

INTERIM REPORT

JANUARI 1- MARCH 31, 2017

VICORE PHARMA HOLDING AB (PUBL)

# **SUMMARY OF THE PERIOD**

### **IMPORTANT EVENTS DURING THE FIRST QUARTER 2017**

- On February 23, the Board of Directors took a decision on two share issues. The resolution was taken based on an authorisation from the Annual General Meeting 2016 on 2 million shares and is partly conditional on a favourable decision in the Extraordinary General Meeting's subsequent approval for an additional 1.5 million shares. In total, around SEK 56 million was raised through the two share issues.
- Vicore Pharma received Orphan Drug Designation (ODD) from the US pharmaceutical agency, the Food and Drug Administration (FDA), for Idiopathic Pulmonary Fibrosis (IPF) in January.
- A patent application for new drug molecules based on the C21 was submitted in January.

- An additional clinical study with the Drug Candidate C21 in a metabolic risk group was started in January. The results from the study are due for reporting during june or july 2017 which is a little bit later than earlier communicated but since it is a stand-alone study the delay will not affect the clinical programme.
- C21 showed strong effects on key biomarkers in an in-vitro study of pulmonary fibrosis with human cells presented on March 8.
- A loan agreement with Capital Recal that facilitated extra working capital was entered into in January. The deal brought in 2,4 MSEK and has since then been repayed in shares.

### PUBLISHED STUDIES WITH C21 DURING THE PERIOD

- C21 in combination with an angiotensin receptor-blocker (ARB) enhances the effect in animal models with type 2-diabetes Pandey, Gaikwad et al; Compound 21 and Telmisartan combination mitigates type 2 diabetic nephropathy in rats through amelioration of caspase mediated apoptosis. Link to article
- C21 provides direct neuroprotection as well as indirect protection through IL-10 in acute stroke. Fouda AY, Pillai B, Dhandapani KM, Ergul A, Fagan SC. Role of interleukin-10 in the neuroprotective effect of the Angiotensin Type 2 Receptor agonist, compound 21, after ischemia/reperfusion injury. Link to article
- C21 has a beneficial effect on islet cell function and regeneration, probably via proliferative and antioxidative pathways Wang L, Wang Y, Li XY, Leung PS. Angiotensin II Type 2 Receptor Activation With Compound 21 Augments Islet Function and Regeneration in Streptozotocin-Induced Neonatal Rats and Human Pancreatic Progenitor Cells. Länk till artikeln

### FIRST QUARTER 2017 COMPARED WITH THE FIRST QUARTER 2016 (GROUP)

### TSEK=thousands of sek

- Profit after financial items for the first quarter of 2017 amounted to TSEK-2,514 (-1,921).
- Operating profit amounted to TSEK-2,456 (-1,919).
- Cash flow from operating activities for the period amounted to TSEK-2,474 (-3,968).
- Shareholders' equity amounted to TSEK 101,928 (80,328) on March 31.
- Cash and cash equivalents amounted to TSEK 27,024 (18,421) as of March 31h. After the end of the reporting period, the second directed issue of SEK 24,000,000 has been paid out to the company.
- On March 31, the number of shareholders amounted to just over 1,000 and the total number of shares amounted to 15,868,504.

# **CEO'S COMMENTS**

#### Dear Shareholder,

In order to accelerate the clinical development of C21 for the treatment of IPF, and to finance 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 the drug candidate through phase Ib studies for the chosen indication. The proceeds are also expected to be sufficient enough to finance capsule formulation, interaction studies, a three-month toxicity study and a conceptual clinical study in diabetes. Overall, the capital injections have allowed for the technology to be evaluated in Phase II studies in therapeutic areas that currently lack effective treatments.

The accumulated safety data for C21 now enables us to initiate clinical trials in patients suffering from diseases where C21 has demonstrated strong data in animal experiments.

Our focus will be to, independently or together with a partner, to seek to demonstrate the clinical efficacy and safety, in IPF as the leading indication. In January, C21 received Orphan Drug Designation (ODD) for IPF from the American authorities through the FDA. Since 2016, C21 has had ODD for IPF within the EU.

In January, we initiated a supplementary study to the Phase I study. The purpose of the study is to investigate the safety and tolerability of C21 in a risk group of overweight men and at the same time investigate biomarkers of metabolic impairment in the blood. The biomarkers can be of particular interest for future studies within metabolism and diabetes. The results from the study are due for reporting during june or july 2017 which is a little bit later than earlier communicated but since it is a stand-alone study the delay will not affect the clinical programme.

