

Second quarter report Q2-2022 – green light for the pivotal trial 0205

Cessatech A/S (“Cessatech” or the “Company”) today releases its results for the period 1 April – 30 June 2022. The second 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 with planned activities: Recruitment of trial 0206 was completed (a trial to investigate the pharmacokinetics in children aged 1-17 undergoing elective surgical procedures) and finally regulatory approval was received and thereby a green light to initiate recruitment of the pivotal trial 0205 with CT001, a randomised double-blind placebo controlled trial with 220 patients in adult following impacted mandibular third molar extraction. First patient is expected during Q3 2022.

Second quarter 2022 (1 April - 30 June):

- Net revenue was KDKK 0
- Operating result was KDKK -3.940
- Net result was KDKK -3.319
- Cash at bank end of the period was KDKK 17.846
- Earnings per share* was KDKK -0,54
- Solidity** was 91%

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

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

Highlights during second quarter 2022

- Last patient dosed in pharmacokinetics trial 0206
- Initiated and completed the first usability test on the device for CT001
- Regulatory approval by authorities for pivotal trial 0205
- Business development activities to support a future partnership model
- Continue to build the organisation to execute the final development of CT001

“During the second quarter of 2022 we finalised the recruitment of our Phase 2 trial 0206, the pharmacokinetic study with CT001 and very importantly, obtained regulatory approval for our pivotal trial 0205, a randomised double-blind placebo controlled study with 220 patients. We expect to dose the first patients shortly, bringing us in a selected group of companies in late stage development. We look forward to a very exciting year for the Company with a rich news flow” says Jes Trygved, CEO



developing evidence-based treatments -
specifically for children



Second Quarter Report (Q2-2022)

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

CESSATECH - SECOND QUARTER REPORT (Q2-2022)

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We are very happy with the finalization of recruitment for trial 0206, and the biostatisticians are working hard to have the results ready during Q3'2022. Our most important trial, the pivotal trial 0205 has finally received regulatory approval and we are just about to initiate this trial. So many people have been involved in both trials, and we are grateful to have a truly successful team and collaboration with the partners.

1. Summary

The Board of Directors and CEO of Cessatech hereby publish the second 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	Q2 2022	Q2 2021	1H 2022	2021
	01/Apr/22	01/Jan/21	01/Jan/22	01/Jan/21
Amounts in DKK '000'	30/Jun/22	31/Mar/21	30/Jun/22	31/Dec/21
Net Revenue	0	0	0	0
Operating result	-3.940	-3.088	-7.676	-13.833
Net result	-3.319	-2.641	-6.364	-11.569
Cash at Bank	17.846	9.465	17.846	3.275
Earnings per share *	-0,54	-0,72	-1,04	-3,09
Solidity (%)**	91%	88%	91%	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*

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

Highlights during second quarter 2022

- Last patient dosed in pharmacokinetics trial 0206
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- Business development activities to support a future partnership model
- Continue to build the organisation to execute the final development of CT001

2. CEO comments

During the second quarter of 2022 we focused on our clinical activities and business development activities, we kept the momentum and are confident that 2022 will be a fantastic year for Cessatech.

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 finalized recruitment in May 2022 and following this the analysis has been ongoing at the biolab and now at the biostatisticians. During the initial stages of this trial, we were impacted by challenges due to COVID 19 but have subsequently seen good progress and want to thank the children and their parents who have supported this trial. We very much look forward to communicating the top-line results from the trial during Q3'2022.

Additionally during the quarter, we finally received regulatory approval from the authorities and thereby a green-light 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 earlier and we are obviously challenged by our initial timelines, but the team is confident that we will have the results of this study in early 2023.



We are developing a **novel drug-drug-device combination (CT001)** for children, and this requires that we comply with the updated Medical Device Regulation, which came into effect recently and test accordingly. The path to market requires that we obtain a notified body opinion prior to MAA submission, thus we have initiated the early preparation process and have conducted the first Proof-of-Concept usability test with the device, evaluating the safety and efficacy of the CT001 device design and user interface according to the task analysis and dosing schedule. The Proof-of-Concept usability test was a success, and the results were highly valuable for Cessatech and have provided a solid foundation to execute on device-related activities. These activities include a User-Related-Risk-Analysis, Instructions for Use, and a Usability and Human Factor Engineering Plan to secure a successful market approval.

We are still a small organization, and we **continue to further build the organisation to ensure we have the necessary competences within the team**. I am extremely pleased to welcome experienced CMC professional **Martin Juhl** who joined the team during the second quarter. Martin will be instrumental in bringing the drug through the development process. Martin has a Ph.D. in Organic Chemistry and joined Harvard as a Postdoctoral Researcher before joining H. Lundbeck where he spent the last 14 years before joining Cessatech. He has worked both as a subject-matter-expert (SME), leading CMC project teams, and representing CMC in Global Project Teams and he was involved in more than 15 IMPD/IND submissions.

