cessatech
rethinking child treatments

INVITATION TO SUBSCRIBE FOR UNITS IN
Cessatech A/S

Rethinking child treatments

developing evidence-based treatments – specifically for children

RIGHTS ISSUE 2022

MPORTANT INFORMATION

The following summary is not an offer but is to be seen as an introduction to Cessatech A/S ("Cessatech") and does not necessarily contain all information for an investment decision to be made. The investor is advised to consult the offering memorandum which is available on Cessatech's website (www.cessatech.com), before making an investment decision and to take note of the potential risks associated with the decision to invest in the securities.

Translution Capital

A SHORT INTRODUCTION TO

Cessatech A/S

Cessatech is a Danish late-stage biopharmaceutical 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. The nasal spray is already extensively used in Denmark and Sweden where it is preferred by both patients and doctors because of its needle free administration and fast onset of action. The pivotal trial (0205) of CT001 commenced on September 5, 2022, with results expected in H1 2023. Once approved, expectedly in 2024, CT001 will be the only drug in its class specifically approved for children.

Procedural pain is undertreated in children

It is well known that procedural pain is undertreated in children. For instance, a US study of 279 hospitalized children showed that 76% of the children had experienced pain in the previous 24-hour period. 50% reported the pain as "moderate or severe". Another US study found that procedural pain was the most frequently cited cause of pain. Only half of the children that reported moderate to severe pain received pain medication. A Canadian study of 4,000 hospital admissions found that hospitalized children underwent an average of 6.3 painful procedures during their stay. While a variety of pain management strategies were generally undertaken, in only 28% of the painful procedures was specific pain intervention such as pharmacologic treatment administered in connection with the procedure.

There really is no standard of care for alleviating procedural pain in children

This undertreatment is at least in part a result of the lack of a recognised standard of care, or just an efficient, safe, and approved drug. Tablets are difficult to swallow and has a slow onset of action, especially for small children. Needles are also painful and provoke additional anxiety, and nitrous oxide requires specialised staff and monitoring. Several of the options make the child vomit. It is therefore not surprising that several studies have documented very significant differences in how procedural pain is managed, even across departments at the same hospital.

The market for analgesic drugs is significant

Market reports suggest the global analgesic market to be worth around USD 50 billion per year. Analgesic drugs are defined as pain alleviating substances not affecting consciousness. They include all the NSAIDS such as the salicylates and paracetamol, many of which are non-prescription, and opioids such as morphine and oxycodone which are subject to abuse. Based on estimates of yearly children hospital admissions in the EU and the United States, the number of visits to emergency rooms involving children as well as the number of EMS/ambulance trips involving children every year in these two geographies, the Company estimates that up to 40 million clinical situations involving children every year involve acute or planned procedural pain treatable with an analgesic.

A CLEAR AND FAST ROUTE TO REGULATORY APPROVAL

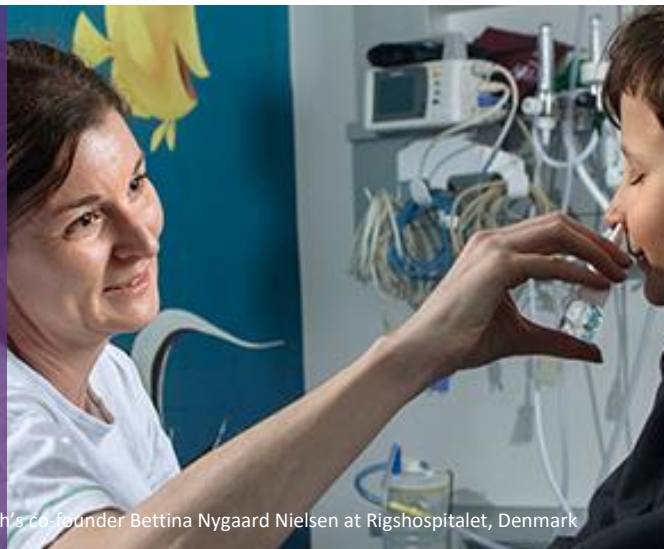
Under Cessatech's already approved PIP (Paediatric Investigation Plan), only the pivotal 0205 study, a 300-children confirmatory trial and two computer-based modelling-simulation studies remain. Positive top-line results from the 0204-bioavailability trial were reported earlier this year, whereas positive results from the 0206 pharmacokinetic trial were reported on September 23, 2022.

