



# YEAR-END REPORT 2024

February 27, 2025



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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.

The Information contains forward-looking statements. All statements other than statements of historical fact included in the Information are forward-looking statements. Forward-looking statements give the Company's current expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Company's control that could cause the Company's actual results, performance or achievements to be materially different from the expected results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company's present and future business strategies and the environment in which it will operate in the future.

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# Presenters



# Where we are right now

## FINANCIALS

- Net sales of SEK 9.9m in Q4 2024 (SEK 5.3m in Q4 2023), cash position of SEK 179m.
- Maintained momentum in Spain, strengthened trend in Germany heading into 2025.
- On track to cash flow positivity at end of 2026.

## HIGHLIGHTS

- During 2024 Oncopeptides successfully completed a consultation with the Japanese regulator PMDA for Pepaxti, confirming alignment on the regulatory pathway in Japan.

### EVENTS OCTOBER-DECEMBER

- Oncopeptides announces that it has come to an agreement with the Italian Medicines Agency AIFA on the pricing and reimbursement of Pepaxti. The decision paves the way for the drug to be commercialized in Italy during H1, 2025.
- Oncopeptides announces that an evaluation of the activity of two peptide drug conjugates (PDCs) developed by Oncopeptides in relapsed or refractory Acute Myeloid Leukemia has been accepted as a poster and will be presented at the 66th annual American Society of Hematology (ASH) Meeting and Exposition.

### EVENTS AFTER THE PERIOD

- Oncopeptides announces that the positive reimbursement decision for Pepaxti has been officially published in Italy. This marks the final regulatory step for the drug's upcoming commercialization in Italy.
- Ulf Jungnelius has decided to step down from the Board of Directors in which he has served since 2011. This due to personal reasons related to a change of domicile from Sweden.
- Oncopeptides announces that a new real-world study on melflufen plus dexamethasone in patients with RRMM has been published in the peer-reviewed journal European Journal of Haematology.

The background is a teal-tinted photograph of an office environment. In the foreground, a person's hands are visible, holding a pen and pointing at a document with a bar chart. Another person's hands are seen in the background, also working with documents. A laptop screen in the upper left corner displays various charts and graphs. The overall scene suggests a professional meeting or a financial review session. On the right side of the slide, there is a decorative pattern of white circles of varying sizes, arranged in a grid-like fashion.

# FINANCIAL UPDATE

**Henrik Bergentoft**  
Chief Financial Officer

## Financial summary

MSEK	Oct-Dec 2024	Oct-Dec 2023	Jan-Dec 2024	Jan-Dec 2023
Net sales	9.9	5.3	31.6	35.2
COGS	-0.7	-0.8	-2.7	1.1
<b>Gross profit</b>	<b>7.8</b>	<b>4.7</b>	<b>29.0</b>	<b>36.3</b>
Expenses	-93.9	-83.7	-318.5	-295.4
Other operating income/expense	1.4	-1.8	5.9	5.7
<b>EBIT</b>	<b>-83.3</b>	<b>-79.1</b>	<b>-283.5</b>	<b>-253.5</b>
Net financial items	0.7	1.9	-0.7	5.0
Tax	-0.8	-2.1	-0.4	-0.7
<b>Net profit</b>	<b>-83.4</b>	<b>-81.2</b>	<b>-284.6</b>	<b>-249.1</b>

