

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, a novel peptide-drug conjugate that rapidly delivers a cytotoxic payload into tumor cells. Melflufen is in development as a new treatment for the hematological cancer multiple myeloma and is currently being tested in multiple clinical studies including the pivotal phase 2 HORIZON study and the ongoing phase 3 OCEAN study. Oncopeptides' head-quarters is in Stockholm, Sweden, and the company is listed in the Mid Cap segment on Nasdaq Stockholm with the ticker ONCO.

**YEAR-END REPORT 2019** 

### Conference call for investors, analysts and the media

The Year-end Report 2019 and an operational update will be presented by CEO Jakob Lindberg and members of Oncopeptides management team, Thursday February 20, 2020 at 14:00 (CET). The conference call will also be streamed via a link on the website: www.oncopeptides.com.

Phone numbers for participants from: Sweden: +46 8 505 583 56 Europe: +44 3333 009 031 USA: +1 833 526 83 82

#### Financial calendar

Annual Report 2019: Week starting April 27

Interim Report Q1, 2020: May 26, 2020
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 February 20, 2020.

# **Summary of Q4**

#### Financial overview October 1 – December 31, 2019

- Net sales amounted to SEK 0.0 M (0.0)
- Loss for the period was SEK 244,9 M (loss: 112.0)
- Loss per share, before and after dilution, was SEK 4.42 (loss: 2.54)
- On December 31 cash and cash equivalents amounted to SEK 926.2 M (375.6)

### Significant events during the period October 1 – December 31, 2019

- In early December, an advisory meeting was held with the FDA is preparing for Oncopeptides' application for accelerated market approval
- At the annual American Hematology Meeting (ASH) in December, Oncopeptides presented updated efficacy and safety data from the pivotal phase 2 study HORIZON in RRMM patients and promising data from the phase 2 combination study ANCHOR
- At the ASH meeting it was also presented preclinical data regarding melflufen for AL amyloidosis, which forms the basis for the clinical program where the patient recruitment has started
- In the process of preparing for a potential launch in the United States, Joseph Horvat was appointed as President North America
- At an Extraordinary General Meeting in December, it was resolved to issue warrants and to extend the board's authorization to issue shares

### Financial overview of the group

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Net sales	-	-	-	_
Operating loss	-244,244	-111,859	-739,392	-410,963
Loss before tax	-244,400	-111,861	-739,920	-410,965
Loss for the period	-244,904	-112,008	-740,705	-411,112
Earnings per share before and after dilution (SEK)	-4.42	-2.54	-14.33	-9.58
Cash flow from operating activities	-216,974	-108,855	-690,566	-333,727
Cash and cash equivalents at the end of the period	926,186	375,617	926,186	375,617
Research & development costs/operating expenses %	64%	81%	74%	76%

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

### **CEO statement**

The fourth quarter ended with a meeting with the FDA and our participation in the ASH annual meeting. We presented several posters from ongoing or completed studies with melflufen, which gave a broad exposure and a positive response. During the fourth quarter, we also initiated significant preparations for a potential launch in the US.

The launch preparations result in an exciting but labor-intensive agenda in 2020. We will submit the application for accelerated market approval in the US based on the HORIZON study and are planning to be ready to launch melflufen at the end of the year. This spring, we will also recruit the last patient in our phase 3 study OCEAN and start new studies. This is an ambitious task, but we are now well on track to evaluate melflufen in several multipel myeloma patient groups in order to provide the best possible conditions for a potential market launch of melflufen.

### **Operational development**

The December FDA meeting gave us a clear picture of what data we will include in our upcoming application for accelerated market approval in the US. The application will be based on all 157 patients from the HORIZON study with sufficient follow-up time to ensure that every patient is evaluable. This means that the appli-cation will be submitted during Q2 2020.

We have increased the pace of preparation for a potential product launch in the US, which is expected in the end of the year. In December, Joe Horvat started as our President North **77** *The next 12 months* will change Oncopeptides radically

America and he will continue to build our US operations, so we're ready when needed.

### Our clinical studies

The ongoing studies are progressing according to plan. We will shortly have six clinical studies underway at the same time - all with the purpose to expand the commercial potential of melflufen. We do this by demonstrating melflufen's clinical efficacy in both more and larger groups of patients with multiple myeloma, and also by mapping out melflufen's clinical profile in patients with the severe disease AL amyloidosis, which currently is a disease without approved treatments. This is the first first step towards broadening the indication of use as it is the first time melflufen is tested outside of multiple myeloma. We opened the first study site for enrollment of patients in late December, followed by additional clinics in January. We experience a great interest in participating in the study, which is exciting, and we expect to start treatment of the first patient

The next study that we will initiate is the randomized phase 3 LIGHTHOUSE combination study, where we will compare combination



treatment with melflufen and daratumumab against daratumumab monotherapy. Daratumumab in the study will be administered in the new and more convenient subcutaneous form.

We presented updated results from the ANCHOR phase 2 combination study at the ASH annual meeting, inidcating very good efficacy so far. This gives confidence for the start of the LIGHTHOUSE study. The ANCHOR study is expected to be fully recruited in 2020. The study consists of two treatment arms. In one arm, patients are treated with melflufen in combination with daratumumab and that arm is now fully recruited, which was faster than expected. In the other arm, patients are treated with melflufen in combination with bortezomib and enrollment is still ongoing but is expected to be completed during the year.

