## •: oncopeptides

INTERIM REPORT JULY - SEPTEMBER 2018

## "Broad based progress"

Oncopeptides is a pharmaceutical company developing drugs for the treatment of cancer. The company is focusing on the development of the lead product candidate Ygalo<sup>®</sup>, an alkylating peptide, belonging to a new class of drugs (Peptidase Enhanced Compounds - PEnCs). Ygalo<sup>®</sup> is intended as an effective treatment of hematological cancers, and in particular multiple myeloma. The goal with the current clinical study program is to demonstrate better results from treatment with Ygalo<sup>®</sup> compared with established alternative drugs for patients with late-stage multiple myeloma. Ygalo<sup>®</sup> will potentially provide physicians with a new treatment option for patients suffering from this serious disease.

## About Ygalo<sup>®</sup>

Ygalo<sup>°</sup>, an alkylating peptide belonging to a novel class of peptidase-enhanced compounds (PEnCs), targets multiple myeloma (MM) cells with a unique mechanism of action. Aminopeptidases are enzymes found in all cells, but are over-expressed in several cancers including MM. Ygalo<sup>°</sup> selectively targets MM cells through aminopeptidase-driven accumulation. In vitro experiments show a 50-fold enrichment of the active substance in MM cells compared with administration of equal amount of an alkylator not enriched by aminopeptidases. The enrichment results in selective cytotoxicity (increased on-target potency and decreased off-target toxicity), and that resistance pathways of existing myeloma treatments (including alkylators) is overcome. Ygalo<sup>°</sup> also demonstrates strong anti-angiogenic properties.

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### Financial calendar

Year-end report 2018: Q1 Report 2019: Q2 Report 2019: Q3 Report 2019: February 22, 2019 May 21, 2019 July 12, 2019 November 19, 2019

## 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. The information was submitted for publication, through the agency of the contact persons set out above, at 08.00 CET on October 26, 2018.

## Interim Report July-Sep 2018

#### Summary of Q3

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#### Financial overview July 1 – September 30 2018

- Net sales amounted to SEK 0.0 M (0.0)
- Loss for the period was SEK 103.0 M (loss: 51.6)
- Loss per share, before and after dilution, was 2.34 (loss: 1.30) SEK
- On September 30 cash and cash equivalents amounted to SEK 488.9 M (443.0)

#### Significant events during the period July 1 to September 30 2018

- During September, the first patient-initiated treatment in Oncopeptides' Phase II-study BRIDGE with Ygalo<sup>®</sup> in RRMM patients with renal impairment
- Anders Martin-Löf appointed as new Chief Financial Officer and commences his position in November
- Oncopeptides' first Capital Markets Day to be held in New York on December 14th

## Financial overview of the group

SEK thousand	2018 Jul-Sep	2017 Jul-Sep	2018 Jan-Sep	2017 Jan-Sep	2017 Jan-Dec
Net sales	-	-	-	-	-
Operating loss	-102,982	-51,573	-308,088	-180,916	-247,620
Loss before tax	-102,982	-51,573	-308,088	-180,916	-247,620
Loss for the period	-102,982	-51,573	-308,088	-180,916	-247,620
Earnings per share before and after dilution (SEK)	-2.34	-1.30	-7.24	-4.78	-6.44
Cash flow from operating activities	-93,506	-86,158	-224,872	-225,818	-271,497
Cash and cash equivalents at the end of the period Research & development costs/	488,869	442,964	488,869	442,964	404,050
operating expenses %	75%	94%	75%	80%	80%

## **Broad based progress**

Our activity level continued to increase during the past quarter with four ongoing clinical studies evaluating Ygalo<sup>®</sup>. In parallel, we continue to develop Oncopeptides' organization to prepare for a successful launch of Ygalo<sup>®</sup> after a potential market authorization based on our pivotal phase III-study OCEAN.

It is satisfying to see how relevant the OCEAN trial is in the current treatment landscape. During 2015 and 2017 new treatment guidelines were introduced. As a consequence of these new treatment guidelines, patients often become lenalidomide resistant already after the first line of treatment. The need for drugs with a new mechanism of action, such as Ygalo<sup>®</sup>, is therefore increasing already in the second line of treatment.

#### Ygalo's market potential is increasing

Broad-spectrum drugs constitute the foundation in myeloma treatment. The two most prescribed drugs today are lenalidomide (IMiD) and bortezomib (PI). Five of the six most prescribed drugs in myeloma are broad-spectrum drugs and belong to the classes IMiDs and PIs. This includes pomalidomide which is a sister molecule to lenalidomide. New targeted therapies are primarily used in combination with the broad-spectrum agents outside of rescue therapy.

Patients treated in accordance with the new guidelines often become resistant to IMiDs after the first line of treatment. At that timepoint the majority of patients have also been treated with a PI. Consequently, there is a large need for treatment options that have other mechanisms of action than IMiDs and PIs already in second line patients. Ygalo<sup>®</sup> strives to become such an alternative.

