INTERIM REPORT Q1 2021



# A strong start for PEPAXTO in the US



#### **Significant events**

#### JANUARY-MARCH

- PEPAXTO® was granted accelerated approval by the FDA for the treatment of adult patients with relapsed or refractory multiple myeloma on 26 February
- The US commercial launch of PEPAXTO was successfully initiated in mid March
- PEPAXTO was included in the in the new Multiple Myeloma Clinical Practice Guidelines of the National Comprehensive Cancer Network® (NCCN) in Oncology in March
- The leadership in Europe was in the beginning of March strengthened with two new significant recruitments to build up European commercial organization
- Oncopeptides strengthened the balance sheet through a directed share issue of SEK 1,106 M (USD 130 M). The share issue was completed in April

#### **AFTER THE REPORTING PERIOD**

- **PEPAXTO April net sales** amounted to SEK 28.0 M (USD 3.3 M)
- An application for conditional marketing authorization of melflufen in the EU was submitted in mid April
- Patient enrollment in the phase 2 PORT study was completed in May
- Positive topline results from the phase 3 OCEAN study were announced on May 25

#### Financial overview

#### JANUARY-MARCH

- Net sales amounted to SEK 19.4 M (0.0)
- Operating loss amounted to SEK 347.3 M (loss: 296.9)
- Loss for the period was SEK 234.7 M (loss: 297.3)
- Loss per share, before and after dilution, was SEK 3.45 (loss: 5.37)
- Cash and cash equivalents amounted to SEK 372.5 M (617.8) on March 31







#### Financial overview of the group

<b>2021</b> <b>Jan-Mar</b> 19,355	2020 Jan-Mar	2020 Jan-Dec
19,355		
	-	-
19,027	-	-
98 %	N/A	N/A
-347,852	-296,876	-1,591,279
-347 852	-297,327	-1,592,442
-3,45	-5.37	-25.57
-386,714	-312,841	-1,296,509
372,453	617,786	840,255
49 %	72 %	54 %
	19,027 98 % -347,852 -347 852 -3,45 -386,714 372,453	19,027 - 98 % N/A -347,852 -296,876 -347 852 -297,327 -3,45 -5.37  -386,714 -312,841 372,453 617,786

#### A STRONG START FOR PEPAXTO IN THE US

**The year** for Oncopeptides got off to a strong start with the accelerated approval and launch of PEPAXTO for multiple myeloma in the United States. This important milestone was enabled by innovative science and driven by research collaborations with leading academic institutions around the world, most notably in Sweden and the United States.

Oncopeptides now stands proudly among the few companies that have successfully navigated the long and difficult path from discovery to commercialization, thus completing our transformation to a fully integrated biotech company. We are delivering on a mission to bring hope to patients through science.

#### STRONG START OF LAUNCH

PEPAXTO was commercially launched in mid-March just two weeks after the accelerated approval and we quickly gained inclusion in the National Comprehensive Cancer Network guidelines, further validating the evidence that our drug is an important option to treat relapsed or refractory multiple myeloma patients. We are excited by the response from our customers and the opportunity to help many patients with limited treatment options. Inspite

of the covid-19 pandemic and with only two weeks of commercialization in the quarter, we are pleased with the performance in late March with recognized sales revenue of SEK 19.4 M (USD 2.3 M), which includes minor stocking and mostly demand pull-through into 37 academic and community centers. Furthermore, awareness of our drug has increased to 90% among our customers and insurance coverage is strong, with 97% covering the drug according to the FDA labelled indication. These are strong measures in the first month of launch.

**The momentum** continued into April and the healthy demand for PEPAXTO generated net sales of SEK 28.0 M (USD 3.3 M) adding 56 new accounts in April to a total of 93. Our assessment is that this trend compares favorably to recently launched competitors with triple class

refractory multiple myeloma labels. Despite the competitive market in RRMM, we remain confident on continued success and are particularly encouraged by the uptake in community centers, representing about 65% of the accounts using our product today. The benefit/risk profile of PEPAXTO, combined with a convenient dosing, make it attractive for patients treated in outpatient community practices. Firmly establishing the drug in the community paves the way for long-term revenue success. We embrace the challenges ahead and look forward to future progress as the launch continues.

## EXPANDING GEOGRAPHIC FOOTPRINT

We have also made significant progress in Europe, highlighted by the submission of an application for conditional marketing authorization of melflufen to

- First commercial patient on PEPAXTO on March 15
- Net sales of USD 2.3 M in March and USD 3.3 M in April
- Strong payor uptake with 97% insurance coverage
- 93 academic and community centers have already administered PEPAXTO
- Efficacy and convenient dosing appreciated by healthcare professionals

the EMA in April. Our ability to attract key talent to lead and expand our footprint in Europe fuels further excitement and capabilities in the company. In addition, we recently launched an early access program in Europe which is highlighting the unmet need in Europe.

