

THE PERIOD IN BRIEF

Compared to corresponding period the previous year

FINANCIAL OVERVIEW JANUARY-MARCH:

- The quarterly loss amounted to -3,663 KSEK (-3,850 KSEK)
- Cash and cash equivalents amounted to 2,321 KSEK (2,877 KSEK) at the end of the period
- Cash flow during the quarter amounted to -7,551 (-6,771 KSEK)
- Equity amounted to 35,581 KSEK (27,991 KSEK) at the end of the period and total assets amounted to 46,667 KSEK (27,991 KSEK)
- Equity/Assets-ratio amounted to 76% (84%) at the end of the period

SIGNIFICANT EVENTS JANUARY-MARCH:

- iCoat Medical announced that it will proceed with its Phase 2b study EMPIRE as the next step in the clinical development of iCM012 in deceased-donor kidney transplantation.
- A Scientific Advisory Board was established to strengthen iCoat Medical's research and development program consisting of three leading international experts: Dr. Gabriel Oniscu, Dr. Stefan Schneeberger and Dr. Stefan Tullius.
- iCoat Medical's CMO Dr. Alireza Biglarnia received a grant for transplant research from the Transplantation Fund (Transplantationsfonden), a collaboration between Skåne University Hospital and the Skåne Kidney Care Network.

SIGNIFICANT EVENTS AFTER THE PERIOD:

- In April, iCoat Medical filed two new patent applications, strengthening its patent portfolio and, thus, the protection for future products.

KEY FIGURES

kSEK	Q1 2024	Q1 2023	Jan-Dec 2023	Jan-Dec 2022
EBIT	-3,663	-3,850	-20,791	-10,483
Assets	44,667	27,991	50,586	31,901
Equity/Assets-ratio	76.2%	84.0%	77.6%	84.8%

CEO STATEMENT

During the first quarter of this year, we continued the development of our preclinical and clinical project portfolio, with a particular focus on the lead product candidate iCM012 in kidney transplantation, where we are now preparing the global clinical phase 2b study EMPIRe, with an expected start in 2024. We have also continued to strengthen our IP position and was recently able to submit two new patent applications that broaden the patent portfolio and thus the protection for future products.

In February, we announced that we have made the formal decision to proceed with the EMPIRe study as the next step in the clinical development of iCM012. We had previously had fruitful and constructive discussions with the Swedish Medicines Agency, and a phase 2b study demonstrating efficacy is deemed to be the logical next step, based on the promising data generated by the now completed phase 1/2a study ATMIRe.

The EMPIRe trial, which is scheduled to start in 2024, will include approximately 100 patients and be performed at selected high-quality clinics in Europe and the United States. The potential for conditional approval, given sufficiently convincing data generated by the phase 2b study, will later be discussed with the regulatory authorities. This progress with our clinical project portfolio is important to the value creation of the company and our assets.

In parallel with these preparations, the work on the preclinical indications CAR T-cell therapy and open-heart surgery has continued according to plan, which all in all means that I view the immediate future of iCoat Medical's development work with great confidence.

We have a significant strength by standing firmly on these two strong legs: on the one hand the clinical development around iCM012, on the other hand the preclinical research that together creates a breadth and a depth. Our future does not stand and fall with a single product or indication, but several parallel indications are continuously developing.

We also continue to develop our unique technology platform and associated IP portfolio based on the company's coating technology. We recently filed two new patent applications that broaden the patent portfolio and thereby the protection for future products. iCoat Medical now has a total of 40 patents and patent applications with international coverage within a total of five patent families.

It is also gratifying to see that our extremely competent employees are being noticed by the scientific community. In March, our Chief Medical Officer Dr. Alireza Biglarnia was one of five research doctors who received a grant for their research in the field of transplantation from the Transplantation Fund, a collaboration between Skåne University Hospital and Skåne's kidney care network.

We also continue to create a solid scientific network, and in February we presented our strong Scientific Advisory Board, with three leading international experts - Dr. Gabriel Oniscu, Dr. Stefan Schneeberger and Dr. Stephen Tullius. I am very pleased and proud that we have been able to attract some of the leading global transplant experts, and their long, combined experience in research and treatment will be invaluable to us as we now continue the clinical development of iCM012 in the upcoming EMPIRe study.

