



# Third Quarter Report Q3-2023

1 July - 30 September | 16 November 2023

Cessatech A/S - CVR no. 41293055  
Kanonbådsvej 2, 1437 Copenhagen, Denmark



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## Highlights Q3-2023 Report

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 July – 30 September 2023. The third quarter report is available as an attached document to this press release and on [www.cessatech.com](http://www.cessatech.com) under Investor/Filings & Reports.

### Third quarter financial results 2023 (1 July - 30 September):

- Net revenue was DKDK 0
- Operating result was DKDK -5.811
- Net result was DKDK -6.609
- Cash at bank end of the period was DKDK 5.192
- Earnings per share\* was DKDK -0,48
- Solidity\*\* was 66%

### The Company has advanced well with its planned activities

- Last participant dosed in pivotal trial 0205
- Agreement with EMA on PIP for CT002
- Loan facility agreement to support US launch of CT001
- US planning & preparation CT001 launch
- Finalization of Study 0202 with competent authorities in selected countries

*\*Earnings per share (DKK per share): Operating result divided by the average number of shares during the period. The total number of shares as of 30 September 2023 amounted to 13.788.755 shares, the average number of shares during the second quarter was 13.788.755.*

*\*\*Solidity: Total equity divided by total capital and liability*

**Comment from CEO, Jes Trygved:** We were pleased to have the last participant enrolled in the pivotal study 0205 during Q3 2023. This was an important milestone for the Company, and we look forward to presenting top-line results towards the end of the year. In addition, our Paediatric Investigation plan for CT002 was agreed with the European regulatory authorities, allowing us to initiate development of this second asset in our pipeline. Our focus is also very much on the planning and preparation for the US launch of CT001 where we expect to book our first income already in 2024. To have a marketed product available for patients in just three years since the company was founded is impressive and I would like to thank the team for its efficiency, hard work and commitment for making this possible.

## 1. Summary

The Board of Directors and CEO of Cessatech hereby publish the third quarter report of 2023. In this interim report, the following definitions apply, unless stated otherwise: The “Company” or “Cessatech” refers to Cessatech A/S with CVR number 41293055.

The Company is not part of a group and does not have any subsidiaries. Cessatech had as expected no revenue for the period and a negative result. The financial result for the period follows the Company's outlined development plans as expected. It is the Board's opinion that the Company is at its late-stage development with the initiation of its pivotal study which will significantly improve its potential revenue generation.

## Key figures

	Q3 2023	Q3 2022	Q1-Q3 2023	Q1-Q3 2022	2022
Key figures	01/Jul/23	01/Jul/22	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	30/Sep/23	30/Sep/22	30/Sep/23	30/Sep/22	31/Dec/22
Operating Loss	-5.811	-3.252	-17.657	-10.967	-17.589
Total financial items	-2.049	-40	-1.953	-171	-210
Loss for the period	-6.609	-2.627	-16.278	-8.969	-14.656
Cash at Bank	5.192	15.001	5.192	15.001	23.343
<b>Ratios</b>					
Solvency ratio	66%	89%	66%	89%	85%
Earnings per share (DKK)	-0,48	-0,43	-1,18	-1,47	-2,06

*\*Earnings per share (DKK per share): Operating result divided by the average number of shares during the period. The total number of shares as of 30 September 2023 amounted to 13.788.755 shares, the average number of shares during the second quarter was 13.788.755.*

*\*\*Solvency: Total equity divided by total capital and liability*

## Highlights during third quarter 2023

- Last participant dosed in pivotal trial 0205
- Agreement with EMA on PIP for CT002
- Loan facility agreement to support US launch of CT001
- US planning & preparation CT001 launch
- Finalization of Study 0202 with competent authorities in selected countries

The third quarter of 2023 had a record high level of activities, especially as we managed to finalize the pivotal study 0205, with last participant dosed in September 2023. In addition, we managed to finalize the agreement with EMA on the second PIP-plan, for CT002 for sedative procedures. We are very excited as this year will potentially be a breakthrough year for the company.

### **Last participant dosed in pivotal trail 0205**

Last participant has been randomised in clinical trial 0205 investigating efficacy and safety of CT001 relative to placebo and two comparative active arms. Primary aim is to show that CT001 offers a better pain reduction and safety profile compared to the comparative arms and placebo. Top-line results are anticipated during Q4 2023 once data has been analysed.

