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Oncopeptides is a global biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary Peptide Drug Candidate platform, PDC, to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Pepaxti® (melphalan flufenamide, also called melflufen) has been granted Marketing Authorization, in the European Union, the EEA-countries Iceland, Lichtenstein and Norway, as well as the UK. Pepaxti is indicated in combination with dexamethasone for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapies, whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody, and who have demonstrated disease progression on or after the last therapy. For patients with a prior autologous stem cell transplantation, the time to progression should be at least 3 years from transplantation. Melflufen was granted an accelerated approval in the US in February 2021, under the trade name Pepaxto®. The product is currently not marketed in the US.

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## **Presenters**







## Where we are right now



#### **KEY Q3 HIGHLIGHTS**

- Revenues of SEK 8.5m in Q3 2024 (SEK 2.8m in Q3 2023), cash position of SEK 250m.
- On track to cash flow positivity at end of 2026.



### **SALES UPDATE**

- Strong start in Spain
- Sales declined due to slow growth in Germany and decline in Greece.



#### **OTHER HIGHLIGHTS**

#### JULY-SEPTEMBER

- Oncopeptides announced that the first patient has entered study evaluating the real-world performance of Pepaxti in German patients.
- Oncopeptides announced that it has signed an exclusive license and supply agreement with SCBIO Inc., a Korean pharmaceutical company for the commercialization of Pepaxti in South Korea.







## **Financial summary**

MSEK	July-Sept 2024	July-Sept 2023	Jan-Sept 2024	Jan-Sept 2023
Net sales	8.6	2.8	21.7	29.9
COGS	-0.7	1.9	-1.9	1.9
Gross profit	7.8	4.7	19.8	31.7
Expenses	-70.1	-47.3	-224.5	(-211.7)
Other operating income/expense	1.1	5.3	4.5	7.5
EBIT	-61.3	-37.3	-200.2	-172.5
Net financial items	0.7	-3.1	-1.4	3.1
Tax	0.4	-0.1	0.4	1.4
Net profit	-60.2	-40.5	-201.2	-167.9

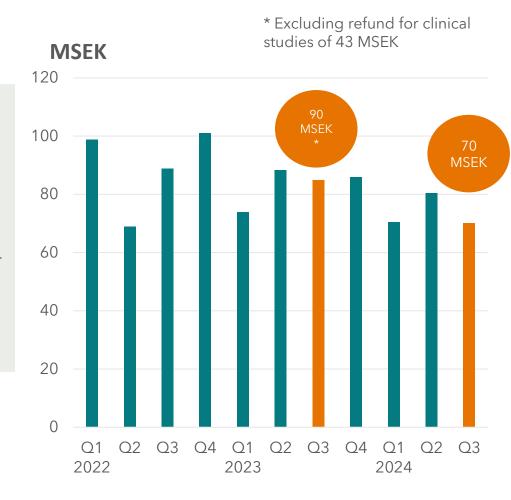
### 2023 'one off items'

- Reversal of return reserve in the USA of 24 MSEK in 2023 underlying full year revenue amounts to 5.6 MSEK.
- o Closed clinical study generated refund of 43 MSEK, underlying expenses Jan-Sept 2023 amounted to 255 MSEK.
- Reversal of write down on inventory generated positive COGS in 2023



## **Operating expenses**

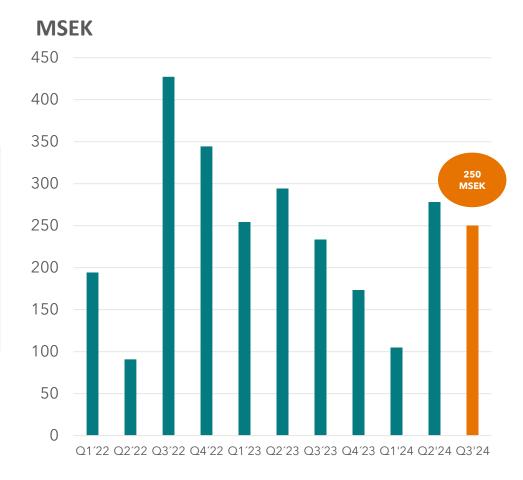
- R&D, decreased from 49 MSEK in Q3-23 to 22 MSEK in Q3-24
  - Above excluding refund of 43 MSEK in 2023
  - No studies currently ongoing.
- S&M, increased from 29 MSEK in Q3 -23 to 30 MSEK in Q3 -24
  - Progressing in Europe with launch in Spain in Q2-24 and advancing market access in primarily Italy
- G&A for 2024 is on the same level as 2023 for the ninemonth period