To be able to continue the business, financing is of course needed, and we will therefore make a convertible loan before the summer. In common with other small and medium-sized biotech companies, we have noticed that the market has been - and to some extent still is - in a wait-and-see mode in the last two to three years, and therefore I believe that a convertible loan is the best strategic financing solution for us in the short term.

I look forward to updating you on our upcoming plans and continued efforts to finally be able to offer a product with the potential to transform the entire large and non-cyclic transplant market. It is likely that more than 200,000 transplants will be carried in 2025, making research and new techniques essential to ensure these people receive the best possible treatment. I am convinced that iCoat Medical will play a key role in this development.

Peder Waern

CEO, iCoat Medical AB

ABOUT ICOAT MEDICAL

iCoat Medical's business idea is to develop and market medicine for successful transplants of vital organs while enabling a greater availability of organs for transplantation. iCoat Medical's product candidate, iCM012, has the potential to transform the transplantation market. The product is based on over 25 years' research and development in collaboration with leading academic institutes. Vast preclinical studies show that iCM012 has the potential to improve the kidney's function following transplantation. The organization includes surgeons and scientists with expertise in all phases of research and development as well as an experienced commercial team. iCM012 will initially be used for kidneys but the plan is that the product will be used also in other organ transplants, for instance heart. The transplantation market is large and non-cyclical, and the company estimates that more than 200 000 transplantations will be performed in 2025.

OUR PRODUCTS

iCM012

- iCM012 is a modified polymer that has the ability to penetrate the cell membrane and create a protective barrier which prevents plasma proteins and immune cells from reacting with the cell surface. Through this process, iCM012 protects ischemic cells, ie cells that have faced a shortage of oxygen, against the patient's innate immune system.
- iCoat Medical is continuously working on quality assurance and analyzing the product and production process for iCM012, which will continue during 2024.

iCM020

- iCM020 is developed based on iCM012 and it has anticoagulative qualities.
- iCoat Medical continuously analyzes and tests to modify the molecule and its function and production process.

GROUNDBREAKING DEVELOPMENT

BUSINESS IDEA

iCoat Medical's business idea is to develop and market medicine for successful transplants of vital organs while enabling a greater availability of organs for transplantation.

ISCHEMIA REPERFUSION INJURY

Ischemia Reperfusion Injury (IRI) is a mechanism that can lead to thrombo inflammation and tissue injury in connection to several clinical states and diseases. IRI contributes to delayed graft function which occurs in 20-50% of deceased donor kidney transplantations. IRI can arise in connection to:

- Organ transplants
- Heart surgery
- Heart attack
- Stroke

IRI is the damage that occurs to the transplanted organ when blood circulation is returned to the organ after a period of ischemia, ie lack of oxygen.

PIPELINE

iCoat Medical’s product portfolio addresses several health issues that are connected to Ischemia Reperfusion Injury. The table below shows what stage each product candidate has reached in the development cycle.

Candidate / Project	Usage area	Research	Preclinical studies	Clinical preparation	Phase 1/2a	Phase 2b study	Expected next step
iCM012	Kidney transplantation	Completed				Planning	IND approval 2024
	Other organs	Ongoing	Planning				Under assessment for next steps
iCM012	Open heart surgery	Completed	Ongoing				Pre-clinical results in 2024
iCM020	Cell therapies	Completed	Ongoing				Pre-clinical results in 2024
iCM023							
(1 st , 2 nd and 3 rd generation molecules)	Myocardial infarction	Ongoing					Ongoing research
	Stroke	Ongoing					Ongoing research

TRANSPLANTATION MARKET

Transplants of organs is a proven method of treatment. There are an estimated 300 transplant clinics in Europe and approximately 250 in the US. For certain patients, transplantation is the only way of survival and for the vast majority, a transplant leads to a better and healthier life while benefitting society since it is more cost efficient than other treatments.

