cessatech
rethinking child treatments

Third Quarter Report Q3-2024

1 July – 30 September | 13 November 2024

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

Table of content

Highlights Q3-2024 Report

Cessatech A/S ("Cessatech" or the "Company") today releases its results for the period 1 July – 30 September 2024. The third quarter report is available as an attached document to this press release and on www.cessatech.com under Investor/Filings & Reports.

Third quarter financial results 2024 (1 July - 30 September):

- Net Revenue was KDKK 3.356
- Operating result was KDKK -925
- Net result was KDKK -1.132
- Cash at bank end of the period was KDKK 5.944
- Earnings per share* was KDKK -0,06
- Solidity** was 77%

The Company has advanced well with its planned activities

- Commercial partnership agreement with Proveca Ltd
- Good progress with Paediatric Safety Study 0202
- Loan Facility Agreement extended to the year 2026
- US manufacturing and launch finalization in process

**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 2024 amounted to 17.425.094 shares, the average number of shares during the third quarter was 17.425.094*
***Solidity: Total equity divided by total capital and liability*

Comment from CEO, Jes Trygved: The commercialization and partnership agreement with Proveca Ltd, was a major effort and milestone for the company. A process that started last year, identifying the right partner for the registration and commercialization of CT001 for Europe and selected markets in rest of the world, has materialized and we are very pleased with the outcome. We are also pleased to have seen very good progress with the Paediatric Safety Study 0202, which has now reached the 50% enrolment mark. We are still spending significant time and effort on the manufacturing and launch of CT001 for the US market, this is another major milestone, and we hope soon to have a final launch date. Thanks for a great effort by the team !

1. Summary

The Board of Directors and CEO of Cessatech hereby publish the third 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

	Q3 2024	Q3 2023	Q1-Q3 2024	Q1-Q3 2023	2023
Key figures	01/Jul/24	01/Jul/23	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	30/Sep/24	30/Sep/23	30/Sep/24	30/Sep/23	31/Dec/23
Income statement					
Operating Loss	-925	-5,811	-10,386	-17,657	-22,510
Total financial items	-153	-2,049	1,264	-1,953	-8,230
Loss for the period	-1,132	-6,609	-7,278	-16,278	-26,527
Cash at Bank	5,944	5,192	5,944	5,192	3,373
Ratios					
Solvency ratio	77%	66%	77%	66%	-23%
Earnings per share (DKK)	-0.06	-0.48	-0.42	-1.18	-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 September 2024 amounted to 17.425.094 shares, the average number of shares during the third quarter was 17.425.094*
***Solidity: Total equity divided by total capital and liability*

Highlights during third quarter 2024

- Commercial partnership agreement with Proveca Ltd
- Good progress with Paediatric Safety Study 0202
- Loan Facility Agreement extended to the year 2026
- US manufacturing and launch finalization in process

The third quarter of 2024 was the quarter we signed the agreement with Proveca – and hence a major milestone for the company as it represents the first commercial agreement for the European market. We really look forward to the collaboration and have been busy planning the process ahead. We are very excited about this collaboration which hopefully will be successful for both parties.

Patient recruitment of Paediatric Safety 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. More than 50% of the patients of the recruitment has now been completed, and as it is open-label, we are able to follow the enrolment and see the initial results, and so far, we are pleased with what we have seen in terms of safety. We anticipate to end the trial by the end of the year and will then close the sites and finalize the analysis and reporting.

Preparation of the US launch of CT001
As we indicated during our recent company presentation, the US manufacturing setup is still not ready for release, but the team is working hard to get this resolved so we can release for distribution and push the marketing activities. We still anticipate to have a launch within the next 3 months, but it can obviously be a few weeks or months further delayed. We are eager to update you when the first shipment has been made to the hospitals.

The Proveca Ltd partnership
In August, the company entered into an exclusive commercialization agreement of CT001 world-wide excluding US. The agreement leverages the Proveca team's expertise in specialised medicines for children and their strong experience with PUMA licensing (Paediatric Use Marketing Authorisation) in Europe, which today includes four PUMA approvals. The detailed terms of the agreement is not disclosed but the partner has projected potential peak sales in the high double digit million euros. The next phase includes a though planning process to ensure we are ready for the regulatory process. More details about the company and the process is outlined on the next page.

