oncopeptides

INTERIM REPORT Q1 2020

Oncopeptides is a pharmaceutical company focused on the development of targeted therapies for difficult-to-treat hematological diseases. The company is focusing on the development of the lead product candidate melflufen (melphalan flufenamide), a first-in-class anti-cancer peptide-drug conjugate that rapidly delivers an alkylating payload into tumor cells. Melflufen is in development as a new treatment for the hematological cancer multiple myeloma and is currently being evaluated in multiple clinical studies including the pivotal phase 2 HORIZON study and the ongoing phase 3 OCEAN study. Oncopeptides' headquarters is in Stockholm, Sweden with U.S. headquarters in Boston, Mass. The company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO.

Conference call for investors, analysts and the media

The Interim Report Q1 2020 and an operational update will be presented by CEO Jakob Lindberg and members of Oncopeptides management team, Tuesday May 26, 2020 at 10:00 (CET). The conference call will also be streamed via a link on the website: www.oncopeptides.com.

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Financial calendar

Annual General Meeting	May 26, 2020
Interim Report Q2, 2020:	August 26, 2020
Interim Report Q3, 2020:	November 19, 2020

For further information

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This information is information that Oncopeptides is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact persons set out above, at 08:00 CET on May 26, 2020.

Melflufen is an abbreviated form of the international non-proprietary name (INN) melphalan flufenamide, an investigational product not yet approved for commercial use in any market globally.

Summary of Q1

Financial overview January 1 – March 31, 2020

- Net sales amounted to SEK 0.0 M (0.0)
- Loss for the period was SEK 297.3 M (loss: 134.1)
- Loss per share, before and after dilution, was SEK 5.37 (loss: 2.82)
- On March 31 cash and cash equivalents amounted to SEK 617.8 M (747.5)

Significant events during the period January 1 – March 31, 2020

- Top line results from the company's pivotal phase 2 study HORIZON were presented and showed a 26% Overall Response Rate (ORR) of melflufen in triple-class refractory multiple myeloma patients
- The Lancet Haematology published detailed results from Oncopeptides international multi-center study, O-12-M1
- Oncopeptides announced that COVID-19 will not affect the company's pivotal studies significantly while recruitment to explorative studies and initiating new studies will temporarily be paused
- The company strengthened its management team with several new senior executives

Significant events after the reporting period

- In May, Oncopeptides completed a directed share issue of SEK 1,414 million (144 MUSD) before issue costs
- The enrollment in the pivotal phase 3 study OCEAN was successfully completed in May including 450 patients from more than 100 hospitals around the world

Financial overview of the group

SEK thousand	2020 Jan - Mar	2019[1)] Jan - Mar	2019 Jan - Dec
Net sales	-	-	-
Operating loss	-296,876	-133,812	-739,392
Loss before tax	-297,327	-133,946	-739,920
Loss for the period	-297,329	-134,077	-740,705
Earnings per share before and after dilution (SEK)	-5.37	-2.82	-14.33
Cash flow from operating activities	-312,841	-142,821	-690,566
Cash and cash equivalents at the end of the period	617,786	747,471	926,186
Research & development costs/operating expenses %	72%	80%	74%

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

CEO statement

During the first quarter of 2020, we have paved the way for the upcoming application for accelerated approval to the FDA of melflufen, based on HORIZON data. With that we have laid the foundation for a potential future commercialization. Our highest priority is to submit a New Drug Application to the FDA before end of Q2.

On March 26, we reached the most important milestone to date in Oncopeptides' history when we presented the final topline results from the pivotal phase 2 HORIZON study. The study evaluates melflufen in patients with relapsed and refractory multiple myeloma (RRMM) and the results showed an improved overall response rate (ORR) than previously reported for triple-class refractory RRMM patients and confirmed that melflufen has a good efficacy and safety profile. There is a strong need for new treatment options, and we are convinced that melflufen can become a valuable addition to the treatment regimen. In May, the last patient was recruited in our phase 3 OCEAN study. This marks an important milestone in the development of Oncopeptides. Our continuous dialogue with healthcare providers and medical experts demonstrates a growing interest in Oncopeptides and our drug development program.

Our clinical studies

We have continued our intense work on finalizing the application for accelerated approval of melflufen in the US. The application is based on data from the 157 patients included in our pivotal phase 2 HORIZON study and will be submitted to the FDA before the end of the second quarter 2020.

We are very excited that we have managed to finalize the patient recruitment in our phase 3 OCEAN study in May, despite the strenuous situation that study sites and healthcare providers have faced during the prevailing COVID-19 pandemic. The OCEAN study was initiated in 2017 and is a randomized, head-to-head study comparing melflufen with pomalidomide in RRMM patients. For a small company like Oncopeptides, it has been an intense and challenging task to run a global phase 3 study with 450 patients in over 100 hospitals. I am extremely proud that we managed to accomplish this. We expect to report topline results from OCEAN during the second half of 2020 and aim to submit an application for market

Full speed ahead

approval in the US based on the phase 3 study during the second quarter of 2021.

Following the outbreak of the COVID-19 pandemic we decided on March 20 to implement temporary measures regarding some of our clinical programs for patient safety reasons. The recruitment of new patients to the clinical studies ANCHOR, BRIDGE and the study in AL amyloidosis was paused, and the initiation of the planned phase 3 LIGHTHOUSE study was postponed. Treatment of patients already enrolled in the studies continues. We expect to restart patient enrollment as soon as this can be done safely.

Detailed results from our O-12-M1 phase 1/2 study were published in The Lancet Haematology in March, and the results were also highlighted in an editorial in the same issue. The study was the first that we conducted in RRMM patients and the results were highly promising with an ORR of 31 percent and a median overall survival of 20.7 months.

Balance sheet strengthened

In May 2020, Oncopeptides carried out a directed share issue to a broad base of highly reputable international specialist investors. The transaction raised proceeds of SEK 1.4 billion before issue costs and represents one of the largest share issues ever in the Swedish life science sector. I interpret the support and interest from both existing shareholders and new international investors as a validation of our goals and strategic direction. This provides us with the financial resources required to successfully prepare and execute the market launch of melflufen in the US, continue our clinical development program and expand into new indications.

Operational development

During Q1, we have accelerated the build-up of our US subsidiary to prepare for a successful launch of melflufen in the US. We have succeeded to attract highly qualified co-workers with extensive medical and commercial experience from the life science industry. Assuming that we obtain a marketing authorization, we expect to launch melflufen around the year end.

