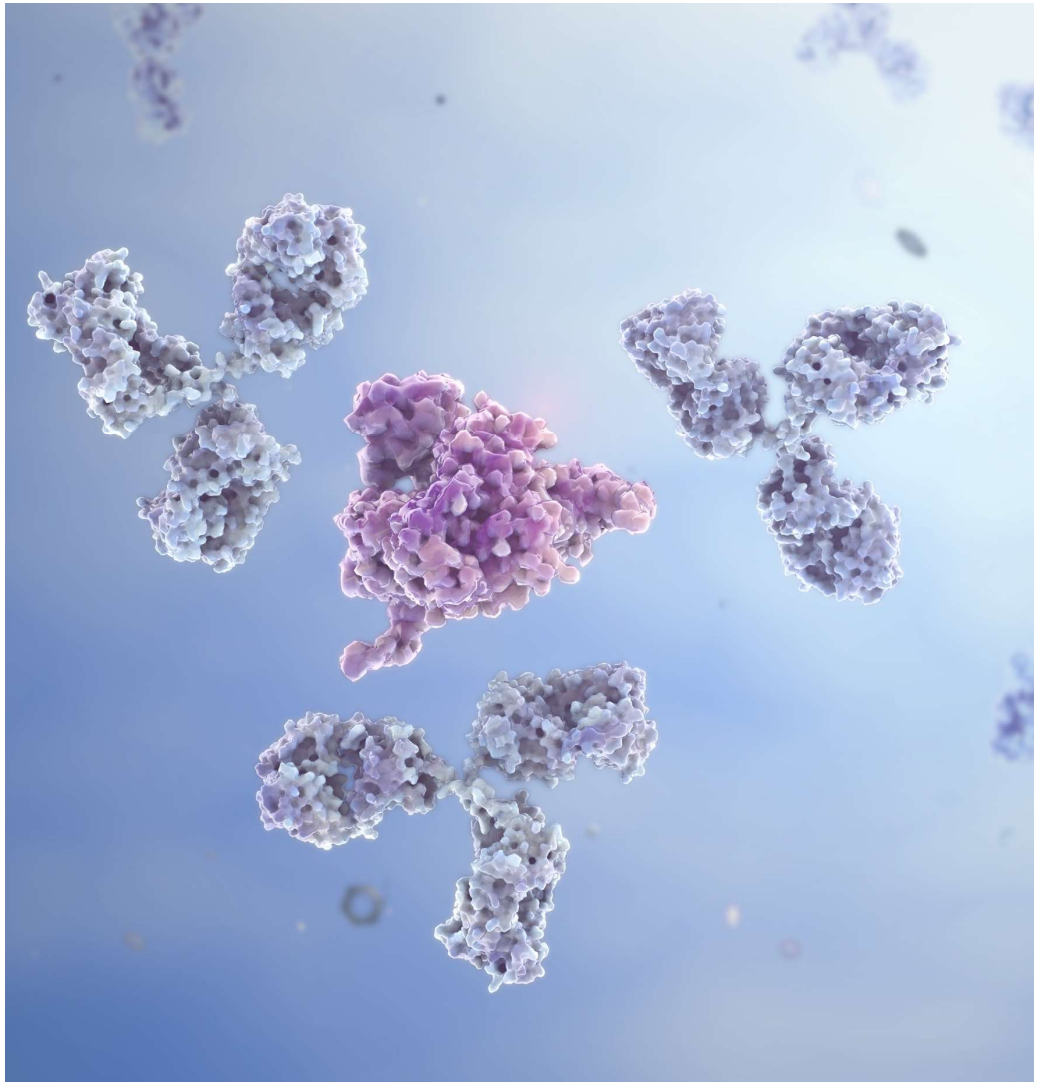
HANSA BIOPHARMA

# Interim Results
# January - September 2025

**October 30, 2025**



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This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations or that of its affiliates or subsidiary companies. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

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# Q3 2025 Results Conference Call Agenda

**30 October 2025**

| | |
|---|---|
| **CEO Remarks** | **Renée Aguiar-Lucander**<br>**CEO** |
| Operational Update | Maria Törnsén<br>COO, President US |
| Pipeline Update | Richard Philipson<br>Chief Medical Officer |
| Financial Results | Evan Ballantyne<br>Chief Financial Officer |
| Close and Q&A | Renée Aguiar-Lucander<br>CEO |

# Key Achievements in Q3 2025

## Transformation of the Business

**Successfully addressed the company's reporting and capital structure**

**Bolstered leadership team**

**Successfully met Phase 3 primary endpoint**
in US ConfIdeS trial in kidney transplantation. Demonstrating a highly statistically significant, and clinically meaningful difference in eGFR at 12 months.

