



Invitation to subscribe for units in

**Cessatech A/S** 

**Rethinking child treatments** 

developing
evidence-based
treatments –
specifically for
children



## IMPORTANT INFORMATION

The following summary is not an offer but is to be seen as an introduction to Cessatech A/S ("Cessatech") prospectus and does not necessarily contain all information for an investment decision to be made. The investor is advised to consult the prospectus which is available on Cessatech's website (www.cessatech.com), before making an investment decision to take note of the potential risks associated with the decision to invest in the securities. Cessatech A/S, CVR.no. 41293055.







### A SHORT INTRODUCTION TO

# Cessatech A/S

Cessatech is a Danish clinical Phase II company developing evidence-based treatment for children. Its lead asset (CT001) is an analgesic nasal spray for treatment of acute and planned painful procedures in children. Cessatech has reached an essential target with the approval by the EMA to launch its Paediatric Investigation Plan (PIP), which grants the company an approved path for a Paediatric-use Marketing Authorization (PUMA) and thereby the opportunity to launch CT001 in Europe in just a few years.

In Europe alone, it is estimated that approx. 25 million children are exposed each year to acute procedural pain<sup>1</sup>. The objective for Cessatech's solution is a peak volume market share of 30-40 %, after 6-8 years on the market, corresponding to approx. six million children treated annually. By then, the company estimates the total market to be approx. DKK 1.5-2 billion. The company also has two follow-on concepts for children, a sedative nasal spray (CT002) for medical/diagnostical 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 PIP for the Company's lead asset, it is Cessatech's ambition to apply for similar development programs for these two treatments as the one recently granted for CT001.

With an approved PIP, CT001 is now expected to enter late stage clinical development in 2021. In parallel with the final studies, Cessatech will develop a regulatory strategy for the U.S. and accelerate the commercialization process for CT001, where the company aims to seek partnership or out-license the product to larger pharmaceutical companies. The EMA and the U.S. Food and Drug Administration (FDA) have agreed on principles for interaction and exchange of information on paediatric matters, to foster the global development of medicines for children. Cessatech is

hopeful that this might help elevate the regulatory strategy for the U.S.

The company is now ready to advance the implementation of its approved PIP program, but also expand business development activities, develop a regulatory strategy for the U.S. and further develop its business model. Cessatech is therefore conducting an issue of units amounting to approx. DKK 41 million (before issue costs), prior to planned listing on Spotlight Stock Market.

# A CLEAR AND FAST ROUTE TO REGULATORY APPROVAL

According to EU regulations, a Paediatric Investigation Plan (PIP) must be obtained to support the authorisation of a new medicine for children. Cessatech started this process back in 2016 and was recently granted an approved PIP-program by the EMA, providing a clear and fast route to regulatory approval for its lead asset CT001. It is Cessatech's ambition to have its nasal spray ready for launch on the market in 2024.

1. Company estimated volume based on various references and data from Eurostat

# TEN YEARS OF MARKET EXCLUSIVITY IN EUROPE

Cessatech's approved PIP consists of four additional short clinical trials and two computer-based modelling-simulation studies, which will be conducted during 2021-2023. After completing the approved PIP and filing for regulatory approval, Cessatech will be able to provide sufficient data to demonstrate the efficiency and safety of its lead asset CT001, which will be the basis of a Paediatric-Use Marketing Authorisation (PUMA) by the EMA and the reward of ten years of market exclusivity in Europe.



# Lead Asset - CT001

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. The product is based on more than ten years of clinical experience and has been proven effective and safe in a clinical Phase II trial in 50 children. Almost all (94 percent) stated that they would like to receive this treatment again rather than existing alternatives (e.g., oral solutions or injections). In addition, Cessatech has delivered promising preliminary results in a retrospective study based on approx. 300 medical procedures during a five-year period in a collaborative study between Rigshospitalet (Denmark) and Astrid Lindgren Children's Hospital (Sweden).

CT001 is based on a fixed combination of two well-known compounds, which are already approved treatments for injection in adults and are also used separately for pain-relief intravenously in children, significantly reducing the risk in upcoming clinical studies and subsequently in the regulatory filing for CT001.

The product targets a large unmet need, as much of the medication currently used for acute pain relief is not approved for use in children. The advantages include needle-free administration, being easy to administer, a fast-acting therapeutic effect and, when it has obtained regulatory approval, also being medically approved for children

# Summary of the offering

Subscription period: 10-24 November 2020

**Subscription price:** One (1) unit consists of two (2) shares and three (3) warrants of series TO 1. The subscription price is DKK 18.80 per unit, which corresponds to DKK 9.40 per share. The warrants are issued free of payment.

