

# Q4 Report Webcast

February 17, 2022

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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



**Jakob Lindberg**

Chief Executive Officer



**Klaas Bakker**

Chief Medical Officer



**Annika Muskantor**

Chief Financial Officer

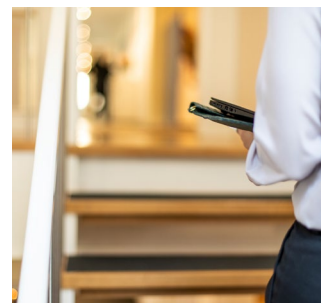


# Status update

Jakob Lindberg, CEO

# Highlights

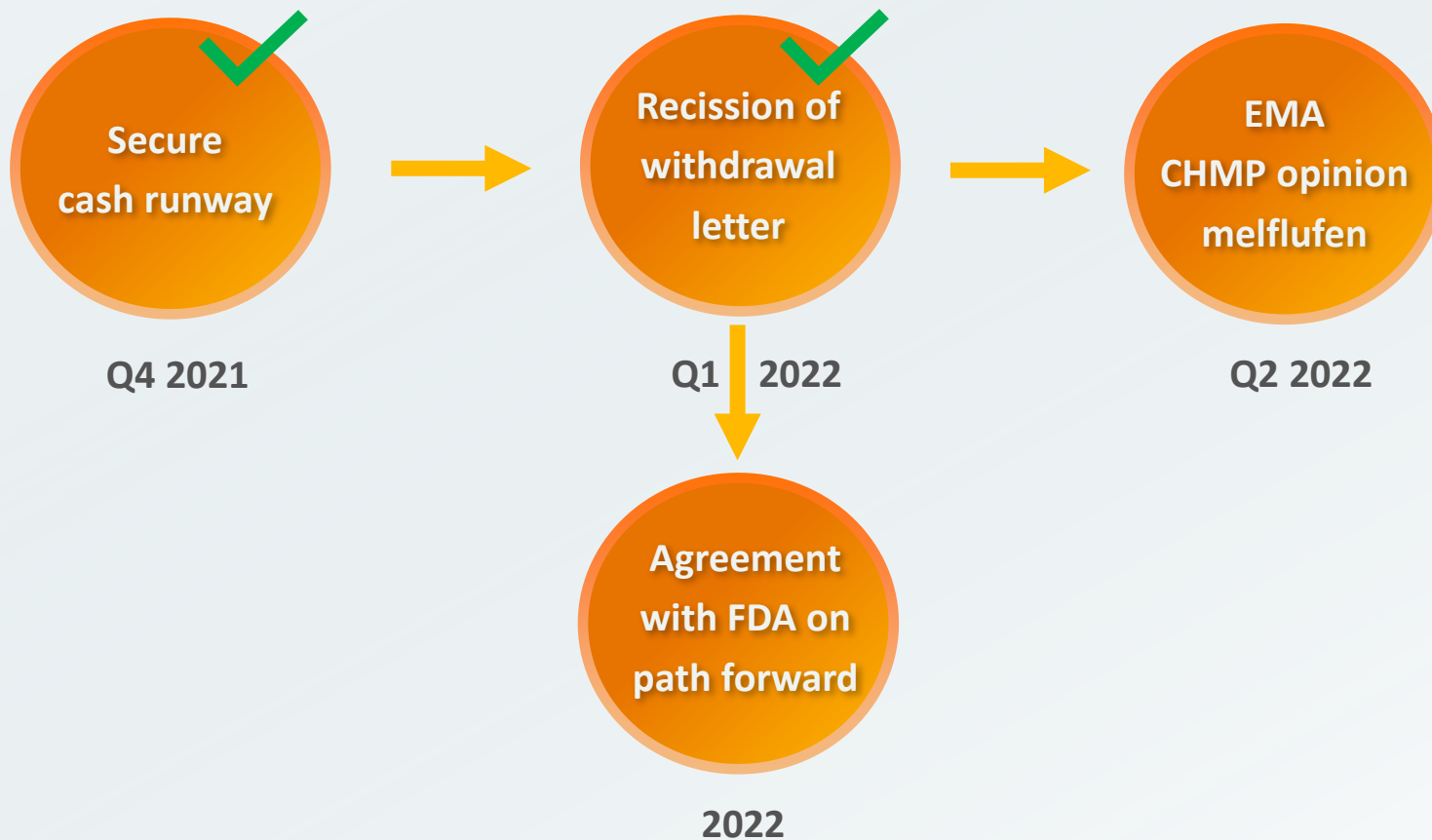
- Q4 2021
  - Pepaxto voluntarily withdrawn from the US market
  - Refocus on R&D, close commercial operations, and scale down Sweden based organization
  - Focused clinical program to support ongoing EMA-review
  - Compassionate use program in the US established
  - Melflufen data presented at ASH meeting
  - Cash position of SEK 362 M by year-end 2021
- After reporting period
  - OCEAN data published in the Lancet Haematology
  - Further analyses of survival data led to a recission of the voluntary withdrawal letter of Pepaxto in the US



