



# Back to the future



## Significant events

### JULY–SEPTEMBER

- **Updated results** from the phase 3 OCEAN study were announced on July 8: melflufen met the primary endpoint of superior PFS
- **FDA requested** on July 8, a partial clinical hold of all clinical studies with melflufen, based on OS data in the ITT-population
- **FDA issued a safety alert** to patients and healthcare professionals on July 28, regarding an increased risk of death associated with Pepaxto® in the OCEAN study
- **FDA announced** an ODAC meeting on September 2, scheduled for October 28. The meeting was later cancelled
- **New data from OCEAN and PORT** were presented at the IMW meeting on September 11

### AFTER THE REPORTING PERIOD

- **Anders Martin-Löf, CFO**, resigned from Oncoceptides on October 15
- **Pepaxto** was withdrawn from the US market on October 22 and as such Oncoceptides will close commercial operations and refocus on R&D
- **Oncoceptides communicated** focused clinical development efforts to increase cash runway on November 4
- **Annika Muskantor** joined as interim CFO on November 8
- **Jakob Lindberg** was appointed CEO of Oncoceptides and Marty J Duvall left the company on November 15

\*Pepaxto® (melphalan flufenamide) is the US trade name. It is known as melflufen during clinical development.

## Financial overview

### JULY–SEPTEMBER

- **Net sales** amounted to SEK 54.3 M (0.0)
- **Operating loss** amounted to SEK 338.9 M (loss: 383.5)
- **Loss for the period** was SEK 777.5 M (loss: 383.4)
- **Loss per share**, before and after dilution, was SEK 10.33 (loss: 5.71)
- **Cash and cash equivalents** amounted to SEK 671.3 M (1,251.6) on September 30

### JANUARY–SEPTEMBER

- **Net sales** amounted to SEK 140.0 M (0.0)
- **Operating loss** amounted to SEK 1,031.1 M (loss: 1,079.7)
- **Loss for the period** was SEK 1,036.3 M (loss: 1,081.7)
- **Loss per share**, before and after dilution, was SEK 14.27 (loss: 17.87)
- **Cash and cash equivalents** amounted to SEK 671.3 M (1,251.6) on September 30



## Financial overview of the group

| (SEK thousand)                                     | 2021<br>Jul-Sep | 2020<br>Jul-Sep | 2021<br>Jan-Sep | 2020<br>Jan-Sep | 2020<br>Jan-Dec |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|
| Net sales  | 54,276          | -               | 140,005         | -               | -               |
| Gross profit                                       | 22,683          | -               | 105,262         | -               | -               |
| Gross margin                                       | 42%             | N/A             | 75%             | N/A             | N/A             |
| Operating loss                                     | -338,913        | -383,498        | -1,031,081      | -1,079,706      | -1,591,279      |
| Loss after tax                                     | -777,547        | -388,357        | -1,036,327      | -1,081,727      | -1,594,693      |
| Earnings per share before and after dilution (SEK) | -10,33          | -5.71           | -14,27          | -17.87          | -25.57          |
| Cash flow from operating activities                | -336,528        | -340,841        | -1,069,937      | -939,347        | -1,296,509      |
| Cash and cash equivalents at the end of the period | 671,269         | 1,251,629       | 671,269         | 1,251,629       | 840,255         |
| R & D costs/operating expenses, %                  | 41%             | 50 %            | 44%             | 59 %            | 54 %            |

## Back to the future

Early July, Oncopeptides presented more data from the phase 3 OCEAN study, a head-to-head evaluation of the efficacy and safety of melflufen versus pomalidomide in patients with relapsed refractory multiple myeloma. Melflufen demonstrated superior progression free survival compared to pomalidomide. However, the non-significant overall survival data in the ITT-population with a hazard ratio of 1.104, led to a request by the U.S. Food and Drug Administration, FDA, to put all clinical studies with melflufen on partial clinical hold. Following an increasingly intense dialogue with the agency, the Company decided on October 22, to withdraw Pepaxto® from the US market.

### SAFETY ALERT BY THE FDA

On July 28, the FDA issued a safety alert regarding “an increased risk of death” associated with Pepaxto in the OCEAN study based on a non-significant overall survival hazard ratio of 1.104 in the ITT population favoring pomalidomide. Patients receiving clinical benefit could stay on treatment if they were informed of the potential risks and gave their consent. FDA announced that they would continue to evaluate OCEAN and considered holding a public advisory committee meeting to discuss patient safety and the marketing authorization of Pepaxto. These regulatory constraints implied headwinds in Q3 with sales flat versus the prior quarter. Net revenue in Q3 was SEK 54.3 M (\$ 6.3M), and YTD SEK 140.0 (\$ 16.5M).

### COMPREHENSIVE DATA PRESENTED AT IMW

At the International Myeloma Working Group meeting in Vienna on September 11, Dr Fredrik Schjesvold from Oslo Myeloma Center presented the full data set from OCEAN. Data from pre-specified subgroups showed that the main benefit of melflufen on progression free survival was driven by patients without a prior autologous stem cell transplant and that the potential ITT survival risk with Pepaxto was isolated to patients with a prior autologous stem cell transplant.

### WITHDRAWAL OF PEPAXTO FROM THE US MARKET

On October 22, we communicated the Company’s decision to withdraw Pepaxto from the US market. This followed

increasingly intense discussions with the FDA where it appeared that the product would be withdrawn from the market after the upcoming Oncologic Drugs Advisory Committee meeting. The FDA emphasized that the OCEAN study, which was a post-approval requirement under the accelerated approval program, would not qualify as confirmatory study. After a careful consideration, the company decided to refocus on R&D, the ongoing process with EMA for a conditional marketing authorization in Europe, dedicate resources on a more focused clinical development program of melflufen and next generation drug candidates from the PDC-platform.

### BACK TO THE FUTURE

To increase cash runway and

build a foundation for a sustainable Swedish R&D company, Oncopeptides decided to rapidly close the commercial operations in the US and Europe, and significantly reduce the Stockholm based organization.

**In June 2020**, after the submission of our new drug application to the FDA for accelerated approval of melflufen, I decided to step down as CEO and assume a new role as Chief Scientific Officer. It was a natural step after a decade as CEO to handover the leadership to Marty J Duvall, given his commercial background, as we transformed into a fully integrated commercial stage biotech company.

**The last 18 months** have been extraordinary eventful and challenging with the most exciting



## Letter from the CEO

milestone being the accelerated approval of Pepaxto in the US in February 2021. The most disappointing event was of course the withdrawal of Pepaxto from the US market that, even as late as in the third quarter, was perceived as a very unlikely scenario. Despite the withdrawal, we remain confident in our science and are convinced that we can make a difference for patients. This is the main reason why we are committed to fulfil the conditional marketing authorization submission in the EU and are intrigued by the opportunities that our proprietary PDC-platform brings.

### REGAIN TRUST

The overarching goal in my new role will be to regain trust for our company and our science. We have identified three near-term priorities, that will be critical for our future development:

**Firstly**, we will increase our cash runway by closing the commercial operations, refocusing our

clinical development program, and downsizing the organization. We estimate that these initiatives will give us a cash runway at least throughout 2022.

**Secondly**, we are engaging in a dialogue with the FDA to potentially lift the clinical hold and enable clinical studies with the next generation drug candidates from our PDC-platform.

**And lastly**, we are moving forward with the conditional marketing authorization application of melflufen to the European Medicines Agency, EMA. We have a continuous dialogue with the agency to ensure that we will fulfill all requirements needed for a potential approval and expect an opinion from EMA's scientific committee CHMP around summer 2022.

**Even though** the development of the company has been significantly below expectations I am proud of the dedication and contribution that we are making

in advancing the care of patients with relapsed refractory multiple myeloma. It has been a journey like no other, but we have gained important learnings. We are now ready to embark on the next phase of our journey as a significantly smaller, but more focused R&D company. I would like to thank each one who has been part of our journey for your relentless contributions, and all our shareholders for your patience and support. We know that we have a lot to prove going forward and we hope to be able to regain your trust as we now take Oncopeptides into a new phase.

**November 24, 2021**

**Jakob Lindberg**  
CEO

## Q3 business highlights

### COMMERCIAL

Approximately 50 new patients started treatment with Pepaxto during the third quarter. FDA's safety alert on July 28 impacted the uptake negatively in the third quarter.

