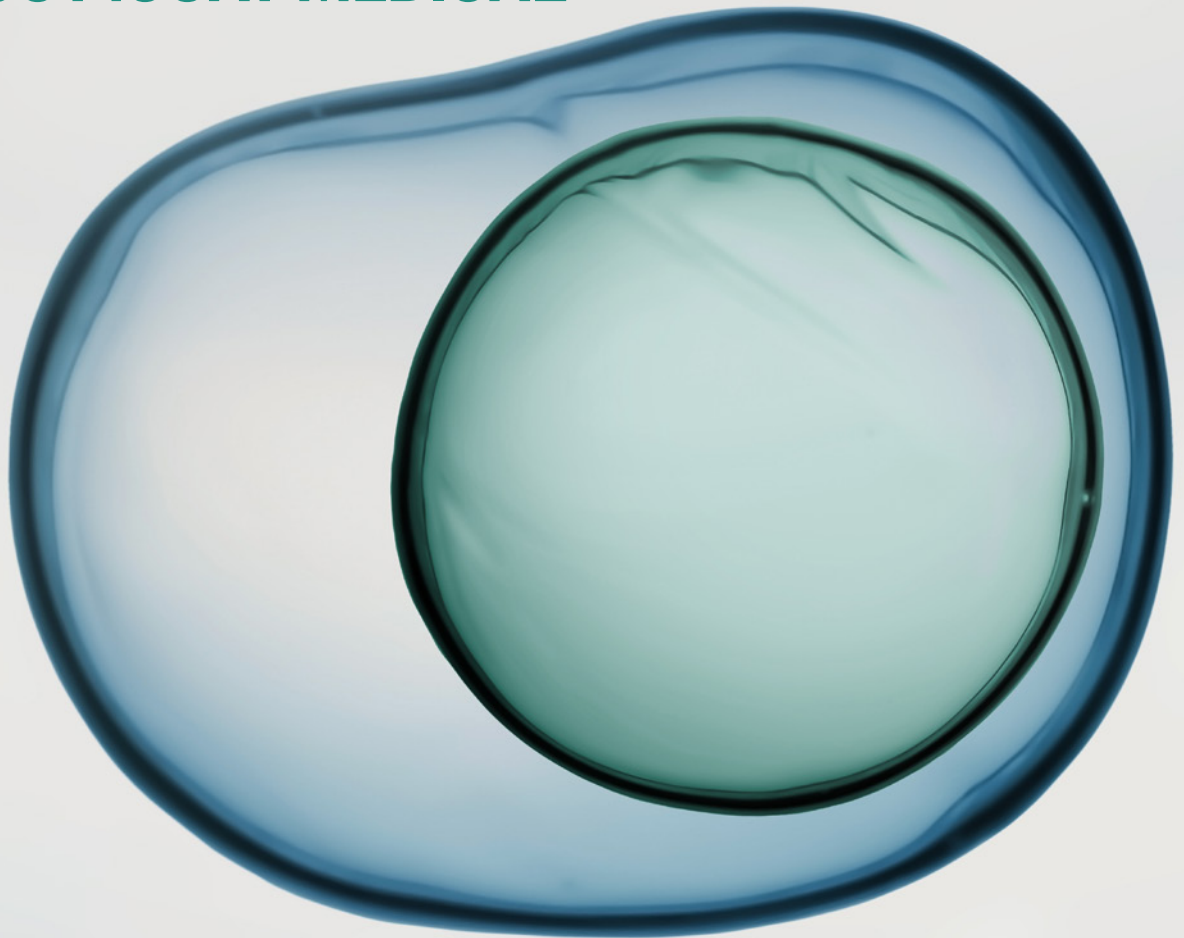




# Q4

INTERIM REPORT  
OCTOBER - DECEMBER 2023

# ABOUT iCOAT MEDICAL



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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.

