

# Q2



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, such as heart and liver. The transplantation market is large and non-cyclical, and the company estimates that more than 200,000 transplants will be performed each year when the company's product is expected to be ready for commercial launch.

# THE PERIOD IN BRIEF

Compared to corresponding period the previous year

## Financial overview April-June

- The quarterly loss amounted to -2,975 KSEK (-277 KSEK)
- Cash and cash equivalents amounted to 18,888 KSEK (126 KSEK) at the end of the period
- Cashflow during the quarter amounted to -4,848 KSEK (-2,330 KSEK)
- Equity amounted to 32,922 KSEK (3,968 KSEK) at the end of the period and total assets amounted to 34,585 KSEK (6,075 KSEK)
- Equity/Assets-ratio amounted to 95% (65%) at the end of the period

## Financial overview January-June

- The period's loss amounted to -4,527 KSEK (-472 KSEK)
- Cashflow during the period amounted to -7,952 KSEK (-4 147 KSEK)

## Significant events January-June

- EMA (European Medicines Agency) approved the company's application for Orphan Drug status for TUM012 in connection to kidney transplants. The EU commission provides Orphan Drug status to treatments that can be used for life threatening or serious diseases that are unusual and lack available treatment. Orphan Drug status gives advantages such as 10 years' market exclusivity for TUM012, support during clinical studies and reduced regulatory fees.
- The first patients in the First in Human study ATMIRe have begun treatment. In total, 18 patients will participate in the study and the patients will be treated at Skånes University Hospital in Malmö, Sweden. The study is expected to be finished in 2023.
- Mattias Springare was appointed CFO and Head of Investor Relations. The purpose of the recruitment is to expand iCoat Medical's financial and accounting function and make necessary preparations ahead of a potential IPO.
- Jacob Westman was appointed Head of Chemistry, Manufacturing and Control (CMC). The purpose of the recruitment is to support ongoing and coming clinical studies, and lead product development.
- Göran Lerenius was appointed iCoat Medical's General Counsel & Contract Manager. The recruitment will strengthen the company's judicial capacity to prepare the company ahead of coming clinical studies.

## Significant event after the period

- On August 10, iCoat Medical reported interim data from the ongoing First-In-Human study ATMIRe which showed that the first patients had successfully been treated without any serious or significant side effects.

# CEO LETTER



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## DEAR SHAREHOLDER,

I am glad to present iCoat Medical's first quarterly report, something we will continue to do during coming quarters to keep investors informed on our clinical and financial progress.

During the first half of 2022 we have continued to take important steps in the development of our product candidate TUM012 which aims to protect organs in connection to transplant. All organs that are transplanted run the risk of Ischemia Reperfusion Injury due to cells lacking oxygen, since the patient's immune system is activated and attacks the damaged cells. TUM012 protects ischemic cells against attacks from the immune system and 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 number of organ transplants have increased during the past 20 years. Serious kidney diseases continue to be one of our most common diseases

and those who are affected face a tough reality. A kidney transplant makes it possible for these patients to return to a more normal life again. However, there is currently a significant shortage in available organs for transplantation across the whole world and currently only 10% of the transplantation needs can be met. With iCoat Medical's products we hope to make more organs available for transplant.

### FIRST PATIENTS HAVE BEEN TREATED WITH NO SIDE EFFECTS

Sweden's Medical Products Agency and Ethics Review Authority approved our application in December 2021 to initiate our First in Human study ATMIRE. The purpose of the study is to show that TUM012 is a safe product and will be the basis for the planned multicenter study afterwards. The first patients have now been transplanted and treated with TUM012 at the kidney transplant

unit at Skåne's University Hospital in Malmö with positive results. The study will include in total 18 patients and is expected to be completed in 2023.

In parallel, our organization has been strengthened to support clinical studies and make necessary preparations ahead of a potential IPO. During the first half of the year we have welcomed Göran Lerenius as General Counsel, Jacob Westman as Head of CMC and Mattias Springare as CFO and Head of Investor Relations. These recruitments strengthen the company's judicial competency required ahead of the company's future clinical studies, allow for necessary preparations in production ahead of market approval and strengthen our financial competence ahead of future capital raisings and a potential IPO.

