

# Annual report 2017



*Health equality for a global population*

## Introduction

The year in brief	3
History	6
CEO's comments	8

## Business, strategy and product candidates

Business concept and objectives	10
Strategy	11
Portfolio of product candidates	12

## Market and partners

Market for biosimilars	14
Partners	18

## Organisation

Organisation and employees	20
Chairman of the Board's comments	22
Board of Directors	24
Management	26

## Financial overview and reporting

The share and ownership structure	28
Administration report	30
Financial statements	37
Notes	46

## Supplement

Auditor's report	76
Annual General Meeting 2018	79
Alternative performance measures	80
Glossary	81

## Financial calendar

Interim report Jan-March	14 May 2018
Annual General Meeting	24 May 2018
Interim report April-June	24 August 2018
Interim report July-Sep	16 November 2018
Year-end report	28 February 2019

## For further information

Martin Åmark, CEO  
martin.amark@xbrane.com

Susanna Helgesen, CFO/IR  
susanna.helgesen@xbrane.com

+46 (0)76 034 67 33  
www.xbrane.com

## About Xbrane Biopharma

Xbrane Biopharma AB is a biotechnology company which develops, manufactures and produces commercial biosimilars. Xbrane has a patented protein production platform for development of biosimilars and world-leading expertise within biosimilars. Xbrane's head quarter is located in Solna, just outside Stockholm, and the company has research and development facilities in Sweden and in Italy. Xbrane has been listed on Nasdaq First North since 3 February 2016 with the ticker XBRANE. Avanza Bank AB is Xbrane's Certified Adviser.

For further information, please visit [www.xbrane.com](http://www.xbrane.com).  
Xbrane Biopharma AB (publ)  
Org. no.: 556749-2375

*This report is a translation of the original version in Swedish.*

## The year in brief

# 150,000

doses of Spherotide sold during 2017 when Xbrane initiated sales in the Middle East.



# 2,400

The number of shareholders quadrupled during the year and amounted to 2,400 on the balance sheet date.

# 79%

Research and development expenses constituted 79% of total operating expenses.

## Financial summary for the Group

Amounts in SEK thousands	2017	2016
Revenue	20,771	-
Research and development expenses (R&D)	-37,982	-23,858
R&D expenses as a percentage of operating expenses	79%	79%
Operating result	-44,718	-27,567
Profit for the period	-44,935	-27,769
Cash and cash equivalents	7,903	31,338
Equity ratio, %	80%	91%
Number of shares at the end of the period before dilution	5,956,770	4,755,546
Number of shares at the end of the period after dilution*	5,956,770	4,755,546
Average number of shares before dilution	5,425,656	4,508,409
Average number of shares after dilution*	5,425,656	4,508,409
Earnings per share basic (SEK)	-8.28	-6.16
Earnings per share diluted (SEK)*	-8.28	-6.16

\* Dilution not taken into account with negative earnings per share. If converted to shares, the outstanding convertible loan as at 31 December 2017 is equivalent to 661,207 shares. Dilution from the share savings program is calculated according to the Treasury Stock method and is equivalent to 3,264 shares.

# Q1

- » Xbrane received GMP-approval of the production facility for Spherotide in Italy from AIFA (the Italian Medical Products Agency).
- » Supplied its first batch of Spherotide at a value of SEK 7 million to its partner in the Middle East.
- » Reported positive biosimilarity data for Xlucane.



*»The absolutely most important milestone for Xlucane during the year was the positive biosimilarity data that was reported. This provides us with comfort for the clinical studies.«*

Siavash Bashiri, Head of Biosimilars

# Q2

- » Xbrane reported positive comparative in-vivo efficacy data for Spherotide.
- » Recruited Susanna Helgesen as new CFO/ Head of Investor Relations.
- » Implemented a targeted share issue of SEK 20 million with Carnegie Investment Bank AB as financial adviser.
- » Launched a long-term share savings program for employees.



*»Being the only listed biosimilar company in Sweden makes Xbrane unique.«*

Susanna Helgesen CFO/Head of Investor Relations

# Q3

- » Received market authorization for Spherotide in Iran.
- » Received orders for Spherotide at a value of SEK 8.5 million.
- » Decision by the Board of Directors to initiate the work to change trading venue to Nasdaq OMX's main list.



*»Market authorization entails launch of the world's first and, to date, only generic for long-acting triptorelin.«*

Paolo Sarmientos, Head of Long-Acting Injectables

# Q4

- » Dina Jurman, Head of Clinical Affairs, appointed as member of the management.
- » Carlo Colombo, Head of long-acting Injectables, member of management, handed in his resignation.
- » Agreement signed with BL&H for sales and marketing of Spherotide in South Korea.
- » Proposal from Serendipity Ixora to distribute its entire shareholding in Xbrane to its shareholders, making Serendipity Group (in January 2018) the largest shareholder in Xbrane.
- » Received a credit facility of SEK 50 million from the largest shareholder, Serendipity Group.

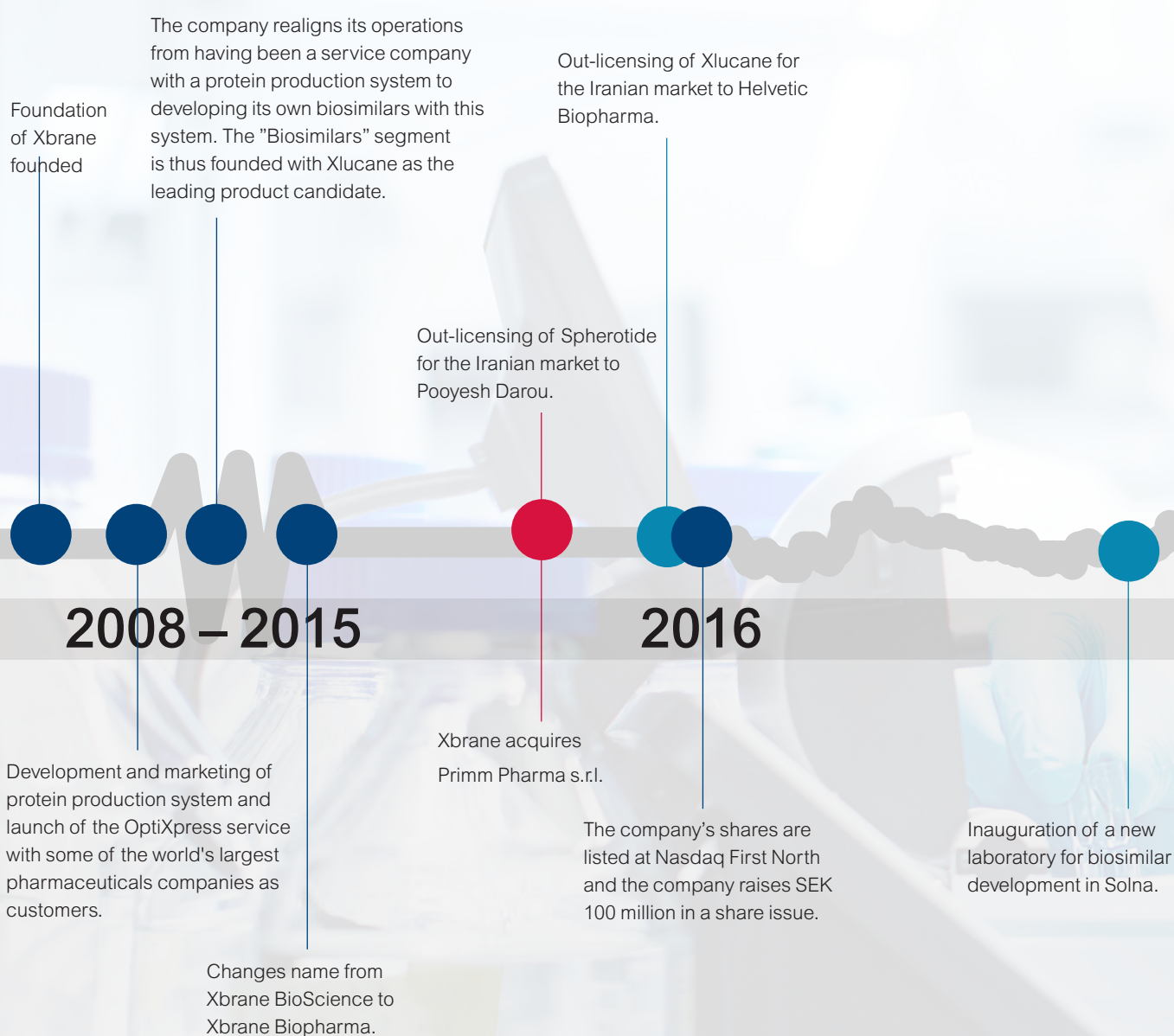


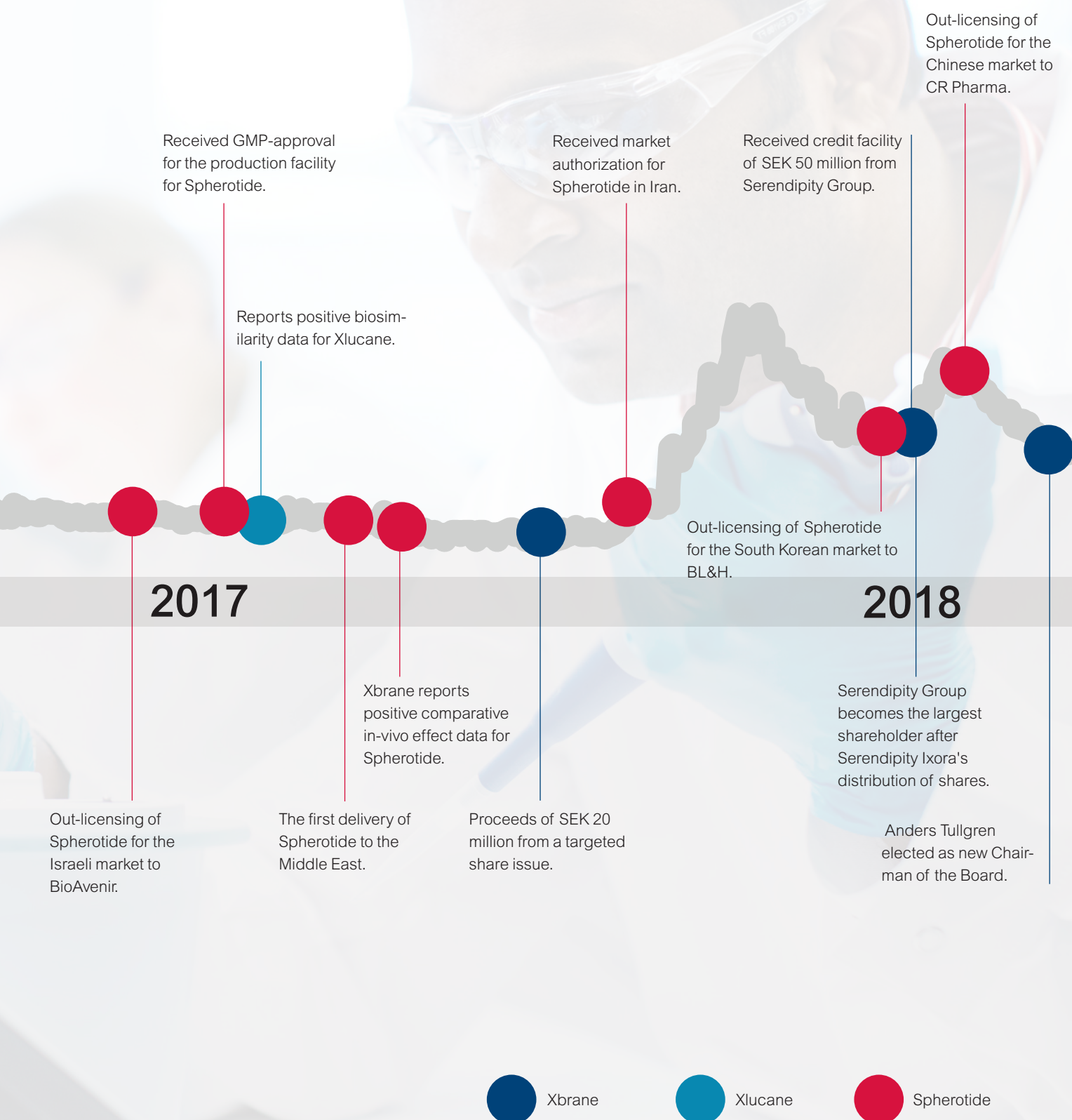
*»The preparations for our pivotal clinical trials are in full swing and I am eagerly looking forward to the continued development of our pharmaceutical candidates. I am convinced that 2018 will be an eventful year for Xbrane.«*

Dina Jurman, Head of Clinical Affairs



# Xbrane – our history





## CEO's comments

As we put 2017 behind us, we can look back on an eventful year in which we moved our positions forward for both our leading product candidates – Xlucane and Spherotide. For 2018, we are aiming to initiate clinical trials for both Spherotide and Xlucane.

**Dear shareholder,**

### **Agreement with CR Pharma for commercialization of Spherotide in China signed**

In the beginning of February, Xbrane signed a license agreement with China Resources Pharmaceutical (CR Pharma) for commercialization of Spherotide in China. According to the agreement, CR Pharma gets exclusive sales and marketing rights for Spherotide for a high single digit USD million license fee payable at signing and along milestones up until market approval in China. The first milestone payment will be booked as revenue in the first quarter of 2018. Xbrane will then produce and sell the product to CR Pharma at an agreed transfer price. We are convinced that CR Pharma will do a great job in sales and marketing of Spherotide in China. CR Pharma has one of the largest distribution networks of pharmaceuticals in China, covering all provinces. Furthermore, CR Pharma with annual sales of over USD 20 billion<sup>1</sup> is one of the largest pharmaceutical companies in China with a broad product portfolio focusing on, among other things, gynaecology and ophthalmology. We therefore see CR Pharma as a good partner in China, also for other products we have under development, particularly Xlucane for which a Letter of Intent regarding potential licensing was signed in December 2017.

### **Sales of Spherotide in Iran advancing**

The sales of Spherotide to our partner in Iran continues according to plan. In 2017, we had annual sales of SEK 20,771 thousand. Spherotide is sold locally by our partner under the brand name Microrelin® and has been well received by doctors and patients. It is too early to comment regarding the sales for 2018 but we plan for and expect sales in line with or just over those of 2017.

### **With target on marketing authorization for Spherotide in Europe and US**

We are now completing the preparations to be able to initiate clinical studies with Spherotide with the target of Marketing Authorisation in Europe and the US. During 2018 we plan to initiate two separate confirmatory

clinical trials with Spherotide 1-month formulation, one in prostate cancer patient and one in endometriosis patients. We have acceptance regarding the design of the studies from regulatory authorities in Europe and the US and the planned study in endometriosis patients will be able to support market authorization also for treatment of breast cancer and uterine fibroids. The studies are estimated to take about a year to complete after which a regulatory process will be initiated to achieve market approval. We have full confidence ahead of these clinical trials as we have demonstrated high similarity compared to the originator in a panel of relevant in-vitro analytical methods as well as in efficacy considering testosterone suppression in minipigs.



References:

<sup>1)</sup> China Resources Pharmaceutical's (CR Pharma) website





»Our greater purpose is making available cost-effective pharmaceutical products to the world's population«

#### **Scale-up of Xlucane to commercial scale successfully completed**

The scale-up process for Xlucane has now been successfully completed. Together with our contract manufacturer BiotechPharma in Lithuania, we have produced three batches at a commercial scale and will produce a further handful of batches during the year in order to generate the full analytical basis to enable initiation of the confirmatory clinical trials with Xlucane on which to base registration. We intend to initiate this study towards the end of 2018 and it is estimated to take about two years to complete, after which a market authorization process will commence in order to obtain market authorization. We have confidence ahead of this clinical study too as we have been able to demonstrate very high similarity compared to the originator drug Lucentis® based on a panel of over 20 in-vitro analytical methods in accordance with requirements from both EMA and FDA.

#### **Portfolio beyond Xlucane and Spherotide**

Xbrane is currently performing a strategic review of its product portfolio with the aim of selecting the product candidates on which the company will focus and invest in as the second wave of products after Xlucane and Spherotide. Xbrane will communicate the results of this strategic review as soon as it is finished and decisions have been taken.

#### **Financial position**

During the fourth quarter of 2017 we increased the rate of investment, particularly in Xlucane, related to commercial scale production, which resulted in research and development expenses during the quarter of SEK 17,531 thousand. We are also expecting higher research and

development expenses during 2018, more in line with the fourth quarter of 2017 than the previous quarters during 2017. At the end of 2017 Xbrane received a credit facility of SEK 50 million from the largest shareholder Serendipity Group. Together with revenues from the out-licensing deal with CR Pharma and expected sales of Spherotide in Iran, this provides us with capital for 2018. In order to subsequently finance the clinical trials for Xlucane and Spherotide, our aim is to out-license the rights, in particular for Europe and the US. We have high confidence in this as a number of companies are in advanced evaluations of the products. Should a financial gap arise for the clinical trials after out-licensing, Xbrane will turn to the capital markets for funding. In order to be able to target institutional investors to a larger extent going forward, we are going through the process of listing the share on Nasdaq's main market. We conducted preparatory work during last year and submitted the application in early 2018.

We are looking forward to an exciting year and are working with full intensity and energy to achieve success with our products and towards our major aim of being able to make cost-effective pharmaceutical products available to the world's population.

Thank you for your continued support,

Martin Åmark  
CEO

# Business concept and objectives

Xbrane develops and manufactures biosimilars and generics of difficult-to-manufacture and often very expensive originator drugs. Xbrane uses unique technology platforms and in-depth knowledge to manufacture biosimilars and generics in which few other developers have been successful. The patented production technology in *E.coli* delivers a significant cost benefit, enabling Xbrane to offer its biosimilar products at a lower cost than the originator drug. For patients that do not have access to the originator drug for cost reasons, Xbrane's lower price point can be crucial in whether the patient can be offered a treatment. Our operation is based on our belief that if there is a treatment, then it should be available for everybody.

## *Vision*

To contribute to global health equality by providing cost-effective alternatives to expensive and difficult-to-manufacture drugs.

## *Business concept*

To develop and manufacture cost-effective biosimilars and generics of difficult-to-manufacture drugs.

## Long-term objectives

### **Xlucane**



Xbrane's objective is to launch Xlucane in 2022 when the patent on the originator drug expires in Europe. Sales of the originator drug are currently estimated to about SEK 28 billion per year in a market with a turnover of more than SEK 76 billion. Xbrane estimates that the value of biosimilar market for originator drug will be above SEK 8 billion, assuming similar penetration and price reduction as for other biosimilars. Xbrane's objective is that, together with its sales and marketing partners, over time take a third of this market and thus achieve peak sales of above SEK 2.5 billion.

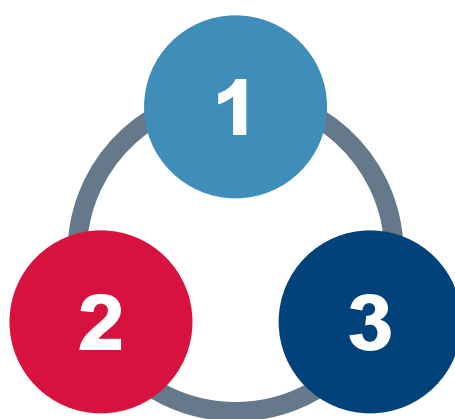
### **Spherotide**



Xbrane's objective is to launch Spherotide in Europe in 2021. Sales of the originator drug are currently estimated to about SEK 4.5 billion per year in a market for GnRH analogues with a turnover of SEK 32 billion. Xbrane's objective is that, together with its sales and marketing partners, as the world's first and only generic, over time achieve peak sales of above SEK 1 billion for Spherotide.

# Strategy

Xbrane's strategy is to develop and manufacture high quality and cost-effective biosimilars and generics based on unique technology platforms and leading expertise. Xbrane is focused on difficult-to-manufacture and niche pharmaceutical products with limited competition from other biosimilar and generic developers. Based on its technology platforms, Xbrane will have a significant competitive advantage in relation to originator drugs and other biosimilar and generics companies by having the lowest production cost within each market.



## Xbrane's strategy is based on three cornerstones

### 1. Leading expertise and unique technology platforms

It is of the utmost importance for Xbrane's long-term success to develop leading expertise within the areas that are critical for development and production of difficult-to-manufacture biosimilars and generics. Critical areas of expertise that Xbrane is establishing are primarily within fermentation, purification and analysis of proteins, development and GMP-production of microsphere products, as well as clinical and regulatory areas of expertise.

We continuously strengthen our technological platforms during the development of our products. We widen our library of internally developed cell lines, methods for fermentation and purification as well as critical analytical methods. All this is the basis for successful development of high quality and cost-effective biosimilars and generics.