# THE PERIOD IN BRIEF

Compared to corresponding period the previous year

## Financial overview October – December:

- The quarterly loss amounted to -5,694 KSEK (-3,899 KSEK)
- Cash and cash equivalents amounted to 9,872 KSEK (9,648 KSEK) at the end of the period
- Cash flow during the quarter amounted to -7,695(-5,584 KSEK)
- Equity amounted to 39,499 KSEK (27,048 KSEK) at the end of the period and total assets amounted to 50,586 KSEK (31,901 KSEK)
- Equity/Assets-ratio amounted to 78% (85%) at the end of the period

## Financial overview January – December:

- The period´s loss amounted to -20,380 KSEK (-10,483 KSEK)
- Cash and cash equivalents amounted to 9,872 KSEK (9,648 KSEK) at the end of the period
- Cash flow during the period amounted to 224 KSEK (-17,191 KSEK)
- Equity amounted to 39,499 KSEK (27,048 KSEK) at the end of the period and total assets amounted to 50,586 KSEK (31,901 KSEK)
- Equity/Assets-ratio amounted to 78% (85%) at the end of the period

## Significant events October – December:

- Initiation of new pre-clinical studies in animal models for heart transplantation and open heart surgery for the company's new indications
- Initiation of cell therapies as a new preclinical focus area
- Initiation of new pre-clinical studies in animal models for open heart surgery
- Continued preparations for the start of a global multicenter trial for iCM012 with a planned start in 2024

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## Significant events after the end of the period:

- In February 2024 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
- In February 2024 iCoat Medical established a Scientific Advisory Board with three leading international experts to strengthen its transplant expertise

# KEY FIGURES

kSEK	Q4 2023	Q4 2022	Jan-Dec 2023	Jan-Dec 2022
EBIT	-5,850	-3,899	-20,537	-10,483
Assets	50,586	31,901	50,586	31,901
Equity/Assets-ratio	78%	85%	78%	85%



## CEO STATEMENT

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We can now put an intense and eventful year behind us, and it is with joy and pride I can say that iCoat Medical made great progress in 2023. Strengthened by a successful issue of SEK 32 million, we were able to relentlessly continue the development of our project portfolio, with special focus on the leading product candidate iCM012 in kidney transplantation. During the fourth quarter, work also continued with the preclinical indications of heart transplantation and open heart surgery, which all in all means that I view the immediate future with great confidence.

The progress with our clinical project portfolio is important for value creation of the company and our assets, and this applies not the least to the work with iCM012 in kidney transplantation. In November, we therefore announced the decision to proceed to a clinical efficacy study based on valuable dialogue with the Swedish Medicines Agency.

Earlier in the year, we completed our First-in-Human study ATMIRE (phase 1/2a) with convincing safety and preliminary efficacy results where iCM012 was studied in connection with kidney transplants. We are now preparing the global phase 2b clinical study EMPIRE, which is expected to start in 2024.

We also see a great deal of interest in our clinical and preclinical program within the scientific community, both via publications and presentations at scientific conferences, which of course gives us extra strength in our continued work with iCM012.

The discussions with the Swedish Medicines Agency also included our preclinical research in transplantation of other solid organs, as well as in open heart surgery, which we see as the next indication in clinical development. The Agency also supports continued preclinical work, which, together with the promising results from the ATMIRE study, should be able to form the basis for future phase 1/2a studies for the transplantation of other organs, as well as in open heart surgery.

