Press release
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Oncopeptides publishes year-end report 2023

Stockholm – February 27, 2024 – Oncopeptides AB (publ), a biotech company focused on difficult-to-treat cancers, today publishes the year-end report for 2023.

"Having delivered on our promise of continuous growth quarter over quarter in 2023, with as many sold vials in the fourth quarter as the rest of 2023 combined, we are ready for a 2024 where sales are expected to take off from current levels through German sales and expanding access to Pepaxti in other European markets." says Sofia Heigis, CEO of Oncopeptides. "Recent progress in Spain with a positive price commission opinion confirms the high unmet need of our drug and is a decisive step towards launch already during the second half of 2024 in a promising market."

Financial overview October-December

- Net sales amounted to SEK 5.3 M (0.6)
- Operating profit amounted to SEK -81.0 M (-100.5)
- Net profit amounted to SEK -81.2 M (-91.1)
- Profit per share, before and after dilution, amounted to SEK-0.90 (-1.01)
- Cash balances at the end of the period amounted to SEK 173.4 M (344.5)

Significant events October-December

- Henrik Bergentoft takes over as CFO on November 13.
- Oncopeptides selected to present additional data from the OCEAN study at the American Society of Hematology (ASH) congress.
- Article from Oncopeptides' OCEAN trial observing longer PFS and OS in melflufen compared to pomalidomide published in the European Journal of Hematology.
- The European Commission decided to formally approve the company's application to the European Medicines Agency (EMA) for an extended indication for Pepaxti to previous lines. Oncopeptides' previously communicated decision to end the process to extend the indication remains.

Events after the period

- On February 15, it was announced that the company will be granted an extension of the key patent that ensures market exclusivity for melflufen, marketed in Europe as Pepaxti, in Europe until 2037, an extension of five years.

- On February 23 it was announced that positive progress has been made in the market access procedure in Spain.
- On February 23 it was announced that a decision has been received from the U.S. Food and Drug Administration reconfirming withdrawal of Pepaxto from the U.S. market.

Financial overview of the group

(SEK thousand)	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Net sales	5 337	560	35 220	8 355
Whereof reversal of returns reserve USA	55	-	24 330	7 795
Operating profit	-80 980	-100 547	-253 447	-349 350
Profit after tax	-81 211	-91 098	-249 111	-337 951
Earnings per share, before and after dilution (SEK)	-0.90	-1.01	-2.76	-4.11
Cash flow from operating activities	-55 395	-77 630	-279 493	-420 509
Cash at the end of the period	173 407	344 515	173 407	344 515
R&D costs/operating expenses, %	39%	57%	37%	61%

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://ir.financialhearings.com/oncopeptides-q4-report-2023

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.financialhearings.com/teleconference/?id=50048285

CEO statement

The fourth quarter sets the stage for revenue acceleration in 2024
Having delivered on our promise of continuous growth quarter over quarter in 2023, with as many sold vials in the fourth quarter as the rest of 2023 combined, we are ready for a 2024 where sales are expected to take off from current levels through German sales and expanding access to Pepaxti in other European markets. Recent progress in Spain with a positive price commission opinion confirms the high unmet need of our drug and is a decisive step towards launch already during the second half of 2024 in a promising market. Outside our core business focus, European Pepaxti sales, we also continue to progress our next generation value drivers: sales opportunities outside of Europe and the development our pipeline assets, areas where we will be able to present new milestones during 2024.

During the last quarter of 2023, Oncopeptides sold about the same number of vials as during the first three quarters of the year combined, while net sales increased 90% between Q3 and Q4. A strong testament to our communicated ambition to continuously increase sales quarter over quarter, supporting our goal to become cash positive by the end of 2026, entailing sales of approx. SEK 400m. A milestone along the way is to ensure capital for the company, currently a high priority for me, the management team, and our board of directors.

I am incredibly proud of everyone involved in ensuring that we have progressed our market access efforts in Spain, well ahead of our original time plans. While we still need to agree to the final terms with the Ministry of Health, I expect us to start seeing sales in Spain during the second half of this year. This accomplishment is further underscored when you look at the time it has taken some of our competitors to reach the same milestone: what we achieved in five months took Belantamab two years and CAR-Ts close to one year, a testament to the abilities of our market access team but also another validation of the high unmet medical need and benefit of our drug.

In Germany, our team continues to engage with key opinion leaders, medical practitioners, and other key stakeholders through multiple channels to generate more awareness and better understanding of the positive benefit/risk profile of Pepaxti in a patient population with very few treatment options left. By the end of 2023 we had delivered our promise to build a team of broad competence and with a good network which will support our acceleration in 2024. To ensure all indicated patients get access to Pepaxti we have also updated our label to allow patients to receive Pepaxti through so called peripheral administration – a feature highly sought after by German doctors.

The market position of Pepaxti is on a slow but steady climb to a market position comparable to drugs such as Selinexor and Belantamab in Germany. And unlike

many of our competitors, we are growing in an increasingly unique market position among elderly patients with at least three previous lines of treatment, an area which many of our competitors are moving away from. According to our analysis of available market data, Pepaxti experienced the largest growth of all new drugs against relapsing, refractory multiple myeloma in Germany during December.

As for the rest of Europe, we look forward to being able to continue announcing market access in new markets. Spain, Italy, the Netherlands, Ireland as well as Norway remain the most advanced in terms of market access, while we have also recently initiated efforts to be able to launch in France and Sweden. As much as we would like to communicate a clear and detailed timeline country per country, we are unable to do so as these processes contain multiple steps and are largely controlled by the payers in the various countries. We will continue to communicate all major milestones in our European market access efforts to our shareholders. Regarding our next generation value drivers, sales of Pepaxti outside of Europe and our pipeline assets, we have continued to make progress during the last quarter of 2023.

As for sales in the rest of the world, our ambition to identify and execute opportunities outside of Europe remains. We have progressed in our business development discussions with China and Japan remaining our current focus areas, with other geographies also being explored.

The process of realizing the potential of our pipelines assets has also progressed during the last quarter of 2023, and we recently made the strategic decision to focus our short-term efforts on advancing our SPiKE platform towards an investigational new drug application (IND). We are currently in the process of selecting a drug candidate. Meanwhile, our PDC platform already has assets ready for clinical development, and we will now make a strategic assessment considering the FDA outcome.

Shortly before the publication of this report, we received the decision from the U.S. Food and Drug Administration, confirming their previously decided withdrawal of Pepaxto on the U.S. market. While we remain confident that we have science on our side we are of course disappointed in the decision. At the same time this is no change to our plans and we will continue to focus all our attention on the commercialization in Europe, progression of our pipeline and rest of world opportunities as outlined above.

If history is any indication, 2024 will be another year of both new challenges and opportunities for Oncopeptides, and I feel both honored and excited to be leading the company. To the Oncopeptides team as well as our shareholders I would like to say thank you for your contribution and support in 2023. Now let's accelerate further!

February 27, 2024
Sofia Heigis, CEO

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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 2024-02-27 08:00 CET.

About Oncopeptides

Oncopeptides is a biotech company focused on research, development, and commercialization 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 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.

Oncopeptides is developing several new compounds based on its proprietary technology platforms and is listed on Nasdaq Stockholm with the ticker ONCO. For more information see: www.oncopeptides.com.