



# Second Quarter Report Q2-2024

1 April – 30 June



21 August 2024

Cessatech A/S - CVR no. 41293055  
Strandvejen 60, 2900 Hellerup, Denmark



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## Highlights Q2-2024 Report

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 April – 30 June 2024. The second 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.

### Second quarter financial results 2024 (1 April - 30 June):

- Net revenue was KDKK 0
- Operating result was KDKK -5.382
- Net result was KDKK -3.435
- Cash at bank end of the period was KDKK 9.896
- Earnings per share\* was KDKK -0,20
- Solidity\*\* was 92%

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

- First patient dosed in Paediatric Safety Study 0202
- Superior simulated pain efficacy in children with CT001
- New member of the Board of Directors, Anders Dyhr D-Toft
- US launch finalization and final approvals still ongoing...

*\*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 June 2024 amounted to 17.425.094 shares, the average number of shares during the second quarter was 17.425.094*

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

**Comment from CEO, Jes Trygved:** Our main focus has still been the planning and preparation for the US launch of CT001, which is now planned for the 2<sup>nd</sup> half of 2024, as the US partners are pending a few local approvals but overall is still looks very promising and we are all eager to get started with the Early Access Program. We are also pleased to have initiated the Paediatric Safety Study 0202, which has made good progress, and which is the final clinical trial before we can prepare for regulatory submission for CT001. Again, a big effort from the Cessatech team and its collaboration partners.

## 1. Summary

The Board of Directors and CEO of Cessatech hereby publish the first quarter report of 2024. 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 and with the initiation of the US Early Access Program will significantly improve its potential revenue generation with its lead candidate CT001.

## Key figures

	Q2 2024	Q2 2023	1H 2024	2023
	01/Apr/24	01/Apr/23	01/Jan/24	01/Jan/23
Key figures	30/Jun/24	30/Jun/23	30/Jun/24	31/Dec/23
<b>Income statement</b>				
Operating Loss	-5,382	-6,185	-9,461	-22,510
Total financial items	50	-164	1,417	-8,230
Loss for the period	-3,435	-5,304	-6,146	-26,527
<b>Balance sheet</b>				
Cash at Bank	9,896	12,435	9,896	3,373
<b>Ratios</b>				
Solvency ratio	92%	76%	92%	-23%
Earnings per share (DKK)	-0.20	-0.38	-20%	-1.92

\*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 June 2024 amounted to 17.425.094 shares, the average number of shares during the second quarter was 17.425.094

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

## Highlights during second quarter 2024

- First patient dosed in Paediatric Safety Study 0202
- Superior simulated pain efficacy in children with CT001
- New member of the Board of Directors, Anders Dyhr D-Toft
- US launch finalization and final approvals still ongoing...

The second quarter of 2024 had good traction on all key activities, especially as we have been busy preparing for the commercial activities with our US partner. We are very excited as this year will potentially be a breakthrough year for the company.

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

We now anticipate the launch in the 2<sup>nd</sup> half of 2024, and there is obviously much effort put in by both teams to get ready. We are pending a few local approvals, final manufacturing and release before distribution can take place. We are eager to update you when the first shipment has been made to hospitals.

### **First patient dosed in Study 0202**

The 0202 study is the last study in the PIP program. It is an open-label, prospective study to assess safety, tolerability, analgesic effect, and feasibility of intranasal CT001 in 150 paediatric patients with moderate to severe pain. Two countries have been selected with a total of 6 sites, and the first patient was treated end of May. All sites are not yet completely up and running, but we are pleased with the progress to date as more than 20% of the patients have been recruited.

### **Welcome to Anders Dyhr D-Toft, to the Board of Directors**

Anders comes with long-standing medical and commercial background in senior leadership positions in both large pharma (Novo Nordisk) and small biotech. His experience with planning and execution of global launches makes him an important addition to our Board at this pivotal moment for Cessatech. It has been great to have Anders on the team since he joined end of June.



### **Initiated the upscale of the manufacturing process**

We have initiated the scale-up of the aseptic manufacturing process of CT001. We are conducting a test run and Operational Qualification (OQ) for our new filling line format. Additionally, we are validating the tubing line, testing performance over various timeframes. We have completed installation of necessary machinery adaptations for the automatic filling process. We anticipate that their successful completion will validate the new filling line format's operational readiness, marking a significant milestone in our commercial production readiness for CT001.