## Commercial & Pipeline Update

**IDEFIRIX sales YTD 102% of 2024 sales**
YTD 143.6 MSEK, increase of 25.4%.
Q3 30.1 MSEK vs 39.8 MSEK Q3 24.
Initiatives planned to accelerate growth in Europe in 2026.

**Clinical data in gene therapy**
Three patients with DMD treated with imlifidase prior to administration of Sarepta's ELEVIDYS. Reduction in anti-AAV antibodies of > 95%. No new safety signals were observed in the trial.

# European Commercial Operations Review

| Challenging Backdrop | | Large Growth Potential |
|---|---|---|
| • Limited clinical data available<br>• Few European sites involved in Phase 2 trial – very limited KOL experience | | • Organizational structure reviewed for accountability, focus and efficiencies |
| • Need for drafting and implementation of guidelines<br>• Long & complex reimbursement<br>• National organ allocation systems | Action | • Investment in systems, KPIs, reporting and training |
| • Large clinical study initiated at 23 European sites - 50 patient transplant trial<br>• Broad rather than focused approach | | • Focus on dissemination of clinical data, delisting education, best practice and peer to peer interactions |

# USA Market Overview

Large and robust clinical trial data available pre-launch
Significant KOL experience

Data read out from PAES study
Real world data from Europe

Price set by company based on research and setting
Centralised organ allocation system

Well researched and structured launch plan
Strong market analytics capabilities

Strategic, focused approach
Base of 25 sites in Phase 3 with subsequent roll-out plan
100 clinics initial target

Active patient advocacy,
Strong kidney organizations
Physician demand

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# Q3 Performance impacted by seasonality and Germany pause of prioritized AM* program

## Performance

- Slower than expected due to few transplants during summer and impact of pause in German AM program
- No sales in Germany in Q3; expect continued negative impact in near- and mid-term
- Lack of local transplant protocols impact IDEFIRIX® usage in some key regions e.g. Andalusia (SP)

## Market Access

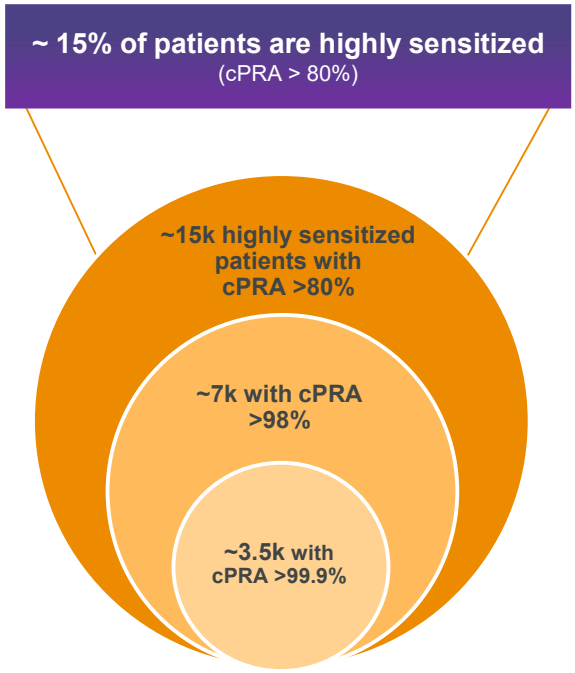
- National coverage in 21 countries (incl two international markets)
- >90% of European population covered by national reimbursement
- Regional reimbursement challenges in some major regions e.g. Catalunya (SP)

## Priority Activities

- Continued P2P education on guidelines and delisting practices
- Upcoming large European scientific event with ~80 KOLs
- Targeted public affairs and medical activities in Germany
- Focus on resolving regional market access challenges