### 2. High quality and cost-effective niche products

Xbrane selects products to develop after a thorough analysis of the sales and profitability potential among different products and also of where the strength in Xbrane's technology platforms can be fully utilised. For Xbrane, this means niche products with limited competition. The focus for the development is to develop products which meet the high level of regulatory requirements for quality at the lowest possible production cost. Xbrane's patented technology constitutes the basis for cost-effective production, but the focus is also on other aspects that affect cost such as fermentation and purification protocol, selection of contract manufacturer and administration system.

### 3. Establish networks of locally strong sales and distribution partners

Xbrane is gradually developing a network of local and regional collaborative partners for sales and marketing of its products. The aim is to use this network to enable launch of the leading product candidates Xlucane and Spherotide as well as additional products over time. It is critical for Xbrane to establish partners that have a strong local presence and that can realise the full sales potential of the respective products in their market.

# Portfolio of product candidates

## Xlucane



Xlucane is a ranibizumab biosimilar (originator drug Lucentis®) which is used in the treatment of age-related macular degeneration (AMD), diabetes-related macular edema (DME), diabetic retinopathy (DME) and retinal vein occlusion (RVO). The originator product generated annual sales during 2017 of USD 28 billion and will lose its patent protection in 2020 in the USA and in 2022 in Western Europe.

Xbrane has completed the development of the production process for Xlucane and has been able to demonstrate a high level of similarity compared with the originator drug on the basis of a panel of over 20 in-vitro analysis methods in accordance with guidelines from EMA and FDA. Xbrane has successfully completed the work of scaling up the production process to a commercial scale together

with its contract manufacturer BiotechPharma in Lithuania. Xbrane has produced two batches on a commercial scale during 2017, and will produce a further handful of batches during 2018. These batches will constitute the basis for an updated in-vitro biosimilarity analysis and also comprise material for the planned confirmatory clinical trial as a basis for registration.

The confirmatory clinical trial as a basis for registration will consist of about 500-600 patients with the wet form of age-related macular degeneration. The primary aim of the study is to evaluate efficacy in terms of sight improvement in Xlucane compared with the originator drug. Xbrane has acceptance for the study design from both EMA and FDA and the study will also be able to provide approval for Xlucane within the additional indications for which the originator drug is approved; diabetes-related macular edema, diabetic retinopathy (DME) and retinal vein occlusion (RVO).

Xbrane currently has a partner to bring Xlucane to market in Iran (Helvetic Biopharma, fellow subsidiary to Pooyesh Darou). A number of pharmaceuticals companies are conducting a detailed evaluation of the product, including CR Pharma, with which a memorandum of understanding was signed in Q4 2017 for the Chinese market. Xbrane's objective is to sign contracts with at least one additional marketing partner before the clinical study is initiated and to thus be able to completely or partially finance the study.





## Spherotide



Spherotide is a long-acting injectable with the active substance triptorelin. It is used principally in the treatment of prostate cancer, breast cancer, endometriosis and myoma. The drug is based on encapsulation of the active substance in biological degradable microspheres which are broken down in the body after injection, creating a long-acting effect. Spherotide is the world's first generic of long-acting triptorelin (originator drug Decapeptyl®/Pamorelin®/Trelstar®), which has an annual sales of about SEK 4.5 billion.

The focus during 2017 has been on preparations for confirmatory clinical trials as a base for registration for Europe and US for 1-month formulation. Xbrane intends to initiate two confirmatory clinical trials during 2018, one in prostate cancer patients and one in endometriosis patients. Both constitute the basis for registration and the one for endometriosis patients will also be able to provide approval for the additional indications for which the originator drug is used in women; myoma and breast cancer. The studies

will comprise about 200 and 150 patients respectively, and the aim is to evaluate the efficacy of Spherotide, in terms of hormone suppression levels in the patients after treatment, in comparison with the originator drug. In addition, Xbrane is in the final stage of development of Spherotide 3-month formulation, after which the production process will be scaled up in the same production facility where the 1-month formulation is produced. A confirmatory clinical trial in prostate cancer patients as a base for registration will subsequently be conducted. Xbrane also plans to develop a 6-month formulation, however, as a patent which protects the original manufacturer until 2028 is expected to be approved shortly, the development will be initiated when the development of the 3-month formulation is completed.

Xbrane currently has commercial partners for Spherotide in China (CR Pharma), South Korea (BL&H), Israel (Bio-avenir) and Iran (Pooyesh Darou). Spherotide received market approval in Iran in July 2017 through its local partner under the Microrelin® brand. During 2017 Xbrane generated sales of SEK 20,771 thousand from its partner in Iran. Market approval in China and Israel will be based on the EU-approved product, while market approval in South Korea may be obtained in parallel with the approval process in the EU. Achieving market approval for Spherotide in China also requires local clinical trials which will be conducted and financed by Xbrane's partner in China.

A couple of large pharmaceutical companies are currently conducting an evaluation of Spherotide, primarily for Europe, which is the largest potential market for the product. The aim is to be able to finance the clinical programme with royalties from the commercial partners.



# The market for biosimilars

## What are Biological drugs?

Biological drugs are highly-effective protein drugs produced in living cells. With the advent of recombinant DNA technology in the late 1970s, biologics emerged as a new source of medicines. Since then biological drugs have revolutionized the treatment of serious disease such as diabetes, multiple sclerosis, cancer, and more recently, also arthritis, skin and eye diseases.

The size and complexity of the proteins which constitute active pharmaceutical ingredients (APIs) in biological drugs is much higher compared with ordinary small molecules which are produced through chemical synthesis. A small molecule, such as Aspirin, has a weight of 180 Daltons compared with ranibizumab, the active pharmaceutical ingredient in Lucentis®, which has a mass of

48,000 Daltons.

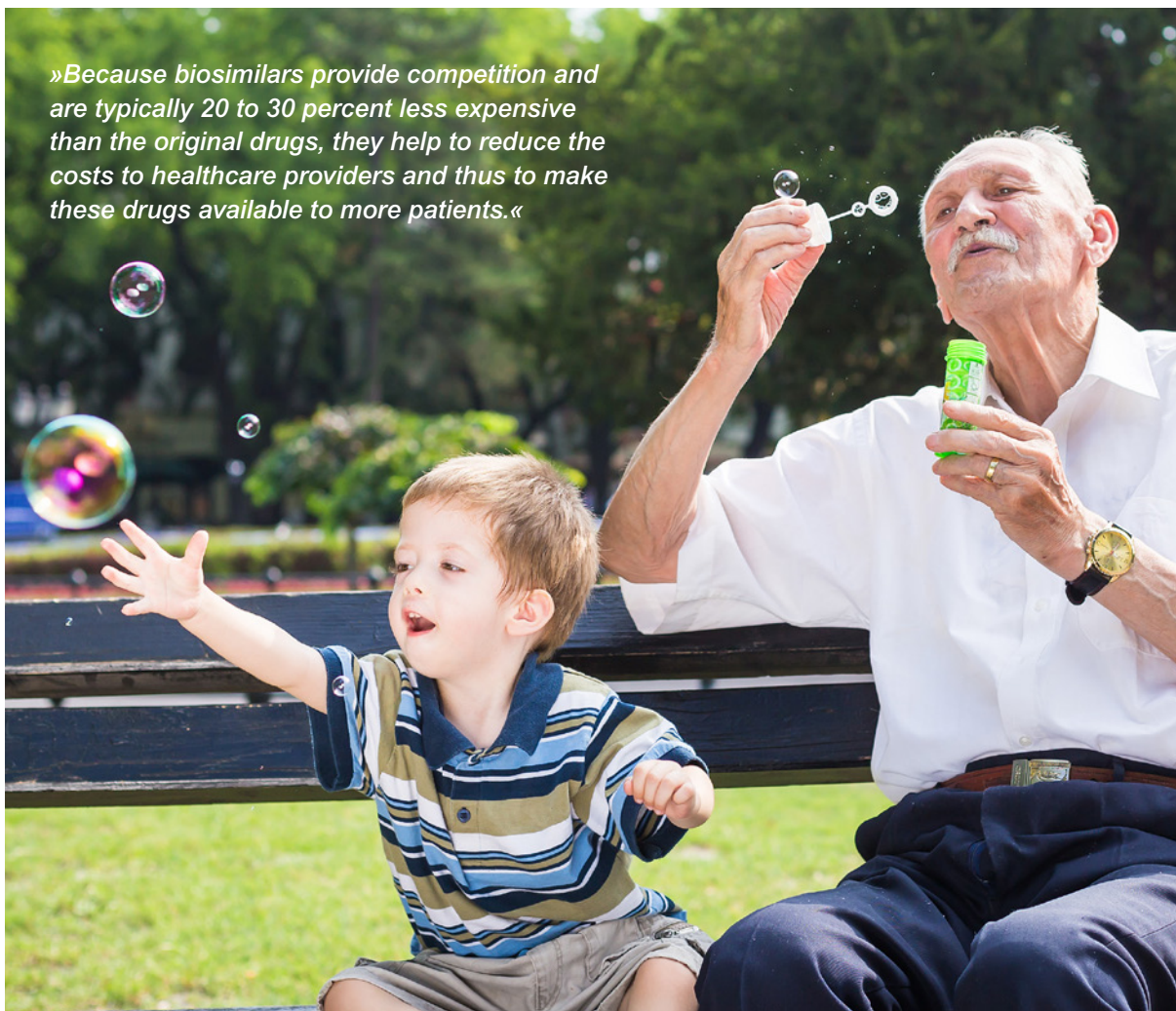
## What are Biosimilars?

Biosimilars are approved pharmaceuticals that are similar to a biological reference product in terms of quality, safety and efficacy. They are approved in highly regulated markets such as the EU and the US via stringent regulatory pathways following loss of exclusivity of their originator reference products. Development of biosimilars requires deep expertise in protein expression, purification, analytics as well as clinical and regulatory aspects.

## Development and manufacturing of Biosimilars

Because of the size, the structural complexity, and the living cell systems they are derived from, the development and production of biosimilars demand a great deal of

*»Because biosimilars provide competition and are typically 20 to 30 percent less expensive than the original drugs, they help to reduce the costs to healthcare providers and thus to make these drugs available to more patients.«*



time, effort and expertise. The reverse engineering of these drugs is made even more difficult because of the natural variations which occur in these biological molecules. The essential principle in the development of any biosimilar drug is similarity with the established reference drug. To achieve this threshold, the producer of the biosimilar must ensure that the drug quality, safety and efficacy are comparable to the biological reference product. A small molecule can be characterized and compared in-vitro with the original molecule and shown to be an exact copy. This is not the case for proteins where different analytical methods have to be used to characterize the protein and demonstrate a high a likeness, or biosimilarity, compared with the originator drug as possible. The time it takes to complete the development of a biosimilar is, on average, six to seven years. Because of the great challenges involved in developing and producing biosimilars, there are only a very limited number of companies in the world with the know-how and capabilities to develop and produce these new-generation drugs, particularly if it comes to meet the strict regulatory standards in Europe and in US.

### Regulatory approval of Biosimilars

While the European Union began to lay out the regulatory approval process for biosimilars already in 2004/2005, the governing framework the United States has only been in place since late 2010. The first biosimilar has been

approved in the EU in 2006, whereas it took nine more years until the US approved the first biosimilar in 2015. Biosimilar drugs require a far greater investment of time and effort to gain regulatory approval than conventional generic drugs. To attain regulatory approval, the producer of the biosimilar must demonstrate similar quality, safety and efficacy, of the biosimilar and the original biopharmaceutical. This is proven by intensive analytical testing and clinical studies.

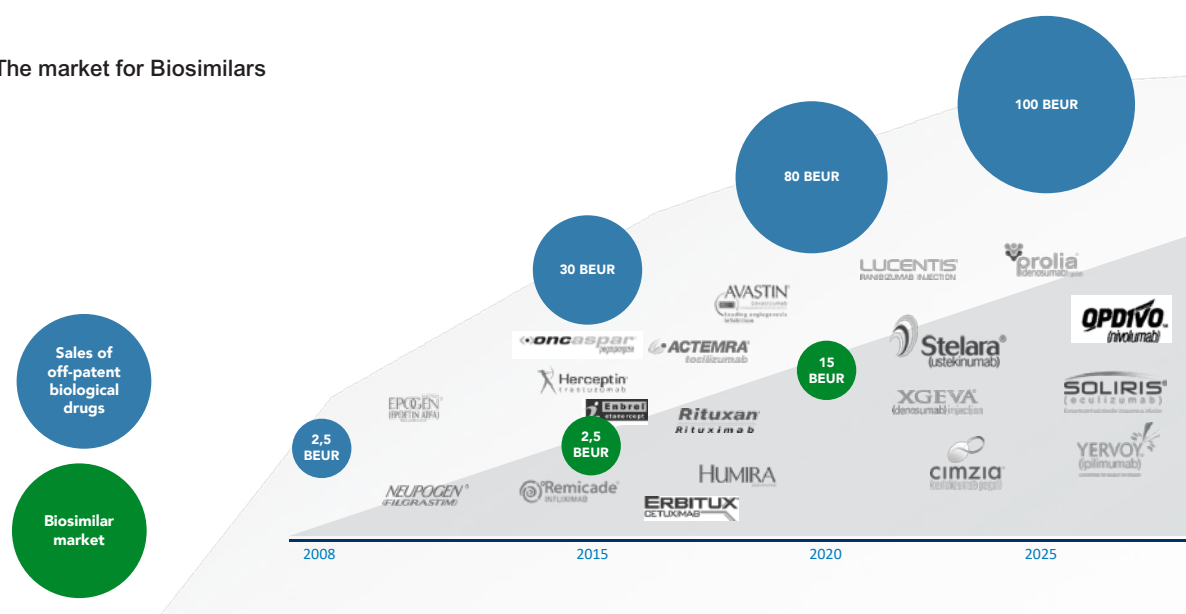
### The market for Biosimilars

While biopharmaceuticals are remarkably effective at treating serious diseases, they are at the same time often very costly, posing a financial burden for the healthcare systems even of wealthy developed countries. Because biosimilars provide competition and are typically 20-30 percent less expensive than the original drugs, they help to reduce the costs to healthcare providers and thus to make these drugs available to more patients. We estimate that, by the year 2025, biological drugs with combined annual revenue of some EUR 100 billion will have lost their patent protection. The global market for biosimilar drugs, is estimated to approximately SEK 47 billion for 2017<sup>1</sup>, therefore has a significant growth potential coming years.

#### References:

1) Biosimilars: Global Markets, April 2018, BCC Research

### The market for Biosimilars





## The market for VEGF-inhibitors for treatment of eye diseases

The macula, is the central area of the retina where we have our detailed and contrast vision. Changes in the retina are called macular degeneration and produce a gradual loss of central vision. The most common cause is age-related and the condition is then called age-related macular degeneration and is, after cataracts, the most common cause of impaired vision in people over 70 years of age. There are two different forms of age-related macular degeneration, dry and wet. The wet form arises when defective blood vessels are formed beneath the retina. These blood vessels bleed and leak liquid, which causes swelling and leads to significant loss of vision and image distortion. If it is not treated in time, a scar forms underneath the retina and there is a risk of losing the central vision including detailed vision. The principal treatment for wet age-related macular degeneration is so-called VEGF inhibitors, which are injected into the eye's vitreous body where they can prevent scar formation and preserve or improve vision. VEGF inhibitors are also used in treatment of a number of other eye diseases, diabetes-related macular edema, diabetic retinopathy and retinal vein occlusion with the same mechanism. The VEGF inhibitors approved for treatment of these eye diseases is Lucentis® and Eylea®. They are usually administered 6-12 times per year for a couple of years, and in Europe the cost on average is approximately SEK 8,000 per dose.

The prevalence of age-related macular degeneration globally is around 170 million<sup>1</sup>, 10-20%<sup>2</sup> of whom have the wet form which can be treated with VEGF inhibitors. Of the approximately 285 million people who suffer from diabetes globally, it is estimated that about 10% suffer from

vision impairing diabetic retinopathy or diabetes-related macular edema<sup>3</sup>. The prevalence of retinal vein occlusion is estimated at about 0.5% of the global population<sup>4</sup>. There are consequently large patient populations suffering from impaired vision as a result of the different illnesses. During 2017 the approved VEGF inhibitors for treatment of eye diseases generated global sales of about SEK 76 billion, of which Lucentis® accounted for about SEK 28 billion<sup>5,6</sup> and Eylea® about SEK 48 billion<sup>7</sup>. In addition to this, the drug Avastin®, a VEGF inhibitor approved for treatment of certain cancer indications, is used "off-label" in certain regions. Overall, Xbrane estimates that 10-15 million doses of VEGF inhibitor are administered globally per year, equivalent to 1.5-2.5 million patients. It is thus clear that many patients suffering from impaired vision as a result of the illnesses are not being treated, primarily in developing countries. General awareness surrounding the diseases, as well as the number of eye clinics and ophthalmologists per capita, play a role, but it is primarily the high cost of the originator drugs that is preventing large patient populations from benefiting from this effective treatment.

The patent for Lucentis® expires in 2020 in the USA and 2022 in the bulk of Europe, after which the market for biosimilars will open up. Xbrane estimates that the value of biosimilar market for originator drug Lucentis® will be above SEK 8 billion provided that the penetration and price reduction compared with the originator drug develops in line with biosimilars of other products such as Filgrastim, human growth hormone and EPO. In addition to this, there might be potential for lower priced biosimilars of Lucentis® to take market shares of "off-label" use of Avastin® and Eylea®.

### References:

- 1) Epidemiology of age-related macular degeneration (AMD): associations with cardiovascular disease phenotypes and lipid factors  
Katie L. Pennington and Margaret M. DeAngelis
- 2) Antiangiogenic drugs in the management of ocular diseases: Focus on anti-vascular endothelial growth factor Yukio Sassa and Yasuaki Hata
- 3) Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss Ryan Lee, Tien Y. Wong, and Charumathi Sabanayagam
- 4) The prevalence of retinal vein occlusion: pooled data from population studies from the United States, Europe, Asia, and Australia. Rogers S1, McIntosh RL, Cheung N, Lim L, Wang JJ, Mitchell P, Kowalski JW, Nguyen H, Wong TY; International Eye Disease Consortium.
- 5) Novartis Annual Report 2017
- 6) Roche Annual report 2017
- 7) Regeneron Annual report 2017

### Facts:

**Disease:** Eye diseases; age-related macular degeneration (the wet form) (Wet AMD), diabetes-related macular edema, diabetic retinopathy (DME) and retinal vein occlusion (RVO)

**Prevalence:** 85-120 million patients

**Patients treated:** 1.5-2.5 million patients

**VEGFa-inhibitor market 2017:** SEK 76 billion

**Potential ranibizumab biosimilar market:** Over SEK 8 billion



»Xbrane estimates that a biosimilar market for the originator drug will be created of over SEK 8 billion«



## GnRH analogues for treatment of prostate cancer, endometriosis, myoma and breast cancer

GnRH analogues are hormone inhibiting drugs which reduce the production of the sex hormone in the body, testosterone in men, oestrogen in women. GnRH analogues are principally used in men for treatment of prostate cancer and in women for treatment of endometriosis, breast cancer and myoma. Certain types of prostate cancer and breast cancer have proven to be hormone-dependent, i.e. the cancer grows and spreads depending on supply of testosterone and oestrogen respectively. It

is therefore accepted medical practice in these situations to prescribe GnRH analogues which reduce the production of sex hormones. Endometriosis is essentially the endometrium growing outside the uterus and myomas are fibroids which grow inside or outside the womb. Both conditions lead to severe pain in connection with menstruation and the symptoms can be alleviated through treatment with GnRH analogues. The principal approved GnRH analogues with formulation for long-acting effect are goserelin (originator drug Zoladex®), leuprolide (originator drug Lupron®) and triptorelin (originator drug Decapeptyl®/Pamorelin®/Trelstar®). The drugs are usually administered through injections 2-12 times per year over a period of 4-5 years for cancer patients and over a couple of months for patients with endometriosis and myoma.

Overall, prostate and breast cancer respectively are the most common cancer diseases. The prevalence of prostate cancer is estimated at about 3.8 million men globally and for breast cancer about 6.2 million women globally<sup>1</sup>. The prevalence of endometriosis is estimated to be about 1% of the global female population<sup>2</sup> and for myoma to be 5-10% in women prior to menopause<sup>3</sup>. The market for GnRH analogues is estimated too be about SEK 32 billion during 2017, of which drugs with triptorelin as active ingredient are estimated to have turned over about SEK 4.5 billion. For the whole market as a total this is estimated to correspond to treatment of about 2.5-3 million patients, as the approximate cost per month is roughly SEK 1,000.

Spherotide is the world's first generic of long-acting formulation with triptorelin (originator drug Decapeptyl®/Pamorelin®/Trelstar®) Xbrane estimates that a generic market for long-acting triptorelin is SEK 1 billion assuming generic penetration in conformity with the global average and a price reduction compared with the originator in accordance with similar situations with one or a small number of active generics competitors.

