iCoat Medical

INTERIM REPORT THIRD QUARTER 2022

Q3

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 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 July–September

- The quarterly loss amounted to -2,047 KSEK (-831)
- Cash and cash equivalents amounted to 15,232 KSEK (31,312) at the end of the period
- Cash flow during the quarter amounted to -3,656 KSEK (31,185)
- Equity amounted to 30,874 KSEK (38,123) at the end of the period and total assets amounted to 32,785 KSEK (39,134)
- Equity/Assets-ratio amounted to 94% (97%) at the end of the period

Financial overview January–September

- The period's loss amounted to -6,575 KSEK (-1,302)
- Cash and cash equivalents amounted to 15,232 KSEK (31,312) at the end of the period
- Cashflow during the period amounted to 15,232 KSEK (31,312)
- Equity amounted to 30,874 KSEK (38,123) at the end of the period and total assets amounted to 32,785 KSEK (39,134)
- Equity/Assets-ratio amounted to 94% (97%) at the end of the period

Significant events July–September:

- Pre-clinical studies for TUM012 in heart transplantation and heart surgery were initiated in September.
- Alireza Biglarnia, Chief Medical Officer, presented the company's research at the 29th International Congress for the Transplant Society in Buenos Aires, Argentina, in September.

Significant events after the period:

- The application for Orphan Drug Designation in the US for the company's product candidate TUM012 was approved by FDA in October.
- Since the start in April until end of October, more than 50 percent of patients have been included in iCoat Medical's First-in-Human study (phase I) ATMIRe for the product candidate TUM012 without any serious or significant side effects. The study is expected to be completed during the first half of 2023.

CEO LETTER

DEAR SHAREHOLDER,

The third quarter has been characterized by high intensity and continued progress for iCoat Medical. During the period we have continued to make important progress in the development of our product candidate TUM012 with the purpose of protecting organs in connection to transplantation. 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 marginalized organs for transplantation and reduces societal costs associated with kidney failure.

Our ongoing First-in-Human study (phase I) ATMIRe reported its first interims data, showing that none of the patients had any negative side effects from our product TUM012 and after the period more than 50 percent of patients that will be included in the study had been treated without any negative side effects. While ATMIRe progresses, the business has already begun planning for a coming phase II study for use of TUM012 in kidney transplants and also begun preparing pre-clinical studies with a focus on the use of TUM012 in heart transplant and open heart surgery. This broadened focus is the result of our belief that TUM012 has great potential to create medical benefits in connection to other procedures as well, not just kidney tranplants, in which Ischemia Reperfusion Injury is a problem.

The business climate remains challenging for many companies and this is also true for iCoat Medical. Rising inflation and a more troublesome geopolitical development has to some extent meant higher purchasing prices for iCoat Medical, it has simply become a bit more expensive to carry out our research and development. However, iCoat Medical runs a focused and cost efficient operation thanks to our academic collaborations and close relations to Skåne's University Hospital in Malmö.

iCoat Medical continues to run a solid business, despite recent economical and geopolitical developments, and we continue to make progress according to our plans. Initial results from the clinical study ATMIRe looks promising and we expect to complete the study in the first half-year of 2023. At the same time, work continues to evaluate TUM012 and TUM020 also for other medical conditions and organ transplants.

I look forward to continuously updating you on the company's development and clinical results going forward.

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. This is expected to lead to better quality and longevity of the transplanted kidney. TUM012 will initially be reviewed for kidney transplants, heart transplantation and open heart surgery but also other organ transplants can become applicable in the future.
- iCoat Medical has during the period continued to treat patients with TUM012 in the First-in-human study ATMIRe. 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.

GROUND BREAKING 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

Pharmaceutical products	Candidate / Project	Usage area	Research	Preclinical studies	Clinical preparation Phase I	Phase II	Phase III [1]	Expected next step
iCoat Medical's technology platform	TUM012	Kidney transplantation						Completion of study - H1 2023
		Heart transplantation						Development plan completed – Q1 2023
		Cardiopulmonary bypass – open heart surgery, ECMO						Development plan completed – Q1 2023
		Lung transplantation						Cell tests initiated – H2 2022
	TUM020	Stroke						
		Myocardial infarction						Ongoing research
		Cardiopulmonary bypass – open heart surgery, ECMO						

COMPLETED ONGOING PLANNING

[1] Depending on Orphan Drug Designation and outcome of phase I + phase II studies, a traditional phase III study may not be needed

- 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.