### **Agreement with EMA on PIP for CT002**

The Paediatric Committee (PDCO) under The European Medicines Agency (EMA) has agreed to the Paediatric Investigational Plan (PIP) for CT002. CT002 is the second asset in Cessatech's pipeline that has secured a PIP aimed at ensuring the necessary data to support a future authorisation for use in children. CT002 is developed to address the unmet medical need of a non-invasive sedative procedure for children undergoing MRI scanning or other procedures requiring sedation.

### **Loan facility agreement to support US launch of CT001**

Loan facility agreement with a group of investors, which includes some existing shareholders. • Loan facility agreement for up to DKK 5 million maturing at the latest on 31 Dec 2024 • Provides Cessatech financial flexibility and support to the planned US launch of CT001

### **US planning & preparation CT001 launch**

The agreement with Ventis Pharma was signed in June 2023, and since then both teams have been busy preparing for manufacturing and release of CT001 under the special early access program. We have initiated a tech transfer of the analytical methods and sterilized vials and pumps, alongside GMP APIs have been shipped to the manufacturing site.



### **Post Q3 event - Finalization of Study 0202 with competent authorities**

The European Paediatric Committee (PDCO) has agreed to a 50% reduction in the number of children required in the final safety study (0202) of CT001 for the treatment of acute and procedural pain in children. New safety data from both adult and paediatric studies has been presented to PDCO and based on this information, the PDCO agreed to the proposed reduction in number of children. With this PDCO opinion, study 0202 will have a much shorter recruitment period and at less costs than previously anticipated. The study is now approved by the competent authorities in Spain and UK.

### **Business Strategy and Major Milestones**

Going forward we would like to give a short quarterly update on our Business Strategy and major Company milestones as this is our foundation for success. Please see next page for an overview.

### 1: Focused business model

- Targeting large unmet paediatric needs - in hospitals and emergency units
- Repositioning existing medicine to fit children’s needs - an accelerated and highly de-risked route-to-market approach



### 2: Pipeline delivering value

- CT001 - an analgesic nasal spray for acute painful procedures in children, based on >10 years of clinical experience.
- CT002 - a nasal spray for sedative procedures for children from 0-17 years of age



### 3: Building a business

- Commercialization intended to be based on partnerships - aiming at generating a positive cash-flow trend faster
- Supply and manufacturing are outsourced to leading expert companies in Europe

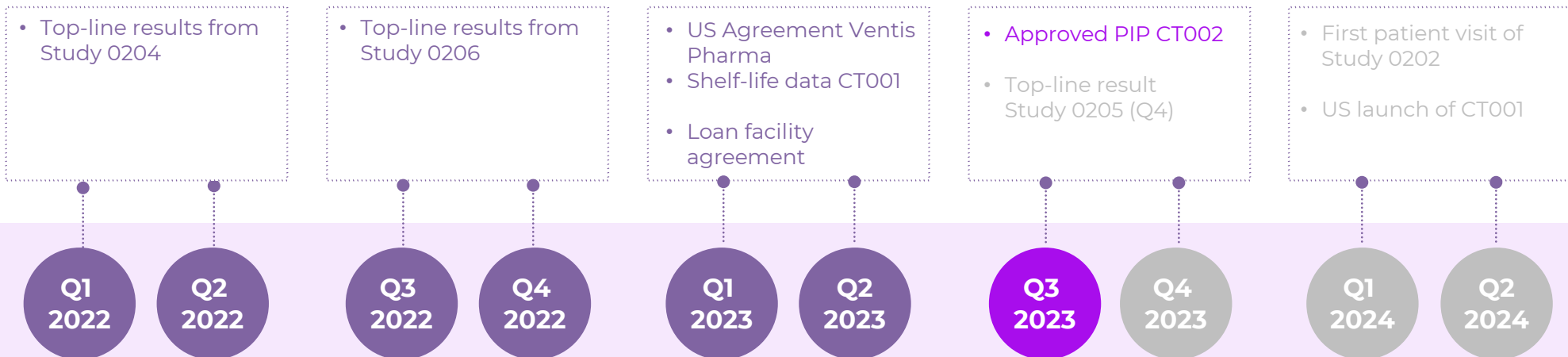


*During Q3'2023 we successfully managed to add an extra product to the development pipeline.*