### References:

- 1) International agency for research on cancer, WHO
- 2) Epidemiology of endometriosis: a large population – based database study from a healthcare provider with 2 million members, VH Eisenberg/IC Weill/G Chodick/V Shalev.
- 3) Epidemiology of uterine fibroids: a systematic review EA Stewart/CL Cooks RA Gandolfo/R Schulze Rath.



*»Xbrane estimates that a generics market for the original drug will be created of over SEK 1 billion«*

### Facts:

**Disease:** Prostate cancer, breast cancer and other diseases which affect women such as endometriosis and myoma.

**Prevalence:** 10 million patients (prostate and breast cancer)

**Patients treated:** 2.5-3 million patients

**Market for GnRH-analogue 2017:** SEK 32 billion

**Potential market for generic long-acting triptorelin:** SEK 1 billion

# Partners



Xbrane's strategy is to out-license its products to the primary markets before clinical trials are commenced. Discussions and negotiations are currently ongoing with potential partners in relation to out-licensing the rights to distribute and market Xlucane and Spherotide in the EU and North America. Xbrane has out-licensed its products to the following partners.

**CR Pharma (China Resource Pharmaceutical)**

Spherotide in China. Sales start after conducted clinical trials and market approval.

[crpharm.com](http://crpharm.com)

**Pooyesh Darou**

Spherotide in Iran. Spherotide has been sold in Iran since 2017.

[pooyeshdarou.com](http://pooyeshdarou.com)

**Helvetic Biopharma**

Xlucane in Iran. Sales start after local clinical trials and market approval.

[helveticbio.com](http://helveticbio.com)

**BL&H Co.Ltd.**

Spherotide in South Korea. Preparation for application of market approval is ongoing.

[blnh.co.kr](http://blnh.co.kr)

**Bioavenir**

Spherotide in Israel. Sales start after conducted clinical trials and market approval.

[bioavenir.com](http://bioavenir.com)

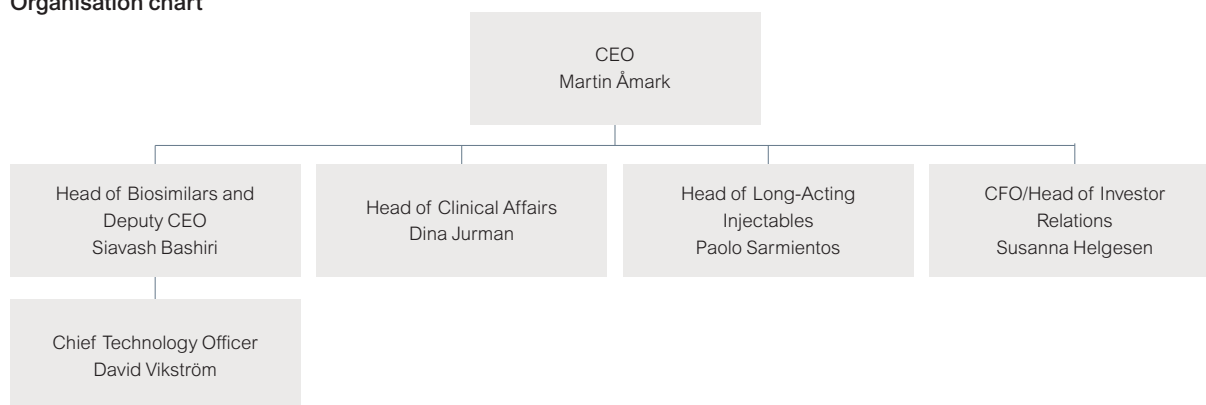


*»Xbrane's strategy is to out-license its products to the primary markets before clinical studies are commenced«*



# Organisation and employees

## Organisation chart



Xbrane is a knowledge-intensive company and its employees constitute its most important asset and the key to the company's success. As a growth company within biotech, Xbrane is characterised by innovation and entrepreneurship.

Xbrane had 20 employees on the balance sheet date, 16 at the head quarter and research laboratory in Solna, and four employees in the Italian subsidiary in Milan. Xbrane has a diverse range of employees in the form of over 10 nationalities and languages, cultures and skills which extend over a number of areas within research and development and production engineering.

Despite the fact that Xbrane is a small company in terms of number of employees, the company has developed a structure where the skills that are critical to the company are to be found among its employees. For other support functions such as regulatory advice, contract manufacturing etc, the company has chosen to engage external consultants and collaborative partners, with the aim of ensuring access to supplementary expertise, and in order to minimise costs and maintain the desired level of flexibility. Such an organisational structure enables resources to be allocated as needed and also that the right expertise can be brought in at the right time.







# 11%

The company's employees own a total of 11% of Xbrane's outstanding shares

Just below half the Group's employees were women in 2017 and the management comprised of 29% women.

Xbrane's working method is results-oriented with annual targets that the employees work towards. Individual targets are set in relation to the Group's overall targets and reviewed annually. Creating targets for both the company and employees, establishes an environment where our employees sense that job satisfaction, involvement and personal development are a priority.

There is a training plan for each employee where the aim is ongoing development to ensure that the company has the expertise required for each task. All employees undergo a company-wide training program. This program

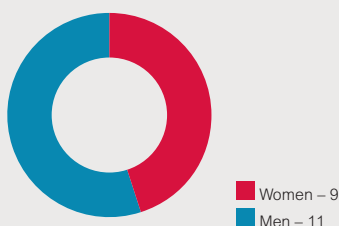
includes a general orientation in the company's operations and processes, rules and regulations, quality system and security-related issues.

#### Shareholding and share savings program

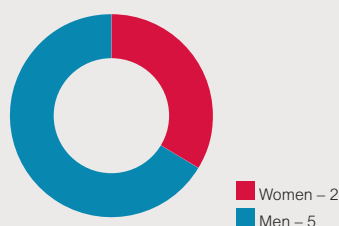
60 per cent of the employees participated in the company's share savings program, LTIP 2017, which was launched in 2017 with a total subscription rate of 25%. Further information about the share savings program is available in the administration report as well as in note 5.

A majority of the company's employees owns shares in Xbrane and in total the company's employees owned about 11 per cent of the company's outstanding shares on the publication date of this annual report.

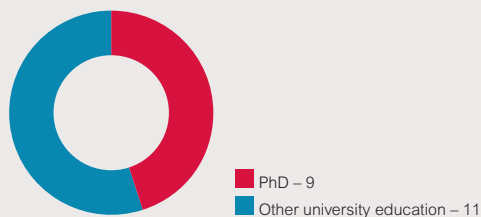
Gender distribution employees



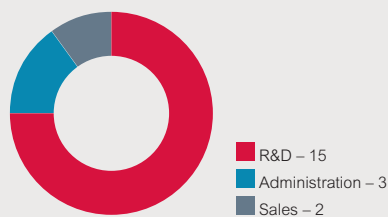
Gender distribution management



Educational level



Personnel distribution



# Departing Chairman of the Board's comments

Dear shareholder,



I was one of the founders of Xbrane Biopharma in 2008 together with world-leading researchers from Stockholm University. The basis for the company was a unique technology for production of proteins in *E.coli* host cells. Xbrane's first

year entailed establishing this technological platform, protecting it via patents and establishing critical expertise and knowledge within the organisation. This was achieved through close collaboration with leading companies within production of proteins and enzymes, where Xbrane's technology could be applied. We then came in contact with the market for biosimilars. The patents for the first really major biological drugs, Filgrastim, EPO and human growth hormone, which had proteins as active components, had expired and a number of so called biosimilars had come onto the market. We realised that this was a large and attractive market opportunity and during 2014 Xbrane consequently made a strategic shift to focusing on development of our own biosimilars.

Since then the company has developed well. Subsequent to its listing on Nasdaq First North, Spherotide has been launched together with our partner in the Middle East,

generating sales during 2017 of SEK 21 million. We have driven the development of both Spherotide and Xlucane forward and are in the final stage of the pre-clinical work to enable initiation of the confirmatory clinical trials of the respective products and market approval to be obtained in Europe and in the USA. The company is also currently developing a network of sales and marketing partners throughout the world, most recently through a deal with the leading pharmaceuticals distributor, CR Pharma, in China.

In this phase of the company's development, I feel that the time is right to hand over the baton as Chairman of the Board for the company to a person with solid experience of the pharmaceuticals industry. Anders Tullgren has the experience and background and I am convinced that he is the right person for this position. I am therefore delighted that the Extraordinary General Meeting on 3 April 2018 elected Anders as Chairman of the Board. I thereby thank you shareholders for entrusting me up to now and welcome Anders to the company.

Saeid Esmaeilzadeh  
Board member (former Chairman of the Board)

# Incoming Chairman of the Board's comments

Dear shareholder,



I would like to start by thanking you shareholders to entrusting me in connection with my election as Chairman of the Board for Xbrane on 3 April 2018.

I am convinced that Xbrane has an important

role to play within the global pharmaceuticals industry in the future. I have worked internationally for over 30 years with development, sales and marketing of several biological drugs within specialised healthcare. It is within this segment that the majority of research and development takes place and most new innovative products are launched. In recent years I have personally been responsible for the launch of Opdivo® on numerous markets and the revolution within the cancer treatment to which Opdivo®, the leading biological immuno-oncology drug, has contributed to. Biosimilars are going to be very important for healthcare in the future to ensure cost-effective supply of these revolutionary biological drugs to more patients globally.

However, biosimilars are very difficult to develop and manufacture and there are only a limited number of companies globally that possess the technology and expertise that is required. This means that an attractive niche is created for those companies which possess this unique

expertise. A global development consisting of only a small number of biosimilars per blockbuster originator drug creates highly attractive business opportunities. Thus far the prices for biosimilars in Europe have been an average of 20-30% below the respective originator drug, which should ensure good margins in the future too. Moreover, the risk in the clinical trials is significantly lower than clinical phase III trials of completely new drugs, as biosimilars are based on molecules which effect, and safety in humans has already been demonstrated.

Xbrane's technological platform and expertise makes it one of the rare companies in the world which can position itself extremely well in this rapidly growing segment of the global drugs market. I am looking forward to accelerating the development of the company and, together with the team at Xbrane, being involved in building one of the world's leading biosimilar companies. The focus areas I perceive going forward are in line with those the company is already working towards, getting the two leading products, Xlucane and Spherotide, through confirmatory clinical studies towards market approval in Europe and in US, and accelerating the development work on the company's next wave of biosimilars.

Thank you for entrusting me,

Anders Tullgren  
Chairman of the Board

# Board of Directors



## Anders Tullgren

Chairman of the Board since 2018.

**Born:** 1961

**Education:** M. Sc. in Pharmaceutical Science. Over 30 years' experience of the global pharmaceutical industry in leadership roles in the US, Germany, France, the UK and the Nordic region. Most recently as President of the Intercontinental Region at Bristol Myers Squibb with responsibility for over 30 countries, 5,000 employees and a turnover of over 20 billion SEK.

**Other assignments:** Chairman of the Board of Trialbee AB and board member of BrandingScience Ltd.

**Previous assignments:** President of the Intercontinental Region, Bristol Myers Squibb.

**Shares:** 32,857

**Warrants:** 49,285

Independent in relation to major shareholders



## Saeid Esmaeilzadeh

Board member since 2018, former Chairman of the Board 2008-2018. Chairman of Remuneration Committee and Transaction Committee.

**Born:** 1974

**Education:** Adj. Prof. in Materials Chemistry PhD from Stockholm University in 2000. Became Sweden's youngest associate professor in 2002. Has received numerous awards and distinctions for his research and initiatives as an entrepreneur.

**Other assignments:** Chairman of the boards of Serendipity Ixora AB and Premune AB. Board member of Diamorph AB, Sdiptech AB, Serendipity Group AB, IRRAS AB, Nextseal AB, Nextmune HoldCo AB, Nextmune MC AB, Nextmune AB and Swecure AB. Deputy board member of Serendipity Invest AB, Serendipity Ventures AB, Serendipity Innovations AB, VZL Vilande AB, S. Professionals AB, Leonova Consulting AB, Swecure Europe AB, Auremune AB, Premune IPR AB, Swecure IPR AB, DynaSeal LCT AB, Decicure AB and Intelligent Art AB.

**Previous assignments:** CEO of Sdiptech AB and Diamorph AB.

**Shares:** 683,305 via company and 43,971 held privately.

**Warrants:** -

Not independent in relation to major shareholders



## Giorgio Chirivi

Board member since 2016.

Member of Audit Committee and Remuneration Committee.

**Born:** 1961

**Education:** M. Sc. in Economics and business administration.

Background within auditing but has worked with investment banking for the last 30 years. Long career as a board member with directorships in over 15 companies during the last 20 years.

**Other assignments:** Head of SMEs Strategic Coverage at UBI Corporate & Investment Banking and board member of Axxam SpA.

**Shares:** 2,000

**Warrants:** 3,000

Independent in relation to major shareholders and the company






**Peter Edman**

Board member since 2015.

Member of Transaction Committee.

**Born:** 1954

**Education:** Ph. D. in Pharmacy and associate professor in biochemistry.

Long experience of drug development with a number of senior research positions within Orexo, Sobi, Biovitrum, AstraZeneca, Astra and Pharmacia. Previously Associate professor at the Swedish Medical Products Agency and Professor at Faculty of Pharmacy, Uppsala University

**Other assignments:** Board member of Mind the Byte, S.L.

**Previous assignments:** Chief Scientific Officer and R&D Manager at Sobi and Orexo.

**Shares:** 7,500

**Warrants:** 2,250

Independent in relation to major shareholders and the company


**Maris Hartmanis**

Board member since 2015.

Member of Remuneration Committee.

**Born:** 1953

**Education:** Ph. D. in Science and associate professor in biochemistry.

Long experience in the Life Science industry with senior positions as CEO and R&D Manager, as well as directorships. Wide ranging experience from small start-ups to large global organisations.

**Other assignments:** Board member of Xspray Pharma, Applied Photophysics Ltd and BioLamina.

**Previous assignments:** CEO of Medivir and BioPhausia, global research manager, Gambro.

**Shares:** 7,500

**Warrants:** 2,250

Independent in relation to major shareholders and the company


**Alessandro Sidoli**

Board member since 2016.

Member of Transaction Committee.

**Born:** 1959

**Education:** M. Sc. in Biology.

Background as biology researcher with involvement and directorships within biochemical industry organisations, and founder of Italian Association of Business Angels for Biotech.

**Other assignments:** CEO of Axxam SpA and IMAX Discovery GmbH, Deputy Chairman of the Board, Italian Angels for Biotech.

**Previous assignments:** Biotechnology manager, Istituto Sieroterapico Milanese as well as founder and CEO of Primm s.r.l.

**Shares:** 76,885

**Warrants:** 3,000

Independent in relation to major shareholders and the company


**Karin Wingstrand**

Board member since 2015.

Member of Audit Committee.

**Born:** 1957

**Education:** M. Sc. in Pharmaceutical Science.

Long and solid experience of the international pharmaceuticals industry with senior positions within regulatory, pharmaceutical and analytical R&D, project management and clinical development.

**Other assignments:** Board member Adenovir Pharma AB, Mevia AB, PULS AB, Swecure AB, T-bolaget AB and Xintela AB

**Previous assignments:** Global Head and Deputy CEO for clinical development, AstraZeneca.

**Shares:** 7,900

**Warrants:** 3,000

Independent in relation to major shareholders and the company

# Management


**Martin Åmark**

CEO since 2015

**Born:** 1980

**Education:** M. Sc. in Industrial Economics as well as an MBA.

**Previous positions:** Background as management consultant at Bain & Co where he was involved for eight years with company acquisitions, strategy and organisational work within various industries including pharmaceuticals and life science.

**Shares:** 111,890

**Warrants:** 24,000

Independent in relation to major shareholders and the company


**Siavash Bashiri**

Head of Biosimilars and Deputy CEO since 2015

**Born:** 1983

**Education:** M. Sc. in Molecular Biotechnology.

**Previous positions:** Experience within international sales of pharmaceutical products at Agilent Technologies as well as various roles within business development and sales at IBM and Oriflame. CEO of Xbrane between 2012 and 2015.

**Shares:** 87,294

**Warrants:** 7,000

Independent in relation to major shareholders and the company


**Susanna Helgesen**

CFO/Head of Investor Relations since 2017

**Born:** 1985

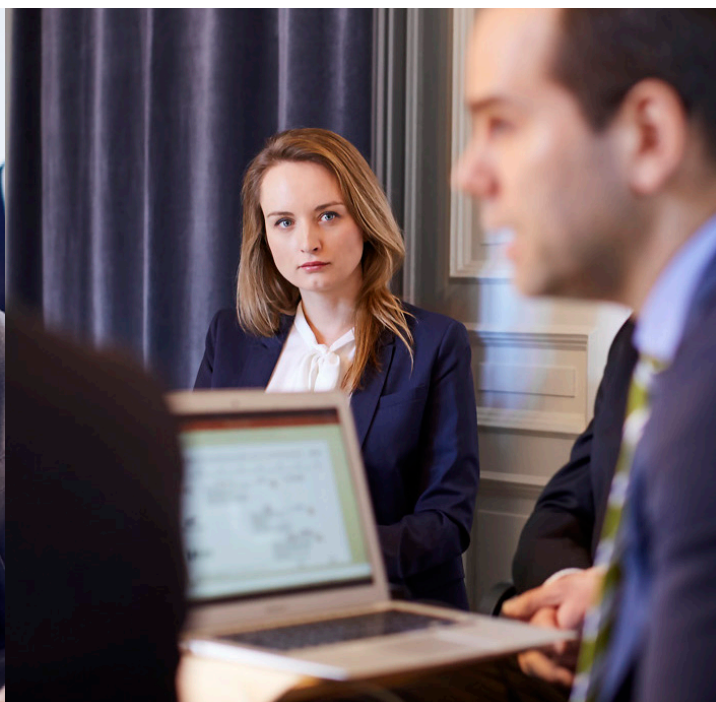
**Education:** M. Sc. in Business Administration.

**Previous positions:** Background within equity research and has different positions within listed global energy companies. Most recently CFO at Dome Energy.

**Shares:** 3,860

**Warrants:** 24,000

Independent in relation to major shareholders and the company



**Paolo Sarmientos**

Head of long-acting injectables since 2015

**Born:** 1957

**Education:** Ph.D. in Bio-organic Chemistry.

**Previous positions:** Over 25 years' experience of senior positions within the pharmaceutical industry including at Pfizer, Genetica and Menarini. CEO and co-founder of Primm S.r.l.

**Shares:** 445,682

**Warrants:** -

Independent in relation to major shareholders and the company

**David Vikström**

CTO since 2014

**Born:** 1977

**Education:** Ph. D. Biochemistry.

**Previous positions:** Almost 15 years' experience of how to manufacture high quality proteins. Research within expression systems for proteins in *E.coli* and has published a number of articles in scientific journals. Has worked in research and development at Xbrane since 2010.

**Shares:** 23,000

**Warrants:** 24,000

Independent in relation to major shareholders and the company

**Dina Jurman**

Head of Clinical Affairs since 2017

**Born:** 1982

**Education:** M. Sc. in Biomedicine.

**Previous positions:** 12 years' experience within the pharmaceutical and biotechnology industries, most recently as Director Clinical Operations at a full service CRO. Possesses all-round experience of clinical trials from start-up companies to global pharmaceutical companies and has worked with protein drugs, small molecules as well as advanced therapies and medical technology.

**Shares:** -

**Warrants:** -

Independent in relation to major shareholders and the company

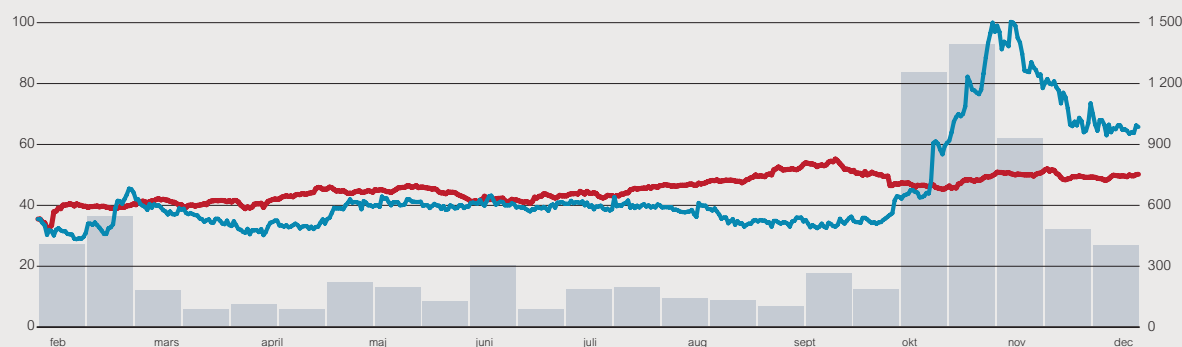
**Carlo Columbo**, Head of Production of Long-Acting Injectables, was part of the management until 28 February 2018. His successor started 9 April 2018 and will not be part of the Management.





