**Press Release**
24 August 2023

# Second quarter report Q2-2023

- **US co-development and commercialization partnership signed for CT001 - potential income already from 2024**
- **Strong clinical progress**
  - **Pivotal study 0205 recruitment on track - last patient expected Q3-2023**
  - **Clinical Trial Application (CTA) for study 0202 submitted and under review by competent authorities**
- **Post-period event: Loan facility agreement signed to support US launch and strengthening the cash position**

Cessatech A/S ("Cessatech" or the "Company") today releases its results for the period 1 April – 30 June 2023. The second quarter report is available as an attached document to this press release and on www.cessatech.com under Investor/Filings & Reports. A US partnership agreement has been finalized, which is expected to be transformative to the Company with income anticipated potentially already from 2024. The Company has advanced well with planned activities, finalization of recruitment of pivotal study 0205 is expected in the third quarter of 2023 (a randomised double-blind placebo-controlled trial with 220 adults following impacted mandibular third molar extraction) and study 0202 is currently undergoing competent authority review and will be initiated later this year.

**Second quarter financial results 2023 (1 April - 30 June):**

- Net revenue was KDKK 0
- Operating result was KDKK -6.185
- Net result was KDKK -5.304
- Cash at bank end of the period was KDKK 12.435
- Earnings per share* was KDKK -0,38
- Solidity** was 76%

**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 2023 amounted to 13.788.755 shares, the average number of shares during the second quarter was 13.788.755.*
***Solidity: Total equity divided by total capital and liability.*

**Highlights during second quarter 2023**

- US co-development and commercialization partnership for CT001
- Continue good enrolment for study 0205, last patient expected during Q3-2023
- CT001 shelf-life study completed with more than two years at controlled room temperature
- CTA for study 0202 submitted for competent authority review in selected countries
- Progress with EU business development activities to support the future commercial partnership model

***"During the second quarter of 2023 we were extremely pleased to enter a US partnership with Ventis Pharma to secure the future development and commercialisation of CT001 in the important and large US market. This transformational deal is part of our commercial strategy to leverage the value of our products in different geographical areas and ensure our much-needed solution for pain management in children experiencing acute pain, can reach the patients who need it. At the same time, we continued to build momentum in our clinical development activities, submitting a clinical trial application for our 0202 study. We also look forward to completing patient recruitment in the coming months in our pivotal study with 0205." says Jes Trygved, CEO***


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# Second Quarter Report (Q2-2023)

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

# CESSATECH - SECOND QUARTER REPORT (Q2-2023)


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We are excited about the progress during the second quarter of 2023 as we were extremely pleased to enter a US partnership with Ventis Pharma to secure the future development and commercialisation of CT001 in the important and large US market. This transformational deal is part of our commercial strategy to leverage the value of our products in different geographical areas and ensure our much-needed solution for pain management in children experiencing acute pain. Thanks to the team for its high spirit and commitment.

# 1. Summary

The Board of Directors and CEO of Cessatech hereby publish the second quarter report of 2023. 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.

| | **Q2 2023** | **Q2 2022** | **1H 2023** | **2022** |
|---|---|---|---|---|
| **Key figures** | 01/Apr/23 | 01/Apr/22 | 01/Jan/23 | 01/Jan/22 |
| Amounts in DKK ´000´ | 30/Jun/23 | 30/Jun/22 | 30/Jun/22 | 31/Dec/22 |
| Operating Loss | -6.185 | -3.940 | -11.846 | -17.589 |
| Total financial items | -164 | -54 | 96 | -210 |
| Loss for the period | -5.304 | -3.319 | -9.669 | -14.656 |
| Cash at Bank | 12.435 | 17.846 | 12.435 | 23.342 |
| **Ratios** | | | | |
| Solvency ratio | 76% | 91% | 76% | 85% |
| Earnings per share (DKK) | -0,38 | -0,54 | -0,38 | -2,06 |

**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 2023 amounted to 13.788.755 shares, the average number of shares during the second quarter was 13.788.755.*
***Solidity: Total equity divided by total capital and liability*

**Highlights during second quarter 2023**

- US co-development and commercialization partnership for CT001
- Continue good enrolment for study 0205, last patient expected during Q3-2023
- CT001 shelf-life study completed with more than two years at controlled room temperature
- CMC and device collaboration with AI partner to support further data analysis
- CTA for study 0202 submitted for competent authority review in selected countries
- Progress with EU business development activities to support the partnership model

# 2. CEO comments

The second quarter of 2023 had a record high level of activities, especially as we manged to finalize the agreement for the US partner setup together with US Ventis Pharma – in addition, we continue to focus on clinical activities which have had good progress this year. An extremely important milestone for the company to maintain the business progress in bringing new options to treat children with pain. We are very excited as this year will potentially be a breakthrough year for the company.

