

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.

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THE PERIOD IN BRIEF

Compared to corresponding period the previous year

Financial overview July - September:

- The quarterly loss amounted to -5,604 KSEK (-2,047 KSEK)
- Cash and cash equivalents amounted to 17,567 KSEK (15,232 KSEK) at the end of the period
- Cash flow during the quarter amounted to -9,467 KSEK (-3,656 KSEK)
- Equity amounted to 44,602 KSEK (30,874 KSEK) at the end of the period and total assets amounted to 53,629 KSEK (32,785 KSEK)
- Equity/Assets-ratio amounted to 83% (94%) at the end of the period

Financial overview January - September:

- The period's loss amounted to -14,687 KSEK (-6,575 KSEK)
- Cash and cash equivalents amounted to 17,567 KSEK (15,232 KSEK) at the end of the period
- Cash flow during the period amounted to 7,918 KSEK (-11,607 KSEK)
- Equity amounted to 44,602 KSEK (30,874 KSEK) at the end of the period and total assets amounted to 53,629 KSEK (32,785 KSEK)
- Equity/Assets-ratio amounted to 83% (94%) at the end of the period

Significant events July - September:

- Extensive preparations for a pivotal study including site selection in several countries.
- In July, the last follow-up visit with patient 18/18 in the company's First-in-Human study was conducted with results according to plan.
- In September, results from the First-in-Human study (ATMIRe) were finalized.

Significant events after the period:

• Initiation of new pre-clinical studies in animal models for heart transplantation and open-heart surgery for the company's new indications.

KEY FIGURES

kSEK	Q3 2023	Q3 2022	Jan-Sept 2023	Jan-Sept 2022	2022
EBIT	-5,604	-2,047	-14,678	-6,575	-10,483
Assets	53,629	32,785	53,629	32,785	31,901
Equity/Assets-ratio	83%	94%	83%	94%	85%

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During the third quarter, the intensive work that has characterized this entire year for iCoat Medical continued, and during the period, we were able to advance the development of our prioritized clinical project in kidney transplantation, as well as continue to work with the preclinical indications of heart transplantation and open heart surgery, which together means that I look forward to the near future with great confidence.

All organs that are transplanted are at risk of ischemia-reperfusion damage due to the cells lack of oxygen, which in turn activates the immune system that attacks and further damages these cells. Our lead product candidate iCM012 protects ischemic cells against the immune system and thereby reduces the risk of inflammation and organ rejection. Its use has the potential to improve patient outcomes, increase the availability of organs that can be used for transplantation, and reduce societal costs.

In July, the last follow-up visit with the 18th and last patient (Last Patient Last Visit, LPLV) was conducted in the company's First-in-Human study ATMIRe (phase I/IIa), where iCM012 has been studied in connection with kidney transplants. Fortunately, everything went according to plan, and the results of the study were completed in September. Later in the fall, we were able to start the work linked to publications and presentations at international scientific conferences. We are seeing a great deal of interest in our clinical and preclinical program in scientific circles, which of course gives encourages us in our continued work.

During the third quarter, extensive preparations were also made for our pivotal clinical study EMPIRe (phase IIb/III), including visits to hospitals around the US and Europe. Nearly 40 transplant centers were included in the evaluation with positive responses, and our goal is to have the study approved in H1 2024 and then start enrolling patients, which is an important milestone for us.

In addition to the development of iCM012 for kidney transplantation, preclinical research in heart transplantation and open-heart surgery is also progressing, which are intended to be the next indications to advance towards clinical development. The development of our other potential drug candidate iCM020, which aims to counteract damage from so-called warm ischemia that can occur in connection with transplantation and thromboses, such as heart attack and stroke, is also continuing.

After the period, we initiated new pig studies/animal models regarding heart transplantation and openheart surgery, and in early October we had a meeting with the Swedish Medical Products Agency to discuss them as potential new clinical indications for iCM012. Initial results are expected in Q1 2024.

As our development program continues to take shape, the company is growing, and during the quarter we moved into larger premises in the Medicon Village research park in Lund, which creates a good foundation for expanded future clinical activities.

Earlier this year, we carried out a directed share issue that secures the financing of our ongoing costs for ATMIRe, preparations for EMPIRe and continued preclinical studies for new indications and iCM020.

I look forward to updating you on our plans going forward and to continue our efforts to ultimately offer a product that has 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 will have an important role to play in this development.

Peder Waern

CEO, iCoat Medical AB



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, this work will continue during coming months.

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.

ISCHEMIA REPERFUSION INJURY

Ischemia Reperfusion Injury (IRI) is a mechanism that can lead to trombo 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:

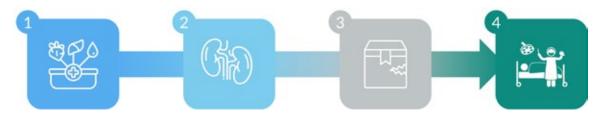
- · Organ transplants
- Heart surgery
- Heart attack
- Stroke

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.





