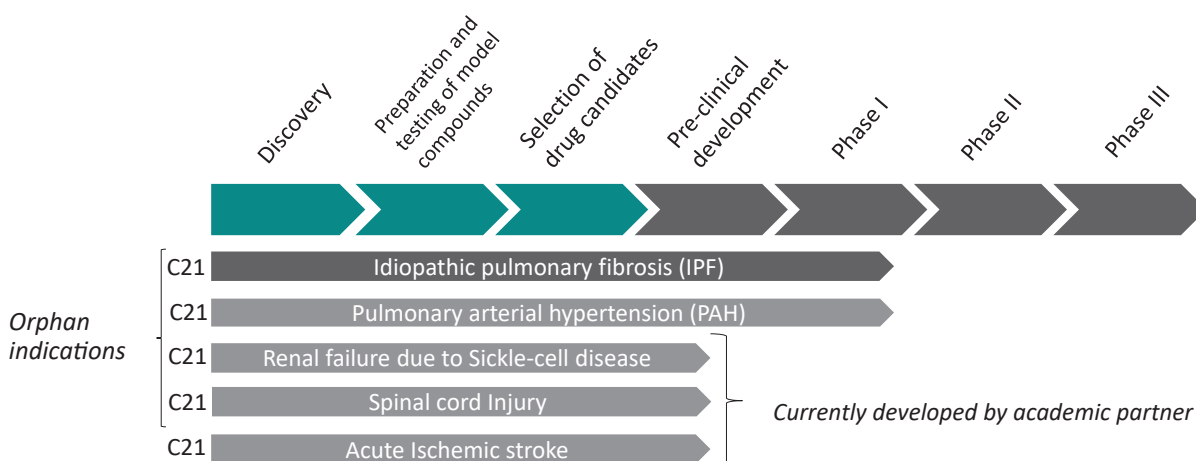
## I-TECH, FINANCIAL ASSET

In addition, Vicore Pharma Holding owns 16.5 percent in I-Tech AB who commercializes Selektepe®, a substance that prevents fouling of boat and ship hulls and marine installations as an critical ingredient in antifouling paints.

Selektepe is used in antifouling paints, and the first commercial paint containing Selektepe was launched in Japan in spring 2015. In autumn 2015, Selektepe received the final approval from EU's body for biocide products (BPR). The EU approval was an important milestone and a seal of quality that Selektepe meets EU's tough requirements for biocidal products. In addition, Selektepe was also approved in China, Japan and South Korea, which together cover more than 80% of the commercial markets for fouling paints for ships and marine installations.

In 2016, sales of Selektepe grew markedly when the company's first customer Chugoku Marine Paints launched two commercial so called antifouling paints for the international market, as well as two domestic products for Japan.

## PIPELINE





**USA**

- University of Florida, Gainesville (stroke, PAH)
- University of Virginia (renal)
- University of Texas (metabolism)
- University of Georgia (stroke)
- University of Nebraska (cardiac)
- University of Iowa (muscular dystrophy)
- University of Cincinnati (sickle-cell disease)

**CANADA**

- Montreal (cardioprotection)
- Dalhousie University, Halifax (wound healing)
- McGill University, Montreal (AD)

**ARGENTINA**

- University of Buenos Aires (glucose and insulin)

**BRAZIL**

- University of Goias (high sodium intake)
- University of Sao Paulo (AT2-receptor mechanisms)

**UNIVERSITIES PERFORMING RESEARCH ON C21**

The interest for C21 is huge and there are more than 200 universities performing research on C21 within different indications (pre clinic). See the map.

**ITALY**

- University of Milano (renal)
- University of Padua (effects on aldosterone)

**SLOVAKIA**

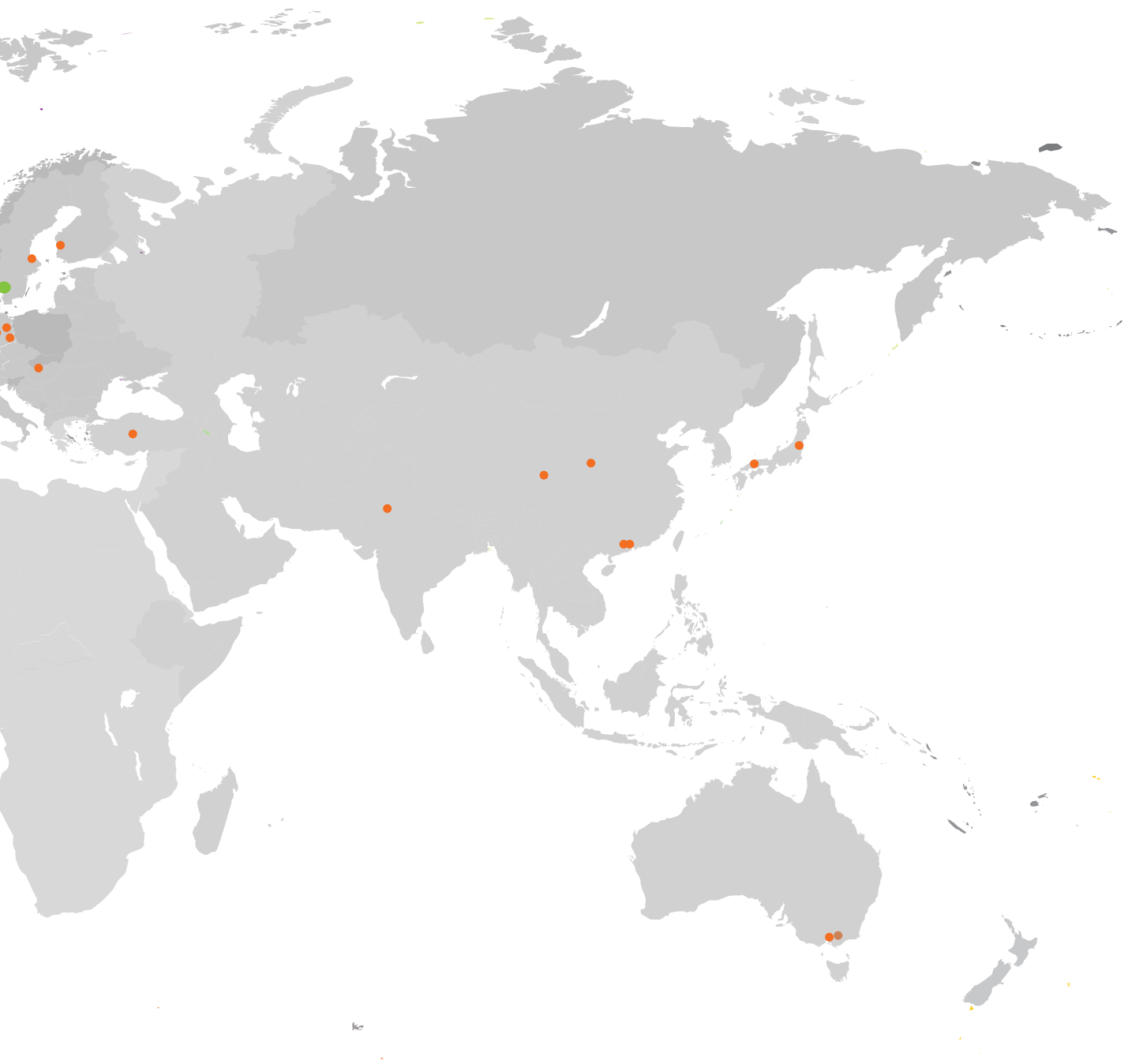
- University of Bratislava (vascular)

