iCoat Medical

YEAR END REPORT 2022

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 October – December

- The quarterly loss amounted to -3,899 KSEK (-1,290)
- Cash and cash equivalents amounted to 9,648 KSEK (26,838) at the end of the period
- Cash flow during the quarter amounted to -5,584 KSEK (4,473)
- Equity amounted to 27,057 KSEK (36,832) at the end of the period and total assets amounted to 31,901 KSEK (39,052)
- Equity/Assets-ratio amounted to 85% (94%) at the end of the period

## Financial overview January–December

- The period's loss amounted to -10,474 KSEK (-2,593)
- Cash and cash equivalents amounted to 9,648 KSEK (26,838) at the end of the period
- Cashflow during the period amounted to -17,191 KSEK (22,566)
- Equity amounted to 27,057 KSEK (36,832) at the end of the period and total assets amounted to 31,901 KSEK (39,052)
- Equity/Assets-ratio amounted to 94% (97%) at the end of the period



## Significant events October–December

- Interim data was published for the ongoing First-in-Human study on TUM012. More than 50 percent of patients that will participate in the study have now been treated with TUM012 in connection to transplantation and no negative side effects connected to the medication have been observed. The study is expected to be completed during the first half of 2023.
- FDA has approved the company's application for orphan drug designation for TUM012 in connection to organ transplants.

## Significant events after the period

- No significant events have been announced after the period.

# CEO LETTER

## DEAR SHAREHOLDER,

iCoat Medical was able to finish the year in the best possible way – with continued progress and positive results from the ongoing clinical studies. During the period, we've taken important steps in clinical development of our product candidate TUM012 which aims to protect organs in connection to transplants. At the same time we've initiated pre-clinical development of TUM012 for new indications, heart transplants and open heart surgery. Pre-clinical development also continues for TUM020 which aims to prevent damage from warm ischemia.

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 updated interims data when more than 50 percent of the patients that will participate in the study had been treated. Data clearly shows that none of the patients that had been treated with TUM012 in connection to a transplant had experienced any negative side effects. Our preliminary conclusion is therefor that we have created a safe product. In parallel we continue to make preparations ahead of the next clinical phase for TUM012 for use in kidney transplants, an international phase II study. We have, among other things, recruited an experienced project manager who will be responsible for carrying out the phase II study and we will shortly have completed the study design.

Since we see great potential in that TUM012 will also be able to create significant medical benefits also in connection to other treatments, we have initiated pre-clinical studies for TUM012 in connection to heart transplants and open heart surgery which are expected to take approximately two years. Ischemia reperfusion damage poses serious problems also in these treatments.

We continue to see that specialist care is facing a shortage of personnel but thankfully transplant operations at Skåne's university hospital in Malmö have proceeded without significant disruptions.

Preparations ahead of a market listing continues and we plan to complete a listing on Nasdaq First North Growth Market during the second half of 2023. In order to finance the business until then, the business is now completing a bridge financing arrangement which we expect to finalize shortly and this financing enables us to maintain momentum in the business and complete the First-in-Human study, planning of a future phase II study as well as continued pre-clinical studies for new indications and TUM020.

iCoat Medical continues to make steady progress and I look forward to presenting the final results from our clinical study ATMIRe in the first half of 2023.

**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



| 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 | | | | | | |


[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 FOURTH QUARTER 2022, OCTOBER-DECEMBER 2022

### Result

Other external costs amounted to -3,350 KSEK (-2,987) during the fourth quarter. Other external costs primarily include costs for research and development but also for organization of support functions and advisory services in law, communication and regulatory issues. Personnel costs amounted to -2,171 KSEK (-167) during the fourth quarter. The companies personnel costs have increased during the year and especially the fourth quarter due to new recruitments and more employees compared to previous periods. Total operating costs amounted to -6,788 KSEK (-5,784) during the fourth quarter. The company reports a net loss of -3,899 KSEK (-1,290) during the fourth quarter. The net loss has increased due to new recruitments, larger reserves and certain timing effects.

