



# Launch dynamics encouraging, but US regulatory situation challenging



## Significant events

### APRIL–JUNE

- **Topline results** from the phase 3 OCEAN study were announced in May
- **An application** for conditional marketing authorization of melflufen\* in the EU was submitted in April
- **Patient enrollment** in the phase 2 PORT study was completed in May
- **Clinical abstracts** on melflufen was presented at the 2021 American Society of Clinical Oncology in June
- **New clinical** and preclinical melflufen data was presented at the European Hematology Association meeting in June
- **A German affiliate** was established in May

### AFTER THE REPORTING PERIOD

- **Updated results** from the phase 3 OCEAN study were announced on July 8: melflufen met the primary endpoint of superior PFS
- **Overall survival data**, also released on July 8, led to the FDA requesting a partial clinical hold of all clinical studies with melflufen, pending further investigation
- **FDA issued a safety alert** to patients and health care professionals on July 28, regarding an increased risk of death associated with Pepaxto® in the OCEAN study

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

## Financial overview

### APRIL–JUNE

- **Net sales** amounted to SEK 66.4 M (0.0)
- **Operating loss** amounted to SEK 344.8 M (loss: 399.3)
- **Loss for the period** was SEK 24.1 M (loss: 401.0)
- **Loss per share**, before and after dilution, was SEK 0.32 (loss: 6.79)
- **Cash and cash equivalents** amounted to SEK 999.4 M (937.8) on June 30

### JANUARY–JUNE

- **Net sales** amounted to SEK 85.7 M (0.0)
- **Operating loss** amounted to SEK 692.2 M (loss: 696.2)
- **Loss for the period** was SEK 258.8 M (loss: 698.4)
- **Loss per share**, before and after dilution, was SEK 3.63 (loss: 12.20)
- **Cash and cash equivalents** amounted to SEK 999.4 M (937.8) on June 30

10.2

Sales Jan–June  
USD M

1.0

Cash  
SEK B

>330

patients  
treated with  
PEPAXTO

## Financial overview of the group

(SEK thousand)	2021 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
Net sales	66,374	-	85,729	-	-
Gross profit	63,552	-	82,579	-	-
Gross margin	96 %	N/A	96 %	N/A	N/A
Operating loss	-344,836	-399,332	-692,167	-696,208	-1,591,279
Loss after tax	-24,116	-401,041	-258,780	-698,370	-1,594,693
Earnings per share before and after dilution (SEK)	-0.32	-6.79	-3.63	-12.20	-25.57
Cash flow from operating activities	-346,695	-285,665	-733,409	-598,506	-1,296,509
Cash and cash equivalents at the end of the period	999,384	937,773	999,384	937,773	840,255
R & D costs/operating expenses, %	41 %	57 %	45 %	63 %	54 %

## Launch dynamics encouraging, but US regulatory situation challenging

**We are very pleased** with the strong second quarter adoption of Pepaxto® in the United States and since the launch in mid-March. Important interactions with the FDA on the OCEAN data continue in the wake of their safety communication on our drug.

Through the end of Q2, YTD net sales revenue was SEK 85.7 M (10.2 M), representing the first full quarter of sales added to the first two weeks of sales in March. The Q2 revenue was fueled by an accelerating customer use of the product, partly offset by a reduction in wholesaler inventory levels. On a month-to-month basis, Pepaxto® vials shipped to customers consistently recorded double-digit growth, attributed to strong interest in Pepaxto and high unmet need in the market. This growth continued in July when ~460 vials were shipped to accounts, representing an impressive 32% increase over June despite the announcement of the partial clinical hold on July 8. In Q2, we recognized net revenue of SEK 66.4 M (\$7.9 M)

which was partially blunted by a decrease in inventory on hand at distributors. Inventory levels are now where one would expect at 1-2 weeks of product.

**Feedback** from healthcare professionals makes us confident that Pepaxto offers an important treatment option and brings value to patients with relapsed or refractory multiple myeloma.

**With the FDA safety** communication on July 28, it is difficult to predict the sales trend in the near-term. We continue to work with the FDA and our customers to better understand the profile of our drug. The OCEAN trial provides comparative data that helps us further identify the patients who can benefit the most from Pepaxto, improving

the benefit to risk profile for the right patients.

### **GAINING MARKET SHARE IN 5L+**

In Q2, we made significant inroads in the 5L+ RRMM segment. Since Q1, the number of unique accounts using the drug have nearly doubled to ~200 by the end of June, excluding additional new accounts added in July. Through Q2, we continue to strengthen our position in the community setting: nearly 2/3 of Pepaxto patients are now in the community setting. The convenient administration in an outpatient setting and the higher use of doublet therapies in the community, are believed to be important drivers for future growth of Pepaxto in RRMM.

**Pepaxto** has been well received

- YTD net sales of \$10.2 M
- Q2 net sales of \$7.9 M
- 2/3 of Pepaxto patients in a community setting
- Convenient dosing appreciated by healthcare professionals

by customers and we are now a leading doublet therapy in the 5L+ segment, in terms of patient share, with favorable comparisons to the more recent launches.

### **UPDATED OCEAN DATA – STUDY MET PRIMARY ENDPOINT**

Our major clinical development highlight was the release of topline data from OCEAN, our most important clinical trial that compares melflufen and pomalidomide, one of the most widely used products in RRMM. Following the first release of topline data on May 25, a second release of data occurred on July 8. These results from the phase 3 OCEAN study followed a blinded reassessment by the Independent Review Committee (IRC). This final



analysis demonstrated that melflufen met the primary endpoint of superior PFS compared to pomalidomide.

**In addition** to the updated IRC result, we also disclosed the secondary endpoint of Overall Survival (OS) in the ITT population. Here, the results favored pomalidomide with a hazard ratio of 1.104.

### **FDA SAFETY COMMUNICATION**

While we work towards a common understanding and interpretation of this result, the FDA has put our development program on a partial clinical hold, which means that we are not recruiting new patients to our clinical studies. The FDA safety communication on July 28 characterized a “detriment to survival” with melflufen in the ITT population. As the FDA continues to evaluate the results from OCEAN, they have indicated that a public meeting may be held later this

year to discuss the safety findings and the continued marketing of the drug in the US. There are a wide range of outcomes that could result from the FDA discussions and we are ready to act on either of these.

**Patient safety** is paramount to Oncopeptides and we will continue our dialogue with the FDA to clearly define the role of melflufen in the future treatment of multiple myeloma. Our goal is to work a common view of the data and conclude that melflufen has a very important role to play for myeloma patients.

### **DATA TO BE PRESENTED AT IMW**

We have submitted abstracts on OCEAN to upcoming conferences and look forward to the disclosure of the full clinical data, accepted for presentation at the IMW meeting in Vienna on September 8-11.

### **EU REGULATORY UPDATE**

In April we successfully submitted the application for a conditional marketing authorization of melflufen in the EU. The review process is proceeding according to plan. The successful launch of the Early Access Program in Europe continued during the quarter. The team proactively worked to amend the protocol and consent process based on the ongoing FDA discussions. With that, the program in Europe continues for the patient population similar to the US labeled population.