### CLINICAL DEVELOPMENT

On July 8, Oncopeptides announced updated and additional results from the phase 3 OCEAN study. This final analysis demonstrated that melflufen met the primary endpoint of superior PFS compared to pomalidomide with a Hazard Ratio (HR) of 0.792 (95% CI 0.640-0.979, p-value 0.0311. In conjunction with the presentation of the final PFS results from the OCEAN study, overall survival data from the ITT-population was disclosed. Based on a HR of 1.104 (95% CI 0.846-1.441) favoring pomalidomide, the FDA requested a partial clinical hold, pending further investigation. On July 28, the FDA issued a safety alert to patients and health care professionals regarding an increased risk of death associated with Pepaxto in the OCEAN study. The partial clinical hold means that no new patients have been enrolled in the clinical studies. Ongoing

patients could continue treatment if they received benefit and signed a new informed consent. An updated informed consent form was provided to all patients currently enrolled in the clinical studies and 124 out of 126 ongoing patients decided to continue treatment.

**The clinical program** is on partial clinical hold.

**The results** from the OCEAN study were presented at IMW in Vienna, September 8-11 by Dr Fredrik Schjesvold. An extensive analysis of data in pre-specified subgroups showed that the PFS benefit of melflufen was mainly driven by patients without a prior autologous stem cell transplant (ASCT), with a median PFS of 9.3 months versus 4.6 months and a HR of 0.59, compared to pomalidomide. The OS data in patients with no prior ASCT also favored melflufen with a median OS of 21.6 months compared to 16.5 months for pomalidomide with a HR of 0.78. However, the OS results in patients with a prior autologous stem cell transplant favored pomalidomide, with a median OS of 31.0 months versus 16.7 months for melflufen, and a HR of 1.61. This benefit of

pomalidomide over melflufen in the ASCT subgroup has contributed to the HR of 1.1 in the ITT population.

**Data** from the phase 2 PORT study, comparing pharmacokinetics, and assessing the safety and tolerability of peripheral and central administration of melflufen in patients with RRMM was presented as a poster at the IMW meeting. It was a successful study outcome, as both central and peripheral administration were comparable and support the potential use of peripheral infusion as a convenient alternative.

**Clinical study reports** are being developed for the OCEAN study, the PORT study as well as for the phase 2 BRIDGE study. BRIDGE is evaluating the use of melflufen in patients with RRMM who have moderate to severe renal impairment.

**The Early Access Program** for RRMM patients in Europe continued to enroll patients in Q3. Physicians may apply for melflufen treatment for eligible patients who cannot be adequately treated with approved and commercially available

medications, or drugs that are available through clinical trials. To be eligible for treatment in the program patients must have relapsed or refractory multiple myeloma, received at least two prior lines of therapy and be refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody (i.e. be triple class refractory). The protocol and consent process for the EAP was amended during Q2 to the reflect the ongoing discussions with the FDA and the program continues for the patient population similar to the US labeled indication. As of September 30, 56 patients across 6 countries in Europe have been approved for participation in the program.

### SCIENTIFIC ENGAGEMENT

During Q3 abstracts International Myeloma Workshop (IMW) and American Society of Hematology (ASH) were submitted. Nine abstracts have been accepted at ASH and three of them will be presented as posters:

- Melflufen/Dexamethasone Compared With Pomalidomide/ Dexamethasone in Patients

With Relapsed/Refractory Multiple Myeloma—Age Subgroup Analysis of Older Patients

- Melflufen/Dexamethasone (Dex) Compared with Pomalidomide (Pom)/Dex in Patients (Pts) with Relapsed/Refractory Multiple Myeloma (RRMM) — Safety and Tolerability Analyses
- Single Cell RNA Sequencing Identifies Potential Molecular Indicators of Response to Melflufen in Multiple Myeloma

**To the Lymphoma, Leukemia and Myeloma Congress**, we submitted 3 encore abstracts, and all have been accepted as presentations.

**At IMW** in Vienna, the OCEAN data was presented by Dr Schjesvold in an oral session and data from PORT was presented in a poster session. In addition, Oncopeptides sponsored an educational symposium where a prominent international faculty discussed current and future treatment options and remaining challenges in relapsed/refractory multiple myeloma.

**The Society** of Hematologic Oncology (SOHO) took place in

Houston in September, where Oncopeptides presented 3 encore posters with data from HORIZON and ANCHOR (earlier presented at the European Hematology Association Annual Meeting).

**In total** eight manuscripts were submitted to eight scientific publications during Q3.

### PRE-CLINICAL DEVELOPMENT

During Q3 Oncopeptides continued research on the PDC platform, with the objective to develop selective and differentiated clinical candidates.

### SUSTAINABILITY (ESG)

#### Environmental

We continuously strive to minimize the environmental impact of our own operations and those of our suppliers. During Q3 we improved our waste sorting at HQ in Stockholm to be optimized for the return of employees to the premise. Our pre-clinical laboratory in Stockholm is effectively a closed system with virtually no impact on the local environment. As with all modern-day labs in highly regulated geographies such as the EU, chemical handling and disposal and waste disposal is tightly controlled.

## Q3 business highlights

### Social

In Q3 we continued to support a number of patient advocacy events, online learning opportunities and fundraisers in the third quarter through employee participation and support on social media. During this time, posts through our LinkedIn and Twitter (U.S. only) channels highlighted patient advocacy and healthcare organizations like the International Myeloma Foundation (IMF), Indiana University Health and the Multiple Myeloma Research Foundation. We shared information on Blood Cancer Awareness Month activities throughout September, as well as a multiple myeloma webinar by Cancer Dudes, a Living Well with Myeloma webinar by IMF in August and much more.

**The Early Access program** in Europe started as an initiative to support patients with relapsed refractory multiple myeloma with a large unmet medical need. Physicians may apply for melflufen treatment for eligible patients who cannot be adequately treated with approved and commercially available medications, or drugs that are available through clinical trials.

**In light of** lifted restrictions in Sweden due to the pandemic,

preparations for employees to be able to safely return to the office have been carried out.

### Governance

During Q2 the governance project phase 1 was implemented and completed within the R&D organization. The team has during Q3 worked according to the established governance structure.

### ORGANIZATION

After the third quarter the company initiated a restructuring process as a consequence of the withdrawal of Pepaxto from the US market. Many employees have and will have to leave the company. Because of this there is a negative effect on share-based related remunerations in the third quarter due to the expected reduction of the number of instruments that can be utilized. The allocated instruments will thereby be revoked.

### SHARE PRICE DEVELOPMENT

FDA's safety alert on July 28 significantly impacted sales of Pepaxto in the third quarter. This also had a considerable impact on the share price. The costs related to social security contributions in share-related remunerations vary on a quarterly basis based on the underlying share price. As a consequence of the significant decrease in share price during

2021, the reserve of social security contributions associated with incentive programs has become less. This, due to the revaluation of the value of the tax benefits for the participants.

### AFTER THE REPORTING PERIOD

On October 22 Oncopeptides announced the withdrawal of Pepaxto from the US-market. The decision was taken after intense interactions and dialogue with the US Food and Drug Administration, FDA, following the overall survival result in the phase 3 OCEAN study.

**Oncopeptides** is committed to keeping Pepaxto available for patients currently on treatment who benefit from it, free of charge.

**As of November 4**, Oncopeptides will reduce the activity level in the clinical development program with melflufen to increase the company's cash runway and at the same time support the ongoing marketing authorization application process in Europe.

**This will have implications** on the following studies:

- OCEAN study will continue with long-term follow-up and documentation in accordance to previous plans



- Patient recruitment has been completed in both PORT and BRIDGE and the studies can be closed with relevant scientific data sets
- ANCHOR will close without the last 10 previously planned patients in the bortezomib + melflufen study arm – data sets will be large enough to draw relevant scientific conclusions
- ASCENT, COAST and

LIGHTHOUSE will close with incomplete number of patients, it will not be possible to draw any relevant scientific conclusions from these data sets

**CFO Anders Martin-Löf** resigned from the company on October 15. Annika Muskantor, joined Oncopeptides on November 8 as interim CFO.

**Jakob Lindberg** was appointed

Chief Executive Officer, CEO of Oncopeptides on November 15. Jakob Lindberg replaces Marty J Duvall, who has been the CEO since July 1, 2020. ■

**We use our proprietary peptide-drug conjugate platform, PDC, to expand our portfolio, and develop a pipeline of drug candidates for several hematological conditions.**

**We are exploring** innovative candidates and treatments for multiple hematological diseases. The platform gives us a unique competitive advantage because it enables us to build a robust, flexible drug candidate pipeline. This, combined with our collaborations with leading research centers worldwide, enables us to further leverage the PDC platform and expand our portfolio of treatment for difficult-to-treat hematological conditions.