### **Superior simulated pain efficacy in children with CT001**

Cessatech presented strong data on paediatric pain relief at the PAGE conference on the 28 June in Rome favouring its lead candidate CT001. The simulated pain reduction in NRS in children using CT001 was -87%, compared to -52%, -32% and +10% for sufentanil, ketamine and placebo respectively. Data on estimates for the opioid sparing effect also presented and showed more than a doubling effect from CT001. All in all, we could have wished for better data and the data strongly support our hypothesis that CT001 is very effective in children relative to its active comparators and will be instrumental in our final development.

### **Post-period updates...**

In August we extended the Loan Facility Agreement with a group of investors from MFO Private Equity of KDDK 10.000 to support our US launch and organisation. This gives the Company more flexibility for the coming 18-24 months and we are very pleased with the trust the group has given us during the years.

We are ready and excited about the outlook for the 2<sup>nd</sup> half of 2024.

### 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 pain in children, based on >10 years of clinical experience.
- CT002 - a nasal spray for sedative procedures in children from 0-17 years of age



### 3: Building a business

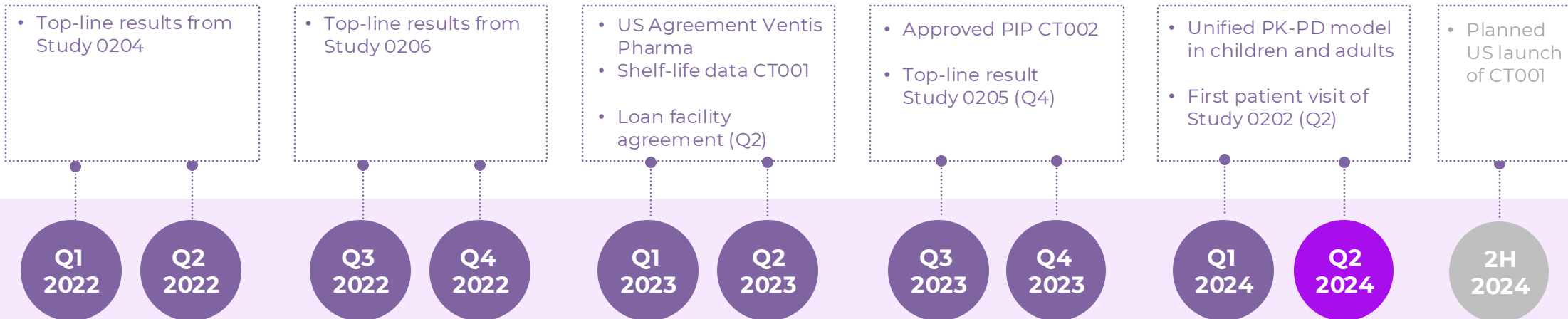
- Commercialization intended to be based on partnerships - aiming at generating a positive cash-flow trend faster
- Supply and manufacturing are outsourced to leading expert companies in Europe






#### 2021 major milestones

- Favourable data from Registry Study 0203
- US patent issuance

During Q2'2024 we spent much time on our US preparations together with our partners, but also the initiation of the Paediatric Safety Study 0202 with CT001 had a high priority.



# 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 analgesic nasal spray PIP plan (CT001) in agreement with 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 Q2-2024 were as expected  
 Net revenue amounted to DKK 0  
 Operating result was KDKK -5.382 in Q2-2024

The operating result was as expected as the company is currently conducting development activities. Main cost driver for Q2-2024 was:

- The initiation of the Paediatric Safety Study 0202
- The increased CMC (manufacturing setup costs) related to planned upscaling

## BALANCE SHEET AND SOLIDITY

The total equity at 30 June 2024 was KDKK 18.909  
 The solidity as per 30 June 2024 was 95%

## CASH FLOW AND INVESTMENTS

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

Cash at the end of June 2024 was KDKK 9.896

The majority of the cash flow during Q2 2024 is related to clinical activities which will continue as planned through 2024

We believe we have a good cash position for the coming periods, as we in August 2024 managed to extend the loan facility agreement of KDDK 10.000 to support our US launch and organisation, which gives the Company more flexibility for the coming 18-24 months.