# The share and ownership structure

## Share price development



Average value of daily turnover for the Xbrane share on Nasdaq First North in 2016 was SEK 375 thousand and in 2017 SEK 1,484 thousand. The average turnover volume per day was 23,223 shares during 2017.

## General information

The Xbrane share (STO:XBRANE) has been listed on Nasdaq First North Stockholm under the company name Xbrane Biopharma since 3 February 2016. Xbrane's market cap at year-end was SEK 392 million. The share price has increased by 55 per cent since being listed in February 2016. The highest closing price per share during 2017 was SEK 100.25 on 10 October 2017 and the lowest was SEK 32.50 on 12 June 2017.

According to Xbrane's articles of association, as of 31 December 2017, the share capital must constitute a minimum of 500,000 SEK and a maximum of 2,000,000 SEK, distributed over a minimum of 2,200,000 shares and a maximum of 8,800,000 shares.

The company's shares have been issued in accordance with Swedish law and are nominated in SEK. The

shares are fully paid and freely transferable. The company's shares are registered in a CSD register in accordance with the Central Securities Depository and Financial Instruments Accounts Act (1998:1479). The register is kept by Euroclear Sweden AB. No share certificates have been issued for the company's shares.

## Share capital

The total number of outstanding shares in Xbrane amounted to 5,956,770 by the end of the year. The company only has one share class. Each ordinary share gives entitlement to one vote. The increase in the number of shares and votes is due to a new issue of 1,201,224 shares. Share capital by the end of the year amounted to SEK 1,335 thousand, distributed over 5,956,770 shares with a quote value of about SEK 0.2242 per share.

Year	Event	Quote value	Change in number of shares	Total number of shares	Change in share capital	Total share capital
2017	New share issue	0.2242	16500	5,956,770	3,699	1,335,425
2017	Conversion of convertible loan	0.2242	528,986	5,940,270	118,591	1,331,725
2017	New share issue	0.2242	655,738	5,411,284	147,007	1,213,134
2016	Conversion of convertible loan	0.2242	132,232	4,755,546	29,644	1,066,127
2016	Share split 10:1	0.2242	2,393,024	4,623,314	536,483	1,036,483
2015	Bonus issue	-	-	2,230,290	399,100	500,000
2015	Share split 10:1	-	-	2,230,290	-	100,900
2015	New share issue	0.4524	1,989	223,029	900	100,900
2014	Share split 10:1	-	-	221,040	-	100,000
2014	New share issue	4.5241	11,052	22,104	50,000	100,000
2013	Decrease in share capital	-	-	11,052	-355,200	50,000
2013	Decrease in share capital	-	-	11,052	-700,000	405,200
2013	Company foundation	100	9,824	11,052	982,400	1,105,200

## Shareholders

As of 31 December 2017, Xbrane had a total of 2,400 shareholders. The number of outstanding shares amounted to 5,956,770. The ten largest shareholders at the end of the year are presented below<sup>1</sup>.

Name	Number of shares	Capital, %
Serendipity Ixora AB	1,236,022	20.75%
Paolo Sarmientos	303,401	5.09%
Försäkringsaktiebolaget Avanza pension	296,615	4.98%
Nordnet Pensionsförsäkring AB	183,285	3.08%
Active Invest-Sweden AB	170,000	2.85%
Michael Löfman	111,890	1.88%
Martin Åmark	111,800	1.88%
Christer Skogum	110,000	1.85%
Swedbank insurance	86,730	1.46%
Jan-Willem De Gier	84,083	1.41%
<b>10 largest shareholders in total</b>	<b>2,693,826</b>	<b>45.22%</b>
<b>Other shareholders</b>	<b>3,262,944</b>	<b>54.78%</b>
<b>Total outstanding shares</b>	<b>5,956,770</b>	<b>100.00%</b>

### Dividends

The Board of Directors proposes that no dividend be paid for the financial year 2017.

### Equity research analysts

Nordea	Dan Johansson
Jarl Securities	Markus Augustsson

### About the Xbrane share

Listing venue	Nasdaq First North
Number of shares	5,956,770
Market cap 31 December 2017	SEK 392 million
Ticker	XBRANE
ISIN code	SE0007789409

### Investor relations contact

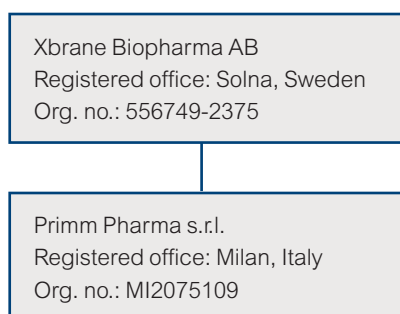
For further information about Xbrane, please visit [xbrane.com](http://xbrane.com) or contact  
Susanna Helgesen, Head of Investor Relations  
+46 708 27 86 36.



1) Modular Finance. Based on complete list of shareholders comprising directly registered and nominee registered shareholders.

# Administration report

The board of directors and CEO of Xbrane Biopharma AB (publ), with Org. no. 556749-2375, hereby submit the Annual Report for the financial year 1 January 2017 to 31 December 2017.



Xbrane owns 100% of Primm Pharma s.r.l..

## Group structure

The Group's structure is described in the above figure, with details of the Group companies' name, registered office and org. no., as well as Xbrane's participating interest in the subsidiary.

## General information about the business

Xbrane Biopharma is a biotechnology company which develops and manufactures biosimilars. The aim of the company is to make difficult-to-manufacture pharmaceuticals available for the global population based on unique technology platforms which enable cost-effective production. Xbrane has a patented protein production platform with up to eight times higher productivity compared with standard systems in *E.coli*, and world-leading expertise within development and production of microsphere-based pharmaceuticals which have a long-acting effect in the body.

Xbrane's leading product candidate within the biosimilar segment is Xlucane. Xlucane is a ranibizumab biosimilar (originator drug Lucentis®) which is used in the treatment of various eye diseases, principally the wet form of age-related macular degeneration. Xbrane's leading product candidate within the segment of long-acting injectables is Spherotide. Spherotide is a long-acting formulation with the active ingredient triptorelin which is used primarily in the treatment of prostate cancer, endometriosis and myoma.

## Significant events during the financial year

### Xlucane

#### *Positive biosimilarity data*

In the beginning of the year Xbrane reported positive biosimilarity data for Xlucane.

### *Production of test batches*

Scaling up production from 20 litres in the company's research laboratory to 300 litres at the company's contract manufacturer, UAB BioTechPharma, in Lithuania commenced during the autumn. The scaling up has proceeded according to plan and a total of three batches have been produced.

### **Spherotide**

#### *Positive comparative in-vivo efficacy data*

Xbrane reported positive comparative in-vivo efficacy data for Spherotide. This is based on a study in mini-pigs and is an important step before initiating clinical trials.

#### *GMP-approval of production facility*

Xbrane received GMP-approval at the beginning of the year for its production facility for Spherotide in Italy from AIFA.

#### *Market approval in Iran*

During the summer Xbrane received market approval for Spherotide in Iran, which is launched under the name of Microrelin®.

### *Revenue*

Xbrane commenced sales of Spherotide during the year and generated revenue of SEK 20,771 thousand, which was in line with the forecast.

#### *Out-licensing to South Korea*

By the end of the year Xbrane entered into an agreement with BL&H for sales and marketing of Spherotide in South Korea.

## **The Group**

### *Changes in management*

Xbrane recruited Susanna Helgesen to the new position as CFO/Head of Investor Relations in May. Dina Jurman was recruited to the new position Head of Clinical Affairs in September. Carlo Colombo, Head of Long-Acting Injectables handed in his resignation by the end of the year. The position was replaced in April 2018, with the new production manager not being part of the Management team.

#### *Applying for listing on Nasdaq OMX's main market*

The Board of Directors decided in September to initiate the work of applying for a listing at Nasdaq OMX's main market during 2018.



### Important events after the end of the financial year

#### *Out-licensing of Spherotide to China*

In the beginning of 2018, Xbrane entered into an out-licensing agreement with China Resource Pharmaceutical (CR Pharma) for sales and marketing of Spherotide in China. The company has also signed a memorandum of understanding with CR Pharma regarding collaboration in relation to Xlucane, and views the company as a solid and long-term partner for the Chinese market.

#### *Election of new chairman of the Board of Directors*

The Extraordinary General Meeting on 3 April 2018 elected Anders Tullgren as Chairman of the Board of Xbrane Biopharma. Anders Tullgren has been employed in the pharmaceutical industry for 30 years with numerous international management assignments within big pharma companies.

#### *Issue av warrants and shares*

Following the decision of the Extraordinary General Meeting on 3 April 2018, the directed issues of shares and warrants presented below were issued:

- 32,857 shares issued at SEK 60.87 per share and 49,285 warrants with maturity in 2021 priced according to Black & Schole's option pricing model to the Chairman of the Board Anders Tullgren.

- A total of 9,000 shares issued at SEK 61.04 per share plus a total of 13,500 warrants with maturity in 2021 priced according to Black & Schole's option pricing model were issued to the following board members: Maris Hartmanis, Peter Edman, Karin Wingstrand, Alessandro Sidoli and Giorgio Chirivi.

- A total of 79,000 warrants with maturity in 2022 priced according to Black & Schole's option pricing model which were issued to the following persons from the management: Martin Åmark, Susanna Helgesen, Siavash Bashiri and David Viklund.

### Environment, ethics and responsibility

Xbrane works actively with corporate responsibility and sustainability issues. These issues comprise areas which

principally relate to ethical questions, environmental and work environment questions, questions of a social character and transparency in relation to the shareholders.

Xbrane's contribution to society lies in offering critical medical treatments for people all over the world at a lower cost than the originator drug. Xbrane thus works to lower the cost for the patient and make existing treatments available to a larger population, something that is of particular importance in developing countries.

Xbrane operates in an industry where ethical and regulatory aspects are of major importance in how the business is configured. The company is consequently continuously engaged in these issues with the objective of always meeting the set requirements by a good margin.

Xbrane's environmental policy is to include environmental considerations as a natural component in the company's operations. Xbrane has both its own manufacturing and contract manufacturing, which means in part that the company is engaged with this internally, and in part evaluates contract manufacturers' and partners' work from an environmental and sustainability perspective.

The company's main suppliers are certified and meet requirements on ethical issues as well as environmental and work environment issues.

Being transparent and giving shareholders and stakeholders full insight into the company has the highest priority for Xbrane. Current and relevant information will consequently always be available on the company's website under Investors Relations. Stakeholders and owners can access complete and reliable information to meet the shareholders' needs, regardless of level of expertise. Communication with shareholders and stakeholders takes place via the website, newsletters and press releases. Xbrane's structured board work ensures that Corporate Responsibility issues are being handled and is on the management's agenda.

## Five year summary

Amounts in SEK thousands	2017	2016	2015	2014	2013
Revenue	20,771	-	-	190	190
Operating result	-44,718	-27,567	-10,348	-2,574	-2,107
Profit for the period	-44,935	-27,769	-10,642	-2,572	-2,107
Balance sheet total	110,960	124,694	76,394	6,689	9,195
Equity ratio	80%	91%	-8%	94%	95%
Earnings per share	-8.28	-6.16	-4.78	-11.60	-9.50

### The Group's result

Since 1 July 2017, Xbrane has changed from K3 to IFRS, and also changed to present the operating expense in the Statement of profit and loss in accordance to function.

#### Revenue

The Group's revenue amounted to SEK 20,771 thousand (0) during the year and relates to revenues from sales of Spherotide.

#### Gross margin

Cost of goods sold amounted to SEK 15,829 thousand (0) and comprises of raw materials, manufacturing costs from the contract manufacturer, leasing costs for production equipment, salaries and depreciation. Both raw materials and manufacturing costs are affected by scale, which means that the gross margin, which amounted to 24% during the period, is expected to increase with increased production.

#### Other income

Other income amounted to SEK 2,515 thousand (4,824) and relates primarily to royalties for protein expression technology and tax relief for the Italian subsidiary.

#### Operating expenses

Selling and distribution expenses arose during 2017 period as the company commenced the sales of Spherotide, amounting to SEK 1,381 thousand (0), primarily for salaries. Administration expenses amounted to SEK 11,567 thousand (8,398), with the increase compared with the previous period primarily relating to an expanded administrative department and costs associated with the company's planned listing on the Nasdaq OMX main market. Research and development expenses amounted to SEK 37,982 thousand (23,858), SEK 27,326 thousand (16,572) of which relate to Xlucane and SEK 10,656 thousand (7,286) relate to Spherotide. The increase that particularly concerns the last quarter of the year, is due to the fact that the development of Xlucane is proceeding and being intensified. In particular it is the cost of producing test batches at the contract manufacturer in Lithuania and preparations for clinical trials that are contributing to increased costs. All development costs are expensed. Other operating expenses amounted to SEK 1,245 thousand (135), primarily comprising exchange losses on trade receivables and payables.

#### Operating profit

The Group's operating profit amounted to SEK -44,718 (-27,567) thousand.

#### Financial items

Financial items amounted to SEK -217 (-202) thousand. Finance income was marginal, amounting to SEK 0 thousand (3). Finance expenses amounted to SEK -217 thousand (-205), primarily comprising interest charges for leases and credit facility.

#### Profit for the year

Profit for the year amounted to -44,935 SEK (-27,769) thousand.

#### Other comprehensive income

Comprehensive income for the year amounted to SEK 2,218 (2,786) and relates to translation difference of foreign operations.

#### Cash flow

Cash flow from operating activities amounted to SEK -36,848 thousand (-39,143). Cash flow from investing activities amounted to SEK -3,347 thousand (-12,766), principally comprising investments in property, plant and equipment, amounting to SEK -3,347 thousand (-8,899). Cash flow from financing activities amounted to SEK 16,728 thousand (80,529) and relates to share issues which raised a total of SEK 20,004 thousand (101,770) before transaction costs, as well amortization of leasing debt of SEK -257 thousand (-305).

#### Financial position

The Group's cash and cash equivalents at the end of the period amounted to SEK 7,903 thousand (31,338). Existing cash and cash equivalents, working capital and estimated revenues and existing credit facility of SEK 50 million are expected to finance the Group's ongoing operations for the next 12 months. A larger amount of capital is required for the planned development of the company's research and development project, which can either be financed through milestone payments from out-licensing to partners, through loans or through equity. The management is actively evaluating different financing options.

#### Equity ratio

The equity ratio amounted to 80 (91) percent.

#### Intangible assets

Intangible assets amounted to SEK 6,297 thousand (6,869) and consist of capitalized development expenditure. No development expenditure has been capitalized during 2017.

#### Changes in equity

A share issue directed to four investors took place during the second quarter, with Carnegie Investment Bank AB acting as financial adviser. The subscription price amounted to SEK 30.50 per share, which represents a dis-

count of 7.5 per cent to the closing price on 23 May. The share issue generated SEK 20,004 thousand and issue expenses amounted to SEK 3,019 thousand. The number of outstanding shares increased by 655,738.

During the second quarter, SEK 22,482 thousand of the outstanding convertible loan was converted to shares, which increased the number of outstanding shares by 528,986. This did not affect equity or cash flow, apart from minor transaction costs.

A share issue directed to certain employees was conducted during the third quarter at quote value as a part of previous year's incentive program. This increased the number of outstanding shares by 16,500 and had a marginally adverse impact on equity as transaction costs exceeded the payment for the shares, which amounted to SEK 4 thousand.

### **The Parent Company's result**

#### *Revenue*

The Parent Company, whose operations solely comprise biosimilars with the leading product candidate, Xlucane, has reported no revenue or costs for goods sold during the period.

#### *Other income*

Other income amounted to SEK 838 thousand (3,270) and relates to royalties for protein expression technology.

#### *Operating expenses*

The Parent Company has no selling and distribution expenses. Administration expenses amounted to SEK 9,841 thousand (7,291), with the increase compared with the previous period primarily relates to an expanded administrative department and costs associated with the company's planned listing on the Nasdaq OMX main market. Research and development expenses amounted to SEK 27,326 thousand (16,572). The increase that particularly concerns the last quarter of the year, is due to the fact that the development of Xlucane is proceeding and being intensified. In particular it is the cost of producing test batches at the contract manufacturer in Lithuania and preparations for clinical trials that are contributing to increased costs. All development costs are expensed. Other operating expenses amounted to SEK 1,169 thousand (135) and primarily refers to exchange losses on trade receivables and payables.

#### *Operating profit*

The Parent Company's operating profit amounted to SEK -37,498 thousand (-20,727).

#### *Financial items*

Financial items amounted to SEK -56 thousand (-64).

Finance income was marginal, amounting to SEK 0 thousand (1). Finance expenses amounted to SEK -56 thousand (-64), and consist of interest for the credit facility.

#### *Profit for the year*

Profit for the year amounted to SEK -37,553 thousand (-20,791).

### **Risks, uncertainty factors and risk management**

If any of the risks described below were to materialise, it could entail extensive adverse effects to the Group's operations, earnings, financial position and prospects.

#### *Clinical trials*

Xbrane plans to initiate confirmatory clinical trials for Xlucane and Spherotide respectively during 2018, which will constitute the basis for regulatory approval of the products. The clinical studies have the aim of confirming similar efficacy and safety with the products compared with the respective originator drug. The pre-clinical data for both Spherotide and Xlucane provides a high level of comfort for these studies.

Based on a panel with a large number of analytical methods, Xlucane has demonstrated a very high similarity with the originator drug. Xlucane has demonstrated identical primary structure (amino acid sequence), no differences have been identified in higher structure, as well as very high similarity in functionality and purity. The functionality is of particular importance where the binding capacity for the growth factor VEGF is measured in-vitro. As this is the mechanism of action in the drug, the high similarity in the functionality of Xlucane compared with the originator drug provides additional reassurance. The principal aim of the clinical trial is to confirm that Xlucane has the same effect in terms of improving the vision of patients as the originator drug. The clinical trial will have a statistical power of 90%.

Spherotide has an identical active substance as the originator drug, the peptide triptorelin, which Xbrane procures from a leading European manufacturer. The microspheres in which Xbrane encapsulates the active ingredient has in-vitro demonstrated very high similarity in its release pattern, size and structure compared with the originator drug. Further, Spherotide has demonstrated similar suppression of testosterone production as the originator drug in minipigs. This is also the primary objective of the clinical trials, to demonstrate similar suppression of testosterone production as the originator drug, though in human beings. The clinical trials will have a statistical power of 90%.

Xbrane is working actively to minimise the risk in the clinical studies. This is done principally through ensuring as high a similarity as possible in its products compared with



the originator drugs through a large number of in-vitro analytical methods as well as in-vivo studies. In addition to this, Xbrane is conducting a close dialogue with the regulatory authorities in order to ensure that the studies include all aspects required to achieve regulatory approval. Xbrane is also working actively to ensure the quality of the service providers that Xbrane selects to work with, including that of the clinicians involved in the clinical studies.

#### *Regulatory authorization*

To be able to market and sell products, authorization must be obtained from the authority responsible in the respective country. Xbrane cannot guarantee that such regulatory authorization will be received to the extent required to enable future objectives to be achieved. Xbrane's objective is to be able to submit the application for marketing authorization approval in Europe and the US during 2021 for Xlucane and 2020 for Spherotide. Xbrane is working actively on risk mitigation through having a close and ongoing dialogue with the most important authorities, for example, FDA (USA), EMA/BfArM/MHRA (Europe), CFDA (China) and PMDA (Japan). Further, Xbrane is working with prominent regulatory consultants to ensure development in accordance with current guidelines.

#### *Collaborative partners*

The Group is dependent on, and will continue to be dependent on, collaborations with a range of partners in order to produce, market and sell its current product candidates and develop product candidates for the future. The Group's business is thus largely dependent on external partners. If these partners do not fulfil their obligations as agreed, do not meet expected deadlines, or if there is inadequate quality or precision in the work performed, ongoing and planned sales activities and product development can be adversely affected. The principal collaborative partners with which Xbrane works are contract manufacturers, specifically Biotechpharma for Xlucane and ICI for Spherotide, service providers within analysis, in-vivo studies, regulatory consultancies and clinical studies, as well as sales and marketing partners. The risk exposure is greatest in relation to collaborative partners, which are expensive and time consuming to replace, e.g. contract manufacturers and sales and marketing partners. Xbrane is working actively on risk mitigation in relation to these partners. For example, for ICI, which is undergoing a reconstruction process, Xbrane took the necessary measures at an early stage in order to minimize the effect of commercial production of Spherotide in the event of potential bankruptcy proceedings. Xbrane has expanded its inventory to 12 months and is in active dialogue with ICI, lenders and legal advisers to resolve the situation and be able to continue production with no significant disruption.

#### *Delay of product launch*

Delays in the development programs can lead to delays in launching product candidates which in turn can have an adverse impact on their sales potential and the possibility of entering into sales and marketing agreements with potential partners. The development programs are currently running according to plan and the risk of potential delays is thus greatest during the next phase, the confirmatory clinical trials.