Our pivotal phase III-study OCEAN has been designed to compare the efficacy of Ygalo<sup>®</sup> with pomalidomide in patients that have become lenalidomide resistant. Lenalidomide and pomalidomide have large similarities and have overlapping resistance profiles. As a consequence of the new treatment guidelines, pomalidomide is increasingly used as second line treatment. This use is "off-label" and is a driver for the revenue growth of pomalidomide. Since OCEAN is a direct comparison between Ygalo® and pomalidomide, the study also addresses this positive market development. However, a complication is that the use of pomalidomide in second line treatment is "off-label" (i.e. not in accordance with pomalidomide's market approval). A clinical study such as OCEAN should generally be conducted in accordance with the approved label for pomalidomide.

One consequence of this "off label" use is a more challenging patient recruitment environment for OCEAN. We manage this in two ways. Firstly, we have opened several new clinical centers in the trial and secondly, we investigate the possibility of allowing second line patients in OCEAN together with the authorities. Overall, the market development is very positive given the increasing number of lenalidomide resistant patients already after the first line of treatment.

#### **Our clinical studies**

We have reported our phase II study O-12-M1, which shows that Ygalo<sup>®</sup> has a high

activity in late-stage relapsed and refractory multiple myeloma patients (RRMM) combined with a good tolerability profile. Currently, we have four ongoing clinical studies with Ygalo<sup>®</sup> to characterize its profile and activity in different groups of myeloma patients. It is important to map Ygalo's activity and safety profile at different stages of the disease to guide treating physicians which patients benefit the most from treatment with Ygalo<sup>®</sup>. Together, these studies will form the foundation for the regulatory process to apply for a potential market authorization for Ygalo<sup>®</sup> in the spring of 2020 as well as give us guidance for the future clinical development of Ygalo<sup>®</sup>.

The clinical study BRIDGE is our fourth ongoing study. This phase II study is in patients with renal impairment and started in September 2018. It is an important positioning study, as Ygalo's treatment profile seemingly is not affected by the patient's renal function as is common for other myeloma drugs such as pomalidomide (thus limiting their use and activity).

## The American Hematology Meeting (ASH) is the next important milestone for our clinical data

We will present new data at the American Society of Hematology Meeting (ASH) in December 2018. At ASH, data from a first interim analysis in the ongoing ANCHOR study will be presented, and updated interim data from the ongoing HORIZON study.

On November 1st, the abstract book will be released. The content of the abstracts published on November 1st was submitted only a few weeks after the European Hematology Association Meeting (EHA) in June, and thus do not contain much of an update. At the actual meeting in early December, data from patients all the way into November will be presented.

#### Capital Market Day in New York to increase knowledge in the US

We recently announced that we will conduct our first Capital Markets Day. We decided to hold this in New York on December 14th. It will of course be possible to participate via a webcast. The focus will be on strategy, market and clinical data.

Stockholm October 26, 2018



## The market for treatment of multiple myeloma

The market is expected to continue to grow rapidly to an expected market value of approximately **27 billion USD** in 2022. During 2017, approximately **14 billion USD** worth of pharmaceuticals were sold.

# 14<br/>billion<br/>USD27<br/>billion<br/>USDUSA4Rest of the<br/>world201720172022

#### Source: EvaluatePharma and Annual reports

patients are treated with one drug at a time. In addition, we intend to prove through ANCHOR that Ygalo<sup>®</sup> can be combined with other myeloma therapies (daratumumab and bortezomib) for the minority of patients receiving more than one drug, apart from steroids, in late-stage disease.

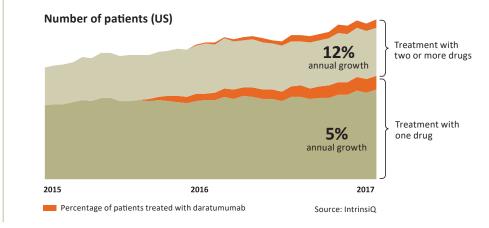
The clinical development program also opens the possibility for treatment of secondline patients (early RRMM patients) through the ANCHOR trial, since IMiDs and proteasome inhibitors are already used together upon diagnosis for the majority of patients today.

#### Broad-spectrum agents dominate the treatment landscape

Despite the launch of several new drugs, the market continues to be dominated by broad-spectrum agents (alkylators, IMiDs and proteasome inhibitors, PI:s) 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. This is demonstrated in the graph on the right.

#### The present clinical development with Ygalo® addresses all relevant segments of the RRMM market

The treatment landscape and market segments for multiple myeloma in the US and Europe – and how Ygalo<sup>®</sup> and our development program address these different segments – is summarized on the next page. The center of the graph shows the patient timeline, from diagnosis to the later stages of the disease. At the top of the graph, the market size is distributed between newly diagnosed patients and relapsed and relapsed-refractory (the latter RRMM) patients (and between the US and the rest of the world). Ygalo's clinical development program addresses the relapsed refractory (RRMM) market segment. The overall market for RRMM amounted to 8.2 billion USD in 2017, with sales of pomalidomide corresponding to 1.6 billion USD of this.