## Liquidity

- Cash was 250 MSEK by end of Q3-24
- Rights issue completed in May 2024 infused 270 MSEK after issue related costs.
- Operating cash in Q3 includes a negative timing effect of in and out going VAT payments of 105 MSEK, corresponding positive effect in Q2.



Q2 excluding the 105 MSEK timing of VAT.



## **COMMERCIAL UPDATE**

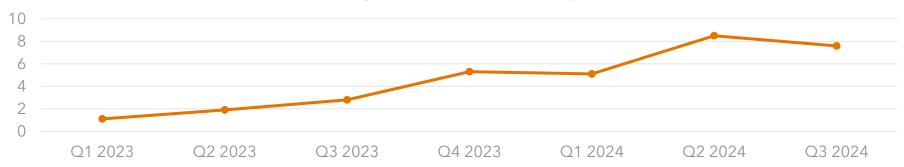
**Sofia Heigis**Chief Executive Officer

# Drivers of European growth in Q4 2024 and onwards moving toward profitability end 2026

- ✓ Innovative price negotiated in Germany, Austria,
   Spain Italy progressing according to plan
- National Guideline updates in Germany, Spain
- ✓ Increased positive clinical experience, KOL advocacy, peer-to-peer exchange and awareness in Germany.

- ✓ Sales pickup in Spain during 2nd half of 2024.
- ✓ Focus on being cost-effective.

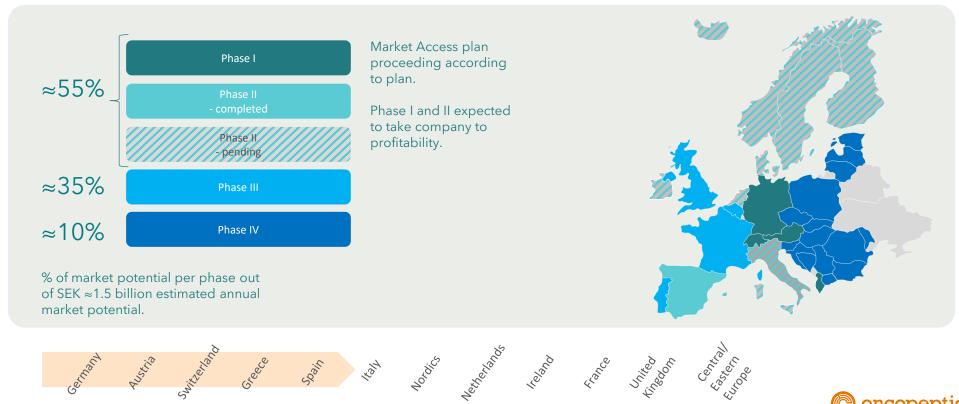
## Quarterly Revenue Development





## **European Launch Sequence**

Our ambition: launch as fast as possible with a price reflecting our innovation – providing patient and shareholder value.





## From authorization to sales in European markets

Process between receiving marketing authorization and healthcare professional uptake



Marketing authorization received

Value dossier and **KOL** engagement

Cost effectiveness benefit discussion

**Price negotiations** 

**Regional access** 



#### 6-12 months

Provide info with supporting evidence, customized for local or national payers, and engaging with key opinion leaders.

#### 2-6 months

Based on the dossier, input from KOLs and Oncopeptides, Pepaxti is evaluated on how effective it is relative to how much it costs.