The recruitment of patients to OCEAN progresses according to plan and the aim is to enroll the last patient in the end of Q1 2020. The evaluation of the study results will be done when a stipulated number of patients in the study have relapsed in their disease. Topline results from OCEAN are estimated to be reported in Q3 2020. Given that we have a positive outcome in the study, the regulatory application process to expand the melflufen label will start immediately thereafter. We aim to submit the application based on OCEAN during Q2 2021. From a regulatory perspective, these timelines will not be critical provided we are granted accelerated approval based on the results of the HORIZON study.

The BRIDGE study is designed to study melflufen's pharmacokinetics (PK) in multiple myeloma patients who also suffer from renal impairment, which is a very common comorbidity for myeloma patients. In BRIDGE, we are testing the melflufen in groups of patients with increasingly severe renal problems and the ambition is to recruit the last patient during Q2 2020.

### Going forward in 2020

The company is facing many challenges and opportunities. Given the current pace of change, it is vital that we set our priorities right to achieve the greatest possible success. In the near term, our focus is set on completing the application for accelerated approval in the US and accelerating launch preparations both in the US as well as at the headquarter in Stockholm. We have a rapidly growing focused organization that is fully determined to seize the opportunity.

The importance of presenting data at scientific conferences is increasing and remains as an important channel for building awareness. We will participate at most of the major scientific conferences during the year and thus have

a steady flow of information from our clinical studies.

I would like to thank the physicians, clinics and staff who are committed in developing melflufen and thus Oncopeptides. Your hard work in 2019 makes a difference for patients, which is our mission. I'm looking forward continuing this work in the coming year.

Stockholm, February 20, 2020

Jakob Lindberg CEO, Oncopeptides AB

# **Summary – our clinical studies**

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 U.S. 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 in the second quarter of 2020. This could then potentially lead to the first market approval for melflufen in the U.S. in 2020. Given that the FDA grants a accelerated market approval, the overall regulatory risk will decrease considerably.

### The clinical development program

We are currently conducting four clinical studies to characterize melflufen in multi-refractory multiple myeloma patients: OCEAN (OP-103), HORIZON (OP-106), ANCHOR (OP-104) and BRIDGE (OP-107).

The program will provide a clear picture of how melflufen can be used for relapsed refractory multiple myeloma (RRMM) patients in various stages of the disease. This has lowered the development risk and given rise to several potential paths for obtaining approval for melflufen.

Melflufen has previously undergone both preclinical studies and clinical phase 1 and 2 studies with positive results in terms of both safety and efficacy in patients with multiple myeloma. Based on these results, the next logical step was to further develop melflufen through the studies OCEAN, HORIZON, ANCHOR and BRIDGE, and the planned additional pivotal combination study LIGHT-HOUSE that we expect to start Q2 2020.

Our phase 3 study, OCEAN, and phase 2 study, HORIZON, are key studies for the submission of an NDA/MAA to potentially obtain

marketing authorization for melflufen in the US and the EU for the treatment of RRMM. In addition to proving melflufen's efficacy in relation to the existing standard treatment for RRMM (meaning pomalidomide), as evaluated by OCEAN, the development program also aims to demonstrate, through HORIZON, the activity of melflufen in patients with relapsed refractory multiple myeloma whose disease is triple-class refractory (i.e. refractory to at least one IMiD, one proteasome inhibitor and one anti-CD38 monoclonal antibody). Our phase 1/2 study, ANCHOR, is aimed at demonstrating how melflufen can be administered in combination with other multiple myeloma drugs. It is important to generate knowledge and understanding among physicians about how melflufen can be used together with dexamethasone and either bortezomib or daratumumab in relapsed refractory MM patients. BRIDGE is a phase 2 pharmacokinetic study to study melflufen's safety in patients with reduced renal function. We are now in the final stage of preparations for the phase 3 combination study, called LIGHTHOUSE, which we aim to start in O2 2020.

### The regulatory path ahead

The work for preparing all the material to submit a registration application 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.

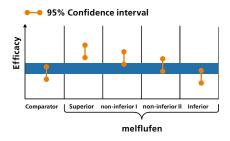
The phase 3 study OCEAN is expected to lay the foundation for an application to broaden the indication for melflufen in Q1 2021. The application can act as a confirmatory study after a potential accelerated approval - including label extension into RRMM patients with only single class refractory disease (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 markets.

In the OCEAN clinical phase 3 study, the efficacy of Oncopeptides' product candidate, melflufen, is compared with pomalidomide, both are administered in combination with the steroid dexamethasone. Pomalidomide is currently the market-leading medication for the

treatment of RRMM, with sales of USD 2.0 billion in 2018. 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.

### **Outcome scenarios for OCEAN**

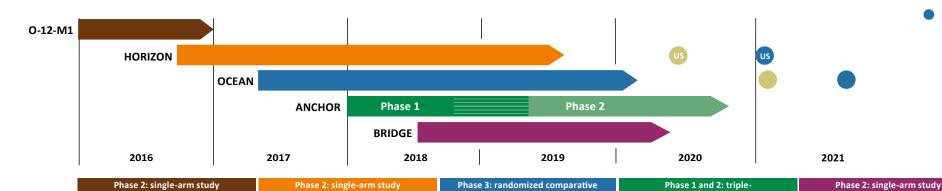


A superiority outcome is expected to result in approval both in the US and the EU. A non-inferiority result is expected to result in approval in the EU and potentially also in the US assuming that the forthcoming application for accelerated market approval based on HORIZON data is approved by the FDA.