The lower segment of the graph below

shows that the majority of the RRMM

market consists of the treatment of patients

with one drug at a time (in combination with

addresses all relevant segments of the

RRMM market. This is achieved by us con-

ducting a direct comparison with pomalido-

mide in our phase III study OCEAN in

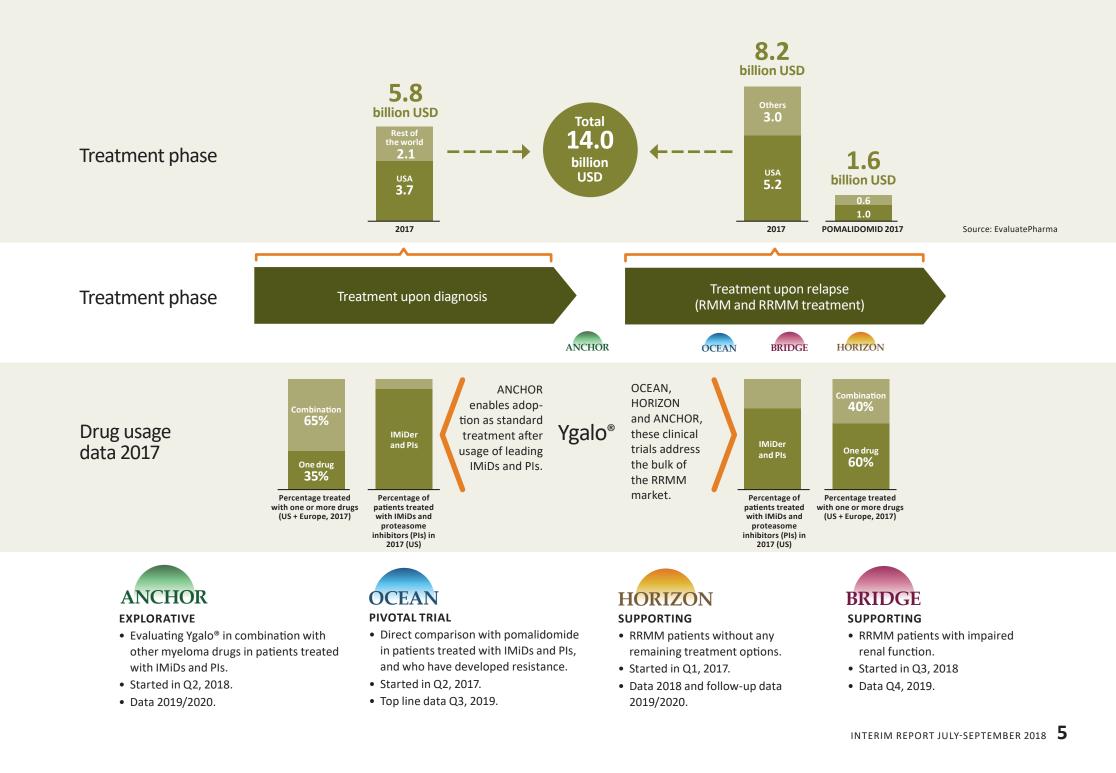
patients previously treated with IMiDs and

proteasome inhibitors (which is nearly all

patients). As mentioned, most RRMM

Ygalo's clinical development program

or without steroids).



## Summary – our clinical trials

Our phase III trial, OCEAN, and phase II trial, HORIZON, are key studies for the submission of an NDA/MAA application to potentially obtain marketing authorization for Ygalo<sup>®</sup> in the US and in the EU for the treatment of late-stage RRMM.

In addition to proving Ygalo's efficacy in relation to standard of care (i.e pomalidomide) in late-stage RRMM, as evaluated by OCEAN, the development program also aims to demonstrate, through HORIZON, the activity of Ygalo<sup>®</sup> in patients with latestage RRMM with few or no remaining treatment options.

With the initiation of the phase I/II trial, ANCHOR, the development program will demonstrate how Ygalo<sup>®</sup> can be administered in combination with other multiple myeloma drugs. This study will genarate knowledge and understanding among physicians about how Ygalo<sup>®</sup> can be used for patients with RRMM in combination therapy, and to open up Ygalo<sup>®</sup> as a treatment option, as early as in second-line of therapy of patients (meaning relapsed patients).

During Q3, 2018, a fourth study - BRIDGE, started. This is a positioning study, in which Ygalo<sup>®</sup> will be studied in patients with impaired renal function.

HORIZON

80 patients.

• Ongoing phase II trial for up to

• Including patients with few or no

• Supports OCEAN for market approval.

• Potential for conditional approval if

· Results expected in 2018, with follow-

remaining treatment options.

