

## Press Release

19 April 2022

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### First quarter report Q1-2022 - preparing for the pivotal trial

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 January – 31 March 2022. The first 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 nearly complete (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 trial 0205 to start recruitment during Q2 2022.

#### First quarter 2021 (1 January - 31 March):

- Net revenue was KDKK 0
- Operating result was KDKK -3.736
- Net result was KDKK -3.045
- Cash at bank end of the period was KDKK 21.204
- Earnings per share\* was KDKK -0,50
- Solidity\*\* was 95%

*\*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 2022 amounted to 6.112.535 shares, the average number of shares during the first quarter was 6.112.353. There has been an increase in the number of shares in Q4 2021 related to the exercise of warrant TO 1.*

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

#### Highlights during first quarter 2022

- Successful topline results of clinical trial 0204 investigating the absolute bioavailability of CT001 showed clinical relevant exposures following nasal administration
- Very good progress with trial 0206 (pharmacokinetic trial in children)
- Annual General Meeting, including the appointment of Rachel Curtis Gravesen to the Board of Directors
- Continue to build the organisation to execute the final development of CT001

***“During the first quarter of 2022 we have nearly finalised the recruitment in our Phase 2 (0206) pharmacokinetic study with CT001, and importantly we announced Topline results of clinical trial 0204 investigating the absolute bioavailability of CT001 showed clinical relevant exposures following nasal administration. We are still pending formal approval of trial 0205 from regulatory authorities and we expect to start this study during Q2. We have been off to a good start of 2022 and anticipate a very exciting year for the Company.” says Jes Trygved, CEO***



developing evidence-based treatments -  
specifically for children



## First Quarter Report (Q1-2022)

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

# CESSATECH - FIRST QUARTER REPORT (Q1-2022)

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We are very happy with the topline results of clinical trial 0204, investigating the absolute bioavailability of CT001, showed clinical relevant exposures following nasal administration. Primary aim of the trial was to investigate drug-exposure following nasal administration of CT001 relative to the IV injection of the approved drug counterparts

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

**Jes Trygved, CEO**

# 1. Summary

The Board of Directors and CEO of Cessatech hereby publish the first 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 significantly will improve its potential revenue generation.

SUMMARY	Q1 2022	Q1 2021	2021
	01/Jan/22	01/Jan/21	01/Jan/21
Amounts in DKK '000'	31/Mar/22	31/Mar/21	31/Dec/21
Net Revenue	0	0	0
Operating result	-3.736	-2.863	-13.833
Net result	-3.045	-2.458	-11.569
Cash at Bank	21.204	11.148	3.275
Earnings per share *	-0,50	-0,67	-3,09
Solidity (%)**	95%	98%	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 March 2021 amounted to 6.112.535 shares, the average number of shares during the first quarter was 6.112.535  
There has been an increase in the number of shares in Q4 2021 related to the execution of warrant TO 1.*

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

We are still making great progress, we are on track with most of our activities and this is following our financial planning. We are a few months behind with the initiation of 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. 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 first quarter of 2022 we focused on our clinical activities and early business development activities, we kept the momentum and are confident that 2022 will be a fantastic year for Cessatech.

We were pleased to have reported the **successful outcome of bioavailability trial 0204 with CT001**. In this randomised, three-treatment, three-period, single dose crossover trial 15 healthy subjects were allocated to treatment with CT001, IV ketamine, and IV sufentanil at three different dosing visits. Approximately 40% of sufentanil and 50% of ketamine was absorbed into the systemic circulation when administered via the nasal spray as compared to intravenous infusions in the subjects, meeting the objective of the trial. The reported side effects were of mild severity and CT001 was assessed to be safe and well tolerated in the trial. The most common side effects reported for CT001 was headache.



In late 2021 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 within a few months, 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, and are only missing a few patients.

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 Q2.

The annual report was approved during **Annual General Meeting** 17 March 2022, in addition we are very pleased that Rachel Curtis Gravesen (former head of IR communications at Genmab for more than 8 years) was elected to the board of directors, and Martin Olin appointed vice chairman.

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.

### **Highlights during Q1-2022**

- Successful topline results of clinical trial 0204, investigating the absolute bioavailability of CT001, showed clinical relevant exposures following nasal administration
- Very good progress with trial 0206 (pharmacokinetic trial in children)
- Annual General Meeting, including the appointment of Rachel Curtis Gravesen to the Board of Directors
- Continue to build the organisation to execute the final development of CT001

### **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 Q1-2022 were as expected.

Net revenue amounted to DKK 0 and the operating result was KDKK -3.736 in Q1-2022. The operating result was as expected as the Company is currently conducting development activities.

### BALANCE SHEET AND SOLIDITY

The total equity at 31 March 2022 was KDKK 24.648

The solidity as per 31 March 2022 was 95%

### CASH FLOW AND INVESTMENTS

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

Cash at the end of March 2022 was KDKK 21.204. 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 Q1 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.

### 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%
Steen Winther Henneberg	500.000	8,18%
Bettina Nygaard Nielsen	500.000	8,18%
All other shareholders	4.546.050	74,37%
<b>SUM</b>	<b>6.112.535</b>	<b>100,00%</b>

<b>Board of Directors</b>		
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 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. However, clause 3.1.2 was not correctly updated as it still states "however in no event more than 368,000 warrants", this implies that the allocation is not possible. Most likely there will be a need to call for an extraordinary general meeting to remove the maximum number of warrants to make the Incentive Warrants allocated effective.

