

Welcome to Q1 2026

2025 has been a year of significant progress for Cessatech. Our work is dedicated to improving the treatment of acute pain in children, benefiting patients, families and healthcare professionals. Throughout the year, we have continued to advance our lead paediatric programme, and we enter 2026 positioned for what we expect to be a transformative year for the company.

All hands on deck to support the coming US launch

In the US, the collaboration with Vantis Pharma (commercial partner) and STAQ Pharma (manufacturing partner) is progressing well, and all efforts are focused on finalizing the marketing and training materials needed prior to the US launch.

The requisite development batches have been successfully produced, and stability studies are currently ongoing. This represents the concluding quality assurance step prior to market release. Note that for the US market, we are validating compliance against specific FDA requirements, which entail distinct acceptance criteria compared to the EMA framework. Upon confirmation of the final stability data from our manufacturing partner, the product can be released to hospitals.



STAQ PHARMA
Safety | Transparency | Availability | Quality

CT001 poster presentation at SPPM in Denver

In March 2026, the team will be in Denver at the Annual SPPM (Society for Pediatric Pain Medicine) meeting. The SPPM supports the goals of the Society for Pediatric Anesthesia to continually advance the quality of anesthesia care, perioperative management, and, in particular, the alleviation of acute and chronic pain-related conditions in children up to 21 years of age and young adults still in the transition of care to adult practice. During the meeting, the team will participate at a poster session with data from the Study 0202 for CT001.



Highlights from 2025

Relevant articles

There is still much new literature on the large unmet need in the paediatric setting. If you did not read the articles related to paediatric pain management we sharing during 2025, below is a short overview and link to the articles. Enjoy the reading.



DEC 2025: A newly published registry study from the Region of Southern Denmark highlights a clear dilemma in prehospital pain management for children

JUN 2025: A NIHR Open Research protocol (PANDA) is tackling an uncomfortable reality: despite best intentions, prehospital pain management for children is often ineffective

MAR 2025: Pediatric pain management is a constantly developing field. Despite extensive research, several studies have concluded that children's pain is still underestimated and undertreated.

[Link 2025 Articles](#)

MDR opinion and EMA Regulatory submission

In early 2025 we received a positive Notified Body opinion under MDR for CT001. The MDR opinion ensures medical devices with a drug component are safe and effective. The EMA reviews the drug part, while a Notified Body evaluates the device – and later in 2025 the Marketing Authorisation Application (MAA) for CT001 was submitted to the European Medicines Agency (EMA) for acute pain management in children. The regulatory review process is currently ongoing.

New CT001 Patents

In 2025, additional patents were granted for CT001, intended to further strengthen our market position. We secured another patent in the US and one in the Asia-Pacific region. We will continue to pursue our patent strategy in the coming years.

Welcome to Sarah

In November, we welcomed Sarah Margaux Toft-Jørgensen to our team, as our new Senior Director of Finance & Investor Relations. Sarah has a strong background within the life science industry and will be instrumental in our future journey.

Comment from the CEO, Jes Trygved - Looking ahead to 2026

"Reflecting on our journey, we are very pleased with the progress made throughout 2025 and are looking forward to an incredibly productive 2026.

I know many of our investors are eager for updates, particularly regarding our upcoming US launch. While we are currently focused on the final, intensive stages of bringing the product to market, we remain committed to our promise of increased communication as the year unfolds.

We are extremely busy laying the groundwork for this next chapter, both for US and also Europe and we appreciate your continued support and patience as we move toward these major milestones. Many thanks!"

About Cessatech

Cessatech is a pivotal-stage paediatric biotech company developing first-in-class specialty hospital medicines for children, focused on high-impact unmet needs in acute and emergency care. The company's lead program, CT001, is advancing toward near-term commercialization.

Cessatech operates an efficient, partnership-driven model, combining a lean, experienced team with best-in-class partners for development, manufacturing and commercial execution across key markets. Headquartered in Hellerup, Denmark.

Cessatech is led by a seasoned leadership team with a strong track record in drug development and product launches in Europe, the US and Asia.