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 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.

FINANCIAL INFORMATION

QUARTERLY REPORT FOR THE THIRD QUARTER 2022, JANUARY-SEPTEMBER 2022

Result

Total operating costs amounted to -3,928 KSEK (-2,631) during the third quarter which includes development costs and costs related to intellectual property rights, and amounted to -11,336 KSEK (-6,587) during the period January-September. The cost increase primarily relates to a growing organization with for instance more employees in support functions and the ongoing clinical study ATMIRe. The company reports a net loss of -2,047 KSEK (-831) during the third quarter and a net loss of -6,575 KSEK (1,302) during the period January-September. Personnel costs amounted to -1,110 KSEK (0) during the third quarter and -2,669 KSEK (0) during the period January-September.

Other external costs, which include costs related to consultancy fees and costs for hired personnel, amounted to -1,958 KSEK (-1,799) in the third quarter and to -6,749 KSEK (-5,024) during the period January-September.

Cash flow

Cash flow from operating activities amounted to -1,788 KSEK (-2,001) in the third quarter and -7,205 KSEK (-2,592) during the period January-September. Cash flow from operating activities is primarily driven by costs associated with strengthening of the company's organization, support functions and consultancy services. The company's total investments amounted to -1,868 KSEK (1,800) in the third quarter and -5,019 KSEK (-5,285) during the period January-September. Investments relate to expenditure for manufacturing costs and project costs for the product candidate TUM012 in the ongoing First-in-Human study ATMIRe (phase I) at Skåne's University Hospital in Malmö. Cash flow from financing activities amounted to 0 KSEK (34,986) in the third quarter and 617 KSEK (34,916) during the period January-September. Cash and cash equivalents amounted to 15,232 KSEK (31,312) on 30 September 2022.

Intangible assets

Investments in the development of product candidate TUM012 is accounted for as an intangible asset in the company's balance sheet. The value of intangible assets amounted to 14,529 KSEK (6,727) at the end of the period. Costs associated with the company's work to attain patent protection and necessary rights are also activated in the balance sheet. The value of the patent amounted to 1,719 KSEK (487) at the end of the period.

Depreciation of activated costs for development and patents is initiated once the product has received market approval.

Equity

Equity amounted to 30,874 KSEK (38,123) at the end of the period and the company's equity/assets ratio amounted to 94% (97%).

