

Third quarter report Q3-2022

- **Successful outcome of trial 0206, a phase 2 pharmacokinetics trial in children undergoing elective surgical procedures**
- **First patient dosed in pivotal trial 0205 in adult patients**
- **Cash position at the end of Q3 is dkk 15 mill – further extended by successful execution of rights issue after the period raising approximately dkk 14,7 mill before transaction costs**

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 July – 30 September 2022. The third 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, successful outcome of trial 0206 and first patient dosed in pivotal trial 0205 (a randomised double-blind placebo-controlled trial with 220 patients in adult following impacted mandibular third molar extraction).

Third quarter financial results 2022 (1 July - 30 September):

- Net revenue was KDKK 0
- Operating result was KDKK -3.252
- Net result was KDKK -2.627
- Cash at bank end of the period was KDKK 15.001
- Earnings per share* was KDKK -0,43
- Solidity** was 89%

**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 2022 amounted to 6.112.535 shares, the average number of shares during the third quarter was 6.112.535*

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

Highlights during third quarter 2022

- First patient dosed in pivotal trial 0205
- Successful outcome of pharmacokinetic trial 0206 in children
- Finalized the regulatory MDR strategy for the CT001 pump device
- Successful outcome of capital raise from Rights issue (subsequent event October 2022)
- Business development activities to support a future partnership model in Europe
- Continue to optimize the organisation to execute the final development of CT001

“During the third quarter of 2022 we announced the successful outcome of our Phase 2 trial 0206, the pharmacokinetic study with CT001 and very importantly, we initiated our pivotal trial 0205, a randomised double-blind placebo-controlled study with 220 patients with dosing of the first patient. We are now in an exclusive group of selected companies in late stage development, great effort from the team and our partners”, says Jes Trygved, CEO



developing evidence-based treatments -
specifically for children



Third Quarter Report (Q3-2022)

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

CESSATECH - THIRD QUARTER REPORT

(Q3-2022)

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We are very happy with the announcement of the successful outcome of the pharmacokinetic trial 0206 in children – and that we finally have initiated the pivotal trial 0205 with first patient dosed in the third quarter, despite a delay due to the authorities long approval timelines. We can now look ahead again and 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 third quarter report of 2022. 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.

SUMMARY	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	2021
	01/Jul/22	01/Jul/21	01/Jan/22	01/Jan/21	01/Jan/21
Amounts in DKK '000'	30/Sep/22	31/Sep/21	30/Sep/22	30/Sep/21	31/Dec/21
Net Revenue	0	0	0	0	0
Operating result	-3.252	-3.484	-10.967	-9.434	-13.833
Net result	-2.627	-2.876	-8.969	-7.975	-11.569
Cash at Bank	15.001	5.935	15.001	5.935	3.275
Earnings per share *	-0,43	0,78	-1,47	-2,17	-3,09
Solidity (%)**	89%	87%	89%	87%	86%

**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 2022 amounted to 6.112.535 shares, the average number of shares during the third quarter was 6.112.535*

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

Highlights during third quarter 2022

- First patient dosed in pivotal trial 0205
- Successful outcome of pharmacokinetic trial 0206 in children
- Finalized the regulatory MDR strategy for the CT001 pump device
- Successful outcome of capital raise from Rights issue (subsequent event)
- Business development activities to support a future partnership model in Europe
- Continue to optimize the organisation to execute the final development of CT001

2. CEO comments

During the third quarter of 2022 we had strong momentum in our clinical and business development activities, in order to maintain business progress in bringing new options to treat children with pain.

In late 2021 we initiated the **pharmacokinetics trial 0206 in children** aged 1-17 undergoing elective surgical procedures. The primary aim of this trial is to obtain pharmacokinetic data from this age group and to demonstrate that CT001 nasal spray is feasible as premedication in children undergoing anaesthesia. We finalized recruitment in May 2022 and following the analysis we in September announced that primary endpoint was successfully met by obtaining pharmacokinetic data in this age group, showing relevant clinical exposure ranges and secondary objectives of safety, pain assessment, and acceptance of intranasal administration was at an acceptable level – meaning no changes to the profile of CT001.

Additionally during the third quarter, we announced in September that first patient had been dosed in pivotal trial 0205 of lead candidate CT001. **This trial 0205 investigates the postoperative analgesic efficacy of CT001**, in adult participants following impacted mandibular third molar extraction, a randomised, double-blind placebo-controlled trial with 220 patients. This is a pivotal trial, which had undergone much preparation, so we are obviously very pleased that we are now in progress again.