The pivotal double blinded, placebo controlled 0205 trial commenced on September 5, 2022. Meanwhile, the last, mostly confirmatory open-label 0202-trial is currently in preparation. On that basis, Cessatech expects to file for marketing approval in EU around the end of 2023.

TEN YEARS OF MARKET EXCLUSIVITY IN EUROPE

CT001 is based on the two well-known active substances ketamine and sufentanil which are already approved for adults. Under EU regulations, medicines developed specifically for children based on previously authorised substances are eligible for a so-called Paediatric-Use Marketing Authorisation (PUMA).

Once PUMA is granted, the product will benefit from 8+2 years of data and market protection, meaning that no similar product will be developed or approved in the EU.



Cessatech's co-founder Bettina Nygaard Nielsen at Rigshospitalet, Denmark

Lead Asset – CT001

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, CT001 has also delivered promising results in a retrospective study (0203) based on approximately 700 medical procedures during a 10-year period in 328 children at Astrid Lindgren Children's Hospital (Sweden).

CT001 is based on a fixed combination of two well-known compounds, ketamine and sufentanil, 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. Most medication currently used for acute pain relief is not approved for use in children. The advantages of CT001 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

Cessatech's shareholders have pre-emptive rights: One (1) existing share held on the record date of October 25, 2022 entitles to one (1) unit right. Four (4) unit rights entitle to subscription of one (1) Unit consisting of six (6) new shares and three (3) warrants free of charge of series TO2.

New investors: New investors are offered the opportunity to subscribe for units without the support of unit rights.

Subscription period: October 27 – November 9, 2022

Subscription price: The subscription price is DKK 12 per unit, corresponding to DKK 2 per share. The warrants are issued free of payment.

Offering size: The offering comprises up to 9,168,802 new shares and up to 4,584,401 warrants of series TO2, corresponding to approx. DKK 18.3 million before costs. If the issue of units is fully subscribed and all associated warrants are eventually exercised, Cessatech will receive a capital injection totalling approx. DKK 45.8 million before costs.

Guarantees and subscription commitments: The Offering is 80 percent secured through subscription commitments guarantee undertakings.

Number of shares before the offering: 6,112,535

Ticker, ISIN: CESSA, DK0061411964.

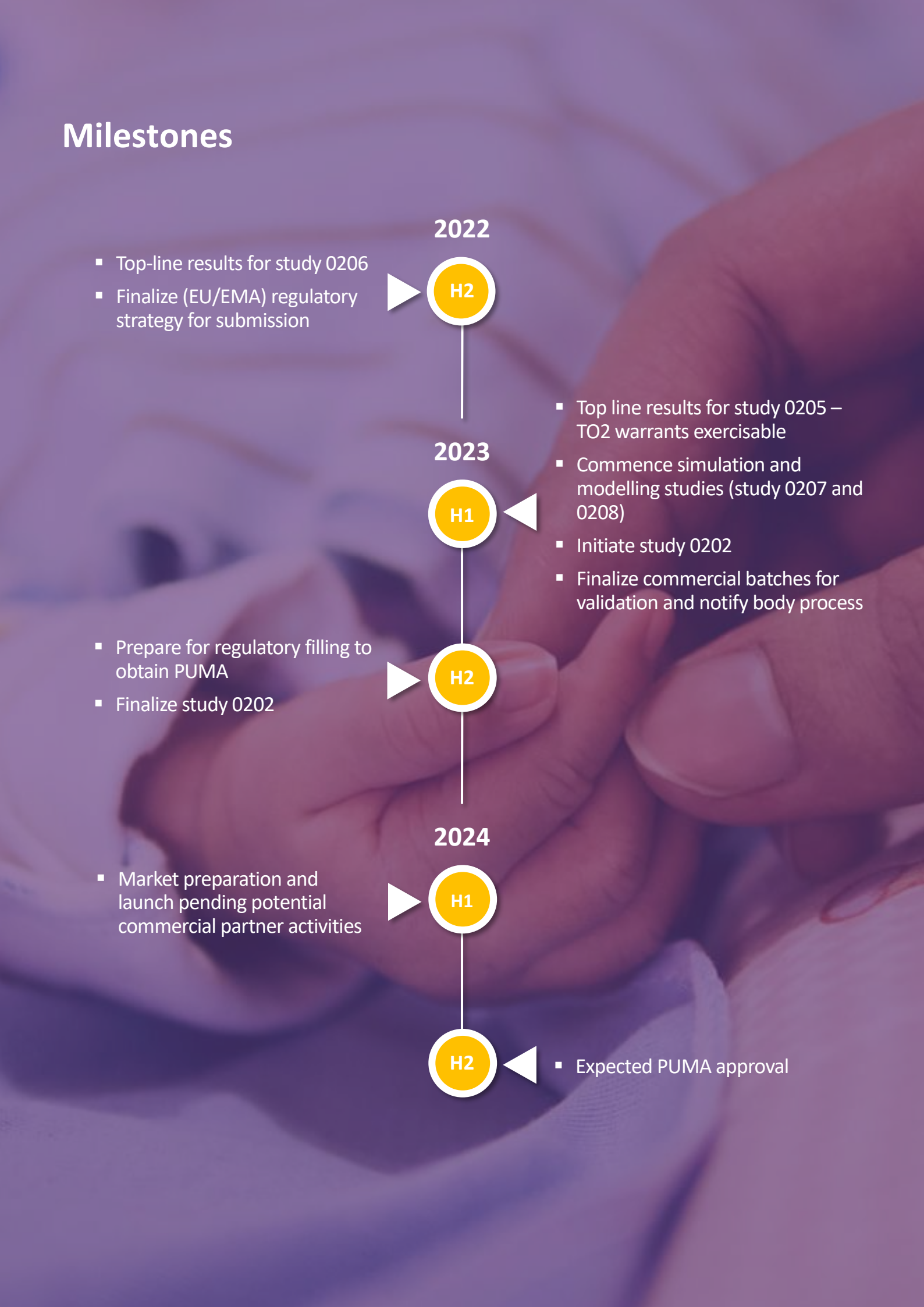
Summary of the consideration free warrants