Volume of issuance: The offer comprises no more than 1,680,000 shares and no more than 2,520,000 warrants of series TO 1, corresponding to approx. DKK 15.8 million and approx. DKK 25.2 million respectively. If the issue of units is fully subscribed and all associated warrants are exercised, Cessatech will receive a capital injection totaling approx. DKK 41 million (before issue costs). The minimum subscription is 200 units, corresponding to DKK 3,760.

Valuation (pre-money): Approx. DKK 18.8 million.

**Subscription commitments:** The company has received subscription commitments of approximately DKK 9.8 million, corresponding to approximately 62 percent of the initial issue of units. Members of the Board of Directors, executive management and major shareholders have committed to subscribe for units to a total value of approx. DKK 1.1 million.

Number of shares before the issue of units: 2,000,000

Expected first day of trading on Spotlight Stock Market: 16 December 2020

Ticker, ISIN: CESSA, DK0061411964.

Summary of the consideration free warrants

Exercise period: 25 November - 16 December 2021.

**Exercise price:** One (1) warrant gives the right to subscribe for one (1) new share at DKK 10.00.

**Issue volume:** If all warrants are exercised during this period, the company will receive an additional approx. DKK 25.2 million before issue costs.

Ticker, ISIN: CESSA TO 1, DK0061416849.



# **Milestones**

- Publication of results from registry study (0203)
- Receive authorization from Regulatory and Ethics Committee to initiate first clinical trials
- Initiate the first three late stage clinical trials, PK, Bioavailability and Efficacy in children and adults (studies 0204-06)
- Last patient last visit (study 0205)
- Simulation and modelling studies to be initiated (studies 0207 & 0208)
- Initiate prehospital paediatric study (0202)
- Cessatech potential trade sale based on pivotal trial results (0203) – or consider other options

- Finalize negotiations and select manufacturer for clinical and commercial batches
- Submit fast-track patent application for the U.S.
- Finalize registry study (0203) from 10-year data of approx.
   2,500 procedures in children from Karolinska University Hospital
- Submit clinical trial application for the first three trials of the late stage clinical program
- Finalize the two late stage clinical trials (studies 0204 & 0206) in children and adults
- Safety Data Committee evaluation - midterm target (study 0205)
- Finalize U.S. regulatory pathway project and U.S. development strategy
- 20 22
- Finalize simulation and modelling studies (0207 & 0208)
- Finalize (EU/EMA) regulatory strategy for submission

- Finalize clinical activities, and pre-hospital trial (study 0202)
- Prepare for regulatory filling to obtain PUMA

20 23

• Expected PUMA approval

 Market preparation and launch (not part of current funding plans)

20 24

# **CEO, Jes Trygved comments**

I have three children who have all been to the hospital for minor accidents – and for some reason they have all had stitches in their faces (suturing of lacerations), essentially without any analgesia except for some local topical cream. It is a very painful experience also for the parent.

In Europe alone, it is estimated that approx. 25 million children are exposed each year to acute procedural pain and, 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 children². 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.

About four years ago, I was introduced to the paediatric nasal spray project team at Rigshospitalet and was immediately convinced by their concept – a non-invasive intervention developed for children. Many of the people involved in CT001 over the years have had a strong passion for making it available on the market, and the time has come to finalize the development program approved by the EMA, and most importantly make the product available in hospitals across Europe and eventually in the rest of the world. We are well

positioned to get there in just a few years and in order to advance the implementation, we are conducting an issue of units, prior to planned listing on Spotlight Stock Market, which will help us to finalize the late stage clinical trials for CT001.

I am now looking forward to leading Cessatech into the next phase as a listed company. My vision is clear – a company rethinking child treatments, while maintaining a lean company that remains agile and flexible through close collaboration with partners and consultants to minimize overheads and ensure focus on what really matters. Together with our strong leadership team, with a proven track-record within drug development, paediatric analgesic research, and market launches, I strongly believe we have all the conditions in place to reach our goals.

I hope you will support Cessatech on this journey, and we will do everything possible to make it a success specifically for the children.

**Jes Trygved** CEO, Cessatech A/S

"The time has come to finalize the development program approved by the EMA, and most importantly make the product available in hospitals across Europe and eventually in the rest of the world."