In March, a BioMAP® study with C21 on fibrotinized human endothelial cells from lungs and kidneys was conducted using C21 or established IPF drugs. The objective of the BioMAP® study was to benchmark Vicore Pharma's drug candidate C21 to the two IPF-approved drugs with documented antifibrotic properties in a panel of biomarkers for inflammation and fibrosis and expressed by human primary cell cultures.

The study showed that C21 was most active in the fibrotic lung disease model where it positively affected several markers indicative of inflammation and fibrosis in a dose dependent manner. C21 exerted stronger effects in the



BioMAP® system than the currently approved drugs for IPF. Positive effects on both matrix-related and inflammation-related readouts demonstrated by C21 may translate to a stronger clinical impact than current therapies. C21 was also shown to be active and non-cytotoxic in the BioMAP® panel for the concentration range tested.

The outcome of this study further indicates a strong case for C21 within fibrosis related diseases, such as IPF, as the lead indication for clinical development of C21. Data from the study confirms that C21 exerts its positive antifibrotic effects in primary human cells further giving strength to the well documented antifibrotic effects already demonstrated in animal models.

In parallel, we will also initiate smaller clinical studies for other diseases, for example kidney damage caused by diabetes. This is to be regarded as an expression of the breadth of the technology and of our pursuit to enhancing the value of the same

To meet the growing needs within indications related to cardiovascular diseases, diabetes and kidney diseases, Vicore Pharma has developed new pharmaceutical substances based on knowledge gained from the lead candidate C21. In January a patent application was filed for these new substances. On behalf of Vicore Pharma, Emeriti Bio—a Swedish company specializing in drug discovery—has designed and synthesized a new set of molecules using Vicore Pharma's drug candidate C21 as a design template.

After optimization and preclinical validations, the new compounds will be directed towards disease areas in the cardio-metabolic field. AT2R agonism has demonstrated strong results in animal models in this field and there are considerable unmet medical needs, e.g. in diabetic nephropathy and heart failure.

The progress made during the year is; additional preclinical data in key areas, clinical safety, obtaining orphan drug status and development of a new generation of drug molecules. This has collectively increased interest from industry and

qualified investors. 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 ultimately seek partnership for the technology.

The first quarter of 2017 has been interesting in many aspects with several positive events taking place based on the value of the Company, bringing us reassurance as we go forward with our development plans.

Per Jansson, CEO

### **ORPHAN DRUGS**

A drug intended to treat a rare disease is classified as an orphan drug. In the United States and Europe, approximately 60 million people are expected to suffer from 7,000 identified rare diseases. Since the pharmaceutical industry, under normal conditions, has not considered it worth investing in developing a drug that is only used by a limited patient group, different forms of regulatory framework have been designed to increase industry driving forces. In 1983, the United States became the first to introduce a specific regulation for this type of disease. Since its inception, the FDA has approved more than 500 drugs for sale under this regulation and has given more than 3,300 orphan drug statuses. The success of the American program led to Japan (1993) and subsequently Europe (2000) establishing their own legislation.

The definition of a rare disease appears as follows for the different markets:

USA: <200,000 patients per indication Japan: <50,000 patients per indication

Europe: <5 per 10,000 (approximately 250,000 patients

per indication)

Financial drivers include:

Market exclusivity

USA: 7 years from approval- market exclusivity blocks similar products if they do not show clinical superiority (a mix of effectiveness and side effects)

EU: 10 years from approval

Other benefits of orphan drug status USA: 50% tax credit on R & D expenses USA: Discounts on fees to the FDA

EU: Assistance with drug development

EU: Reduced fee

Despite the limited patient population, many large companies focus exclusively on orphan drugs. The American companies Genzyme, Celgene and Alexion Pharmaceuticals are probably the most famous examples. Genzyme was acquired by Sanofi in 2010 for almost \$ 19 billion. Celgene and Alexion Pharmaceuticals have market values of 98 and 38 billion dollars, respectively.

# **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 antiproliferative 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.

#### **PERSONELL**

As of March 31, the Group had five employees. In addition to employed staff, the company engages a group of qualified consultants with selected specialist skills.