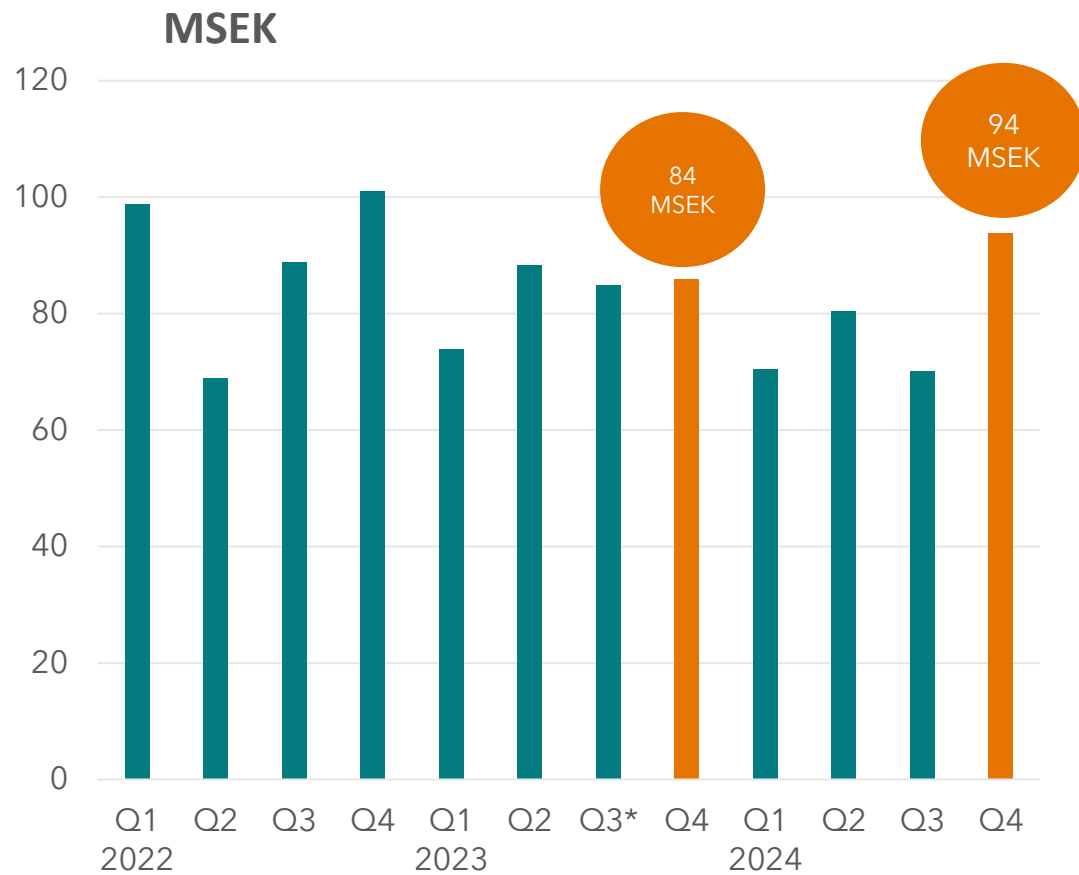
### 2023 one off items

- Reversal of return reserve in the USA of 24 MSEK – underlying revenue amounts to 10.9 MSEK.

- Closed clinical study generated refund of 43 MSEK, underlying expenses Jan-Dec 2023 amounted to 338 MSEK.