Roadmap for Oncopeptides in 2020

In the coming quarters, we will complete the transformation of Oncopeptides from a small research-based company to a fully integrated commercial pharmaceutical company with our first product on the market. We are entering an exciting and transformative period in which we will finally be able to make a true difference for myeloma patients. The main 2020 objectives are: to gain FDA acceptance of the application for marketing authorization of melflufen based on the HORIZON data, obtain accelerated approval in the US and finally provide US RRMM patients access to melflufen.

Other key milestones are to present and publish the complete final results from the HORIZON study and present the topline results from the OCEAN study. Provided that we receive positive data from the OCEAN study, we will submit an application for marketing authorization in 2021 for patients in earlier lines of RRMM treatment in all major markets including the US.

We will have a rich news flow during the year, and we will maintain a strong presence at scientific conferences to increase awareness of Oncopeptides and knowledge of the value of melflufen in patients with multiple myeloma. The ongoing pandemic poses challenges as a significant amount of the interactions with opinion leaders and experts around the world will be done virtually. However, we are well-prepared to fully leverage the digital opportunities.

I would like to extend my sincere appreciation to the clinicians and co-workers who, despite the prevailing pandemic, enable the development of melflufen and Oncopeptides and therefore make it possible for patients with relapsed and refractory multiple myeloma to gain access to this new and improved treatment.

Stockholm May 26, 2020

Jakob Lindberg
CEO, Oncopeptides AB

Oncopeptides' technology platform, PDC

Oncopeptides' drug development program is based on the unique proprietary peptide-drug conjugate (PDC) technology platform. In parallel with the clinical development of melflufen, the company is engaged in preclinical development to generate new candidate drugs based on the PDC platform. This has to date resulted in two new peptide-drug conjugate candidates that can enter the clinical setting in late 2020 and 2021.

A solid research foundation allows us to focus on cancer in its various forms

The strength of the company's research lies in the technology platform and collaborations with leading research centers around the globe.

The core of the company´s competence lies in inducing molecules to selectively concentrate in tumour cells, often by benefiting from the tumour's inherent differences in comparison to normal cells.

The technology platform: Peptide-drug conjugates – or PDCs

The peptide-drug conjugate platform allows Oncopeptides to concentrate a toxin in cancer cells by exploiting the difference in peptidase activity (and to some extent also esterase activity) between cancer cells and normal cells. By doing this, the company delivers more and different cytotoxic activity to the cancer cells while protecting the healthy cells.

New drug candidates for potential new indications

Over the past years, Oncopeptides has developed various drug candidates from its PDC platform. The ambition is to shortly initiate clinical evaluation of the next molecule, OPD5, in the area of bone marrow transplantation. The company hopes to be able to initiate clinical studies before the end of 2020. Following this, it expects to be ready to clinically evaluate the next molecule, OPS2, in 2021. OPS2 is currently being evaluated in various preclinical disease models, primarily non-Hodgkin's lymphoma, acute myeloid leukemia and triple negative breast cancer.

Clinical strategy

Oncopeptides' development of targeted therapies for difficult-to-treat hematological diseases and malignancies is based on its peptide-drug conjugate platform. The company is currently focusing on the development of its lead product candidate melflufen for the treatment of multiple myeloma. Melflufen is a first-in-class anti-cancer peptide-drug conjugate candidate that rapidly delivers an alkylating payload into tumour cells.

Our ongoing and coming clinical studies will provide us with a broad set of data and information about melflufen's efficacy in various patient groups. We are working with the preparations for submitting a New Drug Application (NDA) to the US Food & Drug Administration (FDA) for accelerated market approval in the United States based on all available data from the HORIZON study. The objective is to submit the application at the end of Q2 2020. This could then potentially lead to the first market approval for melflufen in the US around year-end.

In addition, Oncopeptides has several drug candidates in late stage preclinical development for other malignancies, which will potentially move to clinical development in the future.

Several clinical studies for broader applications

The goal of Oncopeptides' clinical program is to establish melflufen as a backbone therapy in relapsed-refractory multiple myeloma.

Melflufen is currently extensively studied in a robust clinical development program in multiple myeloma. The clinical strategy has evolved over time, based on the results from Oncopeptides' first clinical study O-12-M1, a phase 1/2 study in multiple myeloma conducted between 2013 and 2017. Presently, we are committed to five clinical studies.

In our pivotal phase 2 study HORIZON, we recently announced final top-line results. In the confirmatory phase 3 study OCEAN the patient recruitment was completed in May with 450 patients included according to plan. Other ongoing clinical studies have been put on temporary pause for patient safety reasons due to the COVID-19 situation. This includes the phase 2 studies ANCHOR and BRIDGE and the recently started AL-Amyloidosis study. The initiation of new studies, including the confirmatory phase 3 combination study LIGHTHOUSE, is postponed due to the exceptional COVID-19 situation at hospitals.

Base treatment after first-line treatment of multiple myeloma

Our strategy aims for melflufen to become a backbone drug for the treatment of multiple myeloma after the first line of therapy. In addition, the company will broaden the indication base for melflufen outside multiple myeloma in e.g. AL-Amyloidosis. To further broaden its potential use, we will also study melflufen in other malignancies. The aim is to fully explore the benefit that melflufen can bring to patients across the cancer spectrum.

The regulatory path ahead

The work for preparing all the material to submit a registration application in late Q2 in the US, for an accelerated approval of melflufen for the treatment of RRMM patients with triple-class refractory disease, develops according to plan. This is the first step in building a potential label for melflufen within myeloma. A potential accelerated approval results in a regulatory approval that later needs to be confirmed with clinical data from a randomized study. Both OCEAN and LIGHTHOUSE can independently act as confirmatory studies for a potential full approval. Additionally, both OCEAN and LIGHTHOUSE – assuming positive outcome from the studies – can result in broadening of the label into less advanced RRMM patient populations (both studies) as well as in combination with daratumumab (LIGHTHOUSE).

Oncopeptides has collaborated with leading experts and held discussions with governing medical agencies and professional bodies in the US and Europe to create the development program for melflufen in RRMM.

Upon receiving approval of the phase 3 OCEAN study design through the FDA Special Protocol Assessment in August 2016, detailed preparations commenced for the development program of melflufen. The program aims to fully characterize melflufen in the treatment of RRMM and thereby maximize the product candidate's market potential.

The phase 3 study OCEAN is expected to lay the foundation for an application to broaden the indication for melflufen in Q2 2021. The application can act as a confirmatory study after a potential accelerated approval - including label extension into RRMM patients with only single class refractory disease (compared to the potential accelerated approval for the treatment of RRMM patients with triple-class refractory disease) – as well as act as an independent application for market authorization across additional geographic markets.