## Near-term objectives Q4-2021



## Near-term objectives – current status



# Secure cash runway

## ➔ Target achieved

- Closed commercial organizations in US and EU
- Significantly downsized the Sweden based HQ organization
- Decreased operational burn rate
- Reduced clinical trial activity





# Regulatory process

Klaas Bakker, CMO

## Rescission of voluntary withdrawal letter

- No intention to market Pepaxto in the US at this time
- Reach mutual understanding with the FDA on interpretation of the OCEAN study
- Dialogue with the FDA continues
- Oncopeptides will continuously work with the FDA to make melflufen available for those patients in the US currently being treated with the drug

## EMA filing: CHMP opinion for melflufen

- Ongoing application process
  - Further analyses of survival data shared with EMA
  - 180-day questions end of March
- Unmet need: 70 patients included in Early Access Program in Europe
- Based on EMA process, market access preparations in Germany ongoing



# Financial highlights

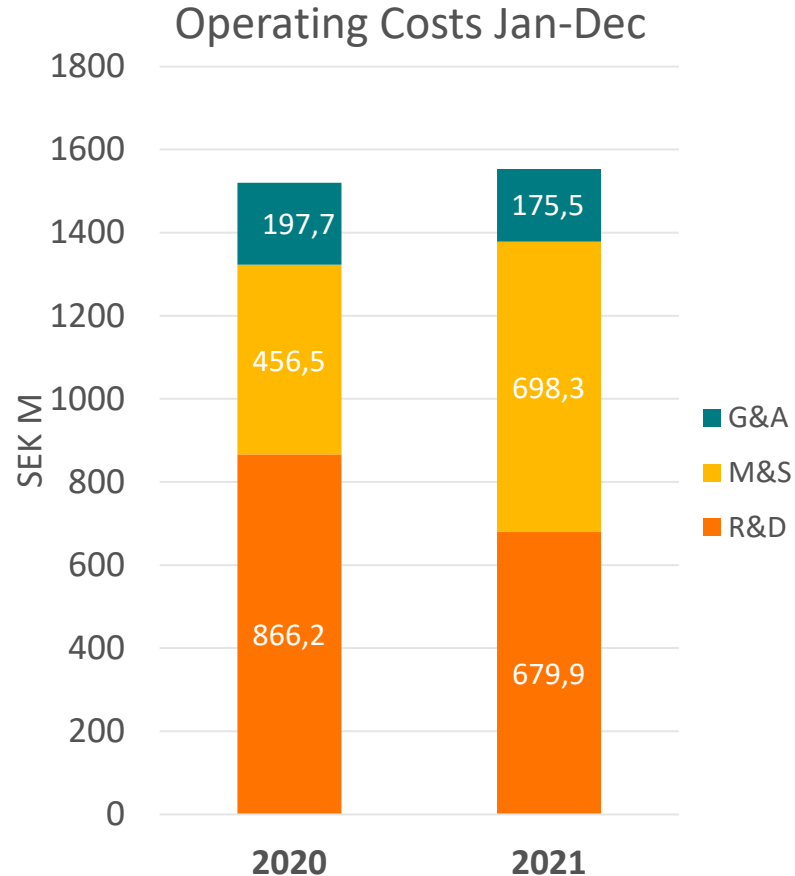
Annika Muskantor, CFO

# Financial highlights October – December 2021



- Operating loss decreased to SEK 389.8 M (loss: 511.6)
  - Closing US- and European organizations and downsizing all global units
  - R&D decreased primarily due to less cost in the OCEAN project
    - OCEAN SEK 31 M (67)
  - Number of co-workers decreased from 321 to 162 (to be reduced further during Q1 2022 as notice periods end)
- Cash flow from operating activities neg. SEK 446.5 M (neg. 357.2)

# Financial highlights January – December 2021



- Operating loss decreased to SEK 1,420.9 M (loss: 1,591.3) for Jan-Dec
  - R&D decreased primarily due to less cost in OCEAN and HORIZON studies
    - OCEAN SEK 140 M (314)
  - Build-up of commercial- and medical affairs in the US and EU through September - and closing thereof in Q4 – drove increase in M&S
  - Number of co-workers decreased to 162 (280) as of Dec 31<sub>2021</sub> (To be reduced further during Q1 -22 as notice periods end)
- Cash flow from operating activities neg. SEK 1,516.4 M (neg. 1,296.5)
- Cash position was SEK 362.2 M (840.3) as of Dec 31, 2021
  - Directed share issue of net SEK 1,039 M in April 2021



# Q&A



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