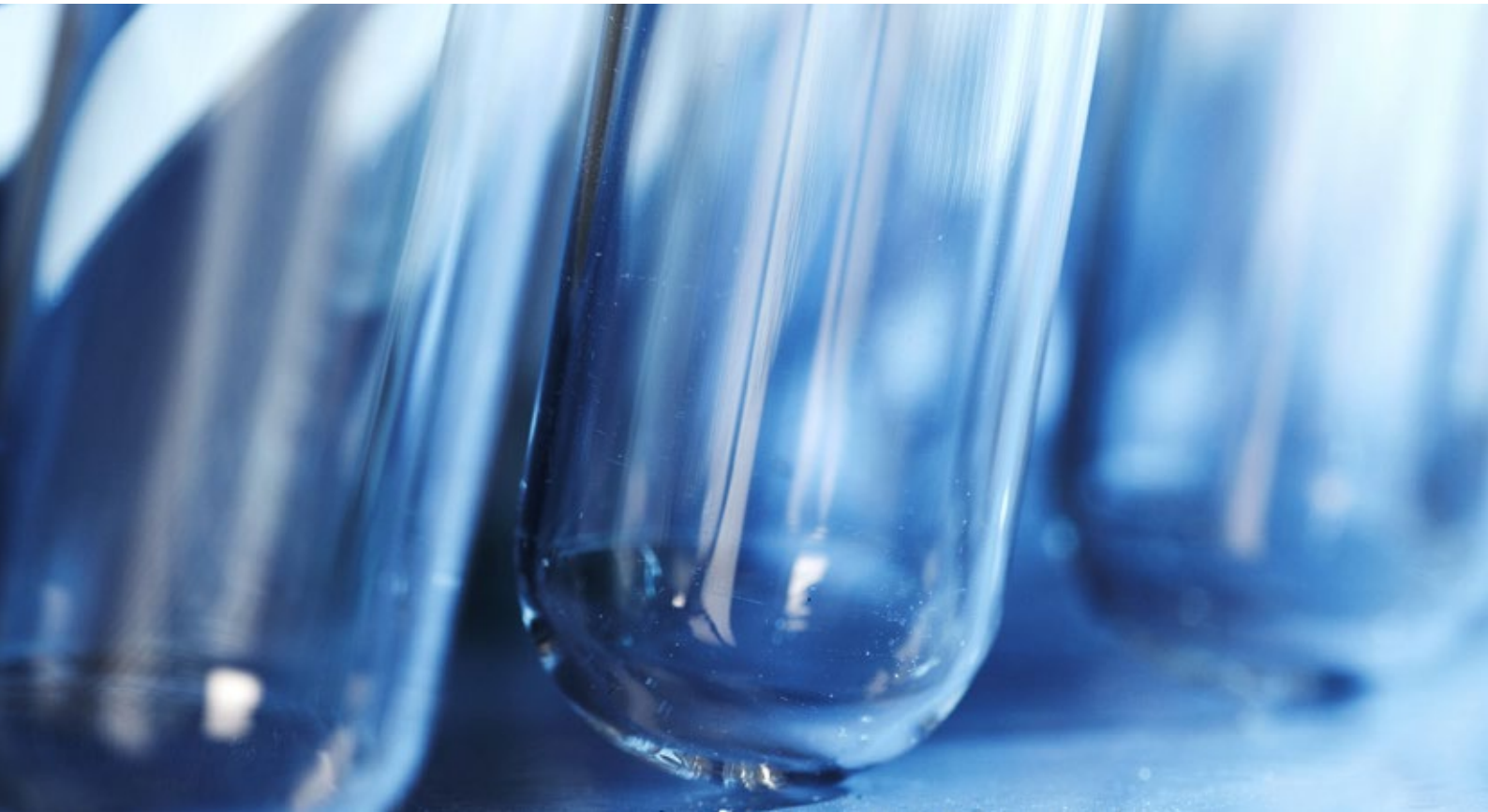
Other external costs amounted to -10,100 KSEK (-1,802) during the full year. This is the company's first year with directly employed staff in the business which has thus resulted in increased personnel costs, which amounted to -4,840 KSEK (-167). Total operating costs amounted to -18,382 KSEK (-16,941) during the full year and these costs primarily include costs related to ongoing clinical and pre-clinical studies and recruitment of specialists. The company reports a net loss of -10,474 KSEK (-2,593) during the full year.

### Cash flow

Cash flow from operating activities amounted to -2,777 KSEK (-396) and cash flow from investing activities amounted to -2,889 KSEK (-4,077) during the fourth quarter. Investments relate to production costs for the product candidate TUM012, the clinical study ATMIRe and initiated planning of a future phase II study. All investments are accounted for as intangible assets. During the fourth quarter, development costs for a future phase II study have been activated, in total -503 KSEK. Cash flow for the fourth quarter amounted to a total of -5,584 KSEK (-4,473).

Cash flow from operating activities amounted to -9,983 KSEK (-2,990) and cash flow from investing activities amounted to -7,907 KSEK (-9,360) during





the full year. Cash flow for the full year amounted to a total of -17,191 KSEK (-22,566).

Cash and cash equivalents amounted to 9,648 KSEK (26,838) on December 31, 2022.

## 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 17,215 KSEK (10,316) on December 31, 2022. 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 1,923 KSEK (938) on December 31, 2022.

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

## Equity

Equity amount to 27,057 KSEK (36,832) on December 31, 2022 and the company's equity/assets-ratio amounted to 85% (94%).

## Debt and receivables

Short term receivables amounted to 3,056 KSEK (924) on December 31, 2022 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 a larger cost base. Short term debt amounted to 4,844 KSEK (2,220) at the end of the period and primarily include accounts payables of 2,736 KSEK (1,905) and personnel related debt of 614 KSEK (96) for taxes and fees.

## Personnel

The number of employees has increased during the year and amounted to 4,5 FTE (0) on December 31, 2022.

## Share

The company's share capital amounted to 615 KSEK on December 31, 2022. 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 28. The company's share is currently not traded on a listed exchange.



