

Press Release

19. November 2021

Third quarter report Q3-2021 - focusing on next trial (0205)

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 July – 30 September 2021. 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 on track with planned activities, has initiated recruitment of trial 0206 - a trial to investigate the pharmacokinetics in children aged 1-17 undergoing elective surgical procedures, and getting ready for trial 0205.

Third quarter 2021 (1 July – 30 September):

- Net revenue was KDKK 0
- Operating result was KDKK -3.484
- Net result was KDKK -2.876
- Cash at bank end of the period was KDKK 5.935
- Earnings per share* was KDKK -0,78
- Solidity** was 87%

**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 2021 amounted to 3.680.000 shares, the average number of shares during the third quarter was 3.680.000. There have been no increases in the number of shares since the completion of the IPO in December 2020.*

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

Highlights during third quarter 2021

- Ongoing analysis of trial 0204, final results expected end of the year
- Initiated (first patient enrolled) and ongoing recruitment for trial 0206
- Submitted protocol for authorities approval for trial 0205
- Cessatech announced the issuance of its first US patent covering CT001 (2 Nov 2021)
- Finalisation of GMP clinical manufacturing batch production of CT001 for trial 0205
- Continue to build the organization to lead the development of CT001

“The third quarter of 2021 has focused much on getting trial 0205 ready for recruitment - trial 0205 is 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. We hope to receive regulatory approval from authorities by the end 2021 so we can initiate recruitment. The outlook is really encouraging for the Company especially also with the first US patent issuance for CT001” says Jes Trygved, CEO



developing evidence-based treatments -
specifically for children




cessa tech
rethinking child treatments

Third Quarter Report (Q3-2021)

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

CESSATECH - THIRD QUARTER REPORT (Q3-2021)

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Coordinating and executing three (3) clinical trials in parallel has been a major effort, especially with **trial 0205** being a randomised, double-blind, parallel-group, study in 220 patients. The Company announced the issuance of its **first US patent** covering CT001 which will be instrumental in our potential US activities going forward. The year 2021 is really about execution of our development plan for CT001, thanks for a great effort from all, including our collaboration partners and principal investigators. We are doing all the right things...

Jes Trygved, CEO

1. Summary

The Board of Directors and CEO of Cessatech hereby publish the third 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 - has a relatively short time from initiation of product development to potential revenue generation.

SUMMARY	Q3 2021	Q1-Q3 2021	Q2 2021	2020
	01/Jul/21	01/Jan/21	01/Apr/21	06/Apr/20
Amounts in DKK '000'	30/Sep/21	30/Sep/21	30/Jun/21	31/Dec/20
Net Revenue	-	-	-	-
Operating result	-3.484	-9.434	-3.088	-901
Net result	-2.876	-7.975	-2.641	-849
Cash at Bank	5.935	5.935	9.465	13.506
Earnings per share *	-0,78	-2,17	-0,72	-0,55
Solidity (%)**	87%	87%	88%	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 30 September 2021 amounted to 3.680.000 shares, the average number of shares during the third quarter was 3.680.000. There have been no increases in the number of shares since the completion of the IPO in December 2020.*

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

It is great to see nearly all clinical trials in progress, and the team and partners are performing really well. Overall we are following our activities as planned and this is also reflected in the expenses for third quarter. The upcoming Warrants which can be exercised during the period 25 November 2021 until 16 December 2021 could provide the Company with a total of approx. DKK 25,2 million of cash (before issuing costs) if all warrants are exercised - the warrant is currently 'in the money' - and will be sufficient to continue the planned activities.

Jes Trygved, CEO

2. CEO comments

The third quarter of 2021 has been focusing on the clinical activities, in particular trial 0205 - a randomised, double-blind study comparing the analgesic effect of CT001 for treatment of acute pain in adults. We are really happy with the progress we have made on all clinical and manufacturing activities, including a very important IP milestone for our US potential.