#### POSITIVE OCEAN OUTCOME

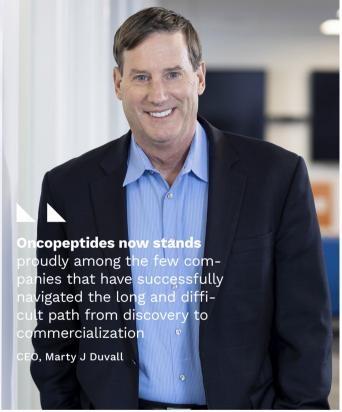
The topline results from the OCEAN study announced May 25, mark another major milestone for Oncopeptides. By demonstrating that melflufen is at least as efficacious as pomalidomide, we pave the way for a potential use of melflufen in earlier lines of therapy in a substantially larger patient population in the US. This is very exciting news for patients and indicates that melflufen has the potential to

become part of the standard of care in relapsed refractory multiple myeloma.

I am proud of the achievements of our dedicated team and I would like to thank the investors who have provided the resources needed to deliver on our milestones. Together, we bring hope to the patients we serve.

May 26, 2021

Marty J Duvall, CEO



#### Q1 business highlights

#### COMMERCIAL

Following the accelerated approval of PEPAXTO in the U.S. by the end of February, we finalized our preparations to make the drug commercially available for patients. On March 15 the first patients were treated with PEPAXTO. The inclusion of PEPAXTO in the NCCN guidelines may facilitate the management of previously treated multiple myeloma patients, who need additional treatment options.

We have proactively engaged with payors that resulted in strong payor coverage confirming their intent to cover PEPAXTO, coupled with representation of PEPAXTO in 98 percent of Electronic Health Records systems, and our robust ONCOURSE Patient Assistance Programs.

Our oncology account management and medical field teams have found that Health Care Providers (HCPs) appreciate PEPAXTO's efficacy, convenient dosing and manageable adverse events profile. Many HCPs have already begun using PEPAXTO in patients that have exhausted their therapeutic options and we anticipate that further trial and usage in 5th and 6th lines will be forthcoming.

Market research reveals that a substantial part of multiple myeloma physicians intend to prescribe PEPAXTO in the future. We recognize an opportunity to further educate the HCPs about PEPAXTO's innovation as the first anticancer peptide-drug conjugate approved by the FDA for multiple myeloma.

#### **CLINICAL DEVELOPMENT**

During O1 the clinical team was busy gathering and confirming data in the phase 3 OCEAN study and preparing for the Data Base Lock. Topline data were announced on May 25. The PFS, as assessed by the independent review committee, demonstrated a Hazard Ratio favoring melflufen of 0.817 (95% CI: 0.659-1.012. p=0.0640) for the primary endpoint and shows that melflufen is non-inferior to pomalidomide. The Hazard Ratio for PFS as per investigator assessment was 0.790 (95% CI: 0.639-0.976). In both assessments, the median PFS for the melflufen arm was more than 40% higher than for the pomalidomide arm. The Overall Response Rate for melflufen was 32.1% vs. 26.5% for pomalidomide.

**The team** has also secured additional regulatory and ethics

approvals across European countires for the phase 3 LIGHTHOUSE study. Additional sites have been activated and the recruitment of patients in these sites has been initiated. The Covid-19-pandemic is still impacting the clinical program and extra attention is needed to make sure the patients that are included in our ongoing clinical studies are receiving their medication on time.

Following the FDA-approval of our IND-submission for the drug candidate OPD5 in Q4 2020, we presented the study design for COAST during O1: an open-label. phase 1 dose escalation study of safety and tolerability of OPD5 as a myeloablative conditioning regimen followed by autologous stem cell transplant in patients with relapsed refractory multiple myeloma. OPD5 is the second drug candidate from Oncopeptides' proprietary PDC platform. OPD5 is an analogue of melflufen, that has been formulated to meet the requirements for high dose myeloablative therapy. The first patient is expected to be enrolled in the phase 1 COAST study, in Q2 2021.

**The signal seeking** studies in Acute Myeloid Leukemia and

Relapsed Diffuse Large B-cell Lymphoma are progressing according to plan and the synopses were completed so a broadening into new cancer indications can be initiated later in 2021.

An Early Access Program for

RRMM patients was initiated in Europe. Physicians may apply for melflufen treatment for 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).

#### SCIENTIFIC ENGAGEMENT

Q1 was a very eventful quarter for the scientific team; 19 abstracts were submitted to key international congresses such as American Society of Clinical Oncology (ASCO) and European Hematology Assiciation (EHA), 8 manuscripts were published and 1 manuscript was submitted. The team participated in 3 scientific

congresses including European School of Hematology, European Myeloma Network Meeting and The European Society for Blood and Marrow Transplantation. The scientific engagement has further strengthened our scientific share of voice and demonstrated the potential value that PEPAXTO can bring to patients.

In February, Oncopeptides together with the Embassy of Sweden, Uppsala University, and the Dana-Farber Cancer Institute, arranged a successful seminar at the House of Sweden in Washington DC, USA. Numerous health care stakeholders, researchers, medical profession and more than 70 different companies and organizations attended.

The purpose was to acknowledge the Swedish life science research innovation model, emphasize the importance of Swedish-American research collaboration in cancer research, and spur future research projects.

