

Q3 report

November 24, 2021

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Oncopeptides is a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary peptide-drug conjugate (PDC) platform to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug coming from the PDC platform, Pepaxto® (INN melphalan flufenamide), also called melflufen was granted accelerated approval in the U.S., on February 26, 2021 in combination with dexamethasone, for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Oncopeptides voluntarily withdrew the drug from the U.S. market on October 22, 2021, due to worse overall survival data in the phase 3 OCEAN study. The study was a post-approval requirement under the accelerated approval program. Oncopeptides is developing several new compounds based on the PDC platform. Melflufen is not approved by any other registration authorities.

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Participants



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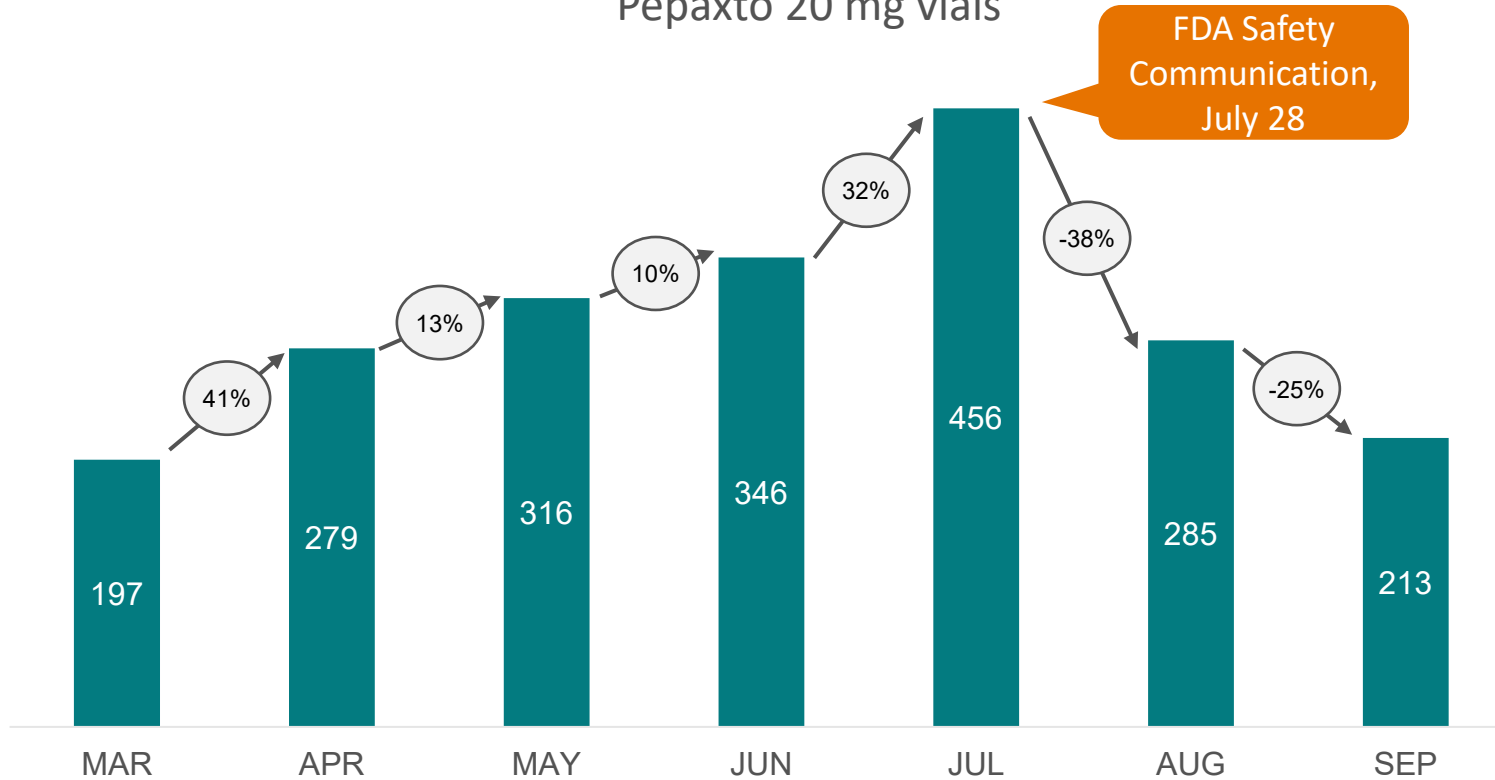
Highlights Q3