Exercise period: The warrants will be exercisable after the announcement of the data from the Company's 0205 study, currently expected in Q2/Q3, 2023, or after the announcement of the Company's 2023 annual report, whichever is sooner.

Exercise price: The exercise price shall correspond to 70% percent of the VWAP of the Company's share price on Spotlight Stock Exchange at the time of exercise but at least DKK 2 and no more than DKK 6.

Ticker, ISIN: CESSA TO2, DK0061926888.

Milestones


2022
H2
Top-line results for study 0206
Finalize (EU/EMA) regulatory strategy for submission
2023
H1
Top line results for study 0205 – TO2 warrants exercisable
Commence simulation and modelling studies (study 0207 and 0208)
Initiate study 0202
Finalize commercial batches for validation and notify body process
H2
Prepare for regulatory filling to obtain PUMA
Finalize study 0202
2024
H1
Market preparation and launch pending potential commercial partner activities
H2
Expected PUMA approval

CEO, Jes Trygved comments

I am happy to report that until now, CT001 has met all its development objectives. With the initiation of the pivotal 0205 trial, we are now entering the final phases of development. This places Cessatech in the small group of late-stage Nordic biopharma companies.

We consider the 0205 study that just started *pivotal* because it is powered to demonstrate, with a high degree of statistical certainty, that CT001 is safe and effective as a treatment of procedural pain in patients, and superior to sufentanil and ketamine alone. As such, the 0205 study serves as the *de facto* phase III trial of the entire CT001 clinical program.

We expect to be able to report the results during Q2/Q3 next year. Concurrent with this trial, we will be launching several adjacent development activities. The two smaller simulation studies agreed with EMA called 0207 and 0208 are scheduled to be conducted in the first half of 2023. Here we use the information gained in the 0205 trial along with the other available data on CT001 to model and extrapolate the expected dosing and efficacy in children. No patients are enrolled in these studies.

The 0202 study is the last study in the development program. It will use all the dosing and pharmacokinetic information obtained from the previous trials to conduct an open-label, prospective study to assess safety, tolerability, analgesic effect, and feasibility of intranasal CT001 in 300 paediatric patients with moderate to severe pain. As per our agreement with EMA, this study is neither blinded nor placebo controlled. Rather, its objective is to obtain the final confirmation in a real prehospital care setting.

In short, we are getting closer to the finish line with CT001. Meanwhile, no real clinical progress in the treatment of acute and procedural pain in children has been reported by others since Cessatech went public almost two years ago. But it is our impression that there is a growing awareness of the detrimental effects of the continued widespread off-label use of medicine in children of all age groups. The treatment of acute- and procedural pain in children remains a significant unmet medical need. Everybody knows it's time to do something about it.

This indeed, is Cessatech's mission: To rethink 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.

I want to thank you for your support as we continue our journey. We promise to do everything possible to make it a success – especially 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