

Science Leads the Way

Q1 Webcast, May 4, 2022

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Oncopeptides is a biotech company focused on research and development of therapies for difficult-to-treat hematological diseases. The company uses its proprietary peptide-drug conjugate (PDC) platform to develop compounds that rapidly and selectively deliver cytotoxic agents into cancer cells. The first drug coming from the PDC platform, Pepaxto® (INN melphalan flufenamide), also called melflufen was granted accelerated approval in the U.S., on February 26, 2021, in combination with dexamethasone, for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. Oncopeptides voluntarily withdrew the drug from the U.S. market on October 22, 2021, due to worse overall survival data in the phase 3 OCEAN study. The study was a post-approval requirement under the accelerated approval program. Oncopeptides is developing several new compounds based on the PDC platform. Melflufen is not approved by any other registration authorities.

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Participants



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Highlights Q1-2022

- EMA review process of melflufen in Europe is proceeding as expected, includes HORIZON and OCEAN data sets
- Rescission of the voluntary withdrawal of Pepaxto was announced on January 21
- Phase 3 OCEAN study was published in Lancet Haematology on January 13, data have been shared with regulatory authorities



EMA review process of melflufen on track

- EMA review process of melflufen in Europe is proceeding as expected. EMA will hold a Scientific Advisory Group meeting. CHMP opinion is anticipated in Q2, and an EC decision in Q3, 2022
- The EMA application, which originally was based on the pivotal phase 2 HORIZON-study, includes OCEAN as a potential confirmatory study

Rescission of voluntary withdrawal

- Voluntary withdrawal of Pepaxto in the US has been rescinded, based on further review and analyses of the heterogenous overall survival data from phase 3 OCEAN study and other relevant trials
- We do not market Pepaxto in the US at this time and have a dialogue with FDA to reach a mutual understanding and interpretation of OCEAN data. We cannot speculate on the timetable and outcome
- We are committed to provide US patients continued access to melflufen via the Individual Patient Expanded Access Investigational Drug Application (IND) process if deemed appropriate by their physician

Phase 3 OCEAN data published

“Results from OCEAN provide evidence that melflufen, with its novel mechanism of action, plus dexamethasone, can improve progression-free survival for patients with lenalidomide-refractory relapsed or refractory multiple myeloma who have received two to four previous lines of therapy.

The results also suggest that treatment with melflufen should be carefully tailored on the basis of a patient's previous medical history.”

Source: The Lancet Haematology, MD Fredrik H Schjesvold, et.al

THE LANCET Haematology

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Melflufen or pomalidomide plus dexamethasone for patients with multiple myeloma refractory to lenalidomide (OCEAN): a randomised, head-to-head, open-label, phase 3 study

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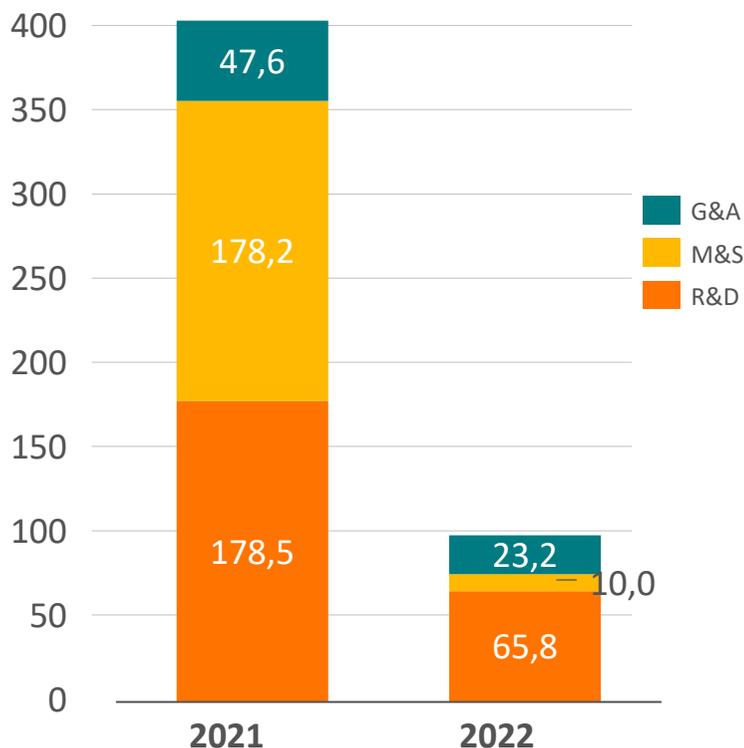
Wojciech Legiec, MD  et al. [Show all authors](#)  [Show footnotes](#)

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Financial Highlights January – March 2022

Operating Costs Jan-Mar



- Operating loss decreased to SEK 98.9 M (loss: 347.3)
 - Lower overall cost driven by the downsizing in general, and the close of US operations in particular
 - R&D decreased primarily driven by close of studies
 - OCEAN SEK 14 M (49)
 - Number of co-workers decreased from 162 at end of Q4 2021 to 76 at the end of Q1 2022 (to be reduced further during Q2 2022 as notice periods end)
- Cash flow from operating activities neg. SEK 166.0 M (neg. 386.7)



Q&A



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