## Operating expenses

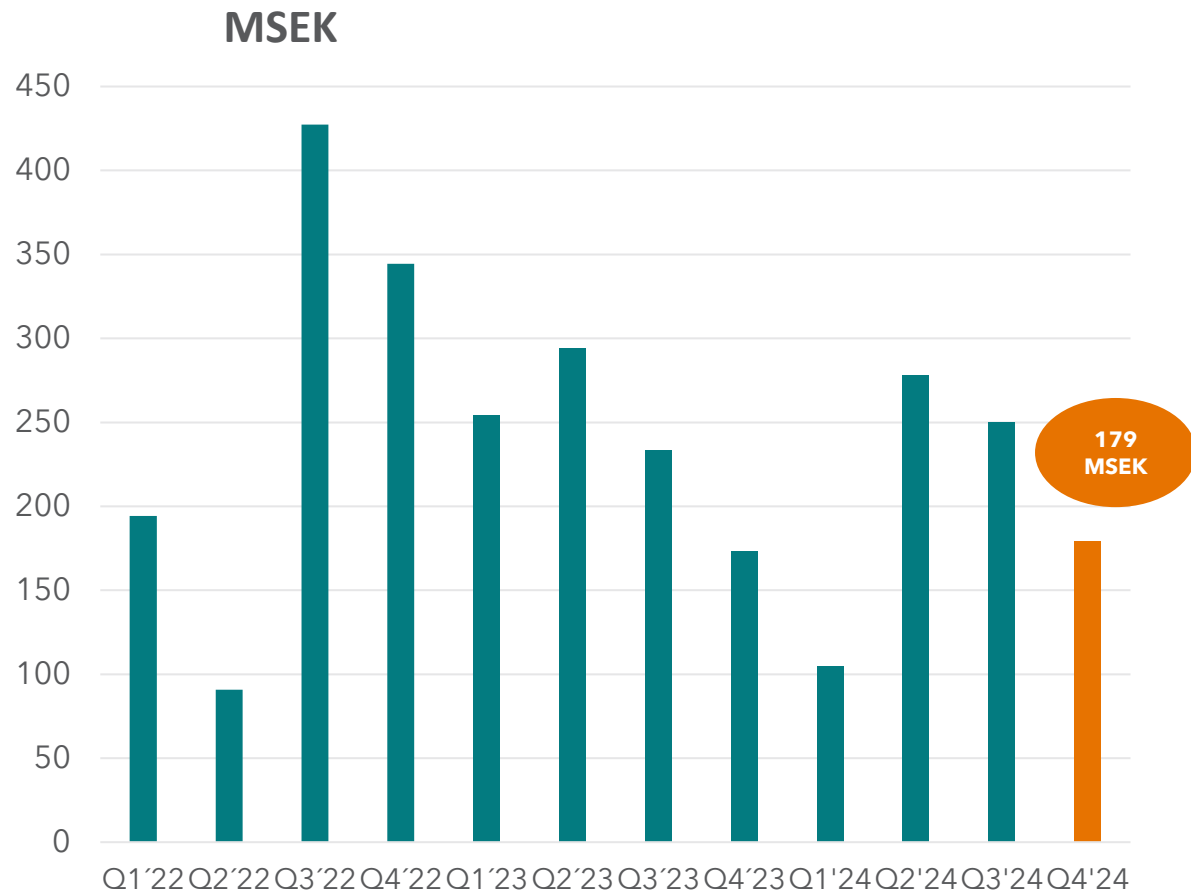
- S&M, increased from 35 MSEK in Q4 -23 to 43 MSEK in Q4 -24
  - Progressing in Europe with sales in Germany, Austria, Greece and Spain and preparations for Italy based on approved price.
- G&A decreased from 16 to 8 MSEK, mainly due to cost reductions initiated.
- R&D, increased from 33 MSEK in Q4-23 to 43 MSEK in Q4 -24
  - No studies currently ongoing.
  - Advancements made in our pre-clinical portfolio
  - Cost focus will reduce R&D expenses in 2025



\* Excluding refund for clinical studies of 43 MSEK

## Liquidity

- Cash was 179 MSEK by end of 2024
- Cash position in line with expectations
- Liquidity position after rights issue estimated to last until cash flow positive end of 2026





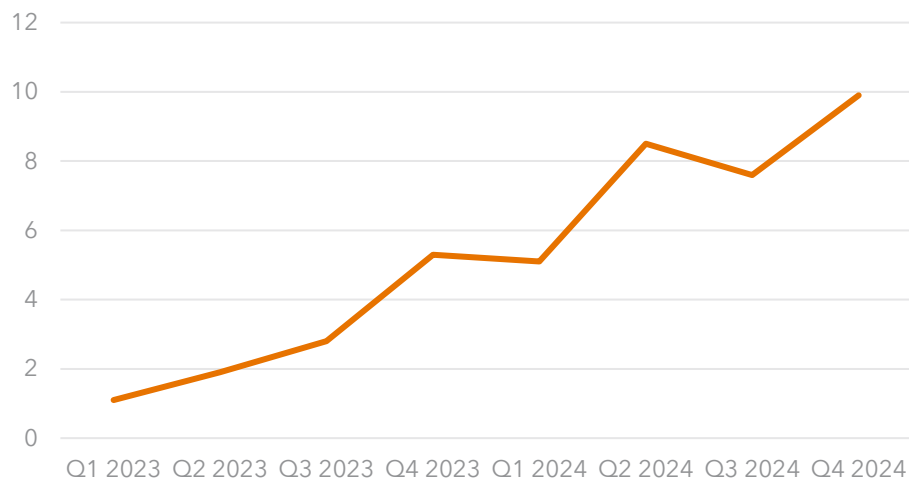
# COMMERCIAL UPDATE

**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 and Italy.
- ✓ National Guideline updates in Germany, Spain.
- ✓ Increased positive clinical experience, KOL advocacy, peer-to-peer exchange and awareness in Germany.
- ✓ 85 % regional access secured in Spain, sales starting to pickup during 2H of 2024.
- ✓ Italy expected to get first regional access and sales during H1.
- ✓ Maintained focus on cost-effectiveness.