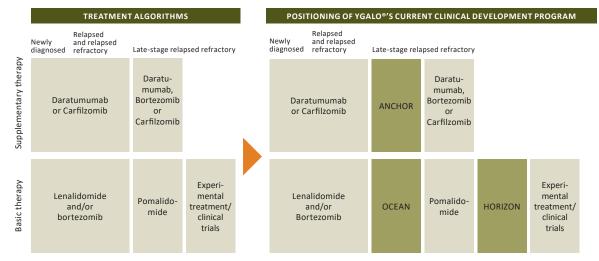
data are exceptionally strong.

updata in 2019/2020.



- Ongoing phase III trial in 450 patients.
- Inclusion of late-stage RRMM patients who are refractory to lenalidomide.
- The trial is designed to demonstrate benefit in comparison with pomalidomide. To obtain approval in Europe, the only requirement is to demonstrate that Ygalo<sup>®</sup> has the same benefit.
- Results expected in Q3 2019.

The current clinical development program is designed to identify how Ygalo® can help myeloma patients in the late stage of their illness



Note: The figure represents treatment algorithms for the majority of patients in the US.



- Ongoing phase I/II trial in up to 64 patients.
- Demonstrates how Ygalo<sup>\*</sup> can be given as a combination therapy used with daratumumab and with bortezomib.
- Also opens up the possibility for potentially using Ygalo<sup>®</sup> in earlier lines of therapy.
- Will significantly increase Ygalo's market potential as combination therapy.
- Results from phase I and phase II expected in 2019 and 2020 respectively.



- Phase II trial of up to 25 patients.
- Single armed, open label study in patients with impaired renal function.
- Positioning study to show Ygalo<sup>®</sup> treatment profile in these patients.
- Results expected Q4 2019.

## Oncopeptides' clinical development program

We are in process of conducting four clinical trials to characterize Ygalo<sup>®</sup> in multi-refractory multiple myeloma patients: OCEAN, HORIZON, ANCHOR and BRIDGE.

Recently, our clinical phase I and II trial, O-12-M1, was completed in *Late-Stage Relapsed Refractory* multiple myeloma patients. The final results were presented at the annual American Haematology Meeting (ASH) in December 2017.

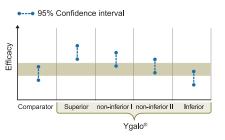
#### OCEAN

OCEAN is a phase III clinical trial and a head-to-head comparison between Ygalo<sup>®</sup> + dexamethasone (steroid) and the current standard of care in *Late-Stage Relapsed Refractory* multiple myeloma patients, which is pomalidomide + dexamethasone. The trial is a multicenter, pivotal study and is being run in Europe, USA and Israel. The study started in June 2017 and the top-line results are expected Q3 2019.

The OCEAN clinical trial protocol has undergone Special Protocol Assessment with the FDA and has been discussed and agreed in detail with European authorities. The primary read-out in OCEAN is a comparison between Ygalo<sup>®</sup> and pomalidomide regarding PFS (Progression Free Survival). This comparison can simplistically result in three different outcomes i.e. that Ygalo<sup>®</sup> 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 Ygalo<sup>®</sup>. OCEAN has been powered to show superiority of Ygalo<sup>®</sup> 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

#### Outcome scenario for OCEAN



in approval in the EU and a discussion with the FDA in the US regarding the totality of data from all clinical studies in RRMM. In a non-inferiority scenario, HORIZON data in pomalidomide refractory late-stage RRMM patients, and from BRIDGE in patients with renal impairment, will be a key point for the case to receive approval also in the US.

#### HORIZON

HORIZON is a phase II clinical trial where Ygalo<sup>®</sup> + dexamethasone is being studied in multiple myeloma patients that are refractory to pomalidomide and/or daratumumab (i.e. *Quad- and Penta-refractory* patients). The trial is being conducted in Italy, Spain and the USA. During the last year we have presented interim data on two occasions. At ASH in December 2017 and in June 2018 at EHA in Stockholm. We will present additional interim data at the forthcoming ASH meeting in December 2018.

#### ANCHOR

ANCHOR is a phase I/II combination study where Ygalo<sup>®</sup> + dexamethasone is used in combination with bortezomib or daratumumab. The first patient started treatment in April 2018 and last patient out from the study is estimated in Q1 2020. During the ASH meeting in December 2018, we will present the first interim data from the on going trial.

#### BRIDGE

BRIDGE is a Phase II study that will evaluate pharmacokinetics, safety and also efficacy in treatment with Ygalo + dexamethasone in patients with impaired renal function.

25 RRMM patients with renal impairment are scheduled to be included. The first patient started treatment during September 2018 and the last patient is expected to complete treatment during Q3 2019.

#### 0-12-M1

Final O-12-M1 data were presented at the American Haematology meeting (ASH) in December 2017.