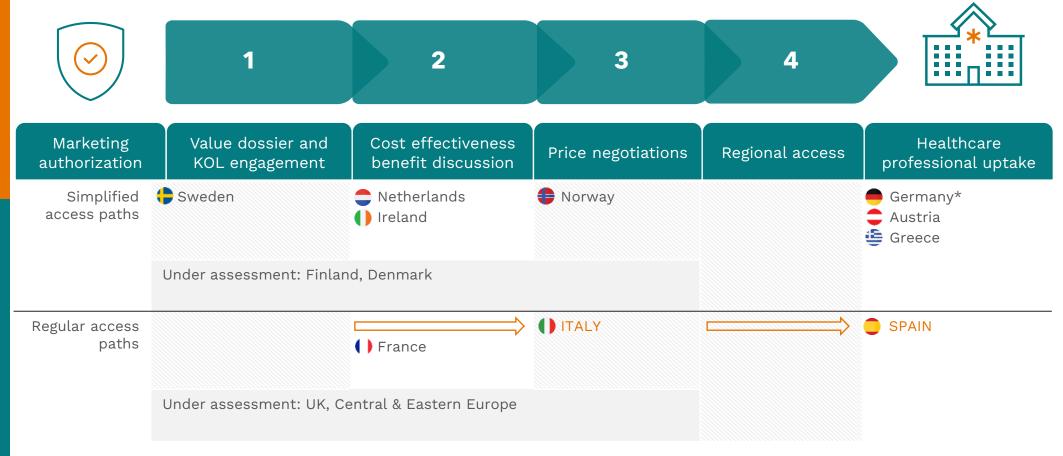
#### 3-24 months

**Negotiations** with payers for pricing and reimbursement levels.

#### 1-12 months

In some countries, such as Sweden, healthcare is regional, meaning an additional step in the process.

# Roadmap to commercialization in Europe Objective: maximized value for patients and shareholders





## KEY MARKET DEEP DIVE



## Our key markets - a comparison

#### **GERMANY**

- Clinical experience at launch: 1
   KOL with experience from Early
   Access use
- Recruiting clinical trial sites: 0
- Patients in clinical trials: 0
- Number of MM prescribers:
   ≈ 2000
- Number of target patients for Pepaxti ≈ 2500

#### **SPAIN**

- 15 KOLs with previous experience from Early Access use
- Recruiting clinical trial sites: 23
- Patient in clinical trials: 107
- Number of MM prescribers: ≈ 300
- Number of target patients for Pepaxti ≈ 1500

#### **ITALY**

- Clinical experience at launch: 16
  KOL with experience from Early
  Access use
- Recruiting clinical trial sites: 10
- Patients in clinical trials: 79
- EAP patients: 85
- Number of MM prescribers:
   ≈ 240
- Number of target patients for Pepaxti ≈ 1800



## **EFFICACY**

Pepaxti + dex showed clinically meaningful efficacy and a manageable safety profile in patients with heavily pre-treated RRMM, including those with TCR and EMD<sup>1</sup>

### **SAFETY**

The safety profile of Pepaxti primarily consists of hematological adverse events which are manageable<sup>1,3,4</sup>



## **QUALITY OF LIFE**

Treatment with Pepaxti + dex in patients with RRMM demonstrated maintained HRQoL<sup>5,6</sup>

1. Richardson PG, et al. J Clin Oncol. 2021;39(7):757-767. 2. Pepaxti Summary of Product Characteristics. Oncopeptides AB (publ), February, 2024. 3. Richardson PG, et al. Lancet Haematology. 2020;7:e395-e407. 4. Schjesvold F.H., et al. Article and Supplementary Material. Lancet Haematol. 2022; 9: e98-110. 5. Larocca et al. 2021. British Journal of Haemotology. 2022; 196:639-48. 6. Schjesvold FH, et al. Haematologica. 2024;109(7):2331-2336.



## **Germany - where we are**

BARRIERS	CRITICAL SUCCESS FACTORS IN GERMANY	OPPORTUNITIES
One (1) Key Opinion Leader with clinical experience at launch in Germany	Key Opinion Leaders with positive clinical experience	9/17 Key Opinion Leaders today have gained positive clinical experience
First national guideline update since launch occurs in 2024	Guideline inclusion	Draft guidelines presented and Pepaxti is included according to label
No clinical experience at launch among prescribing physicians in hospitals or in office-based setting.	Peer-to-peer exchange	Generated clinical experience is positive and exchange can grow through different activities and in every-day practice. Several local protocols and guidelines updated.