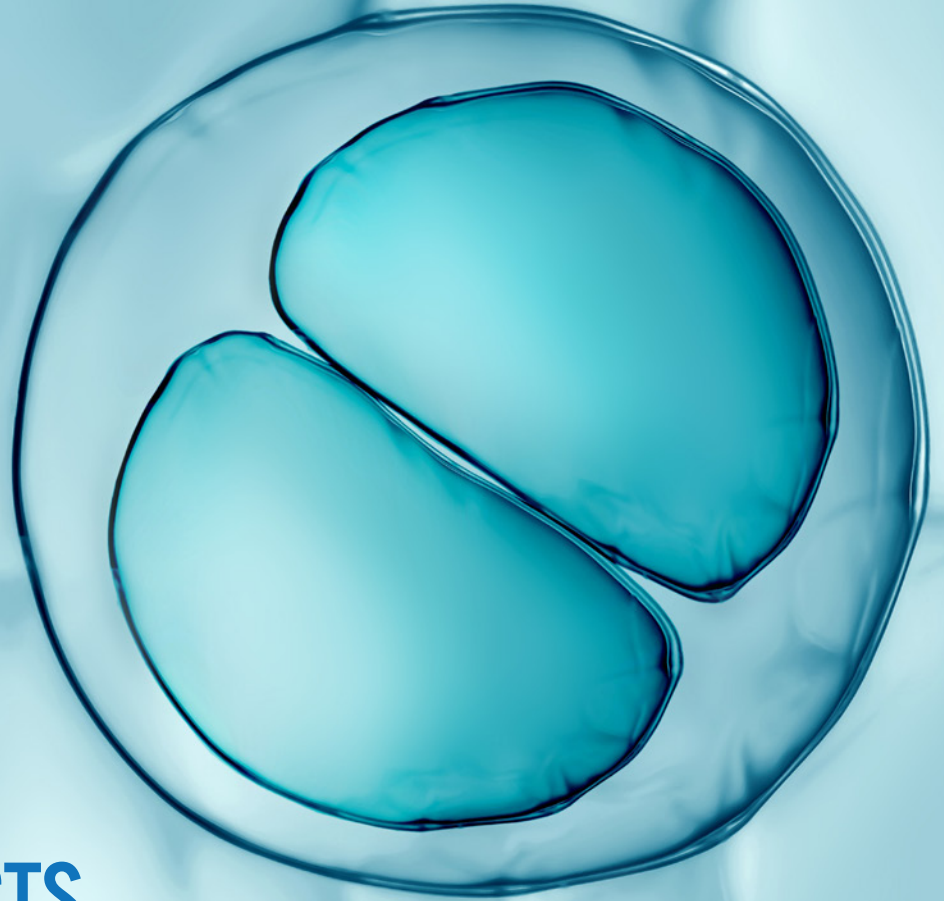
As our development program takes shape, the company continues to grow, and during the third quarter, the operations for our clinical studies moved into larger premises in the research and development campus Medicon Village in Lund, Sweden, with the aim of creating a good foundation for expanded future clinical operations.

We also continue to strengthen the scientific competence in and around the company. We have created a strong Scientific Board, where Dr. Stefan Tullis, Dr. Stefan Schneeberger, and Dr. Gabriel Oniscu are the latest additions. Earlier in 2023, Carl Bjartmar, MD, PhD, also joined the company as Chief Commercial Officer and is part of iCoat Medical's management team; a clear proof that we can attract people with great expertise and a broad scientific network.

During the year, we carried out a directed issue of SEK 32 million which secures the financing of our running costs for the phase 1/2a study ATMIRE, the preparations with EMPIRE and continued preclinical studies with new indications, as well as the work with our second product candidate iCM020. The focus is primarily the EMPIRE study, which is expected to start in 2024, but it will also be exciting to continue the development of the preclinical portfolio where we see significant potential.

I look forward to updating you on our upcoming plans and continued efforts to finally offer a product with the potential to transform the entire large and non-cyclical transplant market, where it is estimated that more than 200,000 transplants will be performed in 2026 alone. I am convinced that iCoat Medical and our exciting project portfolio will have an important role to play in this development.

**Peder Waern**  
CEO, iCoat Medical AB



## OUR PRODUCTS

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### 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 has during the period worked on quality assurance and analyzing the production process for iCM012, which will continue during the first half of 2024.

### iCM020

- iCM020 is developed based on iCM012 and it has anticoagulative qualities.
- iCoat Medical has during the period analyzed and tested a modified version of the molecule and its function. This biochemical development work is ongoing.