**In closing**, I would like to thank the whole Oncopeptides team for all their outstanding work during this quarter. We are succeeding on several key fronts and are up to the challenges of the ongoing FDA interactions. Our near-term focus is to continue the successful commercialization of Pepaxto in the US in a 5L+ setting and, as soon as

possible, align with the agency on a path going forward to be able to continue our clinical studies again. Given the uncertainty, we have implemented measures to preserve cash and developed contingency plans. We will work hard to ensure that the patients who can benefit from our drug will have sustainable access to it.

**August 19, 2021**

**Marty J Duvall, CEO**

## Q2 business highlights

### COMMERCIAL

More than 330 patients have been treated with Pepaxto since the commercial launch in March 2021. New and large accounts across academic and community settings have been added with approximately 200 unique new accounts having administered Pepaxto to at least one patient through June. The cross functional team has worked diligently to roll out new customer-facing materials based on launch-to-date insights and customer needs identified by the field teams and market research functions. New accounts with potential Pepaxto eligible patients are continually identified and activities to increase the awareness of Pepaxto's efficacy, safety and tolerability profile are being carried out.

**In May** the US team was strengthened by the recruitment of Pierre Sayad as Senior Vice President, U.S. Medical Affairs, in May 2021. Pierre brings more than 20 years of experience from the pharmaceutical industry, including numerous leadership positions in the multiple myeloma space.

**In June**, the Centers for Medicare and Medicaid Services (CMS) established a new reimbursement C-Code for Pepaxto and

CMS also approved pass-through status for Pepaxto at its List Price (WAC) + 3%. These updates were taken into effect as of July 1, 2021. This C-Code will allow for more timely claims, submissions and reimbursement, particularly in the hospital outpatient setting. The established C-codes are unique temporary product codes to help supporting Fee-for-Service pass-through payments in the Hospital Outpatient Prospective Payment System (OPPS). A permanent J-Code, in addition to the C-Code, will be effective from October 1, 2021. The J code may be utilized across all settings of care including government insurers and commercial payers.

**During Q2** a German affiliate was established. Germany will be the first country to launch depending on the outcome for the EMA application for a conditional marketing authorization.

### CLINICAL DEVELOPMENT

On May 25th topline data from the phase 3 OCEAN study was announced. On July 8, after the end of the reporting period, Oncopeptides announced updated and additional results from phase 3 OCEAN study following a blinded reassessment by the Independent Review Committee. 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). During the preparations of the clinical study report and regulatory documents after the presentation of topline data it became apparent that the IRC was not provided with all the information available in the clinical database during the time of their initial assessment. This led to a thorough investigation of all 495 patients where a comparison was made between the data provided to the IRC and what data was available in the clinical database. Consequently, data from 29 patients had to be reassessed. The final OCEAN data has been submitted as a late breaker presentation to the International Myeloma Workshop, IMW, in September 8-11.

**In conjunction** with the presentation of the final PFS results from the OCEAN study as assessed by the IRC, we disclosed Overall Survival data from the ITT-population. Based on a HR of 1.104 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. FDA encourages health care professionals to review patients' progress on Pepaxto and discuss the risks of continued administration with each patient in the context of other treatments. Patients receiving benefit from melphalan flufenamide may continue treatment if they are informed of the risks and have signed a revised written informed consent. During the partial clinical hold we cannot enroll new patients. Oncopeptides will co-operate closely with the FDA to expeditiously perform necessary analysis to fully understand the benefit/risk profile of melflufen and take any other steps needed.

**In April** the last patient in the phase 2 PORT study was dosed, patient enrollment was completed and the randomization target of 27 patients to achieve 20 PK evaluable patients was reached. The aim of the PORT study is to compare pharmacokinetics, and assess the safety and tolerability of peripheral and central administration of melflufen in patients with RRMM. Data from PORT is intended to be submitted to IMW, in September 8-11.

**The patient** recruitment to the LIGHTHOUSE study was on track

in Q2. More than 50 investigational sites have been initiated across Europe and the US. LIGHTHOUSE is on partial clinical hold per the FDA as of July 8.

**The phase 2 BRIDGE** study recruited patients into Cohort 2 during Q2. The study is evaluating the use of melflufen in patients with RRMM who have severe renal impairment. Cohort 1 (a and b) are fully recruited. At EHA in June 2021, the first clinical data included interim results which support the use of melflufen in patients with relapsing refractory multiple myeloma who have moderate renal impairment, was presented. BRIDGE is on partial clinical hold per the FDA as of July 8.

**An application** to the European Medicines Agency, EMA, for conditional marketing authorization of melflufen (melphalan flufenamide) in the EU, based on the pivotal phase 2 HORIZON study in relapsed refractory multiple myeloma was submitted in April. Pending a positive validation from the EMA, melflufen will be subject to a regulatory assessment according to the standard timelines.

**The Early Access Program** for RRMM patients in Europe which was initiated in Q1 continued to

## PEPAXTO

On February 26 2021, the U.S. Food and Drug Administration, FDA, approved Pepaxto® (melphalan flufenamide, known as melflufen during clinical development) in combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy.

enroll patients in Q2. 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 has been amended to reflect the ongoing discussions with the FDA and the program continues for the patient population similar to the US labeled indication. As of June 30, nearly 40 patients across



## Q2 business highlights

Europe have been approved for participation in the program.

### SCIENTIFIC ENGAGEMENT

Q2 was a busy period for the cross-functional congress team. At Controversies in Multiple Myeloma (COMy), an international conference with 7,120 active participants, Oncopeptides was granted one oral and two poster presentations. The international congresses American Society of Clinical Oncology (ASCO) and European Hematology Association (EHA) took place in June. At ASCO three posters were presented and at EHA six.

**At EHA** we hosted a successful educational symposium with the title: “Navigating change in relapsed/refractory multiple myeloma: the patient journey”. This was led by a distinguished international faculty.

**A total of nine encore abstracts** have been submitted to several international and national congresses in Germany, Italy, Spain, the US and in Austria taking place later in the fall. Three manuscripts have been published and two submitted.

### PRE-CLINICAL DEVELOPMENT

During Q2 Oncopeptides continued the development of the PDC platform, with the objective to

produce more clinical candidates to follow melflufen and OPD5 into clinical development.

**In addition**, three preclinically abstracts were presented at EHA, and two articles have been published where the mechanism of action of melflufen is discussed in more detail, one with focus on PI resistant cell-lines, and the second one on potential effects within the bone structure: “Hemisphere: Novel Peptide-drug Conjugate Melflufen Efficiently Eradicates Bortezomib-resistant Multiple Myeloma Cells Including Tumor-initiating Myeloma Progenitor Cells”. “Bone reports: Melphalan flufenamide inhibits osteoclastogenesis by suppressing proliferation of monocytes”

### SUSTAINABILITY (ESG)

During the second quarter Oncopeptides launched a sustainability section on the external website to ensure transparency and to facilitate for stakeholders in their valuation of the company’s sustainability work.

### Environmental

We continuously strive to minimize the environmental impact of our own operations and those of our suppliers. 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. The dialogue with our CMO’s to start reviewing their sustainability work is ongoing and we encourage all suppliers to align with appropriate standards to minimize impacts.

### Social

During Q2 an exercise challenge for all coworkers globally was launched. The purpose was to strengthen collaboration and at the same time encourage physical activity for good health. All collected points was converted into a donation and the winning team got to choose where to donate the money. Two different Multiple Myeloma Foundations were selected.