We have finalized the **regulatory MDR strategy** for Cessatech's novel drug-device combination (CT001) for children, based upon completion of risk assessments including a User-Related-Risk-Analysis. Cessatech have successfully executed on plans for readiness towards a notified body submission by building on the first Proof-of-Concept usability test and task analysis and have developed both an Instructions for Use and a Usability and Human Factor Engineering Plan. Next step is initiating a formative usability study and design verification tests following the relevant regulatory requirements for an integral nasal spray drug-device combination.

As we get started on our pivotal trial and are getting closer to a submission process, we have **strengthened our competences within Quality Assurance**. We have previously built our quality management system (QMS) and related documentation around a network of individual consultants, but we have now involved a larger and much more professional external vendor to ensure that we are compliant and following the relevant standards both within drug development, launch readiness, and device management. The new vendor has expertise in all areas of quality assurance relevant for Cessatech and will assist Cessatech in continuing to have a high focus on quality and safety. Additionally, this will bring Cessatech up to the state of the art within risk management.

Our **financial position** is on track in terms of our prioritized activities, ongoing and planned clinical trials. We continue to have focus on progressing our business and ensuring we can attract the needed resources, which also includes a continuous evaluation of our financial resources. Post the third quarter report period, it was decided to conduct a capital raise through an 80% guaranteed Rights issue to finance and ensure the pivotal development of CT001, and the successful outcome of the capital raise will further increase our cash position in 2022 by approximately DKK 14.7 million before costs related to the Offering. I am confident that we will continue the good work and successfully take the company to a higher level.

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 and planned painful procedures in children. The advantages include needle-free administration, being easy to administer, a fast-acting therapeutic effect and being medically approved for children. CT001 is at its pivotal stage of clinical development.

Product portfolio

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.

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 adult patients, 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 Q3-2022 were as expected.

Net revenue amounted to DKK 0 and the operating result was KDKK -3.252 in Q3-2022.

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

BALANCE SHEET AND SOLIDITY

The total equity at 30 September 2022 was KDKK 20.047

The solidity as per 30 September 2022 was 89%

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 2022 was KDKK 15.001

The majority of the cash flow during Q3 2022 is related to clinical activities which will continue as planned through 2022.

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 December 2021 amounted to 6.112.535. There was an increase to the number of shares during the fourth quarter of 2021, related to the exercise of warrant TO 1. Every share equals the same rights to the Company's assets and results.

5. Miscellaneous

Shareholders	Number of shares (Q3)	Votes and capital
Shareholders >5%		
Jes Trygved (CEO)	566.485	9,27%
Steen Winther Henneberg	500.000	8,18%
Bettina Nygaard Nielsen	500.000	8,18%
All other shareholders	4.546.050	74,37%
SUM	6.112.535	100,00%
Board of Directors		
Charlotte Videbæk (C- ApS)	69.462	1,14%
Martin Olin	66.485	1,09%
Adam Steensberg	33.074	0,54%
Peter Birk	10.152	0,17%
Flemming Jensen	-	-
Rachel Curtis Gravesen	-	-

INCENTIVE WARRANTS

In December 2020 it was decided to grant incentive warrants to the CEO and the Board of Directors (in total 316,200 warrants). 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. During the Annual General Meeting 17 March, a prolongation of the authorization to issue warrants until 1 January 2027 was approved. The board allocated warrants to both CEO, Board of Directors and key employees, in total additional 283,200 warrants.

ACCOUNTING POLICY

This unaudited results announcement for Q3 2022 contains condensed financial information for the three months ended 30 September 2022 and should be read in conjunction with the Annual Report 2021, 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 2021. 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: 19 April 2022

Q2 and Half-year Report: 19 August 2022

Q3 Report: 18 November 2022

Q4 and Year-end Report 2022: 3 March 2023

Annual Report release 3 March 2023 - Annual General Meeting: 17 March 2023

ANNUAL GENERAL MEETING AND AVAILABILITY OF THE ANNUAL REPORT

The Annual General Meeting 2021 was held online due to the COVID19 situation on Thursday 17 March 2022 at 8.00 AM. The annual report and the minutes from the annual general meeting is available on Cessatech's website.

Next Annual General Meeting 2022 will take place in March 2023.

SUBMISSION OF Q3 REPORT

The Board of Directors hereby certifies that this Q3 2022 report provides a true and fair view of the Company's business.

