iCoat Medical

INTERIM REPORT SECOND QUARTER 2023

Q2 2024

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, TUM012, 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 TUM012 has the potential to improve the kidney's function following transplantation. The organisation includes surgeons and scientists with expertise in all phases of research and development as well as an experienced commercial team. TUM012 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 April–June

- The quarterly loss amounted to -5,232 KSEK (-2,975)
- Cash and cash equivalents amounted to 27,032 KSEK (18,888) at the end of the period
- Cash flow during the quarter amounted to 24,155 KSEK (-4,847)
- Equity amounted to 50,207 KSEK (32,922) at the end of the period and total assets amounted to 55,680 KSEK (34,585)
- Equity/Assets-ratio amounted to 90% (95%) at the end of the period

Financial overview January–June

- The period's loss amounted to -9,082 KSEK (-4,527)
- Cash and cash equivalents amounted to 27,032 KSEK (18,888) at the end of the period
- Cash flow during the period amounted to 17,384 KSEK (-7,951)
- Equity amounted to 50,207 KSEK (32,922) at the end of the period and total assets amounted to 55,680 KSEK (34,585)
- Equity/Assets-ratio amounted to 90% (95%) at the end of the period

Significant events April–June

- In the beginning of May, the 18th and final patient was included in the company's First-in-Human study, ATMIRe, at the University Hospital in Malmö, Sweden.
- Carl Bjartmar was appointed the company's Chief Commercial Officer and is thereby a member in the executive management. Carl is also a Board member in iCoat Medical. Carl has extensive experience of pharma development and IPOs and has been part of management in Wilson Therapeutics and Ascelia Pharma, among other companies.
- A directed issue provided proceeds of 33 MSEK.

Significant events after the period

- No significant events have taken place after the period.

KEY FIGURES

kSEK	Q2 2023	Q2 2022	Jan-Jun 2023	Jan-Jun 2022	2022
EBIT	–5,232	–2,975	–9,082	–4,527	–10,483
Assets	55,680	34,585	55,680	34,585	31,901
Equity/Assets-ratio	90%	95%	90%	95%	85%

CEO LETTER

DEAR SHAREHOLDER,

During the quarter, iCoat Medical continued to make progress in the ongoing clinical study ATMIRe, in which our leading product candidate TUM012 is tested for use in connection to kidney transplants. All 18 patients that have been included in the study have now completed their treatments and we have therefor initiated analysis of data to better understand patient security. In parallel, planning continues for the coming clinical study for TUM012, EMPIRe, with the aim of initiating the study during the first half of 2024.

All organs that are transplanted run the risk of Ischemia Reperfusion Injury since cells suffer from a lack of oxygen and thereby the immune system is activated and it attacks and damages these cells. TUM012 protects ischemic cells from the immune system and thereby reduces the risk of inflammation and organ rejection. Its use improves patient outcome, increases availability of organs for transplantation and reduces societal costs associated with kidney failure.

The final patient to be included in our First-in-Human study (phase I) ATMIRe was transplanted in May and we expect to announce the study's headline results during the third quarter 2023. We have previously presented interim data that showed that no patient in the study experienced any negative side effects associated with the treatment.

We also continue to work on the study design for the upcoming phase II/III study, EMPIRe, for TUM012 for use in kidney transplants. EMPIRe is an international study which will include patients at several clinics, both in the US and Europe. Within short, we will have a meeting with the FDA which will allow us to present the study design and we expect that the application will be approved later this year so that we can initiate the study in the beginning of next year.

EMPIRe will require external funding and this is why preparations are underway to complete an IPO for a listing on Nasdaq First North Growth Market. During the quarter, we performed a directed issue that secures funding of the business's ongoing costs for ATMIRe, preparations ahead of EMPIRe and continued pre-clinical studies for new indications and TUM020 until we complete the IPO. It is pleasing to see that iCoat Medical continues to make steady clinical progress and I look forward to soon present headline results from our clinical study ATMIRe.

Peder Waern
CEO, iCoat Medical AB

OUR PRODUCTS

TUM012

- TUM012 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, TUM012 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 TUM012, this work will continue during coming months.