- Q3 net sales of SEK 54.3 M (USD 6.3M) and YTD net sales of SEK 140.0 M (USD 16.5M)
- Melflufen met the primary endpoint of superior PFS in phase 3 OCEAN study
- FDA requested a partial clinical hold of all clinical studies with melflufen on July 8
- FDA issued safety communication on July 28
- FDA announced an upcoming ODAC meeting scheduled for October 28
- OCEAN data presented at the IMW meeting on September 11



Double digit growth through July until FDA safety communication

Monthly demand growth
Pepaxto 20 mg vials



Rationale behind withdrawal of Pepaxto from the US market

USA - FDA

According to the FDA, based on the Overall Survival Hazard Ratio of 1.104 in the ITT population, Pepaxto should not be commercially available in the market until further studies have been conducted



Near-term objectives



Focus on R&D and European approval

➔ Refocus the company

- Dedicate resources on a more focused clinical development program of melflufen
- New management structure and organization
- Further develop the next generation of drug candidates coming from the PDC platform in collaboration with the FDA and EMA

➔ Support EMA filing

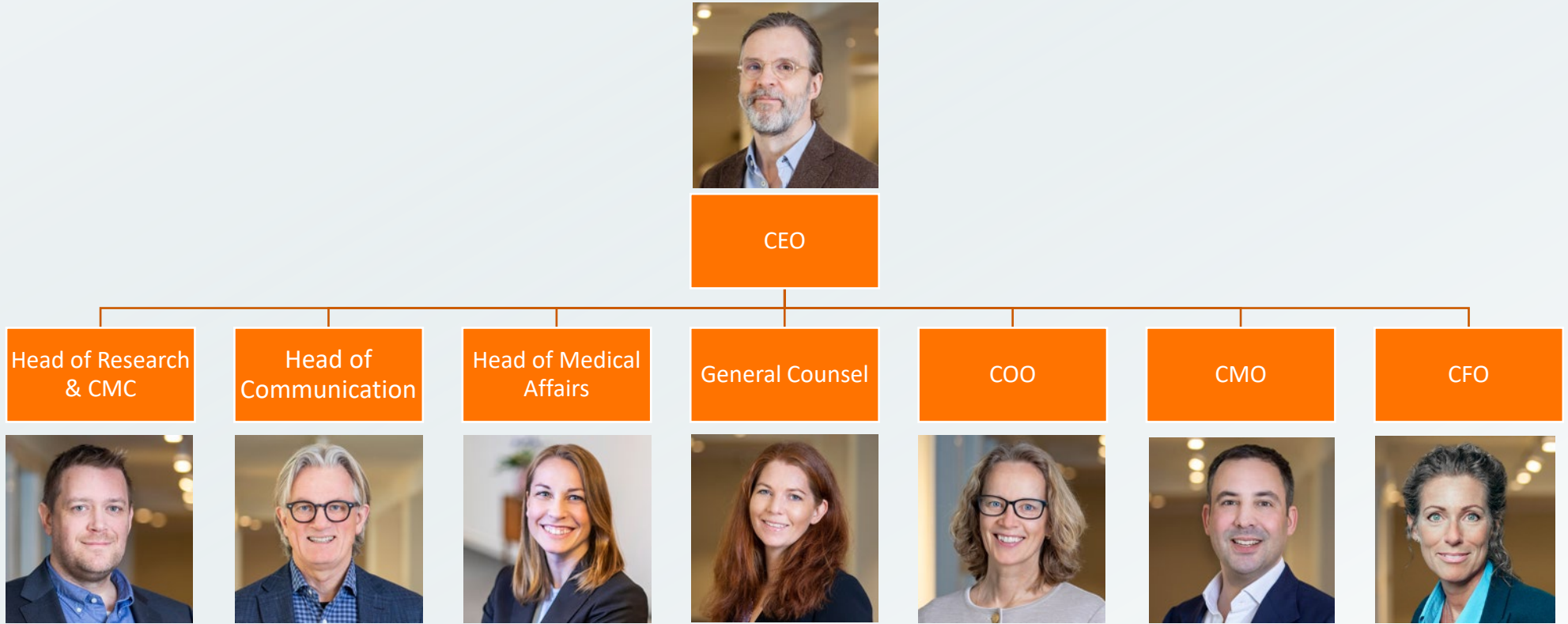
- To fulfil all requirements for a potential Conditional Marketing Authorization of melflufen in the EU