Copenhagen 18 November 2022

The Board of Directors

6. Income statement

INCOME STATEMENT			Q1-Q3	Q1-Q3	
	Q3 2022	Q3 2021	2022	2021	2021
	01/Jul/22	01/Jul/21	01/Jan/22	01/Jan/21	01/Jan/21
Amounts in DKK '000'	30/Sep/22	30/Sep/21	30/Sep/22	30/Sep/21	31/Dec/21
Revenue	0	0	0	0	0
Other operating expenses	-2.297	-2.645	-7.015	-6.914	-10.340
Staff expenses	-955	-839	-3.953	-2.520	-3.492
Operating loss before net financials	-3.252	-3.484	-10.967	-9.434	-13.833
Financial costs	-40	-19	-171	-57	-60
Loss before tax	-3.292	-3.503	-11.139	-9.491	-13.893
Tax on loss for the period	666	626	2.170	1.516	2.324
Net loss for the period	-2.627	-2.876	-8.969	-7.975	-11.569
Other comprehensive income for the period	0	0	0	0	0
Total comprehensive income	-2.627	-2.876	-8.969	-7.975	-11.569

7. Balance sheet

BALANCE SHEET	Q3 2022	Q3 2021	2021
Amounts in DKK '000'	30/Sep/22	30/Sep/21	31/Dec/21
Assets			
<i>Fixed Assets</i>			
- Patents	203	203	203
Intangible Assets	203	203	203
Total non-current assets	203	203	203
<i>Current assets</i>			
- Tax receivables	4.493	1.576	2.324
- Capital increase receivables	0	0	24.325
- Other receivables	333	252	495
- Prepayments	17	55	31
- Cash at bank	15.001	5.935	3.275
Total current assets	19.844	7.818	30.450
Total assets	20.047	8.021	30.653
Equity and liabilities			
<i>Equity</i>			
Share capital	1.223	736	1.223
Retained earnings	16.521	6.280	25.019
Total equity	17.744	7.016	26.242
<i>Liabilities</i>			
- Trade payables	1.190	355	3.070
- Other payables	1.113	650	1.341
Current liabilities	2.303	1.005	4.411
Total liabilities	2.303	1.005	4.411
Total equity and liabilities	20.047	8.021	30.653

8. Statement of changes in equity

STATEMENT OF CHANGE IN EQUITY Q3, 2022	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
At 30 September 2022	1.223	0	16.521	17.744

STATEMENT OF CHANGE IN EQUITY Q3, 2021	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 July 2021	736	0	8.836	9.572
Incentive Warrant Scheme	0	0	320	320
Total comprehensive income for the period	0	0	-2.876	-2.876
At 30 September 2021	736	0	6.280	7.016

STATEMENT OF CHANGE IN EQUITY 2021	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 January 2021	736	0	12.875	13.611
Share capital increase	487	23.838	0	24.325
Transfer	0	-23.838	23.838	0
Incentive Warrant Scheme	0	0	1.567	1.567
Expenses in connection with capital increase	0	0	-1.692	-1.692
Total comprehensive income for the period	0	0	-11.569	-11.569
At 31 December 2021	1.223	0	25.019	26.242

9. Cash flow statement

CASH FLOW STATEMENT	Q3 2022	Q3 2021	Q1-Q3 2022	Q1-Q3 2021	2021
	01/Jul/22	01/Jul/21	01/Jan/22	01/Jan/21	01/Jan/21
Amounts in DKK '000'	30/Sep/22	30/Sep/21	30/Sep/22	30/Sep/21	31/Dec/21
Loss before tax	-3.292	-3.503	-11.139	-9.491	-13.893
Financial expenses, reversed	40	19	171	57	60
Other non-cash items	122	320	472	1.380	1.567
Tax credit paid out	0	0	0	0	60
Change in working capital	325	-262	-240	667	2.162
Cash flow from operating activities before net financials	-2.805	-3.426	-10.737	-7.387	-10.044
Financial expenses paid	-40	-19	-171	-57	-60
Cash flow from operating activities	-2.845	-3.445	-10.908	-7.444	-10.104
Purchase of intangible assets	0	-86	0	-127	-127
Cash flow from investing activities	0	-86	0	-127	-127
Cash capital increase, TO1 exercise	0	0	24.325	0	0
Transaction cost, cash capital increase	0	0	-1.692	0	0
Cash flow from financing activities	0	0	22.633	0	0
Total cash flow for the period	-2.845	-3.531	11.726	-7.571	-10.231
Cash, beginning of the period	17.846	9.466	3.275	13.506	13.506
Cash, end of the period	15.001	5.935	15.001	5.935	3.275

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