## **ACCOUNTING POLICY**

This unaudited results announcement for Q1 2022 contains condensed financial information for the three months ended 31 March 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 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 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 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 Q1 REPORT**

The Board of Directors hereby certifies that this Q1 2022 report provides a true and fair view of the Company's business.

Copenhagen 19 April 2022

The Board of Directors

## 6. Income statement

<b>INCOME STATEMENT</b>	<b>Q1 2022</b>	<b>Q1 2021</b>	<b>2021</b>
	01/Jan/22	01/Jan/21	01/Jan/21
Amounts in DKK '000'	31/Mar/22	31/Mar/21	31/Dec/21
Revenue	0	0	0
Other operating expenses	-2.205	-2.030	-10.340
Staff expenses	-1.531	-834	-3.492
<b>Operating loss before net financials</b>	<b>-3.736</b>	<b>-2.863</b>	<b>-13.833</b>
Financial costs	-76	-20	-60
<b>Loss before tax</b>	<b>-3.811</b>	<b>-2.883</b>	<b>-13.893</b>
Tax on loss for the period	767	425	2.324
<b>Net loss for the period</b>	<b>-3.045</b>	<b>-2.458</b>	<b>-11.569</b>
Other comprehensive income for the period, net of tax	0	0	0
<b>Total comprehensive income</b>	<b>-3.045</b>	<b>-2.458</b>	<b>-11.569</b>

## 7. Balance sheet

<b>BALANCE SHEET</b>	<b>Q1 2022</b>	<b>Q1 2021</b>	<b>2021</b>
Amounts in DKK '000'	31/Mar/22	31/Mar/21	31/Dec/21
<b>Assets</b>			
<i><b>Fixed Assets</b></i>			
- Patents	203	76	203
<b>Intangible Assets</b>	<b>203</b>	<b>76</b>	<b>203</b>
<b>Total non-current assets</b>	<b>203</b>	<b>76</b>	<b>203</b>
Current assets			
- Tax receivables	3.091	485	2.324
- Capital increase receivables	0	0	24.325
- Other receivables	138	234	495
- Prepayments	12	93	31
- Cash at bank	21.204	11.148	3.275
<b>Total current assets</b>	<b>24.445</b>	<b>11.961</b>	<b>30.450</b>
<b>Total assets</b>	<b>24.648</b>	<b>12.037</b>	<b>30.653</b>
<b>Equity and liabilities</b>			
<i><b>Equity</b></i>			
Share capital	1.223	736	1.223
Retained earnings	22.169	11.055	25.019
<b>Total equity</b>	<b>23.392</b>	<b>11.791</b>	<b>26.242</b>
<i><b>Liabilities</b></i>			
- Trade payables	39	99	3.070
- Other payables	1.217	147	1.341
<b>Current liabilities</b>	<b>1.256</b>	<b>246</b>	<b>4.411</b>
<b>Total liabilities</b>	<b>1.256</b>	<b>246</b>	<b>4.411</b>
<b>Total equity and liabilities</b>	<b>24.648</b>	<b>12.037</b>	<b>30.653</b>

## 8. Statement of changes in equity

### STATEMENT OF CHANGE IN EQUITY

#### Q1, 2022

Amounts in DKK '000'	Share-Capital	Share Premium	Retained earnings	Shareholders 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
<b>At 31 March 2022</b>	<b>1.223</b>	<b>0</b>	<b>22.169</b>	<b>23.392</b>

### STATEMENT OF CHANGE IN EQUITY

#### Q1, 2021

Amounts in DKK '000'	Share-Capital	Share Premium	Retained earnings	Shareholders equity
At 1 January 2021	736	0	12.875	13.611
Incentive Warrant Scheme	0	0	638	638
Total comprehensive income for the period	0	0	-2.458	-2.458
<b>At 31 March 2021</b>	<b>736</b>	<b>0</b>	<b>11.055</b>	<b>11.791</b>

### STATEMENT OF CHANGE IN EQUITY

#### 2021

Amounts in DKK '000'	Share-Capital	Share Premium	Retained earnings	Shareholders 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
<b>At 31 December 2021</b>	<b>1.223</b>	<b>0</b>	<b>25.019</b>	<b>26.242</b>

## 9. Cash flow statement

<b>CASH FLOW STATEMENT</b>	<b>Q1 2022</b>	<b>Q1 2021</b>	<b>2021</b>
	01/Jan/22	01/Jan/21	01/Jan/21
Amounts in DKK '000'	31/Mar/22	31/Mar/21	31/Dec/21
<b>Loss before tax</b>	-3.811	-2.883	-13.893
Financial expenses, reversed	76	20	60
Other non-cash items	194	638	1.567
Tax credit paid out	0	0	60
Change in working capital	-1.086	-112	2.162
<b>Cash flow from operating activities before net financials</b>	<b>-4.627</b>	<b>-2.337</b>	<b>-10.044</b>
Financial expenses paid	-76	-20	-60
<b>Cash flow from operating activities</b>	<b>-4.703</b>	<b>-2.358</b>	<b>-10.104</b>
Purchase of intangible assets	0	0	-127
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>-127</b>
Cash capital increase, TO1 exercise	24.325	0	0
Transaction cost, cash capital increase	-1.692	0	0
<b>Cash flow from financing activities</b>	<b>22.633</b>	<b>0</b>	<b>0</b>
Total cash flow for the period	17.930	-2.358	-10.231
Cash, beginning of the period	3.275	13.506	13.506
<b>Cash, end of the period</b>	<b>21.205</b>	<b>11.148</b>	<b>3.275</b>



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