Extended Loan Facility Agreement
In August, we also extended the Loan Facility Agreement with a group of investors from the MFO Private Equity of KDDK 10.000 to support our US launch and organisation. This agreement has been extended into 2026 which gives us more flexibility for the next years. We have not utilized this loan facility.

We are really busy and all excited about the outlook for the remaining part of the year.

Key terms
The agreement includes a smaller upfront payment upon signature and double-digit royalties to Cessatech than net sales in the licensed territory. First sales are anticipated during the year of 2026.

Regulatory process
Once the Paediatric Safety Study 0202 has been completed together with the manufacturing process validation, among many other items, the regulatory file for EMA can be compiled and submitted. Proveca will take the lead on this process, given their prior experience, and we expect to be able to submit during 2025. It is unlikely that we will share detailed submission timelines.

Market access and commercial efforts
Once the regulatory process is completed, the reimbursement and market access evaluations will take place, and this will also be heading up by Proveca. As with all products, this will vary from country to country, and unfortunately some countries take more time than the average. Some countries also have a short process so initial sales will take place during 2026.

Timelines
- Agreement signed August 2024
- Finalization of Study 0202 – end 2024
- Regulatory submission 2025
- First commercial sales 2026

About Proveca
Proveca is a global pharmaceutical company who specialise in the development and licensing of medicines to address the unmet medical needs for children. Working with clinicians, parents, carers and children, Proveca are leading the way to provide licenced medicines that are tailored to children's specific requirements.

Proveca therapy area
Proveca design, develop and license medicines for children, with a core focus in neurology, cardiology and immunology. Proveca identify products which require a new paediatric license (new indication) and/or an improved format for administration.

Commercial outlook
In Europe alone, it is estimated that more than 20 million children are exposed each year to acute and procedural pain without access to adequate approved medicine. Projected potential peak sales in the high double digit million euros.

3 – Milestones & Business Strategy

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 Q3'2024 we signed the important contract with Proveca, a commercialisation process and model that that taken much effort and time by the entire team, well done!

Q1 2022
- Top-line results from Study 0204

Q2 2022

Q3 2022
- Top-line results from Study 0206

Q4 2022

Q1 2023
- US Agreement Ventis Pharma
- Shelf-life data CT001
- Loan facility agreement (Q2)

Q2 2023

Q3 2023
- Approved PIP CT002
- Top-line result Study 0205 (Q4)

Q4 2023

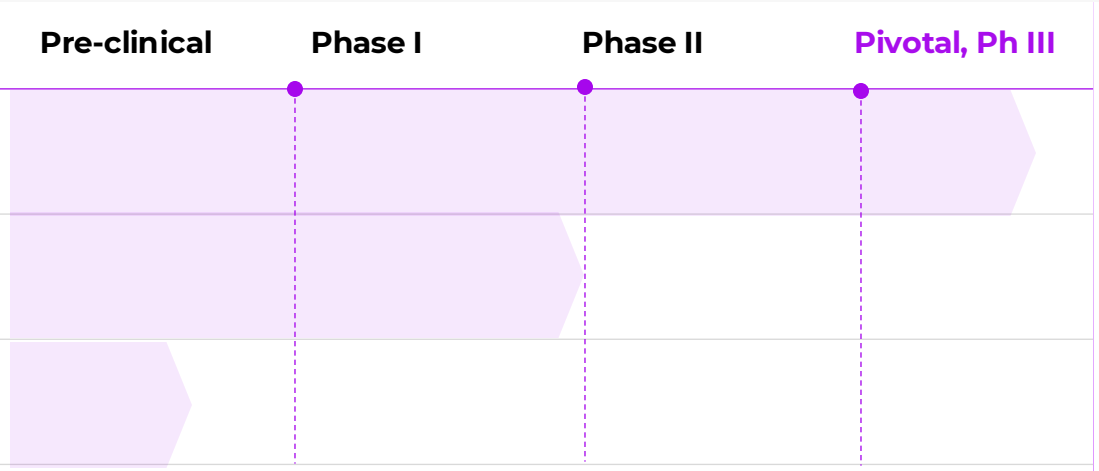
Q1 2024
- Unified PK-PD model in children and adults
- First patient visit of Study 0202 (Q2)

Q2 2024

Q3 2024
- Proveca contract for CT001
- Loan facility agreement

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

	Use	Indication
CT001 Fixed combination	Non-invasive nasal spray	Acute pain
CT002 Sedative-analgesic	Non-invasive nasal spray	Sedation
CT003 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.