**The internal work** with building our global culture has continued with lunch speakers and our global weekly meetings.

**In Q2**, we supported several patient advocacy events and fundraisers through employee participation and/or support on social media. Our employees ran 5K races for the Lazarex Cancer Foundation and the Multiple Myeloma Research Foundation rallied around a webinar on the



African American Experience in Multiple Myeloma which helped spread the word about the disease and the challenges living with it.

### Governance

During Q2 quarter the governance project phase 1 was implemented and completed. All R&D cross-functional business driving teams have charters with clear remit, roles & responsibilities

as well as expectations set. Workshops with all teams have taken place and implementation have involved more than 70 employees. Baseline surveys for all teams have been conducted to measure progress.

**In June** a scientific committee was established with the purpose to advise in scientific matters. The review of policies continued and the Board of

directors resolved to adopt several updated policy’s including the Information policy and Insider policy. ■

## Pipeline

We have developed a broad, proprietary, Peptide Drug Conjugate (PDC) candidate platform which is unique for a company of our size and the only PDC pipeline for targeting cancer. This maximizes our ability to deliver new and multiple clinical compounds for a wide range of hematological diseases.

We have all the necessary experience at our advanced research facility in Solna to enable us to deliver new PDCs independently. We also have all the chemical tools we need in-house.

Our clinical development program is underpinned by several

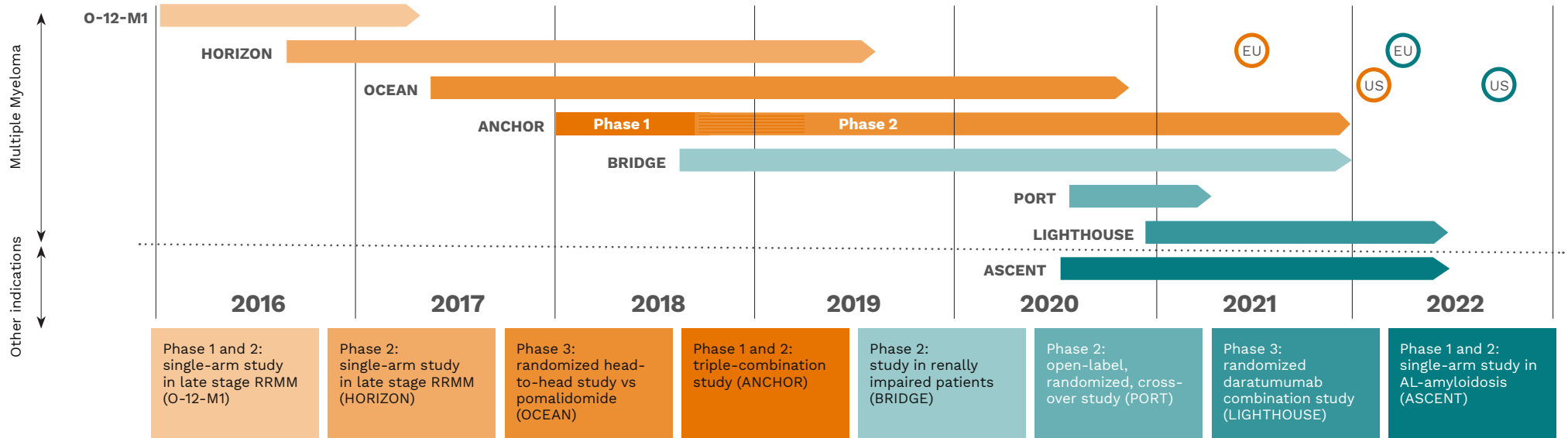
studies being conducted in parallel to one another. The broad-based structure of the program further strengthens our ability to address unmet medical need.

The melflufen clinical program is currently on partial clinical hold per the FDA as of July 8. The clinical study with OPD5 is

on full clinical hold per the FDA as of July 8. The partial clinical hold means that we cannot enroll new patients. Patients receiving benefit from melphalan flufenamide may continue treatment if they are informed of the risks and have signed a revised written informed consent. ■

## MELFLUFEN CLINICAL DEVELOPMENT PROGRAM

Potential to provide data in different patient populations



The arrows show First Patient In (FPI) and estimated Last Patient In (LPI).



Regulatory submission



Potential market authorization

## Pipeline

Study	Phase/indication	Study design	Positioning	Regulatory status*
<b>ANCHOR</b>	EXPLORATIVE <ul style="list-style-type: none"> <li>• <b>Phase 1/2 study</b> with up to 64 patients</li> <li>• <b>Multiple myeloma</b></li> </ul>	<ul style="list-style-type: none"> <li>• A triple-combination study</li> <li>• A in patients who have received 1–4 earlier lines of therapy including IMiDs and PIs.</li> </ul>	<ul style="list-style-type: none"> <li>• Explores potential of using melflufen in earlier lines of therapy.</li> <li>• May significantly increase melflufen’s market potential as a combination therapy.</li> </ul>	<ul style="list-style-type: none"> <li>• Started in Q2 2018, daratumumab arm is fully recruited. Recruitment to the bortezomib arm was temporarily paused during March–May 2020 due to the COVID-19 pandemic.</li> </ul>
<b>ASCENT</b>	EXPLORATIVE <ul style="list-style-type: none"> <li>• <b>Phase 1/2 study</b> with up to 40 patients</li> <li>• <b>AL-amyloidosis</b></li> </ul>	<ul style="list-style-type: none"> <li>• A single-arm study in patients with systemic light-chain (AL) amyloidosis who have undergone at least one prior treatment.</li> </ul>	<ul style="list-style-type: none"> <li>• New indication with melflufen to provide therapeutic alternatives to patients who have poor prognosis and currently have limited treatment options</li> </ul>	<ul style="list-style-type: none"> <li>• Study start in December 2019. LPI expected in H2 2021.</li> </ul>
<b>BRIDGE</b>	SUPPORTING <ul style="list-style-type: none"> <li>• <b>Phase 2</b> study with up to 25 patients</li> <li>• <b>Multiple myeloma</b></li> </ul>	<ul style="list-style-type: none"> <li>• Open-label, single-arm trial for patients with reduced renal function.</li> </ul>	<ul style="list-style-type: none"> <li>• Show melflufen’s treatment profile for patients with reduced renal function.</li> </ul>	<ul style="list-style-type: none"> <li>• Study started in Q3 2018. LPI expected in H2 2021.</li> </ul>
<b>HORIZON</b>	PIVOTAL <ul style="list-style-type: none"> <li>• <b>Phase 2</b> study with 157 patients.</li> <li>• <b>Multiple myeloma</b></li> </ul>	<ul style="list-style-type: none"> <li>• Evaluating melflufen in combination with dexamethasone in RRMM patients.</li> <li>• Patients have received ≥2 earlier lines of therapy with IMiDs and PIs and are resistant to pomalidomide and/or daratumumab.</li> </ul>	<ul style="list-style-type: none"> <li>• To treat adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Approved by the US FDA in Q1 2021.</li> <li>• An application for conditional marketing authorization of melflufen in the EU was submitted in Q1 2021 - approval expected in H1 2022</li> </ul>
<b>LIGHTHOUSE</b>	CONFIRMATORY <ul style="list-style-type: none"> <li>• <b>Phase 3</b> combination study to include more than 240 patients.</li> <li>• <b>Multiple myeloma</b></li> </ul>	<ul style="list-style-type: none"> <li>• Randomized daratumumab combination study</li> <li>• In patients who are resistant to an IMiD and a PI, alternatively have received at least three previous treatment lines including an IMiD and a PI.</li> </ul>	<ul style="list-style-type: none"> <li>• Confirm the efficacy and safety of combination therapy with melflufen plus daratumumab compared to daratumumab.</li> <li>• To expand label into combination treatment and in earlier lines of therapy.</li> </ul>	<ul style="list-style-type: none"> <li>• The study started in December 2020.</li> <li>• LPI expected in H1 2022</li> </ul>
<b>OCEAN</b>	PIVOTAL/CONFIRMATORY <ul style="list-style-type: none"> <li>• <b>Phase 3</b> combination study with 495 patients. Fully recruited.</li> <li>• <b>Multiple myeloma</b></li> </ul>	<ul style="list-style-type: none"> <li>• Randomized head-to-head study with pomalidomide in patients treated with IMiDs and PIs, and who have become resistant to their last line of therapy.</li> <li>• RRMM patients who are resistant to lenalidomide.</li> </ul>	<ul style="list-style-type: none"> <li>• Direct comparison with pomalidomide to demonstrate benefit for melflufen</li> <li>• To expand label into earlier lines of therapy.</li> </ul>	<ul style="list-style-type: none"> <li>• The study started in Q2 2017.</li> <li>• LPI November 2020.</li> <li>• Topline results in Q2 2021.</li> </ul>
<b>PORT</b>	SUPPORTING <ul style="list-style-type: none"> <li>• <b>Phase 2</b> study in 25 patients.</li> <li>• <b>Multiple myeloma</b></li> </ul>	<ul style="list-style-type: none"> <li>• Open-label, randomized, cross-over phase 2 study evaluating an alternative administration of melflufen in patients with RRMM.</li> <li>• Comparing safety, tolerability and efficacy of peripheral versus central intravenous administration of melflufen in combination with dexamethasone</li> </ul>	<ul style="list-style-type: none"> <li>• Data could potentially provide a pathway to include an additional mode of administration into the label</li> </ul>	<ul style="list-style-type: none"> <li>• Started in August 2020.</li> <li>• LPI Q2 2021</li> <li>• Study is fully recruited.</li> </ul>