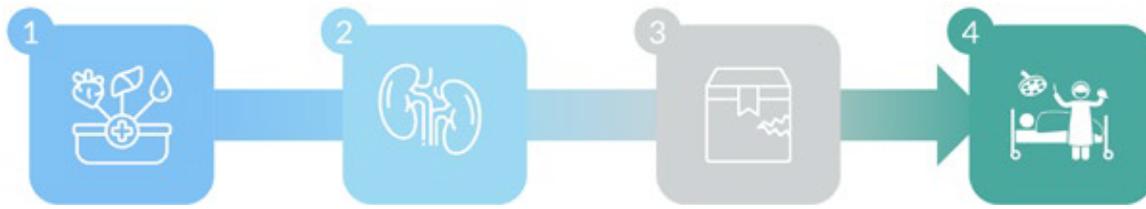
The number of patients that await a transplant has doubled during the past 10 years and currently only 10% of the global transplant needs can be met. In the US and Europe, 160,000 patients were waitlisted for kidney transplant in 2021, but only a quarter of those received a kidney during the year. The lack of available organs is growing due to a number of factors: the population is getting older, more people suffer from organ failure and demands on healthcare are increasing.

KIDNEY TRANSPLANTATION

Kidney disease is a global problem and more than 850 million people suffer from some kind of kidney disease, which makes it into one of the most common diseases. End-Stage Renal Disease (ESRD) implies that the kidney ceases to function and over 2 million patients suffer from the disease globally. Kidney transplant is the best treatment for patients that suffer from ESRD and leads to a higher quality of life for the patient.

Patients may need to wait for several years before a matching donor is located. Approximately 70-80% of transplanted organs come from deceased donors and these kidneys are heavily impacted by ischemia which leads to worse health outcomes for the patient.

The average patient that has received a trans- planted kidney will live 10-15 years longer compared to a patient that receives dialysis. Moreover, the potential savings from transplantation are significant in addition to the positive impact on patients' quality of life.



- World-wide organ shortage
- Continuously growing waiting lists and unnecessary deaths

- Less than 10% of the global need of organs is covered¹⁾
- Each year kidney disease kills more people than breast or prostate cancer²⁾

- Transplanted organs experience lack of oxygen during process and transport
- Lack of oxygen causes ischemia and thereafter, due to the recipient's immune system, a reperfusion injury will occur which worsens the organ's function

- iCoat Medical will significantly decrease the associated levels of organ damage
- This will increase the life length and pool of organs available to patients

¹⁾ Global Observatory on Donation and Transplantation.

²⁾ National Institute of Diabetes and Digestive and Kidney Diseases.

MARKET POTENTIAL

The target group for iCoat Medical includes approximately 25,000 patients annually in Europe and the US that run the risk of delayed graft function. iCoat Medical expects to launch its first product ICM012 in 2027 and the estimated value of the addressable market amounts to +850 MUSD. iCoat Medical could potentially review additional markets.



FINANCIAL INFORMATION

First quarter, January – March 2024

Results

For the first quarter of 2024, the company reports a loss amounting to KSEK -3,663 (KSEK -3,850). Total operating expenses amounted to KSEK -7,497 (KSEK -7,553 thousand), which also includes development costs and costs for patents and IP.

The costs have more than doubled in the past year in line with the preparation, planning and process for finalizing the application to the authorities (EMA/FDA) for the planned multi-center study, EMPIRe in 2024. Cost drivers have mainly consisted of new recruitments, hired specialist expertise in clinical and regulatory areas and production costs.

During FY 2023 and into the new year, the business has invested significant resources in its research department and research program with an increased workforce in new preclinical areas/indications for the product groups that the company has been working on in recent years (iCM012 and iCM020). The company's research and development costs, in 2023, accounted for almost 70% of the total costs of the business, including the planned multi-center study in 2024 (EMPIRe).

Development costs for the company's ongoing clinical projects, ATMIRe and EMPIRe, amounted to KSEK -3,698 (KSEK -3,540) for the first quarter.

Personnel costs for the quarter amounted to KSEK -1,616 (KSEK -1,288) and the increase in personnel costs is due to the expansion of the workforce in research and development and to the company's ongoing clinical studies. The number of employees in the company has gone from 3.0 FTEs at the beginning of Q1 2023 to 6 FTEs for the corresponding period in 2024.

Investments

Investment consist of the company's development costs and costs for intellectual property.

Cash and cash equivalents

As of March 31, 2024, cash and cash equivalents amounted to KSEK 2,321 (KSEK 2,877).