At the beginning of the year, we laid out the goal to finalize the commercial business setup for Europe and the US during 2023 – and during the second quarter we were pleased to sign **the US partnership agreement**. An agreement that includes both an option for short-term income with the early access program and a mid-term co-development for the FDA development program, of which most of the clinical studies from the EU program can be used for a potential FDA filing. We anticipate finalizing the commercial business setup for Europe later this year in addition to completing the pivotal clinical study 0205.

In September 2022 the first patient was dosed in the pivotal study 0205 with our lead candidate CT001, **investigating the postoperative analgesic efficacy of CT001** in adults following impacted mandibular third molar extraction. The study is a randomised, double-blind placebo-controlled trial with 220 participants. During the second quarter we saw a positive impact from actions we took to improve recruitment rates, including increasing the number of referring dental clinics participating in the study – and now we are close to ending the study. We look forward to completing recruitment during the third quarter of this year and reporting top-line results shortly thereafter.

Ongoing **stability studies of CT001** have shown that CT001 remains stable over a prolonged period of time and is now estimated to have a shelf-life of more than two years at controlled room temperature. This will greatly benefit future supply chain management and will be a major advantage for hospitals and clinics storing and working with CT001. The final anticipated market shelf-life will most likely be even longer and based on the outcome from stability studies of upcoming process validation batches.

During the second quarter we submitted study protocol for the final study of CT001. Study **0202 is an open-label, prospective study to access safety, tolerability, analgesic effect and feasibility** of CT001 with 300 paediatric patients in an emergency setting. The study is mainly focusing on safety. We anticipate an approval so the study can start recruitment during the 2nd half of 2023. All sites and investigators have been identified and training will start later this year.

Our **financial position** is on track in terms of our prioritized activities, ongoing and planned clinical trials. Due to the very challenging financial market conditions the company management and the board continually evaluate our financial position to ensure we can prioritise activities. To maximise the chances of success our current priorities are:

- The **US partnership agreement** with Ventis Pharma provides potential for revenue already for 2024, again much earlier than originally anticipated.
- The recently signed **loan facility agreement** (post the Q2 report) of up to DKK 5 million will support the US launch and strengthening the cash position.
- Activities to secure an **EU commercial partnership** are ongoing and anticipated to be finalized during the second half of 2023.

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

## Product portfolio

| | Use | Indication | Pre-clinical | Phase I | Phase II | Pivotal - Ph III |
|---|---|---|---|---|---|---|
| **CT001** Fixed combination | Non-invasive nasal spray | Acute pain | CT001 | | | |
| **CT002** Sedative-analgesic | Non-invasive nasal spray | Sedation | CT002 | | | |
| **CT003** Local analgesia | Local gel | Topical anaesthesia | CT003 | | | |

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. An update to the pipeline is expected later during 2023.

# 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 adults, few of these have been developed for children. A study on unlicensed drug prescription revealed that up to 75 percent of all medications for children 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 Q2-2023 were as expected.
Net revenue amounted to DKK 0 and the operating result was KDKK -6.185 in Q2-2023.
The operating result was as expected as the Company is currently conducting development activities.

**BALANCE SHEET AND SOLIDITY**
The total equity at 30 June 2023 was KDKK 14.681
The solidity as per 30 June 2023 was 76%

**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 2023 was KDKK 12.435
The majority of the cash flow during Q2 2023 is related to clinical activities which will continue as planned through 2023.

**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 June 2023 amounted to 13.788.755. There was an increase to the number of shares during the fourth quarter of 2022, related to the rights issue. Every share equals the same rights to the Company's assets and results.