O-12-M1 is a completed phase I and II clinical trial in 'Late-Stage Relapsed Refractory' multiple myeloma patients. In O-12-M1 we established the dose and dose modification schedule for Ygalo<sup>®</sup> as well as the activity of Ygalo<sup>®</sup> in 'Late-Stage Relapsed Refractory' multiple myeloma patients.

#### Additional opportunities

The Company is also exploring the possibility to use Ygalo<sup>®</sup> in conjunction with for example, stem-cell transplantation in multiple myeloma, for the treatment of non-Hodgkin's lymphoma as well as for the treatment of amyloidosis.



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## Financial overview and other information

#### Revenue

Net sales amounted to SEK 0.0 M (0.0) during the third quarter and SEK 0.0 M (0.0) for the first nine months of the year.

#### **Operating expenses**

Operating expenses for the third quarter amounted to SEK 103.0 M (51.6) and to SEK 308.1 M (180.9) for the first nine months.

#### **Research and development costs**

During the third quarter, research and development costs increased to SEK 77.3 M (48.2) and to SEK 231.9 M (145.0) for the first nine months. The increase is mainly explained by a rise in clinical costs due to increased activity in the ongoing pivotal study OCEAN and in the newly started clinical studies AN-CHOR and BRIDGE.

The costs for share-based incentive programs related to R&D amounted to a negative SEK 3.2 M (neg: 1.3) for the third quarter and to SEK 16.1 M (7.6) for the first nine months.

#### Marketing and distribution costs

Marketing and distribution costs for the third quarter amounted to SEK 13.2 M (2.3) and to SEK 35.1 M (9.1) for the first nine months. The main reason for the cost increase is the continued expansion of the medical relations and marketing functions and related activities.

The costs for share-based incentive programs related to marketing and distribution

amounted to SEK 1.8 M (neg:0.4) for the third quarter and to SEK 8.3 M (3.6) for the first nine months.

#### Administration costs

During the third quarter, administration expenses amounted to SEK 10.2 M (1.0) and to SEK 50.8 M (26.8) for the first nine months. The increase that is not attributable to costs for the share-based incentive programs 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 3.9 M (neg: 2.2) for the third quarter and to SEK 28.3 M (11.7) for the first nine months.

#### Costs for share-based incentive program

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

The total costs for the share-based incentive programs in the third quarter amounted to SEK 2.5 M (neg: 3.9) and to SEK 52.8 M (22.9) for the first nine months. The cost has no cash impact. The company holds warrants that are allocated as hedge for social security contributions arising from the exercise of employee stock options.

The cost of SEK 52.8 M (22.9) for the first nine months consists of provisions for social

security contributions of SEK 46.7 M (21.4) and IFRS 2 classified salary costs of SEK 6.0 M (1.6).

#### Earnings

Loss for the period was SEK 103.0 M (loss: 51.6) and a loss of 308.1 M (loss: 180.9) for the first nine months. This corresponds to a loss per share, before and after dilution of SEK 2.34 (loss: 1.30) for the period and a loss of SEK 7.24 (loss: 4.78) for the first nine months.

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No tax was reported for the quarter (-). The group's tax-loss carryforwards according to the latest estimated taxation in 2018 (related to the income year 2017) amounted to SEK 542.2 M. The group's tax-loss carryforwards have not been valued and have not been recognized as a deferred tax asset. These tax-loss carry forwards will be valued only when the group has established a level of earnings that management believes is likely to lead to tax costs.

#### Cash flow, investment and financial position

Cash flow from operating activities for the third quarter amounted to a negative SEK 93.5 M (neg: 86.2) and to a negative 224.9 M (neg: 225.8) for the first nine months. The continued negative cash flow is according to plan and is explained by the company's increased clinical activities as well as work within the company's medical affairs and marketing functions.

Cash flow from investing activities was a negative SEK 0.1 M (neg: 0.2) for the third quarter and a negative SEK 0.4 M (neg: 1.5) for the first nine months.

Cash flow from financing activities amounted to SEK 9.7 M (0.0) for the third quarter and to SEK 304.7 M (636.8) for the first nine months. During the third quarter, warrants corresponding to 62,900 shares were exercised to cover social security contributions related to exercised employee stock options, which contributed with SEK 9.7 M. In addition, the company raised SEK 314.4 M before issue costs of SEK 19.4 M in connection with the directed share issue in March 2018.

Cash flow for the third quarter was a negative SEK 84.0 M (neg: 86.4) and SEK 79.5 M (409.5) for the first nine months. As of September 30 2018, cash and cash equivalents amounted to SEK 488.9 M (443.0) and equity to SEK 420.6 M (477.0).

#### Share-based incentive programs

The purpose of share-based incentive programs is to promote the company's longterm 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 seven active programs that include part of the management team, certain board members, founders and employees. In 2013, two option programs were implemented. "Founder Option Program" and "Employee option program 2012/2019" and in 2016 a program "Employee option program 2016/2023" was implemented. At the 2017 Annual General Meeting two additional incentive programs; "Co-worker LTIP 2017" and "Board LTIP 2017" were introduced. For more information about these programs see note 21 in the Annual Report 2017.