*CT002 is developed to address the unmet medical need of a non-invasive sedative procedure for children undergoing MRI scanning or other procedures requiring sedation*

#### 2021 major milestones

- Favourable data from Registry Study 0203
- US patent issuance



# We are a pivotal-stage biotech company with a unique focus on children's medicine

	Use	Indication	Pre-clinical	Phase I	Phase II	Pivotal, Ph III
<b>CT001</b> Fixed combination	Non-invasive nasal spray	Acute pain	█	█	█	█
<b>CT002</b> Sedative-analgesic	Non-invasive nasal spray	Sedation	█	█		
<b>CT003</b> Local analgesia	Local gel	Topical anaesthesia	█			

**Introduction to CT001:** Despite the many pain-relieving products available for adults, few of these have been developed for children. A study on unlicensed drug prescription revealed that up to 75 percent of all medications for children currently prescribed in hospital settings are administered off-label, meaning that the use deviates from the dose, is not tested, documented, or approved for children.

A commonly used treatment as Midazolam only has a sedative effect, thus leaving the pain untreated. Morphine/opioids require intravenous access for fast pain relief, causing further pain for the child. The treatment of acute pain in children is therefore characterised by a significant unmet medical need, which has been recognized by both regulatory authorities and health care professionals.

Cessatech's first product and lead asset, CT001, is an analgesic non-invasive nasal spray for children aged 1-17 years that experience acute pain or pain related to medical procedures. Today's analgesic solutions often require an intravenous access which is not always feasible or easy and can be painful. In contrast, CT001 has a fast onset and is easy to use. Its composition includes a fixed combination of the two well-known analgesics ketamine and sufentanil (an opioid), which are already approved treatments for injection in adults. The two compounds are also used separately for analgesia but only intravenously in children. The potential advantages of the fixed combination of sufentanil and ketamine include improved analgesia with approx. 30 percent lower dose of sufentanil and consequently the avoidance of undesirable side effects such as prolonged sedation and risk of respiratory depression.

**Introduction to CT002:** Magnetic resonance imaging (MRI) is a medical imaging technique used to form detailed images of the anatomy and the physiological processes of the body. An MRI examination is a painless procedure, but to be of good quality it requires the child to remain still for approx. 45-90 minutes, that is to be carried out without undue concern or anxiety. Thus, sedation of the child is often necessary and sometimes also requires a general anaesthetic (a medically induced coma). A general anaesthetic is very resource demanding, why an effective and safe sedation procedure should be of preference.

Cessatech's second asset is a fixed dose non-invasive nasal spray for children to optimize the process and provide a better non-invasive solution for children. Currently, the sedative drug is administered intravenously, but a new formulation will be investigated for intranasal administration which would provide several advantages over current clinical practice. Activation of centrally located receptors produces a sedation that mimics normal sleep and the drug also has a direct analgesic effect. It is Cessatech's ambition to develop a standardized nasal spray formulation tested and approved for children, with a similar concept to the anesthetic nasal spray PIP plan (CT001) approved by the EMA.

Cessatech has agreed with the European Medicines Agency on a Paediatric Investigational Plan for CT002 for medical procedural sedation in children. Cessatech has not yet communicated on its timelines for initiating the development of CT002, but it will be related to the commercial partnerships.

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## **OPERATING INCOME AND OPERATING RESULTS**

The operating income and result for Q3-2023 were as expected  
 Net revenue amounted to DKK 0  
 Operating result was KDKK -5.811 in Q3-2023

The operating result was as expected as the company is currently conducting development activities. Main cost driver for Q3-2023 was:

- The main cost driver for third quarter of 2023 was the finalization of study 0205, in which the clinical costs accounted for 53% of total costs for the period.

## **BALANCE SHEET AND SOLIDITY**

The total equity at 30 September 2023 was KDKK 8.224  
 The solidity as per 30 September 2023 was 66%

## **CASH FLOW AND INVESTMENTS**

There have been no significant investments during the period, only activities focused on clinical development.

Cash at the end of September 2023 was KDKK 5.192

The majority of the cash flow during Q3 2023 is related to clinical activities which will continue as planned through 2023, as Study 0202 is soon to be initiated.