#### **UNIQUE PDC PLATFORM**

The PDC platform allows us to concentrate toxins in cancer cells by exploiting differences between cancer cells and healthy cells. By doing this, we can deliver more and different types of cytotoxic activity to

cancer cells while protecting healthy cells. This is known as “signal to noise”. This means that we get more signal – toxin – into cells to damage or kill tumors, while minimizing noise – harm – to healthy cells.

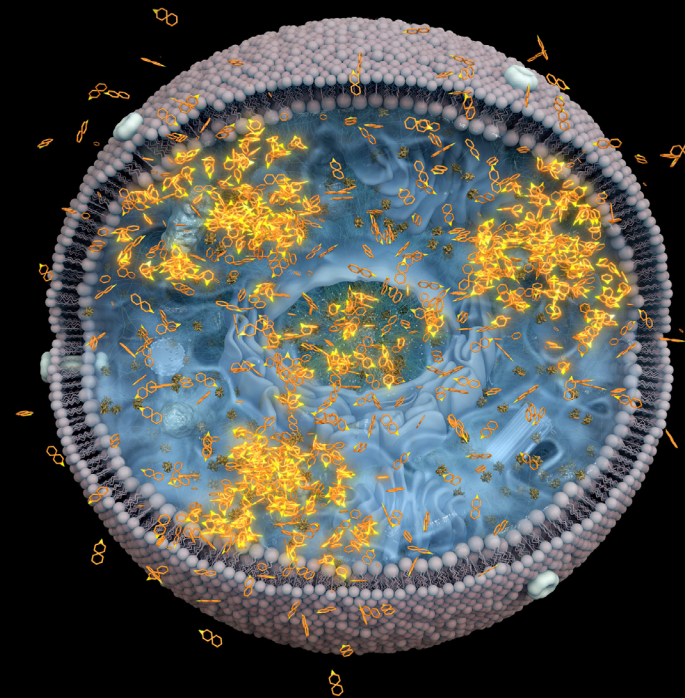
#### **STATE-OF-THE-ART RESEARCH LABORATORY**

Over the past years, Oncopeptides has developed several drug candidates from the PDC platform.

**In 2020**, we opened our state-of-the-art drug development facility in Solna, just outside Stockholm, Sweden. The laboratory will play a vital role in further developing the PDC platform.

#### **LOOKING AHEAD**

Our unique PDC platform, our drug development facility in Solna and in-house expertise devoted to cutting-edge discovery research and drug development, along with our active engagement in academic collaborations with top-tier universities in Europe and the US, mean that we are ideally positioned to establish a continuous flow of new drug candidates going forward. ■



#### **The multiple myeloma cell**

Melfufen is our first in class anti-cancer PDC that targets aminopeptidases and rapidly releases alkylating agents into tumor cells. Aminopeptidases are a group of enzymes over expressed in tumor cells, including multiple myeloma cells. The binding of Melfufen to aminopeptidases results in the release of a toxic payload that damages DNA and kills cancer cells.

### REVENUE

Net sales in the third quarter amounted to SEK 54.3 M (-) and SEK 140.0 M (-) in the period January to September. The revenue has been affected by expected returns due to the course of events regarding the withdrawal of PEPAXTO in the US market. The accrual estimated for the returns amounts to SEK 20.2 M. Gross profit amounted to SEK 22.7 M (-) for the third quarter and SEK 105.3 M (-) for the first nine months of the year, corresponding to a gross margin of 41.8% (n/a) for the third quarter and 75.2% (n/a) for the first nine months of the year. The gross margin has been affected in the third quarter by the accrual recorded based on the assumed increased amount of returns as a consequence of the withdrawal of PEPAXTO.

### OPERATING EXPENSES

Operating expenses for the third quarter amounted to SEK 361.6 M (383.5) and SEK 1,136.3 M (1,079.7) for the first nine months of the year. As a result of the withdrawal of PEPAXTO, the assets have been revaluated and impaired by SEK 22.0 M in the group

and by SEK 152.3 M in the parent company. Impairment of assets are essentially including inventories amounting to SEK 9.0 M in the group whereof SEK 8.2 M in the parent company. Impairment of right-of-use assets amounts to SEK 5.0 M in the group. Impairment of intra-group receivables in the parent company amounts to SEK 144.1 M. All impairments are of a non-recurring nature, directly connected to the business re-structuring previously communicated.

In addition to the above mentioned costs and adjustments for share-based remuneration programs, no other costs, linked to the withdrawal of PEPAXTO nor from the restructuring, has affected the quarter.

### RESEARCH AND DEVELOPMENT COSTS

Research and development costs amounted to SEK 149.8M (193.4) for the third quarter and to SEK 495.6 M (634.8) for the first nine months of the year. The reduced cost in the OCEAN study and the HORIZON study, which is in its final stage are main reasons for the lower costs.

### MARKETING AND DISTRIBUTION COSTS

Marketing and distribution costs amounted to SEK 147.9 M (134.0) for the third quarter and to SEK 530.5 M (282.9) for the first nine months of the year. The full-scaled sales and marketing organization that has been established together with the commercialization activities to advance the sales of PEPAXTO in the US are contributing factors to the increased costs.

### ADMINISTRATION EXPENSES

For the third quarter administration expenses amounted to SEK 53.4 M (49.8) for and to SEK 141.8 M (137.0) for the first nine months of the year.

### SHARE-BASED PAYMENTS

The costs for social security contributions related to share-based incentive programs vary from quarter to quarter due to the change in the underlying share price. As the share price has decreased significantly during the year, the provision for social security contributions linked to incentive programs also decreased as a result of the continuous revaluation of the value of the tax benefit for the participants.

Related provisions are reported as long- and short-term liabilities.

In the third quarter, a negative effect arises on share-based payments as a result of the expected reduction in the number of instruments that can be utilized, which has been caused by the restructuring the company is undergoing and which means that most employees have and will be notified of termination. The assigned instruments will then be revoked. The cost for the share-based incentive programs have thus been reduced during the year and amounted to SEK negative 27.8 M (12.4) in the third quarter and to SEK negative 22.0 M (38.3) for the first nine months of the year out of which SEK negative 43.4 M (12.2) was provisions and payments of social security contributions and SEK 21.4 M (26.1) was costs for share-based remuneration. These costs have no cash impact. The company has issued warrants that are exercised to cover social security contributions exceeding the paid premiums that may arise from the exercise of granted employee stock options. See note 9.

### IMPACT OF COVID-19

COVID-19 has less impact on the company as a result of the lifted restrictions in countries where the company is conducting business. The pandemic, is therefore not considered to have a significant impact on the finances of the company.

### TAXES AND EARNINGS

The loss before taxes was SEK 338.6 M (383.8) for the third quarter and SEK 1,031.9 M (1,080.7) for the first nine months of the year. As a result of intra-group sales of stock items, a deferred tax asset arose on temporary differences in the group. The internal profit is in its entirety reversed consequently of the inventory being returned to the parent company and the deferred tax claim has thus been reversed with -436.7 M (0.0) for the third quarter and SEK 0.0 M (0.0) MSEK for the first nine months of the year. The parent company does not report any corresponding tax expense on the sale, as a result of loss carryforwards. Tax revenue has no cash impact. See note 7. The loss for the third quarter was SEK 777.5 M (383.4) and SEK 1,036.3 M (1,081.7) for the

first nine months of the year. This corresponds to a loss per share, before and after dilution, of SEK 10.33 (neg. 5.71) for the third quarter and to a loss per share of 14.27 (neg. 17.87) for the first nine months of the year.

### CASH FLOW, INVESTMENTS AND FINANCIAL POSITION

Cash flow from operating activities amounted to a negative SEK 336.5 M (neg. 340.8) for the third quarter and negative SEK 1,069.9 M (neg. 939.3) for the first nine months of the year, of which 0 SEK is attributable to expenses of a non-recurring nature connected to the restructuring.

The negative cash flow is mainly explained by the company's activities to support the sale of PEPAXTO in the USA and by the expansion of the company's medical affairs and marketing functions.

Cash flow from investing activities amounted to SEK 0.0 M (neg. 6.8) for the third quarter and to negative SEK 0.3 M (neg. 15.6) for the first nine months of the year. Cash flow from financing activities amounted to negative SEK 0.9 M (670.9) for the third quarter and SEK 1,038.0 M (1 319.8) for the first nine

months of the year. Cash flow for the third quarter amounted to negative SEK 337.4 M (323.3) for the third quarter and to negative SEK 32.3 M (364.8) for the first nine months of the year. As of September 30, 2021, cash and cash equivalents amounted to SEK 671.3 M (1,251.6). In addition the company has a committed loan facility of € 40 M from the E5B that has not been utilized. Usage terms of this loan facility are being renegotiated. Equity amounted to SEK 612.1 M (1,071.5).