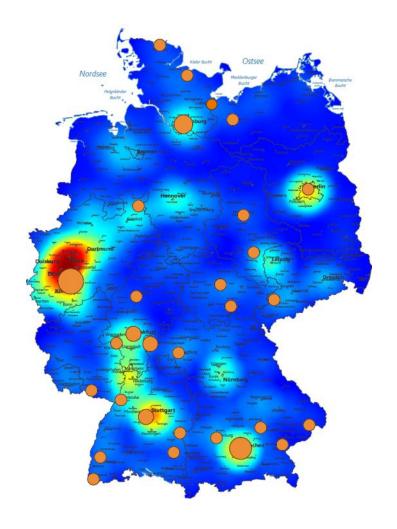
Germany is a scattered market with 900+ accounts and 2,000+ MM

treaters



## **Heatmap Germany**

- ✓ Focused on the most population dense areas
- In regions with generated clinical experience in key accounts sales uptake accelerate
- Regions starting to generate experience 2H of
   2023 stand for the majority of sales
- Several regions started to gain experience in Q2-Q3 and are expected to increase coming 6 months





# Pepaxti experience at key accounts & focused regional peer-to-peer exchange accelerate Pepaxti adoption in that region

Cumulative Pepaxti vials by selected regions





## **OUR POTENTIAL**

# **Pipeline assets** Pepaxti in rest of the world Pepaxti in Europe

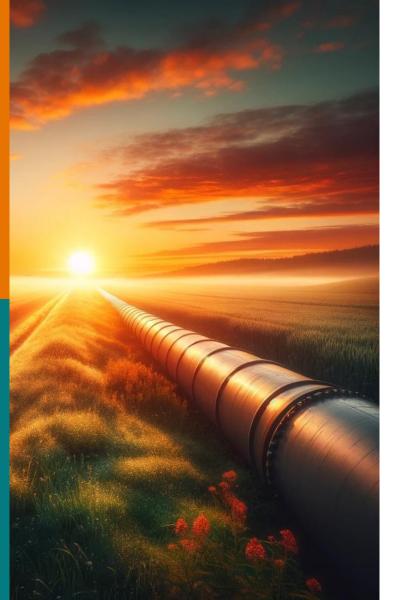
#### **NEXT STEP VALUE DRIVERS**

- Our pipeline contains promising assets in terms of new platforms.
- A high global unmet medical need creates sales potential - current focus is on Japan and China.

#### PEPAXTI IN EUROPE

Market potential approx. 1.5+ billion SEK.
 Current ongoing commercialization.





## **Pipeline assets**

#### **SPiKE: A platform with exciting potential**

- Small Polypeptide based innate Killer Engager (SPiKE) immunotherapy takes advantage of natural killer (NK) cells, the immune system's first-line of defense against viruses and other foreign cells (e.g. cancer cells).
- The SPiKE platform presents an opportunity to create effective and tolerable immunotherapies generating value for patients and shareholders.

<u>Status and next steps:</u> candidate drug selected. Own R&D continues while we also look into entering partnerships.

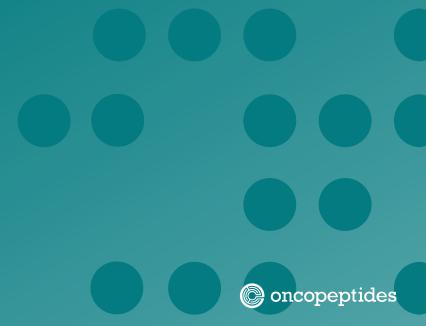
#### PDC: Building onto our existing innovation

- Targets cancer by capitalizing on the metabolic differences between healthy cells and cancer cells while maintaining the patient's quality of life through less side effects.
- We are developing two candidate drugs with potential to target multiple indications:
  - OPD5 "sister" molecule to Pepaxti granted "Investigational New Drug" status by the FDA.
  - OPDC3 build upon Pepaxti benefits with even more enhanced selectivity.

<u>Status and next steps:</u> our first PDC, Pepaxti, has been commercialized, next generation PDCs are in early R&D stage.



A&D



## Bringing hope through science