 *AM=Accepted Mismatch

# The US Market Represents a Significant Opportunity




## US Transplant Waitlist

### The US represents a significant market opportunity

**~100,000**
on the wait list

**~45,000**
new additions to the wait list each year with highly sensitized representing 20%

**~10,000**
die or become too sick to transplant, with highly sensitized representing 25%

**7 years**
median wait time for an organ for highly sensitized patients

**~27,000**
transplants each year with diseased donor representing 80%



Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization

# Following positive ConfIdeS data, US Launch Planning Activities are ongoing

## US Represents a Significant Market Opportunity

- **~15,000 Highly Sensitized (HS)* patients** on the waitlist – each year ~2,500 HS patients pass away while waiting for a transplant, or become too sick to transplant
- Today, there are **3,500 patients with a cPRA ≥99.9%** on the waitlist
- **Half of patients with cPRA ≥99.9% wait more than 7 years for a transplant**
- **Dialysis is a burden for patients and a cost to Medicare** – Dialysis cost is ~$100,000/year and >80% patients who receive a transplant are alive at 5 years, compared to ~40% of patients on dialysis
- **No approved desensitization approaches** and very few centers try experimental desensitization approaches
- **Patients and transplant teams are waiting for an approved therapy** – Patient preference study shows that 61% of patients discuss desensitization with their physician

## US and European markets are different

- US has a **National Organ Allocation System** where HS patients are prioritized
- **Administrative efforts to improve transplant care** in the US – transplant outcomes, organ utilization
- **Kidney transplants are paid by Medicare** through DRG codes – Hansa will work with stakeholders to ensure adequate funding for HS patients, including outlier payments and NTAP**
- Hansa is entering the US market with significant imlifidase experience in top US transplant centers: **ConfIdeS centers represent 25% of total transplant market in the US**
- Small footprint required for US launch – 200 adult transplant centers, with **100 centers representing 80% of transplant market**
- **Current US team bring significant experience** in transplant, nephrology, hospital sales and leading US launches – future hiring efforts will bring in additional similar experience



Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization; * Highly Sensitized (HS) defined as cPRA ≥80% **NTAP = New Technology Add on Payment

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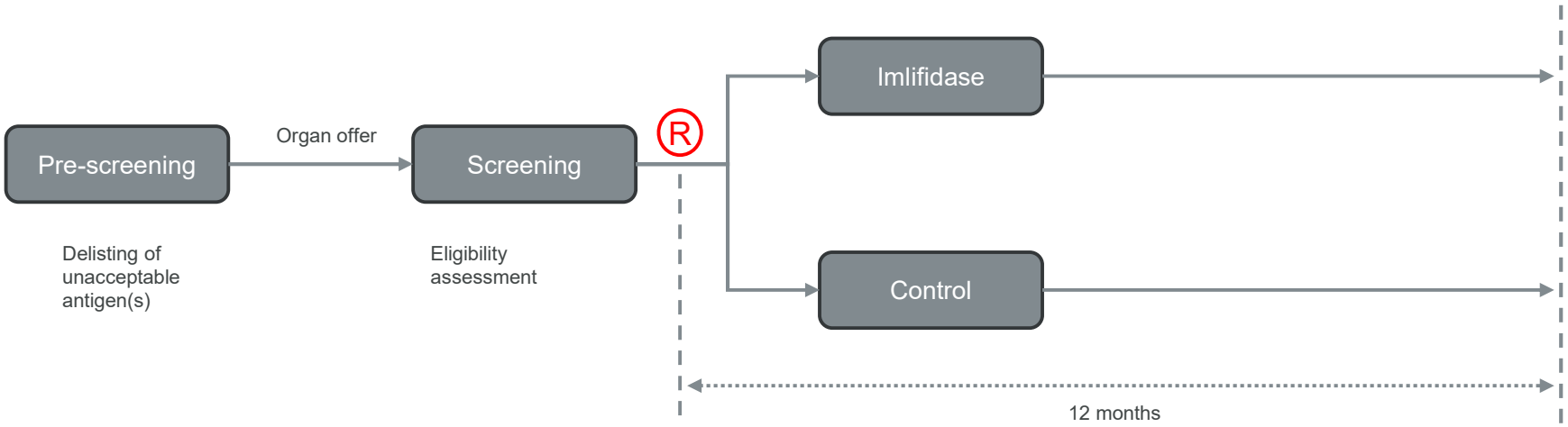
# ConfIdeS

***An open-label, controlled, randomized Phase 3 trial evaluating 12-month kidney function in highly sensitized (cPRA>99.9%) kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care***

**Renal function in highly sensitized patients 12 months after desensitization with imlifidase and transplantation of kidneys from deceased donors**