Debts and receivables

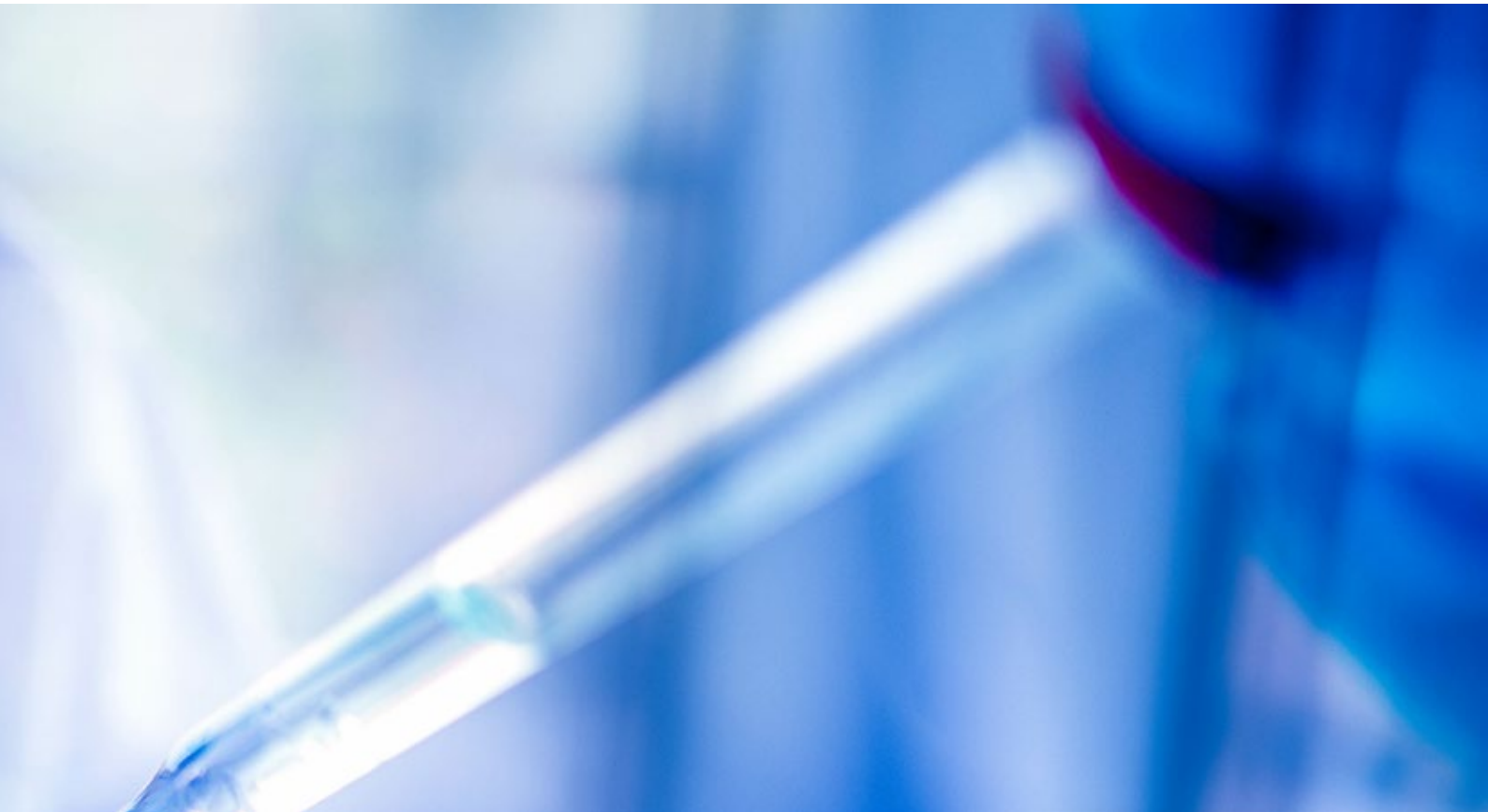
Current receivables amounted to 1,245 KSEK (608) at the end of the period and primarily includes tax assets in the form of value added tax. Current receivables amounted to 1,911 KSEK (1,011) and primarily includes accounts payable of 1,213 KSEK (938) and personnel related debt of 251 KSEK (0).

Personnel

The number of employees amounted to 3,5 FTE (0) on 30 September 2022.

The share

The company's share capital amounted to 615 KSEK (615) on 30 September 2022. The number of shares amounted to a total of 149,869 (124 864) of which 100,000 are A-class shares and 49,869 are B-class shares. There were 32 shareholders at the end of the period. The company's share is currently not listed on a public exchange.



INCOME STATEMENT

KSEK	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Net sales					
Activated work	1,316	1,630	4,213	5,004	8,593
Other operating income	12	-	25	-	1
	1,328	**1,630**	**4,238**	**5,004**	**8,594**
Operating expenses					
Clinical study	-305	-644	-1,386	-1,249	-9,138
Other external expenses	-1,958	-1,799	-6,749	-5,024	-1,802
Personnel costs	-1,110	-	-2,669	-	-167
Other operating expenses	-2	-18	-9	-33	-80
Operating profil	**-2,047**	**-831**	**-6,575**	**-1,302**	**-2,593**
Financial items	-	-	-	-	-
Profit after financial items	**-2,047**	**-831**	**-6,575**	**-1,302**	**-2,593**
Tax	**-**	**-**	**-**	**-**	**-**
PROFIT/LOSS FOR THE PERIOD	**-2,047**	**-831**	**-6,575**	**-1,302**	**-2,593**

