iCoat Medical

INTERIM REPORT FIRST QUARTER 2023

Q1 2023

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 globally almost 170 000 transplantations were made in 2021.

THE PERIOD IN BRIEF

Compared to corresponding period the previous year

Financial overview January–March

- The quarterly loss amounted to –3,850 KSEK (–1,553)
- Cash and cash equivalents amounted to 2,877 KSEK (23,735) at the end of the period
- Cash flow during the quarter amounted to –6,771 KSEK (3,104)
- Equity amounted to 23,647 KSEK (35,897) at the end of the period and total assets amounted to 27,991 KSEK (37,602)
- Equity/Assets-ratio amounted to 84% (95%) at the end of the period

Significant events January–March

- The company filed an international patent application for a new indication for PEG-phospholipid molecules. The molecule is connected to iCoat Medical's focus area ischemic reperfusion injury and is expected to contribute to a strengthening of the company's product portfolio.

Significant events after the period

- In the beginning of May, the 18th and final patient was included in the company's First-In-Human study, ATMIRe, at Skåne's University Hospital in Malmö.
- 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 was completed in May and provided proceeds of 33 MSEK.

KEY FIGURES

kSEK	Q1 2023	Q1 2022	2022
Net sales	3,544	1,916	6,923
EBIT	–3,850	–1,553	–10,483
Total assets	27,991	37,602	31,901
Equity/Assets-ratio	84%	95%	85%

CEO LETTER

DEAR SHAREHOLDER

During the quarter, iCoat Medical continued to make progress in the ongoing clinical trial ATMIRe, which evaluates the safety and tolerability of ex vivo allograft treatment with TUM012 to mitigate ischemia-reperfusion injury in kidney transplantation. In parallel, pre-clinical development of TUM012 continues for the indications heart transplants and open heart surgery, as well as of TUM020 which aims to prevent damage from warm ischemia.

Ischemia-reperfusion injury is a detrimental event that inevitably occurs during organ or cell transplantation. This condition can lead to early inflammation and inferior short and long-term transplant outcome. TUM012 has shown promise in reducing the severity of ischemia-reperfusion injury by providing protection against injurious immune attacks. This novel intervention holds the potential to improve patient outcome, increases the availability of organs for transplantation, and reduces costs associated with premature transplant failure.

In our ongoing First-in-Human study (phase I) ATMIRe, the enrollment of all intended 18 patients has recently been completed. As the study progresses, we eagerly await the completion of the 3-month follow-up period for all patients, after which a comprehensive data analysis will be conducted. Subsequently, we will present the final results of the study.

We also continue to work on the study design for the upcoming efficacy trial, known as EMPIRe. EMPIRe is a multicenter phase II trial that aims to evaluate the efficacy and safety of TUM012 in kidney transplantation. The study is planned to include between 100-150 patients across several transplant centers. We have recruited a project manager for EMPIRe and are negotiating with a Clinical Research Organization (CRO) which will be responsible for carrying out the study. Our team is working on preparing the necessary documentation and data required for the study's application to regulatory authorities, including the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). We anticipate submitting the application for the study in the third quarter of 2023, and based on our current projections, we expect the application to be approved during the second half of 2023.

Preparations ahead of a market listing on Nasdaq First North Growth Market continue even though its timing has become more uncertain due to a more uncertain market environment. After the period, we completed a directed issue of 33 MSEK that ensures financing of the business's ongoing costs for ATMIRe, preparations for EMPIRe and continued pre-clinical studies for new indications and TUM020 during the coming 12 months. iCoat Medical continues to make steady clinical progress and I look forward to soon present final 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 will continue during fall.

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 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 following 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.

GLOBAL 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. The lack of available organs is growing due to a number of factors: the population is getting

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
		Stroke						
	TUM020	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.

older, more people suffer from organ failure and demands on healthcare are increasing.

KIDNEY TRANSPLANTATION

NKidney 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.