# INCOME STATEMENT

| KSEK | Oct-Dec 2022 | Oct-Dec 2021 | Jan-Dec 2022 | Jan-Dec 2021 |
|---|---|---|---|---|
| **Net sales** | | | | |
| Activated work | 2 685 | 3 591 | 6 898 | 8 593 |
| Other operating income | - | 1 | 25 | 1 |
| | **2 685** | **3 592** | **6 923** | **8 594** |
| **Operating expenses** | | | | |
| Clinical study | –1 060 | –1 680 | –2 446 | –9 138 |
| Other external expenses | –3 350 | –2 987 | –10 100 | –1 802 |
| Personnel costs | –2 171 | –167 | –4 840 | –167 |
| Other operating expenses | –3 | –48 | –11 | –80 |
| **Operating profil** | **–3 899** | **–1 290** | **–10 474** | **–2 593** |
| Financial items | - | - | - | - |
| **Profit after financial items** | **–3 899** | **–1 290** | **–10 474** | **–2 593** |
| **Tax** | **-** | **-** | **-** | **-** |
| **PROFIT/LOSS FOR THE PERIOD** | **–3 899** | **–1 290** | **–10 474** | **–2 593** |

# BALANCE SHEET

| kSEK | Dec 31, 2022 | Dec 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| Development costs | 17 215 | 10 316 |
| Patents | 1 923 | 938 |
| Inventories, equipment and installations | - | - |
| Financial assets | 59 | 36 |
| **Total non-current assets** | **19 197** | **11 290** |
| | | |
| Current receivables | 3 056 | 924 |
| Cash and cash equivalents | 9 648 | 26 838 |
| **Total current assets** | **12 704** | **27 762** |
| **TOTAL ASSETS** | **31 901** | **39 052** |
| | | |
| **EQUITY AND LIABILITIES** | | |
| **Restricted equity** | | |
| Share capital | 615 | 615 |
| Fund for development costs | 19 138 | 11 255 |
| **Total restricted equity** | **19 753** | **11 870** |
| | | |
| **Un-restricted equity** | | |
| Share premium reserve | 34 883 | 34 883 |
| Balanced profit or loss | –17 105 | –7 328 |
| Result during period | –10 474 | –2 593 |
| **Total un-restricted equity** | **7 304** | **24 962** |
| Minority interest | - | - |
| **Equity** | **27 057** | **36 832** |
| | | |
| Non-current debt | - | - |
| Current debt | 4 844 | 2 220 |
| **Total liabilities** | **4 844** | **2 220** |
| **TOTAL EQUITY AND LIABILITIES** | **31 901** | **39 052** |

# CASH FLOW

| kSEK | Oct-Dec 2022 | Oct-Dec 2021 | Jan-Dec 2022 | Jan-Dec 2021 |
|---|---|---|---|---|
| **Operating activities** | | | | |
| Profit after financial items | –3 899 | –1 290 | –10 474 | –2 593 |
| **Cash flow from operating activities before changes in working capital** | **–3 899** | **–1 290** | **–10 474** | **–2 593** |
| *Cash flow from changes in working capital* | | | | |
| Increase (-)/Decrease (+) of current receivables | –1 811 | –315 | –2 133 | –631 |
| Increase (+)/Decrease (-) of current liabilities | 2 933 | 1 209 | 2 624 | 234 |
| **Cash flow from operating activites** | **–2 777** | **–396** | **–9 983** | **–2 990** |
| **Investment activities** | | | | |
| Acquisitions of intangible fixed assets | –2 889 | –4 042 | –7 883 | –9 325 |
| Acquisitions of financial fixed assets | - | –35 | –24 | –35 |
| **Cash flow from investment activities** | **–2 889** | **–4 077** | **–7 907** | **–9 360** |
| **Financing activities** | | | | |
| Share capital | - | - | - | 103 |
| Warrants | 82 | - | 699 | - |
| Share premium reserve | - | - | - | 39 905 |
| Costs related to rights issue | - | - | - | –5 022 |
| Repaid shareholder contributions | - | - | - | –70 |
| New loans | - | - | - | - |
| **Cash flow from financing activities** | **82** | **-** | **699** | **34 916** |
| **Cash flow for the period** | **–5 584** | **–4 473** | **–17 191** | **22 566** |
| Cash and cash equivalents at the beginning of the period | 15 232 | 31 312 | 26 839 | 4 273 |
| Exchange rate differences in cash | - | - | - | - |
| **Cash and cash equivalents at the end of the period** | **9 648** | **26 839** | **9 648** | **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 | | 7 883 | | –7 883 |
| Rights issue | | | | |
| Rights issue costs | | | | |
| Bonus issue | | | | |
| Warrants | | | | 699 |
| Repayment of shareholder contributions | | | | |
| Transfer of share premium reserve from previous year | | | | |
| Results from period | | | | –10 474 |
| **Balance at December 31, 2022** | **615** | **19 137** | **34 883** | **–27 578** |

| | | | | |
|---|---|---|---|---|
| **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** |

# 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 2021.

*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

# 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, February 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

Annual General Meeting, April 20, 2023
Interim report Q1 (January–March 2023), 15 May 2023.

This year end 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 February 15, 2023, 08.00 (CET).



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