BALANCE SHEET

kSEK	2022-09-30	2021-09-30	2021-12-31
ASSETS			
Development costs	14,529	6,727	10,316
Patents	1,719	487	938
Inventories, equipment and installations	-	-	-
Financial assets	60	-	36
Total non-current assets	**16,308**	**7,214**	**11,290**
Current receivables	1,245	608	924
Cash and cash equivalents	15,232	31,312	26,838
Total current assets	**16,477**	**31,920**	**27,762**
TOTAL ASSETS	**32,785**	**39,134**	**39,052**
EQUITY AND LIABILITIES			
Restricted equity			
Share capital	615	615	615
Fund for development costs	16,248	7,214	11,255
Total restricted equity	**16,863**	**7,829**	**11,870**
Un-restricted equity			
Share premium reserve	34,883	39,031	34,883
Balanced profit or loss	-14,297	-7,435	-7,328
Result during period	-6,575	-1,302	-2,593
Total un-restricted equity	**14,011**	**30,294**	**24,962**
Minority interest	-	-	-
Equity	**30,874**	**38,123**	**36,832**
Non-current debt	-	-	-
Current debt	1,911	1,011	2,220
Total liabilities	**1,911**	**1,011**	**2,220**
TOTAL EQUITY AND LIABILITIES	**32,785**	**39,134**	**39,052**

CASH FLOW

kSEK	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Operating activities					
Profit after financial items	-2,047	-831	-6,575	-1,302	-2,593
Cash flow from operating activities before changes in working capital	**-2,047**	**-831**	**-6,575**	**-1,302**	**-2,593**
Cash flow from changes in working capital					
Increase (-)/Decrease (+) of current receivables	13	-74	-321	-383	-631
Increase (+)/Decrease (-) of current liabilities	246	-1,096	-309	-907	234
Cash flow from operating activites	**-1,788**	**-2,001**	**-7,205**	**-2,592**	**-2,990**
Investment activities					
Acquisitions of intangible fixed assets	-1,868	-1,800	-4,994	-5,285	-9,325
Acquisitions of financial fixed assets	-	-	-25	-	-35
Cash flow from investment activities	**-1,868**	**-1,800**	**-5,019**	**-5 ,285**	**-9,360**
Financing activities					
Share capital	-	103	-	103	103
Warrants	-	-	617	-	-
Share premium reserve	-	39,905	-	39,905	39,905
Costs related to rights issue	-	-5,022	-	-5,022	-5,022
Repaid shareholder contributions	-	-	-	-70	-70
New loans	-	-	-	-	-
Cash flow from financing activities	**-**	**34,986**	**617**	**34,916**	**34,916**
Cash flow for the period	**-3,656**	**31,185**	**-11,607**	**27,039**	**22,566**
Cash and cash equivalents at the beginning of the period	18,888	127	26,839	4,273	4,273
Exchange rate differences in cash	-	-	-	-	-
Cash and cash equivalents at the end of the period	**15,232**	**31,312**	**15,232**	**31,312**	**26,839**

CHANGES IN EQUITY

kSEK	Share capital	Fund for development costs	Share premium reserve	Balance income incl profit from period
Balance at Jan 1, 2022	**615**	**11,254**	**34,883**	**-9,920**
Fund for development costs		4,994		-4,994
Rights issue				
Rights issue costs				
Bonus issue				
Warrants				617
Repayment of shareholder contributions				
Transfer of share premium reserve from previous year				
Results from period				-6,575
Balance at September 30, 2022	**615**	**16,248**	**34,883**	**-20,872**

Balance at Jan 1, 2021	**62**	**1,723**	**4,597**	**-1,873**
Fund for development costs		5,491		-5,491
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				
Result from period				-1,302
Balance at September 30, 2021	**615**	**7,214**	**39,030**	**-8,736**

Balance at Jan 1, 2021	**62**	**1,723**	**4,597**	**-1,873**
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
Balance at December 31, 2021	**615**	**11,254**	**34,883**	**-9,920**

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 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.

NOTE 2 DEFINITIONS

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

OTHER INFORMATION

DATE FOR PUBLICATION OF FINANCIAL INFORMATION

Interim report Q4 (October–December 2022), 15 februari 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 November 15, 2022, 08.00 (CET).

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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, November 15, 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