\*Timelines are preliminary and pending on when the partial clinical hold, requested by the FDA, is lifted.

**Multiple myeloma** is a blood and bone marrow cancer. It forms in plasma cells, accumulates in the bone marrow, and crowds out healthy blood cells. There is currently no cure. And while patients being treated for multiple myeloma experience symptom-free periods, they eventually relapse as they become resistant to treatment.

### NEW TREATMENT OPTIONS INCREASE SURVIVAL RATES

The prevalence of multiple myeloma is increasing as the population ages, and new treatment regimens are introduced on the market. Approximately 250,000 patients live with multiple myeloma in Europe and the US. Every year, 80,000 patients are diagnosed with multiple myeloma and 44,000 patients die from the disease<sup>1</sup>. The number of patients diagnosed is growing by almost one percent a year. Patients may experience long disease-free periods by using different pharmaceutical classes and combination therapies.

The number of patients with multiple myeloma who have undergone several lines of therapy has increased significantly, and is expected to continue to grow, as new treatment options and algorithms are introduced.

**Despite therapeutic** advances

and the use of new treatment options earlier in the disease, multiple myeloma remains incurable. As more patients than ever are living with the disease and are becoming resistant to treatment, there is a significant need for additional treatment options.

**The pharmaceutical classes** consist of several drugs and offer different therapeutic options. However, resistance development, where patients become resistant to their therapy and other underlying medical conditions, limit the use of several drugs used in MM treatment.

### MORE TREATMENT OPTIONS ARE NEEDED

The rapid growth of resistance in multiple myeloma and associated diseases means that most myeloma patients lack treatment options when they finish their second line of therapy. After first line therapies, the myeloma market is fragmented, and there

is an unmet need of new and innovative treatment options. Even though patients are staying on treatment longer, and survival rates are increasing, the need for new therapies enabling a better quality of life is growing.

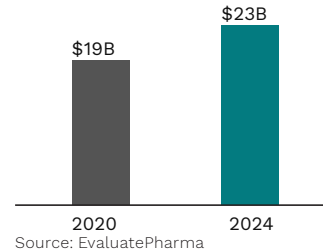
### RAPIDLY GROWING MARKET IN THE US

The global myeloma market amounted to USD 19 billion in 2019 and is expected to grow rapidly over the coming years. Following recent drug launches, the growing number of patients in later lines of therapy is expected to increase the overall number of patients receiving treatment, and thus the value of the market.

**The European** myeloma market was estimated to be worth USD 3.8 billion in 2019. The EU tends to be more conservative about the adoption of new treatments, and consequently adoption takes longer time.

### RESISTANCE AND LINES OF THERAPY

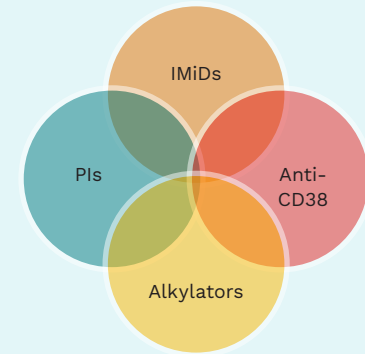
A patient undergoing myeloma therapy can become resistant to the two primary classes of pharmaceuticals, IMiDs and PIs, after the first line of therapy. If patients have also been treated with an anti-CD38 inhibitor, they are defined as triple-class refractory patients. Patients respond differently to therapy, and this has resulted in the development of personalized treatments. Consequently, it is therefore important to understand the role of resistance, in addition to what line of treatment the patients has undergone, to estimate the market potential for a particular indication.



<sup>1</sup>) The Global Cancer Observatory – <https://gco.iarc.fr/>, National Cancer Institute – <https://seer.cancer.gov/>

## The Standard of Care

Multiple myeloma is primarily treated with drugs from four different pharmaceutical classes in combination with steroids.



### Antibody drugs (Anti-CD38)

Antibody drugs used in treatment of multiple myeloma consist of monoclonal antibodies, i.e., proteins that are designed to identify and bind to specific receptors on cancer cells, enabling the immune system to kill them.

### Immunomodulatory drugs (IMiDs)

Immunomodulatory drugs are derivatives of thalidomide and have an effect on different systems in the body. IMiDs inhibit myeloma cells from dividing and stimulate the immune system to target cancer cells.

### Alkylators

Alkylators are a form of cytotoxins that kill cancer cells and thereby reduce or disrupt tumor growth. Melflufen is the first anti-cancer peptide-drug conjugate that uses aminopeptidases and rapidly delivers an alkylating payload into tumor cells. Aminopeptidases are over-expressed in cancer cells.

