

### Malmö 19 December 2025

**NEWSLETTER** 

# Toward a New Trajectory: The CEO's Reflections on Aptahem's 2025

# A Year of Transformation, Deepening Capabilities, and Global Positioning

Looking back at 2025, one thing is clear: this was the year when Aptahem truly began its transition from a promising Nordic biotech company into an organization with international presence, rigor, and ambition. We executed one of the most comprehensive advancement cycles in our history - scientifically, regulatorily, and strategically - with a single goal in mind: to bring Apta-1 to patients lacking effective treatment options.

This progress unfolded against the backdrop of an increasingly alarming global outlook. The World Health Organization's <u>report</u> in October on accelerating antibiotic resistance underscores the urgency for new mechanisms to prevent the fatal complications associated with infections, not least sepsis. This is precisely the clinical setting where Apta-1 is intended to make a meaningful difference, and that mission has guided every decision we made this year.

Below is a summary of what we achieved and how we are now taking the next critical steps into 2026.

## Clinical Progress, Strengthened Phase 2 Readiness, and Strong Potential

In 2025, we finalized the synopsis and preparations for our Phase 2 study. Our focus has been clear: to create the best possible conditions to demonstrate clinical proof of concept in patients with life-threatening inflammatory and coagulation-driven disorders.

Apta-1's unique mechanism of action - modulating uncontrolled coagulation and inflammation without suppressing the immune system, counteracting tissue degradation, and stimulating the body's own protective pathways - continues to set the molecule apart from both established and experimental therapies. The most obvious application is sepsis, which can arise whenever the immune system fails to control, for example, an infection. Effective treatment options remain largely unavailable, which is why sepsis so often results in death or severe morbidity.

A noteworthy market dynamic is that many so-called blockbuster drugs are nearing their patent cliff. The top 20 drugs losing exclusivity within the next three years currently generate more than USD 200 billion annually. Several of these address disease areas where we believe Apta-1 may have an important, and potentially superior, role to play. This trend should further increase interest in Apta-1.

## **Strengthened IP Position and Expanded Therapeutic Potential**

2025 was a strong year for our intellectual property portfolio.

- We filed a new U.S. provisional patent application covering expanded indications, based on encouraging preclinical findings suggesting relevance in neurodegeneration, oncology, fibrosis, and severe viral infections.
- We also secured significant patent approvals in Asia, including China and South Korea, further strengthening our global protection and commercial positioning.

This expansion not only makes Apta-1 more attractive for future partnerships, it positions Aptahem as an innovator with broad scientific potential, particularly important in the U.S. market, where IP strength is fundamental.



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# Manufacturing and Quality Assurance: A New Level of Scalability

Throughout 2025, we deepened our collaboration with Hongene Biotech to develop a more scalable and cost-efficient manufacturing process. We also confirmed that our previously GMP-manufactured clinical batch continues to exhibit excellent long-term stability. These impressive stability data enhance our ability to deliver clinical material of the highest quality and reproducibility. This is a strong signal to regulatory bodies, investors, and potential partners.

## Partnerships: Deepened Dialogues and Strengthened Confidence

In 2025, we sharpened and tailored our partnering materials, particularly our clinical synopsis, which was well-received. With these materials, we conducted a wide range of meetings at BioEurope Spring and Fall, BioJapan, and several oligo/aptamer-focused events, where interest in Apta-1 was both broad and serious.

Many of these interactions have progressed to confidential data exchanges, pre-inquiries, and continued requests for information. This clearly indicates that Apta-1 is viewed as innovative, relevant, and clinically compelling.

At the same time, it is evident that potential partners place significant value on patient-level clinical datamaking the execution of Phase 2 our most critical priority. The challenge of financing this next step led us to reevaluate where we could most effectively secure Phase 2 funding.

# A Strategic Shift Toward the United States - A Structural Breakthrough Year

Against this backdrop, the U.S. capital markets emerged as an increasingly relevant strategic path. One of our most important steps in 2025 was therefore initiating the preparatory work to potentially establish Aptahem on the U.S. capital market. The objective: to raise funding for the Phase 2 program, increase liquidity in our share, and secure long-term access to specialized life science investors.

### During the year, we:

- translated and restructured our financial and regulatory documentation into IFRS to meet U.S. investor and banking due-diligence standards,
- conducted multiple in-person work sessions in the U.S. with auditors, legal advisors, investors, and life-science-focused banks,
- initiated dialogues with U.S. clinical CROs regarding study timelines, regulatory guidance, and preliminary budget estimates,
- took key preparatory steps in the FDA process, including an application to the PreCheck program,
- and built a network of relevant U.S. stakeholders ahead of the next phase.

These steps form the foundation of our U.S. ambitions, and the work continues. In January, we will participate in the J.P. Morgan Healthcare Conference in San Francisco, the world's leading platform for life science financing. Several follow-up meetings are already scheduled with U.S.-based counterparts.

# Operational Development and a New Base at Medeon

Effective January 1, 2026, Aptahem will relocate to Medeon Science Park in Malmö. This move places us in an internationally oriented innovation environment with strong research, business, and lifescience focus which is an excellent fit for our current trajectory.



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## Capital Raising, Cost Discipline, and Shareholder Support

During the year, we completed two financings totaling more than SEK 10 million. These resources, and your continued confidence, were essential in enabling the strategic progress we have made.

At the same time, we optimized the organization to minimize costs and maximize agility. We have scaled down, streamlined operations, and reprioritized to ensure that every krona is invested where it creates the most value.

## Looking Ahead to 2026: A Year of Opportunity and Critical Steps

As we enter 2026, we do so with determination. Our key focus areas will be:

- advancing the process toward a potential U.S. market presence,
- deepening partner dialogues,
- preparing to launch the Phase 2 study,
- and continuing to manage our resources with prudence and precision.

Our goal is to create a steadily rising value trajectory where science, capital strategy, and business development reinforce one another.

We remain mindful that markets and regulatory processes can shift, but we enter 2026 stronger and better positioned than just one year ago.

### **Closing Reflections**

I would like to express my sincere gratitude to our shareholders, partners, advisors, and our dedicated team. 2025 was the year we adjusted our course and 2026 will be the year we accelerate.

We are building something that has the potential to transform the treatment of some of the world's most acute medical conditions. And we are doing so with the conviction that Apta-1 can play a meaningful role in the future of critical care.

With warmth and optimism, I wish you a peaceful holiday season and a prosperous New Year.

Follow us at aptahem.com or our social media, LinkedIn and Facebook.

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Mikael Lindstam CEO, Aptahem AB