**BELGIUM**

- University of Leuven (aneurysms)
- University of Brussels (central blood pressure regulation)

**FRANCE**

- INSERM, Paris (cancer)
- University of Limogés (pain)
- University of Angers (vascular, immunology)



## RESEARCHING RESEARCH ON C21

More than 80 universities and hospitals doing research with some of the more notable are mentioned below.

### SWEDEN

University of Uppsala (chemistry, MS)

### DENMARK

University of Odense (vascular, stroke, NMO, signaling)

### GERMANY

University of Regensburg (renal)

Aachen university (vasoactive mechanisms)

### FINLAND

University of Turku (Clinical Phase I)

### HOLLAND

University of Maastricht (spinal cord, vascular)

### SPAIN

University of Madrid (stroke)

University of Santiago de Compostela (parkinson)

### UK

University College of London (UCL) (PF, Clinical development)

### AUSTRALIA

Baker Institute, Melbourne (diabetic complications)

Monash university, Melbourne (gender differences)

### JAPAN

University of Ehime (stroke, diabetes)

University of Yokohama (cancer)

### CHINA

University of Hong-Kong (stem-cells and re-generation)

PLA hospital, Beijing (pancreas)

# THE SHARE AND SHAREHOLDER STRUCTURE

## THE SHARE

Vicore Pharma Holdings shares were listed on Nasdaq First North on December 10, 2015, with the ticker VICO and ISIN SE0007577895. As of December 31, 2016, the number of shareholders was approximately 1,000 and the total number of shares was 12,368,504. The market capitalization on December 31 amounted to SEK 272,107,088 (price 22 SEK). The company's shares are issued in one class of shares and each share carries one vote at the General Meeting.

## CERTIFIED ADVISER

Vicore Pharma Holding has engaged Redeye as the Certified Adviser on Nasdaq First North.

## PROPOSAL FOR THE DISTRIBUTION OF RESULTS

The Board of Directors will propose that no dividend be paid for the year 2016.

## SHARE ISSUES

Vicore Pharma Holding did not perform any share issues during 2016.

## THE LARGEST SHAREHOLDERS

During 2017, two directed share issues have been performed where of the later one is under registration at the Swedish Companies Registration Office (Bolagsverket). Below list shows the largest shareholders after both share issues have been registered.

Shareholder	Number of shares	%
Protem Wessman incl. private	2 621 137	17%
Pomona-gruppen AB	1 705 830	11%
Mikael Lönn	1 559 470	10%
HBM Healthcare Investments (Cayman) Ltd	1 200 000	8%
Kjell Stenberg	1 148 478	7%
Eriksam Invest AB incl private	607 010	4%
Unionen	600 000	4%
AFA Försäkring	585 000	4%
BD Medical consulting AB	340 000	2%
Other (ca 1000 aktieägare)	5 501 579	35%
<b>Total number of shares</b>	<b>15 868 504</b>	<b>100%</b>

## DEVELOPMENT OF SHARE CAPITAL

Year	Event	Quota Value	Increase in number of shares	Increase in share capital	Total number of shares	Total share capital
2005	Formation	100	1 000	100 000,00	1 000	100 000
2008	Bonus Issue	100	4 601	460 100,00	5 601	560 100
2008	Breakdown of shares 1:2000	0,05	11 196 399	-	11 202 000	560 100
2008	Share issue	0,05	688	34,4	11 202 688	560 134
2010	Share issue	0,05	5 601 344	280 067,20	16 804 032	840 202
2010	Share issue	0,05	5 601 344	280 067,20	22 405 376	1 120 269
2010	Set-off issue	0,05	1 000 000	50 000,00	23 405 376	1 170 269
2011	Share issue	0,05	10 402 389	520 119,45	33 807 765	1 690 388
2012	Set-off issue	0,05	474 498	23 724,90	34 282 263	1 714 113
2013	Share issue	0,05	34 282 263	1 714 113,15	68 564 526	3 428 226
2015	Share issue	0,05	12 639 073	631 953,65	81 203 599	4 060 180
2015	Reversed split 1:10	0,50	-73 083 239	-	8 120 360	4 060 180
2015	Share issue/IPO	0,50	3 248 144	1 624 072	12 368 504	5 684 252
2017	Share issue	0,50	2 000 000	1 000 000	14 368 504	7 184 252
2017	Share issue*	0,50	1 500 000	750 000	15 868 504	7 934 252

\* Under registration at the Swedish Companies Registration office

# BOARD, MANAGEMENT AND AUDITOR



## GÖRAN WESSMAN

Chairman since 2013.