#### **SHARES**

Vicore Pharma Holdings shares have been listed on Nasdaq First North Stockholm since December 10, 2015 with the short name VICO. As of March 31, the number of shareholders amounted to approximately 1,000 and the total number of shares amounted to 15,868,504. The company's shares are only issued as common shares and each share casts one vote at the Annual General Meeting.

#### **CERTIFIED ADVISER**

Vicore Pharma Holding appoints Redeye as Certified Adviser on Nasdaq First North Stockholm.

#### **RISKS AND UNCERTAINTIES**

Vicore Pharma Holding AB (publ) leads and supports the operations of the subsidiary Vicore Pharma. In addition to the subsidiary, Vicore Pharma Holding owns 16.52% of the shares in I-Tech AB.

Vicore Pharma is a development company that is in a phase of clinical development and is exposed to the risks associated with drug development. Vicore Pharma is dependent on being able to enter into licensing and cooperation agreements for ultimate development of the company technology.

There is a risk that the two holdings do not achieve their respective financial targets. If financial targets are not met, this may have negative effects on the future performance of Vicore Pharma Holding and on the performance of the shares on the stock market.

#### **AUDIT OF AUDITOR**

The interim report has not been reviewed by the Company's auditor.

# **UPCOMING FINANCIAL REPORTS**

August 24 Interim report, Q2 October 19 Interim report, Q3

Financial reports will be available on the Company's webpage, www.vicorepharma.com from the date of publication.

# **FINANSIELLA REPORTS GROUP**

INCOME STATEMENT SUMMARY					
Consolidated	Jan- Mar	Jan-Mar	Jan-Dec		
KSEK	2017	2016	2016		
Operating income etc					
Net turnover	247	176	852		
Own work capitalized	666	251	1221		
Other operating income	2	46	60		
	915	473	2133		
Operating expenses					
Other external expenses	-1425	-1282	-5006		
Personell costs	-1323	-1108	-3770		
Depreciation and write-down of	-2	-2	-6		
tangible assets  Depreciation and write-down of	-621	0	0		
intangible assets	-021	U	U		
0.000	-3371	-2392	-8782		
Operating profit/loss	-2456	-1919	-6649		
Profit/loss from financial items					
Interest income from group companies	0	0	0		
Interest expense to group companies	-58	0	-3		
	-58	-2	-3		
Profit/loss after financial items	-2514	-1921	-6652		
Tax	0	0	0		
Profit/loss for the period	-2514	-1921	-6652		

BALANCE SHEET SUMMARY			
Consolidated	31-mar	31-mar	31-dec
KSEK	2017	2016	2016
Assets			
Fixed assets			
Intagible assets	59 198	45 866	56 201
Tangible assets	34	6	2
Financial assets	20 610	20 110	20 610
=	70.040	CE 000	76.010
Total fixed assets	79 842	65 982	76 813
Current assets			
Current recievables			
Customer recievables	141	77	122
Other recieveables	733	301	223
Prepaid expenses and accrued income	229	114	188
Cash and bank	27 025	18 422	4 266
Total current assets	28 128	18 914	4 799
Total assets	107 970	84 896	81 612
Total assets	107 970	84 830	81 012
EQUITY AND LIABILITIES			
Equity, group			
Restricted equity	19 581	6 184	18 581
Non-restricted equity	82 347	74 144	57 016
Total equity, group company	101 928	80 328	75 597
Provisions			
Deferred tax liability	1 978	1 978	1 978
Current liabilites			
Trade payables	2 572	1 020	2 146
Current tax liability	16	0	86
Other liabilities	229	256	188
Accrued expenses	1 247	1 314	1 617
and the same and a same	4 064	2 590	4 037
TOTAL EQUITY AND LIABILITIES	107 970	84 896	81 612

# **FINANCIAL REPORTS PARENT**

INCOME STATEMENT SUMMARY			
Parent company	Jan-Mar	Jan-Mar	Jan-Dec
KSEK	2017	2016	2016
Operating income etc			
Net turnover	737	536	2 175
Other operating income	0	0	633
	737	536	2 808
Operating expenses			
Other external expenses	-930	-990	-3 332
Personell costs	-726	-644	-2 443
Depreciation and write-down of tangible and	-2	-2	-6
intangible assets	-1658	-1 636	-5 781
	-1038	-1 030	-5 761
Operating profit/loss	-921	-1 100	-2 973
Profit/loss from financial items			
Profit/loss from financial items	223	135	745
Other interest income from group companies	0	0	0
Interest expense and similar profit/loss items	-58	-2	-3
	165	133	742
Profit/loss after financial items	-756	-967	-2 231
Тах	0	0	0
Profit loss for the period	-756	-967	-2 231