#### GOING CONCERN AND FINANCING

On October 22 the company decided after dialogue with the US Drug Administration, FDA, to voluntarily withdraw Pepaxto® from the US market. As a result the board decided to immediately change direction and resume being a Sweden-based R&D company, focused on further development of the proprietary PDC platform, including the next generation of drug candidates OPD5 and OPDC3. The company has also emphasized its commitment to meet all requirements needed to support

the application to the European Medicines Agency EMA for a potential conditional marketing authorization of melflufen in Europe. A decision was made by the board to significantly downsize the organisation and build a platform for long-term development and growth.

Reduced expenses will improve the Group's cash flow. The board and the CEO continuously assesses the Group's cash and financial resources both on short and long term. The quarterly report has been prepared based on the assumption that the company has the ability to continue operations in the coming 12 month period, in line with the going concern principle. The basis for this assumption is that Oncopeptides AB and its subsidiaries have taken great measures since October 2021 to reduce expenses and thereby strengthen the financial situation. The commercial activities in the United States and Europe will be terminated and the organization in Stockholm will be reduced significantly during the last quarter of the year. As Oncopeptides returns to being a research and development company without revenue generation, the company will not

generate positive cash flow from current business operations in the near future. During ongoing research and product development, when the company has no commercial product and thus no source of revenue, the company may be in need of additional external capital.

The assessment of the board and the CEO is that given that the reorganization of the business proceeds according to plan, the group is deemed to have the necessary cash and cash equivalent to continue business operations during at least the coming twelve months. Would the above conditions do not fulfilled, for example if the company's reorganization entails higher costs than expected, there is a risk concerning the Group's continued operation. This suggests that there are conditions that indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. ■

## Other information

#### CO-WORKERS

As of September 30, 2021, the number of co-workers amounted to 321 (232).

#### PARENT COMPANY

Since the operations of the parent company are consistent with those of the group in all material respects, the comments for the group are also largely relevant for the parent company.

During the third quarter, returns resulting from the development of the withdrawal of Pepaxto from the subsidiary affected revenue in the parent company.

#### THE ONCOPEPTIDES SHARE

As of September 30, 2021, the number of registered shares and votes in Oncopeptides amounted to 75,291,841.

#### EVENTS AFTER THE END OF THE REPORT PERIOD

**Anders Martin-Löf, CFO,** resigned from Oncopeptides on October 15.

**Pepaxto** was withdrawn from the US market on the October 22 and as a consequence from that comes the commercial the business to be wound up and the focus is again on Research and

Development. In order to meet all required requirements to support the application to the European Medicines Agency EMA on a potential conditional marketing approval of melflufen in Europe the company has strengthened its commitment further.

**Oncopeptides** announced on November 4 that the company focuses clinical development efforts to increase cash runway.

**Annika Muskantor** assumed the position as interim CFO on November 8.

**Jakob Lindberg** was appointed CEO on November 15. ■

Stockholm, November 24, 2021

**Jakob Lindberg**  
CEO



Oncopeptides AB (publ) corp.  
reg. no. 556596-6438.

### INTRODUCTION

We have reviewed the condensed interim report for Oncopeptides AB as at September 30, 2021 and for the nine months period then ended. The Board of Directors and the CEO and President are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### SCOPE OF REVIEW

We conducted our review in accordance with the International Standard on Review Engagements, ISRE 2410 *Review of Interim Financial Statements Performed by the Independent Auditor of the Entity*. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International

Standards on Auditing and other generally accepted auditing standards in Sweden.

The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act regarding the Group, and in accordance with the Swedish Annual Accounts Act regarding the Parent Company.

### MATERIAL UNCERTAINTY RELATED TO GOING CONCERN

We draw attention to the section Going concern and financing on page 8 in the interim report, which indicates that the company will not generate positive cash flows from current business operations in the near future, and that if the company's reorganization entails higher

costs than expected, there is a risk concerning the company's ability to continue as a going concern. These events or conditions, along with the other matters mentioned, indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

Stockholm November 24, 2021

Ernst & Young AB

Anna Svanberg  
Authorized Public Accountant

## Condensed consolidated statement of comprehensive income

| SEK thousand  | Note | 2021<br>Jul-Sep | 2020<br>Jul-Sep | 2021<br>Jan-Sep   | 2020<br>Jan-Sep   | 2020<br>Jan-Dec   |
|---|------|-----------------|-----------------|-------------------|-------------------|-------------------|
| Net sales   | 5    | 54,276          | -               | 140,005           | -                 | -                 |
| Cost of goods sold  |      | -31,593         | -               | -34,743           | -                 | -                 |
| <b>Gross profit</b>                                       |      | <b>22,683</b>   | <b>-</b>        | <b>105,262</b>    | <b>-</b>          | <b>-</b>          |
| <b>Operating expenses</b>                                 |      |                 |                 |                   |                   |                   |
| Research and development costs                            |      | -149,792        | -193,433        | -495,632          | -634,798          | -866,214          |
| Marketing and distribution costs                          |      | -147,895        | -134,024        | -530,514          | -282,918          | -456,529          |
| Administrative expenses                                   |      | -53,430         | -49,811         | -141,827          | -136,965          | -197,662          |
| Other operating income/expenses <sup>1</sup>              |      | -10,480         | -6,230          | 31,630            | -25,025           | -70,874           |
| <b>Total operating expenses</b>                           |      | <b>-361,596</b> | <b>-383,498</b> | <b>-1,136,343</b> | <b>-1,079,706</b> | <b>-1,591,279</b> |
| <b>Operating loss</b>                                     |      | <b>-338,913</b> | <b>-383,498</b> | <b>-1,031,081</b> | <b>-1,079,706</b> | <b>-1,591,279</b> |
| Net financial items                                       |      | 346             | -286            | -799              | -947              | -1,163            |
| <b>Loss before tax</b>                                    |      | <b>-338,568</b> | <b>-383,784</b> | <b>-1,031,880</b> | <b>-1,080,653</b> | <b>-1,592,442</b> |
| Income tax  | 7    | -438,979        | 427             | -4,447            | -1,074            | -2,251            |
| <b>Loss for the period<sup>2</sup></b>                    |      | <b>-777,547</b> | <b>-383,357</b> | <b>-1,036,327</b> | <b>-1,081,727</b> | <b>-1,594,693</b> |
| <b>Other comprehensive income</b>                         |      |                 |                 |                   |                   |                   |
| <b>Items to be reclassified to profit or loss</b>         |      |                 |                 |                   |                   |                   |
| Translation differences from foreign operations           |      | 25,255          | 54              | 451               | -118              | -1,544            |
| <b>Total other comprehensive income, net of tax</b>       |      | <b>25,255</b>   | <b>54</b>       | <b>451</b>        | <b>-118</b>       | <b>-1,544</b>     |
| <b>Total comprehensive income, net of tax</b>             |      | <b>-752,292</b> | <b>-383,303</b> | <b>-1,035,875</b> | <b>-1,081,845</b> | <b>-1,596,237</b> |
| <b>Earnings per share before and after dilution (SEK)</b> |      | <b>-10.33</b>   | <b>-5.71</b>    | <b>-14.27</b>     | <b>-17.87</b>     | <b>-25.57</b>     |

- 1) Exchange rate differences on assets and liabilities in operational activities.  
2) Loss for the period is in total attributable to parent company shareholders.