**Born:** 1948

**Holdings in the Company:** 2,621,137 shares (incl.companies and related parties)

Göran has over twenty years' experience in management positions in pharmaceutical and medical device companies, as well as from the CRO business area of clinical research. Göran has held senior leadership positions at Nobel Biocare, Boule Group and Carmel Pharma.

**Other assignments:** Board member of ITIN Holding AB, I-Tech AB, Vicore Pharma AB (chairman), Protém Wessman AB (Chairman) and Protém Företagsförvaltning AB.



## KJELL STENBERG

Board member since 2010.

**Born:** 1946

**Holdings in the Company:** 1,148,478 shares

Kjell has extensive board experience in a large number of companies that are active across a range of industries.

**Other assignments:** Board member of WntResearch AB, Kjell Stenberg AB and CN Stenberg AB.



## PETER STRÖM

Board member since 2015.

**Born:** 1952

**Holdings in the Company:** 84 000

Peter Ström has an MBA from the Stockholm School of Economics. He has held senior positions at companies including KabiPharmacia UK (CEO) and IMSHealth Europe (VP).

**Other assignments:** Chairman of WntResearch AB. Board member of Stockholm Corporate Finance AB, Dentosystem Scandinavia AB. Deputy board member of Comtax Support Limited.



**LEIF DARNER**

Board member since 2016

**Born:** 1952

**Holdings in the Company:** 30,000 shares

Leif is the owner of consulting firm Darner Asset Management AB. Prior to this, he was an Executive Director on the Board of Management at AkzoNobel, where he was responsible for Performance Coatings from 2008 and for Chemicals from 2004.

**Other assignments:** Board member of Flowserve Corporation, Dallas, US, LKAB AB, Sweden, and I-Tech AB.



**PER JANSON**

CEO since 2013. Also CEO of Vicore Pharma AB.

**Holdings in the Company:** 155,097 shares. 150,000 share option rights

Per is a trained dentist and has more than 20 years' business experience in the life science sector. Nobel Biocare is one of many companies that he has worked for, and for some years he was CEO of a venture-funded medical device company which was successfully sold to a major American company. Since 2004, Per has been linked to the group that evolved into Vicore Pharma Holding, and Per also led operations in I-Tech until 2013. Since 2007, he has held the position of Managing Director of Vicore Pharma.

**Other assignments:** Chairman of the Board in Taurys Energy AB

**AUDITOR**

The company's auditor is Ernst & Young AB, Parkgatan 49, 401 82 Gothenburg. Auditor in charge is Mr Stefan Kylebäck, chartered accountant.

# **ANNUAL REPORT AND CONSOLIDATED ACCOUNTS**

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# BOARD OF DIRECTORS REPORT

The annual accounts are prepared in KSEK.

## BUSINESS CONCEPT & OVERVIEW

Vicore Pharma Holding AB (publ), corporate identity number 556680-3804, is the parent company of the Group. The group's operations are conducted primarily in the subsidiary Vicore Pharma AB and consists of drug development. The parent company's operations consist primarily of finance and administration. Vicore Pharma Holding's profit for the year amounted to SEK-2.2 million (-1.9). The parent company's liquid assets at the end of the period to SEK 3.1 million (24.9). The equity of the parent company at year end was 78.2 million (80.1) and the equity ratio was 97.71% (93.93%).

Vicore Pharma Holding AB (publ) has today three holdings, the wholly owned subsidiaries Vicore Pharma AB (100%) and ITIN Holding Ltd (100%) which is a dormant company and a financial asset, I-Tech AB (16.50%)

The company's registered office is Västra Götaland Mölndal.

## BRIEF DESCRIPTION OF VICORE PHARMA

For more than ten years, Vicore Pharma AB has developed a new type of pharmaceutical substances known as AT2 agonists. Extensive preclinical studies show, among other things, general anti-inflammatory, antifibrotic and antiproliferative properties which counteract diseases where there is a need for organ and tissue protective properties.

AT2 agonists may have a clinical application in a variety of disease areas where acute or chronic diseases have caused organ damage. Vicore Pharma has developed a drug candidate, C21, and has conducted extensive preclinical work together with academic researchers, with the aim of identifying diseases where C21 can improve the condition of patients compared with current drugs.

## CLINICAL TRIALS

Several indications have been evaluated in order to identify an area where there is significant commercial potential, as well as conditions to conduct clinical trials at a manageable cost. Vicore Pharma has selected idiopathic pulmonary fibrosis (IPF) as the first indication for the clinical development of C21. IPF is a fatal lung disease for which at present, there are no effective treatments. IPF is viable for a so-called orphan drug designation (ODD), which means that the technology will receive exclusive marketing rights for a number of years, regardless of patents; the company is

supported by the authorities for the development of clinical protocols; and only limited clinical studies are needed to be able to demonstrate clinical effectiveness. Vicore Pharma has received an ODD for IPF in the EU and the US.

## NEW DRUG MOLECULES

Vicore Pharma expands its portfolio with novel drug molecules based on their lead candidate C21. The new drug molecules may supplement C21 for diseases outside the orphan drug area where the company has strong preclinical data with C21, e.g. in heart/cardiovascular medicine, diabetes and nephrology. By applying the new molecules exhibiting similar biological properties to C21, much of the results that were previously demonstrated are expected for the newly developed drug molecules. A patent application was filed in January 2017.

## ONGOING AND COMING CLINICAL STUDIES

In 2016, Vicore Pharma carried out the first studies in humans in collaboration with the Åbo, Finland based clinical CRO company, CRST. The first two investigations were safety studies, where increasing doses of C21 were given to healthy subjects, first in single doses and then in repeated doses. The aim was to ensure that the C21 is safe and well tolerated. To prepare for future clinical studies, the concentration of C21 in the blood was also measured at different times, as well as how C21 is broken down and excreted. The conclusions of the first two studies show that the C21 has been well tolerated with no serious side effects and with an acceptable degradation profile.