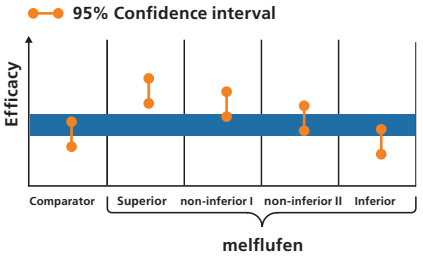
In the OCEAN clinical phase 3 study, the efficacy of Oncopeptides' product candidate, melflufen, is compared with pomalidomide, both being administered in combination with the steroid dexamethasone. Pomalidomide is currently the market-leading medication for the treatment of RRMM, with sales of USD 2.5 billion in 2019. The objective of the OCEAN study is to prove that melflufen has a superior efficacy and safety profile compared with pomalidomide.

The primary read-out in OCEAN is a comparison between melflufen and pomalidomide regarding PFS (Progression Free Survival). This comparison can simplistically result in three different outcomes i.e. that melflufen is superior, non-inferior or inferior to pomalidomide. As seen in the graphic below, the non-inferior outcome can be broken down in different scenarios with stronger or weaker data to support marketing efforts of melflufen. OCEAN has been statistically powered to show superiority of melflufen over pomalidomide based on historical data for the two compounds.

A superiority outcome is expected to result in approval both in the US and the EU. A non-inferiority result is expected to result in approval in the EU and potentially also in the US assuming that the forthcoming application for accelerated market approval based on HORIZON data is approved by the FDA.

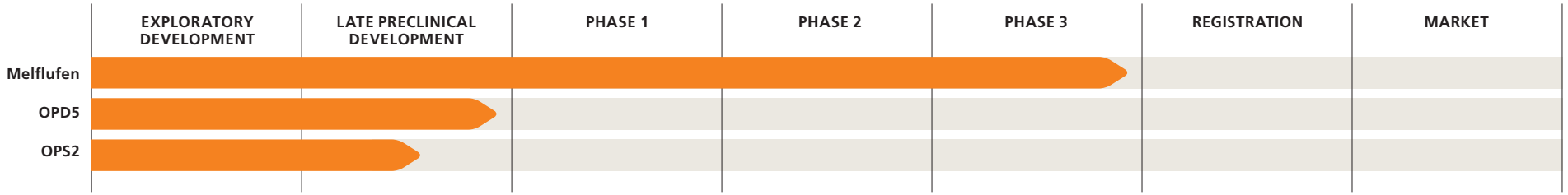
The planned LIGHTHOUSE pivotal phase 3 study is designed to further broaden the indication for melflufen. The application can act as a confirmatory study after a potential accelerated approval - including label extension where melflufen is approved also in combination with daratumumab for the treatment of RRMM patients – as well as act as an independent application for market authorization across markets.

Outcome scenarios for OCEAN



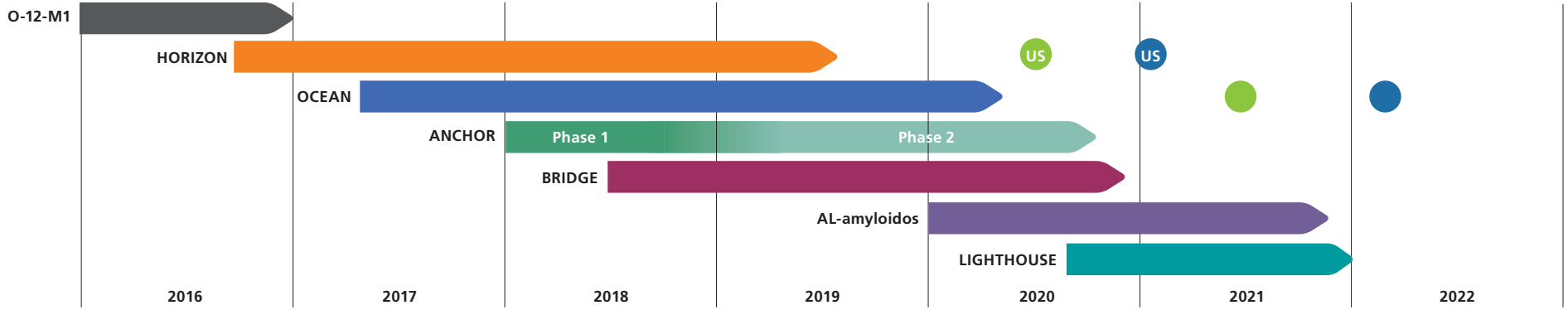
Clinical development program

Oncopeptide's development portfolio of peptide-conjugated drug candidates



Melflufen in clinical development

Provided a positive regulatory assessment, the clinical program will provide a broad set of data including its effect in different patient groups.



Phase 1 and 2: single-arm study (O-12-M1)

Phase 2: single-arm study (HORIZON)

Phase 3: randomized comparative superiority study (OCEAN)

Phase 1 and 2: triplecombination study (ANCHOR)

Regulatory submission

Potential market authorization

Phase 2: (BRIDGE)

Phase 1 and 2 single-arm study AL-amyloidos

Phase 3: randomized combination study (LIGHTHOUSE)

SUPPORTING

- Completed phase 2 clinical study with 45 patients.
- Included RRMM patients who had received a median of four prior lines of therapy, and became refractory to lenalidomide (immunomodulatory pharmaceutical – IMiD) and bortezomid (proteasome inhibitor – PI).
- Completed enrolment in late 2016 and presented final results in 2017.

HORIZON

PIVOTAL

- Completed pivotal phase 2 study with 157 patients.
- RRMM patients with few or no remaining treatment options.
- Patients have received ≥2 earlier lines of therapy with IMiDs and PIs and are refractory to pomalidomide and/or daratumumab.
- Supports OCEAN for marketing authorization.
- Potential for FDA accelerated approval if data is exceptionally strong.
- Started in Q1 2017, data reporting in 2018/2019 and follow-up in 2019/2020.

OCEAN

PIVOTAL / CONFIRMATORY

- Ongoing phase 3 study with up to 450 patients, including RRMM patients who are refractory to lenalidomide.
- Direct comparison with pomalidomide in patients treated with IMiDs and PIs, and who have become refractory to their last line of therapy.
- The trial is designed to demonstrate benefit in comparison with pomalidomide.
- To obtain approval in Europe, the only requirement is to demonstrate that melflufen has the same benefit.
- Started in Q2 2017 with the last patient included in May 2020.