## Condensed consolidated statement of financial position

| SEK thousand                    | 2021<br>30 Sep | 2020<br>30 Sep   | 2020<br>31 Dec |
|---------------------------------|----------------|------------------|----------------|
| <b>ASSETS</b>                   |                |                  |                |
| <b>Non-current assets</b>       |                |                  |                |
| Intangible assets               | 1,513          | 1,971            | 1,830          |
| Property, plant and equipment   | 10,879         | 14,078           | 17,273         |
| Right-of-use assets             | 6,581          | 25,756           | 21,057         |
| Financial non-current assets    | 851            | 3,914            | 3,622          |
| Deferred tax assets             | 10,834         | 2,871            | 8,175          |
| <b>Total non-current assets</b> | <b>30,658</b>  | <b>48,590</b>    | <b>51,957</b>  |
| <b>Current assets</b>           |                |                  |                |
| Inventory                       | -              | -                | 8,665          |
| Accounts receivable             | 72,876         | -                | -              |
| Other current receivables       | 27,198         | 15,276           | 23,229         |
| Prepaid expenses                | 25,452         | 6,173            | 22,650         |
| Cash and cash equivalents       | 671,269        | 1,251,629        | 840,255        |
| <b>Total current assets</b>     | <b>796,796</b> | <b>1,273,078</b> | <b>894,799</b> |
| <b>TOTAL ASSETS</b>             | <b>827,454</b> | <b>1,321,668</b> | <b>946,756</b> |

|  | 2021<br>30 Sep | 2020<br>30 Sep   | 2020<br>31 Dec |
|--|----------------|------------------|----------------|
| <b>EQUITY AND LIABILITIES</b>  |                |                  |                |
| <b>Equity</b>  |                |                  |                |
| Share capital  | 8,366          | 7,530            | 7,549          |
| Additional paid-in capital   | 4,989,265      | 3,899,237        | 3,919,036      |
| Reserves   | -1,091         | -116             | -1,542         |
| Retained earnings (including net profit/loss for the period)                   | -4,384,472     | -2,835,180       | -3,348,146     |
| <b>Total equity<sup>1</sup></b>  | <b>612,068</b> | <b>1,071,471</b> | <b>576,897</b> |
| <b>Long-term liabilities</b>   |                |                  |                |
| Provision for social security contributions,<br>share based incentive programs | 816            | 14,423           | 8,530          |
| Other long-term liabilities  | 191            | 9,890            | 6,929          |
| <b>Total long-term liabilities</b>   | <b>1,006</b>   | <b>24,313</b>    | <b>15,459</b>  |
| <b>Current liabilities</b>   |                |                  |                |
| Provision for social security contributions,<br>share based incentive programs | 4,435          | 30,074           | 47,202         |
| Trade payables   | 29,886         | 67,807           | 136,135        |
| Other current liabilities  | 14,203         | 17,779           | 35,045         |
| Accrued expenses and deferred income   | 165,855        | 110,224          | 136,018        |
| <b>Total current liabilities</b>   | <b>214,379</b> | <b>225,884</b>   | <b>354,400</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>  | <b>827,454</b> | <b>1,321,668</b> | <b>946,756</b> |

1) Equity is in total attributable to parent company shareholders.

## Condensed consolidated statement of changes in equity

| SEK thousand                                      | 2021<br>Jul-Sep  | 2020<br>Jul-Sep  | 2021<br>Jan-Sep   | 2020<br>Jan-Sep   | 2020<br>Jan-Dec   |
|---|------------------|------------------|-------------------|-------------------|-------------------|
| <b>Opening balance</b>                            | <b>1,376,085</b> | <b>769,909</b>   | <b>576,897</b>    | <b>797,013</b>    | <b>797,013</b>    |
| Profit/loss of the period                         | -777,547         | -383,357         | -1,036,327        | -1,081,727        | -1,594,693        |
| Other comprehensive income                        | 25,255           | 54               | 451               | -118              | -1,544            |
| <b>Comprehensive income (loss) for the period</b> | <b>-752,292</b>  | <b>-383,303</b>  | <b>-1,035,875</b> | <b>-1,081,845</b> | <b>-1,596,237</b> |
| <b>Transaction with owners</b>                    |                  |                  |                   |                   |                   |
| New issue of ordinary shares                      | -                | 716,450          | 1,106,000         | 1,413,925         | 1,413,925         |
| Cost attributable to new share issue              | -                | -42,987          | -67,053           | -85,228           | -85,231           |
| Share based payments                              | -15,218          | 9,578            | 21,611            | 25,780            | 38,398            |
| Exercise of warrants                              | 3,494            | 1,824            | 10,488            | 1,826             | 9,029             |
| <b>Total transaction with owners</b>              | <b>-11,724</b>   | <b>684,865</b>   | <b>1,071,047</b>  | <b>1,356,303</b>  | <b>1,376,121</b>  |
| <b>CLOSING BALANCE</b>                            | <b>612,068</b>   | <b>1,071,471</b> | <b>612,068</b>    | <b>1,071,471</b>  | <b>576,897</b>    |

## Condensed consolidated statement of cash flow

| SEK thousand  | 2021<br>Jul-Sep | 2020<br>Jul-Sep  | 2021<br>Jan-Sep   | 2020<br>Jan-Sep   | 2020<br>Jan-Dec   |
|---|-----------------|------------------|-------------------|-------------------|-------------------|
| Loss before financial items   | -338,913        | -383,498         | -1,031,081        | -1,079,706        | -1,591,279        |
| Adjustment for non-cash-items <sup>1</sup>                                  | 47,743          | 22,650           | 140,197           | 83,378            | 160,906           |
| Interest received   | 0               | 202              | 5                 | 202               | 322               |
| Interest paid   | -126            | -389             | -713              | -1,149            | -1,485            |
| Tax paid  | -139            | -174             | -12,070           | -3,472            | -7,243            |
| <b>Cash flow from operating activities before change in working capital</b> | <b>-291,435</b> | <b>-361,209</b>  | <b>-903,661</b>   | <b>-1,000,747</b> | <b>-1,438,779</b> |
| Cash flow from changes in working capital                                   | -45,093         | 20,368           | -166,275          | 61,400            | 142,270           |
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>                                  | <b>-336,528</b> | <b>-340,841</b>  | <b>-1,069,937</b> | <b>-939,347</b>   | <b>-1,296,509</b> |
| Cash flow from investing activities   | 0               | -6,745           | -339              | -15,631           | -20,127           |
| Cash flow from financing activities   | -880            | 670,860          | 1,038,014         | 1,319,790         | 1,323,461         |
| <b>Cash flow for the period</b>   | <b>-337,409</b> | <b>323,274</b>   | <b>-32,262</b>    | <b>364,812</b>    | <b>6,825</b>      |
| Cash and cash equivalents at beginning of period                            | 999,384         | 937,773          | 840,255           | 926,186           | 926,186           |
| Change in cash and cash equivalents   | -337,409        | 323,274          | -32,262           | 364,812           | 6,825             |
| Foreign exchange difference in cash and cash equivalents                    | 9,294           | -9,418           | -136,723          | -39,369           | -92,756           |
| <b>Cash and cash equivalents at the end of period</b>                       | <b>671,269</b>  | <b>1,251,629</b> | <b>671,269</b>    | <b>1,251,629</b>  | <b>840,255</b>    |

<sup>1</sup>) Pertains mainly to changes in share-based remuneration programs including social security contributions and exchange rate differences.

## Condensed Parent Company income statement

| SEK thousand                                 | 2021<br>Jul-Sep   | 2020<br>Jul-Sep | 2021<br>Jan-Sep   | 2020<br>Jan-Sep   | 2020<br>Jan-Dec   |
|--|-------------------|-----------------|-------------------|-------------------|-------------------|
| Net sales <sup>1</sup>                       | -1,703,207        | -               | 160,339           | -                 | -                 |
| Cost of goods sold                           | -8,208            | -               | -20,279           | -                 | -                 |
| <b>Gross profit</b>                          | <b>-1,711,415</b> | <b>-</b>        | <b>140,060</b>    | <b>-</b>          | <b>-</b>          |
| <b>Operating expenses</b>                    |                   |                 |                   |                   |                   |
| Research and development costs               | -148,037          | -193,503        | -492,885          | -635,077          | -866,509          |
| Marketing and distribution costs             | -162,673          | -132,567        | -557,567          | -286,261          | -460,860          |
| Administrative expenses                      | -46,073           | -49,079         | -139,809          | -138,722          | -201,751          |
| Other operating income/expenses <sup>2</sup> | -10,919           | -6,230          | 31,300            | -25,025           | -70,874           |
| <b>Total operating expenses</b>              | <b>-367,702</b>   | <b>-381,379</b> | <b>-1,158,960</b> | <b>-1,085,085</b> | <b>-1,599,994</b> |
| <b>Operating loss</b>                        | <b>-2,079,117</b> | <b>-381,379</b> | <b>-1,018,900</b> | <b>-1,085,085</b> | <b>-1,599,994</b> |
| Net financial items <sup>3</sup>             | -143,607          | 106             | -144,128          | 229               | 375               |
| <b>Loss before tax</b>                       | <b>-2,222,725</b> | <b>-381,273</b> | <b>-1,163,028</b> | <b>-1,084,856</b> | <b>-1,599,620</b> |
| Tax  | -                 | -               | -                 | -                 | -                 |
| <b>Loss for the period</b>                   | <b>-2,222,725</b> | <b>-381,273</b> | <b>-1,163,028</b> | <b>-1,084,856</b> | <b>-1,599,620</b> |

1) Refers to intra-group revenues.

2) Exchange rate differences on assets and liabilities in operational activities.

2) Refers mainly to impairment of intra-group balances.