FINANCIAL INFORMATION

QUARTERLY REPORT FOR THE FIRST QUARTER 2023, JANUARY-MARCH 2023,

Result

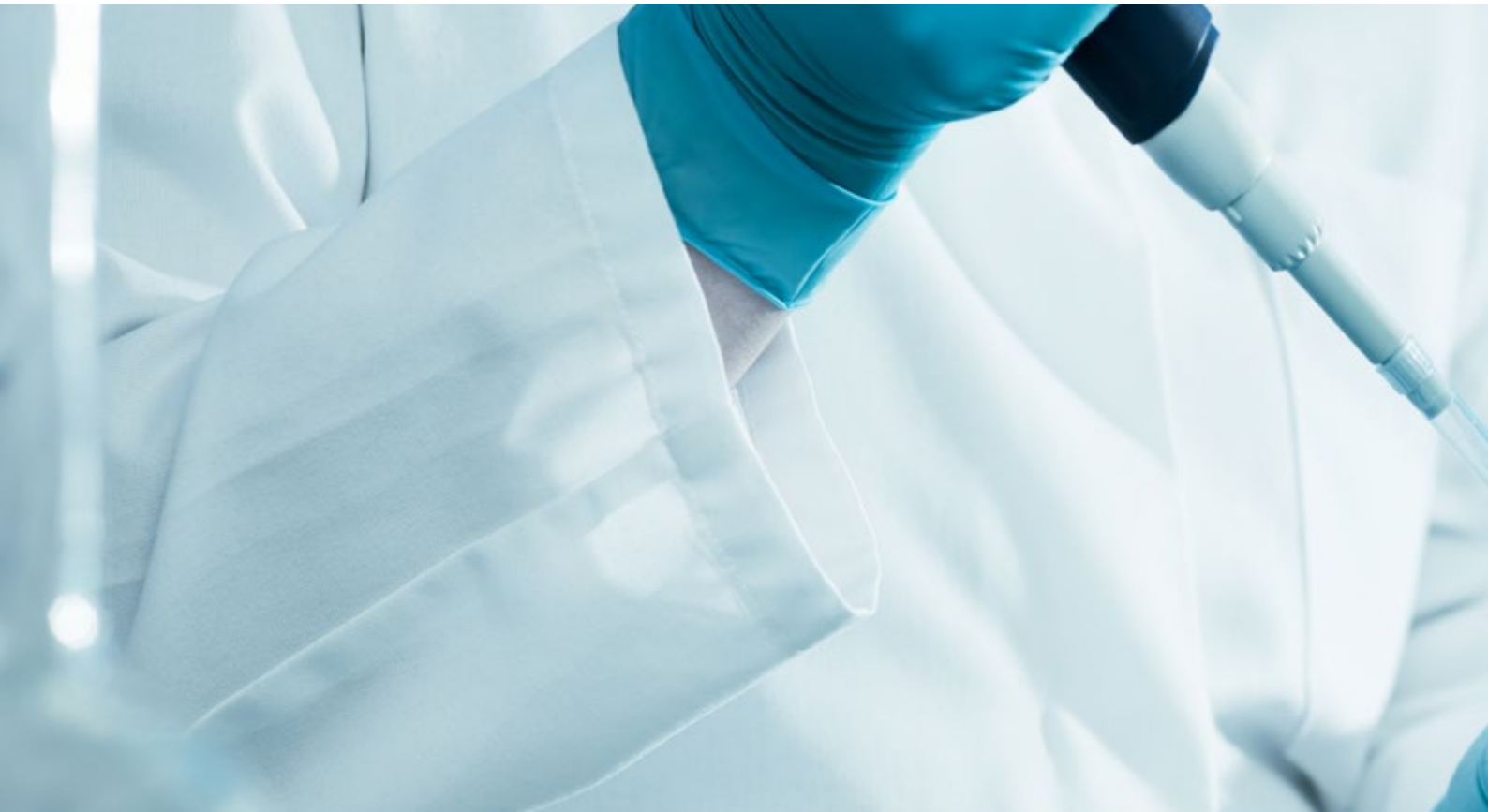
The company made a loss of -3,850 KSEK (-1,553) during the first quarter. The total operating costs amounted to -7,553 KSEK (-3,506) during the quarter and include costs for product development and patents of -3,699 KSEK (-1,953). The cost base has grown steadily since the second quarter 2022 as the ongoing clinical study ATMIRe has progressed at Skåne's University Hospital in Malmö, the pre-clinical research has been expanded for several new indications and due to preparations ahead of the company's coming phase II study for TUM012, known as EMPIRe.

Other external costs amounted to -5,006 KSEK (-1,936) and have increased significantly compared to the corresponding period last year primarily due to increasing consultancy costs associated with the compnay's clinical studies, ATMIRe and EMPIRe. Consultancy services in legal, communication and regulatory areas have also contributed to increasing costs. Other external costs include costs for ongoing studies which amounted to -3,540 KSEK, costs for patent protection of the company's patent portfolio which amounted to -159 KSEK during the quarter.

Personnel costs amounted to -1,288 KSEK (-513) during the quarter and the increase is due to increased personnel costs associated with R&D and the companies ongoing clinical studies. The number of employees have increased to 4 FTE (1.5 FTE) during the first quarter.

Cash flow

Cash flow from operating activities amounted to -3,850 KSEK (-1,553) during the first quarter and cash flow primarily relates to a strengthening of the company's organization, support functions, consultancy services and pre-clinical work. Cash flow from investing activities amounted to -3,699 KSEK (-1,953) during the first quarter and relate to development costs for the ongoing clinical study ATMIRe. Investments have increased compared to the corresponding period last year due to increased personnel costs, production costs and preparatory work ahead of the coming phase II study EMPIRe.



Cash and cash equivalents

Cash and cash equivalents amounted to 2,877 KSEK (23,735) on March 31, 2023.