Secure cash runway

➔ Refocus on R&D

- Close of commercial organizations in US and EU (appr. 135 employees leaving)
- Significantly downsize the Sweden based HQ organization (appr. 70 employees are affected)
- Company focused on clinical development of PDC platform and EMA filing

New Executive Leadership Team





Clinical development and regulatory pathway

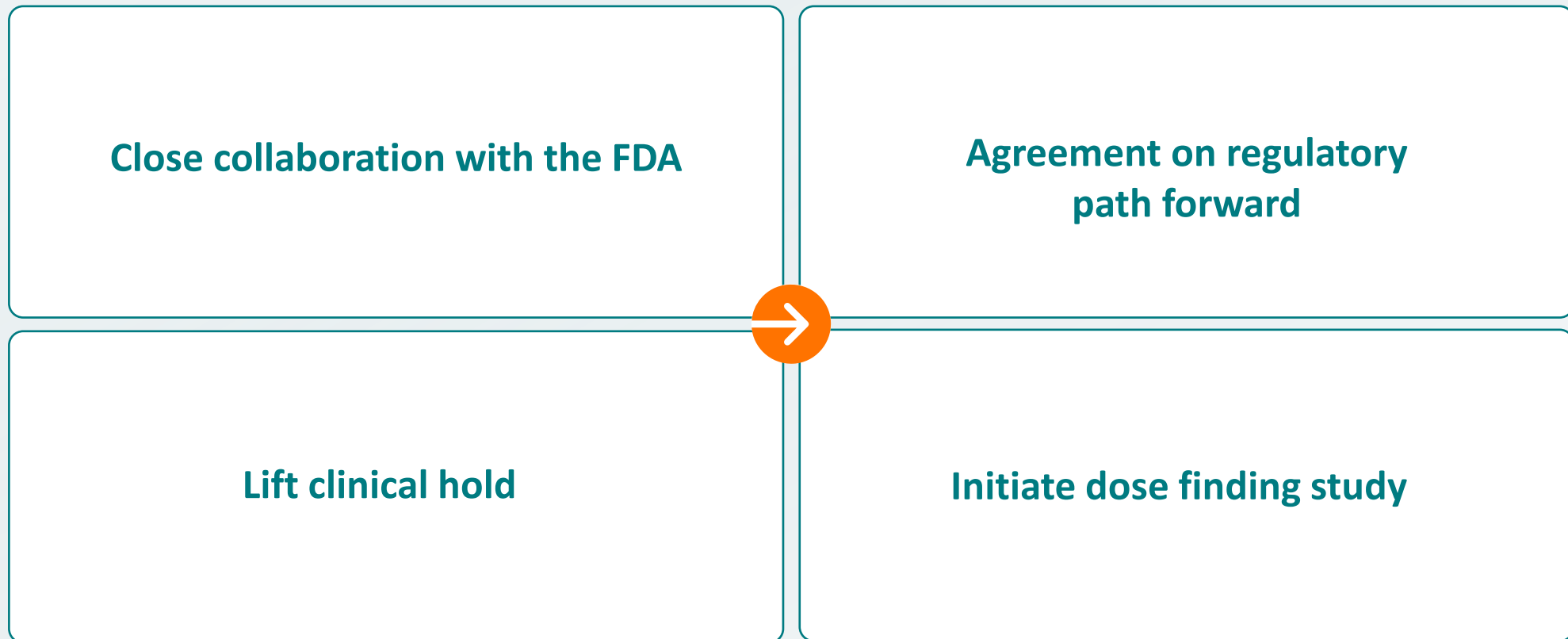
Klaas Bakker, CMO

Focused clinical development program

- OCEAN - continues with long-term follow-up and documentation
- PORT and BRIDGE - Patient recruitment completed. Studies closed with relevant scientific data
- ANCHOR - close without 10 patients in the bortezomib + melflufen study arm. Data sets will be large enough to draw relevant scientific conclusions
