
First quarter report Q1-2023

- Study 0205 is progressing, with last patient expected in Q3
- Protocol finalized for study 0202, ready for submission in Q2
- Good progress with the commercialization strategy

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 January – 31 March 2023. The first quarter report is available as an attached document to this press release and on www.cessatech.com under Investor/Filings & Reports. The Company is progressing well with planned activities, finalization of recruitment of pivotal study 0205 is expected in the third quarter of 2023 (a randomised double-blind placebo-controlled trial with 220 adults following impacted mandibular third molar extraction) and study 0202 is ready for submission and will be initiated later this year.

Please submit questions to our Q1-Release Q&A session to info@cessatech.com which will be released Tuesday 16 May afternoon 16.00

First quarter financial results 2023 (1 January - 31 March):

- Net revenue was KDKK 0
- Operating result was KDKK -5.661
- Net result was KDKK -4.365
- Cash at bank end of the period was KDKK 16.442
- Earnings per share* was KDKK -0,32
- Solidity** was 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 2023 amounted to 13.788.755 shares, the average number of shares during the third quarter was 13.788.755.

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

Highlights during first quarter 2023

- Continue enrolment for study 0205
- Successful completion of second usability test with 8 HCPs
- Finalized protocol for study 0202 and clinical sites identified, ready for submission (in Q2)
- Continued optimization of analytical methods and promising stability data for CT001
- AGM and appointment of new chairman of the board, Martin Olin
- Business development activities to support the future commercial partnership model

“During the first quarter of 2023 focus was on ensuring progress in our clinical activities. Having implemented actions to improve recruitment levels into our pivotal 0205 study we are now confident that recruitment will be finalized during Q3 with top-line results following shortly after. We also finalized the protocol of our 0202-safety study which we expect to submit to authorities for approval during the second quarter of this year. Additionally, we continued to work on our commercialisation strategy in both the EU and US for CT001 and look forward to moving our plans forward in this area in the coming time” says Jes Trygved, CEO



developing evidence-based treatments -
specifically for children



First Quarter Report (Q1-2023)

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

CESSATECH - FIRST QUARTER REPORT (Q1-2023)

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We are very happy with the progress of clinical trial 0205 and trial 0202, it is an extremely important study and we do not want to increase the risk of any potential noise both studies. We are a biotech company focusing on clinical development of new formulations and solutions approved for children – but we also want to ensure that we get the right commercial partnership in place. We continue the good work to get CT001 available for the hospitals. Thanks to the team for its high spirit and commitment.

1. Summary

The Board of Directors and CEO of Cessatech hereby publish the first 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.

	Q1 2023	Q1 2022	2022
Key figures	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	31/Mar/23	31/Mar/22	31/Dec/22
Operating Loss	-5.661	-3.736	-17.589
Total financial items	260	-76	-210
Loss for the period	-4.365	-3.045	-14.656
Cash at Bank	16.422	21.204	23.342
Ratios			
Solvency ratio	92%	95%	85%
Earnings per share (DKK)	-0,32	-0,50	-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 31 March 2023 amounted to 13.788.755 shares, the average number of shares during the third quarter was 13.788.755.*

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

Highlights during first quarter 2023

- Continue enrolment for study 0205
- Successful completion of second usability test with 8 HCPs
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2. CEO comments

During the first quarter of 2023 we had strong momentum in our clinical, CMC and business development activities, in order to maintain the business progress in bringing new options to treat children with pain.

We have had a very **good start into 2023**, the most important year of Cessatech, considering the short history of the company. This year we anticipate finalizing the commercial business setup for Europe and US, and to complete the pivotal clinical study 0205. We are very excited as this year will potentially be a breakthrough year for the company.



In September 2022 the first patient was dosed in the pivotal study 0205 with our lead candidate CT001, **investigating the postoperative analgesic efficacy of CT001** in adults following impacted mandibular third molar extraction. The study is a randomised, double-blind placebo-controlled trial with 220 participants. During the first quarter we saw a positive impact from actions we took to improve recruitment rates, including increasing the number of referring dental clinics participating in the study – even though some have done extremely well. We now look forward to completing recruitment during the third quarter of this year and reporting top-line results shortly thereafter.

