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rethinking child treatments

INTRO

We have had a good start of the year - we are progressing well with our activities and looking forward to an exciting year. We had many good questions related to our business progress and the Q1 Report.

Q1-2023 report is out

Link to full Report

Financial Report

Q1-2023

Study 0205 is progressing, with last patient expected in Q3
Protocol finalized for study 0202, ready for submission in Q2
Good progress with commercialization strategy

Comment from the CEO: *"During the first quarter of 2023 focus was on ensuring progress in our clinical activities. Having implemented actions to improve recruitment levels into our pivotal 0205 study we are now confident that recruitment will be finalized during Q3 with top-line results following shortly after. We also finalized the protocol of our 0202-safety study which we expect to submit to authorities for approval during the second quarter of this year. Additionally, we continued to work on our commercialisation strategy in both the EU and US for CT001 and look forward to moving our plans forward in this area in the coming time" says Jes Trygved, CEO*

Feedback on the Q&A session

Thanks for the many questions for our Q1 Q&A session, please see the replies below or use the link - Thanks for supporting us!

Cessatech Q1 Report - Q&A
Selected top 10 investor questions

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1.	**Last patient in study 0205 is expected to be in Q3, following top-line results shortly - what is defined as 'shortly'; is this weeks, months or?**	A: As it is only top-line results and not including biostatistical data, this should be within weeks (hopefully 4-7 weeks)	
2.	**Why is study 0205 a pivotal study, and what is meant with 'pivotal'?**	A: study 0205 is a blinded study, with comparator arms including placebo, and study 0202 has no comparator and more focusing on safety	
3.	**Is there a risk for a approval delay of study 0202 from ethics committee? Similar problem as for 0205?**	A: hopefully not as this will not be in Denmark and partly under the new EU CTIS system where timelines are fixed	
4.	**What is the long-term aspiration with Cessatech?**	A: within the next 5 years to become a company with 3-5 products in development and partly commercially engaged in selected regions	
5.	**When can we expect any news or progress on the pipeline and CT002?**	A: we have focused mainly on CT001, we wanted to prove that we are on track and close to finalization before we initiate more on the pipeline - and hopefully our future commercial setup will also accelerate this process	
6.	**What is your overall commercial business strategy?**	A: Ideally we want to be partly engaged in one major region, and completely out-license to other regions. We hope within the next 6 months to share details of our strategy	
7.	**Where are you in the process to receive a FDA roadmap for a US approval of CT001?**	A: We have had early meetings with the FDA, these have been positive and we are optimistic about a potential process	
8.	**Do you estimate that the current European CT001 clinical trials, will be sufficient for a US Approval? Or that FDA will require additional clinical trials done in the US?**	A: based on the early interaction with the FDA, we anticipate to use all European clinical trials in the upcoming FDA process. FDA will require some additional trials	
9.	**What is the biggest risk with the company?**	A: Even though CT001 has been studied in several clinical trials, there is always a risk with the last studies, but we are optimistic	
10.	**What is the biggest milestone in 2023, or are there several and what is timing of these?**	A: The study 0205 results in 2H of 2023 is a major milestone, but a successful commercial strategy could potentially be even much bigger...	

LEAD ASSET CT001:
AT LATE-STAGE DEVELOPMENT

Pipeline update

During 2023 we will give more updated on the remaining clinical trials and our accomplicements...

Teaching Old Drugs New Tricks
Gaps in peadiatric therapeutics often result in off-label use and specifically, novel uses for existing medications, termed "drug repurposing.

In 2022 the first patient was dosed in pivotal trial (0205) in adult patients - this trial investigates the postoperative analgesic efficacy of CT001.

Read full article

Find out more

Financials including Q1 results

Income Statement ('000)	Q2'22	Q3'22	Q4'22	Q1'23
Operating expenses	2.473	2.297	5.232	4.876
Staff expenses	1.467	955	1.390	785
Loss before tax	3.994	3.292	6.622	5.401
Net loss	3.319	3.319	5.370	4.365

Balance Sheet ('000)	Q2'22	Q3'22	Q4'22	Q1'23
Assets	22.323	20.047	28.187	21.526
Cash	17.846	15.001	23.343	16.422
Equity	20.228	17.744	23.855	19.762
Solidity rate	91%	89%	85%	92%

Cessatech management team

Jes Trygved
CEO

Helle Sickmann Bendixen
CLINICAL

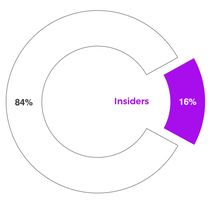
Martin Juhl
CMC & DEVICE

Louise Bak
REGULATORY LEAD

Shareholders

Management, Board of Directors and other Insiders.

Together currently hold **16%**



	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			

THERE IS AN UNMET NEED
FOR PAIN TREATMENT OF CHILDREN.

Studies show that of label use of medication is the rule rather than the exception and that 79% of the emergency rooms in Scandinavia use physical restraint on children.

Cessatech aims to meet that need – and the first product and lead asset, CT001, is a nasal spray for children aged 1-17 years that experience acute pain or pain related to medical procedures.

Drugs that are developed by Cessatech should be proven effective in adults and represent a medical unmet need in children where a good effect can be documented. Thus offering economic value creation by identifying and developing drugs with a short time to market and risk-reduced profile.

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