# 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.

IRI can arise in connection to:

- Organtransplants
- Heart surgery
- Heart attack
- Stroke

## ISCHEMIA REPERFUSION INJURY

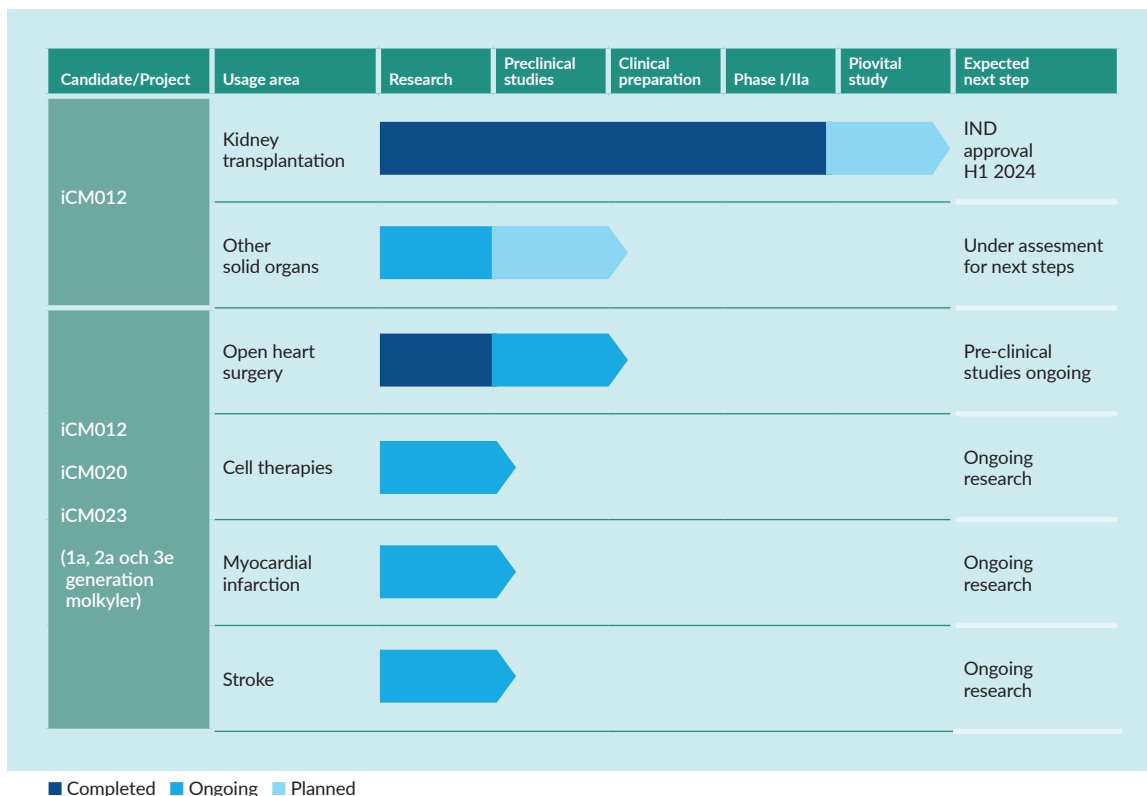
Ischemia Reperfusion Injury (IRI) is a mechanism that can lead to thrombo inflammation and tissue injury in connection to several clinical states and diseases. IRI contributes to delayed graft function which occurs in 20-50% of deceased donor kidney transplantations.

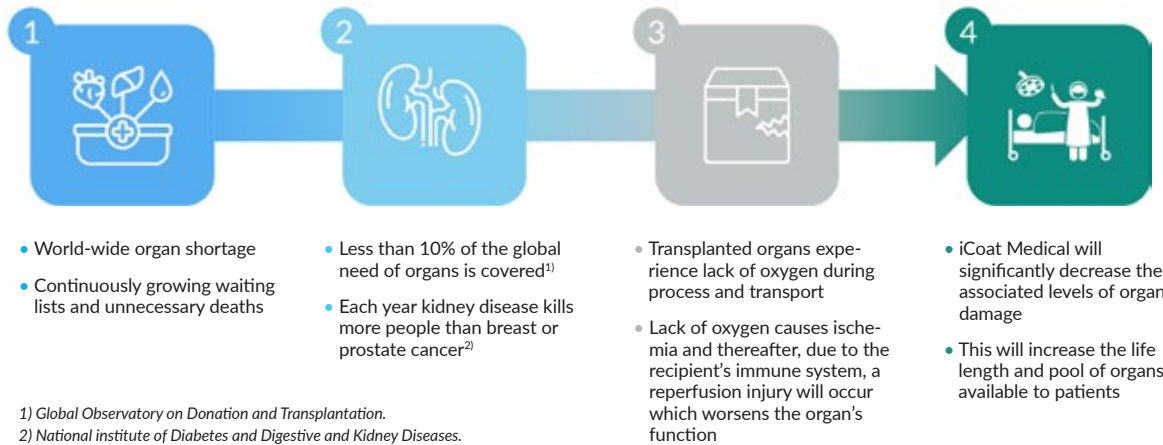
IRI is the damage that occurs to the transplanted organ when blood circulation is returned to the organ after a period of ischemia, ie lack of oxygen.