Quarterly Growth QoQ

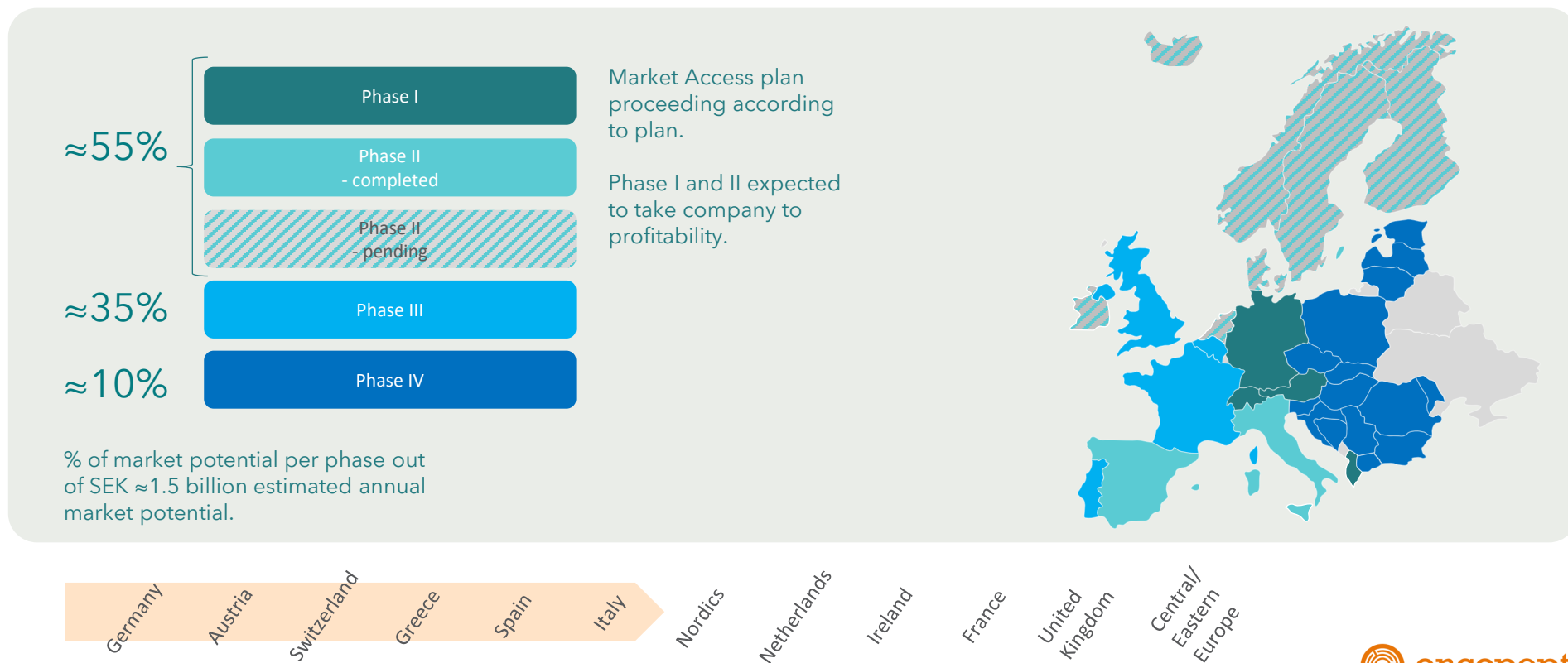


Q1 2023 Q2 2023 Q3 2023 Q4 2023 Q1 2024 Q2 2024 Q3 2024 Q4 2024

Revenue, European sales, million SEK

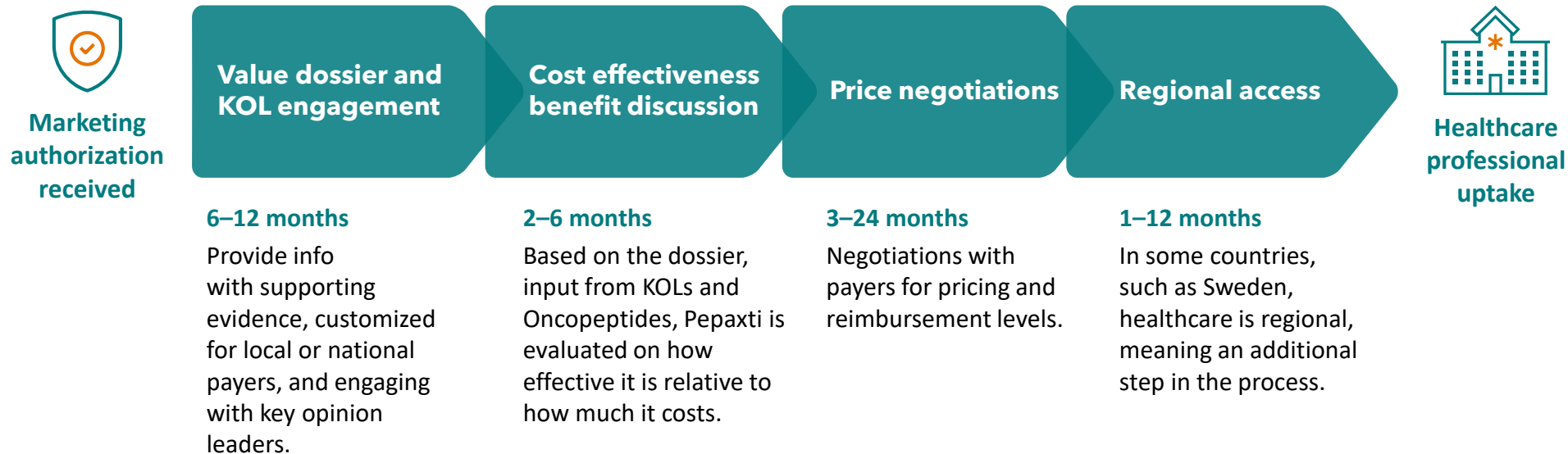
