

## Press Release

24. February 2022

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### Fourth quarter report Q4-2021 - preparing for the pivotal trial

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 October – 31 December 2021. The fourth 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. The company is progressing with planned activities: Recruitment of trial 0206 is progressing (a trial to investigate the pharmacokinetics in children aged 1-17 undergoing elective surgical procedures) and we are currently finalising the preparation for the initiation of our pivotal trial with CT001 (0205). We anticipate the results from trial 0204 in Q1 2022.

#### Fourth quarter 2021 (1 October – 31 December):

- Net revenue was KDKK 0
- Operating result was KDKK -4.399
- Net result was KDKK -3.594
- Cash at bank end of the period was KDKK 3.275
- Earnings per share\* was KDKK -0,92
- Solidity\*\* was 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 31 December 2021 amounted to 6.112.535 shares, the average number of shares during the fourth quarter was 4.080.967. There has been an increase in the number of shares in Q4 related to the exercise of warrant TO 1.*

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

#### Highlights during fourth quarter 2021

- Improved recruitment for trial 0206
- Final statistical analysis of trial 0204, final results should be ready any day
- Successful warrant TO 1 exercise, overall exercise rate of approximately 97 percent
- Announced the issuance of the company’s first US patent covering CT001
- Preparation of US regulatory strategy
- Continue to build the organisation to execute the final development of CT001

***“During the fourth quarter of 2021 we saw improved recruitment in our Phase 2 (0206) pharmacokinetic study with CT001. We had hoped to initiate our pivotal trial (0205), a randomised, double-blind study comparing the analgesic effect of CT001 for treatment of acute pain in adults undergoing surgical removal of an impacted mandibular third molar, by the end of last year. However, formal approval of the trial is still pending from regulatory authorities and we now expect to start this study shortly. CT001 is a unique asset for the company and we look forward to a rich newsflow from the product during the first half of 2022. Like others in our industry we have also been impacted by the COVID 19 pandemic, although we very much anticipate that this will be less of an issue during the coming year. “***  
***says Jes Trygved, CEO***



developing evidence-based treatments -  
specifically for children



  
cessa tech  
rethinking child treatments

## Fourth Quarter Report (Q4-2021)

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

# CESSATECH - FOURTH QUARTER REPORT (Q4-2021)

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We are very happy with the successful warrant exercise and welcome all new and existing shareholders supporting us on our continued journey. We look forward to exciting 2022 and the many planned milestones ahead of us. Despite a few delays, we are still doing all the right things and we are confident that CT001 will make a big difference for the children in the future - there is no standard of care for pain management in paediatrics today but there will soon be....

Thanks for a great effort from all, including our collaboration partners and principal investigators.

**Jes Trygved, CEO**

# 1. Summary

The Board of Directors and CEO of Cessatech hereby publish the fourth quarter report of 2021. 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 - in contrast to many biotech companies - is at its late stage development with the initiation of its pivotal study which significantly will improve its potential revenue generation.

SUMMARY	Q4 2021	Q1-Q4 2021	Q4 2020	Q1-Q4 2020
	01/Oct/21	01/Jan/21	01/Oct/20	01/Jan/20
Amounts in DKK '000'	31/Dec/21	31/Dec/21	31/Dec/20	31/Dec/20
Net Revenue	-	-	-	-
Operating result	-4.399	-13.833	-722	-901
Net result	-3.594	-11.569	-667	-849
Cash at Bank	3.275	3.275	13.506	13.506
Earnings per share *	-0,92	-3,09	-0,61	-0,55
Solidity (%)**	86%	86%	99%	99%

*\*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 December 2021 amounted to 6.112.535 shares, the average number of shares during the fourth quarter was 4.080.967. There has been an increase in the number of shares in Q4 related to the execution of warrant TO 1.*

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

We are still making great progress, basically with only 1-2 months delay which will not have any overall impact on final timelines. Overall we are following our activities as planned and this is also reflected in the expenses for the fourth quarter. The exercise of warrant TO 1 is not reflected in the numbers above, but has increased Cash at bank with approx. DKK 24.3 million in 2022. This will be sufficient for 2022 and part of 2023 as planned. The year 2022 will focus more on business development and geographical scoping, apart from the clinical development program.