## 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.

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## 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.

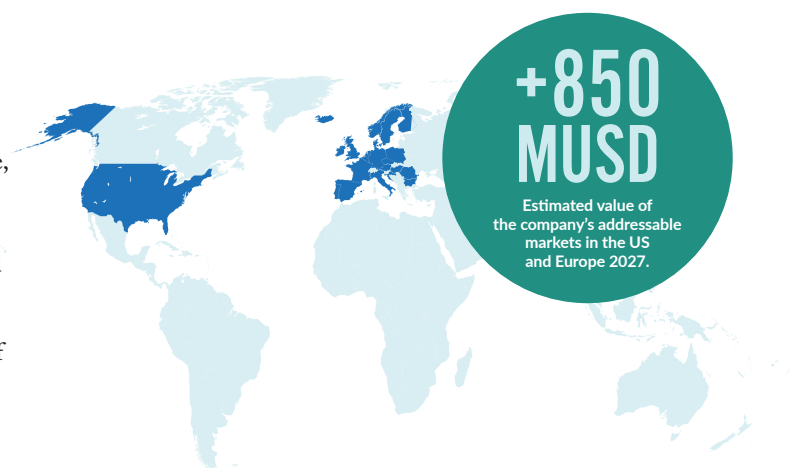
Patients may need to wait for several years before a matching doner is located. Approximately 70-80% of

transplanted organs come from deceased doners and these kidneys are heavily impacted by ischemia which leads to worse health outcomes for the patient.

The average patient that has received a transplanted kidney will live 10-15 years longer compared to a patient that

## 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

## FOURTH QUARTER

October – December 2023

### Results

For the fourth quarter of 2023, the company reports a loss amounting to -5,694 KSEK (-3,899 KSEK) and a total loss for the period January - December of -20,380 KSEK (-10,483 KSEK). Total operating expenses amounted to -11,153 KSEK (-6,788 KSEK) for the quarter and corresponding to -40,783 KSEK (-18,391 KSEK) for January-December. The total costs include development costs and costs for intellectual property.

The cost base has more than doubled in the past financial year in line with the progress and completion of the company's First in Human study (ATMIRe), conducted at Malmö University Hospital in 2022/2023, as well as planning, procurement, regulatory work and start-up of an upcoming multicenter study with a planned start in 2024. Cost drivers have mainly consisted of new recruitments, hired specialist competence in clinical and regulatory areas and production costs.

During the year, the company has invested considerable resources in its research department and research program with an increased workforce in new pre-clinical areas/indications for the product groups that the company has developed in recent years (iCM012 and iCM020). The company's costs in the RnD area account for almost 70% of the company's total costs, including the planned multicenter study in 2024.

Development costs for the company's ongoing clinical projects, ATMIRe and EMPIRE, amounted to -4,797 KSEK during the quarter and a total of -19,360 KSEK for the full year. Costs for IP protection for the company's patent portfolio during January-December amounted to -826 KSEK and have so far been capitalized as assets in the balance sheet with a total of 2,749 KSEK (1,923 KSEK). The corresponding capitalized development costs amount to a total of 36,575 KSEK (17,215 KSEK) as of 2023-12-31. Both development costs and patent costs are reported in the company's balance sheet under intangible assets.

Personnel costs for the quarter amounted to -2 788 KSEK (-2 171 KSEK) and for the full year to -7 486 KSEK.

(-4 849 KSEK). The increase in personnel costs is attributable 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 FTE in the last quarter of 2022, to 6 FTE for the corresponding in 2023.