# Study Design




Imlifidase arm: accept organ offer; if treatment results in xm-conversion from positive to negative, then proceed to transplant

Control arm: EITHER accept organ offer, use non-approved desensitisation* and proceed to transplant, OR reject organ offer and wait for more compatible organ offer(s) later in the 12-month follow-up period

* institution-specific desensitisation protocol may include any combination of PLEX, rituximab and other anti-CD20 antibodies, IVIg and eculizumab

# Disposition and Demographics

| Disposition n (%) | Imlifidase (N=32) | Control (N=32) | Total (N=64) |
|---|---|---|---|
| | | | |
| **Randomized** | **32 (100)** | **32 (100)** | **64 (100)** |
| **Treated with imlifidase** | **30 (93.8)** | **0 (0)** | **30 (46.9)** |
| **Completed study** | **30 (93.8)** | **28 (87.5)** | **58 (90.6)** |
| | | | |
| **Sex, n (%)** | | | |
| Female | 18 (56.3) | 15 (46.9) | 33 (51.6) |
| Male | 14 (43.8) | 17 (53.1) | 31 (48.4) |
| | | | |
| **Age, (years)** | | | |
| Mean (SD) | 45.8 (12.3) | 44.7 (12.5) | 45.3 (12.3) |

# Efficacy Outcomes

| | Imlifidase n | Control n | Imlifidase eGFR (mean) | Control eGFR (mean) | p-value |
|---|---|---|---|---|---|
| Primary endpoint eGFR at 12 months in FAS | 32 | 32 | 51.5 | 19.3 | <0.0001 |
| Rank-based non-parametric analysis of eGFR at 12 months | 32 | 32 | 50.0* | 0* | 0.0001 |
| eGFR at 12 months in patients transplanted based on organ offer at randomization | 27 | 3 | 59.3 | 23.1 | 0.0138 |

*Median

- At 12 months, mean eGFR was 51.5 mL/min/1.73m$^2$ in the imlifidase arm vs 19.3 mL/min/1.73m$^2$ in the control arm with a statistically significant and clinically meaningful difference of 32.2 mL/min/1.73m$^2$ **(p<0.0001)**
- A key secondary endpoint of dialysis dependency at 12 months was statistically significant **(p=0.0007)** in favor of imlifidase

# Safety Outcomes in Imlifidase-Treated Patients

- **Tolerability of imlifidase was good**
  - There was a low incidence of infusion reactions, and no infusions were interrupted due to an infusion reaction
- **Infections observed in imlifidase-treated patients were typically not related to treatment**
- **The AE and SAE profile of imlifidase reflected a population of patients undergoing kidney transplantation**
  - Most SAEs were considered unrelated to imlifidase treatment

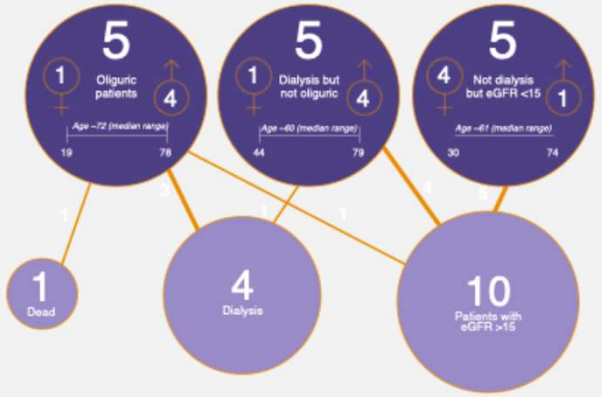
# ConfIdeS - Conclusions

- **The treatment arms were well-balanced** at baseline, and the demographic characteristics reflected a highly sensitised, dialysis-dependent population wait-listed for transplantation
- **Retention in the study was excellent**; 58/64 patients (90.6%) completed the study
- **The primary endpoint was statistically significant** and showed a clinically relevant difference
  - At 12 months, mean eGFR was 51.5 mL/min/1.73m$^2$ in imlifidase arm vs 19.3 mL/min/1.73m$^2$ in the control arm ($p<0.0001$)
- **The tolerability of imlifidase was good**, and the safety profile was consistent with previous clinical trial experience, reflecting a population of patients undergoing kidney transplantation

# GOOD-IDES-02 Phase 3 Trial Top Line Data Expected in Q4 2025

## Results from Phase 2 Study Results Published in JASN (2022)

10 out of 15 patients were dialysis independent after six months vs. the historical cohort, where only 18% had functioning kidney