TUM020

- TUM020 is developed based on TUM012 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

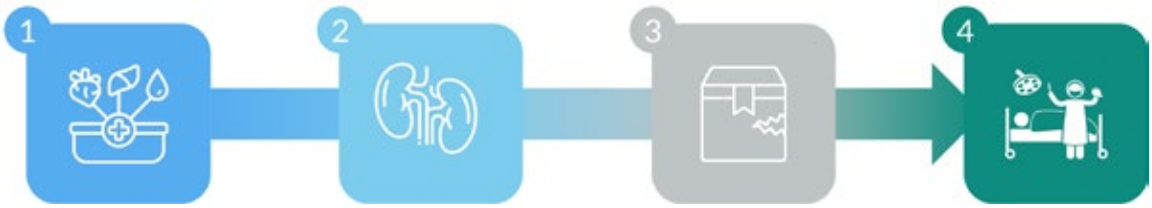
IRI is the damage that occurs to the transplanted organ when blood circulation is returned to the organ after a period of ischemia, ie lack of oxygen.

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.

Pharmaceutical products	Candidate / Project	Usage area	Research	Preclinical studies	Clinical preparation Phase I	Phase II	Phase III	Expected next step
iCoat Medical's technology platform	TUM012	Kidney transplantation						Data readout Q2–Q3, 2023
		Heart transplantation						Development plan completed – Q1 2023
		Cardiopulmonary bypass – open heart surgery, ECMO						Development plan completed – Q1 2023
		Lung transplantation						Ongoing research
	TUM020	Stroke						
		Myocardial infarction						Ongoing research
		Cardiopulmonary bypass – open heart surgery, ECMO						

COMPLETED ONGOING PLANNING



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

- Less than 10% of the global need of organs is covered[1)]
- Each year kidney disease kills more people than breast or prostate cancer[2)]

- 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.

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

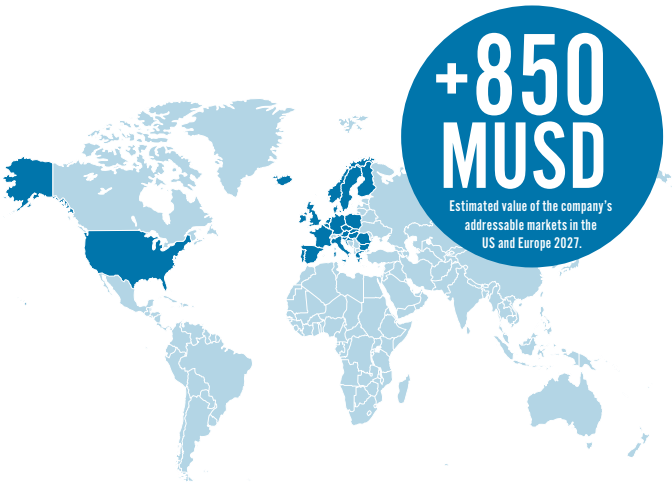
Kidney disease IS a global problem and more than 850 million people suffer from some kind of kidney disease, which makes it into one of the most common diseases. End-Stage Renal Disease (ESRD) implies that the kidney seizes to function and over 2 million patients suffer from the disease globally. Kidney 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

SECOND QUARTER 2023

Results

The company made a loss of -5,232 KSEK (-2,975) during the second quarter. The loss has increased primarily due to recruitment of staff, larger reserves and some timing effects. The total operating costs amounted to -8,845 KSEK (-3,969) during the second quarter and include other external costs of -6,285 KSEK (-2,855). Other external costs primarily include costs for research and development but also for the organization of the company's support functions as well as advisory services in law, communication and regulatory. Other external costs have primarily increased due to increased development costs for completion of the company's First-in-Human study ATMIRe and due to new pre-clinical indications for TUM012. Personnel costs amounted to -1,965 KSEK (-1,046) during the second quarter. Personnel costs have increased due to recruitments and a larger share full time employees.

The company made a loss of -9,082 KSEK (-4,527) during the period January-June. The total operating costs amounted to -16,239 KSEK (-7,437) during the period January-June, of which other external costs amount to -11,292 KSEK (-4,791). Personnel costs amounted to -3,253 KSEK (-1,558) during the period January-June. The reasons for the changes during the period January-June are the same as for the quarter.