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.



# **Oncopeptides clinical studies Q4 2019**



Regulatory submission

 Potential marketing authorization

### O-12-M1

(O-12-M1)

#### **SUPPORTING**

- Completed phase 2 clinical study with 45 patients
- Included RRMM patients who had received a median of 4 prior lines of therapy, and became refractory to lenalidomide (immunomodulatory pharmaceutical – IMiD) and bortezomid (proteasome inhibitor – PI)
- Completed enrollment late 2016 and presented final results in 2017



(HORIZON)

#### **PIVOTAL STUDY**

- The phase 2 study is fully enrolled with 157 patients
- RRMM patients with few or no remaining treatment options
- Patients have received
   ≥2 earlier lines of therapy with
   IMiDs and Pls 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 2019/2020



superiority study (OCEAN)

#### 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 Pls, and who have become refractory to their last line of therapy
- The study is designed to demonstrate benefit in comparison with pomalidomide
- To obtain approval in Europe, the requirement is to demonstrate that melflufen has the same benefit or better
- Started in Q2 2017 with last patient in expected in Q1 2020



combination study (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 Pls
- 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, data reporting in 2018/2019, with the results from phase 1 and phase 2 expected in 2019 and 2020, respectively



(BRIDGE)

#### **SUPPORTING**

- Ongoing phase 2 study with up to 25 patients
- Open-label, single-arm study for patients with reduced renal function
- Positioning study to show melflufen's treatment profile within this patient group
- Started in Q3 2018, with the initial results expected in Q2 2020

# The market for treatment of multiple myeloma

The market continues to grow rapidly and is expected to have a market value of approximately USD 22 billion in 2023. The global market amounted to USD 17 billion in 2018.

### The market is growing sharply

As treatment results for a disease with a poor prognosis improve – even marginally – the market for later lines of therapy grows significantly. The driving factor for this growth is the fact that patients live longer, which means that more patients will receive additional treatments, compared with before.

### **Broad-spectrum agents dominate the market**

Despite the launch of several new drugs, the market continues to be dominated by broad-spectrum agents (alkylators, IMiDs and proteasome inhibitors) and the trend is expected to continue. The reason for this is that the disease is highly heterogeneous, and modern antibody agents cannot treat the

entire disease due to a lack of any target proteins common to all myeloma tumor cells. Consequently, increased usage of antibody drugs is primarily linked to their combination with broad-spectrum agents to ensure the targeting of all tumor cells.

#### The market in USD

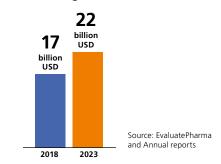
The global market for myeloma drugs amounted to USD 17 billion in 2018. The market for the treatment of myeloma patients after the first line of therapy totaled USD 10 billion. The myeloma market is expected to reach USD 22 billion in 2023. The growth is a concequence of the higher number of patients in later lines of therapy as well as drug launches.

# The number of cases of multiple myeloma in second line plus treatment is growing rapidly

Roughly 170,000 patients are living with multiple myeloma in the EU and the US, while 57,000 patients are newly diagnosed and 26,000 patients die from the disease annually. The number of patients diagnosed with multiple myeloma is growing approximately with 1 percent per year, mainly caused by an aging population. However, the number of patients with multiple myeloma who have undergone several previous lines of therapy is increasing exponentially, which is boosting the need for drugs with new modes of action, such as melflufen.

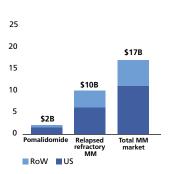
Oncopeptides phase 2 study HORIZON for which the company is in the process of submitting an application for accelerated market approval in the US, is focused on addressing the needs of these patients, whose numbers are

### Global growth, 2018 to 2023



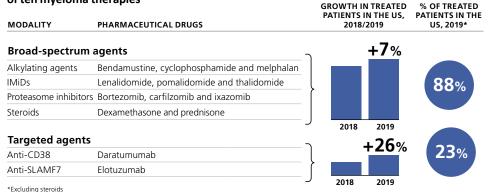
increasing sharply due to recent improvements in earlier lines of therapy. The company's phase 3 study OCEAN addresses patients in earlier lines of treatment. Despite these therapeutic improvements, multiple myeloma remains incurable. This means that more patients than ever are living with the disease for longer periods of time and becoming multi-refractory patients with a significant need for additional treatment options. For the average growth rate in the US over the past three years, see diagram below.