**Imlifidase granted orphan drug designation by US FDA and EMA**

## GOOD-IDES-03 Open Label Phase 3 Trial

- Fully enrolled 50 patients from 30+ centers in US, UK and EU
- Primary endpoint: eGFR at 6 months
- Key secondary endpoint: proportion of patients with functioning kidney at 6 months
- Other secondary endpoints: anti-GBM Ab levels; other measures of kidney function (e.g., CrCl); safety
- 25 patients were randomized to receive imlifidase in combination with SOC and 25 patients received only SOC

SOC: Standard of Care consisting of a combination of immunosuppressives, glucocorticoids, and plasma exchange,


Ohlin et al. JASN (2022)
Journal of the American Society of Nephrology https://pubmed.ncbi.nlm.nih.gov/35260419/
McAdoo et al.: Patients double-seropositive for ANCA and anti-GBM antibodies have varied renal survival, frequency of relapse, and outcomes compared to single-seropositive patients. Kidney Int 92: 693–702, 2017

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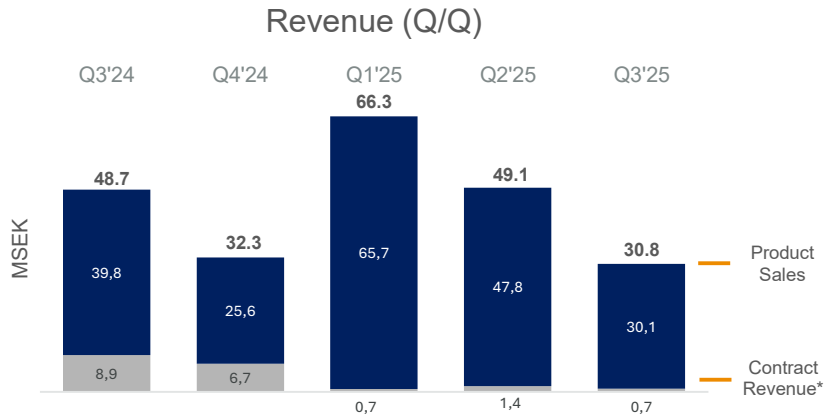
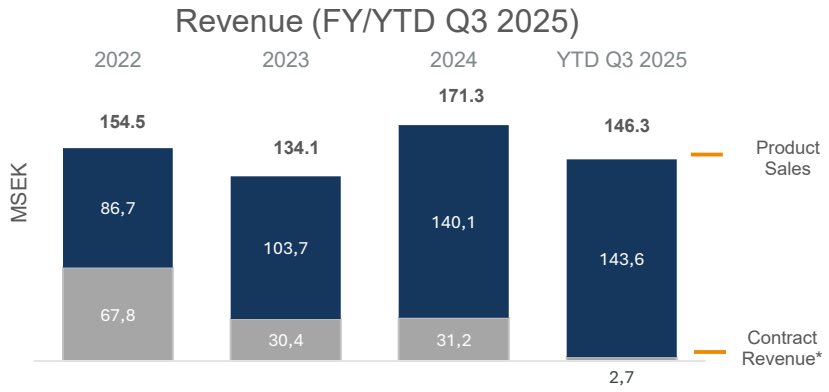
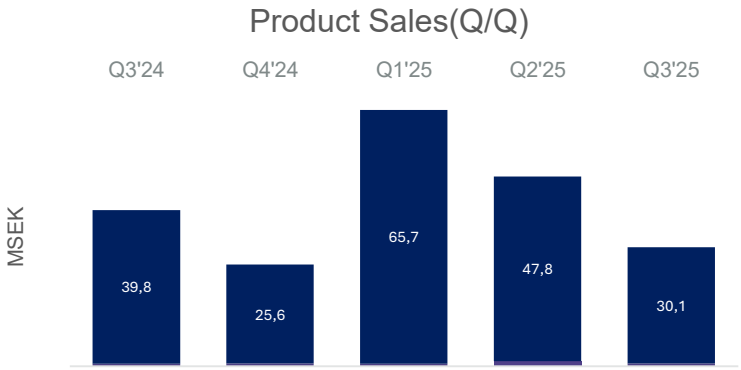
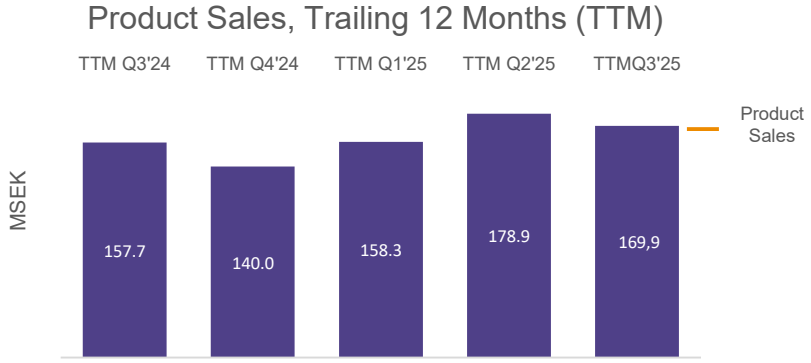
# Q3 & YTD 2025 IDEFIRIX Sales Performance