The market environment continues to be challenging which also affects iCoat Medical. As the pandemic has softened its grip on society, the war in Ukraine and rising inflation and interest rates coupled with turbulence on global stock markets has resulted in a more unsecure environment. So far, iCoat Medical has not seen any negative consequences but we see rising prices and increasing wages in our business. iCoat Medical's business does however remain stable and progresses according to plan. The capital raising in 2021 which raised 40 MSEK together with our strengthened organization ensures that we can complete our First In Human study according to plan.

iCoat Medical consists of world-class scientists and doctors that carry out groundbreaking research in innate immunity, and people with commercial expertise that together build a stronger iCoat Medical. I look forward to updating you on the company's development and clinical studies in coming quarterly reports. We have an exciting time ahead of us!

**Peder Waern**

CEO, iCoat Medical AB

# OUR PRODUCTS

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## 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. This is expected to lead to better quality and longevity of the transplanted kidney. TUM012 will initially be reviewed for kidney transplants but also other organ transplants can become applicable in the future.
- iCoat Medical has during the period initiated treatment of the first patients with TUM012 in a First In Human study. The company has also worked on quality assurance of and analyzing production processes for TUM012, this work will proceed during coming months.

## TUM020

- iCoat Medical's patented platform makes it possible to develop different forms of purpose specific molecules which can protect different cell membranes from Ischemia Reperfusion Injury. TUM020 is an example of such a molecule and which is being developed to prevent damage from warm ischemia by creating a protective barrier on the cell membrane. Potential applications that are being considered include stroke and heart attack.
- iCoat Medical has carried out analysis and tests to modify molecules and their function. This biochemical development work will progress during coming quarters.

# FINANCIAL INFORMATION

## RESULTS

The company reports a loss of -2,975 KSEK (-277 KSEK) during the second quarter and a loss of -4,527 KSEK (-472 KSEK) during January-June. Total operating expenses amounted to -3,969 KSEK (2,711 KSEK) during the second quarter, including development costs and expenses related to intellectual property. During January-June, total operating expenses amounted to -7,437 KSEK (-3,845 KSEK).

Total development costs for the second quarter amounted to -982 KSEK (-2,434 KSEK) and primarily relate to consultancy and personnel costs associated with the Phase I-study (First in Human) at the company's clinical hub in Malmö/Lund. The company's development costs during January-June amounted to -2,897 KSEK (-3 373 KSEK) includes costs for production of the product candidate TUM012 and project costs for the ongoing clinical Phase I-study.

Total personnel costs amounted to -1,046 KSK (0) during the second quarter and to -1,558 KSEK (0) during January-June. The increase is related to the recruitment of new employees.

Other external costs amounted to -1,873 KSEK (-277 KSEK) during the second quarter and to -1,894 KSEK (-458 KSEK) during January-June. Other external costs primarily include consultancy costs and costs for rental of staff as well as external services in accounting and advisory in investor relations and legal. The increased expenses during the period compared to the previous year is primarily due to increased use of consultancy services, increased use of accounting services, new offices and advisory services in investor relations which were not used last year.

## INVESTMENTS

The company's investments during the second quarter included production costs for the product candidate TUM012 and the ongoing clinical Phase I-study, amounting to -981 KSEK (-2,434 KSEK), as well as costs for the company's intellectual property, amounting to -191 KSEK (-106 KSEK). Corresponding investments during January-June amounted to -2,897 KSEK (-3,373 KSEK) for TUM012 and -228 KSEK (-111 KSEK) for intellectual property.

## CASH AND CASH EQUIVALENTS

Cash and cash equivalents amounted to 18,888 KSEK (126 KSEK) at the end of the period.

## CASH FLOW

Cash flow from operating activities amounted to -3,675 KSEK (209 KSEK) during the second quarter and to -5,418 KSEK (-593 KSEK) during January-June. Cash flow from operating activities is primarily affected by costs associated with strengthening the company's organization, support functions and advisory services. Cash flow from investment activities amounted to -1,173 KSEK (-2,539 KSEK) during the second quarter and to -3,151 KSEK (-3,484 KSEK) during January-June. These investments relate to ongoing product development, the clinical study and patent costs. All investments are accounted for as intellectual property rights in the balance sheet. Cash flow from financing activities amounted to 617 KSEK (-70 KSEK) during January-June.