BALANCE SHEET SUMMARY			
Parent company	31-mar	31-mar	31-dec
KSEK	2017	2016	2016
Assets			
Fixed assets			
Intangible assets			
Tangible assets	34	7	2
Financial assets	80 624	48 724	49 224
Recievables from group companies	7 917	15 475	26 936
Total fixed assets	88 575	64 206	76 162
Current assets			
Current recievables			
Trade recievables	120	77	101
Recievables from group companies	448	0	431
Other recievables	555	86	29
Prepaid expenses and accrued income	223	105	175
Cash and bank	18 346	16 949	3 119
Total current assets	19 692	17 217	3 855
TOTAL ASSETS	108 267	81 423	80 017
EQUITY AND LIABILITIES			
Equity			
Restricted equity	7 184	6 184	6 184
Non-restricted equity	99 090	73 265	72 002
Total equity	106 274	79 449	78 186
Long-term liabilities			
Liabilities to group companies	400	400	400
Current liabilities			
Trade payables	484	256	318
Current tax liability	8	66	64
Other liabilities	145	90	89
Accrued expenses and deferred income	956	1162	960
	1593	1574	1 431
TOTAL EQUITY AND LIABILITIES	108 267	81 423	80 017

## **CASH-FLOW ANALYSIS FOR GROUP AND PARENT COMPANY**

CASH FLOW STATEMENT	Group		Par	Parent Company		
	2017-01-01	2016-01-01	2016-01-01	2017-01-01		2016-01-01
	2017-03-31	2016-12-31	2016-03-31	2017-03-31	2016-12-31	2016-03-31
Operating activities						
Operating profit/loss	-2 456	-6 649	-1 919	-921	-2 973	-1 100
Adjustments for non-cash items, etc.	622	6	2	2	6	2
Interest received etc	0	0	0	223	745	135
Interest paid	-58	-3	-2	-58	-3	-2
Income tax paid	0	-40	-131	0	-58	0
Cash flow from operating activities						
before changes in working capital	-1 892	-6 686	-2 050	-754	-2 283	-965
Cash flow from changes in working capital						
Decrease(+)/increase(-) in accounts receivable	-19	24	69	-36	286	741
Decrease(+)/increase(-) in receivables	-552	614	610	-574	375	388
Decrease(-)/increase(+) in accounts payable	388	-166	-1 292	166	-1 665	-1 727
Decrease(-)/increase(+) in current liabilities	-399	-1 075	-1 305	-7	-1 615	-1 470
Cash flow from operating activities	-2 474	-7 289	-3 968	-1 205	-4 902	-3 033
Investing activities						
Acquisition of capitalised expenditure for research etc.	-3 228	-12 397	-2 869	0	0	0
Acquisition of concessions, patents, licences etc.	-352	-1 043		0	0	0
Acquisition of equipment, tools, fixtures and fittings	-33			-33		
Sale of long-terms valuable document	0	-500	0	0	-500	0
Acquisition of group companies	0	0	0	-31 400		
Amortisation payments during the year from group compani	0	0	0	19 019		
Loans granted during the year to group companies	0	0	0	0	-16 781	-5 320
Cash flow from investing activities	-3 613	-13 940	-3 104	-12 414	-17 281	-5 320
Financing activities						
New issue for the year	28 845	319	318	28 845	319	318
Cash flow from financing activities	28 845	319	318	28 845	319	318
Change in cash and cash equivalents	22 758	-20 910	-6 754	15 226	-21 864	-8 035
Cash and cash and cash equivalents  Cash and cash equivalents at beginning of year	4 266	-20 910 25 175		3 119	24 983	-8 035 24 983
Cash and cash equivalents at year-end	27 024	4 265	18 421	18 345	3 119	16 948
casii aliu casii equivalellis at year-eliu	27 024	4 205	10 421	10 343	2 119	10 348

# The Board and the CEO ensure that the interim report provides a true and fair view of the Company's position and results

Mölndal May 10, 2017

Göran Wessman, Chairman

Kjell Stenberg, Board member

Peter Ström, Board member

Leif Darner, Board member

Per Jansson, CEO

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