Table of content

OPERATING INCOME AND OPERATING RESULTS

The operating income and result for Q3-2024 were as expected
Net revenue amounted to DKK 0
Operating result was KDKK -925 in Q3-2024

The operating result was as expected as the company is currently conducting development activities. Main cost driver for Q3-2024 was:

- The Paediatric Safety Study 0202
- Increased CMC activities (manufacturing setup costs) related to planned validation

BALANCE SHEET AND SOLIDITY

The total equity at 30 September 2024 was KDKK 15.093
The solidity as per 30 September 2024 was 77%

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 September 2024 was KDKK 5.944
The majority of the cash flow during Q3 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 until 2026 of KDDK 10.000 to support our US launch and organisation, which gives the Company more flexibility for the coming 18-24 months. In addition, there is an upfront income from the agreement with Proveca and expected royalties from 2026. The cash position does not include the loan facility of KDDK 10.000 or the tax return due in Q4 2024.

Shareholders	Q3 2024 Number of shares	Q3 2024 Votes and capital
Shareholders >5%		
Jes Trygved (CEO)	926,899	5.3%
All other shareholders	16,498,195	94.7%
SUM	**17,425,094**	**100.0%**
Board of Directors		
Martin Olin (chairman)	356,686	2.0%
Rachel Curtis Gravesen	204,417	1.2%
Charlotte Videbæk (C- ApS)	174,663	1.0%
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 September 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 T0 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 Q3 2024 contains condensed financial information for the three months ended 30 September 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 third 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

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
Q2 Report:	21 August 2024
Q3 Report:	13 November 2024
Q4 & year-end report:	28 February 2025

Annual General Meeting 2024: March 2025

ANNUAL GENERAL MEETING
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 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 Q3 REPORT
The Board of Directors hereby certifies that this Q3 2024 report provides a true and fair view of the Company's business.

Copenhagen 13 November 2024
The Board of Directors

Highlights during third quarter 2024

- Commercial partnership agreement with Proveca Ltd
- Good progress with Paediatric Safety Study 0202
- Loan Facility Agreement extended to the year 2026
- US manufacturing and launch finalization in process

Table of content

7 – Income statement

INCOME STATEMENT	Q3 2024	Q3 2023	Q1-Q3 2024	Q1-Q3 2023	2023
	01/Jul/24	01/Jul/23	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	30/Sep/24	30/Sep/23	30/Sep/24	30/Sep/23	31/Dec/23
Revenue	3,356	0	3,356	0	0
Other external expenses	-2,740	-4,772	-10,075	-14,482	-16,592
Staff expenses	-1,542	-1,040	-3,667	-3,176	-5,918
Operating loss before net financials	**-925**	**-5,811**	**-10,386**	**-17,657**	**-22,510**
Financial expenses, net	-153	-2,049	1,264	-1,953	-8,230
Loss before tax	**-1,079**	**-7,860**	**-9,122**	**-19,610**	**-30,740**
Tax on loss for the period	-53	1,251	1,844	3,332	4,213
Net loss for the period	**-1,132**	**-6,609**	**-7,278**	**-16,278**	**-26,527**
Other comprehensive income for the period	0	0	0	0	0
Total comprehensive income	**-1,132**	**-6,609**	**-7,278**	**-16,278**	**-26,527**
Basis and diluted earnings per share	**-0.06**	**-0.43**	**-0.42**	**-1.18**	**-1.92**

Comments to the income statement

- There has been a positive income contribution for the third quarter from the agreement with Proveca, The deferred revenue at 30 September 2024 is expected to be recognised as income in Q4 2024, as the last patient in the study is expected to be enrolled before year-end.
- The operating costs 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.