- ASCENT, COAST and LIGHTHOUSE - close with incomplete number of patients. Not possible to draw any relevant scientific conclusions

Oncopeptides is committed to provide patients continued access to melflufen via compassionate use if deemed appropriate by their treating physician and if local rules and regulations allow.

Agreement with FDA on path forward for clinical program



EMA filing: CHMP opinion for melflufen

Ongoing dialogue with the European Medicines Agency, EMA

Fulfil all requirements for a potential Conditional Marketing Authorization of melflufen in the EU



Recruitment to Early Access Program in Europe ongoing

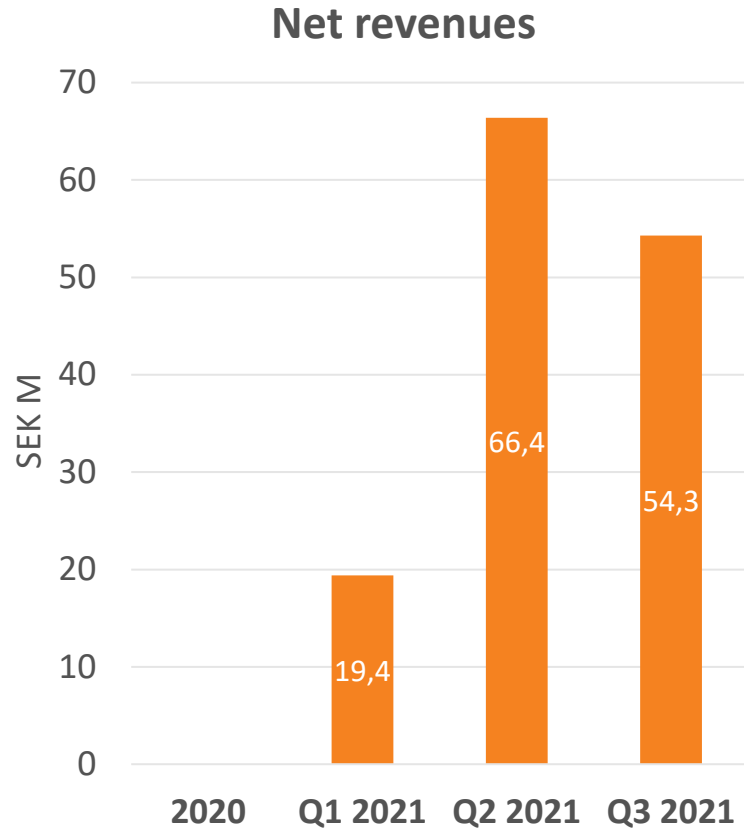
Market access preparations in Germany continues



