cessatech
rethinking child treatments

First Quarter Report Q1-2024

1 January - 31 March | 15 May 2024

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

Table of content

Highlights Q1-2024 Report

Cessatech A/S ("Cessatech" or the "Company") today releases its results for the period 1 January – 31 March 2024. The first quarter report is available as an attached document to this press release and on www.cessatech.com under Investor/Filings & Reports.

First quarter financial results 2024 (1 January - 31 March):

- Net revenue was KDKK 0
- Operating result was KDKK -4.079
- Net result was KDKK -2.711
- Cash at bank end of the period was KDKK 15.041
- Earnings per share* was KDKK -0,16
- Solidity** was 95%

The Company has advanced well with its planned activities

- US planning & preparation for CT001 launch
- CT001 device verification completed
- Study 0202 initiation visits and supply of IMP medicine
- Submission of abstract for unified PK-PD model in children

**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 31 March 2024 amounted to 17.425.094 shares, the average number of shares during the first quarter was 16.602.837*
***Solidity: Total equity divided by total capital and liability*

Comment from CEO, Jes Trygved: Our focus has also very much been on the planning and preparation for the US launch of CT001 where we expect to have first packs shipped to selected US hospitals under the Early Access Program in just a few months. Thanks to teams for its efficiency, hard work and commitment for making this possible. We are also pleased to soon initiate the Paediatric Safety Study 0202, which is the final clinical trial before we can prepare for regulatory submission for CT001, and we have submitted an abstract on the paediatric population data, a PK-PD model, which will be presented end of June at a conference in Europe.

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 with the initiation of its pivotal study which will significantly improve its potential revenue generation.

Key figures

	Q1 2024	Q1 2023	2023
Key figures	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	31/Mar/24	31/Mar/23	31/Dec/23
Income statement			
Operating Loss	-4.079	-5.661	-22.510
Total financial items	1.367	260	-8.230
Loss for the period	-2.711	-4.365	-26.527
Balance sheet			
Cash at Bank	15.040	16.422	3.373
Ratios			
Solvency ratio	95%	92%	-23%
Earnings per share (DKK)	-0,16	-0,32	-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 31 March 2024 amounted to 17.425.094 shares, the average number of shares during the first quarter was 16.602.837*
***Solidity: Total equity divided by total capital and liability*

Highlights during first quarter 2024

- US planning & preparation for CT001 launch
- CT001 device verification completed
- Study 0202 initiation visits and supply of IMP medicine
- Submission of abstract for unified PK-PD model in children

The first quarter of 2024 had a 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

Previous quarters has focused more on the manufacturing, teach transfer and validations, and first quarter this year has had more emphasis on the commercial aspects, including brand name, packaging design and marketing material. We look forward to share these soon. Extensive planning and meetings have set the stage for a successful initial rollout, thus ensuring physicians understand the product, its profile and limitations and especially that patients have a positive experience. The first month is hence limited to selected states and hospitals before a wider distribution and promotion will take place. We will share more updates on the process after a few months on the market.

CT001 device verification completed

Our pump manufacturer successfully completed their obligations under the contract with Cessatech, delivering comprehensive regulatory and technical support for the device verification of the paediatric nasal spray project. This included the design verification and performance testing of the two nasal spray pumps and actuators in combination with specific glass vials, ensuring their suitability for Cessatech's nasal spray configuration. These deliverables are crucial for Cessatech as they are an integral part of the documentation to support regulatory submissions to both the notified body and EMA, ensuring compliance with the EU's MDR 2017/745 and facilitating market authorization. This accomplishment is a significant milestone in advancing Cessatech's product towards clinical use and commercialization, demonstrating robust device performance and getting a step closer to regulatory readiness.

Supply of IMP for 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. Two countries have been selected with a total of 6 sites, all approvals and IMP medicine is in place and any day we will have the first patient. The trial is conducted in an emergency room setting.

Submission of Abstract - simulation of Study 0205/0207 & 0208

We anticipate this important unified PK-PD model, developed based on all available both adult and paediatric study data (0201, 0204, 0205, and 0206), which are modelling and simulating exposure-response, is to be published at the end of Q2 this year. This will have significant importance to the company, the regulatory process and later commercialisation of CT001.