Jes Trygved CEO, Cessatech A/S





## Subscription form – for subscription of units in Cessatech A/S

Subscription period:	10 November - 24 November 2020				
Subscription price per unit:	DKK 18.80				
Allocation:	Any allotment will be notified via a settlement note via e-mail.				
Payment:	be made in accordance with instructions on the settlement note. Around 4 December, 2020. Payment shall be dermera Fondkommission at hand no later than five bank days after received settlement note.				
First day of trading:	The first day of trading in Cessatech A/S´s shares and warrants on Spotlight Stock Market is scheduled to be 16 December, 2020.				
In an assessment of Cessatech A/S future development and operations, it is of great importance to consider all relevant risks. Each investor must make their own assessment of the impact of these risks by reading and understanding all available information published concerning this offer. The prospectus is available for download at www.sedermera.se, www.spotlightstockmarket.com and at www.cessatech.com.					
Please note  For subscribers who has a custody account or account with specific rules, such as an ISK/KF account, the subscription must be made in agreement with the bank/trustee that holds the account.					
If you have a	n account with Nordnet or Avanza, please make your subs	cription directly throu	gh your bank.		
of DKK 18.80 per unit. Ĕach unit d	or subscription of the following number of units in Cessatech A/s onsists of two (2) shares and three (3) warrants of series TO 1. The free of payment. Minimum allowed subscription is of 200 units (	price per share is DKK	Number of units		
2. Please enter your securities ac	count number where allotted shares and warrants are to be de	·livered:			
Custody account	Bank/Trustee				
Please note! It is the investor's custody account stated at this	own responsibility to control with his or her bank that deli-	very of Danish shares a	nd warrants is possible to the		

#### 4. Subscription over 15,000 EURO?

If the subscription amounts to or exceeds 15,000 EURO, or if the answer on question 3. is Yes, a money laundering form which can be found at Sedermera Fondkommissions website. Please note: Sedermera Fondkommission cannot guarantee that the subscription form will be considered if Sedermera Fondkommission does not receive a completed money laundering form before the subscription period has ended.

**3.** Do you invest regularly through Sedermera Fondkommission? I.e., have you, through Sedermera Fondkommission, invested ten (10) times during the last twelve (12) months, or six (6) times each year for the last five (5) years? Yes No

### 5. Fill in your name and address information (PLEASE WRITE CLEARLY)

Last name/company name		First name	National ID number/Corp.ID.no.
Street address (or PO Box or equivalent)		Daytime telephone	NID-number (private person)*/LEI (company)**
Postal code	City	Country (if other than Sweden)	E-mail (mandatory)
Place and date		Signature (authorized company signature, or guardian, if applicable)	

- 6. By signing this subscription form I confirm the following:
  That I have read the prospectus (Swedish use) and understood the risks associated with investing in this particular financial instrument;
  That I have read and understood the information stated in the section "Terms and Conditions" in the prospectus;
- That I have read and accepted the information stated on the subscription form;
- That no modifications or amendments may be made to the printed text in this subscription form;
  That an incomplete or incorrect subscription form may be disregarded;
- That I am aware that no customer relationship exists between Sedermera Fondkommission and the subscriber with respect to this subscription;
   That I am aware that Sedermera Fondkommission will not make any assessment of whether the subscription to the instrument in question is suitable for me or the person
- on whose behalf I am subscribing;
   That I have observed that the offer is not addressed to persons resident in the USA, Australia, Japan, Canada, New Zealand, South Africa, Hong Kong, Switzerland, Singapore
- or other countries where participation requires additional prospectus, registration or other measures other than those required by Swedish and Danish law,

  That I am aware that the application is not covered by the right of return that follows from the Swedish Distant and Doorstep Sales Act or the Danish Consumer Contracts Act;
- That the subscription is binding;
  That in signing this subscription form, I authorize Sedermera Fondkommission, at the undersigned's expense, to implement the subscription of units pursuant to the terms
- and conditions stated in the prospectus issued by the board of directors of Cessatech A/S in November 2020;

  That personal data will be stored and processed in accordance with the General Data Protection Regulation (GDPR);
- That I am aware that I am only allowed to submit one subscription form per signatory. In case several subscription forms are submitted, only the last received will be considered;
   That the allocation of units in accordance with the subscription cannot be guaranteed.

### By checking this box, the subscriber agrees that information provided on the subscription form may also be used for communication regarding offers in the future.

### 7. Send the application form by one of the following options:

Subject: Cessatech Sedermera Fondkommission Norra Vallgatan 64 211 22 Malmö, Sweden

### E-mail:

issuingservices@sedermera.se

### Other questions:

Phone: 0046 40-615 14 10 Web site: www.sedermera.se

Please note: If you wish to have your allotted shares and warrants delivered to a bank or nominee outside of Sweden or Denmark, you are required to submit with Standard Settlement Information (SSI) to Sedermera Fondkommission. The SSI can be provided to you through your bank/trustee.

Please also make sure that your bank can trade shares on Spotlight Stock Market, if you want to be able to sell or buy shares in Cessatech A/S after first day of trading.

<sup>\*</sup> NID is a national ID for physical persons, required when subscribing for, trading, buying, selling and moving securities. Please fill in ff you have dual citizenship or citizenship or utside Sweden and Denmark.
\*\* LEI is a global ID-code for legal persons, required when subscribing for, trading, buying, selling and moving securities. Application for LEI-code can be made with support from your bank, but is also possible to conduct directly through companies providing LEI-codes.