

# Q2 Webcast – Science leads the way

August 11, 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 PDC platform to develop peptide-drug conjugated 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. The Company voluntarily withdrew the drug on October 22, 2021, and then rescinded the withdrawal on January 21, 2022. Due to regulatory hurdles the product is currently not marketed in the U.S. On June 23, 2022, the CHMP adopted a positive opinion recommending full approval of Oncopeptides Pepaxti® (melphalan flufenamide), in the EU in patients with triple class refractory multiple myeloma. Oncopeptides is developing several new compounds based on its technology platforms.

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# Speakers



**Jakob Lindberg**  
Chief Executive Officer



**Klaas Bakker**  
Chief Medical Officer



**Annika Muskantor**  
Chief Financial Officer



# Company update

Jakob Lindberg, CEO

# Highlights

- CHMP issued a positive opinion recommending full marketing authorization approval of Pepaxti in EU
- FDA Oncologic Drugs Advisory Committee (ODAC) announced to discuss benefit/risk of Pepaxto
- Preclinical portfolio including OPDC3 and NK cell engager (SPiKE), further advanced
- Directed share issue completed raising approx. SEK 435.6 million (USD 41.1 million) before transaction costs



# Hit the ground running

- Commercialize Pepaxti in Europe
- Support EMA application for marketing authorization of Pepaxti in earlier treatment lines
- Create a foundation for marketing of Pepaxto in the US
- Attract and retain the best people in the industry



# Regulatory update

Klaas Bakker, CMO

## CHMP issues Positive Opinion for Pepaxti

- CHMP unanimously recommended the European Commission to grant Pepaxti a full Marketing Authorization Approval in EU for patients with triple class refractory multiple myeloma
- The opinion is based on the phase 2 HORIZON study + phase 3 OCEAN study (confirmatory)
- EMA confirms that the overall survival data in OCEAN is a case of true survival heterogeneity
- European Commission will make a legally binding decision within 60 days, once granted the marketing authorization is valid in EU and EEC countries; Iceland, Lichtenstein and Norway

# Orphan designation withdrawal in EU

- Orphan designation of melflufen for the treatment of plasma cell myeloma, originally granted by the EC on March 19, 2015, has been withdrawn
- EMA (COMP) acknowledges that melflufen provides a major contribution to patient care as compared to CART therapy, however
- With an indication in 3 + lines, melflufen has to demonstrate a significant patient benefit over the authorized CAR T therapies to keep designation
- Withdrawal of designation will not have any impact on market exclusivity nor OD status in US

## ODAC meeting scheduled 22nd of September

- Positive CHMP opinion in EU has resulted in an intensified dialogue with the FDA
- Public hearing with FDA's Oncologic Drug Advisory Committee
- Preparations ongoing including third party engagement
- Briefing book publicly available third week of September
- Until then – no public communication anticipated