ANCHOR

EXPLORATIVE

- Ongoing phase 1/2 study with up to 64 patients.
- The patients have received 1–4 earlier lines of therapy including IMiDs and PIs.
- Demonstrates how melflufen can be administered as a combination therapy with daratumumab or bortezomib.
- Explores potential for using melflufen in earlier lines of therapy.
- May significantly increase melflufen's market potential as a combination therapy.
- Started in Q2 2018, daratumumab arm is fully recruited. Recruitment to the bortezomib arm has temporarily been paused due to the COVID-19 situation.

BRIDGE

SUPPORTING

- Ongoing phase 2 study with up to 25 patients.
- Open-label, single-arm trial for patients with reduced renal function.
- Positioning trial to show melflufen's treatment profile within this patient group.
- Started in Q3 2018, the study is temporarily paused due to the COVID-19 situation.

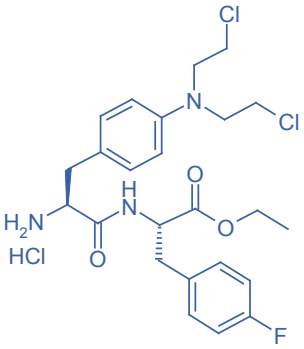
LIGHTHOUSE

CONFIRMATORY

- Phase 3 combination study to include more than 170 patients.
- Will include patients who are refractory to an IMiD and a PI, alternatively have received at least three previous treatment lines including an IMiD and a PI.
- The aim is to confirm the efficacy and safety of combination therapy with melflufen plus daratumumab compared to daratumumab.
- The study is expected to start in 2020.

AL-AMYLOIDOS

- First study outside of multiple myeloma.
- Phase 1/2 study in approximately 40 patients.
- In patients with systemic light-chain (AL) amyloidosis who have undergone at least one prior treatment.
- The primary efficacy parameter in the phase 1 study is safety, tolerability and to find the right dose for phase 2. In phase 2, the Overall response Rate (ORR) is measured.
- The study started in December 2019 and have been temporarily paused due to the COVID-19 situation.



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The multiple myeloma market

The number of patients with multiple myeloma is increasing as the population ages. Roughly 250,000 patients are living with multiple myeloma in Europe and the US, while 80,000 patients are newly diagnosed and 44,000 patients die from the disease annually.* The number of patients diagnosed with multiple myeloma is growing by nearly one percent per year, mainly due to an aging population. There is no cure for the disease, but long disease-free periods can be attained through treatment using several different pharmaceutical classes.

More treatment early in the disease timeline

The number of patients with multiple myeloma who have undergone several lines of therapy has increased dramatically, and this growth is expected to continue. This development is attributable to changes in treatment algorithms over the past few years, with patients now treated with more pharmaceuticals early in their disease. Multiple myeloma remains incurable, despite therapeutic advancements. This means that more patients than ever are living with the disease and are becoming multi-resistant, with a significant need for additional treatment options. The figure below illustrates how patient growth in the US has developed by line of therapy, comparing 2016 to 2019.

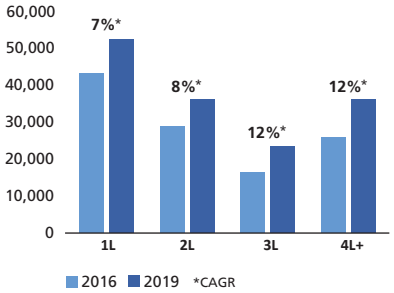
The basis of treatment today

Multiple myeloma is mainly treated with drugs from four different pharmaceutical classes. The basis of all treatments is steroids. A combination of an IMiD and a proteasome inhibitor (PI) is frequently used for newly diagnosed patients.

At present, the various classes may consist of several different approved drugs. Within each class, the existing drugs largely share the same mode of action and resistance mechanism, which means that the value for patients lies squarely in the pharmaceutical class and not in the individual drug. If a patient stops responding – or has responded poorly – to treatment using a drug from one particular class, the patient will likely also respond poorly to treatment using the other drugs in the same class of pharmaceuticals. This phenomenon is called resistance development. Another problem is that other diseases associated with myeloma (so called co-morbidities) limit the use of several drugs for myeloma treatment. The most frequent problems are renal failure, cardiovascular disease and peripheral neuropathy.

*NCI SEER and WHO Globocan

Improved outcomes lead to fast growth in number of treated patients in later lines of therapy



Source: Intrinsiq december 2018, MAT
Note: 3-year annual growth rate for 2015 -2018

Broad-spectrum agents used in nine out of ten myeloma therapies*

MODALITY	PHARMACEUTICAL DRUGS	GROWTH IN TREATED PATIENTS IN THE US, 2017/2018	% OF TREATED PATIENTS IN THE US, 2018*
Broad-spectrum agents			
Alkylating agents	Bendamustine, cyclophosphamide and melphalan	+7% (2018–2019)	88%
Immunomodulators (IMiD:s)	Lenalidomide, pomalidomide and thalidomide		
Proteasome inhibitors (PI)	Bortezomib, carfilzomib and ixazomib		
Steroids	Dexamethasone and prednisone		
Targeted agents			
anti-CD38	Daratumumab	+26% (2018–2019)	23%
anti-SLAMF7	Elotuzumab		

*Excluding steroids Source: Annual reports from Global Data, internal analysis and IntrinsiQ.

Lack of alternatives

The rapid development of resistance in myeloma and its associated diseases means that the majority of myeloma patients will lack treatment alternatives upon completing their second line of therapy. This is reflected in a fragmented pharmaceutical market by the time the first line of therapy is completed. Physicians try to use other drugs from pharmaceutical classes that the patient has already built a resistance to in an attempt to control the disease, which yields varying results.

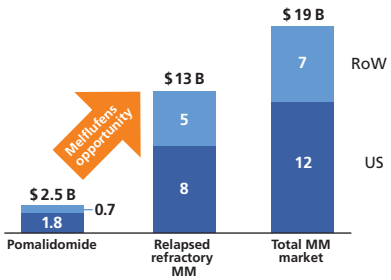
Rapidly growing market in the US

The global market for myeloma drugs amounted to USD 19 billion in 2019. Of this amount, USD 6 billion concerned first line treatment, where Revlimid (lenalidomide), an IMiD sold by Bristol-Myers Squibb, and Velcade (bortezomib), a PI sold by Takeda, are the predominant products. The market for the treatment of myeloma patients after the first line of therapy totalled USD 13 billion.