## EQUITY

Equity amounted to 32,922 KSEK (3968 KSEK) and the equity/assets ratio amounted to 95% (65%).

## LIABILITIES AND RECEIVABLES

Current receivables amounted to 1,257 KSEK (535 KSEK) at the end of the period and primarily relates to tax receivables for value added tax. Current debt amounted to 1,663 KSEK (2,107 KSEK) and primarily includes accounts payable which amounted to 933 KSEK (2,046 KSEK) and personnel related debt, 235 KSEK (0 KSEK), related to tax and fees.

## INTELLECTUAL PROPERTY

Costs related to development of the product candidate TUM012 are accounted for as intellectual property in the balance sheet and its value amounted to 13,214 KSEK (5,096 KSEK) at the end of the period. Costs related to the company's work on patent applications and rights are activated in the balance sheet and its value amounted to 1,166 KSEK (318 KSEK) at the end of the period.

Depreciation of activated development costs and patents begins once products receive market approval.

## PERSONNEL

There were 3.5 (0) full time employees at the end of the period.

## SHARE

The company's share capital amounted to 615 KSEK (512 KSEK) on June 30, 2022. The number of shares amounted to 149,869 (124,864), of which 100,000 are A-class shares and 49,869 are B-class shares. The number of shareholders amounts to 32. The company's share is currently not listed on a public exchange.



# INCOME STATEMENT

KSEK	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
<b>Net sales</b>					
Activated work	982	2,434	2,897	3,373	8,593
Other operating income	12	-	13	-	1
	<b>994</b>	<b>2,434</b>	<b>2,910</b>	<b>3,373</b>	<b>8,594</b>
<b>Operating expenses</b>					
Clinical study	-67	-591	-1,081	-606	-9,138
Other external expenses	-2,855	-2,120	-4,791	-3,225	-1,802
Personnel costs	-1,046	-	-1,558	-	-167
Other operating expenses	-1	-	-7	-14	-80
<b>Operating profit</b>	<b>-2,975</b>	<b>-277</b>	<b>-4,527</b>	<b>-472</b>	<b>-2,593</b>
Financial items	-	-	-	-	-
<b>Profit after financial items</b>	<b>-2,975</b>	<b>-277</b>	<b>-4,527</b>	<b>-472</b>	<b>-2,593</b>
<b>Tax</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>PROFIT/LOSS FOR THE PERIOD</b>	<b>-2,975</b>	<b>-277</b>	<b>-4,527</b>	<b>-472</b>	<b>-2,593</b>

# BALANCE SHEET

kSEK	2022-06-30	2021-06-30	2021-12-31
<b>ASSETS</b>			
Development costs	13,214	5,096	10,316
Patents	1,166	318	938
Inventories, equipment and installations	-	-	-
Financial assets	60	-	36
<b>Total non-current assets</b>	<b>14,440</b>	<b>5,414</b>	<b>11,290</b>
Current receivables	1,257	535	924
Cash and cash equivalents	18,888	126	26,838
<b>Total current assets</b>	<b>20,145</b>	<b>661</b>	<b>27,762</b>
<b>TOTAL ASSETS</b>	<b>34,585</b>	<b>6,075</b>	<b>39,052</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Restricted equity</b>			
Share capital	614	512	614
Fund for development costs	14,380	5,414	11,255
<b>Total restricted equity</b>	<b>14,994</b>	<b>5,926</b>	<b>11,869</b>
<b>Un-restricted equity</b>			
Share premium reserve	34,883	4,148	34,883
Balanced profit or loss	-12,428	-5,634	-7,327
Result during period	-4,527	-472	-2,593
<b>Total un-restricted equity</b>	<b>17,928</b>	<b>-1,958</b>	<b>24,963</b>
Minority interest	-	-	-
<b>Equity</b>	<b>32,922</b>	<b>3,968</b>	<b>36,832</b>
Non-current debt	-	-	-
Current debt	1,663	2,107	2,220
<b>Total liabilities</b>	<b>,1,663,</b>	<b>2,107</b>	<b>2,220</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>,34,585,</b>	<b>6,075</b>	<b>39,052</b>