The discovery of melflufen and the accelerated growth of Oncopeptides were recognized as a role model of academic innovation and Swedish-US research collaboration. Joachim

#### **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.

Gullbo. Associate Professor. Consultant in Oncology and Clinical Pharmacology, Theradex Oncology, and his fellow researchers at Uppsala University, Karolinska Institute and the University of Gothenburg created Oncopeptides around an innovative molecule 20 years ago, and the research collaboration with Professor Ken Anderson and Professor Paul Richardson at Dana-Farber Cancer Institute brought the company into the field of multiple myeloma a decade later. Since then, hundreds of international jobs and many international research collaborations have been created, and the scientific advancement has brought new hope to patients with multiple myeloma.

#### Q1 business highlights

#### PRE-CLINICAL DEVELOPMENT During Q1 the Company contin-

ued the development of its R&D strategy.

On March 26 we got an important article published in the peer reviewed publication Cancers: "Aminopeptidase Expression in Multiple Myeloma Associates with Disease Progression and Sensitivity to Melflufen". The objectives were to: establish baseline expression of aminopeptidases in multiple myeloma, establish biological relevance of the aminopeptidases, and demonstrate efficacy of melflufen in patients with relapsed refractory multiple myeloma in relation to expression of aminopeptidases. The results increase the understanding of the critical roles of aminopeptidases in disease progression and the activity of melflufen in multiple myeloma.

#### SUSTAINABILITY (ESG) **Environmental**

We continuously strive to minimize the environmental impact of our own operations and those of our suppliers. Our pre-clincal 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. We have initiated dialogues with our CMO's to start reviewing their sustainability work. We encourage all our suppliers to align with appropriate standards to minimize impacts.

#### Social

In December 2020 co-workers across Oncopeptides participated in an annual employee survey based on four parameters. The results were very encouraging. During the first guarter the outcome from the survey has been presented at a number of internal meetings and workshops have been arranged to build a mutual understanding of the results, identify areas of improvement, and agree on action plans going forward. Insights from these meetings have identified some actions. These include a review of Code of Conduct and Ethics Hotline. leadership training, reinforcement of goals and evaluation, and integrate culture and values assessment into performance reviews.

#### Governance

During the quarter a governance project was launched. Due to the significant growth in the company during the past year, a need to optimize the ways of working

within Oncopeptides was identified. The objective of the project is set clear roles, responsibilities and remits as well as a clear understanding of the expectations for the cross-functional business driving teams.

To ensure good governance throughout the organization. we have systems in place that control how the company takes decisions, meets its legal obligations, and achieves its operational requirements. We have a continues review of our policies and during Q1 a number of policies where updated including the Code of Conduct, the Anticorruption policy as well as the Corporate governance policy.

#### ORGANISATION AND FINANCING

In the beginning of March, the company executed a successful financing through a directed share issue to a broad base of highly reputable international specialist investors. The transaction raised proceeds of SEK 1.106 M before issue costs and was completed in April. Many reputed Swedish and international institutional investors and sector specialists participated in the directed share issue including the US investors Bain Capital, Healthcor Management and Great Point Partners. This provides Oncopeptides with the financial

resources required to launch PEPAXTO in the US, continue our clinical development program. expand into new indications as well as prepare for a future commercialization in the EU.

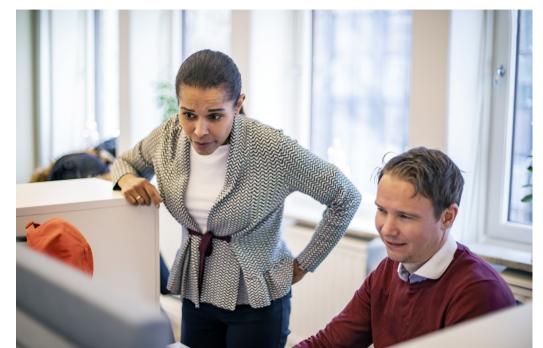
During the quarter the organization was strengthened with the recrutiment of two experienced leaders who will be responsible

for the build-up of the European Team. Andrea Passalacqua was appointed as General Manager in Europe, and Pamela Bacon as Head of Medical Affairs Europe.

#### **INVESTOR RELATIONS**

We participated in several healthcare investor conferences such as Carnegie Healthcare conference. Cowen Healthcare

conference and Jefferies healthcare conference.