- 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

Global Observatory on Donation and Transplantation.
 National institute of Diabetes and Digestive and Kidney Diseases

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

Njursjukdomar är ett globalt problem och mer än 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 seizes 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 receives dialysis. The potential cost savings with transplants are significant and the patient also receives a significantly higher quality of life.

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 TUM012 in 2027 and the estimated value of the addressable market amounts to +850 MUSD. iCoat Medical could potentially review additional markets.



FINANCIAL INFORMATION

THIRD QUARTER

July - September 2023

Results

For the third quarter of 2023, the company reports a loss amounting to -5,604 KSEK (-2,047 KSEK) and a total loss for the period January - September of -14,687 KSEK (-6,575 KSEK). Total operating expenses amounted to -13,043 KSEK (-3,374 KSEK) for the third quarter and corresponding to -29,289 KSEK (-10,813 KSEK) for January-September. The total costs include development costs and costs for intellectual property.

The total costs has more than doubled in the last 12 months 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 the planning, procurement and start-up of the upcoming multicenter study (EMPIRe) in H1 2024. Cost drivers have mainly consisted of new recruitments, hired specialist competence in clinical and regulatory areas and production costs.

During the period, January-September, the company has invested considerable resources in its research department and research program with an expanded workforce in new pre-clinical areas/indications for the product groups 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 upcoming multicenter study (EMPIRe).

Development costs for the company's ongoing projects, ATMIRe and EMPIRe, amounted to -7,411 KSEK during the quarter and a total of -14,563 KSEK for the period. IP protection costs for the company's patent portfolio during January-September amounted to -341 KSEK and have so far been capitalized as assets in the balance sheet with a total of -2,264 KSEK. The corresponding capitalized development costs amount to a total of -31,778 KSEK as of 2023-09-30. Both development costs and patent costs are recognized under intangible assets.

Personnel costs during the quarter amounted to -1,445 KSEK (-1,110 KSEK) and for the entire period -4,698 KSEK (-2,669 KSEK). The increase in personnel costs is connected to the expansion of the workforce in RnD and to the company's ongoing clinical studies. The number of employees in the company has gone from 3.0 FTE in Q3 2022, to 5 FTE for the corresponding quarter of 2023.

Investments

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

Cash and cash equivalents

As of September 30, 2023, cash and cash equivalents amounted to 17,567 KSEK (15,232 KSEK).



Cash flow

Cash flow from operating activities during the quarter amounted to -1,932 KSEK (-1,788 KSEK), which is mainly driven by costs associated with the establishment of the company's organization, support functions, advisory and pre-clinical work. Cash flow from investing activities for the third quarter amounted to -7 535 KSEK (-1,868 KSEK), which 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 support for planning and preparation of the upcoming efficacy study. All investments are recognized as intangible assets. During the period January-September, financing activities have provided the company a contribution of 32,240 KSEK (0 KSEK) through a directed share issue.

Equity

Equity amounted to 44,602 KSEK (30,874 KSEK) on September 30, 2023, and the company's equity/ assets-ratio amounted to 83% (94%).

Debt and receivables

Current receivables as of 30th September 2023 amounts to 1,844 KSEK (1,245 KSEK) and consist mainly of tax receivables of VAT and major items for accruals from the end of 2022 and the previous quarter. Current liabilities amount to 9,027 KSEK (1,911 KSEK) as of September 30, which mainly consist of accounts payable and personnel-related liabilities for

taxes and fees and accrual effects for reserved costs from the previous quarter and the previous year.

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 September 30, 2023, amounting to 31,778 KSEK. Costs relating to the company's work for patent protection and rights are capitalized in the balance sheet, as of September 30, 2023, amounting to 2,264 KSEK. Amortization according to plan for capitalized development costs and patents starts only after completion.

Personnel

The number of employees, based on annual working hours, has gradually increased over the past year and as of September 30 amounts to 5.0 FTE (3.0) and the total personnel costs for the period January-September represents approximately 16% (25%) of total costs in the company.

Share

The company's share capital amounted to 680 KSEK (615) on September 30, 2023. The number of shares amounts to 165,774 (149,869) of which 100,000 are A-class shares and 65,774 are B-shares. The number of shareholders amounts to 43. The company's share is currently not traded on a listed exchange.