The cash position does not include the loan facility of KDDK 10.000 or the tax return due in Q4 2024.

	Q2 2024	Q2 2024
Shareholders	Number of shares	Votes and capital
<b>Shareholders &gt;5%</b>		
Jes Trygved (CEO)	926,899	5.3%
All other shareholders	16,498,195	94.7%
<b>SUM</b>	<b>17,425,094</b>	<b>100.0%</b>
<b>Board of Directors</b>		
Martin Olin (chairman)	356,686	2.0%
Charlotte Videbæk (C- ApS)	174,663	1.0%
Rachel Curtis Gravesen	204,417	1.2%
Anders Dyhr Dombernowsky-Toft	50,860	0.3%
Flemming Jensen	0	0.0%

### 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 2024 amounted to 17.425.094

There was an increase to the number of shares during the first quarter of 2024, related to the TO2 warrant exercise. Every share equals the same rights to the Company's assets and results.

### THE TO 2 WARRENTS – Q1 2024

As part of the Rights Issue in relation to the latest Offering in Q4-2022, the associated warrant TO2 was exercised during Q1 2024 which strengthened the cash-position of the company with approximately KDKK 17.100.



**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 (II) was established in January 2023 also including key employees. In July 2024 a third Scheme (III) was issued with the same objective. See the press release of 24 July 2024 for more details on the latest Incentive Warrant Scheme (III).

**ACCOUNTING POLICY**

This unaudited results announcement for Q2 2024 contains condensed financial information for the three months ended 30 June 2024 and should be read in conjunction with the Annual Report 2023, 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 2023. This second 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

Q1 Report:	15 May 2024
AGM:	27 March 2024
EGM:	5 July 2024
<b>Q2 Report:</b>	<b>21 August 2024</b>
Q3 Report:	13 November 2024
Q4 & year-end report:	28 February 2025
Annual General Meeting 2024: March 2025	

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

The Annual General Meeting 2023 was held on Thursday 27 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 2024 will take place on in March 2025.

### EXTRAORDINARY GENERAL MEETING 5 July 2024

In July 2024 the Company held an Extraordinary General Meeting, with the objective to elect Anders Dyhr Dombernowsky-Toft as a board member and specify clause 3.1.2 in the Articles of Association. Both proposals were adopted.

### SUBMISSION OF Q2 REPORT

The Board of Directors hereby certifies that this Q2 2024 report provides a true and fair view of the Company's business.

Copenhagen 21 August 2024  
The Board of Directors

### Highlights during second quarter 2024

- First patient dosed in Paediatric Safety Study 0202
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## 7 – Income statement

<b>INCOME STATEMENT</b>	<b>Q2 2024</b>	<b>Q2 2023</b>	<b>1H 2024</b>	<b>2023</b>
	01/Apr/24	01/Apr/23	01/Jan/24	01/Jan/23
Amounts in DKK '000'	30/Jun/24	30/Jun/23	30/Jun/24	31/Dec/23
Revenue	0	0	0	0
Other external expenses	-4,131	-4,834	-7,335	-16,592
Staff expenses	-1,251	-1,351	-2,126	-5,918
<b>Operating loss before net financials</b>	<b>-5,382</b>	<b>-6,185</b>	<b>-9,461</b>	<b>-22,510</b>
Financial expenses, net	50	-164	1,417	-8,230
<b>Loss before tax</b>	<b>-5,332</b>	<b>-6,349</b>	<b>-8,043</b>	<b>-30,740</b>
Tax on loss for the period	1,897	1,045	1,897	4,213
<b>Net loss for the period</b>	<b>-3,435</b>	<b>-5,304</b>	<b>-6,146</b>	<b>-26,527</b>
Other comprehensive income for the period	0	0	0	0
<b>Total comprehensive income</b>	<b>-3,435</b>	<b>-5,304</b>	<b>-6,146</b>	<b>-26,527</b>
<b>Basis and diluted earnings per share</b>	<b>-0.20</b>	<b>-0.38</b>	<b>-0.38</b>	<b>-1.92</b>

### Comments to the income statement

- The Operating Loss is somewhat lower compared to the same quarter for the previous year, which reflects a minor change in study costs related to clinical activities, but overall within the same range year-to-date.
- The Corporate Tax was not included in Q1, and this is included in Q2 for the first 6 months and hence at a higher level.