For a Biotech company not yet having an income, the cash position is obviously very important. We believe we have a good cash position for the coming period, as we managed to secure a loan facility agreement of KDDK 5.000 to support our US launch. In addition, the upcoming TO 2 warrant exercise in Q4 will further strengthen our cash position.

If the company does not meet the expectations of Study 0205, it will be a different situation as the TO 2 warrant outcome will be much lower and activities will need to be reconsidered.

	Q3 2023	Q3 2023
Shareholders	Number of shares	Votes and capital
<b>Shareholders &gt;5%</b>		
Jes Trygved (CEO)	904.399	6,56%
All other shareholders	12.884.356	93,44%
<b>SUM</b>	<b>13.788.755</b>	<b>100,00%</b>
<b>Board of Directors</b>		
Martin Olin (chairman)	226.619	1,64%
Adam Steensberg	164.901	1,20%
Charlotte Videbæk (C- ApS)	163.413	1,19%
Rachel Curtis Gravesen	37.917	0,27%
Peter Birk	10.318	0,07%
Flemming Jensen	0	0,00%

### THE SHARE

The shares in Cessatech were listed at Spotlight Stock Market on 16. December 2020. The ticker is CESSA and the ISIN code is DK0061411964. The total number of shares as of 30 June 2023 amounted to 13.788.755. There was an increase to the number of shares during the fourth quarter of 2022, related to the rights issue. Every share equals the same rights to the Company's assets and results.

### THE TO 2 WARRENTS

As part of the Rights Issue in relation to the latest Offering in Q4-2022, the associated warrant TO2 if fully exercised during Q4 2023 will therefore further strengthen the cash-position of the company. It is acknowledged that the important milestone of the outcome of study 0205 will impact the company significantly as it will also result in a positive outcome of the TO 2 warrant, this will increase the company value and hence also an exercise of the TO 2 warrant in the higher end of the range.

Upon full exercise of warrants, Cessatech will receive additional proceeds of up to DKK 22 million before costs related to the Offering



**INCENTIVE WARRANT SCHEME**

The Board of Directors is authorised during the period until 1 January 2025 on one or more occasions to issue warrants up to ten (10) percent of the Company's share capital from time to time, each conferring the right to subscribe one share of nominal DKK 0.20 against cash contribution and to effect the corresponding increase(s) of the share capital.

The background for the implementation of the warrant program is to create possibilities for Cessatech to retain and incentivise the Board of Directors, CEO and key employees by offering a long-term ownership engagement, which will contribute to an alignment of interests between the warrant holders and the shareholders and promote long-term commitment to the Company's development. In December 2020, the Board of Directors and the CEO received warrants as part of Cessatech's Incentive Warrant Scheme. Subsequently to 31 December 2022 a new Incentive Warrant Scheme was established in January 2023 also including key employees. See the press release of 17 January for more details on the Incentive Warrant Scheme.

**ACCOUNTING POLICY**

This unaudited results announcement for Q2 2023 contains condensed financial information for the six months ended 30 June 2023 and should be read in conjunction with the Annual Report 2022, which was prepared in accordance with International Financial Reporting Standards as adopted by the European Union and further requirements in the Danish Financial Statements Act. For further information on accounting policies, please see the Annual Report 2022. This first quarter report has been prepared using unchanged accounting policies for recognition and measurement.

**OPERATIONAL RISKS AND UNCERTAINTIES**

The risks and uncertainties that Cessatech's operations are exposed to relate to factors such as development, competition, permissions, capital requirements, customers, suppliers/ manufacturers, currencies and interest rates. During the current period, no significant changes in risk factors or uncertainties have occurred. For a more detailed description of risks and uncertainties, refer to the prospectus published in December 2020 or the Memorandum in October 2022 at [www.cessatech.com](http://www.cessatech.com)

**AUDITOR'S REVIEW**

This report has not been reviewed or audited by Cessatech's auditor PricewaterhouseCoopers.

## FINANCIAL CALENDAR

Q3 Report: 16 November 2023

Q4 and Annual Year Report 2023: 29 FEB 2024

Annual General Meeting 2023: 27 MAR 2024

### **ANNUAL GENERAL MEETING AND AVAILABILITY OF THE ANNUAL REPORT**

The Annual General Meeting 2022 was held on Thursday 23 March 2023 at 9.00 AM. The annual report and the minutes from the annual general meeting is available on Cessatech's website.