# Size of the multiple myeloma market

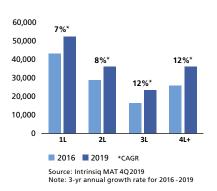


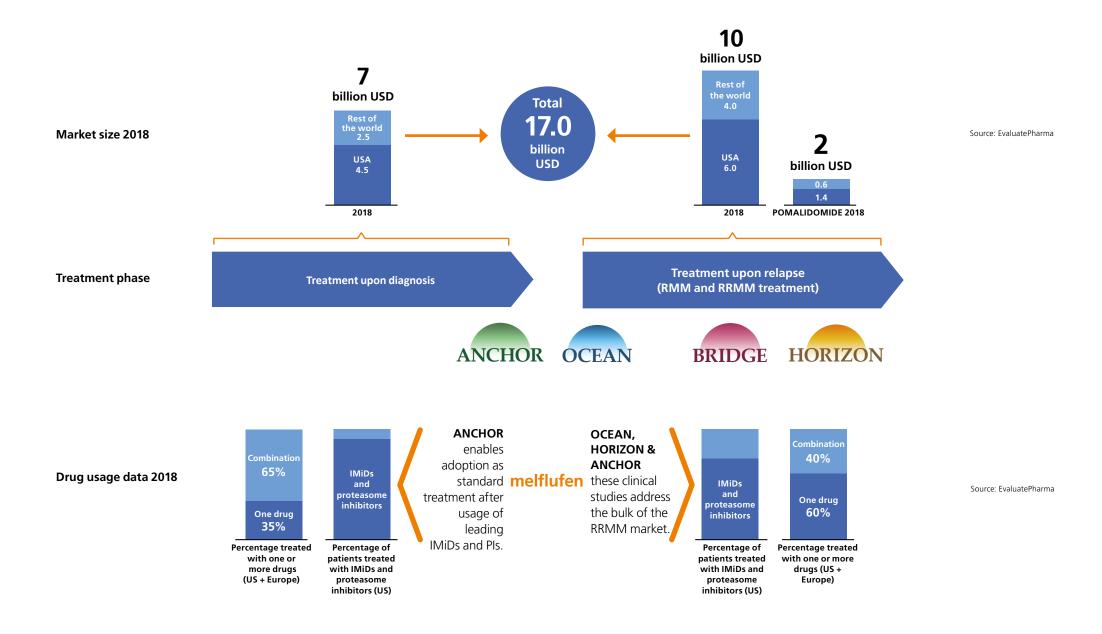
# Broad-spectrum agents used in nine out of ten myeloma therapies\*

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



# Distribution of multiple myeloma patients by lines of therapy in the US





### **Financial overview**

#### Revenue

Net sales amounted to SEK 0.0 M (0.0) during the fourth quarter and to SEK 0.0 M (0.0) for the full year 2019.

### **Operating expenses**

Operating expenses for the fourth quarter amounted to SEK 244.2 M (111.9) and to SEK 739.4 M (411.0) for the full year 2019.

### Research and development costs

During the fourth quarter, research and development costs increased to SEK 156.9 M (90.8) and to SEK 548.3 M (313.7) for the full year. 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 the period the accounting of purchases of study drugs has been changed. The costs were previously recognized when the drugs were used in clinical studies and are now being expensed when the drugs are purchased in accordance with IFRS. Historical periods have been corrected, see Note 7.

The costs for share-based incentive programs related to R&D amounted to SEK 6.2 M (neg: 1.1) for the fourth quarter and to SEK 10.4 M (23.7) for the year.

### Marketing and distribution costs

Marketing and distribution costs for the fourth quarter amounted to SEK 56.2 M (16.0) and to SEK 127.4 M (51.1) for the year. 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 SEK 3.4 M (0.2) for the fourth quarter and to SEK 3.5 M (8.5) for the year.

### Administration expenses

During the fourth quarter, administration expenses amounted to SEK 17.9 M (4.5) and to SEK 72.0 M (55.3) for the first nine months. The increase is due to the company's continued high business activity level and growing organization.

The costs for share-based incentive programs related to administration amounted to SEK 4.2 M (neg: 6.2) for the fourth quarter and to SEK 23.9 M (8.5) for the year.

### Share-based payments

The costs for social security contributions related to share-based incentive programs vary from quarter to quarter due to the change in the underlying share price. Related provisions are reported as long- and short-term liabilities.

The total costs for the share-based incentive programs in the fourth quarter amounted to SEK 13.7 M (neg: 7.1) and for the full year to SEK 37.8 M (54.1), out of which SEK 5.9 M (41.7) was provisions and payments of social security contributions, and SEK 31.9 M (12.4) was IFRS 2 classified salary costs. 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 fourth quarter was SEK 244.9 M (112.0) and the loss for the year 2019 was SEK 740.7 M (411.1). This corresponds to a loss per share, before and after dilution, of SEK 4.42(2.54) for the fourth quarter and SEK 14.33 (9.58) for the full year.

# Cash flow, investments and financial position

Cash flow from operating activities amounted to a negative SEK 217.0 M (neg: 108.9) for the fourth quarter and to a negative SEK 690.6 M (neg: 333.7) for the full year 2019. 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 2.4 M (neg: 0.5) for the fourth quarter and a negative SEK 2.6 M (neg: 0.9) for the year.

Cash flow from financing activities amounted to SEK 37.7 M (0.2) for the fourth quarter and to SEK 1,236.3 M (304.9) for the full year 2019. In January 2019 the company completed a directed share issue raising SEK 546.2 M before issue costs amounting to SEK 31.4 M. In July a second directed share issue was completed, raising SEK 727.2 M before issue costs amounting to SEK 44.3 M.