Financials

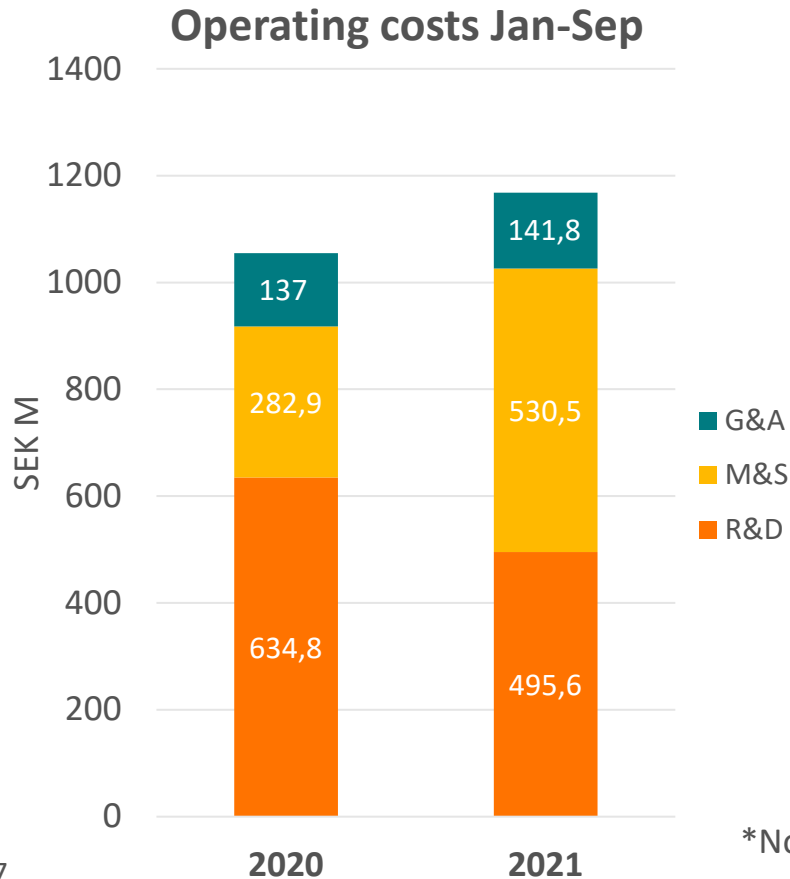
Annika Muskantor, CFO

Quarterly net revenues 2021




- Net revenues YTD amounted to SEK 140.0 M (-)
 - Whereof SEK 54.3 (-) in Q3
 - Gross margin YTD of 75%; 42% in Q3
 - Sales started off well in Q3, but decreased after the FDA Safety Communication on July 28
 - Gross margin 42% in Q3 and 75% Jan-Sep, driven by the withdrawal of the product

Financial results for the Jan-Sep 2021 period



- Operating loss YTD SEK 1 031.1 M (loss: 1079.7)
 - R&D decreased primarily due to less cost in Ocean- and Horizon projects
 - OCEAN YTD SEK 109 M (247)
 - Increase in M&S driven by build-up of commercial- and medical affairs
 - Number of co-workers increased to 321 (232) as of Sep 30
- Cash flow from operating activities YTD neg. SEK 1 069.9 M (neg. 939.3)
 - Where of - 336.5 (-340.8) M in Q3
- Cash position was SEK 671.3 M (1 251.6) as of Sep 30, 2021
 - Loan facility with EIB under discussion

*Nonrecurring restructuring costs do not materially impact Q3 



Summary

Jakob Lindberg, CEO

Cash runway through 2022

- Company estimates a cash runway through at least 2022
- We have done what we promised
 - US commercial organization closing during Q4
 - European commercial organization closing during Q4
 - Negotiations with unions at Sweden based HQ are in final stage
 - Closing of the following clinical studies ongoing; PORT, BRIDGE, ANCHOR, ASCENT, COAST and LIGHTHOUSE. The OCEAN study will remain open to allow for long-term follow-up
 - Non-recurring costs relating to restructuring to impact Q4

Summary and next steps

- Withdrawal of Pepaxto led to refocus on R&D
- Three near-term priorities
 - Secure cash-runway
 - Agreement on regulatory path with the FDA for the PDC-platform
 - EMA filing: CHMP opinion for melflufen
- Measures to preserve cash → cash runway through 2022
- Long-term strategy to be communicated in Q1 2022





Q&A



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