cessa tech
rethinking child treatments

Company Q&A

Q1-2023 Report | May 2023

Cessatech Q1 Report - Q&A

Selected top 10 investor questions

cessatech
rethinking child treatments

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 a potential 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…