### Investments

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

### Cash and cash equivalents

As of December 31, 2023, cash and cash equivalents amounted to KSEK 9,872 (KSEK 9,648).





## Cash flow

Cash flow from operating activities during the last quarter amounted to -5,689 KSEK (-3,899 KSEK), which is mainly driven by costs associated with building up the company's organization, support functions, advisory services and pre-clinical work. Cash flow from investing activities for the fourth quarter amounted to -5,226 KSEK (-2,889 KSEK), which mainly consists of development costs in ongoing clinical studies. Investments have increased compared to the corresponding period last year as a result of expansion in resources, production costs and regulatory advice for planning and preparation of the upcoming efficacy study. All investments are recognized as intangible assets. During the period January-December, financing activities have provided the company contribution of 32,831 KSEK (699 KSEK), of which 1,056 KSEK relates to the exercise of incentive programs.

## Equity

As of December 31, 2023, equity amounted to 39,499 KSEK (27,048 KSEK) and the company's equity ratio was 78% (85%).

## Debt and receivables

Current receivables as of 31 December 2023 amount to 1,275 KSEK (3,056 KSEK) and consist mainly of tax receivables in the form of VAT and major items for accrual from the end of 2022 and the previous quarter. Current liabilities amount to 11,087 KSEK (4,853 KSEK) as of December 31, which mainly consist of

accounts payable and employee-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 asset in the company's balance sheet, as of December 31, 2023, amounting to 36,575 KSEK. Costs relating to the company's work on patent protection and rights are capitalized in the balance sheet, as of December 31, 2023, amounting to 2,749 KSEK.

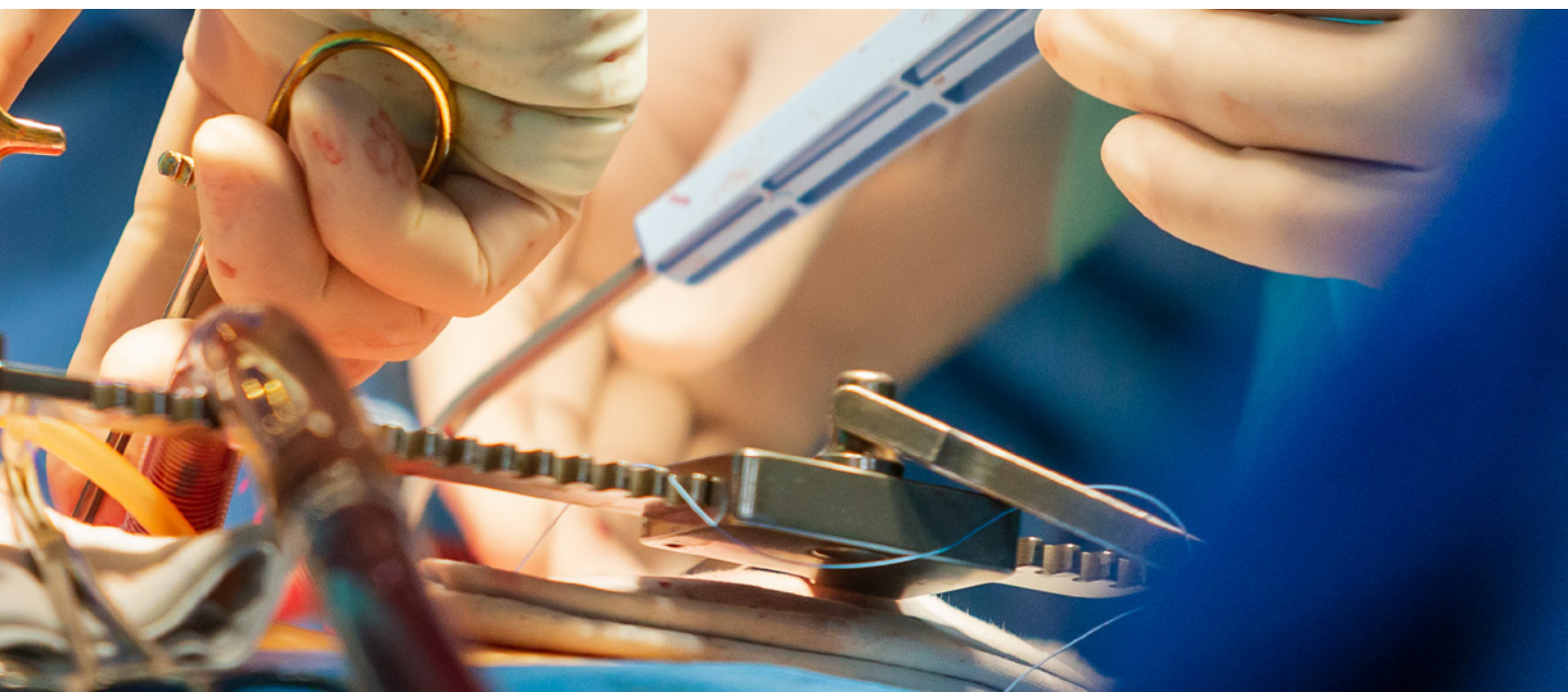
Amortization according to plan for capitalized development costs and patents will start after completion.