**Jes Trygved, CEO**

## 2. CEO comments

During the fourth quarter of 2021 we focused on our clinical activities and preparations for discussions with US regulatory authorities. As a small biotech, despite being agile and having a high degree of flexibility we are also highly networked and dependent on suppliers and outside sources, which sometimes impacts our internal timelines. We were therefore not able to report final results from our bioavailability clinical trial (0204) or initiate the 0205 pivotal study with CT001, as previously communicated. We are doing our utmost to deliver on these very important activities as quickly as possible and are confident in our overall long term timelines and the potential of CT001.

We were pleased to have completed the validation and analyses of our **0204 clinical trial in 12 healthy volunteers** investigating the absolute bioavailability of CT001. The primary aim of this trial is to demonstrate drug-exposure following nasal administration of CT001 relative to the intravenous (IV) injection of the approved analgesic drugs. The finalisation of the entire trial analyses was somewhat delayed mainly due to workload pressure at the biolab and the COVID 19 impact at the laboratory in Austria. We are now carrying out statistical analysis and look forward to reporting the final results.



In August we initiated the **pharmacokinetics trial 0206 in children** aged 1-17 undergoing elective surgical procedures. 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 aim to finalise recruitment by Q1 2022, followed by an analysis which we will report on during the first half of 2022. During the initial stages of this trial we were impacted by challenges due to COVID 19 but have subsequently seen good progress.

In addition, we are still waiting for final regulatory approval from the authorities to be able to initiate our pivotal **trial 0205. This trial 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. We had anticipated initiating the study by end 2021 pending the regulatory approval, but this is still pending. We hope to initiate this trial within Q1.

In early November (Q4), we announced that the United States Patent and Trademark Office (USPTO) had issued U.S. patent number 11.160.799 to the Company, which is directed to a storage stable pre-filled and ready to use nasal spray device comprising sufentanil and ketamine and a method of treating or preventing pain in a child by use of said device. This is the **first US patent covering CT001**. During Q4 we prepared for regulatory meetings focusing on a pathway for a US development program. We look forward to communicating additional information on our US development and regulatory strategy during first quarter of 2022

Like others in our industry, Cessatech has to some extent been negatively impacted by the effects of COVID-19 during Q4 2021, mainly related to study 0204 and study 0206, but we anticipate that it will have a minor impact or delay for the year 2022 and there will be no material impact on timelines, particularly as only trial 0206 is currently running in a hospital setting.

#### Highlights during Q4-2021

- Improved recruitment for trial 0206
- Final statistical analysis of trial 0204, final results should be ready any day
- Successful warrant TO 1 exercise, overall exercise rate of approximately 97 percent
- Announced the issuance of the company's first US patent covering CT001
- Preparation of US regulatory strategy
- Continue to build the organisation to execute the final development of CT001

Our **financial position** is tracking according to plan, and the increase in costs follows the increased activity levels when clinical trials are initiated. This will continue throughout the coming quarters. The outstanding warrants TO 1 were successfully exercised at the end of Q4 2021, with a success rate of approximately 97%; sufficient to continue the planned activities.

#### 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](http://www.cessatech.com)

## 4. Financial development

### OPERATING INCOME AND OPERATING RESULTS

The operating income and result for Q4-2021 were as expected.

Net revenue amounted to DKK 0 and the operating result was KDKK -4,399 in Q4-2021. The operating result was as expected as the Company is currently conducting development activities.

### BALANCE SHEET AND SOLIDITY

The total equity at 31 December 2021 was KDKK 26.242

The solidity as per 31 December 2021 was 86%

### CASH FLOW AND INVESTMENTS

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

Cash at the end of December 2021 was KDKK 3.275. This does not include cash proceeds from the exercise of warrants TO 1 at the end of 2021, which were executed during December 2021, but the proceeds were received early 2022 in total DKK 24.325 million. The majority of the cash flow during Q4 2021 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.

### WARRANTS

The warrants of series TO 1 in Cessatech were listed at Spotlight Stock Market on 16 December 2020. The ticker was CESSA TO1 and the ISIN code is DK0061416849. In total, there were 2.520.000 outstanding warrants. One [1] warrant entitles the holder the right to subscribe for one [1] new share in Cessatech at a subscription price of DKK 10,00 per share during the exercise period 25 November 2021 until 16 December 2021. A total of 2,432,535 warrants were exercised, corresponding to 2,432,535 shares and an overall exercise rate of approximately 97 percent. Cessatech received DKK 24.325 million before deduction of transaction related costs of DKK 1.692 million, corresponding to 6.96 percent of the issue volume in the Company's exercise of warrants.