Along with new drug launches, the growing number of patients in later lines of therapy is expected to continue to increase the overall number of patients treated, and therefore also the value of the market. Prevailing prognoses from various analysts indicate that the market will grow to USD 23 billion by 2024. This includes several significant products, such as Pomalyst (pomalidomide), which is also an IMiD sold by Bristol-Myers Squibb, Darzalex (daratumumab), a monoclonal antibody, and anti-CD38, an inhibitor sold by Janssen. Other proteasome inhibitors including Kyprolis (carfilzomib) sold by Amgen and Ninlaro (ixazomib) sold by Takeda are significant products that are used after the first line of therapy.

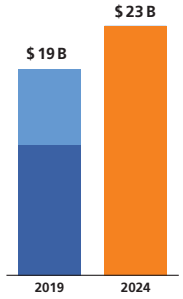
Melflufen opportunity in Relapsed Refractory Multiple Myeloma

2019 Multiple Myeloma Net Sales Breakdown



Source: EvaluatePharma, Intrinsiq, company analysis

Growth in the world 2019 –2024



Resistance and line of therapy

In order to analyze market data and be able to form an opinion of the market, it is important to distinguish between resistance and line of therapy. A patient undergoing therapy today can already become resistant to the two primary classes of pharmaceuticals, namely IMiDs and PIs, after the first line of therapy. If they also have been treated with an anti-CD38 inhibitor, these patients are classed as triple-class resistant (refractory) patients. This naturally varies based on the patient and their response to therapy, which has laid the foundation for highly personalized therapy after the first line based on the outcome of the therapy. Consequently, it is important to carefully assess the resistance status of an individual patient rather than which line of therapy the patient has undergone in order to assess the market potential for a pharmaceutical with a particular treatment label. The market is extremely fragmented.

Market growth in the US driven by longer treatment time

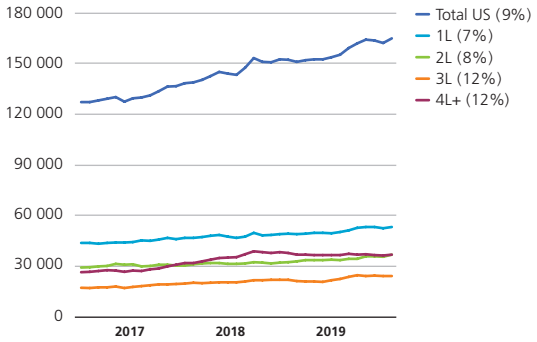
In the US market, growth of patients treated in the second or later lines of therapy is higher than in the first line. This applies to the number of patients treated. The value of the treatment, in turn, is connected to the number of treatment cycles carried out in the various lines, which is connected to the degree of resistance and the patient's health status. To simplify this, we can say that a newly diagnosed patient undergoes 12 treatment cycles or more, while a triple class refractory patient undergoes perhaps four to six cycles.

In the US, the bulk of growth has historically occurred in the number of patients treated in the second or later lines of therapy. It is also important to understand that new products are a supplement to existing ones, and that all products help to broaden the number of tools that can be used by doctors over the long term. The share of patients treated with Revlimid and Velcade, the predominant products used in first line therapy, has been stable over the past three years, during which time the treatment algorithm has been changed.

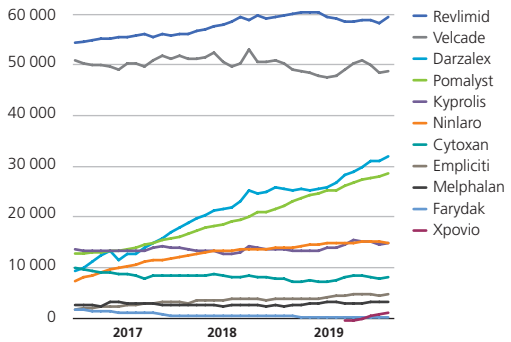
However, the growth in the market is the result of newer products. This is logical given that they represent a new addition to the therapy arsenal, but also because some products belong to new classes of pharmaceuticals or have a new mode of action, thereby providing the patient with extra benefits assuming that they respond to treatment.

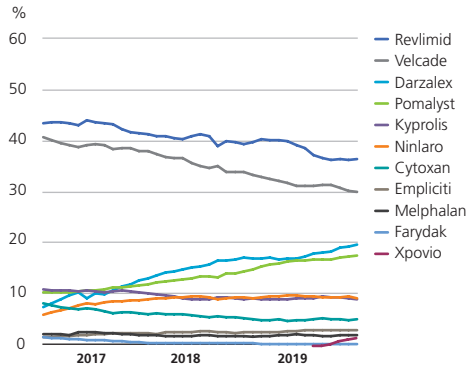
The figures below provide a graphical representation of these facts, showing that second or later lines of therapy are growing most rapidly, that new products are being used in addition to older ones and that new products are driving market growth in the US.

MM patient growth driven by later lines of therapy



Newer products used in addition to older products as survival improves





Melflufen's role

As Oncopeptides has generated new data or interpreted changes to the treatment algorithm, Oncopeptides' clinical development program has been supplemented to be able to offer as many multiple myeloma patients as possible a treatment. Melflufen is a first-in-class anti-cancer peptide-drug conjugate with a new mode of action that rapidly delivers a cytotoxin to the tumour cell. The study results that have been reported, both from monotherapy and combination studies with melflufen, is showing a good efficacy and safety profile.
In light of these clinical results, a clinical strategy for commercialization has been developed. The figures below illustrate how we are addressing the market and its various segments. The first step is to obtain accelerated approval in the US for triple refractory patients.

The market for triple-class refractory patients has grown and continues to grow substantially. In the US, there are approximately 20,000 patients in various lines of therapy, as illustrated in the figure below. In the US, there are approximately 18,000 myeloma patients with metastatic cancer (EMD). The HORIZON study included a large number of patients with EMD.

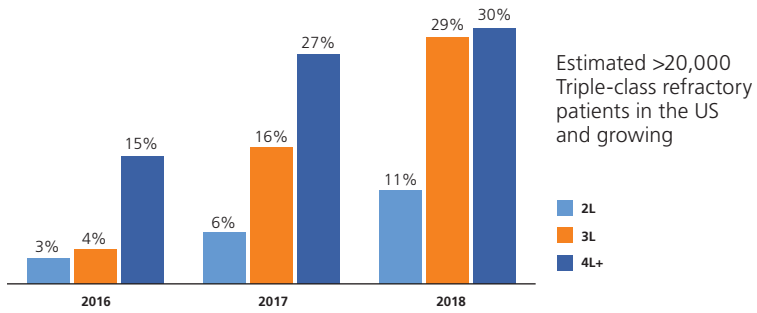
Based on data from HORIZON, which will be submitted for accelerated approval in the US at the end of the second quarter of 2020, an initial launch will be possible provided that approval is obtained in the end of 2020 or beginning of 2021. Data from the OCEAN study will then lead to a broader indication base, provided that the study demonstrates improved efficacy compared with Pomalyst. The ANCHOR exploratory study has provided guidance for the upcoming LIGHTHOUSE phase 3 study, which will establish the necessary conditions for expanded use of melflufen into earlier lines of treatment.

