Press release
30 May 2024 08:00:00 CET

Oncopeptides publishes Q1 report 2024

Stockholm – May 30, 2024 – Oncopeptides AB (publ) (Nasdaq Stockholm: ONCO), a biotech company focused on difficult-to-treat cancers, today publishes the report for the first quarter 2024.

"Seasonal flu and winter infections has posed challenges, but as we have progressed our business in Europe, especially in Spain and Germany and built a new partnership in the Middle East and North Africa (MENA), we have a strong foundation for future growth," says Sofia Heigis, CEO of Oncopeptides. "I am excited about the opportunities ahead as we expand our market reach to impact more patients globally."

Financial overview January-March

- Net sales amounted to SEK 5.1 M (1.1)
- Operating profit amounted to SEK -65.7 M (-72.7)
- Net profit amounted to SEK -67.7 M (-71.0)
- Profit per share, before and after dilution, amounted to SEK -0.75 (-0.79)
- Cash balances at the end of the period amounted to SEK 104.8 M (253.9)

Significant events January-March

- Oncopeptides will be granted an extension of key patents ensuring market exclusivity for melflufen, marketed as Pepaxti, in Europe until 2037, an extension of five years.
- Oncopeptides receives a positive recommendation for Pepaxti from the Spanish price authority.
- Oncopeptides Receives Decision From U.S. Food and Drug Administration confirming withdrawal of Pepaxto from the US market.
- Pepaxti maintains health-related quality of life shows the OCEAN study, article published in Haematologica.
- Oncopeptides' PORT study shows that peripheral venous administration of Pepaxti is as safe as central venous administration.
- Oncopeptides carries out a fully guaranteed rights issue of SEK 314 million to reach profitability in 2026.
- Oncopeptides and Vector Pharma FZCO announce collaboration to offer Pepaxti to patients in the Middle East and North Africa.

Events after the period

- Oncopeptides secures national reimbursement for Pepaxti in Spain.

- The final outcome of the rights issue is announced, where 94 percent is subscribed by rights and subscription notifications and the remaining 6 percent by guaranteed commitments. The rights issue amounted to SEK 314 million before deductions for issue costs.
- Oncopeptides presents new data highlighting treatment benefits of Pepaxti in high-risk multiple myeloma patients at the COMy Congress.
- Oncopeptides announces first treatment of patients in Spain with Pepaxti.

Financial overview of the group

(SEK thousand)	2024 Jan-Mar	2023 Jan-Mar	2023 Jan-Dec	2022 Jan-Dec
Net sales	5 072	1 124	35 220	8 355
Whereof reversal of returns reserve USA	-	-	24 330	7 795
Operating profit	-65 661	-72 740	-253 447	-349 350
Profit after tax	-67 705	-71 025	-249 111	-337 951
Earnings per share, before and after dilution (SEK)	-0.75	-0.79	-2.76	-4.11
Cash flow from operating activities	-67 362	-88 997	-279 493	-420 509
Cash at the end of the period	104 825	253 904	173 407	344 515

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-q1-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.financialhearings.com/teleconference/?id=50048825

CEO statement

Launch ready in Spain in record time

While we and many of our competitors faced flat or declining sales, our performance during Q1 strengthens my confidence in our growth potential and our European sales for Q1 met our expectations at SEK 5.1 million despite the challenging start to the year. Seasonal flu and winter infections has posed challenges, but as we have progressed our business in Europe, especially in Spain and Germany and built a new partnership in the Middle East and North Africa (MENA), we have a strong foundation for future growth. I am excited about the opportunities ahead as we expand our market reach to impact more patients globally.

Our European sales landed in line with our expectations at SEK 5.1 million, comparable to Q4 2023. According to our data most competing drugs in the late line setting have seen flat or even shrinking sales figures during the first quarter of 2024 and I remain fully confident that we will be able to accelerate our sales during 2024. The seasonal flu and other infections that are more common during the winter months temporarily hampered the ability for patients to receive the treatment in the beginning of the year.

As communicated, we expect an acceleration of sales in 2024, which will be supported by the start of sales in Spain and continued growth in Germany. In addition, we look forward to sales outside of Europe as a result of the announced partnership for the MENA region.

In Spain, we have achieved market access quicker than any our competitors, a testament to the high unmet medical need for our drug, the capabilities of our team in Spain and the clinical experience that we have built with more than 100 patients and 16 hospitals having been part of the development of Pepaxti. Although we expect sales to truly kick off after the summer, we have already received our first orders for Pepaxti, just a few weeks after the drug became available in Spain May 1. As the team in Spain, supported by our Stockholm headquarters, is now working diligently on ensuring regional access in key regions of Spain, I look forward to us soon being able to support more patients and capture the potential we see for the drug in Spain.

In Germany, our first launch market, we have seen continued engagement and growing awareness among doctors in the country, and we continue to work hard to penetrate a very scattered market, which is tough in the area of rare diseases.

As for MENA, I see the partnership with Vector Pharma both as an opportunity for sales in a region with potential, but also the beginning of a journey where we can leverage the extended network of the World Orphan Drug Alliance to provide patients all across the globe with access to Pepaxti. By adding new markets to our

revenue stream, we will not only add to our bottom line but also increase diversity and continuity to our sales, which will decrease reliability on specific markets.

In addition to ensuring market access in Spain we have during the first quarter also been able to move closer to access in other European markets. In France, we have taken one step further to gain market access while we continue progressing Italy, the Netherlands, Ireland and the Nordics as part of our second launch wave. These countries along with markets we have already launched in make up more than half of the SEK 1.5 billion market potential in Europe.

During February we also announced the extension of a key patent ensuring market exclusivity for Pepaxti for another five years, between 2032 and 2037. While it might be seen as far into the future, this means that we will be able to sell Pepaxti for five more years at or close to peak sales, a significant opportunity for us as a company and the long-term shareholder.

Beyond the commercialization of Pepaxti, we continued our efforts on next step value drivers during the first quarter: aside from the announced partnership in MENA we have continued to explore business development in China and Japan and added South Korea as a potential Asian market. We have also continued to advance our pipeline assets with clinical development selection ongoing for our SPiKe platform and following the FDA decision we are working on the strategy for our PDC platform. Our belief in the future potential of these assets remains strong.

In February we received a decision from the U.S. Food and Drug Administration (FDA) confirming withdrawal of Pepaxto from the U.S. market, as we discussed in our presentation of the fourth quarter 2023 report. While we still disagree with the FDAs interpretation of our data and regret they are not willing to update the US indication to reflect our target population, we have for a long time focused on the commercialization in Europe. Given that the FDA process is now finished, Jakob Lindberg will soon transition into a new role as senior scientific advisor at Oncopeptides.

Lastly, I would like to express my gratitude towards our shareholders for supporting Oncopeptides during our recently finalized rights issue. The capital raised will support us in all the efforts that I outlined above, bringing us to profitability in 2026. I want to thank both our existing shareholders for your continued support while also welcoming new owners to Oncopeptides.

May 30, 2024
Sofia Heigis, CEO

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The information was submitted for publication, through the agency of the contact persons set out above, at 2024-05-30 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.