# European Launch Sequence

**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

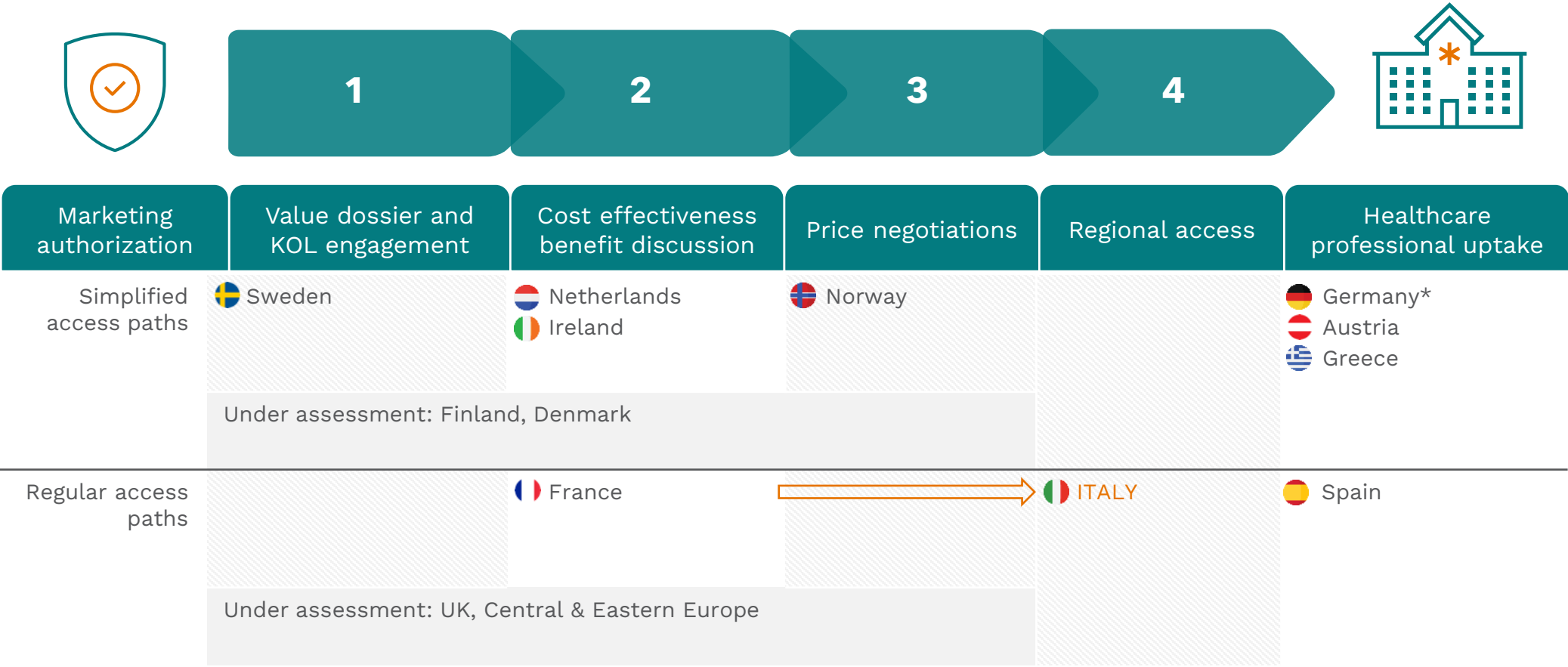
Process between receiving marketing authorization and healthcare professional uptake