We are looking forward to sharing updated **stability data on CT001** for both product strengths, as there have been further optimization of analytical methods and early indications of continued promising stability data for CT001. Furthermore, we have successfully completed a second usability test with 8 HCPs, which have provided excellent input to further improvement of our Leaflet, Label, and especially the Instruction for Use (IFU). This will provide the foundation for the summative validation Human Factor study to be initiated later this year in the US.

During the first quarter we finalized the study protocol for the final study of CT001. Study **0202 is an open-label, prospective study to access safety, tolerability, analgesic effect and feasibility** of CT001 with 300 paediatric patients in an emergency setting. The study is mainly focusing on safety. Until now we have not had any serious adverse events with CT001, and we expect this picture to continue in the next study. We plan to submit the protocol and related documentation to the relevant authorities during Q2 2023 and would hence anticipate an approval so the study can start recruitment during the 2nd half of 2023. All sites and investigators have been identified and training will start later this year.

In March 2023, we held the **Annual General Meeting for 2022**, the annual report was approved, and Martin Olin was elected as the new chairman of the board. Martin Olin has been on the board from the very beginning, and we are very happy that he accepted this role. He is an extremely professional individual, he has been a professional board member for many years and held several CEO positions, currently being the CEO of BerGenBio. Adam Steensberg will continue as a board member of Cessatech.

Our **financial position** is on track in terms of our prioritized activities, ongoing and planned clinical trials. Our focus is to ensure we continue to progress our core activities and build value into our business. Therefore, we follow a strategy of disciplined investment and financial planning to secure the optimal use and timing of our financial resources. As the completion of study 0205 is now expected during Q3 as opposed to previous estimates of end Q2, we anticipate a knock-on effect to the timing of the planned cash injection resulting from the TO 2 warrant exercise. To account for this change in timing of the warrant exercise we have postponed a number of planned activities by some months.

About Cessatech

Cessatech A/S is a Danish pharmaceutical company committed to developing and commercialising evidence-based and innovative medicines for children for the treatment of paediatric acute pain. Its lead asset (CT001) is an analgesic nasal spray for the treatment of acute pain and planned painful procedures in children. The advantages will include needle-free administration, being easy to administer, a fast-acting therapeutic effect with a good safety profile and being medically approved for children. CT001 is at its pivotal stage of clinical development.

Product portfolio

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

The Company has two follow-on concepts for children, a sedative nasal spray (CT002) for medical and diagnostic procedures (e.g., MRI scanning) and a local anaesthetic gel (CT003) that can be applied to open wounds (e.g., before stitching in the emergency room). With the recent success of obtaining an approved paediatric investigation plan (PIP) for the Company's lead asset, it is the Company's ambition to apply for a similar development program as the one recently granted for CT001. An update to the pipeline is expected later during 2023.

3. Cessatech and CT001

Cessatech is confident that intranasal treatment CT001 is a better alternative than intravenous medicine as it is easier and quicker to administer, resulting in fast pain relief, and the child does not have to experience the pain related to injection. Also, it is more feasible to administer compared to non-compliant children than oral medications.

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 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.



The Company'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. For more details regarding company strategy and activities please refer to the prospectus under ['filings and reports'](#) at www.cessatech.com

4. Financial development

OPERATING INCOME AND OPERATING RESULTS

The operating income and result for Q1-2023 were as expected.

Net revenue amounted to DKK 0 and the operating result was KDKK -5.661 in Q1-2023.

The operating result was as expected as the Company is currently conducting development activities.

BALANCE SHEET AND SOLIDITY

The total equity at 31 March 2023 was KDKK 19.762

The solidity as per 31 March 2023 was 92%

CASH FLOW AND INVESTMENTS

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

Cash at the end of March 2023 was KDKK 16.422

The majority of the cash flow during Q1 2023 is related to clinical activities which will continue as planned through 2023.

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 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.

