Aptahem

Mangold Insight – Commissioned Research – CEO Interview – 25 March 2025

Mangold Insight follows up on the previous interview with Mikael Lindstam, CEO at Aptahem, from BIO-Europe in Milan. In this interview, Mikael explains in more detail about the potential of its drug candidate Apta-1, the coming phase 2 study, and the next steps.

See the previous interview here: https://youtu.be/AgdQzp85SC4

Following recent press release about Apta-1's planned Phase 2 study and recent BIO-Europe partnering event, can you provide more insight into the rationale behind the study design?

Absolutely, Apta-1 is a unique immunomodulatory and anti-thrombotic therapy with broad potential across acute inflammatory and coagulation-related conditions. Our decision to structure the Phase 2 study as a basket trial that includes several different patient populations comes from extensive discussions with leading clinical experts and regulatory authorities. This design allows us to evaluate Apta-1's efficacy and safety across multiple indications simultaneously, providing a comprehensive understanding of its therapeutic potential.

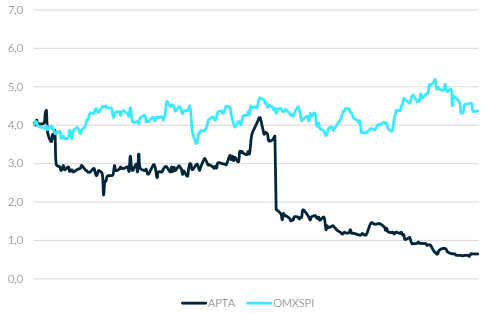
How has engagement with potential pharmaceutical partners influenced your clinical strategy?

These discussions have been invaluable, and interest has been reiterated during last week´s BIO-Europe partnering event in Milan. Large pharma companies are particularly drawn to the versatility of Apta-1 and its broad range of potential applications. Their input has reinforced our focus on generating robust, actionable data through a well-structured trial design which we reported about last week. This collaborative feedback has helped us align and confirm our study design with expectations of the industry and regulatory agencies, enhancing Apta-1's attractiveness for future partnerships and commercialization.

Could you expand on how the study will be structured beyond the planned basket study?

Certainly, it is essential to conduct a broad evaluation of Apta-1 across multiple indications. This initial open-label trial will help us identify disease areas where Apta-1 shows promise. Following these initial signal seeking studies, we plan to move forward with a double-blind, randomized and placebo-controlled study. This two-tiered approach not only deepens our understanding of Apta-1's potential across diverse conditions but also ensures that subsequent studies are targeted, statistically robust, and capable of supporting future regulatory submissions as well as a timely potential market entry.

Information	
Price (SEK)	0,65
Market value (MSEK)	8,1
No. of shares (M)	12,5
Free float	82,3%
Ticker	APTA
Next earnings report	2025-05-31
Website	aptahem.com
Analyst	Jan Glevén



Price performance %	1m	3m	12m
APTA	-17,7	-43,2	-84,1
OMXSPI	-4,0	4,7	2,8

Ownership Structure	Capital %
Investment Balticum	8,1
Avanza Pension	7,3
Tuvedalen Ltd	5,2
Ivar Nordqvist	3,6
Fenja Capital	2,8

Conflicts of interest Mangold	
Ownership own stock	Yes
Liquidity guarantor	Yes
Advisor publ transactions 12m	Yes

The press release mentioned key therapeutic areas where Apta-1 could be impactful. Could you provide additional details on the significance of these indications?

Certainly, we are targeting acute urogenital diseases, acute kidney injury, pulmonary diseases like ARDS, coagulation disorders, and acute inflammatory conditions—all areas with significant unmet medical needs. For instance, acute kidney injury (AKI) has limited treatment options and high morbidity; our preclinical data indicate that Apta-1 could stabilize kidney function by reducing inflammation and micro-thrombosis. Similarly, ARDS remains an area with critical medical need, particularly considering the ongoing challenges highlighted during the COVID-19 pandemic. By modulating both immune and coagulation responses, Apta-1 has the potential to improve patient outcomes across these conditions.

You also touched on the potential in rare and orphan indications. What opportunities do you see in this space?

The orphan drug market is expanding rapidly, driven by strong incentives for developing treatments for rare diseases. Apta-1 holds promise in conditions like atypical hemolytic uremic syndrome (aHUS) and ANCA-Associated Vasculitis (AAV), where dysregulated coagulation and inflammation are key challenges. Achieving orphan drug designation in these areas would offer regulatory advantages such as market exclusivity and accelerated approval pathways, helping us expedite patient access and achieve faster market introduction.

How does Apta-1's mechanism of action align with its potential to prevent sepsis?

Although the study is not directly targeting sepsis, many of the conditions we are investigating can progress to sepsis if not being managed effectively. By addressing early imbalances in inflammation and coagulation, Apta-1 has the potential to reduce the risk of sepsis development. This preventative aspect is a crucial differentiator, as it underscores the drug's ability not only to treat but also to avert the severe complications associated with these acute conditions.

What are the next steps for Apta-1's clinical development?
Our immediate focus is on finalizing the study protocol in collaboration with our clinical experts, investigators, and regulatory authorities. As mentioned, we will start with an open-label basket trial to allow a broad evaluation of Apta-1 across multiple indications. This will be followed by a controlled study with a placebo arm for the most promising indications, ensuring that we obtain high-quality comparative data. Concurrently, we continue to engage with potential pharma partners and investors to secure the necessary resources for efficient study execution. The outcomes of these trials will be pivotal in shaping the subsequent phases of development and determining Apta-1's commercial trajectory.

Finally, what excites you most about Apta-1's future?
The potential impact on patient care is incredibly exciting. We are developing a drug that could fundamentally transform the treatment of acute inflammatory and coagulation-related conditions. With promising preclinical and early clinical data, Apta-1 is poised to become a first-in-class therapy that not only meets significant unmet medical needs but also holds the promise of substantial market presence. This translates into improved outcomes for patients who currently have limited treatment options.

Thank you for your time and insights. We look forward to following Apta-1's progress.

Thank you, we are enthusiastic about what the future holds for Apta-1.

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Increase – 10-20 percent upside in the stock
Neutral – An upside and downside of the stock of 0 to 10 percent
Decrease – A 10-20 percent downside in the stock
Sell – At least a 20 percent downside in the stock
Not rated – Rating temporarily unavailable