# Roadmap to commercialization in Europe

Objective: maximized value for patients and shareholders



13 \*including reactive opportunity for named patient sales in Switzerland

## Italy - our third key market now with national reimbursement

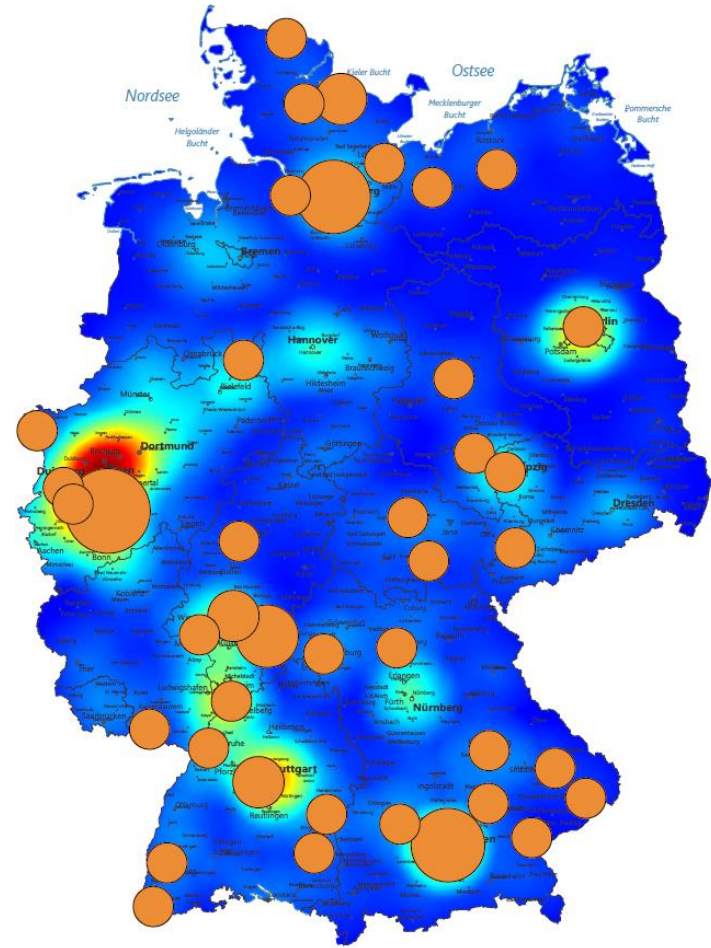
- Clinical experience at launch: 16 KOL with experience from Early Access use
- Recruiting clinical trial sites: 10
- Patients in clinical trials: 79
- EAP patients: 86
- Number of MM prescribers:  $\approx 240$
- Number of target patients for Pepaxti  $\approx 1800$