With the positive results of the first two studies, an additional clinical study in overweight people is right now performed to examine if biomarkers in the blood change with the dosing of C21. The biomarkers may be of interest for future studies on metabolism and diabetes that have no direct link to the IPF, which is the company's leading indication. Looking ahead, Vicore Pharma is preparing for a longer toxicity study, interaction studies and a conceptual clinical study in diabetes. During 2017, a Phase Ib trial for IPF is planned to start.

## PATENT SITUATION

Patents and patent applications in Vicore Pharma's patent portfolio currently consist of seven patent families, substance and user families. The assessment is that it has a strong patent protection for the development plan which the company follows.



## BRIEF DESCRIPTION OF I-TECH AB

Fouling of especially barnacles on the boat and ship hulls is a major problem in the shipping industry, with high costs and inconvenience to the marine industry and recreational boat owners. I-Tech has developed Selektope® as a anti-fouling technology based on medetomidine. The company has patented Selektope as an antifouling agent. Selektope seems efficient already at much smaller doses compared to the amount of copper required to obtain a corresponding antifouling effect.

Selektope is used in antifouling paints, and the first commercial paint containing Selektope was launched in Japan the spring of 2015. In autumn 2015, Selektope received the final approval from EU's body for biocide products (BPR). The EU approval was an important milestone and a seal of quality that Selektope meets EU's tough requirements for biocidal products. In addition, Selektope is also approved in China, Japan and South Korea, which markets together cover more than 80% of the global commercial markets for fouling paints for ships and marine installations.

In 2016, sales of Selektope grew markedly when the company's first customer Chugoku Marine Paints launched two commercial so called antifouling paints for the international market, as well as two domestic products for Japan.

### Multi-year comparison\*, group

	2016	2015	2014	2013	2012
Net sales	852	840	851	2 585	2 594
Profit/loss after financial items	-6 652	-4 570	13 687	-1 603	-3 158
Balance sheet total	81 650	89 225	59 368	50 980	38 337
Equity-assets ratio (%)	92,58	91,82	90,44	78,5	68,5

\*For definitions of key ratios, please see notes

### Multi-year comparison\*, parent

	2016	2015	2014	2013	2012
Net sales	2 804	2 299	2 292	4 080	4 080
Profit/loss after financial items	-2 231	-1 967	3 110	185	-86
Balance sheet total	80 017	85 267	52 873	54 853	39 329
Equity-assets ratio (%)	97,71	93,93	93,16	84,1	78,8

\*For definitions of key ratios, please see notes

## OWNERSHIP CONDITIONS

The major shareholders of Vicore Pharma Holding on December 31, 2016, were Prottem Wessman AB, 21.2%, Pomona-gruppen, 13.8%, Mikael Lönn 12.6%, and Kjell Stenberg 9.3%.

## IMPORTANT EVENTS DURING THE FINANCIAL YEAR

- Private placement of 570,000 warrants were carried out in January
- Phase I trials began in April and was completed in November
- At the AGM in April, Leif Darner was appointed a new Board member
- The holding in the financial asset I-Tech increased by 312,500 shares in a rights issue in July
- In August, Vicore Pharma received orphan drug status in Europe for idiopathic pulmonary fibrosis (IPF)
- Klas Malmberg was recruited to the position of Senior Medical Advisor. The service was transferred in November to the Chief Medical Officer (CMO)

## WARRANTS

Vicore Pharma Holding has issued 570,000 warrants to key employees and key researchers. Due date for these is January 3, 2020.

## THE SHARE

Vicore Pharma Holdings shares were listed on Nasdaq First North on December 10, 2015, with the ticker VICO and ISIN SE0007577895. As of December 31, 2016, the number of shareholders was approximately 1,000 and the total number of shares was 12,368,504. The market capitalization on December 31 amounted to SEK 272,107,088 (price 22 SEK). The company's shares are issued in one class of shares and each share carries one vote at the General Meeting.

## THE COMPANY'S FUTURE DEVELOPMENT

Vicore Pharma Holding had at year-end 2016 SEK 3.1 million in cash. In January 2017 the company raised an interest-free loan from Capital Recall of SEK 2.4 million, which is then repaid with shares. A short-term loan of SEK 5 million was taken up in February and repaid in March. The company completed two directed share issues in March, which yielded a total of SEK 56 million before issue costs. The Board and the CEO assess that existing funds are expected to take C21 until Phase 1b studies for the chosen indication..

## RESEARCH AND DEVELOPMENT

In 2016, the company conducted pharmaceutical development activities through its wholly owned subsidiary Vicore Pharma AB. This is done through the purchase of services, approximately SEK 12,397,000. Patent costs have been capitalised with SEK 1,080,000.

## PERSONELL

As of December 31, 2016, The number of employees amounted to 2 people in the parent company. The subsidiary Vicore Pharma had at the end of the year 3 employees. In addition, consultants were hired by Vicore Pharma for specific tasks during the year.

## CORPORATE GOVERNANCE

Vicore Pharma Holding's governing bodies consist of the General Meeting, the Board, CEO and auditors, and is based on Swedish law, internal rules and regulations, Articles of Association and the Nasdaq Stockholm First North's rules for issuers. Since Vicore Pharma Holding's stock is traded on Nasdaq Stockholm First North, there is no obligation for the company to apply the Swedish Code of Corporate Governance.

## THE BOARD

The Board held 14 minutes meetings during the fiscal year 2016. Issues that were discussed include strategy, investment issues, financing, financial statements and interim reports, warrants, information and communication. The Board receives regular reports on its financial position. During the year, Leif Darner was appointed new Board member.

## RISK FACTORS RELATED TO THE COMPANY AND THE INDUSTRY

### *Financing and capital*

Vicore Pharma's expansion and marketing activities will result in increased costs. Delays in market launch may in the future result in lost revenue. It is likely that the company in the future may need to raise additional capital.