Target

The overarching target is for melflufen to address a market that in 2019 amounted to USD 13 billion. Refer to the figure under the heading "Rapidly growing market in the US" on page 17. There are a number of properties indicating that melflufen could be a compelling treatment option. These new modes of action offer an alternative, both individually and when combined. Melflufen has a promising safety profile and a vital aspect of melflufen as studies has shown synergistic effects with other pharmaceuticals in other classes. In terms of efficacy, melflufen has shown encouraging results, making a difference for the patients treated. The drug is simple to administer and can conveniently be provided by both specialist and general care clinics.

Label journey with current development program in myeloma

Initial indication of triple-class refractory disease is a significant and



Source: Company analysis of IQVIA patient data

Financial overview

Revenue

Net sales amounted to SEK 0.0 M (0.0) during the first quarter.

Operating expenses

Operating expenses for the first quarter amounted to SEK 296.9 M (133.8).

Research and development costs

During the quarter, research and development costs increased to SEK 213.6 M (106.8). The increase is mainly explained by a rise in clinical costs due to increased activity in the ongoing pivotal studies OCEAN and HORIZON and in the clinical studies ANCHOR and BRIDGE.

During 2019 the period the accounting of purchases of study drugs was changed. The costs were previously recognized when the drugs were used in clinical trials and are now being expensed when the drugs are purchased in accordance with IFRS. Historical periods have been corrected, see Note 6.

The costs for share-based incentive programs related to R&D amounted to SEK 4.4 M (3.3).

Marketing and distribution costs

Marketing and distribution costs for the first quarter amounted to SEK 51.0 M (17.9). The main reason for the cost increase is the continued expansion of the medical affairs and commercial functions and related activities.

The costs for share-based incentive programs related to marketing and distribution amounted to a negative SEK 1.9 M (pos: 2.1).

Administration expenses

During the first quarter, administration expenses amounted to SEK 40.7 M (11.3). The increase is due to the company´s continued high business activity level and growing organization, in particular in the US.

The costs for share-based incentive programs related to administration amounted to SEK 2.5 M (2.5).

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 share-based incentive programs in the first quarter amounted to SEK 5.0 M (7.9), out of which a negative SEK 0.7 M (pos: 1.6) was provisions and payments of social security contributions, and SEK 5.7 M (6.3) 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 arising from the exercise of granted employee stock options.

Earnings

The loss for the first quarter was SEK 297.3 M (134.1). This corresponds to a loss per share, before and after dilution, of SEK 5.37 (2.82).

Cash flow, investments and financial position

Cash flow from operating activities amounted to a negative SEK 312.8 M (neg: 142.8). The continued negative cash flow is according to plan and is explained by the company's expansion of clinical programs as well as activities within the company's medical affairs and commercial functions.

Cash flow from investing activities was a negative SEK 3.8 M (0.0).

Cash flow from financing activities amounted to a negative SEK 3.9 M (pos: 514.0). In January 2019 the company completed a directed share issue raising SEK 546.2 M before issue costs amounting to SEK 31.4 M.

Cash flow for the first quarter was a negative SEK 320.5 M (neg: 371.2). As of March 31, 2019, cash and cash equivalents amounted to SEK 617.8 M (747.5) and equity to SEK 505.8 M (652.1).

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 eight 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 two incentive programs were established; "Co-worker LTIP 2017" and "Board LTIP 2017". 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". For more information about these

programs see note 26 in the Annual Report 2019.

Full utilization of granted options and share awards per March 31, 2019, corresponding to 2,845,289 shares, would result in a dilution for shareholders of 4.9 percent. Full utilization of all options and share awards, corresponding to 5,063,173 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 8.4 percent.

During the first nine months 2,170 share awards in Board LTIP 2018.2, 23,291 share awards in Board LTIP 2019, 349,549 options in Co-worker LTIP 2018 and 166,017 options in Co-worker LTIP 2019 have been granted. Options corresponding to 81,000 shares in Founder Option Program and options corresponding to 1,133,100 shares in Employee option program 2012/2019 have been exercised. 1,934 share awards in Board LTIP 2017 and 3,480 share awards in Board LTIP 2018 lapsed.

Below follows a summary of the changes in existing incentive programs during the first quarter and the total number of shares that granted employee stock options and share awards may entitle to as of March 31, 2020.

Changes in existing incentive programs during 2019 (number of shares)	
Granted instruments	
- Co-worker LTIP 2019	492,934
Exercised instruments	-
Lapsed instruments	
- Co-worker LTIP 2017	-94,006
- Co-worker LTIP 2018	-99,044
- Co-worker LTIP 2019	-23,772
Total change	**276,112**

Number of shares granted employee stock options may entitle to	
- Employee option program 2016/2023	276,300
- Co-worker LTIP 2017	1,524,933
- Co-worker LTIP 2018	331,499
- Co-worker LTIP 2019	635,179
Total number of shares employee stock options may entitle to	**2,767,911**
Number of share awards in program Board LTIP 2017	21,266
Number of share awards in program Board LTIP 2018	30,451
Number of share awards in program Board LTIP 2018.2	2,170
Number of share awards in program Board LTIP 2019	23,491
Total number of shares employee stock options and share awards may entitle to	**2,845,289**

Other information

Co-workers
As of March 31, 2020, the number of co-workers amounted to 121 (50).

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, 20120, the number of registered shares and votes in Oncopeptides amounted to 55,413,417.

Events after the end of the report period
In May Oncopeptides completed a directed share issue raising SEK 1,414 M (USD 144 M) before issue costs.

The enrollment in the pivotal phase 3 study OCEAN was successfully completed in May including 450 patients from more than 100 hospitals around the world.