#### *Sales-related risk*

It is difficult to foresee the market's acceptance of a new product. Even if market approval is obtained, a partner for sales and marketing is established and a competitive price set, there is no guarantee of successful sales. Aspects which can lead to the sales not achieving the objectives set are development of the competitive situation, potential new drugs with superior effect and/or safety profile coming into the market, or other changes in the treatment strategy for the illnesses against which the drugs are used.

#### *Financing risk*

The Group has needed, and will also continue to need, extensive capital to pursue research, development and commercialization of the Group's existing and future product candidates. Xbrane currently utilises a credit facility from the largest shareholder, Serendipity Group, which was granted to the company as a bridge financing until completion of important licence agreements. Xbrane's plan is to finance the clinical trials partly through royalties from partners, primarily in Europe, China and the US. In the event of this not being sufficient, Xbrane will look for additional capital from investors to enable it to continue with the development of the leading product candidates Xlucane and Spherotide in accordance with the schedule. However, there is a risk that such additional financing will not be available for the company on acceptable terms, or not at all.

#### *Key individuals*

Xbrane is dependent on a number of key employees, including the senior management and other employees with specialist expertise within the company's field of business. The company's future development and success is dependent on its ability to recruit and retain such key employees. Xbrane is working actively to ensure competitive remuneration and to offer attractive programmes which create long-term incentives to contribute positively to the company's development. Five out of six persons in the management team own shares and/or warrants in the company and 60% of the employees participated in the share saving program for 2017.

### *Credit risk*

Xbrane is currently exposed to limited credit risk. The credit risk arises principally through exposure to customers, i.e., that the Group does not receive payments according to agreement or makes a loss due to counterparties' inability to meet their undertakings in relation to the company. The principal risk is related to the company's partner in Iran, which currently constitutes the entirety of the company's sales. Xbrane is working actively to review changes which would alter this partner's capacity to pay, and improve the terms of payment.

### **Organisation and employees**

Xbrane has its head quarter in Solna outside of Stockholm, Sweden, which is also where the laboratory is located for research and development of biosimilars. The company has modern equipment for small-scale fermentation, purification and characterisation of proteins. Xbrane acquired the Italian company Primm Pharma s.r.l. in 2015 with office in Milan, which develops and produces microsphere products. The company had 20 employees on the balance sheet date, 16 of which are located in Sweden and four in Italy.

### **Annual General Meeting**

The AGM will be held on 24 May 2018. Notification to attend will be announced through a press release as well as in Svenska Dagbladet and on Xbrane's website, [www.xbrane.com](http://www.xbrane.com).

### **Certified adviser**

Xbrane's Certified Adviser at Nasdaq First North is Avanza Bank AB.

### **Proposed distribution of profits**

The board of directors proposes that the profit is distributed as followed:

Proposed distribution of the company's profit or loss in SEK thousands

Share premium reserve	180,560
Profit/loss brought forward	-40,070
Profit/loss for the year	-37,553
Total	102,937
Carried forward to new account	102,937

The Group's and the Parent Company's earnings and position in general are shown in the following income statement and balance sheet, as well as cash flow statements and additional information.

### **Dividends**

The Board of Directors proposes that no dividend be paid for the financial year 2017-01-01–2017-12-31. The Board of Directors proposes that the company's accumulated loss be carried forward.

### **The situation with ICI**

Xbrane produces Spherotide in a production facility installed within premises owned by a pharmaceuticals company named ICI in Italy. Xbrane owns the production facility and all related equipment, but production takes place according to an agreement with Finchimica, ICI's Parent Company, at an agreed cost per unit. Xbrane has been informed that Finchimica's subsidiary ICI is subject to a reconstruction process due to financial difficulties. The reconstruction procedure is being implemented according to Italian law, and a decision on a reconstruction plan from ICI's lender is expected to be made during 2018. Xbrane has taken actions to ensure that the supply of Spherotide can continue without any significant disruption, including expansion of inventory of the product.

### **The Group's future development**

Sales of Spherotide to Iran commenced during 2017, amounting to SEK 20,771 thousand. The company anticipates sales for 2018 being in line or just above this level. As of 1 January 2018 the company has employed a group of four persons who previously managed the production on a consultancy basis. The number of employees has thus increased from 20 to 24 employees.

The situation with the contract manufacturer has led to Xbrane deciding to increase inventory level equivalent to one year's sales.

During February 2018 Xbrane entered into an out-licensing agreement with CR Pharma for sales and marketing of Spherotide in China. The first milestone payment will be booked as a revenue in March 2018.

At the end of 2017 Xbrane received a credit of SEK 50 million from its largest shareholder, Serendipity Group, which the company has started to utilize during 2018.

As the development of the company's two product candidates, Xlucane and Spherotide, has entered a phase of scaling up test production and preparations for clinical trials, the costs are increasing compared to the cost for 2017. The company's strategy is to out-license the rights for sales and marketing of Xlucane and Spherotide for one of the major markets (Europe and US) before going into clinic to enable financing of the clinical trials. If there is then a financing gap, or the company fail to enter into an out-licensing agreement at what the management and

the Board of Directors consider to be attractive terms, the company will turn to the capital market for financing.

The company has applied for a listing on Nasdaq OMX's main list and is hoping to be able to complete the change of listing venue during 2018. This is primarily as a step in being able to attract institutional capital.

Xbrane is currently performing a strategic review of its product portfolio with the aim of selecting the product candidates on which the company will focus and invest in as the second wave of products after Xlucane and Sphe-rotide. Xbrane will communicate the results of this strategic review as soon as it is finished and decisions have been taken.

#### **Guidelines for remuneration to CEO and other senior executives**

##### *Remuneration*

Remuneration and terms of employment for senior executives, which refers to those who are part of the management as of 31 December 2017, will be decided on in accordance with the company's policy for remuneration to persons in senior positions. According to the policy, they will be formulated with the aim of ensuring the company's access to employees with the right expertise. Remuneration and benefits for senior executives are prepared by the Remuneration Committee and decided on by the Board of Directors.

The remuneration comprises fixed salary, variable remuneration in the form of short-term incentive program, opportunity to participate in long-term share savings program plus other benefits, including eligible pension provision. The remuneration will be at the market rate and competitive, and be relative to the respective senior executive's responsibility and authority. Any variable remuneration will be related to well defined objectives and to the fixed salary, and also be limited to a maximum amount equivalent to two monthly salaries (gross).

##### *Contract of employment*

In the event of CEO Martin Åmark giving notice, a mutual period of notice of 6 months will apply and for the rest of the management the period of notice is 1-3 months. Apart from Paolo Sarmientos, Head of Long-Acting Injectables, and Carlo Colombo, Head of Production of Long-Acting Injectables, who are entitled to severance pay in accordance with Italian legislation (see note 28), neither CEO or other members of the management are entitled to severance pay.

##### *Share savings program for employees*

The company launched a long-term share savings program during 2017 which includes all employees and cover the period 2017 to 2019. The employees are offered the opportunity to invest up to SEK 150 thousand in Xbrane shares on the market, in so-called savings shares, by 28 February 2018 at the latest. If approved by the 2020 AGM, at the end of the program, the participants are given the opportunity to either subscribe to shares at quote value or alternatively offered cash equivalent to the value of such shares up to a certain amount. With the latter alternative, the program will consequently be a form of synthetic option linked to the savings shares which are acquired by the respective employee. The size of a cash payment including social expense can however not exceed SEK 10,000 thousand. The cost of the program during 2017 amounted to SEK 313 thousand and in total the program is estimated to amount to SEK 1,467 thousand and with a dilution of 0.28%. On 28 February 2018, when the window for participation closed, a total of 60 per cent of the employees had purchased shares in the program and the total coverage was 25%.

##### *Short-term incentive program*

The company has a short-term incentive program which includes all employees and which offers up to about two months salaries in cash payment. The bonus is conditional on the achievement of certain well defined group objectives as well as, in some cases, individual objectives. For 2017, 50% of the defined group objectives were achieved and the cost of the cash bonus amounted to SEK 564 thousand.



## Consolidated statement of profit or loss

Amounts in SEK thousand	Notes	2017	2016
Revenue	2	20,771	-
Cost of goods sold		-15,829	-
<b>Gross profit</b>	3	<b>4,942</b>	<b>-</b>
Other income	2	2,515	4,824
Selling and distribution expenses		-1,381	-
Administrative expenses		-11,567	-8,398
Research and development expenses		-37,982	-23,858
Other expenses	4	-1,245	-135
<b>Operating profit</b>		<b>-44,718</b>	<b>-27,567</b>
Finance income	8	0	3
Finance cost	8	-217	-205
<b>Net finance cost</b>		<b>-217</b>	<b>-202</b>
<b>Profit before tax</b>		<b>-44,935</b>	<b>-27,769</b>
Income tax expense	9	-	-
<b>Profit for the year</b>		<b>-44,935</b>	<b>-27,769</b>
<b>Profit attributable to:</b>			
- Owner's of the Company		-44,935	-27,769
- Non-controlling interest		-	-
<b>Profit for the year</b>		<b>-44,935</b>	<b>-27,769</b>
<b>Earnings per share</b>			
- Basic earnings per share (SEK)	10	-8.28	-6.16
- Diluted earnings per share (SEK)*	10	-8.28	-6.16
<b>Number of outstanding shares by the end of the period</b>			
- Before dilution		5,956,770	4,755,546
- After dilution*		5,956,770	4,755,546
<b>Average number of outstanding shares</b>			
- Before dilution		5,425,656	4,508,409
- After dilution*		5,425,656	4,508,409

\* Dilution not taken into account with negative earnings per share. If converted to shares, the outstanding convertible loan as of 31 December 2017 is equivalent to 661,207 shares. Dilution from the share savings program is calculated according to the Treasury Stock method and is equivalent to 3,264 shares.

## Consolidated statement of profit or loss and other comprehensive income

Amounts in SEK thousand	Notes	2017	2016
<b>Profit for the year</b>		-44,935	-27,769
<b>Other comprehensive income</b>			
<b>Items that have been transferred or can be transferred to profit for the year</b>			
Foreign currency translation differences for the year		2,218	2,786
<b>Other comprehensive income for the year</b>		<b>2,218</b>	<b>2,786</b>
<b>Comprehensive income for the year</b>		<b>-42,716</b>	<b>-24,983</b>
<b>Comprehensive income for the year attributable to:</b>			
- Parent Company's owners		-42,716	-24,983
- Non-controlling interest		-	-
<b>Comprehensive income for the year</b>		<b>-42,716</b>	<b>-24,983</b>

## Consolidated statement of financial position

Amounts in SEK thousand	Notes	31/12/2017	31/12/2016	01/01/2016
<b>ASSETS</b>				
Goodwill	11	57,360	55,713	53,198
Intangible assets	11	6,297	6,945	5,777
Property, plant and equipment	12	18,569	17,875	9,986
Trade and other receivables	14	635	635	-
<b>Non-current assets</b>		<b>82,860</b>	<b>81,167</b>	<b>68,961</b>
Inventories	15	3,065	2,497	161
Current tax assets		8,043	4,868	2,655
Trade and other receivables		8,072	1,499	169
Prepayments	16	1,018	2,977	43
Other receivables	14	-	347	1,717
Cash and cash equivalents	17	7,903	31,338	2,688
<b>Current assets</b>		<b>28,100</b>	<b>43,526</b>	<b>7,433</b>
<b>TOTAL ASSETS</b>		<b>110,960</b>	<b>124,694</b>	<b>76,394</b>
<b>EQUITY</b>	18			
Share capital		1,335	1,066	500
Share premium		179,874	162,924	18,632
Reserves		1,862	-357	-3,143
Retained earnings		-94,667	-49,733	-21,964
<b>Equity attributable to owners of the company</b>		<b>88,405</b>	<b>113,901</b>	<b>-5,975</b>
<b>Non-controlling interest</b>		<b>-</b>	<b>-</b>	<b>-</b>
<b>Total equity</b>		<b>88,405</b>	<b>113,901</b>	<b>-5,975</b>
<b>LIABILITIES</b>				
Loan and borrowings	19	1,119	1,726	350
Provisions	20	3,545	3,182	4,064
<b>Non-current liabilities</b>		<b>4,664</b>	<b>4,909</b>	<b>4,414</b>
Liabilities from group companies		-	-	10,264
Trade and other payables		10,541	2,364	4,763
Current tax liabilities		-	94	59
Other current liabilities	21	863	362	61,352
Deferred income/revenue	22	6,488	3,065	1,517
<b>Total current liabilities</b>		<b>17,892</b>	<b>5,884</b>	<b>77,955</b>
<b>TOTAL LIABILITIES</b>		<b>22,555</b>	<b>10,793</b>	<b>82,369</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>110,960</b>	<b>124,694</b>	<b>76,394</b>

## Consolidated statement of cash flows

Amounts in SEK thousand	Notes	2017	2016
<b>Cash flows from operational activities</b>	28		
Profit for the period before tax		-44,935	-27,769
Adjustment for items not included in cash flow		3,803	741
Paid income tax		-	-
		<b>-41,131</b>	<b>-27,028</b>
Increase(-)/Decrease (+) in inventories		-568	-2,336
Increase(-)/Decrease (+) in operating receivables		-7,441	-5,106
Increase(-)/Decrease (+) in operating liabilities		12,292	-4,672
<b>Cash generated from operating activities</b>		<b>-36,848</b>	<b>-39,143</b>
<b>Cash flow from investing activities</b>			
Acquisition of property, plant and equipment		-3,347	-8,899
Development expenditure		-	-3,232
Changes of non-current receivables		-	-635
<b>Cash flow from investing activities</b>		<b>-3,347</b>	<b>-12,766</b>
<b>Cash flow from financing activities</b>			
Proceeds from issue of share capital		20,004	101,770
Transaction costs related to share issue		-3,019	-11,463
Proceeds from loan and borrowings		-	527
Repayment of borrowings		-	-10,000
Payment of finance lease liability		-257	-305
<b>Cash flow from financing activities</b>		<b>16,728</b>	<b>80,529</b>
Cash flow for the period		-23,468	28,621
Cash and cash equivalents at January 1		31,338	2,688
Effect of movements in exchange rates on cash held		33	30
<b>Cash and cash equivalents at 31 December</b>		<b>7,903</b>	<b>31,338</b>



## Consolidated statement of changes in equity

Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total	Non-controlling interest	Total equity
<b>Balance at 1 January 2016</b>	<b>500</b>	<b>18,632</b>	<b>-3,143</b>	<b>-21,964</b>	<b>-5,975</b>	<b>-</b>	<b>-5,975</b>
<b>Total comprehensive income for the period</b>							
Profit for the period	-	-	-	-27,769	-27,769	-	-27,769
Other comprehensive income for the period	-	-	2,786	-	2,786	-	2,786
<b>Comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>2,786</b>	<b>-27,769</b>	<b>-24,982</b>	<b>-</b>	<b>-24,982</b>
<b>Transactions with owners of the Company</b>							
<b>Contributions and distributions</b>							
Issue of ordinary shares	536	89,771	-	-	90,308	-	90,308
- Issue of shares	536	101,234	-	-	101,771	-	101,771
- Transaction costs	-	-11,463	-	-	-11,463	-	-11,463
Issue of convertible notes	30	54,521	-	-	54,550	-	54,550
Total contributions and distributions	566	144,292	-	-	144,858	-	144,858
<b>Balance at 31 December 2016</b>	<b>1,066</b>	<b>162,924</b>	<b>-357</b>	<b>-49,733</b>	<b>113,901</b>	<b>-</b>	<b>113,901</b>
Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total	Non-controlling interest	Total equity
<b>Balance at 1 January 2017</b>	<b>1,066</b>	<b>162,924</b>	<b>-357</b>	<b>-49,733</b>	<b>113,901</b>	<b>-</b>	<b>113,901</b>
<b>Total comprehensive income for the period</b>							
Profit for the period	-	-	-	-44,935	-44,935	-	-44,935
Other comprehensive income for the period	-	-	2,219	-	2,219	-	2,219
<b>Comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>2,219</b>	<b>-44,935</b>	<b>-42,716</b>	<b>-</b>	<b>-42,716</b>
<b>Transactions with owners of the Company</b>							
<b>Contributions and distributions</b>							
Issue of ordinary shares	151	16,835	-	-	16,985	-	16,985
- Issue of shares	151	19,853	-	-	20,004	-	20,004
- Transaction costs	-	-3,019	-	-	-3,019	-	-3,019
Equity-settled share-based payment	-	235	-	-	235	-	235
Issue of convertible notes	118	-118	-	-	-	-	-
Total transactions with owners of the Company	269	16,951	-	-	17,220	-	17,220
<b>Balance at 31 December 2017</b>	<b>1,335</b>	<b>179,874</b>	<b>1,862</b>	<b>-94,667</b>	<b>88,405</b>	<b>-</b>	<b>88,405</b>

## Income statement for Parent Company

Amounts in SEK thousand	Notes	2017	2016
Revenue	2	-	-
Cost of goods sold		-	-
<b>Gross profit</b>		-	-
Other income	2	838	3,270
Administrative expenses		-9,841	-7,291
Research and development expenses		-27,326	-16,572
Other expenses	4	-1,169	-135
<b>Operating profit</b>		<b>-37,498</b>	<b>-20,727</b>
<b>Financial items</b>			
Finance income	8	0	1
Finance expenses	8	-56	-64
<b>Net finance costs</b>		<b>-56</b>	<b>-64</b>
<b>Profit before tax</b>		<b>-37,553</b>	<b>-20,791</b>
Income tax expense	9	-	-
<b>Profit for the period</b>		<b>-37,553</b>	<b>-20,791</b>

## Parent Company statement of comprehensive income

Amounts in SEK thousand	2017	2016
Profit for the period	-37,553	-20,791
Other comprehensive income for the period	-	-
<b>Comprehensive income for the period</b>	<b>-37,553</b>	<b>-20,791</b>

## Balance sheet for Parent Company

Amounts in SEK thousand	Notes	2017	2016
<b>ASSETS</b>			
<b>Fixed assets</b>			
Property, plant and equipment	12	6,725	6,112
Financial fixed assets			
Shares in group companies		94,092	88,335
Other non-current receivables	14	635	635
Total financial fixed assets		94,727	88,970
<b>Total fixed assets</b>		<b>101,451</b>	<b>95,082</b>
<b>Current assets</b>			
Current receivables			
Trade and other receivables		-	1,499
Receivables from group company	13	4,178	-
Other receivables	14	278	295
Prepayments	16	814	759
Total current receivables		5,269	2,554
Cash and bank		6,483	30,512
<b>Total current assets</b>		<b>11,752</b>	<b>33,066</b>
<b>TOTAL ASSETS</b>		<b>113,204</b>	<b>128,148</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>	18		
Restricted equity			
Share capital		1,335	1,066
Unrestricted equity			
Share premium		180,560	163,610
Retained earnings		-40,070	-19,278
Profit for the period		-37,553	-20,791
<b>Total equity</b>		<b>104,273</b>	<b>124,606</b>
<b>Current liabilities</b>			
Trade and other payables		3,359	1,923
Other current liabilities	21	760	270
Deferred income/revenue	22	4,812	1,348
<b>Total current liabilities</b>		<b>8,931</b>	<b>3,541</b>
<b>TOTAL LIABILITIES AND EQUITY</b>		<b>113,204</b>	<b>128,148</b>

## Statement of changes in equity for Parent Company

Amounts in SEK thousand	Restricted equity	Unrestricted equity			Total equity
	Share capital	Share premium	Retained earnings	Profit for the year	
<b>Balance at 1 January 2016</b>	<b>500</b>	<b>17,468</b>	<b>-10,017</b>	<b>-9,261</b>	<b>-1,310</b>
Profit for the year	-	-	-	-20,791	-20,791
Other comprehensive income for the year	-	-	-	-	-
<b>Comprehensive income for the year</b>	<b>-</b>	<b>-</b>		<b>-20,791</b>	<b>-20,791</b>
<b>Contributions and distributions</b>			-9,261	9,261	-
Issue of ordinary shares	536	91,621	-	-	92,157
- <i>Issue of shares</i>	-	101,234	-	-	101,234
- <i>Transaction costs</i>	-	-9,614	-	-	-9,614
Issue of convertible notes	30	54,521	-	-	54,550
<b>Balance at 31 December 2016</b>	<b>1,066</b>	<b>163,610</b>	<b>-19,278</b>	<b>-20,791</b>	<b>124,606</b>

Amounts in SEK thousand	Restricted equity	Unrestricted equity			Total equity
	Share capital	Share premium	Retained earnings	Profit for the year	
<b>Balance at 1 January 2017</b>	<b>1,066</b>	<b>163,610</b>	<b>-19,278</b>	<b>-20,791</b>	<b>124,606</b>
Profit for the year	-	-	-	-37,553	-37,553
Other comprehensive income for the year	-	-	-	-	-
<b>Comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-37,553</b>	<b>-37,553</b>
<b>Contributions and distributions</b>	<b>-</b>	<b>-</b>	-20,791	20,791	-
Issue of ordinary shares	151	16,835	-	-	16,985
- <i>Issue of shares</i>	-	19,853	-	-	-
- <i>Transaction costs</i>	-	-3,019	-	-	-
Issue of convertible notes	118	-118	-	-	-
Equity-settled share-based payment	-	235	-	-	235
<b>Balance at 31 December 2017</b>	<b>1,335</b>	<b>180,560</b>	<b>-40,070</b>	<b>-37,553</b>	<b>104,273</b>



## Parent Company's cash flow statement

Amounts in SEK thousand	Notes	2017	2016
<b>Cash flows from operating activities</b>	28		
Profit for the period before tax		-37,553	-20,791
Adjustments for items not included in cash flow		1,685	1,206
Paid income tax		-	-
		-35,869	-19,585
Increase(-)/Decrease (+) of trade and other receivables		-2,716	-981
Increase(-)/Decrease (+) of trade and other payables		5,312	77
<b>Cash flow from current operations</b>		<b>-33,273</b>	<b>-20,489</b>
<b>Investing activities</b>			
Investments in subsidiaries		-5,756	-25,560
Acquisition of property, plant and equipment		-1,985	-7,159
Paid rental depositions		-	-635
<b>Cash flow from investing activities</b>		<b>-7,742</b>	<b>-33,353</b>
<b>Financing activities</b>			
New share issue		20,004	101,771
Transaction costs related to share issue		-3,019	-9,614
Repayment of loan		-	-10,000
<b>Cash flow from financing activities</b>		<b>16,985</b>	<b>82,157</b>
Cash flow for the year		-24,029	28,315
Cash and cash equivalents at beginning of period		30,512	2,197
Effect of movements in exchange rates on cash held		-	-
<b>Cash and cash equivalents at end of year</b>		<b>6,483</b>	<b>30,512</b>

# Notes

## NOT 1 Accounting principles

### (a) Agreement with standards and legislation

The consolidated accounts of Xbrane Biopharma AB (pub) (hereinafter "Xbrane" or "the Group") have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as adopted by the EU. In addition, Financial Accounting Standards Council recommendation RFR 1 Supplementary Accounting Rules for Groups has been applied. Xbrane has applied IFRS since 1 July 2017. The 2015 financial year was the first year in which Xbrane prepared consolidated accounts.