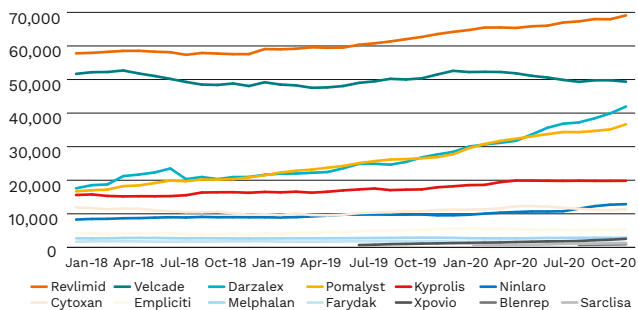
### Proteasome inhibitors (PIs)

Proteasome inhibitors impact cancer cell function and growth. Myeloma cells usually contain large amounts of proteins compared to healthy cells. Proteasome inhibitors can prevent the breakdown of these proteins in cancer cells.



## The multiple myeloma market

### Number of US total multiple myeloma patients by products



Source: Intrinsiq MAT, December 2020

#### PROLONGED TREATMENT DRIVES US MARKET GROWTH

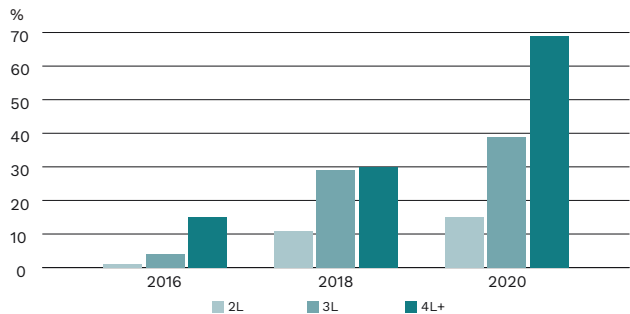
In the US, market growth of patients treated in the second or later lines of therapy exceeds the growth in the first line. Treatment is related to the number of treatment cycles carried out in the various lines of therapy, which in turn is related to the degree of resistance and patients' overall health. As an example, a newly diagnosed patient may undergo 12 treatment cycles or more, while a triple class refractory patient undergoes four to six cycles.

In the US, the bulk of growth has historically been in the number

of patients treated in the second or later lines of therapy. As new products supplement existing ones, all products help to broaden treatment options. The market for triple-class refractory (TCR) patients has grown and continues to grow substantially. In the US, there are approximately 20,000 TCR patients as illustrated in the figure to the right.

**Growth in the triple-class refractory market** is the result of the introduction of new products and therapeutic options. The figure above shows that newer products are being used in addition to older ones as survival rates

### Triple-class refractory multiple myeloma patients, by Line of Treatment



Source: Patient claims data, company market research

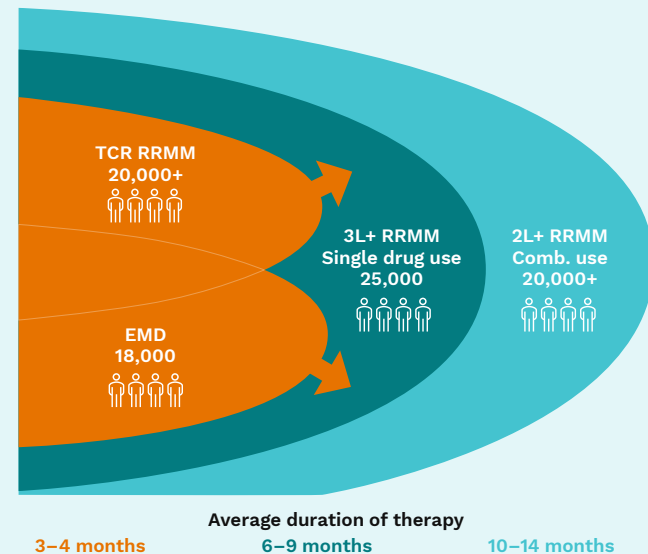
improve, and that new drugs are driving market growth.

#### MELFLUFEN'S ROLE IN THE MULTIPLE MYELOMA MARKET

On February 26 2021, the FDA approved PEPAXTO, in combination with dexamethasone, for the 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. This indication has been granted under accelerated approval based upon the

HORIZON study. Further studies in the clinical program may lead to expansion of the label and thus potentially reaching more patients. The graph to the right illustrates the patient population in relation to the clinical programs. ■

### Clinical program to support label expansion



### Clinical program supports label expansion

- HORIZON**: Approval in triple-class refractory (TCR) patients who have received at least 4L of treatment
- OCEAN**: Head-to-head study with pomalidomide may enable single agent 3L+ use
- LIGHTHOUSE**: Combination with proteasome inhibitor or antibody drugs may enable 2L+ combination treatment

**We use our proprietary peptide-drug conjugate platform, PDC, to develop multiple drug candidates. Melflufen and our drug candidate, OPD5, stem from the PDC platform. Melflufen was commercially launched as PEPAXTO in 2021 and OPD5 is expected to start clinical studies during the first half of 2021. Our goal is to establish a stream of new clinical candidates going forward.**

We are exploring innovative candidates and treatments for multiple hematological diseases – not only myeloma. 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 + IN-HOUSE EXPERTISE + ACTIVE COLLABORATIONS = MULTIPLE NEW CLINICAL CANDIDATES**

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.

**IMPROVING PATIENT OUTCOMES**

Developing pharmaceuticals is a gradual, time-consuming, and capital-intensive process. The latter phases of developing a drug are especially costly in financial terms. A typical phase 3 study often costs more than all the research that has gone into a candidate drug up to that point combined.

**CANDIDATES FOR POTENTIAL NEW INDICATIONS**

Over the past years, Oncopeptides has developed several drug candidates from the PDC platform. In Q4 2020 the FDA approved our IND-application for OPD5. We are initiating clinical studies with OPD5 as a myeloablative treatment before a stem cell transplant during H1 2021.

**STATE-OF-THE-ART RESEARCH FACILITY ESTABLISHED**

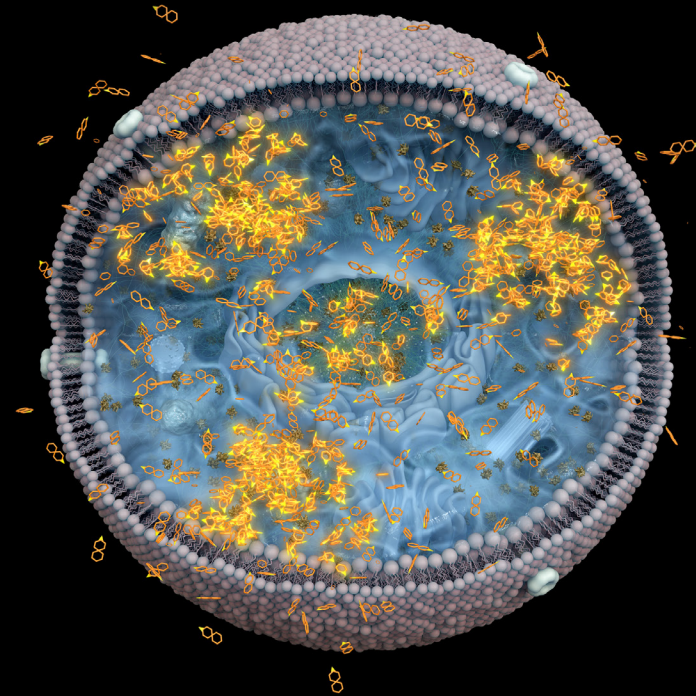
In 2020, we opened our state-of-the-art drug development facility in Solna, just outside Stockholm, Sweden. The laboratory will play a vital role in further developing the PDC platform. The opening of the laboratory is a key part of our continued

professionalization of the company’s infrastructure, preparing Oncopeptides for future growth.