The Annual General Meeting for 2023 will take place on 27 March 2024.

### **SUBMISSION OF Q3 REPORT**

The Board of Directors hereby certifies that this Q3 2023 report provides a true and fair view of the Company's business.

Copenhagen 16 November 2023  
The Board of Directors

### **Highlights during third quarter 2023**

- Last participant dosed in pivotal trial 0205
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## 7 – Income statement

<b>INCOME STATEMENT</b>	<b>Q3 2023</b>	<b>Q3 2022</b>	<b>Q1-Q3 2023</b>	<b>Q1-Q3 2022</b>	<b>2022</b>
	01/Jul/23	01/Jul/22	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	30/Sep/23	30/Sep/22	30/Sep/23	30/Sep/22	31/Dec/22
Revenue	0	-	0	0	0
Other external expenses	-4.772	-2.297	-14.482	-7.015	-12.246
Staff expenses	-1.040	-955	-3.176	-3.953	-5.343
<b>Operating loss before net financials</b>	<b>-5.811</b>	<b>-3.252</b>	<b>-17.657</b>	<b>-10.967</b>	<b>-17.589</b>
Financial expenses, net	-2.049	-40	-1.953	-171	-210
<b>Loss before tax</b>	<b>-7.860</b>	<b>-3.292</b>	<b>-19.610</b>	<b>-11.139</b>	<b>-17.799</b>
Tax on loss for the period	1.251	666	3.332	2.170	3.143
<b>Net loss for the period</b>	<b>-6.609</b>	<b>-2.627</b>	<b>-16.278</b>	<b>-8.969</b>	<b>-14.656</b>
Other comprehensive income for the period	0	-	0	0	0
<b>Total comprehensive income</b>	<b>-6.609</b>	<b>-2.627</b>	<b>-16.278</b>	<b>-8.969</b>	<b>-14.656</b>
<b>Basis and diluted earnings per share</b>	<b>-0,43</b>	<b>-0,43</b>	<b>-1,18</b>	<b>-1,47</b>	<b>-2,06</b>

### Comments to the income statement

- The large increase in financial expenses, it not impacting our cash-flow, as it is mainly related to the calculated estimated fair value of the TO 2 warrants
- The Operating Loss is higher compared to the same quarter for the previous year, which reflects a significant increase in the level of activities. Compared to the previous quarter (Q2 2023) the operating loss is app 5% lower

<b>BALANCE SHEET</b>	<b>Q3 2023</b>	<b>Q3 2022</b>	<b>2022</b>
			01/Jan/22
Amounts in DKK '000'	30/Sep/23	30/Sep/22	31/Dec/22
<b>Assets</b>			
<i>Fixed Assets</i>			
- Patents	203	203	203
<b>Intangible Assets</b>	<b>203</b>	<b>203</b>	<b>203</b>
<b>Total non-current assets</b>	<b>203</b>	<b>203</b>	<b>203</b>
<b>Current assets</b>			
- Receivables corporate tax	6.475	4.493	3.143
- Other receivables	447	333	1.334
- Prepayments	139	17	164
- Cash at bank	5.192	15.001	23.343
<b>Total current assets</b>	<b>12.254</b>	<b>19.844</b>	<b>27.984</b>
<b>Total assets</b>	<b>12.457</b>	<b>20.047</b>	<b>28.187</b>

<b>BALANCE SHEET</b>	<b>Q3 2023</b>	<b>Q3 2022</b>	<b>2022</b>
			01/Jan/22
Amounts in DKK '000'	30/Sep/23	30/Sep/22	31/Dec/22
<b>Equity and liabilities</b>			
<i>Equity</i>			
Share capital	2.758	1.223	2.758
Retained earnings	5.466	16.521	21.098
<b>Total equity</b>	<b>8.224</b>	<b>17.744</b>	<b>23.855</b>
<i>Liabilities</i>			
- Trade payables	1.403	1.190	2.738
- Liabilities measured at fair value	2.380	0	614
- Other payables	451	1.113	979
<b>Current liabilities</b>	<b>4.233</b>	<b>2.303</b>	<b>4.332</b>
<b>Total liabilities</b>	<b>4.233</b>	<b>2.303</b>	<b>4.332</b>
<b>Total equity and liabilities</b>	<b>12.457</b>	<b>20.047</b>	<b>28.187</b>