# 5. Miscellaneous

| Shareholders | Q2-2023<br>**Number of shares** | Q2-2023<br>**Votes and capital** |
|---|---|---|
| **Shareholders >5%** | | |
| Jes Trygved (CEO) | 904.399 | 6,56% |
| All other shareholders | 12.884.356 | 93,44% |
| **SUM** | **13.788.755** | **100,00%** |
| | | |
| **Board of Directors** | | |
| Adam Steensberg | 164.901 | 1,20% |
| Charlotte Videbæk (C- ApS) | 163.413 | 1,19% |
| Martin Olin (chairman) | 86.426 | 0,63% |
| Rachel Curtis Gravesen | 37.917 | 0,27% |
| Peter Birk | 10.318 | 0,07% |
| Flemming Jensen | 0 | 0,00% |

**INCENTIVE WARRANT SCHEME**

The Board of Directors is authorised during the period until 1 January 2025 on one or more occasions to issue warrants up to ten (10) percent of the Company's share capital from time to time, each conferring the right to subscribe one share of nominal DKK 0.20 against cash contribution and to effect the corresponding increase(s) of the share capital.

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. In December 2020, the Board of Directors and the CEO received warrants as part of Cessatech's Incentive Warrant Scheme. Subsequently to 31 December 2022 a new Incentive Warrant Scheme was established in January 2023 also including key employees.

See the press release of 17 January for more details on the Incentive Warrant Scheme.

## ACCOUNTING POLICY

This unaudited results announcement for Q2 2023 contains condensed financial information for the six months ended 30 June 2023 and should be read in conjunction with the Annual Report 2022, 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 2022. 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 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

Q2 and Half-year Report: 24 August 2023
Q3 Report: 16 November 2023
Q4 and Annual Year Report 2023: 29 February 2024
Annual General Meeting 2023: 27 March 2024

## ANNUAL GENERAL MEETING AND AVAILABILITY OF THE ANNUAL REPORT

The Annual General Meeting 2022 was held on Thursday 23 March 2023 at 9.00 AM. The annual report and the minutes from the annual general meeting is available on Cessatech's website.

The Annual General Meeting for 2023 will take place on 27 March 2024.

## SUBMISSION OF Q2 REPORT

The Board of Directors hereby certifies that this Q2 2023 report provides a true and fair view of the Company's business.

Copenhagen 24 August 2023
The Board of Directors

# 6. Income statement

| **INCOME STATEMENT** | **Q2 2023** | **Q2 2022** | **1H 2023** | **2022** |
|---|---|---|---|---|
| | 01/Apr/23 | 01/Apr/22 | 01/Jan/23 | 01/Jan/22 |
| Amounts in DKK ´000´ | 30/Jun/23 | 30/Jun/22 | 30/Jun/22 | 31/Dec/22 |
| | | | | |
| Revenue | 0 | 0 | 0 | 0 |
| Other external expenses | -4.834 | -2.473 | -9.710 | -12.246 |
| Staff expenses | -1.351 | -147 | -2.136 | -5.343 |
| **Operating loss before net financials** | **-6.185** | **-3.940** | **-11.846** | **-17.589** |
| Financial expenses | -164 | -54 | 96 | -210 |
| **Loss before tax** | **-6.349** | **-3.994** | **-11.750** | **-17.799** |
| Tax on loss for the period | 1.045 | 675 | 2.081 | 3.143 |
| **Net loss for the period** | **-5.304** | **-3.319** | **-9.669** | **-14.656** |
| Other comprehensive income for the period | 0 | 0 | 0 | 0 |
| | | | | |
| **Total comprehensive income** | **-5.304** | **-3.319** | **-9.669** | **-14.656** |
| **Basis and diluted earnings per share** | **-0,38** | **-0,54** | **-0,38** | **-2,06** |

# 7. Balance sheet

| BALANCE SHEET | Q2 2023 | Q2 2022 | 2022 |
|---|---|---|---|
| | 01/Apr/23 | 01/Apr/22 | 01/Jan/22 |
| Amounts in DKK ´000´ | 30/Jun/23 | 30/Jun/22 | 31/Dec/22 |
| **Assets** | | | |
| | | | |
| ***Fixed Assets*** | | | |
| - Patents | 203 | 203 | 203 |
| **Intangible Assets** | **203** | **203** | **203** |
| **Total non-current assets** | **203** | **203** | **203** |
| **Current assets** | | | |
| - Receivables corporate tax | 5.224 | 3.766 | 3.143 |
| - Capital increase receivables | 0 | 0 | 0 |
| - Other receivables | 1.238 | 498 | 1.334 |
| - Prepayments | 94 | 10 | 164 |
| - Cash at bank | 12.435 | 17.846 | 23.343 |
| **Total current assets** | **18.991** | **22.120** | **27.984** |
| | | | |
| **Total assets** | **19.194** | **22.323** | **28.187** |
| | | | |
| **Equity and liabilities** | | | |
| | | | |
| ***Equity*** | | | |
| Share capital | 2.758 | 1.223 | 2.758 |
| Retained earnings | 11.923 | 19.005 | 21.098 |
| **Total equity** | **14.681** | **20.228** | **23.855** |
| ***Liabilities*** | | | |
| - Trade payables | 3.607 | 933 | 2.738 |
| - Liabilities measured at fair value | 537 | 0 | 614 |
| - Other payables | 368 | 1.162 | 979 |
| **Current liabilities** | **4.513** | **2.095** | **4.332** |
| **Total liabilities** | **4.513** | **2.095** | **4.332** |
| | | | |
| **Total equity and liabilities** | **19.194** | **22.323** | **28.187** |