**During the year,** we recruited more than 20 pre-clinical researchers from all around the world to work at the new facility. The researchers were drawn from a diverse set of backgrounds, nationalities, ages, and professional experience, adding to the rich and varied set of skill sets and specializations we have in the company.

**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. After many years of hard work, we are now set to start fulfilling our true potential and launch the first of what we hope to be several effective PDC-based treatments for multiple myeloma. ■



**The multiple myeloma cell**

Melflufen 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 Melflufen to aminopeptidases results in the release of a toxic payload that damages DNA and kills cancer cells.

### REVENUE

Net sales amounted to SEK 66.4 M (0.0) in the second quarter and SEK 85.7 M (0.0) in the first six months of the year. Gross profit amounted to SEK 63.6 M (0.0) for the second quarter and SEK 82.6 M (0.0) for the first six months of the year, corresponding to a gross margin of 95.7% (n/a) for the second quarter and 96.3% (n/a) for the first six months of the year.

### OPERATING EXPENSES

Operating expenses amounted to SEK 408.4 M (399.3) for the second quarter and SEK 774.7 M (696.2) for the first six months of the year.

### RESEARCH AND DEVELOPMENT COSTS

Research and development costs amounted to 167.3 M (227.8) for the second quarter and to SEK 345.8 M (441.4) for the first six months of the year. The completion of the HORIZON study and the reduced cost in the OCEAN study are main reasons for the lower costs.

### MARKETING AND DISTRIBUTION COSTS

Marketing and distribution costs amounted to SEK 202.4 M (97.9) and to SEK 382.6 M (148.9) for the first six months of the year. The cost increase is mainly related to the continued build-up of the commercial functions in the US and marketing activities in conjunction with the launch of PEPAXTO in the US.

### ADMINISTRATION EXPENSES

Administration expenses amounted to SEK 40.8 M (46.5) for the second quarter and to SEK 88.4 M (87.2) for the first six 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. Related provisions are reported as long- and short-term liabilities.

The cost for the share-based incentive programs in the second quarter amounted to SEK

0.4 M (20.9) and for the first six months of the year to SEK 5.8 M (25.9) out of which SEK negative 31.0 M (9.7) was provisions and payments of social security contributions and SEK 36.8 M (16.2) 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 345.5 M (399.5) for the second quarter and SEK 693.3 M (696.9) for the the first six months of the year.

As a result of intra-group sales

of inventory items, a deferred tax asset arised on temporary differences in the Group of SEK 322.8 M (0.0) for the second quarter and SEK 436.7 M (0.0) MSEK for the first six months. 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 second quarter was SEK 24.1 M (401.0) and 258.8 M (698.4) for the first six months of the year. This corresponds to a loss per share, before and after dilution, of SEK 0.32 (6.79) for the second quarter and to a loss per share of 3.63 (12.2) for the first half of the year.

### CASH FLOW, INVESTMENTS AND FINANCIAL POSITION

Cash flow from operating activities amounted to a negative SEK 346.7 M (neg. 285.7) for the second quarter and negative SEK 733.4 M (neg. 598.5) for the first six months of the year. The negative cash flow is mainly explained by the company's continued clinical programs and

the expansion of the company's medical affairs and marketing functions to support the launch of Pepaxto in the USA.

Cash flow from investing activities amounted to SEK 0.4 M (neg. 5.1) for the second quarter and to negative SEK 0.3 M (neg. 8.9) for the first six months of the year. Cash flow from financing activities amounted to SEK 1,035.4 M (652.8) for the second quarter and SEK 1,038.9 M (648.9) for the first six months of the year.

In March 2021 it was resolved to make a directed share issue that raised SEK 1,106.0 million before issue costs amounting to SEK 67.1 million. The issue was completed in April.

Cash flow for the second quarter amounted to SEK 689.1 M (362.1) for the second quarter and to SEK 305.1 M (41.5) for the first six months of the year. As of June 30, 2021, cash and cash equivalents amounted to SEK 999.4 M (937.8). In addition the company has a committed loan facility of € 40 M from the EIB that has not been utilized.

Equity amounted to SEK 1,376.1 M (769.9).■

## Other information

### CO-WORKERS

As of June 30, 2021, the number of co-workers amounted to 313 (154).

### 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.

### THE ONCOPEPTIDES SHARE

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

### EVENTS AFTER THE END OF THE REPORT PERIOD

Updated results from the phase 3 OCEAN study were announced on July 8: melflufen met the primary endpoint of superior PFS.

Overall survival data also released on July 8, led to the FDA requesting a partial clinical hold of all clinical studies with melflufen, pending further investigation.

FDA issued a safety alert to patients and health care professionals on July 28, regarding an increased risk of death associated with Pepaxto® in the OCEAN study.

### REVIEW

This report has not been reviewed by the company's auditor.

## Signatures

The Board and the CEO confirm that the interim report provides a true and fair overview of the group's and the parent company's operations, position and earnings and describes the material risks and uncertainty factors faced by the parent company and the companies within the group.

Stockholm, August 19, 2021

**Per Wold-Olsen**  
Chairman

**Jennifer Jackson**  
Board member

**Cecilia Daun Wennborg**  
Board member

**Per Samuelsson**  
Board member

**Jarl Ulf Jungnelius**  
Board member

**Marty J Duvall**  
CEO

**Brian Stuglik**  
Board member

## Condensed consolidated income statement

SEK thousand	Note	2021 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
Net sales	5	66,374	–	85,729	–	–
Cost of goods sold		-2 822	–	-3,150	–	–
<b>Gross profit</b>		<b>63 552</b>	<b>–</b>	<b>82,579</b>	<b>–</b>	<b>–</b>
<b>Operating expenses</b>						
Research and development costs		-167,308	-227,815	-345,840	-441,365	-866,214
Marketing and distribution costs		-204,421	-97,913	-382,619	-148,894	-456,529
Administrative expenses		-40,767	-46,504	-88,397	-87,154	-197,662
Other operating income/expenses <sup>1</sup>		4,108	-27,100	42,110	-18,795	-70,874
<b>Total operating expenses</b>		<b>-408,388</b>	<b>-399,332</b>	<b>-774,746</b>	<b>-696,208</b>	<b>-1,591,279</b>
<b>Operating loss</b>		<b>-344,836</b>	<b>-399,332</b>	<b>-692,167</b>	<b>-696,208</b>	<b>-1,591,279</b>
Net financial items		-624	-210	-1,145	-661	-1,163
<b>Loss before tax</b>		<b>-345,460</b>	<b>-399,542</b>	<b>-693,312</b>	<b>-696,869</b>	<b>-1,592,442</b>
Tax	7	321,345	-1,499	434,533	-1,501	-2,251
<b>Loss for the period<sup>2</sup></b>		<b>-24,116</b>	<b>-401,041</b>	<b>-258,780</b>	<b>-698,370</b>	<b>-1,594,693</b>
<b>Earnings per share before and after dilution (SEK)</b>		<b>-0,32</b>	<b>-6,79</b>	<b>-3,63</b>	<b>-12,20</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 comprehensive income