**Next Step:** 20  
Regions to unlock

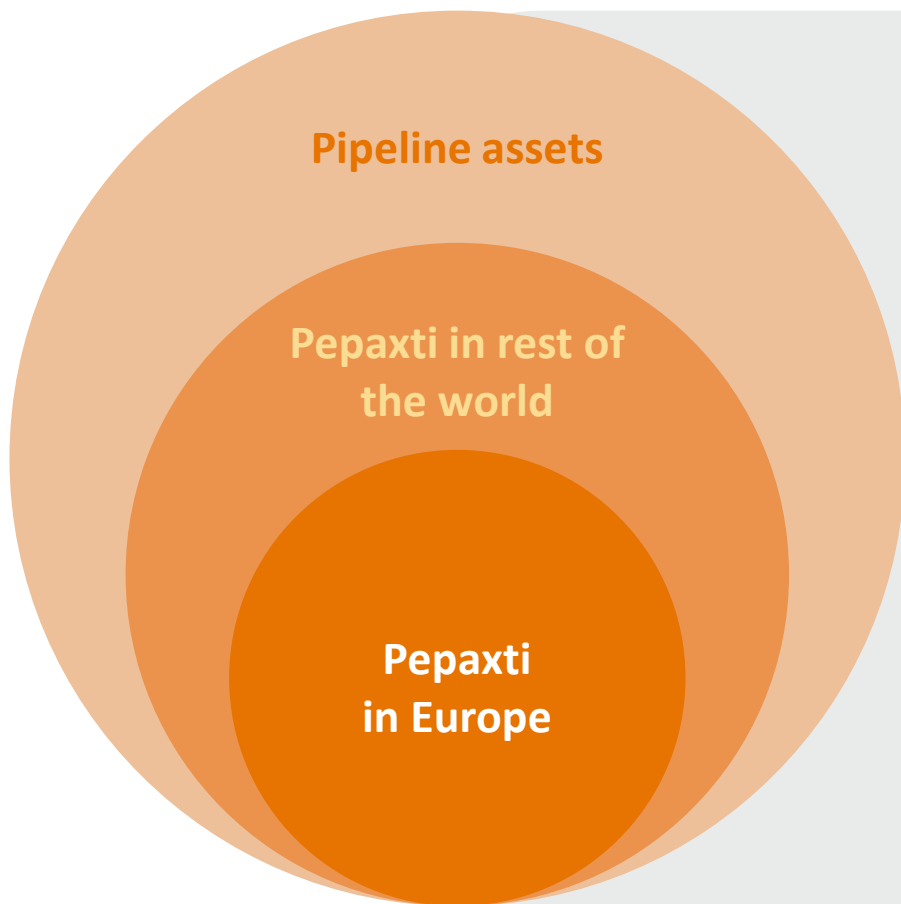
# Heatmap Germany

- ✓ Germany is a **scattered market** - 2500 patients treated by 2000 prescribers.
- ✓ Positive clinical experience in a **key account** leads to **acceleration of sales** in that territory due to peer-to-peer recommendations.
- ✓ **10/12 key accounts** with KOLs are now activated and has gained positive clinical experience.
- ✓ **≈30 percent increase** in number of prescribers in Q4 versus Q3 2024.



Heatmap shows the population density of persons 65 years and older, based on 2022 data. The bubbles show the cumulative number of Pepaxti vials since launch until end Q4 2024, clustered by ordering pharmacy location.

# OUR POTENTIAL



## NEXT STEP VALUE DRIVERS

- Encouraging first signals as we renew effort in USA with OPD5.
- A high global unmet medical need creates sales potential:
  - ✓ Japan is our primary focus.
  - ✓ South Korean partner submitted to Regulatory authorities ahead of plan.
  - ✓ China still being assessed.

## PEPAXTI IN EUROPE

- **Market potential approx. 1.5+ billion SEK.** Current ongoing commercialization in Italy, Spain, Germany, Austria.