Dental Study 0205 updates

In Dec 2023 we published the positive topline data in the important Dental study 0205 supporting further advancement of CT001. The demonstrated significant reduction in on a pain scale, and although superiority was not achieved for the sufentanil control arm in adults, the co-primary endpoint of preliminary modelled exposure-response data substantiates that CT001 is superior in children. The is an important statement and the team has been working hard to publish these data in children.

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

During Q1'2024 we spent much time on our US preparations together with our partners. This included both final manufacturing testing and commercial planning. We believe we have found a really good partner and looking forward to a promising future with CT001 in the US

2021 major milestones
- Favourable data from Registry Study 0203
- US patent issuance

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

Q2 2023
- Loan facility agreement

Q3 2023
- Approved PIP CT002

Q4 2023
- Top-line result Study 0205 (Q4)

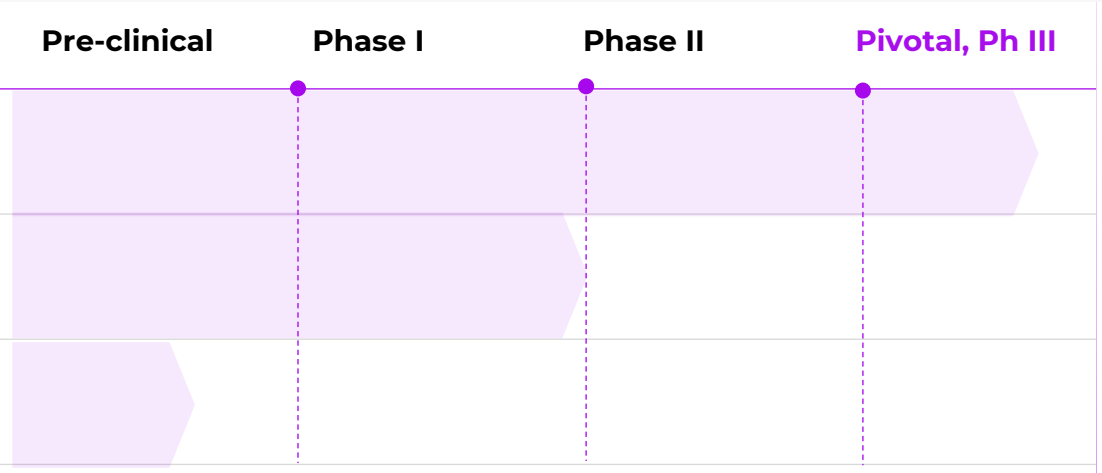
Q1 2024
- Unified PK-PD model in children and adults

Q2 2024
- First patient visit of Study 0202
- US launch of CT001

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

4 – Cessatech and CT001 + CT002

	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 Q1-2024 were as expected
Net revenue amounted to DKK 0
Operating result was KDKK -4.079 in Q1-2024

The operating result was as expected as the company is currently conducting development activities. Main cost driver for Q1-2024 was:

- The main cost driver for first quarter of 2024 was the finalization of Dental Study 0205 and initiation of Safety Study 0202, in which the clinical and device costs accounted for 57% of total costs for the period.

BALANCE SHEET AND SOLIDITY

The total equity at 31 March 2024 was KDKK 18.909
The solidity as per 31 March 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 March 2024 was KDKK 15.041
The majority of the cash flow during Q1 2024 is related to clinical activities which will continue as planned through 2024

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 result and outcome of the TO 2 warrant exercise in Q1-2024 further strengthened our cash position.

Shareholders	Q1 2024 Number of shares	Q1 2024 Votes and capital
Shareholders >5%		
Jes Trygved (CEO)	911.899	5,23%
All other shareholders	16.513.195	94,77%
SUM	**17.425.094**	**100,00%**
Board of Directors		
Martin Olin (chairman)	226.619	1,3%
Charlotte Videbæk (C- ApS)	167.163	1,0%
Rachel Curtis Gravesen	37.917	0,2%
Peter Birk	10.318	0,1%
Flemming Jensen	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 31 March 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

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 was established in January 2023 also including key employees. See the press release of 17 January 2023 for more details on the Incentive Warrant Scheme.

ACCOUNTING POLICY

This unaudited results announcement for Q1 2024 contains condensed financial information for the three months ended 31 March 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 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

AUDITOR'S REVIEW

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

FINANCIAL CALENDAR

Q1 Report: 15 May 2024

Q2 Report: 21 August 2024
Q3 Report: 13 November 2024
Q4 and 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.