### *Profitability*

Until today, Vicore Pharma has not generated any significant revenues. There is a risk that the company may never reach a positive cash flow, which would mean the continued financing and the associated risks and consequences, see the paragraph above.

### *Key individuals and employees*

Key people at Vicore Pharma possess high competence and long experience in their respective fields of activity. The loss of one or more of these key personnel could have negative implications for the company's operations and performance in terms of delays in the execution of the business plan and loss of income.

### *Development costs*

Vicore Pharma plans to continue to develop C21. Time and cost aspects of drug development are difficult to determine in advance with accuracy. This entails the risk that a proposed development will be more costly than expected, which could result in additional financing needs and delayed or lost revenue.

### *Patent*

Vicore Pharma has a number of patents within its field. Patents may always be questioned by others, and there is a risk that these patents will not constitute an adequate commercial protection in the future. The term "adequate" here refers to the protection that makes it impossible for competitors to any way infringe on Vicore's intellectual property rights. If the commercial protection in the future does not appear to be adequate, it can lead to lower or completely lost revenues.

Furthermore, there is a risk that the patent applications currently pending approval will not be approved and thereby impair the prerequisites for the company to reach an adequate commercial protection.

There is a risk that Vicore Pharma's existing patents are subject to patent infringement from other players. If Vicore Pharma is forced to defend its patent rights, this can lead to significant legal expenses. Furthermore, there is a risk that if Vicore Pharma unknowingly was to use meth-

ods or substances that are patented by another player, the owner of these patents may accuse the company of patent infringement. This can lead to delays in the company's business plan and, at worst, damage claims against the company.

### **Competitors**

Some of Vicore Pharma's competitors are large pharmaceutical companies, biotech companies and academic institutions. A number of Vicore Pharma's competitors currently have an approved, fully developed drug in the same or related applications as Vicore Pharma focuses on. There is a risk that a competitor manages to develop a similar and/or a more secure product than Vicore Pharma. If this product is manufactured and marketed effectively, it can have significant negative effects on Vicore Pharma's sales and earnings.

### **Clinical trials**

Obtaining regulatory approval of a drug does mean several successful trials in different phases. These phases include implementation of preclinical and clinical trials in order to determine the drug's safety and efficacy. There is a risk that clinical trials on humans are not consistent with results from preclinical trials. Furthermore, the results obtained in early clinical trials in humans cannot always

predict what results will be achieved in later stage clinical trials. There is a risk that clinical trials will show that Vicore Pharma's compounds are not sufficiently safe or efficacious for obtaining a regulatory approval. If the substance would not obtain such approval, it would mean lost revenue opportunities for Vicore Pharma, which would lead to significant negative financial impact on the company.

### **The holding in I-Tech**

Vicore Pharma's long-term objective is to sell the holding in I-Tech. There is a risk that a sale of the shares in I-Tech cannot be done in the coming years, or that a sale cannot take place at an attractive price. Although I-Tech currently has a strong financial position, there is a risk that I-Tech in the future may require additional capital. There is a risk that a future capitalisation of In-Tech is made to conditions that are not favourable to Vicore Pharma. If not Vicore Pharma has the opportunity to participate in the capitalisation of In-Tech, there is a risk that the company's holding is diluted significantly.

### Changes in equity, group

	Share capital	Other restricted equity	Other non-restricted equity	Profit/loss for the year	Total non-restricted equity
Opening amount	6 184	76 306	-560	0	81 930
Paid options	0	319	0	0	319
Profit/loss for the year			-6 652	0	-6 652
Closing amount	<u>6 184</u>	<u>76 625</u>	<u>-7 212</u>	<u>0</u>	<u>75 597</u>

### Changes in equity

	Share capital	Other restricted equity	Other non-restricted equity	Profit/loss for the year	Total non-restricted equity
Opening amount	6 184	0	75 880	-1 967	73 913
Paid options	0	0	319	0	319
Appropriation of profit as resolved by the Annual General Meeting:			-1 967	1 967	0
Loss for the year				-2 231	-2 231
Closing amount	<u>6 184</u>	<u>0</u>	<u>74 232</u>	<u>-2 231</u>	<u>72 001</u>

### Appropriation of profit/loss

Proposed treatment of the company's profit

At the disposal of the general meeting:

profit brought forward	6 319 384
share premium reserve	67 913 205
loss for the year	<u>-2 231 183</u>
	72 001 406

The board of directors proposes the following:

to be carried forward	<u>72 001 406</u>
	72 001 406

For information about the company's earnings and financial position in other respects, please refer to the income statements, balance sheets and accompanying notes set out on next pages.

# INCOME STATEMENT

	Note	Consolidated		Parent company	
		2016-01-01 2016-12-31	2015-01-01 2015-12-31	2016-01-01 2016-12-31	2015-01-01 2015-12-31
<b>Operating income etc.</b>					
Net turnover	2	852	840	2 804	2 299
Own work capitalised		1 221	816	0	0
Other operating income		60	21	5	0
		<hr/>	<hr/>	<hr/>	<hr/>
		2 133	1 677	2 809	2 299
<b>Operating expenses</b>					
Other external expenses	3	-5 006	-3 360	-3 332	-2 021
Personnel costs	4	-3 770	-2 810	-2 444	-2 405
Depreciation and write-down of tangible and intangible assets		-6	-6	-6	-6
Other operating expenses		0	-44	0	-44
		<hr/>	<hr/>	<hr/>	<hr/>
		-8 782	-6 220	-5 782	-4 476
<b>Operating profit/loss</b>		-6 649	-4 543	-2 973	-2 177
<b>Profit/loss from financial items</b>					
Interest income from group companies		0	-0	0	0
Other interest income from group companies		0	0	745	237
Interest expense and similar profit/loss items		-3	-27	-3	-27
Interest expense to group companies		-0	0	0	0
		<hr/>	<hr/>	<hr/>	<hr/>
		-3	-27	742	210
<b>Profit/loss after financial items</b>		-6 652	-4 570	-2 231	-1 967
<b>Profit/loss for the year</b>		<hr/>	<hr/>	<hr/>	<hr/>
		-6 652	-4 570	-2 231	-1 967