Cash flow for the fourth quarter was a negative SEK 181.7 M (neg: 109.2) and SEK 543.1 M (neg: 29.7) for the year. As of December 31, 2019, cash and cash equivalents amounted to SEK 926.2 M (375.6) and equity to SEK 797.0 M (265.0).

### **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 employ-

In 2013, the option programs "Founder Option Program" and "Employee option program 2012/2019" were implemented. Both of these programs expired during the fourth quar-

ter. 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". For more information about these programs see note 24 in the Annual Report 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 further information about these programs, see the minutes of the Extraordinary General Meeting 2018 and the Annual General Meeting 2019 published on the company's website, www. oncopeptides.com.

Full utilization of granted options and share awards per December 31, 2019, corresponding to 2,569,177 shares, would result in a dilution for shareholders of 4.4 percent. Full utilization of all options and share awards, corresponding to 5,279,995 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 8.7 percent.

Below follows a summary of the changes in existing incentive programs during 2019 and the total number of shares that granted employee stock options and share awards may entitle to as of December 31, 2019.

Changes in existing incentive programs during 2019 (numb	per of shares)
- Co-worker LTIP 2018	349,549
- Co-worker LTIP 2019	166,017
- Board LTIP 2018.2	2,170
- Board LTIP 2019	23,491
Exercised instruments	
- Founder Option Program	-81,000
- Employee option program 2012/2019	-1,133,100
Lapsed instruments	
- Board LTIP 2017	-1,934
- Board LTIP 2018	-3,480
Total shanes	670 207
Total change	-678,287

- Employee option program 2016/2023	276,300
- Co-worker LTIP 2017	1,618,939
- Co-worker LTIP 2018	430,543
- Co-worker LTIP 2019	166,017
Total number of shares employee stock options may entitle to	2,491,799
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	2,569,177

# Other information

### **Co-workers**

As of December 31, 2019, the number of co-workers amounted to 88 (47).

### **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

Oncopeptides completed a directed share issue in January 2019, where a total of 4,750,000 new shares were issued. In July and additional share issue comprising 5,015,000 shares was completed. In the 2019 warrants corresponding to 1,556,496 shares have been exercised within the company's share-based incentive programs, of which 1,214,100 shares were granted to options holders and the remaining 342,396 shares were exercised to cover social security costs.

In total, the number of shares increased by 11,321,493 during the year and as of December 31, 2019, the number of registered shares and votes in Oncopeptides amounted to 55,413,417.

### **Annual General Meeting**

The AGM in Oncopeptides AB will be held at 14.00 CET on Tuesday May 26th, 2020, at Tändstickspalatset, Västra Trädgårdsgatan 15, Stockholm, Sweden.

In accordance with the dividend policy adopted by the board, no dividend is proposed for the year 2019.

### Events after the end of the report period

No significant events have occurred after the end of the report period.

### **Review**

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

Stockholm February 20, 2020

Jakob Lindberg CEO, Oncopeptides AB



### **Condensed consolidated income statement**

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Net sales	_	-	_	-
Gross profit	_	-	-	-
Operating expenses				
Research and development costs	-156,890	-90,793	-548,273	-313,714
Marketing and distribution costs	-56,190	-16,025	-127,409	-51,126
Administrative expenses	-17,935	-4,477	-72,046	-55,298
Other operating income/expenses <sup>2)</sup>	-13,229	-564	8,336	9,175
Total operating expenses	-244,244	-111,859	-739,392	-410,963
Operating loss	-244,244	-111,859	-739,392	-410,963
Net financial items	-156	-2	-528	-2
Loss before tax	-244,400	-111,861	-739,920	-410,965
Tax	-504	-147	-785	-147
Loss for the period <sup>3)</sup>	-244,904	-112,008	-740 705	-411,112
Earnings now share before and after				
Earnings per share before and after dilution (SEK)	-4.42	-2.54	-14.33	-9.58

### **Condensed consolidated statement** of comprehensive income

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Loss for the period	-244,904	-112,008	-740 705	-411,112
Other comprehensive income Items to be reclassified to profit or loss Translation differences from foreign opera-				
tions	-167	22	-20	22
Translation differences on currency hedges	-	-	-	-8
Total other comprehensive income, net of tax	-167	22	-20	14
Total comprehensive loss for the period <sup>3)</sup>	-245,071	-111,986	-740 725	-411,098

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

### **Condensed consolidated statement** of financial position

SEK thousand	December 31st 2019	December 31st 2018 <sup>1)</sup>
Assets		
Non-current assets		
Immateriella non-current assets	2,111	-
Tangible non-current assets	2,499	2,363
Nyttjanderättstillgångar	14,693	-
Financial non-current assets	3,297	851
Total non-current assets	22,600	3,214
Current assets		
Other current receivables	6,976	2,456
Prepaid expenses and accrued income	37,726	12,415
Cash and cash equivalents	926,186	375,617
Total current assets	970,888	390,488
Total assets	993,488	393,702
Equity and liabilities		
Equity		
Share capital	6,157	4,899
Additional paid-in capital	2,544,306	1,272,830
Retained earnings (including net profit/loss for the period)	-1,753,450	-1,012,725
Total equity <sup>2)</sup>	797,013	265,004
Long term liabilities		
Provision for social security contributions,		
share based incentive program	23,052	14,858
Other long term liabilities (note 6)	8,243	-
Total long term liabilities	31,295	14,858
Current liabilities		
Provision for social security contributions,		
share based incentive program	10,733	56,600
Trade payables	80,986	25,270
Other current liabilities (note 7)	12,319	4,056
Accrued expenses and deferred income	61,142	27,914
Total current liabilities	165,180	113,840
Total equity and liabilities	993,488	393,702

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

<sup>2)</sup> Exchange rate differences on assets and liabilities in operational activities.