ONCOPEPTIDES | INTERIM REPORT 01 2021 4 (22)

# **Equity story: an emerging GLOBAL biotech company**Why investing in Oncopeptides creates long-term value

## Focused commercial and regulatory strategy with the first product on the market

## Commercialization phase

- Commericalization in the US with a dedicated sales and medical affairs organisation
- Planned submission to EMA for a conditional marketing authorization of melflufen
- Partnering strategy for Japan

# Rap

#### Rapidly growing market

- The number of patients diagnosed with myeloma is increasing
- Improved treatment outcomes grow number of patients in later lines of therapy
- Resistance to therapy is increasing

## Rapid US MM market growth



## Broad clinical program supporting future growth and value creation

## Comprehensive clinical program

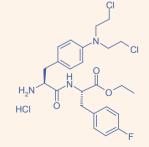
- Clinical program designed to support potential use in a broader patient population and in earlier lines of therapy
- The first confirmatory phase 3 study OCEAN is a head-to-head comparison with pomalidomide
- The LIGHTHOUSE phase 3 combination study may enable melflufen to be used in combination treatments

# HORIZON LIGHTHOUSE

## OCEAN

## Melflufen – a unique mechanism of action

- First anti-cancer peptide drug conjugate leveraging aminopeptidases.
- Comprehensive clinical program designed to broaden label



## Proprietary PDC platform lays foundation for future growth

## Peptide Drug Conjugate Platform (PDC)

- PDC delivers fast and selective cytotoxic activity to cancer cells while protecting healthy cells
- Potential to develop targeted treatments for several forms of cancers e.g AML and DLBCL.
- Second drug candidate OPD5, entering clinical development in stemcell transplantation in multiple myeloma
- PDC platform validated through melflufen



**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.

Although we are a small company, we have a unique type

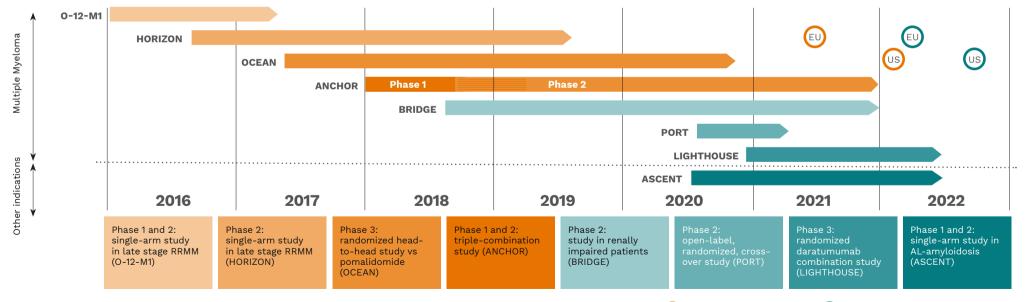
of drug pipeline and have all the pillars in place to address areas of rapidly growing unmet medical need.

**Our clinical development** program is underpinned by several studies being conducted in parallel to one another. The broadbased structure of the program

further strengthens our ability to address unmet medical need.

#### **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
ANCHOR	EXPLORATIVE • Phase 1/2 study with up to 64 patients • Multiple myeloma	<ul> <li>A triple-combination study</li> <li>A in patients who have received 1–4 earlier lines of therapy including IMiDs and Pls.</li> </ul>	<ul> <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> <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>
ASCENT	EXPLORATIVE • Phase 1/2 study with up to 40 patients • AL-amyloidosis	<ul> <li>A single-arm study in patients with systemic light-chain (AL) amyloidosis who have undergone at least one prior treatment.</li> </ul>	<ul> <li>New indication with melflufen to provide thera- peutic alternatives to patients who have poor prognosis and currently have limited treatment options</li> </ul>	Study start in December 2019. LPI expected in H2 2021.
BRIDGE	SUPPORTING • Phase 2 study with up to 25 patients • Multiple myeloma	Open-label, single-arm trial for patients with reduced renal function.	Show melflufen's treatment profile for patients with reducsed renal function.	• Study started in Q3 2018. LPI expexted in H2 2021.
HORIZON	PIVOTAL • Phase 2 study with 157 patients. • Multiple myeloma	<ul> <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>	To treat adult patients with relapsed or refrac- tory multiple myeloma who have received at least four prior lines of therapy	<ul> <li>Approved by the US FDA in Q12021.</li> <li>An application for conditional marketing authorization of melfifen in the EU was submitted in Q1 2021 - approval expected in H1 2022</li> </ul>
LIGHTHOUSE	CONFIRMATORY  • Phase 3 combination study to include more than 240 patients.  • Multiple myeloma	Randomzied daratumumab combination study     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.	<ul> <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>	The study started in December 2020. LPI expected in H1 2022
OCEAN	PIVOTAL/CONFIRMATORY  • Phase 3 combination study with 495 patients. Fully recruited.  • Multiple myeloma	Randomized head-to-head study with pomalid mide in patients treated with IMiDs and PIs,and who have become resistant to their last line of therapy.  RRMM patients who are resistant to lenalidmide.	<ul> <li>Direct comparison with pomalidomide to demonstrate benefit for melflufen</li> <li>To expand label into earlier lines of therapy.</li> </ul>	The study started in Q2 2017. LPI November 2020. Topline results in Q2 2021.
PORT	SUPPORTING • Phase 2 study in 25 patients. • Multiple myeloma	Open-label, randomized, cross-over phase 2 study evaluating an alternative administration of melflufen in patients with RRMM. Comparing safety, tolerability and efficacy of peripheral versus central intravenous administration of melflufen in combination with dexamethasone	Data could potentially provide a pathway to include an additional mode of administration into the label	• Started in August 2020. • LPI Q2 2021