Cash flow

Cash flow from operating activities during the quarter amounted to KSEK -3,723 (KSEK -3,521), which is mainly driven by costs linked to the company's planning for a Phase 2/b study, regulatory advisors, other external advisory services and pre-clinical work. Cash flow from investing activities during the quarter amounted to KSEK -3,828 (KSEK -3,699 thousand), which mainly consists of development costs in ongoing clinical studies, all investments are reported as intangible assets.

Equity

As of March 31, 2024, equity amounted to KSEK 35,581 (KSEK 23,647) and the company's equity ratio was 76% (85%).

Debt and receivables

Current receivables consist mainly of tax receivables from VAT and major items for accruals from the end of 2023 and the current quarter. Current liabilities amount to KSEK 11,086 (KSEK 4,344) as of March 31, which mainly consists of trade payables and personnel-related liabilities for taxes and fees and accrual effects linked to the year-end.

Intangible assets

Costs for the development of the company's drug candidate (iCM012) are reported as an intangible assets in

the company's balance sheet, as of March 31, 2024, amounting to KSEK 40,272. Costs relating to the company's work on patent protection and IP rights are capitalized in the balance sheet, as of March 31, 2024, amounting to 2,879 KSEK.

Amortization according to plan for capitalized development costs and patents starts after completion.

Personnel

The number of employees based on annual working hours (FTE) has gradually increased over the past 12 months and amounted to 6.0 FTE (3.0) as of March 31, and total personnel costs for the period January-March represent approximately 21% (17%) of total costs.

Share

As of March 31, 2024, the company's share capital amounted to KSEK 680 (KSEK 615) and the number of shares amounts to a total of 166,082 (149,869), of which 100,000 A shares and 66,082 B shares distributed among a total of 47 shareholders. The company's shares are currently not admitted to trading on any public marketplace.

INCOME STATEMENT

kSEK	2024	2023	2023
	Jan-Mar	Jan-Mar	Jan-Dec
Net Sales			
Activated work	3,698	3,540	19,360
Other operating income	6	4	60
	3,704	3,544	19,420
Operating expenses			
Clinical study	-519	-1,085	-8,047
Other external expenses	-5,201	-5,006	-24,541
Personnel costs	-1,616	-1,288	-7,486
Depreciation	-5	-	-14
Other operating expenses	-26	-15	-123
Total operating expenses	-3,663	-3,850	-20,791
Net interest income	-	-	156
Profit after financial items	-3,663	-3,850	-20,635
Tax	-	-	-
Profit/loss for the period	-3,663	-3,850	-20,635

BALANCE SHEET

kSEK	2024-03-31	2023-03-31	2023-12-31
Assets			
Development costs	40,272	20,755	36,575
Patents	2,879	2,082	2,749
Inventories, equipment and installations	84	-	89
Financial assets	26	59	26
Total non-current assets	43,261	22,896	39,439
Current receivables	1,085	2,218	1,275
Cash and cash equivalents	2,321	2,877	9,872
Total current assets	3,406	5,095	11,147
Total assets	46,667	27,991	50,586
EQUITY AND LIABILITIES			
<i>Restricted equity</i>			
Share capital	680	615	680
Fund for development costs	43,151	22,837	39,324
Total restricted equity	43,831	23,452	40,004
<i>Un-restricted equity</i>			
Share premium reserve	66,609	34,883	66,609
Balanced profit or loss	-71,196	-30,838	-46,734
Result during period	-3,663	-3,850	-20,635
Total un-restricted equity	-8,250	195	-760
Minority interest	-	-	-
Equity	35,581	23,647	39,244
Non-current debt	-	-	-
Current debt	11,086	4,344	11,342
Total liabilities	11,086	4,344	11,342
Total equity and liabilities	46,667	27,991	50,586

