

Oncopeptides publishes year-end report 2024

Stockholm - February 27, 2025 - Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today publishes the year-end report for 2024.

“Pepaxti sales increased about 35 percent in the fourth quarter compared to the third quarter of 2024. With the launch in Italy now underway, Oncopeptides is present in all our key European markets, and we can focus even more on activities that grow sales,” says Sofia Heigis, CEO of Oncopeptides. “We have also taken other steps to profitability by the end of 2026, including alignment on a regulatory pathway and advanced partnership discussions in Japan for Pepaxti as well as positive discussions with the U.S. Food and Drug Administration regarding our pipeline molecule OPD5.”

Financial overview October-December

- Net sales amounted to SEK 9.9 (5.3) million
- Operating profit amounted to SEK -83.3 (-81.0) million
- Profit after tax amounted to SEK -83.4 (-81.2) million
- Earnings per share, before and after dilution -0.39 (-0.90) SEK
- Cash and cash equivalents at the end of the period amounted to SEK 178.5 (173.4) million

Significant events

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

Significant events October-December

- Oncopeptides announces that it has come to an agreement with the Italian Medicines Agency on the pricing and reimbursement of melflufen, branded in Europe as 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 informed the Board of Directors of his decision to step down from the Board of Directors in which he has served since 2011. This is due to personal reasons related to a change of domicile from Sweden.
- Oncopeptides announces that a new real-world study on melflufen (branded in Europe as Pepaxti) plus dexamethasone in patients with relapsed, refractory multiple myeloma (RRMM) has been published in the peer-reviewed journal European Journal of Haematology.

Financial overview of the group

(SEK thousand)	2024 Oct-Dec	2023 Oct-Dec	2024 Jan-Dec	2023 Jan-Dec
Net sales	9 914	5 337	31 648	35 220
Whereof reversal of returns reserve USA	-	55	-	24 330
Operating profit	-83 334	-80 980	-283 498	-253 447
Profit after tax	-83 426	-81 211	-284 607	-249 111
Earnings per share, before and after dilution (SEK)	-0.39	-0.90	-1.71	-2.76
Cash flow from operating activities	-71 498	-55 395	-260 570	-279 493
Cash at the end of the period	178 536	173 407	178 536	173 407

Conference call for investors, analysts and the media

Investors, financial analysts, and media are invited to participate in a webcast and a subsequent Q&A session, at 09:00 CET today.

The presentation will be hosted by Sofia Heigis, CEO, together with Henrik Bergentoft, CFO. The webcast will be held in English and published on the website of Oncopeptides - www.oncopeptides.com/en - in conjunction with the start of the presentation.

Information for participants

If you wish to participate via webcast, please use the link below.
<https://oncopeptides.events.inderes.com/q4-report-2024>

If you wish to participate via teleconference, please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference.
<https://conference.inderes.com/teleconference/?id=5003623>

CEO statement

Oncopeptides' sales of Pepaxti increased about 35 percent in the fourth quarter compared to the third quarter of 2024. With the launch in Italy now underway, Oncopeptides is present in all our key European markets, and we can focus even more on activities that grow sales. We have also during the fourth quarter and in early 2025 taken several other steps to support our journey to profitability by the end of 2026 and continued growth beyond that.

Pepaxti sales in Q4 2024 were SEK 9.9 million, compared to SEK 7.4 million in Q3 2024. While we believe that significant growth potential remains, we are encouraged by an acceleration of sales, particularly in our most important market Germany, during the end of the quarter. This trend has continued in the early part of 2025.

The premier milestone of the fourth quarter 2024 was the agreement with the Italian Medicines Agency (AIFA) on the pricing and reimbursement of Pepaxti, paving the way for the formal approval of the drug in January of 2025. We expect sales based on regional access during H1 2025. In Spain we have now secured access in all key regions, in total more than 85 percent of the country, and we expect the strong start we saw in H2 2024 to continue in 2025.

During 2024 we successfully completed a consultation with the Japanese regulator PMDA for Pepaxti, confirming alignment on the regulatory pathway in the country and the high unmet need for Pepaxti, which is also affirmed by Japanese Key Opinion Leaders. Following this regulatory milestone, Oncopeptides engaged in negotiations regarding a license agreement for Pepaxti in Japan which are now at an advanced stage. A deal would carry significant potential for the company.

Oncopeptides cash position by the end of 2024 was SEK 179 million. While sales in 2024 did not live up to our expectations, this has been offset by a stronger cost focus leaving our cash position in line with projections as we head into 2025. A signed partnership in Japan along with a continued steady sales growth of Pepaxti would ensure enough liquidity to bring the company to cash flow positivity by the end of 2026. We are also pursuing other avenues to support our cash position until profitability is reached. For example, the company continues its dialogue with the European Investment Bank (EIB) regarding the second tranche of the loan previously granted to Oncopeptides.

Regarding current partnerships, our South Korean partner SCBIO have filed documents for Pepaxti to the regulatory authority for a preliminary review earlier than expected and we anticipate clarity regarding next steps during H1, 2025.

As for our pipeline, we have over the winter been engaged in exploratory discussions with the U.S. Food and Drug Administration (FDA) regarding our molecule OPD5, a follow-on molecule to Pepaxti with a potentially improved risk/benefit profile and enhanced intellectual property protection. The feedback received was positive and in line with expectations. We are currently working on

outlining a clinical development path based on advice from the FDA. While there is a long way from here to commercialization, we are confident that OPD5 is an asset with true potential to get us back to the important U.S. market in the future, as the unmet need for a PDC remains, as confirmed by Key Opinion Leaders. Just this week, an article suggesting strong real-world efficacy and safety-data for Pepaxti, written by researchers at the Dana-Farber Cancer Institute in Boston, was published in the European Journal of Haematology. In parallel, we continue the progression of our other pipeline assets and will continue to keep the market informed of any major milestones.

Summarizing the full 2024, we have tripled our revenue compared to 2023 and expanded our addressable European market from one major market to three. While we continue our market access efforts in the rest of Europe, we have now reached the footprint in Europe we need to reach profitability by the end of 2026.

We enter 2025, Oncopeptides' 25th anniversary, with promising signs of sales growth in Europe driven by Germany, full speed ahead in Spain and regional access in Italy along with advanced discussions regarding a potential partnership in Japan that would be of great significance for the company and a roadmap back to the USA through our pipeline slowly starting to materialize.

Stockholm, February 27, 2025

Sofia Heigis, CEO

For more information, please contact:

David Augustsson, Director of Corporate Affairs, Oncopeptides AB (publ)

E-mail: david.augustsson@oncopeptides.com

Cell phone: +46 76 229 38 68

This information is information that Oncopeptides is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-02-27 08:00 CET.

About Oncopeptides

Oncopeptides is a Swedish biotech company focusing on research, development and commercialization of targeted therapies for difficult-to-treat cancers.

The company uses its proprietary Peptide Drug Candidate platform (PDC) to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. Its flagship drug is currently being commercialized in Europe with partnership agreements for South Korea, the Middle East and Africa and elsewhere.

Oncopeptides is also developing several new compounds based on its two proprietary technology platforms PDC and SPiKE.

The company was founded in 2000, has about 80 employees with operations in Sweden, Germany, Austria, Spain and Italy. Oncopeptides is listed on Nasdaq Stockholm with the ticker ONCO.

For more information see: www.oncopeptides.com.

About Pepaxti

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 in 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.