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

<sup>2)</sup> Equity is in total attributable to parent company shareholders

### **Condensed consolidated statement** of changes in equity

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Opening balance	993,365	370,464	265,004	358,840
Profit/loss of the period	-244,904	-112,008	-740,705	-411,112
Other comprehensive income	-167	22	-20	14
Comprehensive income (loss) for the period	-245,071	-111,986	-740,725	-411,098
Transaction with owners				
New issue of ordinary shares	-	-	1,273,425	314,420
Cost attributable to new share issue	-933	-	-76,595	-19,390
Share based payments	9,722	6,330	32,493	12,368
Exercise of warrants	39,930	195	43,411	9,864
Total transaction with owners	48,720	6,525	1,272,735	317,262
Closing balance	797,013	265,004	797,013	265,004

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

### Condensed consolidated statement of cash flow

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Operating loss	-244,244	-111,859	-739,392	-410,963
Adjustment for non-cash-items2)	26,958	-2,913	-8,187	44,727
Interest received	0	0	0	-
Interest paid	-156	-2	-528	-2
Tax paid	-865	-	-1,158	-
Cash flow from operating activities before change in working capital	-218,307	-114,774	-749,265	-366,238
Cash flow from changes in working capital	1,333	5,919	58,699	32,511
Cash flow from operating activities	-216,974	-108,855	-690,566	-333,727
Cash flow from investing activities	-2,395	-532	-2 628	-907
Cash flow from financing activities	37,705	194	1,236,285	304,893
Cash flow for the period	-181,664	-109,193	543,091	-29,741
Cash and cash equivalents at beginning of period	1,122,297	488,869	375,617	404,050
Change in cash and cash equivalents	-181,664	-109,193	543,091	-29,741
Foreign exchange difference in cash and cash equivalents	-14,447	-4,059	7,478	1,308
Cash and cash equivalents at the end of period	926,186	375,617	926,186	375,617

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

<sup>2)</sup> Pertains mainly to costs of employee stock option program including social security contributions

### **Condensed parent company income statement**

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Net sales	-	-	-	-
Gross profit	-	-	-	-
Operating expenses				
Research and development costs	-156,940	-90,793	-548,419	-313,714
Marketing and distribution costs	-58,312	-17,665	-131,992	-51,844
Administrative expenses	-17,957	-4,477	-72,104	-55,298
Other operating income/expenses <sup>2)</sup>	-13,229	-564	8,336	9,175
Total operating expenses	-246,438	-113,499	-744,179	-411,681
Operating loss	-246,438	-113,499	-744,179	-411,681
Net financial items	12	18	41	18
Loss before tax	-246,426	-113,481	-744,138	-411,663
Tax	_	_	_	-
Loss for the period	-246,426	-113,481	-744,138	-411,663

# Condensed parent company statement of comprehensive income

SEK thousand	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Loss for the period	-246,426	-113,481	-744,138	-411,663
Other comprehensive income				
Items to be reclassified to profit or loss Translation differences on currency hedges	_	_	_	-8
Total other comprehensive income, net of tax	-	-	-	-8
Total comprehensive loss for the period	-246,426	-113,481	-744,138	-411,671

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

### **Parent company balance sheet**

SEK thousand	December 31st 2019	December 31st 2018 <sup>1)</sup>
Assets		
Non-current assets		
Immateriella non-current assets	2,111	-
Tangible non-current assets	2,472	2,363
Financial non-current assets	901	901
Total non-current assets	5,485	3,264
Current assets		
Other current receivables	6,914	2,279
Prepaid expenses and accrued income	37,192	11,640
Cash and bank balances	921,535	375,513
Total current assets	965,641	389,432
Total assets	971,126	392,696
Equity and liabilities		
Restricted equity		
Share capital	6,157	4,899
Statutory reserve	12,320	10,209
Non-restricted equity		
Share premium account	2,486,636	1,247,653
Retained earnings (including net profit/loss for the period)	-1,712,086	-998,331
Total equity	793,027	264,430
Long term liabilities		
Provision for social security contributions, share based incentive		
program	23,052	14,858
Total long term liabilities	23,052	14,858
Current liabilities		
Provision for social security contributions, share based incentive		
program	10,733	56,600
Trade payables	79,864	23,261
Other current liabilities (note 7)	13,430	5,815
Accrued expenses and deferred income	51,020	27,732
Total current liabilities	155,047	113,408
Total equity and liabilities	971,126	392,696

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see note 7.

<sup>2)</sup> Exchange rate differences on assets and liabilities in operational activities

### **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 year-end report for 2019 was approved for publication on February 29, 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 49-53 of the Annual Report for 2018.

IFRS 16 replaces IAS 17 and has been implemented for the group from January 1, 2019. The effect of the implementation of IFRS 16 is presented in Note 6. No other the new or amended standards that became effective January 1st 2019, 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 2018 on pages 35-36.