SEK thousand	2021 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>Loss of the period</b>	<b>-24,116</b>	<b>-401,041</b>	<b>-258,780</b>	<b>-698 370</b>	<b>-1 594 693</b>
<b>Other comprehensive income</b>					
Items to be reclassified to profit or loss	–	–	–	–	–
Translation differences from foreign operations	-2,917	-632	-24,803	-172	-1 544
<b>Total other comprehensive income, net of tax</b>	<b>-2,917</b>	<b>-632</b>	<b>-24,803</b>	<b>-172</b>	<b>-1 544</b>
<b>Total comprehensive income, net of tax</b>	<b>-27,033</b>	<b>-401,673</b>	<b>-283,583</b>	<b>-698 542</b>	<b>-1 596 237</b>



## Condensed consolidated statement of financial position

SEK thousand	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	1,619	2,041	1,830
Property, plant and equipment	16,105	9,582	17,273
Right-of-use assets	14,051	26,711	21,057
Financial non-current assets	3,746	2,160	3,622
Deferred tax assets	453,879	2,270	8,175
<b>Total non-current assets</b>	<b>489,400</b>	<b>42,764</b>	<b>51,957</b>
<b>Current assets</b>			
Inventory	22,214	–	8,665
Accounts receivable	72,790	–	–
Other current receivables	29,410	8,760	23,229
Prepaid expenses	26,640	52,736	22,650
Cash and cash equivalents	999,384	937,773	840,255
<b>Total current assets</b>	<b>1,150,438</b>	<b>999,269</b>	<b>894,799</b>
<b>TOTAL ASSETS</b>	<b>1,639,838</b>	<b>1,042,033</b>	<b>946,756</b>

SEK thousand	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	8,366	6,833	7,549
Additional paid-in capital	5,000,990	3,215,068	3,919,036
Retained earnings (including net profit/loss for the period)	-3,633,271	-2,451,992	-3,349,688
<b>Total equity<sup>1</sup></b>	<b>1,376,085</b>	<b>769,909</b>	<b>576,897</b>
<b>Long-term liabilities</b>			
Provision for social security contributions, share based incentive programs	2,660	12,352	8,530
Other long-term liabilities	1,268	12,776	6,929
<b>Total long-term liabilities</b>	<b>3,929</b>	<b>25,128</b>	<b>15,459</b>
<b>Current liabilities</b>			
Provision for social security contributions, share based incentive programs	15,189	31,090	47,202
Trade payables	46,527	61,761	136,135
Other current liabilities	24,061	19,914	35,045
Accrued expenses and deferred income	174,047	134,231	136,018
<b>Total current liabilities</b>	<b>259,824</b>	<b>246,996</b>	<b>354,400</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1,639,838</b>	<b>1,042,033</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 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>Opening balance</b>	<b>347,192</b>	<b>505,838</b>	<b>576,897</b>	<b>797,013</b>	<b>797,013</b>
Profit/loss of the period	-24,116	-401,041	-258,780	-698,370	-1,594,693
Other comprehensive income	-2,917	-632	-24,803	-172	-1,544
<b>Comprehensive income (loss) for the period</b>	<b>-27,033</b>	<b>-401,673</b>	<b>-283,583</b>	<b>-698,542</b>	<b>-1,596,237</b>
<b>Transaction with owners</b>					
New issue of ordinary shares	1,106,000	697,475	1,106,000	697,475	1,413,925
Cost attributable to new share issue	-67,053	-42,241	-67,053	-42,241	-85,231
Share based payments	16,956	10,508	36,829	16,202	38,398
Exercise of warrants	23	2	6,995	2	9,029
<b>Total transaction with owners</b>	<b>1,055,926</b>	<b>665,744</b>	<b>1,082,771</b>	<b>671,438</b>	<b>1,376,121</b>
<b>CLOSING BALANCE</b>	<b>1,376,085</b>	<b>769,909</b>	<b>1,376,085</b>	<b>769,909</b>	<b>576,897</b>

## Condensed consolidated statement of cash flow

SEK thousand	2021 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
Operating loss	-344,836	-399,332	-692,167	-696,208	-1,591,279
Adjustment for non-cash-items <sup>1</sup>	51,442	-65,465	92,454	60,728	160,906
Interest received	5	0	5	0	322
Interest paid	-277	-309	-587	-760	-1,485
Tax paid	-11,931	-3,296	-11,931	-3,298	-7,243
<b>Cash flow from operating activities before change in working capital</b>	<b>-305,597</b>	<b>-337,472</b>	<b>-612,226</b>	<b>-639,538</b>	<b>-1,438,779</b>
Cash flow from changes in working capital	-41,097	51,807	-121,182	41,032	142,270
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>	<b>-346,695</b>	<b>-285,665</b>	<b>-733,409</b>	<b>-598,506</b>	<b>-1,296,509</b>
Cash flow from investing activities	401	-5,064	-339	-8,886	-20,127
Cash flow from financing activities	1,035,387	652,786	1,038,894	648,930	1,323,461
<b>Cash flow for the period</b>	<b>689,093</b>	<b>362,057</b>	<b>305,146</b>	<b>41,538</b>	<b>6,825</b>
Cash and cash equivalents at beginning of period	372,453	617,786	840,255	926,186	926,186
Change in cash and cash equivalents	689,093	362,057	305,146	41,538	6,825
Foreign exchange difference in cash and cash equivalents	-62,162	-42,070	-146,017	-29,951	-92,756
<b>Cash and cash equivalents at the end of period</b>	<b>999,384</b>	<b>937,773</b>	<b>999,384</b>	<b>937,773</b>	<b>840,255</b>

1) Pertains mainly to costs of employee stock option program including social security contributions and exchange rate differences.

## Condensed Parent Company income statement

SEK thousand	2021 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
Net sales <sup>1</sup>	1,385,437	–	1,863,546	–	–
Cost of goods sold	-9,820	–	-12,071	–	–
<b>Gross profit</b>	<b>1,375,617</b>	<b>–</b>	<b>1,851,475</b>	<b>–</b>	<b>–</b>
<b>Operating expenses</b>					
Research and development costs	-166,463	-227,947	-344,847	-441,574	-866,509
Marketing and distribution costs	-212,302	-100,865	-394,894	-153,694	-460,860
Administrative expenses	-45,873	-47,748	-93,735	-89,643	-201,751
Other operating income/expenses <sup>2</sup>	4,107	-27,100	42,219	-18,795	-70,874
<b>Total operating expenses</b>	<b>-420,532</b>	<b>-403,660</b>	<b>-791,258</b>	<b>-703,706</b>	<b>-1,599,994</b>
<b>Operating loss</b>	<b>955,085</b>	<b>-403,660</b>	<b>1,060,217</b>	<b>-703,706</b>	<b>-1,599,994</b>
Net financial items	-336	111	-521	123	375
<b>Loss before tax</b>	<b>954,749</b>	<b>-403,549</b>	<b>1,059,696</b>	<b>-703,583</b>	<b>-1,599,620</b>
Tax	–	–	–	–	–
<b>Loss for the period</b>	<b>954,749</b>	<b>-403,549</b>	<b>1,059,696</b>	<b>-703,583</b>	<b>-1,599,620</b>

1) Refers to intra-group revenues.