Cash flow

Cash flow from operating activities amounted to -3,842 KSEK (-3,674) and cash flow from investing activities amounted to -3,794 KSEK (-1,173). Investments relates to development costs for the company's ongoing clinical study ATMIRe and coming phase II/III study EMPIRe. Investments have increased compared to the corresponding period last year due to new recruitments, increased production costs for TUM012 and regulatory advisory concerning the company's coming phase phase II/III study EMPIRe. All investments are accounted for as intangible assets. Cash flow from financing activities amounted to 31,791 KSEK (0) following a directed issue. Cash flow for the second quarter amounted to 24,155 KSEK (-4,847).

Cash flow from operating activities amounted to -7,363 KSEK (-5,417) during the period January-June and cash flow from investing activities amounted to -7,493 KSEK (-3,151). Cash flow from financing activities amounted to 32,240 KSEK

(617) during the same period. Cash flow for the period January–June amounted to 17,384 KSEK (–7,951).

Cash and cash equivalents amounted to 27,032 KSEK (18,888) on June 30, 2023.

Intangible assets

Costs associated with development of the company's product candidate TUM012 are activated and accounted for as intangible assets in the company's balance sheet. The value of development costs amounted to 24,368 KSEK (13,214) on June 30, 2023. Also costs connected to the company's work on patent protection and rights are activated in the balance sheet. The value of patents amounted to 2,162 KSEK (1,166) on June 30, 2023.

Depreciation of activated development costs and patents begins once the product has received market approval.

Equity

Equity amounted to 50,207 KSEK (32,922) on June 30, 2023 and the company's equity/assets-ratio amounted to 90% (95%).

Debt and receivables

Short term receivables amounted to 1,960 KSEK (1,257) on June 30, 2023 and primarily include tax receivables related to value added tax and timing effects. The increase is a result of a growing business and receivables have increased in line with the larger cost base. Short term debt amounted to 5,473 KSEK (1,663) on June 30, 2023 and primarily include accounts payable and personnel related debt for tax and fees.

Personnel

The number of employees has increased during the year and amounted to 5.0 FTE (2.0 FTE) on June 30, 2023.

Share

The company's share capital amounted to 661 KSEK (615) on June 30, 2023. The number of shares amounts to 165,324 (149,869) of which 100,000 are A-class shares and 65,324 are B-shares. The number of shareholders amounts to 40. The company's share is currently not traded on a listed exchange.

INCOME STATEMENT

kSEK	Apr-Jun 2023	Apr-jJn 2022	Jan-Jun 2023	Jan-Jun 2022	Jan-Dec 2022
Net sales					
Activated work	3,613	982	7,153	2,897	6,898
Other operating income	-	12	4	13	25
	3,613	**994**	**7,157**	**2,910**	**6,923**
Operating expenses					
Clinical study	–561	–67	–1,645	–1,081	–2,446
Other external expenses	–6,285	–2,855	–11,292	–4,791	–10,100
Personnel costs	–1,965	–1,046	–3,253	–1,558	–4,849
Depreciation	–3	-	–3	-	-
Other operating expenses	–31	–1	–46	–7	–11
Total operating expenses	**–8,845**	**–3,969**	**–16,239**	**–7,437**	**–17,406**
Operating profil	**–5,232**	**–2,975**	**–9,082**	**–4,527**	**–10,483**
Financial items	-	-	-	-	-
Profit after financial items	**–5,232**	**–2,975**	**–9,082**	**–4,527**	**–10,483**
Tax	**-**	**-**	**-**	**-**	**-**
PROFIT/LOSS FOR THE PERIOD	**–5,232**	**–2,975**	**–9,082**	**–4,527**	**–10,483**