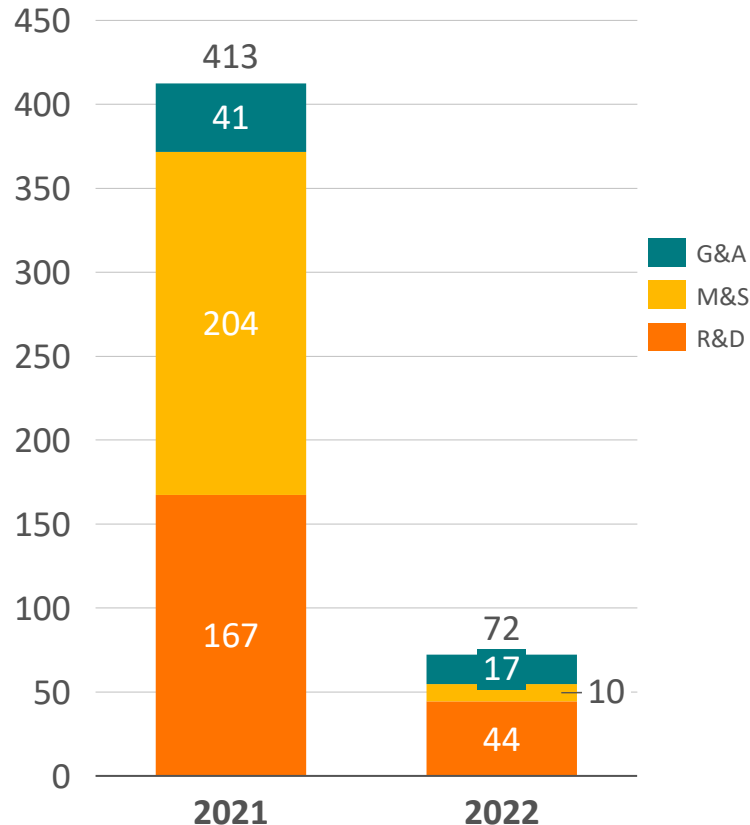


# Financial highlights

Annika Muskantor, CFO

# Financial Highlights April – June 2022

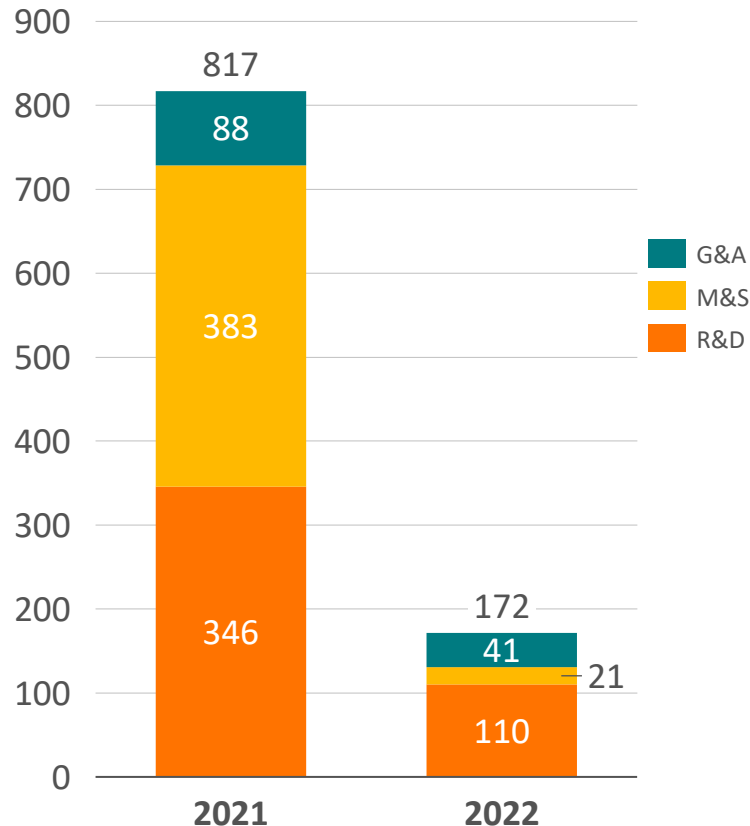
## Operating Costs Apr-June



- Operating loss decreased to SEK 61.1 M (loss: 344.8)
  - Lower overall cost driven by the downsizing in general, and the close of US operations in particular
  - R&D decreased primarily driven by close of studies
    - OCEAN SEK 11 M (29)
  - Net sales of 8.8 M (66.4); reversal of accruals after agreements with suppliers in the US
  - Number of employees decreased from 246 at end of Q2<sub>2021</sub> to 44 at the end of Q2<sub>2022</sub>
- Cash flow from operating activities neg. SEK 106.0 M (neg. 346.7)
  - EIB loan facility still ongoing discussions
- Share issue finalized in July; SEK 435.6 M before transaction related costs

# Financial Highlights January – June 2022

## Operating Costs Jan-June



- Operating loss decreased to SEK 160.0 M (loss: 692.2)
  - Lower overall cost driven by the downsizing in general, and the close of US operations in particular
  - R&D decreased primarily driven by close of studies
    - OCEAN SEK 25 M (78)
  - Net sales of 8.8 M (85.7); reversal of accruals after agreements with suppliers in the US
- Cash flow from operating activities neg. SEK 272.1 M (neg. 733.4)
- Share issue finalized in July gross proceeds of 435.6 M



# Conclusions and way forward

Jakob Lindberg, CEO

## Exciting milestones ahead

- Full approval of Pepaxti in EU and EEA granted by European Commission
- Potential resolution on path forward in the US
- Commercial launch of Pepaxti in Germany
- Communication is pending on decisions by regulators



# Q&A



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