In accordance with a decision by the Shareholder's General Meeting in May 2018, two new share-based incentive programs; "Co-worker LTIP 2018" and "Board LTIP 2018" were introduced. For further information about these programs, see the minutes of the Annual General Meeting 2018 published on the company's website, www.oncopeptides.com.

Full utilization of granted options and share awards per September 30 2018, corre-

sponding to 2,880,664 shares, would result in a dilution for shareholders of 6.1 percent. Full utilization of issued warrants, corresponding to 4,659,544 shares (i.e. including non-granted employee options and hedge for social security contributions), would result in a dilution for shareholders of 9.6 percent.

During the nine-month period 33,931 share awards have been granted in Board LTIP 2018 and options corresponding to 426,933 shares have been granted in Co-worker LTIP 2017. 11,600 share awards in Board LTIP 2017 have been recalled and options corresponding to 199,800 shares in employee option program 2012/2019 have been exercised.

Below follows a summary of the total number of shares that granted employee stock options and share awards may entitle to as of September 30, 2018.

Number of shares granted employee stock options may entitle to:	
- Employee option program 2012/2019	1,154,700
- Founder option program	102,600
- Employee option program 2016/2023	276,300
- Co-worker LTIP 2017	1,289,933
Total number of shares granted employee stock options may entitle	e to: 2,823,533
Number of granted share awards in program "Board LTIP 2017"	23,200
Number of granted share awards in program "Board LTIP 2018"	33,931
Total number of shares granted employee stock options and share awards may entitle to:	2,880,664

#### Co-workers

As of September 30 2018, the number of co-workers amounted to 42 (25).

#### 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.

#### **Oncopeptides' shares**

Oncopeptides completed a directed share issue in March 2018, where a total of 3,980,000 new shares were issued.

During the third quarter warrants corresponding to 262,700 shares have been exercised within the company's share-based incentive programs, of which 199,800 shares were granted to options holders and the remaining 62,900 shares were exercised to cover social security costs. In total, the number of shares increased by 4,305,600 during the nine-month period.

As of September 30, 2018, the number of registered shares and votes in Oncopeptides amounted to 44,048,721.

#### Events after the end of the report period

No significant events have taken place after the end of the period.

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

Stockholm, October 26, 2018

Oncopeptides AB Board of Directors

#### Auditor's report

Oncopeptides AB org nr 556596-6438

#### Introduction

We have reviewed the condensed interim financial information (interim report) of Oncopeptides AB (publ) ("the Parent Company") and its subsidiaries (together "the Group") as of 30 September 2018 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the condensed interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### **Scope of Review**

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

#### Conclusion

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

Stockholm, 26 October 2018 PricewaterhouseCoopers AB

Magnus Lagerberg Auktoriserad revisor

## Condensed consolidated statement of comprehensive income

SEK thousand	2018 Jul-Sep	2017 Jul-Sep	2018 Jan-Sep	2017 Jan-Sep	2017 Jan-Dec
Net sales	-	-	-	-	-
Gross profit	-	-	-	-	-
Operating expenses					
Research and development costs	-77,344	-48,225	-231,905	-145,010	-197,771
Marketing and distribution costs	-13,429	-2,322	-35,101	-9,127	-15,160
Administrative expenses	-10,208	-1,026	-50,821	-26,779	-34,688
Other operating income <sup>1)</sup>	2,742	-	10,078	-	-
Other operating expenses <sup>1)</sup>	-4,744	-	-339		-
Total operating expenses	-102,982	-51,573	-308,088	-180,916	-247,620
Operating loss	-102,982	-51,573	-308,088	-180,916	-247,620
Net financial items	0	0	0	0	0
Loss before tax	-102,982	-51,573	-308,088	-180,916	-247,620
Tax	-	-	-	-	-
Loss for the period	-102,982	-51,573	-308,088	-180,916	-247,620
Earnings per share before and after dilution (SEK)	-2.34	-1.30	-7.24	-4.78	-6.44

## Condensed consolidated statement of comprehensive income

SEK thousand	2018 Jul-Sep	2017 Jul-Sep	2018 Jan-Sep	2017 Jan-Sep	2017 Jan-Dec
Loss for the period	-102,982	-51,573	-308,088	-180,916	-247,620
Other comprehensive income Translation differences on currency hedges		-5,710	-8	-6.758	8
Total other comprehensive income, net		,			
oftax	-	-5,710	-8	-6,758	8
Total comprehensive loss for the period <sup>2)</sup>	-102,982	-57,283	-308,096	-187,674	-247,612

<sup>1)</sup>Exchange rate differences on assets and liabilities in operational activities.