## 5. Miscellaneous

Shareholders	Number of shares	Votes and capital
<b>Shareholders &gt;5%</b>		
Jes Trygved (CEO)	566.485	9,27%
Buhl Krone Holding ApS	546.540	8,94%
Steen Winther Henneberg	500.000	8,18%
Bettina Nygaard Nielsen	500.000	8,18%
All other shareholders	3.999.510	65,43%
<b>SUM</b>	<b>6.112.535</b>	<b>100,00%</b>

<b>Board of Directors</b>		
Ulla Buhl (Buhl Krone Holding ApS)*	546.540	8,94%
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	-	-

\* Ulla Buhl resigned from the Board of Directors on 6 January 2022. Rachel Curtis Gravesen replaced her as Observer.

### INCENTIVE WARRANTS

On 14 December 2020 it was decided to grant 248.000 warrants to the CEO, 24.800 warrants to the Chairman of the Board of Directors and 12.400 warrants to ordinary members of the Board of Directors (five persons). Thus, in total 334.800 warrants are granted under the warrant program. The background for the implementation of the warrant program is to create possibilities for Cessatech to retain and incentivize the Board of Directors and the CEO 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. See more details from the press release on [www.cessatech.com](http://www.cessatech.com)

## **ACCOUNTING POLICY**

This unaudited results announcement for Q4 2021 contains condensed financial information for the twelve months ended 31 December 2021 and 2020 full year (audited), and should be read in conjunction with the Annual Report 2020, 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 2020. This fourth 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 at [www.cessatech.com](http://www.cessatech.com)

## **FINANCIAL CALENDAR**

Annual Report release 3 March 2022 - Annual General Meeting: 17 March 2022

Q1 Report: 19 April 2022

Q2 and Half-year Report: 19 August 2022

Q3 Report: 18 November 2022

Q4 and Year-end Report 2022: 2 March 2023

## **AUDITOR'S REVIEW**

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

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

The Annual General Meeting 2020 was held online due to the COVID19 situation on Friday 26 March 2021 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 2021 will take place on 17 March 2022.

## **SUBMISSION OF Q4 REPORT**

The Board of Directors hereby certifies that this Q4 report provides a true and fair view of the Company's business.

Copenhagen 24 February 2022

The Board of Directors

## 6. Income statement

<b>INCOME STATEMENT</b>	<b>Q4 2021</b>	<b>Q1-Q4 2021</b>	<b>Q4 2020</b>	<b>Q1-Q4 2020</b>
	01/Oct/21	01/Jan/21	01/Oct/20	06/Apr/20
Amounts in DKK '000'	31/Dec/21	31/Dec/21	31/Dec/20	31/Dec/20
Revenue	-	-	-	-
Other operating expenses	-3.426	-10.340	-433	-612
Staff expenses	-972	-3.492	-289	-289
<b>Operating loss before net financials</b>	<b>-4.399</b>	<b>-13.833</b>	<b>-722</b>	<b>-901</b>
Financial costs	-3	-60	-6	-8
<b>Loss before tax</b>	<b>-4.402</b>	<b>-13.893</b>	<b>-727</b>	<b>-909</b>
Tax on loss for the period	808	2.324	60	60
<b>Net loss for the period</b>	<b>-3.594</b>	<b>-11.569</b>	<b>-667</b>	<b>-849</b>
Other comprehensive income for the period, net of tax	-	-	-	-
<b>Total comprehensive income</b>	<b>-3.594</b>	<b>-11.569</b>	<b>-667</b>	<b>-849</b>