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

Stockholm, May 26, 2020

Jakob Lindberg
Chief Executive Officer

Condensed consolidated income statement

SEK thousand	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Net sales	–	–	–
Gross profit	–	–	–
Operating expenses			
Research and development costs	-213,550	-106,805	-548,273
Marketing and distribution costs	-50,981	-17,879	-127,409
Administrative expenses	-40,650	-11,329	-72,046
Other operating income/expenses[2]	8,305	2,201	8,336
Total operating expenses	**-296,876**	**-133,812**	**-739,392**
Operating loss	**-296,876**	**-133,812**	**-739,392**
Net financial items	-451	-134	-528
Loss before tax	**-297,327**	**-133,946**	**-739,920**
Tax	-2	-131	-785
Loss for the period[3]	**-297,329**	**-134,077**	**-740 705**
Earnings per share before and after dilution (SEK)	**-5.37**	**-2.82**	**-14.33**

Condensed consolidated statement of comprehensive income

SEK thousand	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Loss for the period	**-297 329**	**-134 077**	**-740 705**
Other comprehensive income			
Items to be reclassified to profit or loss			
Translation differences from foreign operations	460	33	-
Total other comprehensive income, net of tax	**460**	**33**	**-20**
Total comprehensive loss for the period[3]	**-296 869**	**-134 044**	**-740 725**

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

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

3) Total comprehensive loss for the period is in total attributable to parent company shareholders

Condensed consolidated statement of financial position

SEK thousand	March 31th 2020	March 31th 2019[1]	Dec 31st 2019
Assets			
Non-current assets			
Intangible fixed assets	2,111	-	2,111
Property, plant and equipment	4,938	2,320	2,499
Right-of-use assets	22,696	8,764	14,693
Financial non-current assets	4,709	1,034	3,297
Total non-current assets	**34,454**	**12,118**	**22,600**
Current assets			
Other current receivables	7,393	3,437	6,976
Prepaid expenses and accrued income	6,476	15,598	37,726
Cash and cash equivalents	617,786	747,471	926,186
Total current assets	**631,655**	**766,506**	**970,888**
Total assets	**666,109**	**778,624**	**993,488**
Equity and liabilities			
Equity			
Share capital	6,157	5,427	6,157
Additional paid-in capital	2,550,000	1,793,467	2,544,306
Retained earnings (including net profit/loss for the period)	-2,050,319	-1,146,769	-1,753,450
Total equity[2]	**505,838**	**652,125**	**797,013**
Long term liabilities			
Provision for social security contributions, share based incentive program	23,744	17,312	23,052
Other long term liabilities	11,317	5,082	8,243
Total long term liabilities	**35,061**	**22,394**	**31,295**
Current liabilities			
Provision for social security contributions, share based incentive program	9,345	55,727	10,733
Trade payables	36,292	18,727	80,986
Other current liabilities	18,387	5,997	12,319
Accrued expenses and deferred income	61,186	23,654	61,142
Total current liabilities	**125,210**	**104,105**	**165,180**
Total equity and liabilities	**666,109**	**778,624**	**993,488**

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

2) Equity is in total attributable to parent company shareholders

Condensed consolidated statement of changes in equity

SEK thousand	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Opening balance	**797,013**	**265,004**	**265,004**
Profit/loss of the period	-297,329	-134,077	-740,705
Other comprehensive income	460	33	-20
Comprehensive income (loss) for the period	**-296,869**	**-134,044**	**-740,725**
Transaction with owners			
New issue of ordinary shares	-	546,250	1,273,425
Cost attributable to new share issue	-	-31,409	-76,595
Share based payments	5,694	6,324	32,493
Exercise of warrants	-	-	43,411
Total transaction with owners	**5,694**	**521,165**	**1,272,735**
Closing balance	**505,838**	**652,125**	**797,013**

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

Condensed consolidated statement of cash flow

SEK thousand	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Operating loss	-296,876	-133,812	-739,392
Adjustment for non-cash-items[2]	-4,737	8,219	-8,187
Interest received	0	-	0
Interest paid	-451	-134	-528
Tax paid	-2	-	-1,158
Cash flow from operating activities before change in working capital	**-302,066**	**-125,727**	**-749,265**
Cash flow from changes in working capital	-10,775	-17,094	58,699
Cash flow from operating activities	**-312,841**	**-142,821**	**-690,566**
Cash flow from investing activities	-3,822	-42	-2 628
Cash flow from financing activities	-3,856	514,032	1,236,285
Cash flow for the period	**-320,519**	**371,169**	**543,091**
Cash and cash equivalents at beginning of period	926,186	375,617	375,617
Change in cash and cash equivalents	-320,519	371,169	543,091
Foreign exchange difference in cash and cash equivalents	12,119	685	7,478
Cash and cash equivalents at the end of period	**617,786**	**747,471**	**926,186**

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

2) Pertains mainly to costs of employee stock option program including social security contributions

Condensed parent company income statement

SEK thousand	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Net sales	-	-	-
Gross profit	-	-	-
Operating expenses			
Research and development costs	-213,627	-106,836	-548,419
Marketing and distribution costs	-52,829	-18,559	-131,992
Administrative expenses	-41,895	-11,342	-72,104
Other operating income/expenses[2]	8,305	2,201	8,336
Total operating expenses	**-300,046**	**-134,536**	**-744,179**
Operating loss	**-300,046**	**-134,536**	**-744,179**
Net financial items	12	10	41
Loss before tax	**-300,034**	**-134,526**	**-744,138**
Tax	–	–	–
Loss for the period	**-300,034**	**-134,526**	**-744,138**

Condensed parent company statement of comprehensive income

SEK thousand	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Loss for the period	**-300,034**	**-134,526**	**-744,138**
Other comprehensive income			
Total other comprehensive income, net of tax	–	–	–
Total comprehensive loss for the period	**-300,034**	**-134,526**	**-744,138**

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

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

Parent company balance sheet

SEK thousand	March 31th 2020	March 31th 2019[1]	Dec 31st 2019
Assets			
Non-current assets			
Intangible fixed assets	2,111	-	2,111
Property, plant and equipment	2,529	2,277	2,472
Financial non-current assets	901	901	901
Total non-current assets	**5,541**	**3,178**	**5,485**
Current assets			
Other current receivables	7,118	3,437	6,914
Prepaid expenses and accrued income	3,285	15,312	37,192
Cash and cash equivalents	616,867	744,362	921,535
Total current assets	**627,270**	**763,111**	**965,641**
Total assets	**632,811**	**766,289**	**971,126**
Equity and liabilities			
Restricted equity			
Share capital	6,157	5,427	6,157
Statutory reserve	12,320	10,209	12,320
Non-restricted equity			
Share premium account	2,486,636	1,761,966	2,486,636
Retained earnings (including net profit/loss for the period)	-2,006,426	-1,126,534	-1,712,086
Total equity	**498,687**	**651,068**	**793,027**
Long term liabilities			
Provision for social security contributions, share based incentive program	23,744	17,312	23,052
Total long term liabilities	**23,744**	**17,312**	**23,052**
Current liabilities			
Provision for social security contributions, share based incentive program	9,345	55,727	10,733
Trade payables	27,257	17,443	79,864
Other current liabilities	16,385	1,743	13,430
Accrued expenses and deferred income	57,393	22,996	51,020
Total current liabilities	**110,380**	**97,909**	**155,047**
Total equity and liabilities	**632,811**	**766,289**	**971,126**

1) Earlier periods have been adjusted to reflect correction of errors, see note 6.