The Parent Company applies the same accounting policies as the Group, except in the cases listed below in the section "The Parent Company's accounting policies".

The annual accounts and consolidated accounts were approved for issue by the Board and Chief Executive Officer on 27 April 2018. The consolidated statement of profit or loss, statement of profit or loss and other comprehensive income, statement of financial position and the Parent Company's income statement and balance sheet will be the object of adoption by the Annual General Meeting to be held on 24 May 2018.

### (b) Basis of measurement applied in preparing the financial statements

Assets and liabilities are recognised at historical cost, with the exception of provisions for termination benefits for employees in subsidiaries measured at present value through profit or loss. Liabilities for equity-regulated share-related payment transactions are measured initially at fair value and revaluation then takes place continuously based on change in cost assumptions.

### (c) Functional currency and reporting currency

The Parent Company's functional currency is Swedish kronor (SEK), which is also the reporting currency for the Parent Company and the Group. This means that the financial statements are presented in Swedish kronor. All amounts, unless otherwise stated, are rounded to the nearest thousand.

### (d) Assessments and estimates in the financial statements

Preparing financial statements in accordance with IFRS requires the Board of Directors and the management to make accounting assessments and estimates and make assumptions that affect the application of the accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual result may differ from these estimates and assessments.

Estimates and assumptions are regularly revised. Changes in estimates are recognised in the period in which the change is made if the change only affects that period, or in the period in which the change is made and future periods if the change affects both the current period and future periods.

Assessments made by the management in application of IFRS which have a significant impact on the financial statements and estimates made which may lead to material adjustments to the financial statements for the subsequent year are described more fully in Note 31.

### (e) Material accounting policies applied

The accounting policies indicated below, with the exception of those described more closely, have been applied consistently to all periods presented in the consolidated financial statements. The Group accounting policies have also been consistently

applied by the consolidated entities.

Some figures for comparison have been reclassified to agree with the presentation in the financial statements of the current year. This applies to the conversion to IFRS which the company carried out in 2017 and the switch to operating expenses classified by function. IFRS-bridges for conversion showing all changes are presented in Note 29. IFRS-bridges are also available on the company's website.

### (f) Amended accounting policies

#### (i) Amended accounting policies occasioned by new or amended IFRS standards

Accounting policies applied by the Group with effect from 1 January 2017 are described below. Other amendments of IFRS standards with application from 1 January 2017 have not had a material impact on the consolidated accounts.

The amended IAS 7 Statement of cash flows is applied with effect from 2017. Disclosures have been added to Note 28 in which change in liabilities for the year attributable to the financing operation is reconciled against specifications. Disclosures are made both for changes which have an impact on cash flow and changes which do not have an impact on cash flow.

#### (ii) Voluntary charge of accounting policy

The Group has applied operating expenses classified by function since 1 July 2017. The change is justified by the Group pursuing an operation which is based on the functions of research and development, production and administration.

### (g) New IFRS standards which have not yet started to be applied

A number of new or amended IFRS standards do not enter into force until coming financial years and have not been applied early in preparing these financial statements.

### Estimated effect of the transition to IFRS 9 and IFRS 15

The Group starts to apply IFRS 9 *Financial instruments* and IFRS 15 *Revenue from contracts with customers* with effect from 1 January 2018. The Group had made the assessment that as of 1 January 2018 this has not had any impact on the income statement or balance sheet.

#### IFRS 9 Financial Instruments

IFRS 9 involves changes in the way financial assets are classified and measured, ahead of an impairment model which is based on expected credit losses instead of losses which have occurred and results in changes of policies for hedge accounting in part for the purpose of simplifying and increasing consistency with companies' internal risk management strategies. This standard replaces IAS 39 *Financial Instruments: Recognition and Management*.

#### Classification of financial receivables and financial liabilities

The Group's assessment is that the new categories of financial assets introduced with effect from IFRS 9 will not have any material impact on financial reporting. For the Group, it is only trade receivables that are affected by the introduction of IFRS 9, and as the company at present has relatively low turnover with one customer for sale of drugs and one customer for the company's protein expression system which is recognised under other income, the effect of the introduction of IFRS is marginal. The

Group's assessment is that there are no material effects in the classification of financial assets as of 1 January 2018.

#### **IFRS 15 Revenue from Contracts with Customers**

IFRS 15 is a comprehensive standard to determine what level of revenue is to be recognised and when this revenue to be recognised. It replaces IAS 18 Revenue, IAS 11 Construction Contracts and IFRIC 13 Customer Loyalty Programmes. Under IFRS 15, revenue is recognised when the customer takes control of the goods, in contrast to previously issued standards and interpretations which are concerned with revenue where the revenue is recognised when the goods have been delivered to the customer, which is the time when the customer accepts the goods and risks and benefits pass to the customer.

##### *Sale of goods and licences*

The management has evaluated the impact of the new standard on the consolidated financial statements and makes the assessment that the new standard will not have any impact on consolidated income statements and statements of financial position. Group operating income consists of revenue from sold goods and licences relating to the technology platform. Income from sold goods is recognised as income when an order is placed and therefore not on delivery, and this will continue to be recognised only when contracts have been signed or interim targets have been met. Licence revenue is accrued over the period of use of the licence and is consequently not affected by the transition to IFRS 15.

##### *Transition*

The Group plans to apply IFRS 15 retroactively with the combined effect of the transition recognised on the first day of application, i.e. 1 January 2018. However, this will not affect net profit as the effect totalled SEK 0 thousand on 1 January 2018.

#### **IFRS 16 Leases**

IFRS 16 Leases is a new standard concerning recognition of leasing and replaces existing IFRS standards relating to recognition of leases, such as IAS 17 Leases and IFRIC 4 Determining Whether an Arrangement Contains a Lease. For lessees, the classification under IAS 17 into operational and financial leasing ceases to apply and is replaced by a model in which assets and liabilities for all leases are to be recognised in the balance sheet. Exceptions to recognition in the balance sheet exist for leases of lesser value and contracts which have a term of not more than 12 months. Depreciation is to be recognised in the income statement separately from interest expenses attributable to lease liability. IFRS is to be applied to financial years beginning on 1 January 2019 or later. However, no time for approval has been set by the EU. The Group will be affected by the introduction of IFRS 16 as an operational lessor. No calculations of the amount of the effect of IFRS 16 and choices regarding transition methods have yet been made in full, but they are judged to have a relatively insignificant impact on the consolidated accounts. The disclosures made in Note 24 on commitments provide an indication of the type and scope of the contracts which exist at present.

#### **(h) Classification, etc.**

Non-current assets essentially consist of amounts expected to be recovered or paid after more than twelve months counting from the balance-sheet date, while current assets essentially consist of amounts expected to be recovered or paid within twelve months counting from the balance-sheet date. Long-term liabilities essen-

tially consist of amounts which the company at the end of the reporting period has an unconditional right to choose to pay later in time than twelve months after the end of the reporting period. If the company does not have such a right at the end of the reporting period, or a liability is held for trading or a liability is expected to be settled within the normal business cycle, the amount of the liability is recognised as a current liability.

#### **(i) Business segment reporting**

A business segment is a part of the Group which undertakes a business operation from which it can generate income and incur costs and for which independent financial information is available. The profit or loss of an operating segment is further followed up by the company's senior executive decision-makers to evaluate the profit or loss and to be able to allocate resources to the operating segment. See Note 3 for a further description of the classification and presentation of operating segments.

#### **(j) Principles of consolidation and business combinations**

##### **(i) Subsidiaries**

Subsidiaries are entities over which Xbrane Biopharma AB has controlling influence. Controlling influence exists if the Parent Company has influence over the object of investment, is exposed to or is entitled to variable return from its investment and can use its influence over the investment to affect the return. In assessing whether a controlling influence exists, account is taken of potential shares carrying entitlement to vote and whether de facto control exists.

Subsidiaries are recognised using the purchase method. This method means that an acquisition of a subsidiary is regarded as a transaction by which the Group indirectly acquires the subsidiary's assets and takes over its liabilities. The acquisition analysis establishes the fair value on the day of acquisition of acquired identifiable assets and taken-over liabilities as well as any non-controlling interests. Transaction expenditure, with the exception of transaction expenditure attributable to the issuing of capital instruments or debt instruments which arises is recognised directly in profit or loss for the year.

In business combinations where transferred remuneration, any non-controlling interests and fair value of a previously owned participation (in the case of acquisitions with different milestone payments) exceed the fair value of acquired assets and taken-over liabilities which are recognised separately, the difference is recognised as goodwill. When the difference is negative, 'acquisition at low price', this is recognised directly in profit or loss for the year.

Transferred remuneration in connection with the acquisition does not include payments relating to settlement of previous business relationships. Settlements of this type are usually recognised in profit or loss.

Contingent purchase considerations are valued at fair value at the date of acquisition. In cases where the contingent purchase consideration is classified as an equity instrument, no revaluation is made and settlement is made within equity. For other contingent purchase considerations, these are revalued at fair value at each time of reporting and the change is recognised in profit or loss for the year.

##### *Acquisition of non-controlling interests*

The Parent Company has only one subsidiary which is owned with 100% of shares and voting power. No subsidiaries with non-controlling interest are therefore recognised.

**(ii) Transactions eliminated upon consolidation**

Intra-Group receivables and liabilities, income and expenses, as well as unrealised gains or losses arising from intra-Group transactions between Group companies, are eliminated in their entirety when preparing the consolidated accounts.

**(k) Foreign currency****(i) Functional current and reporting currency**

The Parent Company's reporting currency is SEK. The subsidiary's functional currency is EUR, translation to SEK takes place in the Group.

**(ii) Transactions in foreign currency**

Foreign currency transactions are translated into the functional currency using the exchange rate existing on the transaction date. The functional currency is the currency of the primary economic environment in which the companies operate. Monetary assets and liabilities in foreign currencies are translated into the functional currency using the exchange rate existing on the balance-sheet date. Gains and losses on exchange arising in translation are recognised in net profit for the year. Non-monetary assets and liabilities which are reported at historical cost are translated at the exchange rate applicable at the time of the transaction. Non-monetary assets and liabilities which are recognised at fair value are translated to the functional currency at the rate prevailing at the time of measurement of fair value.

**(iii) Financial statements of foreign operations**

Assets and liabilities in foreign operations, including goodwill and other Group surpluses and deficits, are translated from the functional value of the foreign operation euro to the Group's presentation currency, Swedish kronor, at the exchange rate prevailing on the balance-sheet date. Income and expenses in a foreign operation are translated to Swedish kronor at an average rate which represents an approximation of the exchange rates which existed at the time of the transaction concerned. Exchange differences arising in currency translation of foreign operations are recognised in other comprehensive income and accumulated in a separate component of equity, known as translation reserve.

Since the transition to IFRS, with opening balance on 1 January 2017, exchange differences have been recognised in the translation reserve.

**(l) Income****(i) Sale of goods**

Income from sale of goods is recognised in profit for the year when material risks and benefits associated with ownership of the goods have been transferred to the purchaser. Income is not reported if it is likely that the economic benefits will not accrue to the Group. If significant uncertainty prevails on payment, associated expenses or risk of returns and if the seller maintains an involvement in the continuing administration which is usually associated with ownership, no recognition as income takes place. Income is recognised at that fair value of what has been obtained, or is expected to be obtained, less discounts applied.

**(ii) Sale of licences**

Income from sale of licences is recognised in the same way as sale of goods as described above. In addition, income is accrued over the term of the licence.

**(iii) Income from state aid/grants**

Income from state aid and grants is recognised in the same way as sale of goods as described above.

**(m) Leasing****(i) Operational leases**

Expenses paid for operating leases are reported in the income statement on a straight-line basis over the leasing period. Benefits obtained in connection with the signing of a lease are reported in the income statement as a decrease in lease charges on a straight-line basis over the term of the lease. Variable charges are recognised as an expense in the periods in which they arise.

**(i) Financial leases**

Minimum leasing charges are divided between interest expense and repayment on the outstanding liability. The interest is divided over the lease period so that an amount corresponding to a fixed interest rate on the liability recognised during each period is attributed to each accounting period. Variable charges are recognised as an expense in the periods in which they arise.

**(n) Financial income and expenses**

Financial income consists of interest income on invested funds.

Finance cost consists of interest expenses on loans and other interest expenses which comprise penalty interest on trade payables and interest expenses for taxes and charges.

Gains and losses on exchange on operating receivables are recognised as other operating income and other operating expenses.

**(o) Taxes**

As of the balance-sheet date of 31 December 2017, the Group had not reported any income tax.

Income tax consists of current tax and deferred tax. Income tax is reported in the year's result except when the underlying transaction is reported in Other comprehensive income or in Equity, where the associated tax effect is reported in Other comprehensive income or Equity.

Current tax is tax to be paid or received for the current year, with the application of the tax rates that are established or established in practice as of the balance sheet date. Adjustments of tax paid attributable to previous periods are also included in current tax.

Deferred tax is calculated in accordance with the balance sheet method on the basis of temporary differences between the reported and taxable values of assets and liabilities. Temporary differences are not considered in Group goodwill, nor for difference arising on initial recognition of assets and liabilities that are not business combinations which at the time of the transaction do not affect either reported or taxable profit. Further, neither are such temporary differences as are attributable to participations in subsidiaries or associated companies that are not expected to be reversed in the foreseeable future taken into account. The valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realised or settled. Deferred tax is calculated in accordance with the tax rates and tax rules that have been established or have been established in practice as of the balance sheet date.

Deferred tax assets concerning non-deductible temporary differences and tax-loss carryforwards are only reported to the extent that it is likely that it will be possible for these to be used. The value of deferred tax assets is reduced when it is no longer



considered likely that they can be used.

Any additional income tax arising on payment of dividend is recognised at the same time as when the dividend is recognised as a liability.

#### (p) Financial instruments

At 31 December 2017, the Group had no derivative instruments.

#### Reporting and removal from the report over financial position

A financial asset or liability is reported in the balance sheet when the company becomes a party to the contractual terms for the instrument. A receivable is recognised when the company has performed and there is a contractual obligation for the counterparty to pay, even if the invoice has not yet been sent. Trade receivables are recognised in the statement of financial position when the invoice has been sent. Debts are incurred when the counterparty has performed and there is a contractual obligation to pay, even if the invoice has not yet been received. Trade payables are recognised when the invoice is received. A financial asset is removed from the statement of financial position when the rights in the agreement are realized, due or the company loses control of them. The same applies to part of a financial asset. A financial liability is removed from the statement of financial position when the obligation in the agreement is fulfilled or otherwise terminated. The same applies to part of a financial debt.

A financial asset and a financial liability are offset and recognised with a net amount in the statement of financial position only when there is a legal right to settle the amounts and there is an intention to adjust the items with a net amount or to simultaneously realise the asset and settle the liability.

Acquisitions and disposals of financial assets are recognised on the business day. The business day is the date on which the company undertakes to acquire or sell the asset.

#### Accounts receivable

Accounts receivable are non-derivative financial assets that have fixed or determinable payments and are not listed on an active market. Accounts receivable are recognised at the amount that is expected to be received, i.e. after deductions for doubtful receivables.

#### Other financial liabilities

Loans and other financial liabilities, such as accounts payable, are included in this category. Liabilities are valued at accrued acquisition value.

Regarding to which category the Group's financial assets and liabilities are attributable, see "Note 23 - Financial risks and risk management". The reporting of financial income and expenses is also treated under the principle described in (n) above.

#### (q) Issued convertible loan

Convertible loans can be converted into shares by using the counterparty's option to convert the loan to shares and recognised as equity. Conversion can take place provided certain predetermined goals are achieved within a predetermined schedule. Conversion is conducted at a predetermined conversion rate. If the targets are not achieved within the specified time frame, the entire convertible loan matures without repayment and remains as equity. The debt is recognised at the non-discounted outstanding amount.

#### (r) Tangible fixed assets

##### (i) Owned assets

Property, plant and equipment is reported in the Group at cost less accumulated amortisation and potential write-downs. The acquisition value includes the purchase price and expenses directly attributable to the asset to put it in place and in order to be utilised in accordance with the purpose of the acquisition. Borrowing costs directly attributable to the purchase, construction or production of assets that take a considerable amount of time in order to complete the intended use or sale are included in the acquisition value. Accounting policies for impairment are described below.

Tangible fixed assets consisting of parts with different useful lives are treated as separate components of property, plant and equipment.

The recognised value of a tangible fixed asset is derecognised in the statement of financial position on disposal or divestment or when no future economic benefits are expected from use or disposal/divestment of the asset. Gains or losses arising from the sale or disposal of an asset consist of the difference between the selling price and the asset's book value amount less direct selling expenses. Profits and losses are recognised as other income/expense.

##### (ii) Leased assets

Leasing agreements are classified as either financial or operational leasing. Financial leasing exists when the economic risks and benefits associated with ownership are essentially transferred to the lessee. If this is not the case, it is classified as an operational leasing.

Assets hired under finance agreements are reported as non-current assets in the statement of financial position and are initially valued at the lower of the fair value of the leased asset and the present value of the minimum lease payments at the conclusion of the agreement. The obligation to pay future leasing fees is reported as long-term and current liabilities. The leased assets are depreciated over the asset's useful life, while the lease payments are reported as interest and amortisation of the liabilities.

##### (iii) Additional expenses

Additional expenses are added to the acquisition value only if it is likely that the future economic benefits associated with the asset will be allocated to the company and the acquisition value can be calculated reliably. All other additional expenses are recognised as an expense in the period they arise.

An additional expense is added to the acquisition value if the expenditure relates to exchanges of identified components or parts thereof. The cost is also added to the acquisition value if new components are added.

Any non-depreciated recognised values of exchanged components, or parts of components, are eliminated and expensed in connection with the exchange. Repairs are expensed on an ongoing basis.

##### (vi) Principles for depreciation

Depreciation takes place on a straight-line basis over the estimated useful life of the asset.

Leased assets are also written off over the estimated useful life or, if shorter, over the agreed lease term.

The Group applies component depreciation, which means that the estimated useful life of the components is the basis for the depreciation.

Estimated useful lives;

- machinery and other technical facilities 5-10 years
- fixtures, tools and installations 3-5 years

### **(s) Intangible assets**

#### **(i) Goodwill**

Goodwill is valued at acquisition cost minus any accumulated impairment losses. Goodwill is allocated to cash-generating units and is tested for impairment at least annually.

#### **(ii) Research and development**

Expenses for research aimed at obtaining new scientific or technical knowledge are recognised as costs when they arise.

Development costs, where research results or other knowledge are applied to achieve new or improved products or processes, are recognised as an asset in the statement of financial position if the product or process is technically and commercially useful and the company has sufficient resources to pursue development and then use or sell the intangible asset. The recognised amount includes all directly attributable expenses, for example for materials and services, employee remuneration, registration of a legal right, depreciation of patents and licenses.