CASH FLOW

kSEK	2024 jan-mar	2023 jan-mar	2023 jan-dec
Operating activities			
Profit after financial items	-3,663	-3,850	-20,635
<i>Adjustments for non-cash items (depreciation)</i>	5	-	14
Tax paid	-	-	177
Cash flow from operating activities before changes in working capital	-3,658	-3,850	-20,444
<i>Cash flow from changes in working capital</i>			
Increase (-)/Decrease (+) of current receivables	190	838	1,781
Increase (+)/Decrease (-) of current liabilities	-255	-509	6,312
Cash flow from operating activities	-3,723	-3,521	-12,351
Investment activities			
Acquisitions of intangible fixed assets	-3,828	-3,699	-20,187
Acquisitions of tangible fixed assets	-	-	-103
Disposal of financial fixed assets	0	-	34
Cash flow from investment activities	-3,828	-3,699	-20,256
Financing activities			
Warrants	-	449	449
Paid non-registered share capital	-	-	591
New share issue	-	-	65
Share premium reserve	-	-	31,726
Cash flow from financing activities	-	449	32,831
Cash flow from the period	-7,551	-6,771	224
Cash and cash equivalents at the beginning of the period	9,872	9,648	9,648
Exchange rate difference in cash	-	-	-
Cash and cash equivalents at the end of the period	2,321	2,877	9,872

CHANGES IN EQUITY

kSEK	Share capital	Fund for development costs	Share premium reserve	Balanced income incl. profit from period
Balance at (1 Jan 2024)	680	39,324	66,609	-67,368
Fund for development costs		3,827		-3,827
Warrants				
Results from period				-3,663
Balance at (31 mar 2024)	680	43,151	66,609	-74,858
Balance at (1 Jan 2023)	615	19 138	34,883	-27,587
Fund for development costs		3 699		-3,699
Warrants				449
Results from period				-3,850
Balance at (31 mar 2023)	615	22 837	34,883	-34,687
Balance at (1 Jan 2023)	615	19,138	34,883	-27,587
Fund for development costs		20,186		-20,186
Paid non-registered share capital				591
New share issue	65		31,726	
Warrants				449
Results from period				-20,635
Balance at (31 dec 2023)	680	39,324	66,609	-67,368

NOTES

Note 1 Accounting principles

All figures are denoted in KSEK unless otherwise stated.

General accounting principles

iCoat Medical has prepared this interim report in accordance with the Annual Accounts Act (ÅRL) and BFNAR 2012:1 (K3). These accounting principles in this interim report are unchanged compared to previous years. This interim report does not include all information that is required of a complete financial report. Used accounting principles and valuation methods are the same as those used in the latest annual report for 2023.

Intangible fixed assets – costs for research and development

Costs for research, i.e. planned and systematic search with the purpose of gaining new scientific or technical knowledge and insights, are accounted for as expenses as they arise in the income statement.

Costs for development are activated in the balance sheet. This means that costs that have arisen during the development phase are accounted for as an asset when the following criteria are met:

- It is technically possible to complete the intangible fixed asset so that it can be used or sold.
- There is an intent to complete the intangible fixed asset and use or sell it.
- There are preconditions that enable use or selling of the intangible fixed asset.
- It is likely that the intangible fixed asset will generate future economic benefits.
- There are necessary and adequate technical, economic and other resources to complete development and to use or sell the intangible fixed asset.
- Costs associated with the intangible fixed asset can be estimated reliably.

When preparing an interim report some critical estimations are necessary and management make judgements when applying accounting principles. For additional information on the company's estimations and judgements, please see accounting principles in the Annual Report 2023.

Risks related to the business

Running the business entails risks, both related to the company's specific business, industry and its dependence on external factors. iCoat Medical faces risks such as interest and credit risks, currency risks, liquidity risks, market risks, product development risks, commercialization risks, regulation risks and risks associated with its intellectual property rights.

Note 2 Definitions

Balance sheet total: Total assets.

Equity/Assets ratio: (Total equity + 79.4% of untaxed reserves) / Total assets

OTHER INFORMATION

FINANCIAL CALENDAR

Interim Report Q1 (January-March 2024)	May 28, 2024
Interim Report Q2 (April-June 2024)	August 15, 2024
Interim Report Q3 (July-September 2024)	November 15, 2024
Interim Report Q4 (October-December 2024)	February 14, 2025

This interim report has been published on iCoat Medical's website, www.icoatmedical.com The report has not been reviewed by the company's auditor.

FOR ADDITIONAL INFORMATION, PLEASE CONTACT:

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Information in this interim report is not ruled by EUs Market Abuse Regulation since iCoat Medical AB's shares are currently not listed on a public exchange. The information was submitted for publication, through the agency of the contact person set out above, on May 28, 2024 at 08.00 (CEST).

iCoat Medical AB

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