Notes

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 for the first quarter 2020 was approved for publication on May 26, 2020.

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 53-58 of the Annual Report for 2019.

No new or amended standards that became effective January 1, 2020, 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. A more detailed description of the company's risk exposure and risk management can be found in the Annual Report for 2019 on pages 38-39.

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 58-59 in the Annual Report for 2019.

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 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 6 Correction of errors

Purchases of study drugs used in clinical studies related to the company's development projects have been accounted for erroneously since 2017 as prepaid expenses and have been expensed when the drugs have been used in the clinical rials. According to IFRS purchases of substances should be expensed directly as Research and Development expenses when they are purchased and not when they are used.

The summary below describes the impact of the error corrections on the consolidated and parent company income statements for the periods Jan-Mar 2019, and the impact on the consolidated and parent company balance sheets per Mar 31, 2019. The correction of errors has no impact on consolidated or parent company cash flow statements.

Consolidated statement of income, Jan-Mar 2019

SEK thousand	According to approved Interim Report	Correction of error	After correction of error
Operating expenses			
Research and development costs	-94,927	-11,878	-106,805
Marketing and distribution costs	-17,879	-	-17,879
Administrative expenses	-11,329	-	-11,329
Other operating income/expenses	2,201	-	2,201
Total operating expenses	**-121,934**	**-11,878**	**-133,812**
Operating loss	**-121,934**	**-11,878**	**-133,812**
Net financial items	-134	-	-134
Tax	-131	-	-131
Loss for the period	**-122,199**	**-11,878**	**-134,077**
Other comprehensive income			
Total other comprehensive income, net of tax	**33**	-	**33**
Total comprehensive loss for the period	**-122,166**	**-11,878**	**-134,044**
Earnings per share before and after dilution (SEK)	**-2.57**	**-0.25**	**-2.82**

Consolidated balance sheet, March 31, 2019

SEK thousand	According to approved Interim Report	Correction of error	After correction of error
Assets			
Total non-current assets	12,118	-	12,118
Current assets			
Other current receivables	3,437	-	3,437
Prepaid expenses and accrued income	78,304	-62,706	15,598
Cash and cash equivalents	747,471	-	747,471
Total current assets	**829,212**	**-62,706**	**766,506**
Total assets	**841,330**	**-62,706**	**778,624**
Equity and liabilities			
Equity			
Share capital	5,427	-	5,427
Additional paid-in capital	1,793,467	-	1,793,467
Retained earnings (including net profit/loss for the period)	-1,084,063	-62,706	-1,146,769
Total equity	**714,831**	**-62,706**	**652,125**
Total long term liabilities	22,394	-	22,394
Total current liabilities	104,105	-	104,105
Total liabilities	**126,499**	**-**	**126,499**
Total equity and liabilities	**841,330**	**-62,706**	**778,624**

Parent company income statement, Jan-Mar 2019

SEK thousand	According to approved Interim Report	Correction of error	After correction of error
Operating expenses			
Research and development costs	-94,958	-11,878	-106,836
Marketing and distribution costs	-18,559	-	-18,559
Administrative expenses	-11,342	-	-11,342
Other operating income/expenses	2,201	-	2,201
Total operating expenses	**-122,658**	**-11,878**	**-134,536**
Operating loss	**-122,658**	**-11,878**	**-134,536**
Net financial items	10	-	10
Tax	-	-	0
Loss for the period	**-122,648**	**-11,878**	**-134,526**
Other comprehensive income			
Total other comprehensive income, net of tax	**-**	-	**-**
Total comprehensive loss for the period	**-122,648**	**-11,878**	**-134,526**

Parent company balance sheet, March 31, 2019

SEK thousand	According to approved Interim Report	Correction of error	After correction of error
Assets			
Total non-current assets	3,178	-	3,178
Current assets			
Other current receivables	3,437	-	3,437
Prepaid expenses and accrued income	78,018	-62,706	15,312
Cash and cbank balances	744,362	-	744,362
Total current assets	**825,817**	**-62,706**	**763,111**
Total assets	**828,995**	**-62,706**	**766,289**
Equity and liabilities			
Equity			
Restricted equity	15,636	-	15,636
Non-restricted equity	698,138	-62,706	635,432
Total equity	**713,774**	**-62,706**	**651,068**
Total long term liabilities	17,312	-	17,312
Total current liabilities	97,909	-	97,909
Total liabilities	**115,221**	-	**115,221**
Total equity and liabilities	**828,995**	**-62,706**	**766,289**

Key performance measures

The company presents in this report certain key performance measures, including one measure that is not defined under IFRS, namely expenses relating to research and development / operating expenses %. The company believes that this ratio is an important complement because it allows for a better evaluation of the company's economic trends. This financial performance measure 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 measure as the company has defined it should not be compared with other performance measures with similar names used by other companies. This is because the above-mentioned performance measure is not always defined in the same manner, and other companies may calculate the differently to Oncopeptides.

Key performance measures, shares

	2020 Jan - Mar	2019[1] Jan - Mar	2019 Jan - Dec
Total registered shares at the beginning of period	55,413,417	44,091,921	44,091,921
Total registered shares at the end of period	55,413,417	48,841,921	55,413,417
Number of shares that the outstanding employee options entitle to	2,845,289	3,249,634	2,569,177
Share capital at the end of period, SEK thousand	6,157	5,427	6,157
Equity at the end of period, SEK thousand	505,838	652,125	797,013
Earnings per share before and after dilution, SEK[2]	-5.37	-2.82	-14.33
Operating expenses, SEK thousand	-296,876	-133,812	-739,392
Research and development costs, SEK thousand	-213,550	-106,805	-548,273
Research & development costs/operating expenses %[3]	72%	80%	74%

1) Earlier periods have been adjusted to reflect correction of errors, see Note 6.

2) 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.

3) 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.

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