## Personnel

The number of employees based on annual working hours (FTE) has gradually increased over the past 12 months and as of December 31 amounted to 6.0 FTE (3.0) and total personnel costs for the period January – December represent approximately 17% (26%) of total in the company.

## Share

As of December 31, 2023, the company's share capital amounted to 680 KSEK (615 KSEK) and the number of shares amounts to a total of 165,774 (149,869), of which 100,000 A shares and 65,774 B shares distributed among a total of 43 shareholders. The company's shares are currently not admitted to trading on any public marketplace.



# INCOME STATEMENT

kSEK	Oct-Dec 2023	Oct-Dec 2022	Jan-Dec 2023	Jan-Dec 2022
<b>Net Sales</b>				
Activated work	4,797	2,685	19,360	6,898
Other operating income	21	-	60	25
	<b>4,818</b>	<b>2,685</b>	<b>19,420</b>	<b>6,923</b>
<b>Operating expenses</b>				
Clinical study	-1,967	-1,060	-7,793	-2,446
Other external expenses	-5,864	-3,350	-24,541	-10,100
Personnel costs	-2,788	-2,171	-7,486	-4,849
Depreciation	-5	-	-14	-
Other operating expenses	-44	-3	-123	-11
<b>Total operating expenses</b>	<b>-5,850</b>	<b>-3,899</b>	<b>-20,537</b>	<b>-10,483</b>
Net interest income	156	-	157	-
<b>Profit after financial items</b>	<b>-5,694</b>	<b>-3,899</b>	<b>-20,380</b>	<b>-10,483</b>
<b>Tax</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Profit/loss for the period</b>	<b>-5,694</b>	<b>-3,899</b>	<b>-20,380</b>	<b>-10,483</b>

# BALANCE SHEET

kSEK	2023-12-31	2022-12-31
<b>ASSETS</b>		
Development costs	36,575	17,215
Patents	2,749	1,923
Inventories, equipment and installations	89	-
Financial assets	26	59
<b>Total non-current assets</b>	<b>39,439</b>	<b>19,197</b>
Current receivables	1,275	3,056
Cash and cash equivalents	9,872	9,648
<b>Total current assets</b>	<b>11,147</b>	<b>12,704</b>
<b>TOTAL ASSETS</b>	<b>50,586</b>	<b>31,901</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Restricted equity</b>		
Share capital	680	615
Fund for development costs	39,324	19,138
<b>Total restricted equity</b>	<b>40,004</b>	<b>19,753</b>
<b>Un-restricted equity</b>		
Share premium reserve	66,609	34,883
Balanced profit or loss	-46,734	-17,105
Result during period	-20,380	-10,483
<b>Total un-restricted equity</b>	<b>-505</b>	<b>7,295</b>
Minority interest	-	-
<b>Equity</b>	<b>39,499</b>	<b>27,048</b>
Non-current debt	-	-
Current debt	11,087	4,853
<b>Total liabilities</b>	<b>11,087</b>	<b>4,853</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>50,586</b>	<b>31,901</b>