### 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 54 in the Annual Report for 2018.

### 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 IFRS 16 Leasing

IFRS 16 is applied by the Group as of January 1, 2019. IFRS 16 replaces IAS 17, and according to the new standard, lessees must report the obligation to pay lease payments as a lease debt in the balance sheet. The right to use the underlying asset during the leasing period is reported as an asset. Depreciation of the asset is recognized in profit or loss as well as an interest on the lease debt.

Leasing fees paid are reported partly as interest payment and partly as amortization of the lease liability. The standard excludes leasing agreements with a lease term of less than 12 months (short-term leases) and leasing agreements for assets that have a low value.

The standard means that the majority of existing leases are reported as assets and liabilities in the balance sheet. This means that the cost for these is reported divided into interest expenses and depreciation. In the parent company, the exception is applied in RFR 2 regarding leasing agreements. This means that the parent company's principles for reporting leases are unchanged. Oncopeptides applies the simplified transition method. The right of use assets at the beginning of the period have been calculated to the same value as the lease liabilities at the same point in time. The transition to IFRS 16 meant that the Group had the right to use assets and leasing liabilities of SEK 8.1 M as of January 1, 2019. The transition to IFRS 16 also meant that the operating profit for the Group for the period ended December 31, 2019 improved by SEK 0.3 M, and that the result for the period was decreased by SEK 0.2 M, compared with if the corresponding accounting principles from the previous year had been applied.

#### Leasing agreements

Reported leasing liabilities

January 1, 2019

Deusing ugi cements		
SEK thousand	Right of use assets	Lease liabilities
Opening balance January 1, 2019	8,053	8,053
Additional agreements	10,774	10,774
Depreciation	-4,159	
Amortization, Currency effect		-3 956
Valutaeffekt	25	24
Closing balance December 31, 2019	14,693	14,895
Reconciliation of operational leasing commitments		
Commitments for operational leasing	l	
agreements December 31, 2018		8,352
Discounting effects		-299

8.053

### **Note 7 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-Dec 2018, and the impact on the consolidated and parent company balance sheets per Dec 31, 2018, and Jan 1, 2018. The correction of errors has no impact on consolidated or parent company cash flow statements.

### Consolidated statement of income, Jan-Dec 2018

SEK thousand	According to approved Annual Report	Correction of error	After cor- rection of error
Operating expenses			
Research and development costs	-322,051	8,337	-313,714
Marketing and distribution costs	-51,126	_	-51,126
Administrative expenses	-55,298	_	-55,298
Other operating income/expenses	9,175	_	9,175
Total operating expenses	-419,300	8,337	-410,963
Operating loss	-419,300	8,337	-410,963
Net financial items	-2	_	-2
Tax	-147	_	-147
Loss for the period	-419,449	8,337	-411,112
Other comprehensive income			
Total other comprehensive income, net of tax	14	_	14
Total comprehensive loss for the period	-419,435	8,337	-411,098
Earnings per share before and after dilution (SEK)	-9.77	0.19	-9.58

Consolidated balance sheet, Dec 31, 2018

SEK thousand	According to approved Annual Report	Correction of error	After cor- rection of error
Assets			
Total non-current assets	3,214	-	3,214
Current assets			
Other current receivables	2,456	_	2,456
Prepaid expenses and accrued income	63,243	-50,828	12,415
Cash and cash equivalents	375,617	_	375,617
Total current assets	441,316	-50,828	390,488
Total assets	444,530	-50,828	393,702
Equity and liabilities			
Equity			
Share capital	4,899	_	4,899
Additional paid-in capital	1,272,830	_	1,272,830
Retained earnings (including net profit/loss for the			
period)	-961,897		-1,012,725
Total equity	315,832	-50,828	265,004
Total long term liabilities	14,858	_	14,858
Total current liabilities	113,840	_	113,840
Total liabilities	128,698	-	128,698
Total equity and liabilities	444,530	-50,828	393,702

### Parent company income statement, Jan-Dec 2018

SEK thousand	According to approved Annual Report	Correction of error	After cor- rection of error
Operating expenses			
Research and development costs	-322,051	8,337	-313,714
Marketing and distribution costs	-51,844	_	-51,844
Administrative expenses	-55,298	_	-55,298
Other operating income/expenses	9,175	_	9,175
Total operating expenses	-420,018	8,337	-411,681
Operating loss	-420,018	8,337	-411,681
Net financial items	18	_	18
Tax	_	_	0
Loss for the period	-420,000	8,337	-411,663
Other comprehensive income			
Total other comprehensive income, net of tax	-8	-	-8
Total comprehensive loss for the period	-420,008	8,337	-411,671

### Parent company balance sheet, Dec 31, 2018

SEK thousand	According to approved Annual Report	Correction of error	After cor- rection of error
Assets			
Total non-current assets	3,264	_	3,264
Current assets			
Other current receivables	2,279	_	2,279
Prepaid expenses and accrued income	62,468	-50,828	11,640
Cash and cbank balances	375,513	_	375,513
Total current assets	440,260	-50,828	389,432
Total assets	443,524	-50,828	392,696
Equity and liabilities			
Equity			
Restricted equity	15,108	_	15,108
Non-restricted equity	300,150	-50,828	249,322
Total equity	315,258	-50,828	264,430
Total long term liabilities	14,858	_	14,858
Total current liabilities	113,408	_	113,408
Total liabilities	128,266	-	128,266
Total equity and liabilities	443,524	-50,828	392,696