# BALANCE SHEET

	Note	Consolidated		Parent company	
		2016-12-31	2015-12-31	2016-12-31	2015-12-31
<b>ASSETS</b>					
<b>Fixed assets</b>					
<b>Intangible assets</b>					
Capitalised expenditure for development and similar work	5	36 190	23 792	0	0
Patents	6	20 049	18 969	0	0
		<u>56 239</u>	<u>42 761</u>	<u>0</u>	<u>0</u>
<b>Tangible assets</b>					
Equipment, tools, fixtures and fittings	7	2	8	2	8
		<u>2</u>	<u>8</u>	<u>2</u>	<u>8</u>
<b>Financial assets</b>					
Participations in group companies	8	0	0	42 243	42 243
Receivables from group companies	9	0	0	26 936	10 155
Other securities held as fixed assets	10	20 610	20 110	6 981	6 481
		<u>20 610</u>	<u>20 110</u>	<u>76 160</u>	<u>58 879</u>
<b>Total fixed assets</b>		76 851	62 879	76 162	58 887
<b>Current assets</b>					
<b>Current receivables</b>					
Trade receivables		122	146	101	146
Receivables from group companies		0	0	431	672
Other receivables		223	973	29	527
Prepaid expenses and accrued income	11	188	52	175	52
		<u>533</u>	<u>1 171</u>	<u>736</u>	<u>1 397</u>
<b>Cash and bank</b>					
Cash and bank		4 266	25 175	3 119	24 983
		<u>4 266</u>	<u>25 175</u>	<u>3 119</u>	<u>24 983</u>
<b>Total current assets</b>		4 799	26 346	3 855	26 380
<b>TOTAL ASSETS</b>		<b>81 650</b>	<b>89 225</b>	<b>80 017</b>	<b>85 267</b>

## EQUITY AND LIABILITIES

Equity, group	Note	Consolidated		Parent company	
		2016-12-31	2015-12-31	2016-12-31	2015-12-31
Share capital		6 184	6 184		
Other contributed capital		76 625	76 306		
Other capital incl profit/loss for the year		-7 212	-560		
<b>Total equity, Group</b>		<b>75 597</b>	<b>81 930</b>		
<b>Equity, parent company</b>					
<b>Restricted equity</b>					
Share capital				6 184	6 184
				<u>6 184</u>	<u>6 184</u>
<b>Non-restricted equity</b>					
Share premium reserve				67 913	67 913
Profit or loss carried forward				6 319	7 967
Profit/loss for the year				-2 231	-1 967
				<u>72 001</u>	<u>73 913</u>
<b>Total equity, parent company</b>				<b>78 185</b>	<b>80 097</b>
<b>Provisions</b>					
	12				
Deferred tax liability		1 978	1 978	0	0
<b>Total provisions</b>		<b>1 978</b>	<b>1 978</b>	<b>0</b>	<b>0</b>
<b>Long-term liabilities</b>					
	13				
Liabilities to group companies		0	0	400	400
<b>Total long-term liabilities</b>		<b>0</b>	<b>0</b>	<b>400</b>	<b>400</b>
<b>Current liabilities</b>					
Trade payables		2 184	2 312	318	1 983
Current tax liability		86	126	64	122
Other liabilities		188	1 816	90	1 661
Accrued expenses and deferred income	14	1 617	1 063	960	1 004
<b>Total current liabilities</b>		<b>4 075</b>	<b>5 317</b>	<b>1 432</b>	<b>4 770</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>81 650</b>	<b>89 225</b>	<b>80 017</b>	<b>85 267</b>

# CASH FLOW ANALYSIS

	Note	Consolidated		Parent company	
		2016-12-31	2015-12-31	2016-12-31	2015-12-31
<b>Operating activities</b>					
Operating profit/loss		-6 649	-4 543	-2 973	-2 177
Adjustments for non-cash items, etc.	15	6	50	6	51
Interest received etc		0	0	745	237
Interest paid		-3	-27	-3	-27
<b>Cash flow from operating activities before changes in working capital</b>					
		-6 646	-4 520	-2 225	-1 916
<b>Cash flow from changes in working capital</b>					
Decrease(+)/increase(-) in accounts receivable		24	-54	286	606
Decrease(+)/increase(-) in receivables		614	-731	375	-481
Decrease(-)/increase(+) in accounts payable		-128	1 750	-1 665	1 846
Decrease(-)/increase(+) in current liabilities		-1 115	-127	-1 673	-289
<b>Cash flow from operating activities</b>					
		-7 251	-3 682	-4 902	-234
<b>Investing activities</b>					
Acquisition of capitalised expenditure for research etc.	5	-12 397	-4 684	0	0
Acquisition of concessions, patents, licences etc.	6	-1 080	-973	0	0
Loans granted during the year to group companies		0	0	-16 781	-8 955
Acquisition of long-terms securities	10	-500	0	-500	0
Sale of long-terms valuable document	10	0	0	0	0
<b>Cash flow from investing activities</b>					
		-13 977	-5 657	-17 281	-8 955
<b>Financing activities</b>					
Paid options		319	32 804	319	32 804
<b>Cash flow from financing activities</b>					
		319	32 804	319	32 804
<b>Change in cash and cash equivalents</b>					
Cash and cash equivalents at beginning of year		25 175	1 710	24 983	1 368
<b>Cash and cash equivalents at year-end</b>					
		4 266	25 175	3 119	24 983



# NOTES

## Not 1 Accounting policies

The annual report has been prepared in accordance with the Annual Accounts Act and general advice from the Swedish Accounting Standards Board BFNAR 2012:1 Annual accounts and consolidated accounts.

The policies are unchanged compared with the previous year.

### *Receivables*

Receivables are recorded in the amounts at which they are expected to be received.

### *Other assets, provisions and liabilities*

Other assets, provisions and liabilities are recorded at cost of acquisition unless otherwise stated below.