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**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 disease1. 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

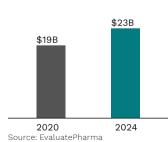
The global myeloma market amounted to USD 19 billion in 2019 and is expected to grow rapidly over the coming years. Following recent drug launches, the growing number of patients in later lines of therapy is expected to increase the overall number of patients receiving treatment, and thus the value of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

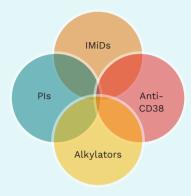
A patient undergoing myeloma therapy can become resistant to the two primary classes of pharmaceuticals, IMiDs and PIs. after the first line of therapy. If patients have also been treated with an anti-CD38 inhibitor. they are defined as triple-class refractory patients. Patients respond differently to 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



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.

#### **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 overexpressed in cancer cells.

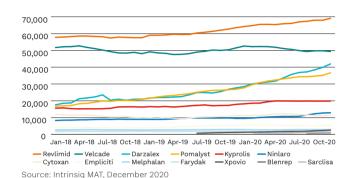
## Immunomodulatory drugs (IMiDs)

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.

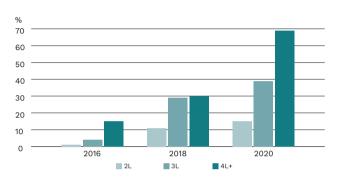
## Proteasome inhibitors (PIs)

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.

## Number of US total multiple myeloma patients by products



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



Source: Patient claims data, company market research

market potential for a particular indication.

## 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 show that newer products are being used in addition to older ones as survival rates 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 **TCR RRMM** 20.000+ 3L+ RRMM 2I + RRMM Single drug use Comb. use 25.000 20.000+ ที่ที่ที่ที ที่ที่ที่ที EMD 18.000 ที่ที่ที่ที่ Average duration of therapy 3-4 months 6-9 months 10-14 months Clinical program supports label expansion Approval in triple-class refractory (TCR) patients who have received at least 4L of treatment HORIZON Head-to-head study with pomalidomide may enable single agent 3L+ use OCEAN Combination with proteasome inhibitor or antibody drugs may enable 2L+ combination LIGHTHOUSE

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 launced 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 INDapplication 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

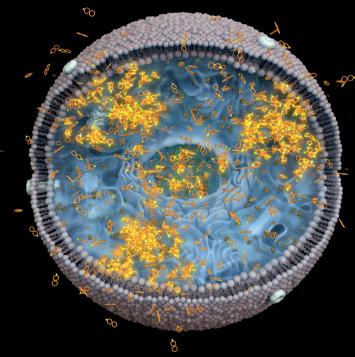
In 2020, we opened our state-of-the-art drug development facility in Solna, just outside Stockholm, Sweden. The laboratory will play a vital role in further developing the PDC platform. The opening of the laboratory is a key part of our continued

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 back grounds, 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 PDCbased treatments for multiple myeloma.



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

#### Financial overview

#### REVENUE

Net sales amounted to SEK 19.4 M (0.0) during the first quarter. Gross result amounted to 19.0 M (0.0), corresponding to a gross margin of 98,3 % (N/A).

#### **OPERATING EXPENSES**

Operating expenses for the first quarter amounted to SEK 366.4 M (296.9).

## RESEARCH AND DEVELOPMENT COSTS

Research and development costs amounted to SEK 178.5 M (213.6). The decrease is mainly explained by a lowered cost in OCEAN trial and the completion of the HORIZON trial.

## MARKETING AND DISTRIBUTION COSTS

Marketing and distribution costs amounted to SEK 178.2 M (51.0). The ost 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 47.6 M (40.7). The increase is due to the company's continued high business activity level and growing organization, in particular in the US.

#### 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 total costs for the sharebased incentive programs in the first quarter amounted to SEK 5.5 M (5.0), out of which SEK -14.4 M (0.7) was provisions and payments of social security contributions, and SEK 19.9 M (5.7) was costs for share-based payments. 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 does have some impact on the group's ability to conduct clinical trial and sales activities in hospitals. The pandemic, is however not considered to have a significant impact on the finances of the company.

#### **TAXES AND EARNINGS**

The loss before taxes for the first quarter was SEK -347.8 M (-297.3).

As a result of intra-group sales of inventory items, a deferred tax asset arised on temporary differences in the Group of SEK 113.9 (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. See note 7.

The loss for the period was SEK -234.7 M (-297.3). This corresponds to a loss per share, before and after dilution, of SEK 3.45 (5.37).

## CASH FLOW, INVESTMENTS AND FINANCIAL POSITION

Cash flow from operating activities amounted to a negative SEK 386.7 M (neg: 312.8). The continued negative cash flow is according to plan and is explained by the company's continuation of clinical activities as well as with the expansion of the company's medical affairs and commercial functions.

Cash flow from investing activities was a negative SEK 0.7 M (neg: 3.8). Cash flow from financing activities amounted to SEK 3.5 M (neg: 3.9).

In March 2021 it was resolved to make a directed share issue that was completed in April, raising SEK 1,106.0 M before issue costs of SEK 67.1 M.