## Condensed Parent Company statement of comprehensive income

| SEK thousand  | 2021<br>Jul-Sep   | 2020<br>Jul-Sep | 2021<br>Jan-Sep   | 2020<br>Jan-Sep   | 2020<br>Jan-Dec   |
|---|-------------------|-----------------|-------------------|-------------------|-------------------|
| <b>Loss of the period</b>                           | <b>-2,222,725</b> | <b>-381,273</b> | <b>-1,163,028</b> | <b>-1,084,856</b> | <b>-1,599,620</b> |
| <b>Other comprehensive income</b>                   | <b>-</b>          | <b>-</b>        | <b>-</b>          | <b>-</b>          | <b>-</b>          |
| <b>Total other comprehensive income, net of tax</b> | <b>-</b>          | <b>-</b>        | <b>-</b>          | <b>-</b>          | <b>-</b>          |
| <b>Total comprehensive loss for the period</b>      | <b>-2,222,725</b> | <b>-381,273</b> | <b>-1,163,028</b> | <b>-1,084,856</b> | <b>-1,599,620</b> |

## Parent Company balance sheet

| SEK thousand                       | 2021<br>30 Sep | 2020<br>30 Sep   | 2020<br>31 Dec |
|------------------------------------|----------------|------------------|----------------|
| <b>ASSETS</b>                      |                |                  |                |
| Subscribed but unpaid capital      | -              | -                | -              |
| <b>Non-current assets</b>          |                |                  |                |
| Intangible fixed assets            | 1,513          | 1,971            | 1,830          |
| Property, plant and equipment      | 10,879         | 8,397            | 12,097         |
| Other financial non-current assets | 1,155          | 5,309            | 8,664          |
| <b>Total non-current assets</b>    | <b>13,546</b>  | <b>15,677</b>    | <b>22,591</b>  |
| <b>Current assets</b>              |                |                  |                |
| Inventory                          | -              | -                | 8,665          |
| Other current receivables          | 11,040         | 13,194           | 10,668         |
| Prepaid expenses                   | 14,277         | 4,725            | 17,057         |
| Cash and cash equivalents          | 542,803        | 1,203,324        | 785,972        |
| <b>Total current assets</b>        | <b>568,120</b> | <b>1,221,243</b> | <b>822,362</b> |
| <b>TOTAL ASSETS</b>                | <b>581,666</b> | <b>1,236,920</b> | <b>844,953</b> |

| SEK thousand   | 2021<br>30 Sep | 2020<br>30 Sep   | 2020<br>31 Dec |
|--|----------------|------------------|----------------|
| <b>EQUITY AND LIABILITIES</b>  |                |                  |                |
| <b>Restricted equity</b>   |                |                  |                |
| Share capital  | 8,366          | 7,530            | 7,549          |
| Unregistered share capital   |                |                  | -              |
| Statutory reserve  | 10,209         | 10,209           | 10,209         |
| <b>Total restricted equity</b>   | <b>18,575</b>  | <b>17,739</b>    | <b>17,758</b>  |
| <b>Non-restricted equity</b>   |                |                  |                |
| Share premium account  | 4,871,586      | 3,815,786        | 3,822,968      |
| Retained earnings  | -3,249,586     | -2,387,777       | -1,671,578     |
| Net profit/loss for the period   | -1,163,028     | -381,273         | -1,599,620     |
| <b>Total non-restricted equity</b>   | <b>458,972</b> | <b>1,046,736</b> | <b>551,770</b> |
| <b>Total equity</b>  | <b>477,547</b> | <b>1,064,475</b> | <b>569,528</b> |
| <b>Long term liabilities</b>   |                |                  |                |
| Provision for social security contributions,<br>share based incentive program  | 636            | 14,209           | 8,404          |
| <b>Total long term liabilities</b>   | <b>636</b>     | <b>14,209</b>    | <b>8,404</b>   |
| <b>Current liabilities</b>   |                |                  |                |
| Provision for social security contributions,<br>share based incentive programs | 4,435          | 30,074           | 46,997         |
| Trade payables   | 20,314         | 45,435           | 115,574        |
| Other current liabilities  | 5,423          | 28,000           | 31,003         |
| Accrued expenses   | 73,311         | 54,727           | 73,447         |
| <b>Total current liabilities</b>   | <b>103,483</b> | <b>158,236</b>   | <b>267,021</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>  | <b>581,666</b> | <b>1,236,920</b> | <b>844,953</b> |

### Note 1 General information

This report covers the Swedish parent company Oncopeptides AB (publ), Swedish corporate identity no. 556596-6438 and its subsidiary Oncopeptides Incentive AB, Oncopeptides GmbH and Oncopeptides Inc, USA. The parent company is a Swedish public limited company registered in and with its registered office in Stockholm. Numbers in parentheses in the report refer to the figures for the corresponding period the previous year.

The interim report Jan-Sep 2021 was approved for publication on November 24, 2021.

### Note 2 Accounting policies

The interim report for the group has been prepared in accordance with IAS 34 Interim Financial Reporting. The parent company applies the Swedish Financial Reporting Board recommendation RFR2 Accounting for legal entities. Oncopeptides applies, except as described below, the same accounting principles as in the last Annual Report. Relevant accounting and valuation principles could be found on pages 60–63 of the Annual Report for 2020.

Revenue is reported at the transaction price of goods sold with deductions for VAT, discounts and returns, see further Note 5. When goods inventory items are sold, the value of these items are reported as a cost in the period in which the corresponding income is reported, in accordance with IAS 2. In addition, any impairment of goods in stock and losses relating to goods in stock are reported as an expense in the period in which the impairment is made or the loss occurs. Any reversal of impairment related to goods in stock, due to an increased net sales value, is reported as a reduction of cost of goods sold in the income statement during the period in which the reversal takes place.

No new or amended standards that became effective January 1, 2021, have had a significant impact on the company's financial reporting. Oncopeptides applies ESMA's (European Securities and Markets Authority) guidelines on alternative performance measures.

### Note 3 Risks and uncertainties in the group and the parent company

#### Operational risks

Research and drug development up to approved registration is subject to considerable risk and is a capital-intensive process. The majority of all initiated projects will never reach market registration due to the technological risk such as the risk for insufficiency efficacy, intolerable side effects or manufacturing problems. If competing pharmaceuticals capture market share or reach the market faster, or if competing research projects achieve better product profile, the future value of the product portfolio may be lower than expected. The operations may also be impacted negatively by regulatory decisions, such as approvals and price changes. External factors such as COVID-19 may also impact the company negatively by hampering the company's possibilities to conduct clinical trials, get necessary regulatory approvals or conduct sales related activities. A more detailed description of the company's risk exposure and risk management can be found in the Annual Report for 2020 on page 53.

#### Financial risk management

Oncopeptides' financial policy governing the management of financial risks has been designed by the board of directors and represents the framework of guidelines and rules in the form of risk mandated and limits for financial activities. The company is primarily affected by foreign exchange risk since the development costs for melflufen are mainly paid in USD and EUR. In accordance with the company's policy for financial risk, the company exchanges cash into USD and EUR in line with entered agreements in order to manage currency exposure. For more information about the group and parent company's financial risk management see note 3 on page 64 in the Annual Report for 2020.

As declared in the section Continued operations and going concern on page 8 there are conditions that can give rise to significant doubts regarding the company's ability to continue operations.

#### Credit risk

Oncopeptide's credit risk is managed at Group level and arises through credit exposure in the form of outstanding receivables from customers. Accounts receivable arise when an item has been delivered and invoiced and accounted with the amount that is expected

to be received. The need for impairment of accounts receivable are continuously evaluated as due date approaches and has been taken into consideration in the financial statement with SEK 3.7 M per September 30.

### Note 4 Estimates and judgements

This report includes forward looking statements. Actual outcomes may deviate from what has been stated. Internal factors such as successful management of research projects, and intellectual property rights may affect future results. There are also external conditions, e.g. the economic climate, political changes and competing research projects that may affect Oncopeptides results.

As a result of the company's restructuring, balance sheet items that are not considered to be able to generate future positive cash flows have been revaluated.

Hence, the company reports impairment of assets which essentially include inventories amounting to SEK 9.0 million in the group whereof SEK 8.2 million in the parent company, fixed assets amounting to SEK 4.3 million in the group whereof SEK 0 in the parent company, right-of-use assets amounting to SEK 5.0 million in the group as well as intra-group receivables in the parent company amounting to SEK 144.1 million. All impairments are of a non-recurring nature, directly connected to the downsizing of the business as previously communicated.