We are finalizing the validation and analysis of the **bioavailability clinical trial 0204** in 12 healthy volunteers investigating the absolute bioavailability of CT001. 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. We expect the results of the analysis to be ready by the end of the year.

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 finalize recruitment by Q1 2022 (originally end 2021), followed by an analysis which we will report on during the first half of 2022.



In addition, we are waiting for final regulatory approval from the authorities to be able to initiate **trial 0205, investigating the postoperative analgesic efficacy of CT001**, in adult participants following impacted mandibular third molar extraction, a randomized, double-blind placebo controlled trial with 220 patients. We anticipate initiating the study by end 2021 pending the regulatory approval. No Safety Data Committee will be needed as originally considered.

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** and the patent is a milestone in the development activities and will be an important element in the activities going forward. More related to our US development and regulatory strategy will be communicated during first quarter of 2022

We have **finalized the GMP manufacturing process** for CT001; the final formulation, validation and stability setup for trial 0205 has been a substantial task which has been completed successfully together with our manufacturing partner. The final specifications were set based on process development results, considering current pharmacopoeial requirements for sterile products and relevant guidelines.

Cessatech has not been negatively impacted by the effects of COVID-19 to date, but with the increasing COVID cases and the challenging nurse situation in Denmark, we anticipate that it will have a minor impact and delay, though mainly on trial 0206 as this is the only trial running in a hospital setting currently. We have hence added an extra quarter to finalize the recruitment. It will hopefully not impact our overall timelines in any material way.

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 which can be exercised during the period 25 November 2021 until 16 December 2021 can provide the Company with a total of approx. DKK 25,2 million of cash (before issuing costs) if all warrants are exercised - the warrant is currently 'in the money'. This will be 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 expected to enter late stage clinical development in 2021.

Highlights during Q3-2021

- Ongoing analysis of trial 0204, final results expected end of the year
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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 characterized 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 Q3-2021 were as expected.

Net revenue amounted to DKK 0 and the operating result was KDKK -3,484 in Q3-2021. The operating result was as expected as the Company is currently conducting development activities.

BALANCE SHEET AND SOLIDITY

The total equity at 30 September 2021 was KDKK 7.016

The solidity as per 30 September 2021 was 87%

CASH FLOW AND INVESTMENTS

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

Cash at the bank at the end of September 2021 was KDKK 5.935. The majority of the cash flow is related to clinical activities which will continue as planned through 2021.

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 30 September 2021 amounted to 3.680.000. There was an increase to the number of shares during the fourth quarter of 2020, related to the IPO. 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 is CESSA TO1 and the ISIN code is DK0061416849. In total, there are 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. The warrants can provide the Company with a total of approx DKK 25,2 million (before issuing costs) if all warrants are exercised.

5. Miscellaneous

Shareholders	Number of shares	Votes and capital
Shareholders >5%		
Jes Trygved (CEO)	526.594	14,31%
Buhl Krone Holding ApS	526.594	14,31%
Steen Winther Henneberg	500.000	13,59%
Bettina Nygaard Nielsen	500.000	13,59%
All other shareholders	1.626.812	44,21%
SUM	3.680.000	100,00%
Board of Directors		
Ulla Buhl (Buhl Krone Holding ApS)	526.594	14,31%
Martin Olin	26.594	0,72%
Charlotte Videbæk (C- ApS)	26.594	0,72%
Adam Steensberg	5.152	0,14%
Peter Birk	5.152	0,14%
Flemming Jensen	-	-

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

ACCOUNTING POLICY

This unaudited results announcement for Q3 2021 contains condensed financial information for the nine months ended 30 September 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 from 31 December 2020. 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 at www.cessatech.com

AUDITOR'S REVIEW

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

FINANCIAL CALENDAR

Annual Report release 12 March 2021 - Annual General Meeting: 26 March 2021

Q1 Report: 19 April 2021

Q2 and Half-year Report: 19 August 2021

Q3 Report: 19 November 2021

Q4 and Year-end Report 2021: 24 February 2022

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

ANNUAL GENERAL MEETING AND AVAILABILITY OF THE ANNUAL REPORT

The Annual General Meeting 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 will take place on 17 March 2022.