Other development expenses are reported in profit or loss as an expense when incurred. In the statement of financial position, reported development costs are stated at cost less accumulated amortisation and any write-downs.

#### **(iii) Additional expenses**

Additional expenses for capitalised intangible assets are recognised as an asset in the statement of financial position only as they increase the future economic benefits of the specific asset to which they relate. All other expenses are expensed when they arise.

#### **(vi) Depreciation principles**

Depreciation is recognised in profit or loss for the year on a straight-line basis over the estimated useful lives of intangible assets, unless such useful lives are indeterminate. The useful lives are reassessed at least annually.

Goodwill and other intangible assets with an indefinite useful life or which are not yet ready to be used are tested for impairment annually, and as soon as indications arise that the asset in question has decreased in value. Intangible assets with determinable useful lives are depreciated from the time they are available for use. The estimated useful lives are:

- Capitalised development expenses 5-7 years.

#### **(t) Inventories**

Inventories are valued at the lower of cost and net sales value. The cost of inventories is calculated using the first-in, first-out method (FIFO) and includes expenses incurred in the acquisition of inventory assets and transportation of these to their current location and condition. For manufactured goods and ongoing work, the acquisition value includes a reasonable proportion of indirect costs based on normal capacity.

Net sales value is the estimated selling price in current operations, after deduction of estimated costs of completion and to achieve a sale.

#### **(u) Impairments**

The Group's reported assets are assessed at each balance-sheet date to determine if there is an indication of impairment.

#### **(i) Impairment of financial assets**

At each time of reporting, the company evaluates whether there is objective evidence that a financial asset or group of assets requires impairment. Objective evidence is partly due to observable conditions that have occurred and which adversely affect the ability to recover the acquisition value. The company classifies accounts receivable as uncertain when these have been due for 60 days. The write-down requirement for receivables is determined based on historical experience of customer losses on similar receivables. Trade receivables with impairment losses are reported at the present value of expected future cash flows. However, short-term receivables are not discounted.

#### **(ii) Impairment of intangible assets**

Intangible assets that have an indefinite useful life, such as goodwill or capitalised development costs where depreciation has not yet begun, are tested at least annually for any impairment requirements and when there is an indication of impairment. Assets written off are to be assessed for impairment whenever events or changes in conditions indicate that the carrying amount is not recoverable. An impairment loss is made in the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less selling costs and its value in use. An impairment loss is recognised immediately in the income statement.

To test the value of intangible fixed assets, the Group uses a probability-adjusted cash flow model. Valuation of ongoing development projects is calculated by estimating net present value of estimated future cash flows and adjusting for probability to take account of the development risk.

Previously recognised write-downs are reversed if the recoverable amount is estimated to exceed the recognised amount. However, reversal does not occur in an amount greater than the recognised value of what it would have been if the write-down had not been reported in previous periods.

#### **(v) Earnings per share**

The calculation of earnings per share is based on the Group's profit or loss for the year attributable to the Parent Company's owner and on the weighted average number of shares outstanding during the year.

When calculating earnings per share after dilution, the profit and the average number of shares are adjusted to take into account the effects of dilutive potential common shares, which during reporting periods derive from convertible loan and share savings programme. Dilution from convertible debentures is calculated by increasing the number of shares by the total number of shares that the convertibles correspond to. Dilution from the share savings programme is calculated by the treasury stock method. The following addition is made to the number of shares before dilution:

- add the number of potential shares on the assumption that all participants in the share savings program remain in employment and that full allocation of performance shares is made.
  - minus total remuneration that the company is expected to receive, divided by average market price during the period.
- Potential ordinary shares are regarded as dilution only during periods when it results in a lower profit or greater loss per share.

**(w) Employee benefits****(i) Short-term benefits**

Short-term employee benefits are calculated without discount and are reported as costs when the related services are obtained. A provision is reported for the expected cost of bonus payments when the Group has a current legal or informal obligation to make such payments as a result of receiving services from employees and the obligation can be calculated reliably.

**(ii) Share-based payments***Share Savings Program*

A share savings program enables employees to acquire shares in the company, known as savings shares, and each invested savings share has the opportunity to acquire a matching share, potentially up to a performance share at quote value when the programme ends. The fair value of matching and performance shares is recognised as a personnel expense with a corresponding increase in equity. The fair value is calculated at the date of allocation and is distributed over the vesting period. The fair value of the matching and performance shares is calculated using a method that takes into account market conditions (share price and social security contributions), earnings conditions (fulfilment of predetermined targets) and terms of service (the participants are still employees of the company). The cost recognised corresponds to the fair value of an estimate of the number of matching and performance shares that are expected to be earned, taking into account market conditions, terms of service and performance terms. This cost is adjusted in subsequent periods to ultimately reflect the actual number of earned matching and performance shares. Social security charges attributable to equity-related instruments to employees as compensation for purchased services are expensed over the periods during which the services are performed. The provision for social security contributions is based on the fair value of matching and performance shares at the reporting date.

*Share-based compensation*

In 2017, a share issue directed to employees at quotient value was conducted as part of the incentive program for 2016. The Annual General Meeting 2017 decided on the issue and no accruals for cost was made in 2016. The issued shares constitute a share-based payment for the employees and social security costs are calculated based on the market value of the shares at the time when payment was received by employees. Payment of shares corresponds to quote value and is recognised in share capital.

**(x) Provisions**

A provision differs from other liabilities because of the uncertainty about the payment date or amount to adjust. A provision is reported in the statement of financial position when there is an existing legal or informal obligation as a result of an event occurring and it is likely that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount can be made.

Provisions are made at the amount that is a best estimate of what is required to settle the existing obligation on the balance sheet date. Where the effect of current payment is significant, provisions are calculated by discounting the expected future cash flow to an interest rate before tax reflecting current market assessments of the money's time value and, if applicable, the risks associated with the debt.

*Non-recurring compensation for employees on termination of employment*

Provisions are reported in the subsidiary Prim Pharma s.r.l and relates to one-time compensation to all employees upon termination of employment. Since 1 July 2017, the provisions have been calculated at net present value in accordance with IFRS. In the net present value calculation, the discount rate is estimated to be one percent (1%) and time to maturity to be 5 years.

**Parent Company's accounting policies**

The Parent Company has prepared its annual report according to the Annual Accounts Act (1995: 1554) and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. Statements issued by the Swedish Financial Reporting Board also apply. RFR 2 means that the parent company in the annual report of the legal entity applies all IFRS and statements adopted by the EU, as far as possible within the framework of the Annual Accounts Act, the Insurance Act and the relationship between accounting and taxation. The recommendation specifies which exceptions and additions to IFRS are to be made.

**Differences between the Group's and the Parent Company's accounting policies**

The differences between the Group and the Parent Company's accounting policies are shown below.

The following accounting policies for the Parent Company have been applied consistently to all periods presented in the Parent Company's financial reports.

**Changed accounting policies**

Unless otherwise specified below, the Parent Company's accounting policies changed in 2017 as stated above for the Group. The same policies apply to the Parent Company as for the Group regarding the disclosure of Changed Accounting Policies (IAS 8.28-31); see above under the Group's changed accounting policies.

However, note that this section of the Parent Company report lists only differences for the Group, which means that the changes listed here are only those that concern the Parent Company.

**Classification and presenting format**

The Parent Company uses the terms balance sheet and cash flow analysis for the reports that in the Group have the titles financial statement and statement of cash flow. Income statement and balance sheet are prepared for the Parent Company in accordance with the Annual Accounts Act, while the statement of income and other comprehensive income and the statement of changes in equity are based on IAS 1 Presentation of Financial Statements. The differences between the Group's reports that are relevant in the Parent Company's income statement and balance sheet are accounted for by investments in subsidiaries as non-current assets.

**Subsidiaries**

Shares in subsidiaries are recognised in the Parent Company in accordance with the acquisition value method.

This means that transaction costs are included in the recognised amount of holdings in subsidiaries.

In the consolidated accounts, transaction costs attributable to subsidiaries are reported directly in the income statement when these arise.

**NOTE 2** Distribution of income

Income per significant category Amounts in SEK thousands	Group		Parent Company	
	2017	2016	2017	2016
Revenue				
<i>Sales of goods</i>	20,771	-	-	-
	<b>20,771</b>	<b>-</b>	<b>-</b>	<b>-</b>
Other income				
<i>Sales from licensing revenues and royalties</i>	774	2,625	774	2,625
<i>Government grants</i>	1,673	544	-	544
<i>Exchange rate gains</i>	64	101	64	101
<i>Other</i>	3	1,554	-	-
	<b>2,515</b>	<b>4,824</b>	<b>838</b>	<b>3,270</b>
<b>Total income</b>	<b>23,285</b>	<b>4,824</b>	<b>838</b>	<b>3,270</b>

**NOTE 3** Operating segment

An operating segment is a part of a group which conducts operations, from which it can generate revenues and incur expenses, and for which separate financial information is available. An operating segment's results are reviewed by the company's chief operating decision makers, who make decisions on the allocation of resources to the segment and assess its long- and short-term financial results. The operating segment reports in a way that corresponds with the internal reporting that is submitted to the operation's chief decision makers. CEO who are responsible for allocating resources and evaluating the operating segment's results, are the chief operating decision makers who make strategic decisions.

The division into operating segments is based on the different pharmaceutical products that Xbrane develops and sells. The following operating segments have been identified:

- "Biosimilars"
- "Long-acting Injectibles".

In addition there are certain revenues and expenses which are classified as "unallocated" or of "administrative character" and comprise the Parent Company's non-core business "Out-licensing of protein expression system" as well as overheads for the Group which concern group-wide administration, board of directors, costs associated with stock-exchange listing, investor relations etc.



**NOTE 3** Operating segment, cont.

Amounts in SEK thousands	Group		Parent Company	
	2017	2016	2017	2016
<b>Income per segment</b>				
<i>Biosimilars</i>	-	-	-	-
<i>Long-acting injectables</i>	22,447	-	-	-
<i>Unallocated revenues</i>	838	4,824	838	3,270
<b>Total income</b>	<b>23,285</b>	<b>4,824</b>	<b>838</b>	<b>3,270</b>
<b>Result per segment</b>				
<i>Biosimilars</i>	-27,326	-16,572	-27,326	-14,265
<i>Long-acting injectables</i>	-5,419	-7,625	-	-2,307
<i>Administration and unallocated earnings</i>	-11,973	-3,369	-10,172	-4,156
<b>Operating profit</b>	<b>-44,718</b>	<b>-27,567</b>	<b>-37,498</b>	<b>-20,727</b>
<b>Finance income</b>				
<i>Biosimilars</i>	-	-	-	-
<i>Long-acting injectables</i>	-	-	-	-
<i>Administration and unallocated earnings</i>	0	3	0	1
	<b>0</b>	<b>3</b>	<b>0</b>	<b>1</b>
<b>Finance expenses</b>				
<i>Biosimilars</i>	-	-	-	-
<i>Long-acting injectables</i>	-69	-90	-	-
<i>Administration and unallocated earnings</i>	-147	-114	-56	-64
	<b>-217</b>	<b>-205</b>	<b>-56</b>	<b>-64</b>
<b>Net financial items</b>	<b>-217</b>	<b>-202</b>	<b>-56</b>	<b>-64</b>
<b>Profit before tax</b>	<b>-44,935</b>	<b>-27,769</b>	<b>-37,553</b>	<b>-20,791</b>

Amounts in SEK thousands	Group		Parent Company	
	2017	2016	2017	2016
<b>Depreciation</b>				
<i>Biosimilars</i>	1,362	1,204	1,362	1,204
<i>Long-acting injectables</i>	1,333	816	-	-
<i>Administration and unallocated earnings</i>	35	1,012	10	2
	<b>2,730</b>	<b>3,032</b>	<b>1,372</b>	<b>1,206</b>

**NOTE 4** Other expenses

Amounts in SEK thousands	Group		Parent Company	
	2017	2016	2017	2016
Exchange losses on trade receivables and payables	1,169	135	1,169	135
Other	76	-	-	-
	<b>1,245</b>	<b>135</b>	<b>1,169</b>	<b>135</b>

**NOTE 5** Employees, salaries and senior executive's remuneration**Expenses for employee remuneration****Group**

Amounts in SEK thousands	2017	2016
Salaries and payments etc.	11,735	7,240
Payments on termination of employment*	149	283
Social security expenses	2,664	1,734
Other personnel expenses	1,018	140
	<b>15,566</b>	<b>9,397</b>

\*Relates to statutory one time payment to employees in Italy which is paid when employment is terminated.

Average number of employees	2017	of which men	2016	of which men
Parent Company	14	57%	10	60%
Subsidiaries	4	75%	4	75%
<b>Group total</b>	<b>18</b>	<b>61%</b>	<b>14</b>	<b>64%</b>

	31/12/2017 Proportion of women	31/12/2016 Proportion of women
<b>Gender distribution in the Board of Directors and management</b>		
<b>Parent Company</b>		
Board of Directors	17%	17%
Other senior executives	40%	-
<b>Group total</b>		
Board of Directors	17%	17%
Other senior executives	29%	-

**Salaries and other payments distributed between senior executives and other employees, as well as social security expenses**

Parent Company	2017			2016		
Amounts in SEK thousands	Senior executives (5 persons)	Other employees	Total	Senior executives (3 persons)	Other employees	Total
Salaries and other payments	4,559	4,798	9,357	2,267	2,781	5,049
- Of which bonus payments and similar	456	538	995	-	-	-
- Of which pension expenses	93	164	258	-	7	7
Social security expenses	996	1,169	2,164	565	750	1,316

Group	2017	2016
Amounts in SEK thousands	Senior executives (7 persons)	Senior executives (5 persons)
Salaries and other payments	5,320	4,267
- Of which bonus payments and similar	559	-
- Of which pension expenses	100	18

**NOTE 5** Employees, salaries and senior executive's remuneration, cont.**Salaries and other remuneration to senior executives, Group, 2017**

Amounts in SEK thousands	Basic salary, directors' fees	Variable remuneration	Pension expenses	Share-related remuneration	Payments on termination of employment**	Total
Chairman of the Board of Directors Saeid Esmailzadeh	100	-	-	-	-	100
Board member Maris Hartmanis	163	-	-	-	-	163
Board member Peter Edman	163	-	-	-	-	163
Board member Karin Wingstrand	163	-	-	-	-	163
Board member Giorgio Chiviri	163	-	-	-	-	163
Board member Alessandro Sidoli	163	-	-	-	-	163
CEO Martin Åmark	919	93	-	-	-	1,012
Deputy CEO Siavash Bashiri	953	93	-	-	-	1,046
Other senior executives (5)	3,268	288	100	188	103	3,947
<b>Total</b>	<b>6,055</b>	<b>474</b>	<b>100</b>	<b>188</b>	<b>103</b>	<b>6,919</b>

**Salaries and other remuneration to senior executives, Group, 2016**

Amounts in SEK thousands	Basic salary, directors' fees	Variable remuneration	Pension expenses	Share-related remuneration	Payments on termination of employment**	Total
Chairman of the Board of Directors Saeid Esmailzadeh	100	-	-	-	-	100
Board member Maris Hartmanis	100	-	-	-	-	100
Board member Peter Edman	100	-	-	-	-	100
Board member Karin Wingstrand	100	-	-	-	-	100
Board member Giorgio Chiviri	100	-	-	-	-	100
Board member Alessandro Sidoli	100	-	-	-	-	100
CEO Martin Åmark	900	-	-	-	-	900
Deputy CEO Siavash Bashiri	753	-	-	-	-	753
Other senior executives (3)	2,307	-	18	-	253	2,578
<b>Total</b>	<b>4,560</b>	<b>-</b>	<b>18</b>	<b>-</b>	<b>253</b>	<b>4,831</b>

\* In accordance with the principle that the company should be result-neutral in payment of director's fees, regardless of whether they are paid as salary or invoiced as a fee, board members who have selected to invoice via companies have the option of invoicing the difference for these amounts as a supplement to the fee. The amounts relate to adjustment for this for 2016 and 2017 and amounts to SEK 63 thousand

\*\*Provision relates to statutory one-off payment to personnel in Italy which is paid when employment is terminated.

**NOTE 5** Employees, salaries and senior executive's remuneration, cont.**Personnel expenses for share-related remuneration**

Group	Group		Parent Company	
Amounts in SEK thousands	2017	2016	2017	2016
Expenses attributable to share savings program 2017–2019	313	-	313	-
Expenses attributable to equity-regulated bonus program 2016	120	-	120	-
<b>Total personnel expense as a result of share-related remuneration</b>	<b>432</b>	<b>-</b>	<b>432</b>	<b>-</b>

**Share savings program 2017-2019**

The company's long-term share savings program, which runs during the period 2017-2019 is estimated on the balance sheet date to comprise 11,165 savings shares which at the end of the program should result in an issue of 16,747 shares, equivalent to 0.28% in dilution, or alternatively a cash payment of the amount which may not exceed SEK 10,000 thousand. The cost of the share savings program amounted to SEK 313 thousand during 2017. The scope of the program is estimated to amount to a total of SEK 1,467 thousand, provided that the 2020 Annual General Meeting decides on an issue of the shares and that an equivalent cash payment is not made.

The estimated cost is based on the following assumptions.

Subscription of 7,605 savings shares up to 28 February 2018.

Employee turnover of 20%.

Annual share price development of 30%.

Number of matching shares 1:1, equivalent to 11,165.

Performance shares 1:0.5 provided that 50% of the targets are met, equivalent to 5,582.

**Incentive program 2016**

The company's short-term incentive program for the 2016 financial year resulted in a directed issue totalling 16,500 shares at an subscription price equivalent to the quote value. The issue was directed to nine employees, six of whom were employed in the Parent Company. The cost to the Group amounted to SEK 120 thousand and relates to social security expenses. The dilution amounted to 0.28 per cent.

**NOTE 6** Fees and reimbursement of expenses to auditors

	Group		Parent Company	
Amounts in SEK thousands	2017	2016	2017	2016
<i>KPMG AB</i>				
Audit assignment	375	264	375	264
Audit work in addition to the audit assignment	656	-	656	-
<i>Other auditors</i>				
<i>KPMG s.r.l.</i>				
Audit assignment	107	103	-	-
Audit work in addition to the audit assignment	324	-	324	-



**NOTE 7** Operating costs by category

Amounts in SEK thousands	Group		Parent Company	
	2017	2016	2017	2016
Raw materials and consumables	611	3,415	-	-
Change in inventory of finished goods and products in progress	-39	-2,276	-	-
Other external expenses	32,606	18,687	23,301	16,152
Personnel expenses	15,566	9,397	12,493	6,504
Depreciation	2,261	3,032	1,372	1,206
Exchange rate losses	1,169	135	1,169	135
	<b>52,174</b>	<b>32,391</b>	<b>38,336</b>	<b>23,998</b>

**NOTE 8** Net financial items

Group			
Amounts in SEK thousands		2017	2016
Interest income		0	3
<b>Financial income</b>		<b>0</b>	<b>3</b>
Interest charges for leasing		-69	-90
Interest charges for long-term liabilities		-60	-20
Interest charges for current liabilities		-	-64
Other financial expenses*		-87	-31
<b>Financial expenses</b>		<b>-217</b>	<b>-205</b>
<b>Net financial income/expense</b>		<b>-217</b>	<b>-202</b>

\* Includes bank charges, penalty interest, interest charges for taxes and fees.

Parent Company	Interest expenses and similar items		Interest income and similar items	
	2017	2016	2017	2016
Interest income			0	1
<b>Total</b>			<b>0</b>	<b>1</b>
Interest charges for non-current liabilities	-45	-		
Interest charges for current liabilities		-64		
Other financial expenses*	-11	0		
<b>Total</b>	<b>-56</b>	<b>-64</b>		

\* Includes penalty interest and interest charges for taxes and fees.

**NOTE 9 Taxes**

Amounts in SEK thousands	Group		Parent Company	
	2017	2016	2017	2016
<b>Current tax expense (-)/[Tax revenue (+)]</b>				
Tax expense [/tax revenue] for the year	-	-	-	-
Deferred tax expense (-)/[Tax revenue (+)]	-	-	-	-
<b>Total tax expense reported in the Group</b>	-	-	-	-

**Reconciliation of effective tax****Group**

Amounts in SEK thousands	2017	2016
Profit before tax	-44,935	-33,289
Tax at the current rate for the Parent Company	9,886	7,324
Effect of other tax rates for foreign subsidiaries	-	-
Non-deductible expenses	557	230
Non-taxable income	-	-359
Increase in loss carry-forward without equivalent activation of deferred tax	-10,442	-7,195
<b>Reported effective tax</b>	-	-

**Parent Company**

Amounts in SEK thousands	2017	2016
Profit/loss before tax	-37,553	-20,791
Tax at the current rate for the Parent Company	8,262	4,574
Non-deductible expenses	214	170
Non-taxable income	-	1
Increase in loss carry-forward without equivalent activation of deferred tax	-8,476	-4,745
<b>Reported effective tax</b>	-	-

As of 31/12/2017, accumulated loss carry-forward for the Parent Company amounted to SEK 77,177 thousand.