### Consolidated balance sheet, Jan 1, 2018

SEK thousand	According to approved Annual Report	Correction of error	After cor- rection of error
Assets			
Total non-current assets	2,601	-	2,601
Current assets			
Other current receivables	1,189	_	1,189
Prepaid expenses and accrued income	71,982	-59,165	12,817
Cash and cash equivalents	404,050	_	404,050
Total current assets	477,221	-59,165	418,056
Total assets	479,822	-59,165	420,657
Equity and liabilities			
Equity			
Share capital	4,423	_	4,423
Additional paid-in capital	956,044	_	956,044
Retained earnings (including net profit/loss for the			
period)	-542,462	-59,165	-601,627
Total equity	418,005	-59,165	358,840
Total long term liabilities	1,825	_	1,825
Total current liabilities	59,993	-	59,993
Total liabilities	61,817	-	61,817
Total equity and liabilities	479,822	-59,165	420,657

### Parent company balance sheet, Jan 1, 2018

SEK thousand	According to approved Annual Report	Correction of error	After cor- rection of error
Assets			
Total non-current assets	2,651	_	2,651
Current assets			
Other current receivables	1,189	_	1,189
Prepaid expenses and accrued income	71,982	-59,165	12,817
Cash and cbank balances	404,000	_	404,000
Total current assets	477,171	-59,165	418,006
Total assets	479,822	-59,165	420,657
Equity and liabilities			
Equity			
Restricted equity	14,632	_	14,632
Non-restricted equity	403,373	-59,165	344,208
Total equity	418,005	-59,165	358,840
Total long term liabilities	1,825	_	1,825
Total current liabilities	59,993	_	59,993
Total liabilities	61,817	-	61,817
Total equity and liabilities	479,822	-59,165	420,657

# **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

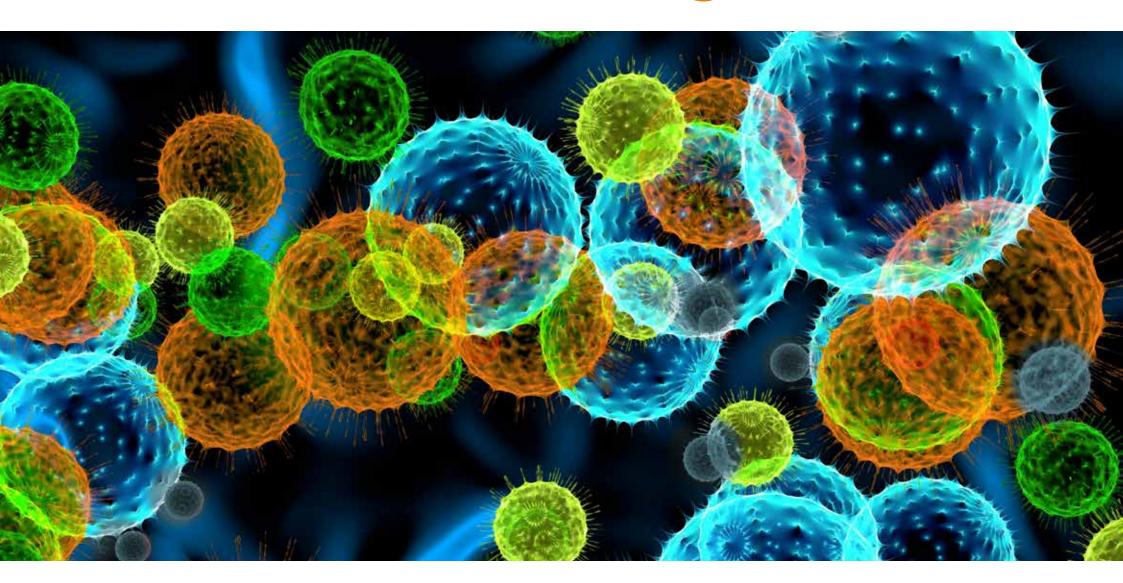
	2019 Oct - Dec	2018 <sup>1)</sup> Oct - Dec	2019 Jan - Dec	2018 <sup>1)</sup> Jan - Dec
Total registered shares at the beginning of period	55,212,008	44,048,721	44,091,921	39,806,021
Total registered shares at the end of period	55,413,417	44,048,721	55,413,417	44,091,921
Number of shares that the outstanding employee options entitle to	2,569,177	3,247,464	2,569,177	3,247,464
Share capital at the end of period, SEK thousand	6,157	4,899	6,157	4,899
Equity at the end of period, SEK thousand	797,013	265,004	797,013	265,004
Earnings per share before and after dilution, SEK <sup>2)</sup>	-4.42	-2.54	-14.33	-9.58
Operating expenses, SEK thousand	-244,244	-111,859	-739,392	-410,963
Research and development costs, SEK thousand	-156,890	-90,793	-548,273	-313,714
Research & development costs/operating expenses % <sup>3)</sup>	64%	81%	74%	76%

<sup>1)</sup> Earlier periods have been adjusted to reflect correction of errors, see Note 7.

<sup>2)</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>3)</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 guick opinion on the proportion of the company's expenses that are attributable to the company's core business.

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