### *Revenue recognition*

Revenue is recorded at fair value of what has been received or will be received. Consequently the company records revenue at nominal value (invoice amount) if the payment is received in cash or cash equivalents directly on delivery. Deduction is made for discounts given.

### *Services*

Revenues from consulting services are recognised in revenue when the services are rendered.

### *Tangible fixed assets*

Tangible fixed assets are recorded at cost of acquisition less accumulated depreciation and any write-downs. The assets are depreciated on a straight-line basis over the estimated useful life, apart from land, which is not depreciated. The useful life is reviewed as at every balance sheet date. The following useful lives are applied:

	Number of years
Inventories, tools and machinery	5

### *Intangible fixed assets*

Intangible fixed assets are recorded at cost of acquisition less accumulated depreciation and any write-downs. The assets are depreciated on a straight-line basis over the estimated useful life. The useful life is reviewed as at every balance sheet date. Depreciation starts when respective project is fully developed and ready for launch. Ongoing projects are tested for impairment annually. This years impairment test shows that no impairment needs to be done.

### *Capitalisation of internally generated intangible fixed assets*

#### Capitalisation model

All costs arising during the research phase are recognised as they are incurred. All costs incurred during the development phase are capitalised when the following criteria are met; the company intends to complete the intangible asset and to use it or sell it and the company is able to use or sell the asset, it is technically feasible for the company to complete the intangible asset so that it can be used or sold and there are adequate technical, financial and other resources to complete the development and to use or sell the asset, it is probable that the intangible asset will generate future economic benefits and the company can reliably measure the expenditure attributable to the asset during its development.

The cost of acquisition includes personnel costs incurred in the development work.

### ***Leasing***

A finance lease is a lease that transfers substantially all the financial risks and rewards incidental to ownership of an asset from the lessor to the lessee. An operating lease is a lease that is not a finance lease.

### ***Lessee***

All leases are recognised as an expense on a straight-line basis over the lease term.

### ***Income tax***

Current tax is income tax for the current financial year that refers to the year's taxable earnings and the as yet unreported part of previous financial years' income tax.

Current tax is stated at the probable amount according to the tax rates and tax rules applicable on the balance sheet date.

Deferred tax assets referring to loss carry forwards or other unused tax credits are recognised to the extent it is probable that there will be sufficient future taxable profit against which the loss or credit carry forward can be utilised.

The company's deductible deficiency amounts to 13 497 ksek. No postponed tax claim have been booked.

### ***Consolidated accounts***

#### ***Subsidiaries***

Subsidiaries are companies in which the parent company directly or indirectly holds more than 50% of the voting rights or otherwise has a controlling influence. Control is the power to govern the financial and operating policies so as to obtain benefits. Accounting for business combinations is based on the entity approach. This means that the acquisition analysis prepared as of the date when the acquirer gains a controlling influence. From this point seen the acquirer and the acquiree as an accounting unit. The application of the device approach also means that all assets (including goodwill) and liabilities and revenues and expenses are included in their entirety also for partly owned subsidiaries.

Cost of the subsidiary is calculated as the sum of the fair value at the acquisition date of the assets plus incurred and assumed liabilities and equity instruments issued, expenditure that is directly attributable to the business combination and any additional consideration. The acquisition analysis establishes the fair value, with some exceptions, at the acquisition date of acquired identifiable assets and assumed liabilities and minority interest. Minority interest is measured at fair value at the acquisition date. From the date of acquisition are included in the consolidated financial statements of the acquired company's income and expenses, identifiable assets and liabilities and any goodwill or negative goodwill

#### ***Elimination of transactions between group companies and associated companies***

Intercompany receivables and liabilities, income and expenses and unrealized gains or losses arising from transactions between consolidated companies are eliminated in full. Unrealized gains arising from transactions with associates are eliminated to the extent of the consolidated holding in the company. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that there is any indication of impairment.

## NOTES TO FINANCIAL STATEMENTS

### Note 2 Intra-group purchases and sales

	Group		Parent company	
	2016	2015	2016	2015
Sales relating to group companies	-	-	1 440	1 440

### Note 3 Leases - operating lease lessee

	Group		Parent company	
	2016	2015	2016	2015
During the year the company's lease payments amounted to	360	260	360	260
Future minimum lease payments for non-cancellable leases, falling due for payment as follows:				
Within 1 year	68	311	68	311
Between 2 and 5 years	135	51	135	51
	<u>203</u>	<u>362</u>	<u>203</u>	<u>362</u>

### Note 4 Personnel

	Group		Parent company	
	2016	2015	2016	2015

#### **Average number of employees**

The average number of employees is based on hours worked related to normal working hours paid for by the company.

The average number of employees was	3,00	3,00	2,00	2,00
of whom women	2,00	2,00	1,00	1,00
of whom men	1,00	1,00	1,00	1,00

#### **Wages/salaries, remuneration etc.**

Wages/salaries, remuneration, social security costs and pension costs have been paid as follows:

Wages/salaries and remuneration	2 508	1 805	1 498	1 520
Pensions	354	283	283	266
Social security costs	796	654	598	563
Total	<u>3 658</u>	<u>2 742</u>	<u>2 379</u>	<u>2 349</u>

**Note 5 Capitalised expenditure for development and similar work**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Opening cost of acquisition	23 793	19 108		
Purchases	12 397	4 684	0	0
Closing accumulated cost of acquisition	36 190	23 792	0	0
Closing carrying amount	36 190	23 792	0	0
Assets acquired with government grants are included at reported cost of acquisition	2 871	2 871	0	0

**Note 6 Patents**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Opening cost of acquisition	18 969	17 996	0	0
Purchases	1 080	973	0	0
Closing accumulated cost of acquisition	20 049	18 969	0	0
Closing carrying amount	20 049	18 969	0	0

**Note 7 Equipment, tools, fixtures and fittings**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Opening cost of acquisition	60	199	60	199
Sales/retirements	0	-139	0	-139
Closing accumulated cost of acquisition	60	60	60	60
Opening depreciation	-52	-140	-52	-140
Sales/retirements	0	94	0	94
Depreciation for the year	-6	-6	-6	-6
Closing accumulated depreciation	-58	-52	-58	-52
Closing carrying amount	2	8	2	8