<sup>2)</sup> Total comprehensive loss for the period is in total attributable to parent company shareholders.

#### Condensed consolidated balance sheet

SEK thousand	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
Assets			
Non-current assets			
Tangible non-current assets	2,455	2,406	2,339
Financial non-current assets	1	263	263
Total non-current assets	2,456	2,669	2,601
Current assets			
Other current receivables	2,155	1,794	1,189
Prepaid expenses and accrued income	59,130	80,168	71,982
Cash and cash equivalents	488,869	442,964	404,050
Total current assets	550,154	524,926	477,221
Total assets	552,610	527,595	479,822
Equity and liabilities			
Equity			
Share capital	4,894	4,423	4,423
Additional paid-in capital	1,266,310	955,099	956,044
Retained earnings (including net profit/loss for the period)	-850,559	-482,524	-542,462
Total equity <sup>1)</sup>	420,645	476,997	418,005
Long term liabilities			
Provision for social security contributions, share based			
incentive program	14,811	750	1,825
Total long term liabilities	14,811	750	1,825
Current liabilities			
Trade payables	21,866	8,857	15,681
Provision for social security contributions, share based	,	,	,
incentive program	70,038	30,800	36,306
Other current liabilities	983	452	954
Accrued expenses and deferred income	24,267	9,738	7,053
Total current liabilities	117,154	49,848	59,993
Total liabilities	131,965	50,597	61,818
Total equity and liabilities	552,610	527,595	479,822

<sup>1)</sup> Equity is in total attributable to parent company shareholders

#### Consolidated statement of changes in equity

		Additional	Retained earnings including net profit/loss	
SEK thousand	Share capital	paid-in capital	for the period	Total equity
Opening balance January 1, 2017	2,449	318,738	-294,850	26,337
Net loss for the period			-187,674	-187,674
Transactions with shareholders				
Issue of new shares	1,679	693,305		694,984
Underwriting expenses	1,079	-58,223		-58,223
Conversion of bridge loans	295	-295		0
Value of participants in the incentive	233	255		0
programs service		1,574		1,574
Closing balance September 30, 2017	4,423	955,099	-482,524	476,997
Opening balance January 1, 2017	2,449	318,738	-294,850	26,337
Net loss for the period			-247,612	-247,612
Transactions with shareholders				
Issue of new shares	1,679	693,305		694,984
Underwriting expenses	1,075	-58,223		-58,223
Conversion of bridge loans	295	-295		0
Value of participants in the incentive				
programs service		2,519		2,519
Closing balance December 31, 2017	4,423	956,044	-542,462	418,005
Opening balance January 1, 2018	4,423	956,044	-542,462	418,005
Net loss for the period			-308,096	-308,096
Transactions with shareholders				
Issue of new shares	442	313,978		314,420
Underwriting expenses	2	-19,390		-19,390
Value of participants in the incentive		10,000		10,000
programs service		6,038		6,038
Exercise of warrants under the compa-				
ny's incentive programs	29	9,640		9,669
Closing balance September 30, 2018	4,894	1,266,310	-850,559	420,645

#### Condenced consolidated statement of cash flow

SEK thousand	2018 Jul-Sep	2017 Jul-Sep	2018 Jan-Sep	2017 Jan-Sep	2017 Jan-Dec
Operating loss	-102,982	-51,573	-308,088	-180,916	-247,620
Adjustment for non-cash-items	-2,030	-3,816	47,640	23,090	30,684
Interest received	0	0	0	0	0
Interest paid	0	0	0	0	0
Cash flow from operating activities before change in working capital	-105,011	-55,390	-260,448	-157,826	-216,936
Cash flow from changes in working capital	11,506	-30,769	35,576	-67,992	-54,562
Cash flow from operating activities	-93,506	-86,158	-224,872	-225,818	-271,497
Cash flow from investing activities	-123	-237	-375	-1472	-1,472
Cash flow from financing activities	9,669	-	304,699	636,761	636,761
Cash flow for the period	-83,960	-86,395	79,452	409,471	363,791
Cash and cash equivalents at beginning of period	568,212	535,069	404,050	40,251	40,251
Cange in cash and cash equivalents	-83,960	-86,395	79,452	409,471	363,791
Foreign exchange difference in cash and cash equivalents	4,616	-5,710	5,368	-6758	8
Cash and cash equivalents at the end of period	488,869	442,964	488,869	442,964	404,050