SUBMISSION OF Q3 REPORT

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

Copenhagen 19 November 2021

The Board of Directors

6. Income statement

INCOME STATEMENT	Q1-Q3			
	Q3 2021	2021	Q2 2021	2020
	01/Jul/21	01/Jan/21	01/Apr/21	06/Apr/20
Amounts in DKK '000'	30/Sep/21	30/Sep/21	30/Jun/21	31/Dec/20
Revenue	-	-	-	-
Other operating expenses	-2.645	-6.914	-2.241	-612
Staff expenses	-839	-2.520	-847	-289
Operating loss before net financials	-3.484	-9.434	-3.088	-901
Financial costs	-19	-57	-17	-8
Loss before tax	-3.503	-9.491	-3.105	-909
Tax on loss for the period	626	1516	464	60
Net loss for the period	-2.876	-7.975	-2.641	-849
Other comprehensive income for the period, net of tax	-	-	-	-
Total comprehensive income	-2.876	-7.975	-2.641	-849

7. Balance sheet

BALANCE SHEET	Q3 2021	Q2 2021	2020
Amounts in DKK '000'	30/Sep/21	30/Jun/21	31/Dec/20
Assets			
Fixed Assets			
- Patents	203	117	76
Intangible Assets	203	117	76
Total non-current financial assets (tax credit)	1.516	890	-
Current assets			
- Tax receivables	60	60	60
- Other receivables	252	304	89
- Prepayments	55	100	77
- Cash at bank	5.935	9.465	13.506
Total current assets	6.302	9.929	13.732
Total assets	8.021	10.936	13.808
Equity and liabilities			
Equity			
Share capital	736	736	736
Retained earnings	6.280	8.836	12.875
Total equity	7.016	9.572	13.611
Liabilities			
Total long term liabilities			
- Trade payables	354	363	108
- Other payables	650	1.001	89
Total current liabilities	1.004	1.364	197
Total liabilities	1.004	1.364	197
Total equity and liabilities	8.021	10.936	13.808

8. Statement of changes in equity

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

CHANGE IN EQUITY Q1-Q3, 2021	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 January 2021	736	-	12.875	13.611
Incentive Warrant Scheme	-	-	1.380	1.380
Total comprehensive income for the period	-	-	-7.975	-7.975
At 30 September 2021	736	-	6.280	7.016

CHANGE IN EQUITY Q2, 2021	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 31 March 2021	736	-	11.055	11.791
Incentive Warrant Scheme	-	-	421	421
Total comprehensive income for the period	-	-	-2.641	-2.641
At 30 June 2021	736	-	8.836	9.572

9. Cash flow statement

CASH FLOW STATEMENT	Q1-Q3			
	Q3 2021	2021	Q2 2021	2020
	01/Jul/21 30/Sep/21	01/Jan/21 30/Sep/21	01/Apr/21 30/Jun/21	06/Apr/20 31/Dec/20
Amounts in DKK '000'				
Loss before tax	-3.503	-9.491	-3.105	-909
Financial expenses, reversed	19	57	17	8
Other non-cash items	320	1.380	421	146
Change in working capital	-262	667	1.042	31
Cash flow from operating activities before net financials	-3.426	-7.387	-1.625	-724
Financial expenses paid	-19	-57	-17	-8
Cash flow from operating activities	-3.445	-7.444	-1.642	-732
Purchase of intangible assets	-86	-127	-41	-76
Cash flow from investing activities	-86	-127	-41	-76
Capital per ApS - A/S formation	-	-	-	440
Cash capital increase, IPO	-	-	-	15.792
Transaction cost, cash capital increase	-	-	-	-1.918
Cash flow from financing activities	-	-	-	14.314
Total cash flow for the period	-3.530	-7.571	-1.683	13.506
Cash, beginning of the period	9.465	13.506	11.148	-
Cash, end of the period	5.935	5.935	9.465	13.506

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