# CASH FLOW

kSEK	Oct-Dec 2023	Oct-Dec 2022	Jan-Dec 2023	Jan-Dec 2022
<b>Operating activities</b>				
Profit after financial items	-5,694	-3,899	-20,380	-10,483
Adjustments for non-cash items (depreciation)	5	-	14	-
Tax paid	-	-	-	105
<b>Cash flow from operating activities before changes in working capital</b>	<b>-5,689</b>	<b>-3,899</b>	<b>-20,366</b>	<b>-10,378</b>
<b>Cash flow from changes in working capital</b>				
Increase (-)/Decrease (+) of current receivables	569	-1,811	1,780	-2,133
Increase (+)/Decrease (-) of current liabilities	2,060	2,933	6,234	2,529
<b>Cash flow from operating activities</b>	<b>-3,060</b>	<b>-2,777</b>	<b>-12,352</b>	<b>-9,982</b>
<b>Investment activities</b>				
Acquisitions of intangible fixed assets	-5,282	-2,899	-20,186	-7,883
Acquisitions of tangible fixed assets	-	-	-103	-
Acquisitions of financial fixed assets	-	-	-22	-24
Disposal of financial assets	56	-	56	-
<b>Cash flow from investment activities</b>	<b>-5,226</b>	<b>-2,889</b>	<b>-20,255</b>	<b>-7,907</b>
<b>Financing activities</b>				
Share capital	-	-	65	-
Warrants	-	82	449	699
Share premium reserve	-	-	31,726	-
Paid non-registered share capital	591	-	591	-
Repaid shareholder contributions	-	-	-	-
New loans	-	-	-	-
<b>Cash flow from financing activities</b>	<b>591</b>	<b>82</b>	<b>32,831</b>	<b>699</b>
<b>Cash flow from the period</b>	<b>-7,695</b>	<b>-5,584</b>	<b>224</b>	<b>-17,191</b>
Cash and cash equivalents at the beginning of the period	17,567	15,232	9,648	26,839
Exchange rate difference in cash	-	-	-	-
<b>Cash and cash equivalents at the end of the period</b>	<b>9,872</b>	<b>9,648</b>	<b>9,872</b>	<b>9,648</b>

# CHANGES IN EQUITY

kSEK	Share capital	Fund for development costs	Share premium reserve	Balanced income incl. profit from period
<b>Balance at (1 jan 2023)</b>	<b>615</b>	<b>19,138</b>	<b>34,883</b>	<b>-27,587</b>
Fund for development costs		20,186		-20,186
Rights issue	65		31,726	
Costs related to rights issue				
Paid non-registered share capital				590
Warrants				449
Repaid shareholder contributions				
Transfer of share premium reserve				
Results from period				-20,380
<b>Balance at (31 december 2023)</b>	<b>680</b>	<b>39,324</b>	<b>66,609</b>	<b>-67,114</b>
<b>Balance at (1 jan 2022)</b>	<b>615</b>	<b>11,255</b>	<b>34,883</b>	<b>-9,920</b>
Fund for development costs		7,883		-7,883
Rights issue				669
Costs related to rights issue				
Warrants				
Repaid shareholder contributions				
Transfer of share premium reserve				
Results from period				-10,483
<b>Balance at (31 december 2022)</b>	<b>615</b>	<b>19,138</b>	<b>34,883</b>	<b>-27,587</b>

# 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 2022.

### 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 2022.

### 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

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



# OTHER INFORMATION

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## Financial calendar

AGM 2024	24 April 2024
Publication of Annual Report 2023	3 March 2024
Interim Report Q1 (January-March 2024)	15 May 2024
Interim Report Q2 (April-June 2024)	15 August 2024
Interim Report Q3 (July-September 2024)	15 November 2024
Interim Report Q4 (October-December 2024)	14 February 2025

This interim report has been published on iCoat Medical's website, [www.icoatmedical.com](http://www.icoatmedical.com)  
The report has not been reviewed by the company's auditor.

## For additional information, please contact:

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Mattias Springare, CFO & Head of Investor Relations  
[mattias.springare@icoatmedical.com](mailto:mattias.springare@icoatmedical.com)

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, at February 23, 2024, 08.00 (CET).

## iCoat Medical AB

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