<b>BALANCE SHEET</b>	<b>Q2 2024</b>	<b>Q2 2023</b>	<b>2023</b>
	01/Apr/24	01/Apr/23	01/Jan/23
Amounts in DKK '000'	30/Jun/24	30/Jun/23	31/Dec/23
<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	6,110	5,224	4,213
- Other receivables	592	1,238	606
- Prepayments	14	94	109
- Cash at bank	9,896	12,435	3,373
<b>Total current assets</b>	<b>16,612</b>	<b>18,991</b>	<b>8,301</b>
<b>Total assets</b>	<b>16,814</b>	<b>19,194</b>	<b>8,504</b>

<b>BALANCE SHEET</b>	<b>Q2 2024</b>	<b>Q2 2023</b>	<b>2023</b>
	01/Apr/24	01/Apr/23	01/Jan/23
Amounts in DKK '000'	30/Jun/24	30/Jun/23	31/Dec/23
<b>Equity and liabilities</b>			
<i>Equity</i>			
Share capital	3,485	2,758	2,758
Retained earnings	12,052	11,923	-4,677
<b>Total equity</b>	<b>15,537</b>	<b>14,681</b>	<b>-1,919</b>
<i>Liabilities</i>			
- Trade payables	899	3,607	657
- Liabilities measured at fair value	0	537	8,636
- Other payables	378	368	1,130
<b>Current liabilities</b>	<b>1,277</b>	<b>4,513</b>	<b>10,423</b>
<b>Total liabilities</b>	<b>1,277</b>	<b>4,513</b>	<b>10,423</b>
<b>Total equity and liabilities</b>	<b>16,814</b>	<b>19,194</b>	<b>8,504</b>

<b>STATEMENT OF CHANGE IN EQUITY Q2. 2024</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 April 2024	3,485	0	15,425	18,909
Incentive Warrant Scheme	0	0	63	63
Total comprehensive income for the period	0	0	-3,435	-3,435
<b>At 30 June 2024</b>	<b>3,485</b>	<b>0</b>	<b>12,052</b>	<b>15,537</b>

<b>STATEMENT OF CHANGE IN EQUITY Q2, 2023</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 April 2023	2,758	0	17,004	19,762
Incentive Warrant Scheme	0	0	223	223
Total comprehensive income for the period	0	0	-5,304	-5,304
<b>At 30 June 2023</b>	<b>2,758</b>	<b>0</b>	<b>11,923</b>	<b>14,681</b>

<b>STATEMENT OF CHANGE IN EQUITY 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	753	753
Total comprehensive income for the period	0	0	-26,527	-26,527
<b>At 31 December 2023</b>	<b>2,758</b>	<b>0</b>	<b>-4,677</b>	<b>-1,919</b>

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<b>CASH FLOW STATEMENT</b>	<b>Q2 2024</b>	<b>Q2 2023</b>	<b>2023</b>
	01/Apr/24	01/Apr/23	01/Jan/23
Amounts in DKK '000'	30/Jun/24	30/Jun/23	31/Dec/23
<b>Loss before tax</b>	-5,332	-6,349	-30,740
Financial expenses, reversed net	-50	164	8,230
Other non-cash items	63	223	754
Tax credit paid out		0	3,143
Change in working capital	124	1,948	-1,148
<b>Cash flow from operating activities before net financials</b>	<b>-5,195</b>	<b>-4,014</b>	<b>-19,762</b>
Financial expenses paid/received	50	28	-208
<b>Cash flow from operating activities</b>	<b>-5,145</b>	<b>-3,986</b>	<b>-19,970</b>
Purchase of intangible assets	0	0	0
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>
Cash capital increase, TO1/2 + Rights Issue		0	0
Transaction cost, cash capital increase		0	0
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>
Total cash flow for the period	-5,145	-3,986	-19,970
Cash, beginning of the period	15,040	16,422	23,343
<b>Cash, end of the period</b>	<b>9,896</b>	<b>12,435</b>	<b>3,373</b>

## Comments to the cash flow statement

- The cash position does not include the loan facility of KDDK 10.000 or the tax return due in Q4 2024.