Share issues that are resolved during the accounting period but completed after the end of the period are recorded as completed in the parent company as share issues are considered as completed upon the resolution date according to Swedish accounting practices, but not in the group as share issues are recorded when the new shares have been paid according to IFRS. See note 10

Cash flow for the first quarter was a negative SEK 383.9 M (neg: 320.5). As of March 31, 2021, cash and cash equivalents amounted to SEK 372.5 M (617.8). Proforma cash and cash equivalents including share issue proceeds of SEK 1,038.9 M after issue expenses, which was paid in April, amounted to SEK 1,411.4 M. Equity amounted to SEK 347.2 M (505.8). ■

#### Other information

#### CO-WORKERS

As of March 31, 2021, the number of co-workers amounted to 294 (121).

#### 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 March 31, 2021, the number of registered shares and votes in Oncopeptides amounted to 68,084,855.

## EVENTS AFTER THE END OF THE REPORT PERIOD

PEPAXTO April net sales amounted to SEK 28.0 M (USD 3.3 M).

In April 2021 Oncopeptides submitted an application to the European Medicines Agency, EMA, for conditional marketing authorization of melflufen (melphalan flufenamide) in the EU.

Patient enrollment in the phase 2 PORT study was completed in May.

Topline results from the phase 3 OCEAN study were announced on May 25.

#### REVIEW

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

Stockholm, May 26, 2021

Marty J Duvall

#### Condensed consolidated income statement

SEK thousand	Note	2021 Jan–Mar	2020 Jan–Mar	2020 Jan–Dec
Net sales	5	19,355	_	-
Cost of goods sold		-328	_	
Gross profit		19,027	-	
Operating expenses				
Research and development costs		-178,532	-213,550	-866,214
Marketing and distribution costs		-178,198	-50,981	-456,529
Administrative expenses		-47,630	-40,650	-197,662
Other operating income/expenses <sup>1</sup>		38,002	8,305	-70,874
Total operating expenses		-366,358	-296,876	-1,591,279
Operating loss		-347,331	-296,876	-1,591,279
Net financial items		-521	-451	-1,163
Loss before tax		-347,852	-297,327	-1,592,442
Tax	7	113,188	-2	-2,251
Loss for the period <sup>2</sup>		-234,664	-297,329	-1,594,693
Earnings per share before and after dilution (SEK)		-3.45	-5.37	-25.57

#### Condensed consolidated statement of comprehensive income

SEK thousand	2021 Jan-Mar	2020 Jan–Mar	2020 Jan–Dec
Loss of the period	-234,664	-297,329	-1,594,693
Other comprehensive income			
Items to be reclassified to profit or loss	_	_	_
Translation differences from foreign operations	-21,866	460	-1,544
Total other comprehensive income, net of tax	-21,866	460	-1,544
Total comprehensive income, net of tax	-256,550	-296,869	-1,596,237

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<sup>1)</sup> 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 Note	2021 Jan-Mar	2020 Jan–Mar	2020 Jan–Dec
ASSETS			
Non-current assets			
Intangible assets	1,724	2,111	1,830
Property, plant and equipment	17,470	4,938	17,273
Right-of-use assets	17,797	22,696	21,057
Financial non-current assets	3,816	2,262	3,622
Deferred tax assets	128,048	2,447	8,175
Total non-current assets	168,855	34,454	51,957
Current assets			
Inventory	11,629	_	8,665
Accounts receivable	21,379	_	_
Other current receivables	25,167	7,393	23,229
Prepaid expenses 10	102,382	6,476	22,650
Cash and cash equivalents	372,453	617,786	840,255
Total current assets	533,010	631,655	894,799
TOTAL ASSETS	701,865	666,109	946,756

SEK thousand Not	2021 e Jan-Mar	2020 Jan–Mar	2020 Jan-Dec
EQUITY AND LIABILITIES			
Equity			
Share capital	7,549	6,157	7,549
Additional paid-in capital	3,945,865	2,550,000	3,919,036
Retained earnings (including net profit/loss for the period)	-3,606,222	-2,050,319	-3,349,688
Total equity <sup>1</sup>	347,192	505,838	576,897
Long-term liabilities			
Provision for social security contributions, share based incentive programs	6,867	23,744	8,530
Other long-term liabilities	3,569	11,317	6,929
Total long-term liabilities	10,436	35,061	15,459
Current liabilities			
Provision for social security contributions, share based incentive programs	32,019	9,345	47,202
Trade payables	86,742	36,292	136,135
Other current liabilities	28,218	18,387	35,045
Accrued expenses and deferred income 10	197,258	61,186	136,018
Total current liabilities	344,237	125,210	354,400
TOTAL EQUITY AND LIABILITIES	701,865	666,109	946,756