<b>STATEMENT OF CHANGE IN EQUITY Q3, 2023</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 July 2023	2.758	0	11.923	14.681
Incentive Warrant Scheme	0	0	152	152
Total comprehensive income for the period	0	0	-6.609	-6.609
<b>At 30 September 2023</b>	<b>2.758</b>	<b>0</b>	<b>5.466</b>	<b>8.224</b>

<b>STATEMENT OF CHANGE IN EQUITY Q3, 2022</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 July 2022	1.223	0	19.026	20.249
Incentive Warrant Scheme	0	0	122	122
Total comprehensive income for the period	0	0	-2.627	-2.627
<b>At 30 September 2022</b>	<b>1.223</b>	<b>0</b>	<b>16.521</b>	<b>17.744</b>

<b>STATEMENT OF CHANGE IN EQUITY Q1-Q3, 2023</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 January 2023	2.758	0	21.098	23.855
Incentive Warrant Scheme	0	0	647	647
Total comprehensive income for the period	0	0	-16.278	-16.278
<b>At 30 September 2023</b>	<b>2.758</b>	<b>0</b>	<b>5.466</b>	<b>8.224</b>

<b>STATEMENT OF CHANGE IN EQUITY Q1-Q3, 2022</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 January 2022	1.223	0	25.019	26.241
Incentive Warrant Scheme	0	0	471	471
Total comprehensive income for the period	0	0	-8.991	-8.991
<b>At 30 September 2022</b>	<b>1.223</b>	<b>0</b>	<b>16.521</b>	<b>17.722</b>

<b>STATEMENT OF CHANGE IN EQUITY 2022</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 January 2022	1.223	0	25.019	26.241
Share capital increase right issue for cash	1.467	13.203	0	14.670
Share capital increase compensation to underwriters	68	614		682
Fair value of warrants issued as part of right issue			-576	-576
Transfer	0	-13.817	13.817	0
Incentive Warrant Scheme	0	0	565	565
Expenses in connection with capital increase, cash	0	0	-2.390	-2.390
Expenses in connection with capital increase, fair value compensation in Units	0	0	-682	-682
Total comprehensive income for the period	0	0	-14.656	-14.656
<b>At 31 December 2022</b>	<b>2.758</b>	<b>0</b>	<b>21.098</b>	<b>23.855</b>

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<b>CASH FLOW STATEMENT</b>	<b>Q3 2023</b>	<b>Q3 2022</b>	<b>Q1-Q3 2023</b>	<b>Q1-Q3 2022</b>	<b>2022</b>
	01/Jul/23	01/Jul/22	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	30/Sep/23	30/Sep/22	30/Sep/23	30/Sep/22	31/Dec/22
<b>Loss before tax</b>	-7.860	-3.292	-19.610	-11.139	-17.799
Financial expenses, reversed net	2.049	40	1.953	171	210
Other non-cash items	152	122	647	472	565
Tax credit paid out	0	0	0	0	2.324
Change in working capital	-1.377	325	-952	-240	27
<b>Cash flow from operating activities before net financials</b>	<b>-7.036</b>	<b>-2.805</b>	<b>-17.963</b>	<b>-10.735</b>	<b>-14.673</b>
Financial expenses paid/received	-207	-40	-187	-171	-172
<b>Cash flow from operating activities</b>	<b>-7.243</b>	<b>-2.845</b>	<b>-18.151</b>	<b>-10.907</b>	<b>-14.845</b>
Purchase of intangible assets	0	0	0	0	0
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Cash capital increase, TO1 + Rights Issue	0	0	0	24.325	38.995
Transaction cost, cash capital increase	0	0	0	-1.692	-4.082,33
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>22.633</b>	<b>34.913</b>
Total cash flow for the period	-7.243	-2.845	-18.151	11.726	20.068
Cash, beginning of the period	12.435	17.846	23.343	3.275	3.275
<b>Cash, end of the period</b>	<b>5.192</b>	<b>15.001</b>	<b>5.192</b>	<b>15.001</b>	<b>23.343</b>

### Comments to the cash flow statement

- The large increase in financial expenses, it not impacting our cash-flow, as it is mainly related to the calculated estimated fair value of the TO 2 warrants
- Cash at the end of the period, does not include the Loan Facility Agreement of KDKK 5.000