# CASH FLOW

kSEK	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
<b>Operating activities</b>					
Profit after financial items	-2,975	-277	-4,527	-472	-2,593
<b>Cash flow from operating activities before changes in working capital</b>	<b>-2,975</b>	<b>-277</b>	<b>-4,527</b>	<b>-472</b>	<b>-2,593</b>
<i>Cash flow from changes in working capital</i>					
Increase (-)/Decrease (+) of current receivables	-658	-255	-334	-309	-631
Increase (+)/Decrease (-) of current liabilities	-42	741	-557	188	234
<b>Cash flow from operating activities</b>	<b>-3,675</b>	<b>209</b>	<b>-5,418</b>	<b>-593</b>	<b>-2,990</b>
<b>Investment activities</b>					
Acquisitions of intangible fixed assets	-1,173	-2,539	-3,126	-3,484	-9,325
Acquisitions of financial fixed assets	-	-	-25	-	-35
<b>Cash flow from investment activities</b>	<b>-1,173</b>	<b>-2,539</b>	<b>-3,151</b>	<b>-3,484</b>	<b>-9,360</b>
<b>Financing activities</b>					
Share capital	-	-	-	-	103
Warrants	-	-	617	-	-
Share premium reserve	-	-	-	-	39,905
Costs related to rights issue	-	-	-	-	-5 022
Repaid shareholder contributions	-	-	-	-70	-70
New loans	-	-	-	-	-
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>	<b>617</b>	<b>-70</b>	<b>34,916</b>
<b>Cash flow for the period</b>	<b>-4,848</b>	<b>-2,330</b>	<b>-7,952</b>	<b>-4,147</b>	<b>22,566</b>
Cash and cash equivalents at the beginning of the period	23,735	2,456	26,839	4,273	4,273
Exchange rate differences in cash	-	-	-	-	-
<b>Cash and cash equivalents at the end of the period</b>	<b>18,887</b>	<b>126</b>	<b>18,887</b>	<b>126</b>	<b>26,839</b>

# CHANGES IN EQUITY

kSEK	Share capital	Fund for development costs	Share premium reserve	Balance income incl profit from period
<b>Balance at Jan 1, 2022</b>	<b>615</b>	<b>11,254</b>	<b>34,883</b>	<b>-9,920</b>
Fund for development costs		3,125		-3,125
Rights issue				
Rights issue costs				
Bonus issue				
Warrants				617
Repayment of shareholder contributions				
Transfer of share premium reserve from previous year				
Results from period				-4,527
<b>Balance at June 30, 2022</b>	<b>615</b>	<b>14,379</b>	<b>34,883</b>	<b>-16,955</b>
<b>Balance at Jan 1, 2021</b>	<b>62</b>	<b>1,723</b>	<b>4,597</b>	<b>-1,873</b>
Fund for development costs		3,691		-3,691
Rights issue				
Rights issue costs				
Bonus issue	450			
Repayment of shareholder contributions				-70
Transfer of share premium reserve from previous year			-449	
Result from period				-472
<b>Balance at June 30, 2021</b>	<b>512</b>	<b>5,414</b>	<b>4,148</b>	<b>-6,106</b>
<b>Balance at Jan 1, 2021</b>	<b>62</b>	<b>1,723</b>	<b>4,597</b>	<b>-1,873</b>
Fund for development costs		9,531		-9,531
Rights issue	103		39,905	
Rights issue costs			-5,022	
Bonus issue	450			-450
Repayment of shareholder contributions				-70
Transfer of share premium reserve from previous year			-4,597	4,597
Result from period				-2,593
<b>Utgående balans (31 dec 2021)</b>	<b>615</b>	<b>11,254</b>	<b>34,883</b>	<b>-9,920</b>

# NOTES

## NOTE 1 ACCOUNTING PRINCIPLES

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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 are unchanged compared to previous years. This interim report does not include all information that is required of a complete financial report.

### *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 2021.

### *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.

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## NOTE 2 DEFINITIONS

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

# OTHER INFORMATION

## DATE FOR PUBLICATION OF FINANCIAL INFORMATION

Interim report Q3 (July-September 2022), 15 November 2022.

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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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 25, 2022, 08.00 (CET).

iCoat Medical AB

Organisation number: 559172-8208

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# 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 25, 2022  
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*