Sales have been reported taking into consideration expected returns as a result of the course of events with regards to the withdrawal of PEPAXTO from the US market. The estimated accrual for returns amounts to SEK 20.2 million. The accrual corresponds to what is expected in terms of returns of the medicinal product sold and not consumed during the last month of the quarter. The parent company has not reported any accruals for returns as inventory items sold to the subsidiary and not yet divested, have been reversed in its entirety and further returns can not be expected.

### Note 5 Revenue recognition

Revenue is reported at the transaction value of goods sold excluding VAT, discounts and returns. At the time of delivery, when the

## Notes to the consolidated and Parent Company financial statements

ownership of the goods passes to the customer, the revenue is reported in full. Customers are defined as the retailers who in the meantime sell the goods to the end user of the goods.

### Group revenue

| SEK,thousand                     | 2021<br>Jul-Sep | 2020<br>Jul-Sep | 2021<br>Jan-Sep | 2020<br>Jan-Sep | 2020<br>Jan-Dec |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Revenue from customer agreements |                 |                 |                 |                 |                 |
| Goods <sup>1</sup>               | 54,276          | -               | 140,005         | -               | -               |
| <b>Total net revenue</b>         | <b>54,276</b>   | <b>-</b>        | <b>140,005</b>  | <b>-</b>        | <b>-</b>        |
| Geografic market                 |                 |                 |                 |                 |                 |
| North America <sup>2</sup>       | 54,276          | -               | 140,005         | -               | -               |

1) PEPAXTO (melphalan flufenamide, also known as melflufen), in combination with dexamethasone, is used for the treatment of adult patients with relapsed or refractory multiple myeloma.

2) Approval has currently only been obtained in the United States, which explains why all revenue refers to one market.

### Parent company revenue

| SEK,thousand                     | 2021<br>Jul-Sep   | 2020<br>Jul-Sep | 2021<br>Jan-Sep | 2020<br>Jan-Sep | 2020<br>Jan-Dec |
|----------------------------------|-------------------|-----------------|-----------------|-----------------|-----------------|
| Revenue from customer agreements |                   |                 |                 |                 |                 |
| Goods <sup>1</sup>               | -1,703,207        | -               | 160,339         | -               | -               |
| <b>Total net revenue</b>         | <b>-1,703,207</b> | <b>-</b>        | <b>160,339</b>  | <b>-</b>        | <b>-</b>        |
| Geografic market                 |                   |                 |                 |                 |                 |
| North America <sup>2</sup>       | -1,703,207        | -               | 160,339         | -               | -               |

1) Refers to reversed intra-group sales of inventories.

2) Refers to intra-group sales to subsidiaries in the USA.

As the final price is related to the discount paid to the patients' insurance company, the transaction price is not known upon delivery. This is regulated by an accrued estimated discount deduction in the Group based on calculation models considering statistical sales data based on the discount agreements entered into in various discount programs. The company also appreciates a reserve for returns of medicines as a result of the withdrawal of PEPAXTO from the US market found in the accounts. In addition, there are no other performance commitments.

### Note 6 Segment reporting

The financial information that is reported to the chief operating decision maker, and used as a basis for the distribution of resources and the assessment of the Group's results, is not broken down by operating segment. The Group thus constitutes a single operating segment.

### Note 7 Deferred tax asset

### Group Taxes

| SEK,thousand                               | 2021<br>Jul-Sep | 2020<br>Jul-Sep | 2021<br>Jan-Sep | 2020<br>Jan-Sep | 2020<br>Jan-Dec |
|--|-----------------|-----------------|-----------------|-----------------|-----------------|
| <b>Tax for the period</b>                  |                 |                 |                 |                 |                 |
| Current tax                                | -1,341          | -287            | -6,395          | -1,788          | -9,247          |
| Deferred tax on intra-group sales of goods | -436,685        | -               | -               | -               | -               |
| Other deferred tax                         | -953            | 714             | 1,948           | 714             | 6,996           |
| <b>REPORTED TAX</b>                        | <b>-438,979</b> | <b>427</b>      | <b>-4,447</b>   | <b>-1,074</b>   | <b>-2,251</b>   |

As a result of the realized intra-group profit from the sale of inventories, has the deferred tax asset on temporary differences in the group returned with SEK -436.7 (0.0) million in the third quarter. The remaining accrued tax is in its entirety attributable to personnel costs in the subsidiary and can be utilized. The reversed tax revenue has not had any effect on cash flow.

### Note 8 Related-party transactions

During the period remuneration to senior management has been paid in accordance with current policies. No other transactions with related parties occurred during the period.

### Note 9 Share-based incentive programs

The purpose of share-based incentive programs is to promote the company's long-term interests by motivating and rewarding the company's senior management, founders, and other co-workers in line with the interest of the shareholders. Oncopeptides has currently ten active programs that include the management team, certain board members, founders and employees.

In 2016 the program "Employee option program 2016/2023" was implemented. In 2017 "Co-worker LTIP 2017" was established. At the AGM in May 2018, two additional incentive programs were adopted: "Co-worker LTIP 2018" and "Board LTIP 2018", the latter expired during the second quarter of 2021. An Extraordinary General Meeting in December 2018 resolved to implement the program "Board LTIP 2018.2" and the Annual General Meeting 2019 resolved to implement two additional programs: "Co-worker LTIP 2019" and "Board LTIP 2019". The Annual General meeting 2020 resolved to implement the program "Board LTIP 2020" and an Extraordinary General Meeting 2020 resolved to implement the program "US Co-worker LTIP 2020". For more information about these programs see note 27 in the Annual Report 2020. The Annual General Meeting 2021 resolved to implement the program "Board LTIP 2021" and "Co-worker LTIP 2021". For more information about these programs see the minutes from the Annual General Meeting on the company's website [www.oncopeptides.com](http://www.oncopeptides.com). Full utilization of granted options and share awards per September 30, 2021, corresponding to 3,595,831 shares, would result in a dilution for shareholders of 4.6 percent. Full utilization of all options and share awards, corresponding to 5,746,349 shares (i.e. including non-granted employee options and warrants set off as hedge for social security contributions), would result in a dilution for shareholders of 7.1 percent.

Below follows a summary of the changes in existing incentive programs during the first nine months of 2021 and the total number of shares that granted employee stock options and share awards may entitle to as of September 30, 2021



## Notes to the consolidated and Parent Company financial statements

### Changes in existing incentive programs during the first nine months 2021 (number of shares)

| Granted instruments                 |                |
|-------------------------------------|----------------|
| – Co-worker LTIP 2019               | 726,301        |
| – US Co-worker LTIP 2020            | 41,371         |
| – US Co-worker LTIP 2021            | 92,090         |
| – Board LTIP 2021                   | 35,000         |
| Exercised instruments               |                |
| – Employee option program 2016/2023 | -180,900       |
| – Co-worker LTIP 2017               | -119,351       |
| Lapsed instruments                  |                |
| Co-worker LTIP 2017                 | -6,000         |
| – Co-worker LTIP 2018               | -81,168        |
| – Co-worker LTIP 2019               | -142,548       |
| – US Co-worker LTIP 2020            | -144,567       |
| Expired instruments                 |                |
| – Board LTIP 2018                   | -30,451        |
| <b>Total change</b>                 | <b>189,777</b> |

### Number of shares allocated instruments may entitle to as of September 30, 2021

|  |                  |
|--|------------------|
| – Employee option program 2016/2023  | 65,700           |
| – Co-worker LTIP 2017  | 1,228,582        |
| – Co-worker LTIP 2018  | 247,481          |
| – Co-worker LTIP 2019  | 1,338,572        |
| <b>Total number of shares employee stock options may entitle to</b>                  | <b>2,880,335</b> |
| – US Co-worker LTIP 2020   | 535,814          |
| – US Co-worker LTIP 2021   | 92,090           |
| – Board LTIP 2018.2  | 2,170            |
| – Board LTIP 2019  | 23,491           |
| – Board LTIP 2020  | 26,931           |
| – Board LTIP 2021  | 35,000           |
| <b>Total number of shares allocated share awards may entitle to</b>                  | <b>715,496</b>   |
| <b>Total number of shares employee stock options and share awards may entitle to</b> | <b>3,595,831</b> |

## Key performance measures

The company presents in this report certain key performance measures, including measures that are not defined under IFRS, namely expenses relating to research and development / operating expenses %, gross

result MSEK and gross margin %. The company believes that these ratios are important complement because it allows for a better evaluation of the company's economic trends. These financial performance measures

should not be viewed in isolation or be considered to replace the performance indicators that have been prepared in accordance with IFRS. In addition, such performance measures as the company has defined them

should not be compared with other performance measures with similar names used by other companies. This is because the above-mentioned performance measure are not always defined in the same manner, and other

companies may calculate them differently to Oncopeptides.