## 7. Balance sheet

<b>BALANCE SHEET</b>	<b>2021</b>	<b>2020</b>
Amounts in DKK '000'	31/Dec/2021	31/Dec/20
<b>Assets</b>		
<i><b>Fixed Assets</b></i>		
- Patents	203	76
<b>Intangible Assets</b>	<b>203</b>	<b>76</b>
<b>Total non-current financial assets (tax credit)</b>	<b>-</b>	<b>-</b>
Current assets		
- Tax receivables	2.324	60
- Capital increase receivables	24.325	-
- Other receivables	495	89
- Prepayments	31	77
- Cash at bank	3.275	13.506
<b>Total current assets</b>	<b>30.450</b>	<b>13.732</b>
<b>Total assets</b>	<b>30.653</b>	<b>13.808</b>
<b>Equity and liabilities</b>		
<i><b>Equity</b></i>		
Share capital	1.223	736
Retained earnings	25.019	12.875
<b>Total equity</b>	<b>26.242</b>	<b>13.611</b>
<i><b>Liabilities</b></i>		
Total long term liabilities		
- Trade payables	3.070	108
- Other payables	1.341	89
<b>Total current liabilities</b>	<b>4.411</b>	<b>197</b>
<b>Total liabilities</b>	<b>4.411</b>	<b>197</b>
<b>Total equity and liabilities</b>	<b>30.653</b>	<b>13.808</b>

## 8. Statement of changes in equity

<b>CHANGE IN EQUITY Q4, 2021</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 30 September 2021	736	-	6.280	7.016
Capital increase	487	23.838	-	24.325
Transfer		-23.838	23.838	-
Expenses in connection with capital increase			-1.692	-1.692
Incentive Warrant Scheme			187	187
Total comprehensive income for the period	-	-	-3.594	-3.594
<b>At 31 December 2021</b>	<b>1.223</b>	<b>-</b>	<b>25.019</b>	<b>26.242</b>

  

<b>CHANGE IN EQUITY Q4, 2020</b>	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 30 September 2020	400	-	-142	258
Capital increase, IPO	336	15.456	-	15.792
Transfer		-15.456	15.456	-
Expenses in connection with capital increase			-1.918	-1.918
Total comprehensive income for the period	-	-	-521	-521
<b>At 31 December 2020</b>	<b>736</b>	<b>-</b>	<b>12.875</b>	<b>13.611</b>

**CHANGE IN EQUITY 2021**

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

**CHANGE IN EQUITY 2020**

Amounts in DKK '000'	Share- Capital	Share Premium	Retained earnings	Shareholders equity
Formation of Company at 6 April 2020	40	-	-	40
Share capital increase	360	40	-	400
Conversion to A/S	-	-40	40	-
Capital increase, IPO	336	15.456	-	15.792
Transfer	-	-15.456	15.456	-
Incentive Warrant Scheme	-	-	146	146
Expenses in connection with capital increase	-	-	-1.918	-1.918
Total comprehensive income for the period	-	-	-849	-849
<b>At 31 December 2020</b>	<b>736</b>	<b>-</b>	<b>12.875</b>	<b>13.611</b>



## 9. Cash flow statement

<b>CASH FLOW STATEMENT</b>	<b>Q4 2021</b>	<b>Q4 2020</b>	<b>2021</b>	<b>2020</b>
	01/Oct/21	06/Apr/20	01/Jan/21	06/Apr/20
Amounts in DKK '000'	31/Dec/21	31/Dec/20	31/Dec/21	31/Dec/20
<b>Loss before tax</b>	-4.402	-727	-13.893	-909
Financial expenses, reversed	3	6	60	8
Other non-cash items	187	146	1.567	146
Tax credit paid out	60	-	60	-
Change in working capital	-21.138	-120	-20.471	31
<b>Cash flow from operating activities before net financials</b>	<b>-25.290</b>	<b>-695</b>	<b>-32.677</b>	<b>-724</b>
Financial expenses paid	-3	-6	-60	-8
<b>Cash flow from operating activities</b>	<b>-25.293</b>	<b>-701</b>	<b>-32.737</b>	<b>-732</b>
Purchase of intangible assets	-	-76	-127	-76
<b>Cash flow from investing activities</b>	<b>0</b>	<b>-76</b>	<b>-127</b>	<b>-76</b>
Capital per ApS - A/S formation	-	-	-	440
Cash capital increase, IPO	-	15.792	-	15.792
Cash capital increase	24.325	-	24.325	-
Transaction cost, cash capital increase	-1.692	-1.918	-1.692	-1.918
<b>Cash flow from financing activities</b>	<b>22.633</b>	<b>13.874</b>	<b>22.633</b>	<b>14.314</b>
Total cash flow for the period	-2.661	13.097	-10.231	13.506
Cash, beginning of the period	5.936	409	13.506	-
<b>Cash, end of the period</b>	<b>3.275</b>	<b>13.506</b>	<b>3.275</b>	<b>13.506</b>

[www.cessatech.com](http://www.cessatech.com)