8 - Balance sheet

BALANCE SHEET	Q3 2024	Q3 2023	2023
	01/Jul/24	01/Jul/23	01/Jan/23
Amounts in DKK ´000´	30/Sep/24	30/Sep/23	31/Dec/23
Assets			
Fixed Assets			
- Patents	203	203	203
Intangible Assets	**203**	**203**	**203**
Total non-current assets	**203**	**203**	**203**
Current assets			
- Receivables corporate tax	6,057	6,475	4,213
- Other receivables	7,501	447	606
- Prepayments	0	139	109
- Cash at bank	5,944	5,192	3,373
Total current assets	**19,501**	**12,254**	**8,301**
Total assets	**19,704**	**12,457**	**8,504**

BALANCE SHEET	Q3 2024	Q3 2023	2023
	01/Jul/24	01/Jul/23	01/Jan/23
Amounts in DKK ´000´	30/Sep/24	30/Sep/23	31/Dec/23
Equity and liabilities			
Equity			
Share capital	3,485	2,758	2,758
Retained earnings	11,609	5,466	-4,677
Total equity	**15,093**	**8,224**	**-1,919**
Liabilities			
- Trade payables	184	1,403	657
- Deferred revenue	4,102	0	0
- Liabilities measured at fair value	0	2,380	8,636
- Other payables	325	451	1,130
Current liabilities	**4,610**	**4,233**	**10,423**
Total liabilities	**4,610**	**4,233**	**10,423**
Total equity and liabilities	**19,704**	**12,457**	**8,504**

9 - Statement of changes in equity

CHANGE IN EQUITY Q3. 2024 Amounts in DKK ´000´	Share-Capital	Share Premium	Retained earnings	Shareholders equity
At 1 July 2024	3,485	0	12,052	15,537
Incentive Warrant Scheme	0	0	688	688
Total comprehensive income for the period	0	0	-1,132	-1,132
At 30 September 2024	**3,485**	**0**	**11,609**	**15,093**

CHANGE IN EQUITY Q3, 2023 Amounts in DKK ´000´	Share-Capital	Share Premium	Retained earnings	Shareholders 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
At 30 September 2023	**2,758**	**0**	**5,466**	**8,224**

CHANGE IN EQUITY 2023 Amounts in DKK ´000´	Share-Capital	Share Premium	Retained earnings	Shareholders 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
At 31 December 2023	**2,758**	**0**	**-4,677**	**-1,919**

CHANGE IN EQUITY Q1-Q3, 2024 Amounts in DKK ´000´	Share-Capital	Share Premium	Retained earnings	Shareholders equity
At 1 January 2024	2,758	0	-4,677	-1,919
Share capital increase T02	727	16,400	7,254	24,381
Transfer		-16,400	16,400	0
Incentive Warrant Scheme			829	829
Expenses in connection with capital increase,	0	0	-920	-920
Total comprehensive income for the period	0	0	-7,278	-7,278
At 30 September 2024	**3,485**	**0**	**11,609**	**15,093**

CHANGE IN EQUITY Q1-Q3, 2023 Amounts in DKK ´000´	Share-Capital	Share Premium	Retained earnings	Shareholders 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
At 30 September 2023	**2,758**	**0**	**5,466**	**8,224**

Table of content

CASH FLOW STATEMENT	Q3 2024	Q3 2023	Q1-Q3 2024	Q1-Q3 2023	2023
	01/Jul/24	01/Jul/23	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	30/Sep/24	30/Sep/23	30/Sep/24	30/Sep/23	31/Dec/23
Loss before tax	-1,079	-7,860	-9,122	-19,610	-30,740
Financial expenses, reversed net	153	2,049	-1,264	1,953	8,230
Other non-cash items	688	152	829	647	754
Tax credit paid out		0	0	0	3,143
Change in working capital	-3,561	-1,377	-3,962	-952	-1,148
Cash flow from operating activities before financials	**-3,798**	**-7,036**	**-13,519**	**-17,963**	**-19,762**
Financial expenses paid/received	-153	-207	-118	-187	-208
Cash flow from operating activities	**-3,952**	**-7,243**	**-13,636**	**-18,151**	**-19,970**
Purchase of intangible assets	0	0	0	0	0
Cash flow from investing activities	**0**	**0**	**0**	**0**	**0**
Cash capital increase, TO1/2 + Rights Issue		0	17,127	0	0
Transaction cost, cash capital increase		0	-920	0	0
Cash flow from financing activities	**0**	**0**	**16,207**	**0**	**0**
Total cash flow for the period	-3,952	-7,243	2,571	-18,151	-19,970
Cash, beginning of the period	9,896	12,435	3,373	23,343	23,343
Cash, end of the period	**5,944**	**5,192**	**5,944**	**5,192**	**3,373**

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. The company has not utilized the loan facility.