## Key performance measures, shares

| SEK,thousand  | 2021<br>Jul-Sep | 2020<br>Jul-Sep | 2021<br>Jan-Sep | 2020<br>Jan-Sep | 2020<br>Jan-Dec |
|---|-----------------|-----------------|-----------------|-----------------|-----------------|
| Net revenue   | 54,276          | -               | 140,005         | -               | -               |
| Gross profit <sup>1</sup>   | 22,683          | -               | 105,262         | -               | -               |
| Gross margin <sup>2</sup>   | 42%             | -               | 75%             | -               | -               |
| Total registered shares at the beginning of period                | 75,291,841      | 61,499,683      | 67,939,715      | 55,413,417      | 55,413,417      |
| Total registered shares at the end of period                      | 75,291,841      | 67,770,683      | 75,291,841      | 67,770,683      | 67,939,715      |
| Number of shares that the outstanding employee options entitle to | 3,595,831       | 2,932,866       | 3,595,831       | 2,932,866       | 3,406,054       |
| Share capital at the end of period, SEK thousand                  | 8,366           | 7,530           | 8,366           | 7,530           | 7,549           |
| Equity at the end of period SEK thousand                          | 612,068         | 1,071,471       | 612,068         | 1,071,471       | 576,897         |
| Earnings per share before and after dilution, SEK <sup>3</sup>    | -10.33          | -5.71           | -14.27          | -17.87          | -25.57          |
| Operating loss, SEK thousand                                      | -338,913        | -383,498        | -1,031,081      | -1,079,706      | -1,591,279      |
| Research and development costs, SEK thousand                      | -149,792        | -193,433        | -495,632        | -634,798        | -866,214        |
| Research & development costs/operating expenses, % <sup>4</sup>   | 41 %            | 50%             | 44%             | 59%             | 54 %            |

1) Defined by subtracting cost of goods sold from total sales. The key figure shows the reader the gross profitability of cost of goods sold in absolute numbers.

2) Defined by dividing the sum of the company's gross profit by total sales. The key figure is useful for the readers of the financial report to clarify the relative profitability of goods sold.

3) Earnings per share before dilution are calculated by dividing earnings attributable to shareholders of the parent company by a weighted average number of outstanding shares during the period. There is no dilution effect for the employee stock option program, as earnings for the periods have been negative.

4) Defined by dividing the research and development costs with total operating expenses. The key performance measure helps the users of the financial statements to get a quick opinion on the proportion of the company's expenses that are attributable to the company's core business.

## Glossary

**AE** Adverse events.

**Alkylator** A broad spectrum cytotoxic chemotherapy.

**Aminopeptidases** Enzymes that hydrolyze peptides. These are over-represented in cancer cells.

**Anti-CD38** A monoclonal antibody targeted to CD 38.

**Autologous Stem cell transplant** Stem cells are taken from the patient when the disease is in a calm stage, so-called remission. They are given back to the patient after, for example, chemotherapy.

**CBR** Clinical benefit rate, measures the number of patients with multiple myeloma who have lost 25 percent or more of their tumor mass.

**CDMO** Contract development and manufacturing organization.

**Chemotherapy** Cancer treatment involving one or more drug to kill cancer cells.

**Clinical studies** Studies to define doses and evaluate safety and efficacy on healthy volunteers and patients.

**CR** Complete tumor response.

**CRO** Contract research organization

**Dexamethasone** A powerful steroid used in cancer treatment.

**DOR** Duration of response refers to the period from an initial tumor reduction until it begins to grow.

**Double-refractory** Resistant to two drugs.

**EHA** European Hematology Association.

**EMA** European Medicines Agency.

**Entrapped** How a hydrophilic alkylator payload stays inside a cell.

**FDA** US Food and Drug Administration.

**Hazard ratio** A measure of the relative risk of an event at each time point during follow-up when receiving melflufen in relation to pomalidomide. A value below 1 indicates a better treatment effect for melflufen, and a value above 1 indicates a better treatment effect for pomalidomide

**Hematology** The science of blood, blood-forming organs, and blood diseases. It includes the treatment of blood disorders and malignancies, including hemophilia, leukemia, lymphoma, and sickle-cell anemia.

**Heterogeneous disease** A disease comprising different but similar sub-diseases.

**IMiDs** Immunomodulatory imide drugs, used in the treatment of multiple myeloma.

**Interim results** Partial results in ongoing trials.

**IND** Investigational New Drug.

**IND-submission** Application to enable clinical development of a drug candidate.

**INN** International non-proprietary name.

**ITT** Intention To Treat population

**Late-stage RRMM** Late-stage relapsed refractory multiple myeloma.

**Lines of therapy** After a cancer diagnosis and decision to treat the patient, the first treatment attempt is known as the first line of therapy, followed by a second line of therapy, etc.

**Lipophilicity** is a key parameter that determines cell uptake of small molecules.

**MAA** Marketing Authorization Application.

**Melflufen** A first-in-class anti-cancer peptide drug conjugate targeting aminopeptidases and releases alkylating agents into tumor cells.

**Melphalan flufenamide** INN (see above) name for melflufen.

**MM** Multiple myeloma, a rare blood cancer that forms in plasma cells. Cancerous plasma cells accumulate in the bone marrow and crowd out healthy blood cells.

**Monoclonal antibodies** Laboratory-produced molecules engineered to serve as substitute antibodies that restore, enhance, or mimic the immune system's attacks on cancer cells.

**MR** Minimal response refers to a 25–50 percent tumor reduction.

**Multi-refractory** Resistant to several different drugs.

**Multiple myeloma** A rare blood-based cancer.

**NDA** New Drug Application.

**OPD5** The second drug candidate coming out of the peptide drug conjugate platform.

**Orphan drug** A drug used to treat a rare disease, life threatening diseases or diseases in very small

patient populations.

**Orphan designation** A status assigned to an investigational drug for a rare disease. Governments often provide economic incentives to encourage companies to develop and market medicines for rare diseases. The drug and the rare disease must fulfil certain criteria to benefit from incentives such as market exclusivity, once approved.

**ORR** Overall response rate, the number of patients who have lost 50 percent or more of their tumor mass.

**OS** Overall survival, the length of time a patient survives from the start of the treatment.

**Payload** Highly active molecules that are too toxic to be administered in untargeted forms at therapeutic doses.

**PD** Progressive disease, where the tumor mass has grown by at least 25 percent.

**PDC** Peptide-drug conjugate. The class of agents that includes melflufen and OPD5.

**Peptidases** Enzymes that break down peptides.

**Peptide** A molecule comprising a chain of amino acids. A key

attribute of melflufen.

**PFS** Progression-free survival, measures the length of time from the start of a patient's treatment until the tumor has grown by at least 25 percent.

**Pharmacokinetics** Data that describe how a drug is distributed and metabolized in the body.

**Phase 1, 2, 3 (studies)** Various phases of clinical development.

**Phase 1** A clinical study to identify appropriate doses of a drug candidate and evaluate safety in healthy volunteers.

**Phase 2** A clinical study to evaluate efficacy and safety of a drug candidate in patients ahead of phase 3.

**Phase 3** A clinical study that repeats phase 2 processes in larger patient groups and compares drug candidates with other treatments.

## Conference call

The interim report Jul-Sep 2021 and an operational update will be presented by CEO Jakob Lindberg and members of Oncopeptides Leadership team, Wednesday November 24, 2021 at 10:00 (CET).

The conference call will also be streamed via a link on the website: [www.oncopeptides.com](http://www.oncopeptides.com).

Phone numbers for participants from:

Sweden:  
+46 8 505 583 53

UK:  
+44 333 300 92 61

US:  
+1 833 823 05 89

## Calendar

February 17, 2022  
April 21, 2022  
May 4, 2022  
May 19, 2022  
Aug 11, 2022

Year-end report 2021  
Annual report 2021  
Q1 interim report 2022  
AGM  
Q2 interim report 2022

## Contact

**Oncopeptides AB**  
Street address and postal address: Luntmakargatan 46, SE-111 37 Stockholm, Sweden

Registered office: Västra Trädgårdsgatan 15, SE-111 53 Stockholm

Telephone:  
+46 (0)8-615 20 40

E-mail:  
[info@oncopeptides.com](mailto:info@oncopeptides.com)

Website:  
[oncopeptides.com](http://oncopeptides.com)



This information is information that Oncopeptides is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact persons set out above, at 08:00 CET on November 24, 2021.