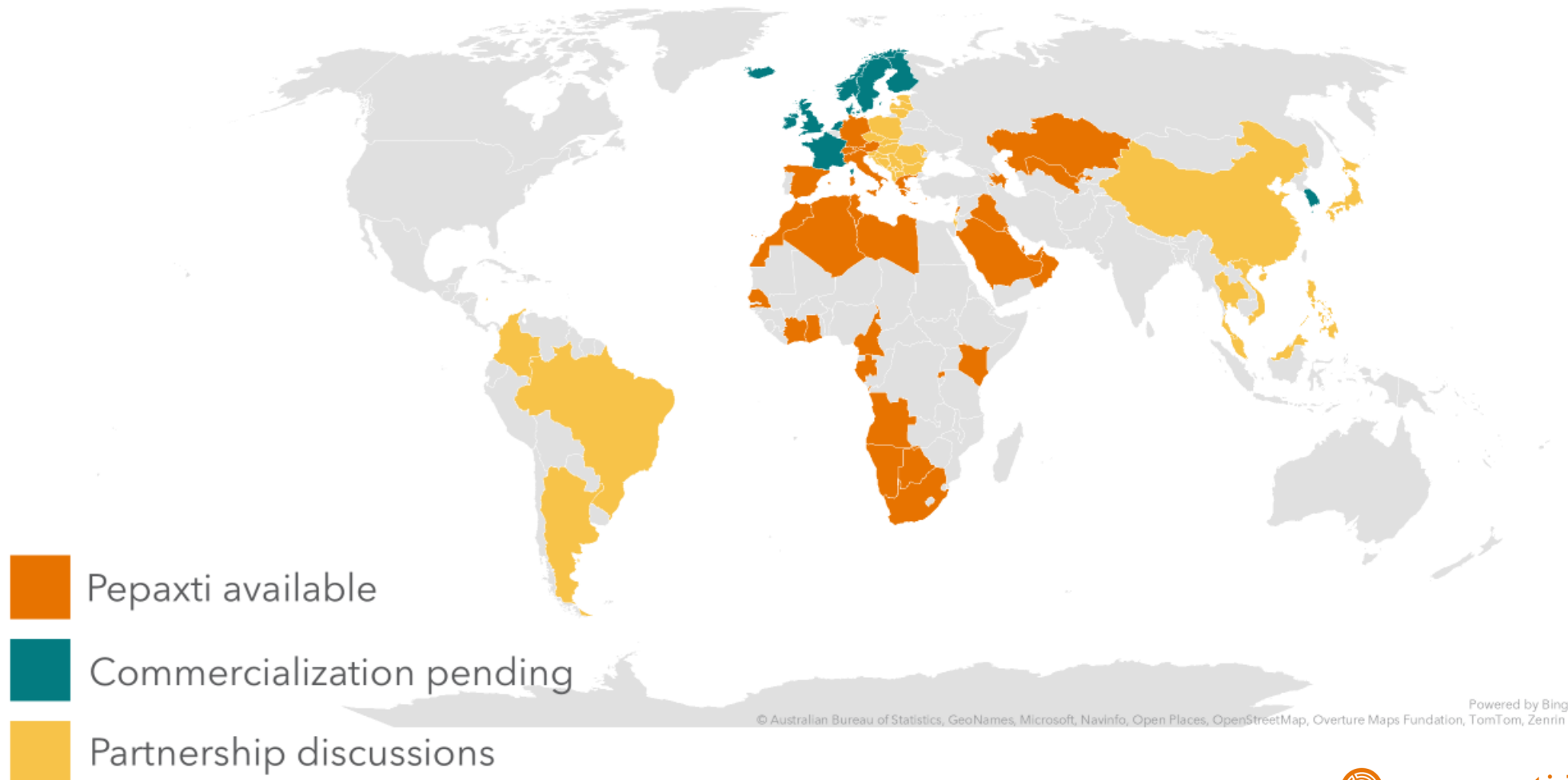
Advanced negotiations with partner.

Alignment with PMDA – Regulatory  
Agency.

Confirmed high unmet need by  
Japanese KOLs.



# Global commercialization progress



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# OPD5 progress

- Now: Exploratory discussions with the U.S. Food and Drug Administration (FDA).
- Potential: improved risk/benefit profile and enhanced intellectual property protection vs. Pepaxti.
- Next step: a clinical development path based on advice from the FDA.

“The results indicate that melflufen’s efficacy and safety profile observed in clinical trials have favorably translated into real-world practice.”

– *Paul Richardson,*  
*MD, Clinical Program Leader and Director of Clinical Research at Dana-Farber Cancer Institute and senior author of the article.*



A large, dark pipeline stretches from the bottom left towards the horizon, where it meets a bright sun setting over a field of tall grass. The sky is filled with orange and red clouds, and the sun's rays create a strong lens flare effect.

# 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.

**Status and next steps: 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: follow-on molecule to Pepaxti granted "Investigational New Drug" status by the FDA.
  - OPDC3 build upon Pepaxti benefits with even more enhanced selectivity.

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



# Q&A

Bringing hope through science