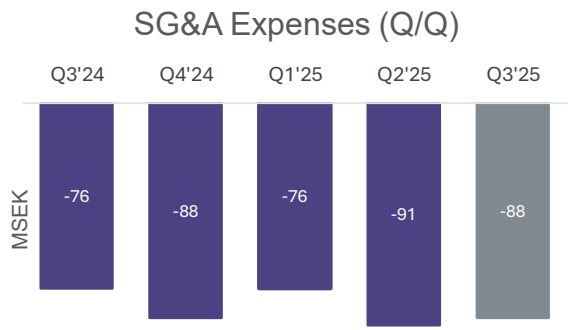



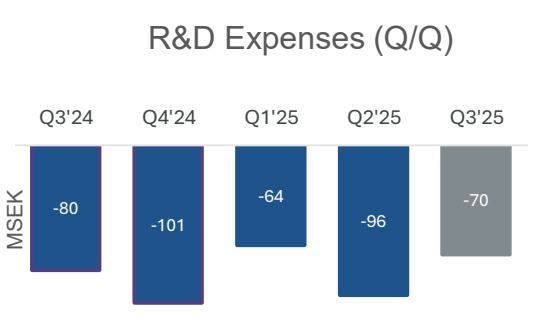



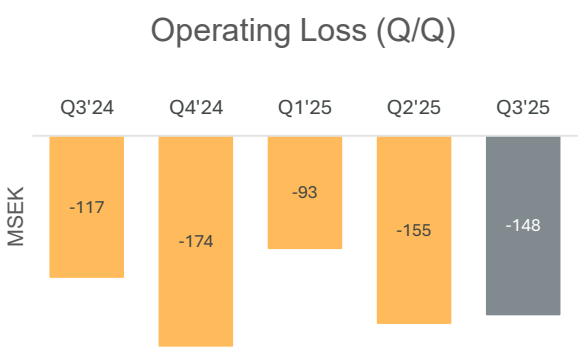



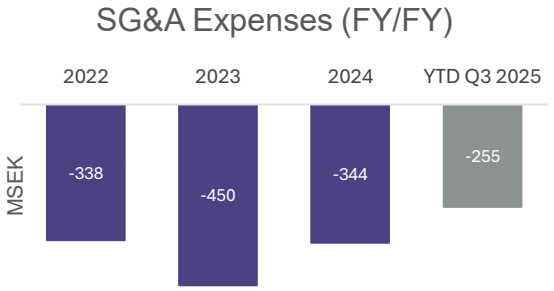

*Contract revenue from agreements with Sarepta, AskBio & Axis-Shield

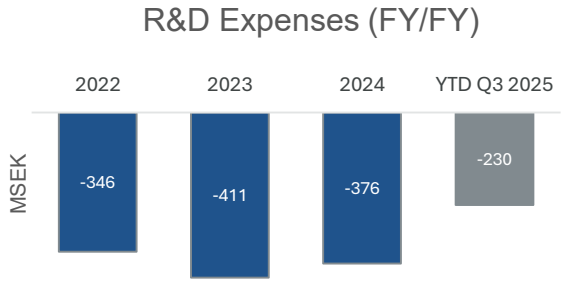
# Continued investments in R&D and commercialization