## Condensed parent company statement of comprehensive income

SEK thousand	2018 Jul-Sep	2017 Jul-Sep	2018 Jan-Sep	2017 Jan-Sep	2017 Jan-Dec
Net sales	-	-	-	-	-
Gross profit	-	-	-	-	-
Operating expenses					
Research and development costs	-77,344	-48,225	-231,905	-145,010	-197,771
Marketing and distribution costs	-12,506	-2,322	-34,179	-9,127	-15,160
Administrative expenses	-10,208	-1,026	-50,821	-26,779	-34,688
Other operating income <sup>1)</sup>	2,742	-	10,078	-	-
Other operating expenses <sup>1)</sup>	-4,744	-	-339	-	-
Total operating expenses	-102,059	-51,573	-307,166	-180,916	-247,620
Operating loss	-102,059	-51,573	-307,166	-180,916	-247,620
Net financial items	0	0	0	0	0
Loss before tax	-102,059	-51,573	-307,166	-180,916	-247,620
Тах	-	-	-	-	-
Loss for the period	-102,059	-51,573	-307,166	-180,916	-247,620

## Condensed parent company statement of comprehensive income

SEK thousand	2018 Jul-Sep	2017 Jul-Sep	2018 Jan-Sep	2017 Jan-Sep	2017 Jan-Dec
Loss for the period	-102,059	-51,573	-307,166	-180,916	-247,620
Other comprehensive income Translation differences on currency hed- ges	-	-5,710	-8	-6,758	8
Total other comprehensive income, net of tax	-	-5,710	-8	-6,758	8
Total comprehensive loss for the period	-102,059	-57,283	-307,174	-187,674	-247,612

<sup>1)</sup> Exchange rate differences on assets and liabilities in operational activities.

#### Parent company balance sheet

SEK thousand	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
Assets			
Non-current assets			
Tangible non-current assets	2,449	2,406	2,339
Financial non-current assets	51	313	313
Total non-current assets	2,500	2,719	2,651
Current assets			
Other current receivables	3,760	1,794	1,189
Prepaid expenses and accrued income	58,931	80,168	71,982
Cash and cash equivalents	488,344	442,914	404,000
Total current assets	551,036	524,876	477,171
Total assets	553,536	527,595	479,822
Equity and liabilities			
Restricted equity			
Share capital	4,894	4,423	4,423
Statutory reserve	10,209	10,209	10,209
Non-restricted equity			
Share premium account	1,256,101	912,125	945,835
Retained earnings (including net profit/loss for the period)	-849,637	-449,759	-542,462
Total equity	421,568	476,997	418,005
Long term liabilities			
Provision for social security contributions, share			
based incentive program	14,811	750	1,825
Total long term liabilities	14,811	750	1,825
Current liabilities			
Trade payables	21,869	8,857	15,681
Provision for social security contributions, share	21,000	0,007	10,001
based incentive program	70,038	30,800	36,306
Other current liabilities	983	452	954
Accrued expenses and deferred income	24,267	9,738	7,053
Total current liabilities	117,157	49,848	59,993
Total liabilities	131,968	50,597	61,818
Total equity and liabilities	553,536	527,595	479,822

#### 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.

	Jul-Sep, 2018	Jul-Sep, 2017	Jan - Sep, 2018	Jan - Sep, 2017	Jan - Dec, 2017
Total registered shares at the beginning of period	43,786,021	39,806,021	39,806,021	22,041,900	22,041,900
Total registered shares at the end of period	44,048,721	39,806,021	44,048,721	39,806,021	39,806,021
Number of shares that the allocated employee options entitle to	2,880,664	2,495,200	2,880,664	2,495,200	2,631,200
Share capital at the end of period, SEK thousand	4,894	4,423	4,894	4,423	4,423
Equity at the end of period, SEK thousand	420,645	476,997	420,645	476,997	418,005
Earnings per share before and after dilution, $SEK^{1)}$	-2.34	-1.30	-7.24	-4.78	-6.44
Operating expenses, SEK thousand	-102,982	-51,573	-308,088	-180,916	-247,620
Research and development costs, SEK thousand	-77,344	-48,225	-231,905	-145,010	-197,771
Research & development costs/operating expenses $\%^{2)}$	75%	94%	75%	80%	80%

1)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. Adjustments have been made to the calculation of earnings per share, since preference shares have existed during part of the previous periods. There is no dilution effect for the employee stock option program, as earnings for the periods have been negative.

2) 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.

#### 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.

The interim report for the third quarter 2018 was approved for publication on October 26, 2018, in accordance with the board decision of October 25, 2018.

#### Note 2 Accounting policies

Oncopeptides applies International Financial Reporting standards (IFRS) as adopted by the European Union. Relevant accounting and valuation principles could be found on pages 46-51 of the Annual Report for 2017.

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. None of the new or amended standards and interpretations that became effective January 1st 2018, have had a significant impact on the company's financial reporting.

Since the first quarter 2018 the company has decided to discontinue hedge accounting.

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 2017 on pages 32-33.

#### 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 Ygalo® 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 for the period up to mid-2019 in order to manage currency exposure.

For more information about the group and parent company's financial risk management see note 3 on pages 51-52 in the Annual Report for 2017.

#### Note 4 Estimates and judgements

This report includes forward looking statement. 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.

#### Not 5 Related-party transactions

No transactions with related parties occurred during the third quarter.

## • oncopeptides

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