## Note 8 Participations in group companies

Parent company		2016-12-31		2015-12-31
Company	Registered Office	Number/Share Of equity, %	Book value	Book value
Vicore Pharma AB 556607-0743	Västra Götaland	10 000	41 743	41 743
ITIN Holding AB 556989-2143	Västra Götaland	100,00% 500 000	500	500
			<u>42 243</u>	<u>42 243</u>
<b>Disclosures on equity and profit/loss</b>		<b>Shareholders' equity</b>		<b>Profit/loss</b>
Vicore Pharma AB		18 325		-4 625
ITIN Holding AB		477		-7

## Note 9 Receivables from group companies

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Opening cost of acquisition	0	0	10 155	1 200
Additional	0	0	16 781	8 955
Closing accumulated cost of acquisition	<u>0</u>	<u>0</u>	<u>26 936</u>	<u>10 155</u>
Closing carrying amount	0	0	26 936	10 155

## Note 10 Other securities held as fixed assets

Group	2016-12-31		2015-12-31	
	Number		Number	
I-Tech AB	10 122 194	<u>20 610</u>	9 809 694	<u>20 110</u>
		20 610		20 110
Opening cost of acquisition		20 110		20 110
Purchases		<u>500</u>		<u>0</u>
Closing accumulated cost of acquisition		<u>20 610</u>		<u>20 110</u>
Closing carrying amount		20 610		20 110
Parent company	2016-12-31		2015-12-31	
I-Tech AB	10 122 194	<u>6 981</u>	9 809 694	<u>6 481</u>
		6 981		6 481
Opening cost of acquisition		6 481		6 481
Purchases		<u>500</u>		<u>0</u>
Closing accumulated cost of acquisition		<u>6 981</u>		<u>6 481</u>
Closing carrying amount		6 981		6 481

**Note 11 Prepaid expenses and accrued income**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
First elevated lease	68	4	68	4
Other prepaid expenses	120	48	107	48
	<u>188</u>	<u>52</u>	<u>175</u>	<u>52</u>

**Note 12 Provisions**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Deferred tax liability	1 978	1 978	0	0
	<u>1 978</u>	<u>1 978</u>	<u>0</u>	<u>0</u>

**Note 13 Long-term liabilities**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Repayment within 2 to 5 years	0	0	400	400

**Note 14 Accrued expenses and deferred income**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Personnel costs	834	532	591	540
Accrued interests	103	103	103	103
Consulting fees	634	112	220	112
Other accrued expenses	46	316	46	249
	<u>1 617</u>	<u>1 063</u>	<u>960</u>	<u>1 004</u>

**Note 15 Adjustment for non-cash items**

	Group		Parent company	
	2016-12-31	2015-12-31	2016-12-31	2015-12-31
Depreciation	6	6	6	6
Loss on sale of tangible and intangible fixed assets	0	44	0	44
	<u>6</u>	<u>50</u>	<u>6</u>	<u>50</u>

**Not 16**      **Important events after the end of the financial year**

- A loan agreement with Capital Recall that facilitates additional working capital was entered in January
- An additional study with the drug candidate C21 in a risk group was started in January
- A patent application for new drug molecules based on C21 was submitted in January
- Vicore Pharma received Orphan Drug Designation from the FDA for IPF in January
- On February 23, the Board took the decision of two directed issues. It was done with the authorisation from the Annual General Meeting 2016 of 2 million shares and partly provided by the Extraordinary General Meeting's subsequent approval of an additional 1.5 million shares, a total of about SEK 56 million. Both issues have now been completed and the second is under registration with the Swedish Companies Registration Office (Bolagsverket).
- C21 showed excellent properties in key markers in an in vitro study of pulmonary fibrosis that was presented on March 88

**Not 17**      **Definitions of business and financial ratios**

Equity-assets

Adjusted equity as a percentage of total assets.





# GLOSSARY

## **AGONIST**

A drug that has affinity for, and stimulates physiological activity, via cellular receptors that are normally stimulated by naturally occurring substances.

## **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 (AT1R) via Angiotensin II provides inter alia a contraction of the blood vessels and increases the blood pressure.

## **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.

## **AT2-RECEPTOR (AT2R)**

The Angiotensin II type 2 receptor or AT2R is regarded as the “protective” receptor of the renin-angiotensin system. Many effects seen after stimulation of the ATR counteracts effects mediated via the AT1 receptor thus counteracting cytokines and growth factors. The AT2R 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 I** is the first time that the drug is tested on humans. This is usually done on a small group (5-9 people) of healthy volunteers with normal weight who are always 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 II** 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 III** is carried out in a very large population (300-30,000) to conclusively define how suitable the drug is to treat the disease. This patient group should as far as possi-

ble 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 IV** 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.

## **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.

## **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.

## **RAS, 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 recognises 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, or biocide registration.

Möln dal 2017-04-06

Kjell Stenberg

Leif Darner

Per Jansson  
CEO

Göran Wessman

Peter Ström

Our audit report was submitted on April 6, 2017

Ernst & Young AB

Stefan Kylebäck  
Chartered Accountant

THIS IS A TRANSLATION FROM THE SWEDISH ORIGINAL

## Auditor's 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

#### Opinions

We have audited the annual accounts and consolidated accounts of Vicore Pharma Holding AB (publ) for the year 2016. The annual accounts and consolidated accounts of the company are included on pages 15 - 35 in this document.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2016 and their financial performance and cash flow for the year then ended in accordance with 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.

#### 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.

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

#### 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 1-64. The Board of Directors and the Managing Director 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. 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 intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

#### 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 consoli-

dated 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.

## Report on other legal and regulatory requirements

### Opinions

In 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 2016 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 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.

Gothenburg, April 6, 2017

Ernst & Young AB

Stefan Kylebäck  
Authorized Public Accountant



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