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

## Condensed Parent Company statement of comprehensive income

SEK thousand	2021 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>Loss of the period</b>	<b>954,749</b>	<b>-403,549</b>	<b>1,059,696</b>	<b>-703,583</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>954,749</b>	<b>-403,549</b>	<b>1,059,696</b>	<b>-703,583</b>	<b>-1,599,620</b>

## Parent Company balance sheet

SEK thousand	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>ASSETS</b>			
Subscribed but unpaid capital	3,499	716,450	–
<b>Non-current assets</b>			
Intangible fixed assets	1,619	2,041	1,830
Property, plant and equipment	11,409	5,013	12,097
Financial non-current assets	19,135	901	8,664
<b>Total non-current assets</b>	<b>32,163</b>	<b>7,955</b>	<b>22,591</b>
<b>Current assets</b>			
Inventory	9,717	–	8,665
Current receivables group companies	1,897,910	–	–
Other current receivables	12,493	8,150	10,668
Prepaid expenses	13,877	5,344	17,057
Cash and cash equivalents	912,065	926,642	785,972
<b>Total current assets</b>	<b>2,846,062</b>	<b>940,136</b>	<b>822,362</b>
<b>TOTAL ASSETS</b>	<b>2,881,724</b>	<b>1,664,541</b>	<b>844,953</b>

SEK thousand	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>EQUITY AND LIABILITIES</b>			
<b>Restricted equity</b>			
Share capital	8,366	6,833	7,549
Unregistered share capital	5	692	–
Statutory reserve	10,209	10,209	10,209
<b>Non-restricted equity</b>			
Share premium account	4,871,587	3,813,967	3,822,968
Retained earnings	-3,234,368	-1,693,773	-1,671,578
Net profit/loss for the period	1,059,696	-703,583	-1,599,620
<b>Total equity</b>	<b>2,715,495</b>	<b>1,434,345</b>	<b>569,528</b>
<b>Long term liabilities</b>			
Provision for social security contributions, share based incentive program	2,106	12,352	8,404
<b>Total long term liabilities</b>	<b>2,106</b>	<b>12,352</b>	<b>8,404</b>
<b>Current liabilities</b>			
Provision for social security contributions, share based incentive programs	15,189	31,090	46,997
Trade payables	44,469	55,949	115,574
Other current liabilities	10,699	18,267	31,003
Accrued expenses	93,767	112,538	73,447
<b>Total current liabilities</b>	<b>164,124</b>	<b>217,844</b>	<b>267,021</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>2,881,724</b>	<b>1,664,541</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 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-Jun 2021 was approved for publication on August 19, 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.

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.

### 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.

### Note 5 Revenue recognition

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

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 data. The company also estimates a reserve for returns of obsolete medicines that is reported in the accounts. The total reserve amounts to SEK 5.1 million. In addition, there are no other performance commitments.

### Group revenue

SEK,thousand	2021 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Revenue from customer agreements					
Goods <sup>1</sup>	66,374	–	85,729	–	–
<b>Total net revenue</b>	<b>66,374</b>	<b>–</b>	<b>85,729</b>	<b>–</b>	<b>–</b>
Geographic market					
North America <sup>2</sup>	66,374	–	85,729	–	–

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.



## Notes to the consolidated and Parent Company financial statements

### 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 Apr–Jun	2020 Apr–Jun	2021 Jan–Jun	2020 Jan–Jun	2020 Jan–Dec
<b>Tax for the period</b>					
Current tax	-3,332	-1,499	-5,054	-1,501	-9,247
Deferred tax on intra-group sales of goods	322,763	–	436,685	–	–
Other deferred tax	1,914	–	2,902	–	6,996
<b>REPORTED TAX</b>	<b>321,345</b>	<b>-1,499</b>	<b>434,533</b>	<b>-1,501</b>	<b>-2,251</b>

As a result of intra-group sales of inventory items, a deferred tax asset arised on temporary differences in the Group of SEK 322.8 (0.0) M. 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.

### 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 June 30, 2021, corresponding to 3,617,880 shares, would result in a dilution for shareholders of 4.6 percent. Full utilization of all options and share awards, corresponding to 5,858,988 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 7.2 percent.

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

## Notes to the consolidated and Parent Company financial statements

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

<b>Granted instruments</b>	
– Co-worker LTIP 2019	726,301
– US Co-worker LTIP 2020	41,371
<b>Exercised instruments</b>	
– Employee option program 2016/2023	-180,900
– Co-worker LTIP 2017	-119,351
<b>Lapsed instruments</b>	
Co-worker LTIP 2017	-6,000
– Co-worker LTIP 2018	-37,133
– Co-worker LTIP 2019	-106,502
– US Co-worker LTIP 2020	-75,509
<b>Expired instruments</b>	
– Board LTIP 2018	-30,451
<b>Total change</b>	<b>211,826</b>

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

– Employee option program 2016/2023	65,700
– Co-worker LTIP 2017	1,228,582
– Co-worker LTIP 2018	291,516
– Co-worker LTIP 2019	1 374,618
<b>Total number of shares employee stock options may entitle to</b>	<b>2,960,416</b>
– US Co-worker LTIP 2020	604,872
– Board LTIP 2018.2	2,170
– Board LTIP 2019	23,491
– Board LTIP 2020	26,931
<b>Total number of shares allocated share awards may entitle to</b>	<b>657,464</b>
<b>Total number of shares employee stock options and share awards may entitle to</b>	<b>3,617,880</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

profit 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 Apr-Jun	2020 Apr-Jun	2021 Jan-Jun	2020 Jan-Jun	2020 Jan-Dec
Net revenue	66,374	-	85,729	-	-
Gross profit <sup>1</sup>	63,552	-	82,579	-	-
Gross margin <sup>2</sup>	96%	-	96%	-	-
Total registered shares at the beginning of period	68,084,855	55,413,417	67,939,715	55,413,417	55,413,417
Total registered shares at the end of period	75,291,841	61,499,683	75,291,841	61,499,683	67,939,715
Number of shares that the outstanding employee options entitle to	3,617,880	2,849,761	3,617,880	2,849,761	3,406,054
Share capital at the end of period, SEK thousand	8,366	6,833	8,366	6,833	7,549
Equity at the end of period SEK thousand	1,376,085	769,909	1,376,085	769,909	576,897
Earnings per share before and after dilution, SEK <sup>3</sup>	-0.32	-6.79	-3.63	-12.20	-25.57
Operating expenses, SEK thousand	-344,836	-399,332	-692,167	-696,208	-1,591,279
Research and development costs, SEK thousand	-167,308	-227,815	-345,840	-441,365	-866,214
Research & development costs/operating expenses, % <sup>4</sup>	41 %	57 %	45%	63%	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.

**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.

**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.

**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 Q2 2021 and an operational update will be presented by CEO Marty J Duvall and members of Oncopeptides Leadership team, Thursday August 19, 2021 at 12:00 (CET).

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

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## Calendar

November 4, 2021  
February 17, 2022  
April 21, 2022  
May 4, 2022  
May 19, 2022  
Aug 11, 2022

Q3 interim report  
Year-end report 2021  
Annual report 2021  
Q1 interim report 2022  
AGM  
Q2 interim report 2022

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