Intangible assets

Costs associated with development of the company's product candidate TUM012 are activates and accounted for as intangible assets in the company's balance sheet. The value of development costs amounted to 20,755 KSEK (12,232) on March 31, 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 2,082 KSEK (977) on March 31, 2023.

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

Equity

Equity amount to 23,647 KSEK (35,897) on March 31, 2023 and the company's equity/assets-ratio amounted to 84% (95%).

Debt and receivables

Short term receivables amounted to 2,218 KSEK (599) on March 31, 2023 and primarily include tax receivables related to value added tax and timing effects. The increase is a result of a growing cost base in the business. Short term debt amounted to 4,344 KSEK (1,705) at the end of the period.

Personnel

The number of employees has increased during the year and amounted to 4.0 FTE (1.5 FTE) on March 31, 2023.

Share

The company's share capital amounted to 615 KSEK on December 31, 2023. The number of shares amount to 149,869 (124,864) of which 100,000 are A-class shares and 49,869 are B-shares. The number of shareholders amounts to 32. The company's share is currently not traded on a listed exchange.

INCOME STATEMENT

kSEK	Jan-Mar 2023	Jan-Mar 2022	Jan-Dec 2022
Net sales			
Activated work	3,540	1,916	6,898
Other operating income	4	-	25
	3,544	**1,916**	**6,923**
Operating expenses			
Clinical study	–1,085	–1,014	–2,446
Other external expenses	–5,006	–1,936	–10,100
Personnel costs	–1,288	–513	–4,849
Other operating expenses	–15	–6	–11
Operating profil	**–3,850**	**–1,553**	**–10,483**
Financial items	-	-	-
Profit after financial items	**–3,850**	**–1,553**	**–10,483**
Tax	**-**	**-**	**-**
PROFIT/LOSS FOR THE PERIOD	**–3,850**	**–1,553**	**–10,483**

BALANCE SHEET

kSEK	Mar 31, 2023	Mar 31, 2022	Dec 31, 2022
ASSETS			
Development costs	20,755	12,232	17,215
Patents	2,082	977	1,923
Inventories, equipment and installations	-	-	-
Financial assets	59	59	59
Total non-current assets	**22,896**	**13,268**	**19,197**
Current receivables	2,218	599	3,056
Cash and cash equivalents	2,877	23,735	9,648
Total current assets	**5,095**	**24,334**	**12,704**
TOTAL ASSETS	**27,991**	**37,602**	**31,901**
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	615	615	615
Fund for development costs	22,837	13,208	19,138
Total restricted equity	**23,452**	**13,823**	**19,753**
Un-restricted equity			
Share premium reserve	34,883	34,883	34,883
Balanced profit or loss	–30,838	–11,256	–17,105
Result during period	–3,850	–1,553	–10,483
Total un-restricted equity	**195**	**22,074**	**7,295**
Minority interest	-	-	-
Equity	**23,647**	**35,897**	**27,048**
Non-current debt	-	-	-
Current debt	4,344	1,705	4,853
Total liabilities	**4,344**	**1,705**	**4,853**
TOTAL EQUITY AND LIABILITIES	**27,991**	**37,602**	**31,901**

CASH FLOW

kSEK	Jan-Mar 2023	Jan-Mar 2022	Jan-Dec 2022
Operating activities			
Profit after financial items	–3,850	–1,553	–10,483
Increase (+) / Decrease (-) in working capital	-	-	105
Cash flow from operating activities before changes in working capital	**–3,850**	**–1,553**	**–10,378**
Cash flow from changes in working capital			
Increase (-)/Decrease (+) of current receivables	838	324	–2,133
Increase (+)/Decrease (-) of current liabilities	–509	–514	2,529
Cash flow from operating activites	**–3,521**	**–1,743**	**–9,982**
Investment activities			
Acquisitions of intangible fixed assets	–3,699	–1,953	–7,883
Acquisitions of financial fixed assets	-	–25	–25
Cash flow from investment activities	**–3,699**	**–1,978**	**–7,908**
Financing activities			
Warrants	449	617	699
Repayment of loans	-	-	-
Cash flow from financing activities	**449**	**617**	**699**
Cash flow for the period	**–6,771**	**–3,104**	**–17,191**
Cash and cash equivalents at the beginning of the period	9,648	26,839	26,839
Exchange rate differences in cash	-	-	-
Cash and cash equivalents at the end of the period	**2,877**	**23,735**	**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		3,699		–3,699
Warrants				449
Results from period				–3,850
Balance at March 31, 2023	**615**	**22,837**	**34,883**	**–34,687**
Balance at Jan 1, 2022	**615**	**11,255**	**34,883**	**–9,920**
Fund for development costs		1,953		–1,953
Warrants				617
Results from period				–1,553
Balance at March 31, 2022	**615**	**13,208**	**34,883**	**–12,809**
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, May 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 Q2 (April–June 2023), August 15, 2023.
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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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 May 16, 2023, 08.00 (CET).

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