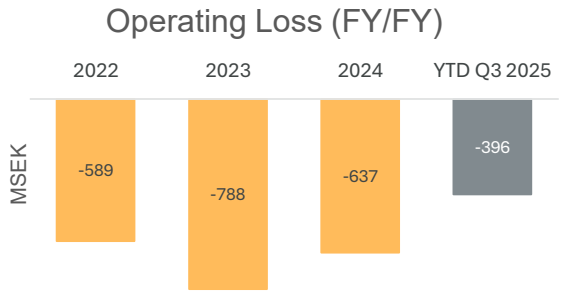


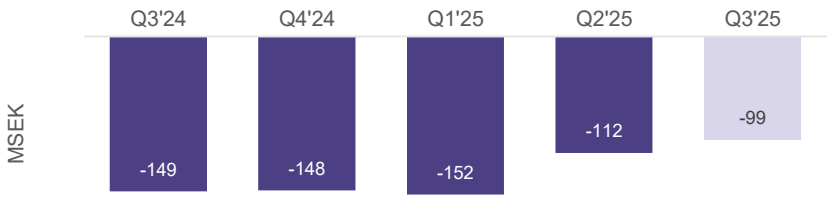



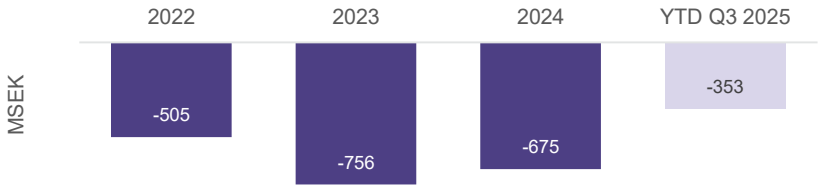



# Summary of Cash & Headcount

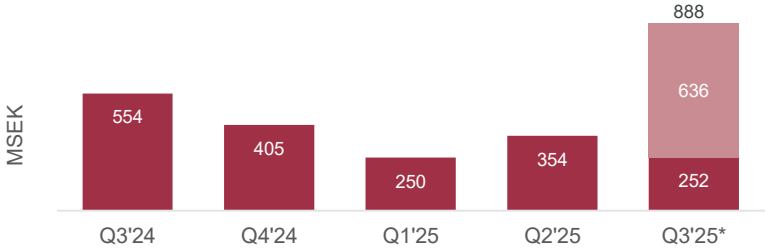
## Operating Cash Flow (Q/Q)




## Operating Cash Flow (FY/FY)

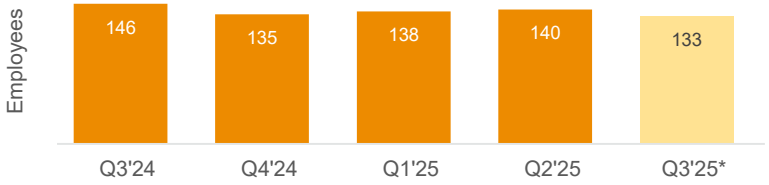



## Cash & Cash Equivalents (Q/Q)




** Pro-forma cash is 888 MSEK including net proceeds from the October 1st capital raise*

## Number of Employees (Q/Q)




** Pro-forma headcount is 116, including 17 employees currently serving notice periods related to the Q2 restructuring actions*

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# Highly experienced leadership team

Proven track record delivering growth, approvals, and launches across renal, rare disease, and immunology

## Renée Aguiar-Lucander

*CEO*

20+ yrs rare disease leader and former investor, took Calliditas to NASDAQ and a $1.1bn exit

## Evan Ballantyne

*CFO*

Veteran biotech CFO with significant public company financing and M&A experience

## Hitto Kaufmann, PhD

*Chief Scientific and Technology Officer*

20+ years of immunology drug development from Sanofi and Boehringer Ingelheim

## Frank Bringstrup

*Global Regulatory Affairs*

Successfully filed several BLAs during his tenure with Novo Nordisk

## Maria Törnsén

*COO, President US*

Successfully launched multiple orphan drugs in the US. Previous roles at Calliditas, Sarepta Therapeutics, Sanofi Genzyme and Shire plc

## Richard Philipson, MD, PhD

*Chief Medical Officer*

Four approvals over 25+ years incl. rare disease & gene therapy; senior roles at Calliditas, GSK and Takeda

## Brian Gorman

*Chief Legal Officer and Corporate Secretary*

Seasoned life-sciences lawyer at Sinclair, Calliditas, Endo, AstraZeneca; led acquisitions, integrations and global expansion

## Sandra Frithiof

*Chief Human Resources Officer*

25 years of experience in human resources in different industries.

# Q&A


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