5. Miscellaneous

	Q1-2023	Q1-2023
Shareholders	Number of shares	Votes and capital
Shareholders >5%		
Jes Trygved (CEO)	904.399	6,56%
All other shareholders	12.884.356	93,44%
SUM	13.788.755	100,00%
Board of Directors		
Adam Steensberg	164.901	1,20%
Charlotte Videbæk (C- ApS)	163.413	1,19%
Martin Olin (chairman)	86.426	0,63%
Rachel Curtis Gravesen	37.917	0,27%
Peter Birk	10.318	0,07%
Flemming Jensen	0	0,00%

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 Q1 2023 contains condensed financial information for the three months ended 31 March 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

AUDITOR'S REVIEW

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

FINANCIAL CALENDAR

Q1 Report: 12 May 2023

Q2 and Half-year Report: 24 August 2023

Q3 Report: 16 November 2023

Q4 and Annual Year Report 2023: 29 February 2024

Annual General Meeting 2023: 27 March 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 Q1 REPORT

The Board of Directors hereby certifies that this Q1 2023 report provides a true and fair view of the Company's business.

Copenhagen 12 May 2023
The Board of Directors

6. Income statement

INCOME STATEMENT	Q1 2023	Q1 2022	2022
	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	31/Mar/23	31/Mar/22	31/Dec/22
Revenue	0	0	0
Other external expenses	-4.876	-2.205	-12.246
Staff expenses	-785	-1.531	-5.343
Operating loss before net financials	-5.661	-3.736	-17.589
Financial expenses	260	-76	-210
Loss before tax	-5.401	-3.812	-17.799
Tax on loss for the period	1.036	767	3.143
Net loss for the period	-4.365	-3.045	-14.656
Other comprehensive income for the period	0	0	0
Total comprehensive income	-4.365	-3.045	-14.656
Basis and diluted earnings per share	-0,32	-0,50	-2,06

7. Balance sheet

BALANCE SHEET	Q1 2023	Q1 2022	2022
	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	31/Mar/23	31/Mar/22	31/Dec/22
Assets			
Fixed Assets			
- Patents	203	203	203
Intangible Assets	203	203	203
Total non-current assets	203	203	203
Current assets			
- Receivables corporate tax	4.179	3.091	3.143
- Capital increase receivables	0	0	0
- Other receivables	589	138	1.334
- Prepayments	133	12	164
- Cash at bank	16.422	21.204	23.343
Total current assets	21.323	24.445	27.984
Total assets	21.526	24.648	28.187
Equity and liabilities			
Equity			
Share capital	2.758	1.223	2.758
Retained earnings	17.004	22.169	21.098
Total equity	19.762	23.392	23.855
Liabilities			
- Trade payables	945	39	2.738
- Liabilities measured at fair value	345		614
- Other payables	474	1.217	979
Current liabilities	1.764	1.256	4.332
Total liabilities	1.764	1.256	4.332
Total equity and liabilities	21.526	24.648	28.187

8. Statement of changes in equity

STATEMENT OF CHANGE IN EQUITY Q1, 2023	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	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 Q1, 2022	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 January 2022	1.223	0	25.019	26.242
Incentive Warrant Scheme	0	0	194	194
Total comprehensive income for the period	0	0	-3.045	-3.045
At 31 March 2022	1.223	0	22.168	23.392

STATEMENT OF CHANGE IN EQUITY 2022	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
At 31 December 2022	2.758	0	21.098	23.855

9. Cash flow statement

CASH FLOW STATEMENT	Q1 2023	Q1 2022	2022
	01/Jan/23	01/Jan/22	01/Jan/22
Amounts in DKK '000'	31/Mar/23	31/Mar/22	31/Dec/22
Loss before tax	-5.401	-3.811	-17.799
Financial expenses, reversed	-260	76	210
Other non-cash items	272	194	565
Tax credit paid out	0	0	2.324
Change in working capital	-1.522	-1.086	27
Cash flow from operating activities before net financials	-6.911	-4.627	-14.673
Financial expenses paid	-9	-76	-172
Cash flow from operating activities	-6.920	-4.703	-14.845
Purchase of intangible assets	0	0	0
Cash flow from investing activities	0	0	0
Cash capital increase, TO1 + Rights Issue	0	24.325	38.995
Transaction cost, cash capital increase	0	-1.692	-4.082
Cash flow from financing activities	0	22.633	34.913
Total cash flow for the period	-6.920	17.930	20.067
Cash, beginning of the period	23.342	3.275	3.275
Cash, end of the period	16.422	21.205	23.342

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