Our **financial position** is on track in terms of our prioritized activities and taking account of the effect from the delay in our regulatory approval of trial 0205. We have postponed certain activities and reduced costs where possible, whilst continuing to build the team to ensure we have the processes and structures in place to carry out our activities. 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. In addition, we also see good progress with our business development activities. 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 Q2-2022 were as expected.

Net revenue amounted to DKK 0 and the operating result was KDKK -3.940 in Q2-2022.

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

BALANCE SHEET AND SOLIDITY

The total equity at 30 June 2022 was KDKK 20.228

The solidity as per 30 June 2022 was 91 %

CASH FLOW AND INVESTMENTS

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

Cash at the end of June 2022 was KDKK 17.846.

The majority of the cash flow during Q2 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	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 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, or the Company will wait until the next general meeting in 2023 to remove the maximum.

ACCOUNTING POLICY

This unaudited results announcement for Q2 2022 contains condensed financial information for the three months ended 30 June 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

AUDITOR'S REVIEW

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

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

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 Q2 2022 report provides a true and fair view of the Company's business.

Copenhagen 19 August 2022

The Board of Directors

6. Income statement

INCOME STATEMENT	Q2 2022	Q2 2021	1H 2022	2021
	01/Apr/22	01/Apr/21	01/Jan/22	01/Jan/21
Amounts in DKK '000'	30/Jun/22	30/Jun/21	30/Jun/22	31/Dec/21
Revenue	0	0	0	0
Other operating expenses	-2.473	-2.241	-4.678	-10.340
Staff expenses	-1.467	-847	-2.998	-3.492
Operating loss before net financials	-3.940	-3.088	-7.676	-13.833
Financial costs	-54	-17	-130	-60
Loss before tax	-3.994	-3.105	-7.806	-13.893
Tax on loss for the period	675	464	1442	2.324
Net loss for the period	-3.319	-2.641	-6.364	-11.569
Other comprehensive income for the period	0	0	0	0
Total comprehensive income	-3.319	-2.641	-6.364	-11.569

7. Balance sheet

BALANCE SHEET	Q2 2022	Q2 2021	2021
Amounts in DKK '000'	30/jun/22	30/Jun/21	31/Dec/21
Assets			
<i>Fixed Assets</i>			
- Patents	203	117	203
Intangible Assets	203	117	203
Total non-current assets	203	117	203
<i>Current assets</i>			
- Tax receivables	3.766	950	2.324
- Capital increase receivables	0	0	24.325
- Other receivables	498	304	495
- Prepayments	10	100	31
- Cash at bank	17.846	9.465	3.275
Total current assets	22.120	10.819	30.450
Total assets	22.323	10.936	30.653
Equity and liabilities			
<i>Equity</i>			
Share capital	1.223	736	1.223
Retained earnings	19.005	8.836	25.019
Total equity	20.228	9.572	26.242
<i>Liabilities</i>			
- Trade payables	933	363	3.070
- Other payables	1.162	1.001	1.341
Current liabilities	2.095	1.364	4.411
Total liabilities	2.095	1.364	4.411
Total equity and liabilities	22.323	10.936	30.653

8. Statement of changes in equity

STATEMENT OF CHANGE IN EQUITY Q2, 2022	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 April 2022	1.223	0	22.169	23.392
Incentive Warrant Scheme	0	0	155	155
Total comprehensive income for the period	0	0	-3.319	-3.319
At 30 June 2022	1.223	0	19.005	20.228

STATEMENT OF CHANGE IN EQUITY Q2, 2021	Share-	Share	Retained	Shareholders
Amounts in DKK '000'	Capital	Premium	earnings	equity
At 1 April 2021	736	0	11.055	11.791
Incentive Warrant Scheme	0	0	421	421
Total comprehensive income for the period	0	0	-2.641	-2.641
At 30 June 2021	736	0	8.835	9.571

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	Q2 2022	Q2 2021	1H 2022	2021
	01/Apr/22	01/Apr/21	01/Jan/22	01/Jan/21
Amounts in DKK '000'	30/Jun/22	30/Jun/21	30/Jun/22	31/Dec/21
Loss before tax	-3.994	-3.105	-7.806	-13.893
Financial expenses, reversed	54	17	130	60
Other non-cash items	155	421	349	1.567
Tax credit paid out	0	0	0	60
Change in working capital	532	1.042	-554	2.162
Cash flow from operating activities before net financials	-3.253	-1.625	-7.881	-10.044
Financial expenses paid	-54	-17	-130	-60
Cash flow from operating activities	-3.307	-1.642	-8.011	-10.104
Purchase of intangible assets	0	-41	0	-127
Cash flow from investing activities	0	-41	0	-127
Cash capital increase, TO1 exercise	0	0	24.325	0
Transaction cost, cash capital increase	0	0	-1.692	0
Cash flow from financing activities	0	0	22.633	0
Total cash flow for the period	-3.307	-1.683	14.622	-10.231
Cash, beginning of the period	21.205	11.148	3.275	13.506
Cash, end of the period	17.898	9.465	17.897	3.275

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