SUBMISSION OF Q1 REPORT

The Board of Directors hereby certifies that this Q1 2024 report provides a true and fair view of the Company's business.

Copenhagen 15 May 2024
The Board of Directors

Highlights during first quarter 2024

- US planning & preparation for CT001 launch
- CT001 device verification completed
- Study 0202 initiation visits and supply of IMP medicine
- Submission of abstract for unified PK-PD model in children

Table of content

7 – Income statement

INCOME STATEMENT	Q1 2024	Q1 2023	2023
	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	31/Mar/24	31/Mar/23	31/Dec/23
Revenue		0	0
Other external expenses	-3.204	-4.876	-16.592
Staff expenses	-875	-785	-5.918
Operating loss before net financials	**-4.079**	**-5.661**	**-22.510**
Financial expenses, net	1.367	260	-8.230
Loss before tax	**-2.711**	**-5.401**	**-30.740**
Tax on loss for the period	0	1.036	4.213
Net loss for the period	**-2.711**	**-4.365**	**-26.527**
Other comprehensive income for the period	0	0	0
Total comprehensive income	**-2.711**	**-4.365**	**-26.527**
Basis and diluted earnings per share	**-0,16**	**-0,32**	**-1,92**

Comments to the income statement

- The large financial income of 1.367 is 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 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.

7 – Balance sheet

BALANCE SHEET	Q1 2024	Q1 2023	2023
	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	31/Mar/24	31/Mar/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	4.213	4.179	4.213
- Other receivables	356	589	606
- Prepayments	110	133	109
- Cash at bank	15.040	16.422	3.373
Total current assets	**19.718**	**21.323**	**8.301**
Total assets	**19.921**	**21.526**	**8.504**

BALANCE SHEET	Q1 2024	Q1 2023	2023
	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	31/Mar/24	31/Mar/23	31/Dec/23
Equity and liabilities			
Equity			
Share capital	3.485	2.758	2.758
Retained earnings	15.425	17.004	-4.677
Total equity	**18.909**	**19.762**	**-1.919**
Liabilities			
- Trade payables	739	945	657
- Liabilities measured at fair value	0	345	8.636
- Other payables	273	474	1.130
Current liabilities	**1.011**	**1.764**	**10.423**
Total liabilities	**1.011**	**1.764**	**10.423**
Total equity and liabilities	**19.921**	**21.526**	**8.504**

8 – Statement of changes in equity

STATEMENT OF CHANGE IN EQUITY Q1, 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
Fair value of warrants issued as part of right issue				0
Transfer		-16.400	16.400	0
Incentive Warrant Scheme	0	0	79	79
Expenses in connection with capital increase,			-920	-920
Total comprehensive income for the period	0	0	-2.711	-2.711
At 31 March 2024	**3.485**	**0**	**15.425**	**18.909**

STATEMENT OF CHANGE IN EQUITY Q1, 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	272	272
Total comprehensive income for the period	0	0	-4.365	-4.365
At 31 March 2023	**2.758**	**0**	**17.004**	**19.762**

STATEMENT OF 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**

Table of content

CASH FLOW STATEMENT	Q1 2024	Q1 2023	2023
	01/Jan/24	01/Jan/23	01/Jan/23
Amounts in DKK ´000´	31/Mar/24	31/Mar/23	31/Dec/23
Loss before tax	-2.711	-5.401	-30.740
Financial expenses, reversed net	-1.367	-260	8.230
Other non-cash items	79	272	754
Tax credit paid out	0	0	3.143
Change in working capital	-525	-1.523	-1.148
Cash flow from operating activities before net financials	**-4.525**	**-6.912**	**-19.762**
Financial expenses paid/received	-14	-9	-208
Cash flow from operating activities	**-4.540**	**-6.921**	**-19.970**
Purchase of intangible assets	0	0	0
Cash flow from investing activities	**0**	**0**	**0**
Cash capital increase, TO1/2 + Rights Issue	17.127	0	0
Transaction cost, cash capital increase	-920	0	0
Cash flow from financing activities	**16.207**	**0**	**0**
Total cash flow for the period	11.667	-6.921	-19.970
Cash, beginning of the period	3.373	23.343	23.343
Cash, end of the period	**15.040**	**16.422**	**3.373**

Comments to the cash flow statement

- Cash at the end of the period, does not include the Loan Facility Agreement of KDKK 5.000