BALANCE SHEET

kSEK	Jun 30, 2023	Jun 30, 2022	Dec 31, 2022
ASSETS			
Development costs	24,368	13,214	17,215
Patents	2,162	1,166	1,923
Inventories, equipment and installations	99	-	-
Financial assets	59	60	59
Total non-current assets	**26,688**	**14,440**	**19,197**
Current receivables	1,960	1,257	3,056
Cash and cash equivalents	27,032	18,888	9,648
Total current assets	**28,992**	**20,145**	**12,704**
TOTAL ASSETS	**55,680**	**34,585**	**31,901**
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	661	615	615
Fund for development costs	26,529	14,380	19,138
Total restricted equity	**27,190**	**14,995**	**19,753**
Un-restricted equity			
Share premium reserve	65,410	34,883	34,883
Balanced profit or loss	–33,311	–12,429	–17,105
Result during period	–9,082	–4,527	–10,483
Total un-restricted equity	**23,017**	**17,927**	**7,295**
Minority interest	-	-	-
Equity	**50,207**	**32,922**	**27,048**
Non-current debt	-	-	-
Current debt	5,473	1,663	4,853
Total liabilities	**5,473**	**1,663**	**4,853**
TOTAL EQUITY AND LIABILITIES	**55,680**	**34,585**	**31,901**

CASH FLOW

kSEK	Apr-Jun 2023	Apr-jJn 2022	Jan-Jun 2023	Jan-Jun 2022	Jan-Dec 2022
Operating activities					
Profit after financial items	–5,232	–2,975	–9,082	–4,527	–10,483
Increase (+) / Decrease (-) in working capital	-	-	-	-	105
Cash flow from operating activities before changes in working capital	**–5,232**	**–2,975**	**–9,082**	**–4,527**	**–10,378**
Cash flow from changes in working capital					
Increase (-)/Decrease (+) of current receivables	259	–658	1,097	–334	–2,133
Increase (+)/Decrease (-) of current liabilities	1,131	–41	622	–556	2,529
Cash flow from operating activites	**–3,842**	**–3,674**	**–7,363**	**–5,417**	**–9,982**
Investment activities					
Acquisitions of intangible fixed assets	–3,692	–1,173	–7,391	–3,126	–7,883
Acquisitions of tangible fixed assets	–102	-	–102	-	-
Acquisitions of financial fixed assets	-	-	-	–25	–25
Cash flow from investment activities	**–3,794**	**–1,173**	**–7,493**	**–3,151**	**–7,908**
Financing activities					
Share capital	46	-	46	-	-
Subscription rights	-	-	449	617	699
Premium fund	31,745	-	31,745	-	-
Cash flow from financing activities	**31,791**	**-**	**32,240**	**617**	**699**
Cash flow for the period	**24,155**	**–4,847**	**17,384**	**–7,951**	**–17,191**
Cash and cash equivalents at the beginning of the period	2,877	23,735	9,648	26,839	26,839
Cash and cash equivalents at the end of the period	**27,032**	**18,888**	**27,032**	**18,888**	**9,648**

CHANGES IN EQUITY

kSEK	Share capital	Fund for development costs	Share premium reserve	Balance income incl profit from period
Balance at Jan 1, 2023	**615**	**19,138**	**34,883**	**–27,587**
Fund for development costs		7,391		–7,392
Rights issue	46		30,527	1,219
Warrants				449
Results from period				–9,082
Balance at June 30, 2023	**661**	**26,529**	**65,410**	**–42,393**
Balance at Jan 1, 2022	**615**	**11,255**	**34,883**	**–9,920**
Fund for development costs		3,125		–3,125
Warrants				617
Results from period				–4,527
Balance at June 30, 2022	**615**	**14,380**	**34,883**	**–16,955**
Balance at Jan 1, 2022	**615**	**11,255**	**34,883**	**–9,920**
Fund for development costs		7,883		–7,883
Warrants				699
Results from period				–10,483
Balance at December 31, 2022	**615**	**19,138**	**34,883**	**–27,587**

NOTER

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

SIGNATURES

The board and the CEO of iCoat Medical AB (publ) declare that this Interim report provides a true and fair overview of the company operations, position and earnings and describes the material risks and uncertainty factors faced by the company.

Stockholm, August 15, 2023
iCoat Medical AB (publ)

Hans Larsson
Chairman

Bertil Villard
Member of the board

Bo Nilsson
Member of the board

Carl Bjartmar
Member of the board

Marianne Jensen Waern
Member of the board

Martin Åmark
Member of the board

Peder Waern
CEO

OTHER INFORMATION

FINANCIAL CALENDAR

Interim report Q3 (July–September 2023), November 15, 2023.

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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Mattias Springare, CFO & Head of Investor Relations
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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 August 15, 2023, 08.00 (CET).

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