INCOME STATEMENT

ksek	July-Sept 2023	July-Sept 2022	Jan-Sept 2023	Jan-Sept 2022	Jan-Dec 2022
Net Sales					
Activated work	7,410	1,316	14,563	4,213	6,898
Other operating income	35	11	39	25	25
	7,445	1,327	14,602	4,238	6,923
Operating expenses					
Clinical study	-4,181	-305,000	-5,826	-1,387	-2,446
Other external expenses	-7,385	-1,958	-18,676	-6,749	-10,100
Personnel costs	-1,445	-1,110	-4,698	-2,669	-4,849
Depreciation	-5	-	-9	-	-
Other operating expenses	-33	-1	-80	-8	-11
Total operating expenses	-5,604	-2,047	-14,687	-6,575	-10,483
Net interest income	-	-	-	-	-
Profit after financial items	-5,604	-2,047	-14,687	-6,575	-10,483
Тах	-	-	-	-	-
Profit/loss for the period	-5,604	-2,047	-14,687	-6,575	-10,483

BALANCE SHEET

ksek	2023-09-30	2022-09-30	2022-12-31
ASSETS	2023-07-30	2022-09-30	2022-12-31
Development costs	31,778	14,529	17,215
Patents		,	
	2,264	1,719	1,923
Inventories, equipment and installations	94	-	-
Financial assets	82	60	59
Total non-current assets	34,218	16,308	19,197
Current receivables	1,844	1,245	3,056
Cash and cash equivalents	17,567	15,232	9,648
Total current assets	19,411	16,477	12,704
TOTAL ASSETS	53,629	32,785	31,901
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	680	615	615
Fund for development costs	34,042	16,248	19,138
Total restricted equity	34,722	16,863	19,753
Un-restricted equity			
Share premium reserve	66,609	34,883	34,883
Balanced profit or loss	-42,042	-14,297	-17,105
Result during period	-14,687	-6,575	-10,483
Total un-restricted equity	9,880	14,011	7,295
Minority interest	-	-	-
Equity	44,602	30,874	27,048
Non-current debt	-	-	-
Current debt	9,027	1,911	4,853
Total liabilities	9,027	1,911	4,853
TOTAL EQUITY AND LIABILITIES	53,629	32,785	31,901

CASH FLOW

	July-Sept	July-Sept	Jan-Sept	Jan-Sept	Jan-Dec
ksek	2023	2022	2023	2022	2022
Operating activities					
Profit after financial items	-5,604	-2,047	-14,687	-6,575	-10,483
Adjustments for non-cash items (depreciation)	5	=	9	=	-
Tax paid	-	-	-	-	105
Cash flow from operating activities before changes in working capital	-5,599	-2,047	-14,678	-6,575	-10,378
Cash flow from changes in working capital					
Increase (-)/Decrease (+) of current receivables	114	13	1,212	-321	-2,133
Increase (+)/Decrease (-) of current liabilities	3,553	246	4,173	-309	2,529
Cash flow from operating activities	-1,932	-1,788	-9,293	-7,205	-9,982
Investment activities					
Acquisitions of intangible fixed assets	-7,513	-1,868	-14,905	-4,994	-7,883
Acquisitions of tangible fixed assets	-	-	-102	-	-
Acquisitions of financial fixed assets	-22	-	-22	-25	-25
Cash flow from investment activities	-7,533	-1,868	-15,029	-5,019	-7,908
Financing activities					
Share capital	-	-	65	-	-
Warrants	-	-	449	617	699
Share premium reserve	-	-	31,726	-	-
Costs related to rights issue	-	-	-	-	-
Repaid shareholder contributions	-	-	-	-	-
New loans	-	-	-	-	-
Cash flow from financing activities	-	-	32,240	617	699
Cash flow from the period	-9,467	-3,656	7,918	-11,607	-17,191
Cash and cash equivalents at the beginning of the period	27,033	18,888	9,648	26,839	26,839
Exchange rate difference in cash	-	-	-	-	-
Cash and cash equivalents at the end of the period	17,566	15,232	17,566	15,232	9,648

CHANGES IN EQUITY

ksek	Share capital	Fund for development costs	Share premium reserve	Balanced income incl. profit from period
Balance at (1 jan 2023)	615	19,138	34,883	-27,587
Fund for development costs		14,904		-14,904
Rights issue	65		31,726	
Costs related to rights issue				
Bonus issue				
Warrants				449
Repaid shareholder contributions				
Transfer of share premium reserve				
Results from period				-14,687
Balance at (30 september 2023)	680	34,042	66,609	-56,729
Balance at (1 jan 2022)	615	11,255	34,883	-9,920
Fund for development costs		4,994		-4,994
Rights issue				
Costs related to rights issue				
Bonus issue				
Warrants				617
Repaid shareholder contributions				
Transfer of share premium reserve				
Results from period				-6,575
Balance at (30 september 2022)	615	16,249	34,883	-20,872
Balance at (1 jan 2022)	615	11,255	34,883	-9,920
Fund for development costs		7,883		-7,883
Rights issue				
Costs related to rights issue				
Bonus issue				699
Warrants				
Repaid shareholder contributions				
Transfer of share premium reserve				
Results from period				-10,483
Balance at (31 dec 2022)	615	19,138	34,883	-27,587

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



FINANCIAL CALENDER

Interim report Q4 (October-December 2023), February 15, 2024.

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, at November 15, 2023, 08.00 (CET).

iCoat Medical AB

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