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

#### Condensed consolidated statement of changes in equity

SEK thousand	2021 Jan-Mar	2020 Jan–Mar	2020 Jan–Dec
Opening balance	576,897	797,013	797,013
Profit/loss of the period	-234,664	-297,329	-1,594,693
Other comprehensive income	-21,886	460	-1,544
Comprehensive income (loss) for the period	-256,550	-296,869	-1,596,237
Transaction with owners			
New issue of ordinary shares	_	_	1,413,925
Cost attributable to new share issue	_	_	-85,231
Share based payments	19,874	5,694	38,398
Exercise of warrants	6,972	-	9,029
Total transaction with owners	26,845	5,694	1,376,121
CLOSING BALANCE	347,192	505,838	576,897

#### Condensed consolidated statement of cash flow

SEK thousand	2021 Jan-Mar	2020 Jan–Mar	2020 Jan-Dec
Operating loss	-337,331	-296,876	-1,591,279
Adjustment for non-cash-items <sup>1</sup>	41,012	-4,737	160,906
Interest received	-	_	322
Interest paid	-310	-451	-1,485
Tax paid	_	-2	-7,243
Cash flow from operating activities before change in working capital	-306,629	-302,066	-1,438,779
Cash flow from changes in working capital	-80,085	-10,775	142,270
CASH FLOW FROM OPERATING ACTIVITIES	-386,714	-312,841	-1,296,509
Cash flow from investing activities	-740	-3,822	-20,127
Cash flow from financing activities	3,507	-3,856	1,323,461
Cash flow for the period	-383,947	-320,519	6,825
Cash and cash equivalents at beginning of period	840,255	926,186	926,186
Change in cash and cash equivalents	-383,947	-320,519	6,825
Foreign exchange difference in cash and cash equivalents	-83,855	12,119	-92,756
Cash and cash equivalents at the end of period	372,453	617,786	840,255

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

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#### Condensed Parent Company income statement

SEK thousand	2021 Jan-Mar	2020 Jan–Mar	2020 Jan–Dec
Net sales <sup>1</sup>	478,109	_	_
Cost of goods sold	-2,251	_	_
Gross profit	475,858		
Operating expenses			
Research and development costs	-178,384	-213,627	-866,509
Marketing and distribution costs	-182,592	-52,829	-460,860
Administrative expenses	-47,862	-41,895	-201,751
Other operating income/expenses <sup>2</sup>	38,112	8,305	-70,874
Total operating expenses	-370,726	-300,046	-1,599,994
Operating loss	105,132	-300,046	-1,599,994
Net financial items	-185	12	375
Loss before tax	104,947	-300,034	-1,599,620
	_		
Loss for the period	104,947	-300,034	-1,599,620

#### Condensed Parent Company statement of comprehensive income

SEK thousand	2021 Jan-Mar	2020 Jan-Mar	2020 Jan–Dec
Loss of the period	104,947	-300,034	-1,599,620
Other comprehensive income	-	_	
Total other comprehensive income, net of tax	-	_	
Total comprehensive loss for the period	104,947	-300,034	-1,599,620

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Refers to intra-group revenues.
 Exchange rate differences on assets and liabilities in operational activities.

### Parent Company balance sheet

SEK thousand	Note	2021 Jan-Mar	2020 Jan–Mar	2020 Jan-Dec
ASSETS				
Subscribed but unpaid capital	10	1,106,000	_	_
Non-current assets				
Intangible fixed assets		1,724	2,111	1,830
Property, plant and equipment		12,296	2,529	12,097
Financial non-current assets		14,266	901	8,664
Total non-current assets		28,286	5,541	22,591
Current assets				
Inventory		10,684	_	8,665
Current receivables group companies		483,443	_	_
Other current receivables		10,479	7,118	10,668
Prepaid expenses		20,139	3,285	17,057
Cash and cash equivalents		332,889	616,867	785,972
Total current assets		857,634	627,270	822,362
TOTAL ASSETS		1,991,920	632,811	844,953

SEK thousand	Note	2021 Jan-Mar	2020 Jan–Mar	2020 Jan–Dec
EQUITY AND LIABILITIES				
Restricted equity				
Share capital		7,565	6,157	7,549
Unregistered share capital		778	_	_
Statutory reserve		10,209	10,209	10,209
Non-restricted equity				
Share premium account		4,868,093	2,486,636	3,822,968
Retained earnings		-3,251,324	-1,704,281	-1,671,578
Net profit/loss for the period		104,947	-300,034	-1,599,620
Total equity		1,740,268	498,687	569,528
Long term liabilities				
Provision for social security contributions, share based incentive program		6,432	23,744	8,404
Total long term liabilities		6,432	23,744	8,404
Current liabilities				
Provision for social security contributions, share based incentive programs		32,019	9,345	46,997
Trade payables		58,283	27,257	115,574
Other current liabilities		8,969	16,385	31,003
Accrued expenses	10	145,949	57,393	73,447
Total current liabilities		245,220	110,380	267,021
TOTAL EQUITY AND LIABILITIES		1,991,920	632,811	844,953

#### 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-Mar 2021 was approved for publication on May 26, 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 2.0 million. In addition, there are no other performance commitments.