# 8. Statement of changes in equity

| **STATEMENT OF CHANGE IN EQUITY Q2, 2023**<br>Amounts in DKK ´000´ | Share-<br>Capital | Share<br>Premium | Retained<br>earnings | Shareholders<br>equity |
|---|---|---|---|---|
| At 1 April 2023 | 2.758 | 0 | 17.004 | 19.762 |
| Incentive Warrant Scheme | 0 | 0 | 223 | 223 |
| Total comprehensive income for the period | 0 | 0 | -5.304 | -5.304 |
| **At 30 June 2023** | **2.758** | **0** | **11.923** | **14.681** |

| **STATEMENT OF CHANGE IN EQUITY Q2, 2022**<br>Amounts in DKK ´000´ | Share-<br>Capital | Share<br>Premium | Retained<br>earnings | Shareholders<br>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 2022**<br>Amounts in DKK ´000´ | Share-<br>Capital | Share<br>Premium | Retained<br>earnings | Shareholders<br>equity |
|---|---|---|---|---|
| At 1 January 2022 | 1.223 | 0 | 25.019 | 26.241 |
| Share capital increase right issue for cash | 1.467 | 13.203 | 0 | 14.670 |
| Share capital increase compensation to underwriters | 68 | 614 | | 682 |
| Fair value of warrants issued as part of right issue | | | -576 | -576 |
| Transfer | 0 | -13.817 | 13.817 | 0 |
| Incentive Warrant Scheme | 0 | 0 | 565 | 565 |
| Expenses in connection with capital increase, cash | 0 | 0 | -2.390 | -2.390 |
| Expenses in connection with capital increase, fair value compensation in Units | 0 | 0 | -682 | -682 |
| Total comprehensive income for the period | 0 | 0 | -14.656 | -14.656 |
| **At 31 December 2022** | **2.758** | **0** | **21.098** | **23.855** |

# 9. Cash flow statement

| CASH FLOW STATEMENT | Q2 2023 | Q2 2022 | 1H 2023 | 2022 |
|---|---|---|---|---|
| | 01/Apr/23 | 01/Apr/22 | 01/Jan/23 | 01/Jan/22 |
| Amounts in DKK ´000´ | 30/Jun/23 | 30/Jun/22 | 30/Jun/22 | 31/Dec/22 |
| | | | | |
| **Loss before tax** | -6.349 | -3.994 | -11.750 | -17.799 |
| Financial expenses, reversed | 164 | 54 | -96 | 210 |
| Other non-cash items | 223 | 155 | 495 | 565 |
| Tax credit paid out | 0 | 0 | 0 | 2.324 |
| Change in working capital | 1.948 | 532 | 425 | 27 |
| **Cash flow from operating activities before net financials** | **-4.014** | **-3.253** | **-10.927** | **-14.673** |
| Financial expenses paid | 28 | -54 | 19 | -172 |
| **Cash flow from operating activities** | **-3.986** | **-3.370** | **-10.907** | **-14.845** |
| Purchase of intangible assets | 0 | 0 | 0 | 0 |
| **Cash flow from investing activities** | **0** | **0** | **0** | **0** |
| Cash capital increase, TO1 + Rights Issue | 0 | 0 | 0 | 38.995 |
| Transaction cost, cash capital increase | 0 | 0 | 0 | -4.082 |
| **Cash flow from financing activities** | **0** | **0** | **0** | **34.913** |
| Total cash flow for the period | -3.986 | -3.307 | -10.907 | 20.067 |
| Cash, beginning of the period | 16.422 | 21.205 | 23.343 | 3.275 |
| | | | | |
| **Cash, end of the period** | **12.435** | **17.898** | **12.435** | **23.342** |

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