#### **Group revenue**

SEK,thousand	2021 Jan-Mar	2020 Jan–Mar	2020 Jan–Dec
Reveue from customer agree- ments			
Goods <sup>1</sup>	19 355	-	-
Total net revenue	19 355	-	-
Geografic market			
North America <sup>2</sup>	19 355	_	

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.

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#### 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**

OFK the constant	2021	2020	2020
SEK,thousand	Jan-Mar	Jan-Mar	Jan-Dec
Tax for the period			
Current tax	-1,722	-2	-9,247
Deferred tax on intra-group sales of goods	113,921	_	-
Other deferred tax	989	-	6,996
REPORTED TAX	113,188	-2	-2,251

As a result of intra-group sales of inventory items, a deferred tax asset arised on temporary differences in the Group of SEK 113.9 (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 nine 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". 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.

Full utilization of granted options and share awards per March 31, 2020, corresponding to 3,876,863 shares, would result in a dilution for shareholders of 5.4 percent. Full utilization of all options and

share awards, corresponding to 5,107,548 shares (i.e. including nongranted employee options and warrants set off as hedge for social security contributions), would result in a dilution for shareholders of 7.0 percent.

Below follows a summary of the changes in existing incentive programs during the first quarter of 2021 and the total number of shares that granted employee stock options and share awards may entitle to as of March 31, 2021.

#### Changes in existing incentive programs during first quarter 2021 (number of shares)

Total change	470,809
	,
– US Co-worker LTIP 2020	-50,828
- Co-worker LTIP 2019	-53,108
- Co-worker LTIP 2018	-8,805
Lapsed instruments	
- CO-WOIKEI LTIP2017	-119,331
- Co-worker LTIP2017	-119,351
- Employee option program 2016/2023	-23,400
Exercised instruments	
- CO-WOIREI LTIP 2019	120,301
- Co-worker LTIP 2019	726,301
Granted instruments	

#### Number of shares allocated instruments may entitle to as of March 31, 2021

Total number of shares employee stock options and share awards may entitle to	3,876,863
Total number of shares allocated share awards may entitle to	671,225
- Board LTIP 2020	26,931
– Board LTIP 2019	23,491
- Board LTIP 2018.2	2,170
– Board LTIP 2018	30,451
– US Co-worker LTIP 2020	588,182
Total number of shares employee stock options may entitle to	3,205,638
– Co-worker LTIP 2019	1 428,012
- Co-worker LTIP 2018	319,844
- Co-worker LTIP 2017	1,234,582
– Employee option program 2016/2023	223,200

#### Note 10 Issue related assets and liabilities

SEK,thousand	2021-03-31	2020-03-31 2	020-12-31
Group			
Issue related prepaid expenses	67,053	-	-
Other prepaid expenses (non issue related)	35,329	6,476	22,650
PREPAID EXPENSES	102,382	6,476	22,650
Issue related accrued expenses	67,053	_	-
Other accrued expenses (non issue related)	130,205	61,186	136,018
ACCRUED AXPENSES	197,258	61,186	136,018
Parent company			
Issue related assets	1,106,000	_	_
SUBSCRIBED BUT UNPAID CAPITAL	1,106,000	_	-
Issue related accred expenses	67,053	_	_
Other accrued expenses (non issue related)	78,896	57,393	73,447
ACCRUED EXPENSES	145,949	57,393	73,447

Share issues that are resolved during the accounting period but completed after the end of the period are recorded as completed in the parent company as share issues are considered as completed upon the resolution date according to Swedish accounting practices, but not in the group as share issues are recorded when the new shares have been paid according to IFRS.

#### **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 Jan-Mar	2020 Jan–Mar	2020 Jan-Dec
Net revenue	19,355	_	-
Gross profit <sup>1</sup>	19,027	-	-
Gross margin <sup>2</sup>	98 %	-	-
Total registered shares at the beginning of period	67,939,715	55,413,417	55,413,417
Total registered shares at the end of period	68,084,855	55,413,417	67,939,715
Number of shares that the outstanding employee options entitle to	3,876,863	2,845,289	3,406,054
Share capital at the end of period, SEK thousand	7,549	6,157	7,549
Equity at the end of period SEK thousand	347,192	505,838	576,897
Earnings per share before and after dilution, SEK <sup>3</sup>	-3.45	-5.37	-25.57
Operating expenses, SEK thousand	-347,331	-296,876	-1,591,279
Research and development costs, SEK thousand	-178,532	-213,550	-866,214
Research & development costs/operating expenses, % <sup>4</sup>	49 %	72 %	54 %

<sup>1)</sup> 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.

<sup>2)</sup> 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.

<sup>3)</sup> 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.

<sup>4)</sup> 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 monocloncal 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 Q1 2021 and an operational update will be presented by CEO Marty J Duvall and members of Oncopeptides Leadership team, Wednesday May 26, 2021 at 12:00 (CET).

The conference call will also be streamed via a link on the website: www.oncopeptides.com.

Phone numbers for participants from:

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Europe: +44 3333 009 268

USA: +1 833 823 05 89

#### Calendar

May 26, 2021 August 19, 2021 November 4, 2021 AGM Q2 interim report Q3 interim report

#### Contact

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