As of 31/12/2017, accumulated loss carry-forward for the Parent Company amounted to SEK 19,110 thousand.

No tax has been charged to other comprehensive income.

**NOTE 10 Earnings per share**

Earnings per share	- Before dilution		After dilution	
Amounts in SEK thousands	2017	2016	2017	2016
Earnings per share	-8.28	-6.16	-8.28	-6.16

The amounts used in numerators and denominators are presented below.

**Earnings per share before dilution (SEK)****Earnings for the year attributable to the Parent Company's ordinary shareholders, before and after dilution**

Amounts in SEK thousands	2017	2016
Earnings for the year attributable to the Parent Company's shareholders	-44,935	-27,769
Earnings for the year attributable to the Parent Company's ordinary shareholders, before dilution	-44,935	-27,769

Weighted average number of shares amounted to 5,425,656 (4,508,409), which has been affected by new share issues in May and September during the current year, as well as conversion of convertible loan. The number of outstanding shares at the end of the year was 5,956,770 (4,755,546).

Weighted average number of ordinary shares, before and after dilution	2017	2016
Weighted average number of ordinary shares during the year, before dilution	5,425,656	4,508,409
Weighted average number of ordinary shares during the year, after dilution	5,425,656	4,508,409

**Instruments which can produce future dilution effect and changes after the balance sheet date**

On the balance sheet date the company had an outstanding convertible loan which if converted to shares would correspond to 661,207 shares. Dilution from the share savings scheme is calculated according to the Treasury Stock method and is equivalent to 3,264 shares. If the Company reports positive earnings per share, the dilution effects will be taken into account.

\* Dilution not taken into account with negative earnings per share. If converted to shares, the outstanding convertible loan as at 31 December 2017 is equivalent to 661,207 shares. Dilution from the share savings scheme is calculated according to the Treasury Stock method and is equivalent to 3,264 shares.

**NOTE 11** Intangible assets

## Group

Amounts in SEK thousands	Internally developed Intangible assets Development expenses	Acquired Intangible assets Goodwill	Total
<b>Accumulated historical cost</b>			
Opening balance 1 January 2016	5,777	53,198	58,975
Reclassification of assets	1,390	-	1,390
Exchange differences for the year	335	2,515	2,850
<b>Closing balance 31 December 2016</b>	<b>7,502</b>	<b>55,713</b>	<b>63,215</b>
Opening balance 1 January 2017	7,502	55,713	63,215
Exchange differences for the year	131	1,647	1,778
<b>Closing balance 31 December 2017</b>	<b>7,634</b>	<b>57,360</b>	<b>64,993</b>
<b>Accumulated depreciation and impairment</b>			
Opening balance 1 January 2016	-	-	-
Depreciation for the year	-545	-	-545
Exchange rate differences	-13	-	-13
<b>Closing balance 31 December 2016</b>	<b>-557</b>	<b>-</b>	<b>-557</b>
Opening balance 1 January 2017	-557	-	-557
Depreciation for the year	-752	-	-752
Exchange rate differences	-27	-	-27
<b>Closing balance 31 December 2017</b>	<b>-1,337</b>	<b>-</b>	<b>-1,337</b>
<b>Reported values</b>			
As of 01/01/2016	5,777	53,198	58,975
As of 31/12/2016	6,945	55,713	62,658
As of 01/01/2017	6,945	55,713	62,658
As of 31/12/2017	6,297	57,360	63,656



**NOTE 11** Intangible assets cont.**Impairment tests for cash generated units containing goodwill**

Goodwill consists in its entirety of the subsidiary Primm Pharma s.r.l.

Group	Carrying amount	Carrying amount
Amounts in SEK thousands	31/12/2017	31/12/2016
Primm Pharma s.r.l.	57,360	55,713
<b>Total Goodwill</b>	<b>57,360</b>	<b>55,713</b>

*Primm Pharma s.r.l.*

No impairments of intangible assets had been made as of the balance sheet date of 31 December 2017.

The impairment test for Primm Pharma s.r.l. was based on estimation of value in use. This value derives from cash flow estimates based on the business forecast up to 2035 which was ratified by the management. The reason that a longer forecast period than five years has been selected is that the principal product candidate that Primm develops is not expected to be launched on the European and Chinese market until 2021 and is subsequently estimated to take up to about eight years before peak sales are achieved. In the light of this, a longer forecast period of 18 years better serves the purpose. The cash flows are estimated according to what the projected global market is like for the originator drug and how great a degree of penetration the company can achieve with its generics of the originator drug. The estimated cash flows have been estimated at present value with a discount rate of 33% before tax. The assumptions that are important in the eighteen year business forecast are described in the table below.

Important variables	Method for estimating values
Market share and growth	The market is estimated on the basis of current sales of the originator drug based on external sales data and growth is expected to be in line with inflation. When the company's product or another generic is launched, they are expected to take market shares from the estimated market for the originator drug. How large a share of the market the company's generics achieve is calculated on the basis of estimated degree of penetration. The degree of penetration is expected to be in line or somewhat higher than the average generic penetration in the respective country.
Sales price	The sales price that the company receives is estimated on the basis of the discount in relation to the originator drug that the product is expected to be sold for in the market, as well as after sharing the revenue with distribution- and marketing partners.
Production cost	Production cost is based on the management's estimates of future costs based on current production cost per dose produced as well as which scale benefits can be achieved when production increases.
Fixed costs	Fixed costs for Primm Pharma's operation comprise personnel expenses, premises and administrative expenses and are based on the management's estimated costs for the next 2 years and thereafter based on an annual incremental increase of about 10%.
Out-licensing	Out-licensing takes place to partners which account for sales and marketing of the product in different geographic markets. Milestone payments from some of the partnerships can generate revenues and also pay for parts of the development expenses and clinical studies.
Discount interest rate	The discount rate is calculated through a number of assumptions about capital structure, the market's risk premium, beta value, risk-free interest, small company premium, liquidity premium, company-specific risk, cost of capital and effective tax rate.

**NOTE 11** Intangible fixed assets cont.

The recoverable amount for Primm Pharma exceeds the reported value with approximately SEK 175 million, but it is reasonable to assume that possible changes in some important assumptions would mean that the unit's recoverable amount is lower than its reported value. The values that are used in the value in use calculations and the changed values that lead to the recoverable amount being the same as the reported value are as follows:

Variable	Assumed value	Changed value
Market share	35-90% degree of penetration	14% degree of penetration
Sales price	13-24% of the originator drug	13% of the originator drug
Cost of goods sold	1-month product 3-months product	Increases by 94% Increases by 168%
Discount interest rate	26% after tax	54% after tax

**NOTE 12** Property, plant and equipment

## Group

Amounts in SEK thousands	Machinery and other technical plant	Equipment, tools, fixtures and fittings	Construction in progress	Total
<b>Accumulated historical cost</b>				
Opening balance 1 January 2016	8,279	966	871	10,116
Other acquisitions	2,573	7,181	-	9,753
Reclassification of assets	871	-	-871	-
Exchange rate differences	473	33	-	506
<b>Closing balance 31 December 2016</b>	<b>12,195</b>	<b>8,180</b>	<b>-</b>	<b>20,375</b>
Opening balance 1 January 2017	12,195	8,180	-	20,375
Other acquisitions	2,593	1,556	-	4,149
Reclassification of assets	6,219	-6,219	-	-
Reclassification to earnings	-	-637	-	-637
Exchange rate differences	309	22	-	331
<b>Closing balance 31 December 2017</b>	<b>21,316</b>	<b>2,902</b>	<b>-</b>	<b>24,218</b>
<b>Accumulated depreciation and impairment</b>				
Opening balance 1 January 2016	-	-130	-	-130
Depreciation for the year	-1,022	-1,322	-	-2,344
Exchange rate differences	-24	-3	-	-27
<b>Closing balance 31 December 2016</b>	<b>-1,046</b>	<b>-1,455</b>	<b>-</b>	<b>-2,501</b>
Opening balance 1 January 2017	-1,046	-1,455	-	-2,501
Depreciation for the year	-2,837	-252	-	-3,089
Reclassification to earnings	-	79	-	-
Exchange rate differences	-54	-6	-	-60
<b>Closing balance 31 December 2017</b>	<b>-3,936</b>	<b>-1,634</b>	<b>-</b>	<b>-5,650</b>

**NOTE 12** Property, plant and equipment, cont.

## Reported values

Amounts in SEK thousands	Machinery and other technical plant	Equipment, tools, fixtures and fittings	Construction in progress	Total
As of 01/01/2016	8,279	836	871	9,986
As of 31/12/2016	11,150	6,725	-	17,875
As of 01/01/2017	11,150	6,725	-	17,875
As of 31/12/2017	17,380	1,268	-	18,569

Reported value for financially leased assets amounts to SEK 2,309 thousand.

**NOTE 13** Receivables at group companies

## Parent Company

Amounts in SEK thousands	31/12/2017	31/12/2016
Accumulated historical cost		
At the start of the year	-	-
Costs for external services are re-invoiced to the subsidiary	4,178	-
<b>Closing balance 31 December</b>	<b>4,178</b>	<b>-</b>

**NOTE 14** Non-current receivables and other receivables

## Group

Amounts in SEK thousands	31/12/2017	31/12/2016
<b>Non-current receivables that are fixed assets</b>		
Non-current receivables (rent deposition)	635	635
	<b>635</b>	<b>635</b>
<b>Other receivables that are fixed assets</b>		
Other receivables	-	347
<b>Total other receivables that are fixed assets</b>	<b>-</b>	<b>347</b>

## Parent Company

Amounts in SEK thousands	31/12/2017	31/12/2016
<b>Non-current receivables</b>		
Other non-current receivables (rent deposition)	635	635
	<b>635</b>	<b>635</b>
<b>Other receivables (current)</b>		
Income taxes recoverable	278	295
	<b>278</b>	<b>295</b>

**NOTE 15** Inventories**Group**

Amounts in SEK thousands	31/12/2017	31/12/2016
Raw materials and consumables	3,065	420
Work in progress	-	-
Finished products and goods for resale	-	2,077
	<b>3,065</b>	<b>2,497</b>

The Parent Company has no inventory.

**NOTE 16** Prepaid expenses and accrued income

Amounts in SEK thousands	Group		Parent Company	
	31/12/2017	31/12/2016	31/12/2017	31/12/2016
Rent	273	252	273	252
Leases	19	-	19	-
Other	726	2,725	522	507
	<b>1,018</b>	<b>2,977</b>	<b>814</b>	<b>759</b>

**NOTE 17** Cash and cash equivalents**Group**

Amounts in SEK thousands	31/12/2017	31/12/2016
The following sub-components are included in cash and cash equivalents:		
Cash and bank balances	7,903	31,338
<i>Total as per the statements of financial position</i>	<i>7,903</i>	<i>31,338</i>
<i>Total as per cash flow statements</i>	<i>7,903</i>	<i>31,338</i>

**NOTE 18 Equity****Types of shares**

	Ordinary shares	
	2017	2016
Issued as of 1 January	4,755,546	2,230,290
Issue of shares paid in cash	655,738	2,393,024
Conversion of convertible loan to shares	528,986	132,232
Issue in respect of incentive program for 2016	16,500	-
<b>Issued as of 31 December</b>	<b>5,956,770</b>	<b>4,755,546</b>

The Group only has one type of share, so-called ordinary shares.

As of 31 December 2017, the registered share capital comprised 5,956,770 ordinary shares (4,755,546).

Holders of ordinary shares are entitled to a dividend that is set in due course and the shareholding gives entitlement to voting rights at the General Meeting of shareholders with one vote per share. All shares have the same right to the company's remaining net assets.

**Dividends**

After the balance sheet date, the Board of Directors has proposed not to distribute a dividend. The dividend will be subject to ratification at the Annual General Meeting on 24 May 2018. The Company did not distribute a dividend for 2016 or earlier.

**Group****Translation reserve**

The translation reserve includes all exchange rate differences that arise when converting financial statements from foreign operations that have prepared their financial statements in a currency other than that in which the Group's financial statements are presented. The Parent Company and the Group present their financial statements in Swedish kronor. Further, the translation reserve consists of exchange rate differences which arise when revaluing goodwill.

**Parent Company****Restricted funds**

Restricted funds must not be reduced through distribution of profits.

**Unrestricted equity**

Together with profit for the year, the following funds constitute unrestricted equity, i.e. the amount that is available for dividends to the shareholders.

*Share premium reserve*

When shares are issued at a premium, i.e. more is to be paid for the shares than their par value, an amount equivalent to the amount received in excess of the shares' quote value is transferred to the share premium reserve. From 1 January 2006, amounts transferred to the share premium reserve are included in unrestricted equity.

*Retained earnings*

Retained earnings comprise previous years' retained earnings and earnings after deduction for dividends made during the year.

**NOTE 19 Interest-bearing debt**

The following provides information about the company's contractual terms in relation to interest-bearing liabilities. For further information about the company's exposure to interest rate risk and risk of exchange rate fluctuations, refer to note 23.

**Group**

Amounts in SEK thousands	2017	2016
Non-current liabilities		
Bank loans	273	384
Financial leasing debts	846	1,342
	<b>1,119</b>	<b>1,726</b>

The Group and the Parent Company have no current interest-bearing liabilities.



**NOTE 19** Interest-bearing liabilities, cont.**Terms and repayment periods**

Terms and repayment periods for the Group's interest-bearing liabilities are presented in the table below. No securities have been pledged for financial leasing and bank loans.

Amounts in SEK thousands	Currency	Nominal interest rate	Maturity	2017		2016	
				Nom. value	Reported value	Nom. value	Reported value
Bank loans	EUR	4.55%	31 January 2016	273	273	384	384
Financial leasing liabilities	EUR	5.90%	17 January 2020	846	846	1,342	1,342
<b>Total interest-bearing liabilities</b>				<b>1,119</b>	<b>1,119</b>	<b>1,726</b>	<b>1,726</b>

**Financial leasing liabilities**

The Group has a financial lease relating to a freeze dryer which is used in production of drugs in the subsidiary. Financial leasing liabilities fall due for payment as below:

Group	Minimum leasing fees	Interest	Capital amount	Minimum leasing fees	Interest	Capital amount
Amounts in SEK thousands	2017	2017	2017	2016	2016	2016
Within one year	-	-	-	-	-	-
Between one and five years	606	85	1,119	583	110	1,726
Later than 5 years	-	-	-	-	-	-
	<b>606</b>	<b>85</b>	<b>1,119</b>	<b>583</b>	<b>110</b>	<b>1,726</b>

**NOTE 20** Provisions**Group**

Amounts in SEK thousands	2017	2016
One-off payment on termination of employment	3,545	3,182
	<b>3,545</b>	<b>3,182</b>

As of 31 December 2017, the Parent Company has no provisions.

**Group one-off payment on termination of employment**

Amounts in SEK thousands	2017	2016
Provisions made during the period	282	234
Change in discounted amount during the period	80	14
<b>Reported value at the end of the period</b>	<b>3,545</b>	<b>3,182</b>

One-off payment on termination of employment refers to employees in Primm Pharma s.r.l. in accordance with Italian legislation. The expected period for outflow is estimated at 5 years.

**NOTE 21 Other liabilities****Group**

Amounts in SEK thousands	2017	2016
<b>Other current liabilities</b>		
Current liabilities to employees	70	8
Current tax liabilities relating to VAT, income tax for personnel and social security expenses	792	345
Other current liabilities	-	9
	<b>863</b>	<b>362</b>

**Parent Company**

Amounts in SEK thousands	2017	2016
<b>Other current liabilities</b>		
Current liabilities to employees	70	8
Current tax liabilities relating to VAT, income tax for personnel and social security expenses	690	253
Other current liabilities	-	9
	<b>760</b>	<b>270</b>

**NOTE 22 Accrued expenses and prepaid income**

Amounts in SEK thousands	Group		Parent Company	
	31/12/2017	31/12/2016	31/12/2017	31/12/2016
Payroll expenses	899	2	797	-
Holiday pay	1,205	444	1,205	444
Interest expenses	45	-	45	-
Prepaid income	1,945	399	371	397
Other accumulated expenses	2,394	2,220	2,394	507
	<b>6,488</b>	<b>3,065</b>	<b>4,812</b>	<b>1,348</b>

**NOTE 23 Financial risks and risk management**

Through its operations, the Group is exposed to various types of financial risks.

- Credit risk
- Liquidity risk
- Market risk

*Framework for financial risk management*

The Group's financial policy for managing financial risks has been designed by the Board and forms a framework of guidelines and rules in the form of risk mandates and limits for financial activities. Responsibility for the Group's financial transactions and risks is handled centrally by the Group's financial function within the Parent Company. The overall objective of the financial function is to provide cost-effective funding and to minimize negative effects on the Group's earnings resulting from market risks. The head of the central finance function is the CFO, who reports to the CEO and Board of Directors on an ongoing basis.

*Liquidity risk*

Liquidity risk is the risk that the Group may have problems fulfilling its obligations associated with financial liabilities. The Group has rolling 12-month liquidity planning covering all Group entities. The schedule is updated every month. The Group's forecasts covering 3 years include liquidity planning in the medium term. Liquidity planning is used to manage the liquidity risk and the costs of financing the Group. The goal is that the Group will be able to meet its financial commitments both in terms of gains and losses, without significant unforeseen costs and without risking the Group's reputation. The Group's policy is to minimize borrowing requirements by using surplus liquidity within the Group through cash pools set up by the central finance function. Liquidity risks are managed centrally for the entire Group by the central finance function. According to the finance policy, there should always be sufficient cash and guaranteed credits to cover

the liquidity needs of the next 12 months. In December 2017, the company received a credit facility of SEK 50 million with maturity date June 2019. By the year-end the credit facility was unutilized. The Company's financial liabilities at year-end amounted to 1,129 SEK thousand and the maturity structure of the debt is shown in the table below.

**Credit facilities**

Amounts in SEK thousands	Nominal value	Utilized	Available
Credit facility, Maturity June 2019	50,000	-	50,000
Total	50,000	-	50,000
Available cash and cash equivalents	7,269	-	7,269
<b>Liquidity reserve</b>	<b>57,269</b>	<b>-</b>	<b>57,269</b>

*Market risk*

Market risk is the risk that the fair value of or future cash flows from a financial instrument will vary due to changes in market prices. Market risks are classified by IFRS into three types, currency risk, interest rate risk and other price risks. The market risks that primarily affect the Group consist of interest rate risks and currency risks.

At present, the CEO and the Board consider that the financial market risks the company is exposed to, interest rate risk and currency risk are limited. This because the Company, until the

**Maturity structure financial liabilities – undiscounted cash flows****Group**

Amounts in SEK thousands	Currency	2017						2016					
		Total	< 1 m	1-3 m	3 m - 1 y	1-5 y	>5 y	Total	< 1 m	1-3 m	3 m - 1 y	1-5 y	>5 y
Bank loan	EUR	273	-	-	-	273	-	384	-	-	-	384	-
Account payables		10,541	10,541	-	-	-	-	2,364	2,364	-	-	-	-
Financial leases liability	EUR	846	-	-	-	846	-	1,342	-	-	-	1,342	-
<b>Total</b>		<b>11,659</b>	<b>10,541</b>	<b>-</b>	<b>-</b>	<b>1,119</b>	<b>-</b>	<b>4,090</b>	<b>2,364</b>	<b>-</b>	<b>-</b>	<b>1,726</b>	<b>-</b>

No settled payments or breach of contract occurred in 2017. The reporting amount of accounts receivable, other short-term receivables, cash and bank accounts, trade payables and other short-term liabilities constitutes a fair approximation of fair value.

**NOT 23** Financial risks and risk management, continued.

balance sheet date was primarily financed by equity and only minor loans relating to leases. Even exposure to currencies other than the Company's respective functional currencies has been limited. This may change as the Company takes up interest-bearing loans, such as the credit facility that the Company received but not utilized in 2017. Currency risk may also increase as costs in foreign currency are expected to increase as exposure to Euro will increase when clinical studies commence. The Board, CEO and CFO continuously monitor changes in the risk profile and the need for price hedging instruments.

*Credit Risk*

The Group's financial operations entail exposure to credit risks. It is primarily counterparty risks in connection with receivables on counterparties arising from the sale of goods and licenses. At the balance sheet date, no accounts receivable were due or written down.

*Credit risks in accounts receivable*

The risk that the Group's customers fail to fulfill their obligations, such as payment not received from customers, constitute a customer credit risk. As the Company in 2017 only had one counterparty for the sale of the Company's products and this counterparty is based in Iran, the credit process is applied to meet the conditions.

Hence, there is a concentration of credit exposure to a customer and a region where the risk of losses is higher than the average. The Group's risk management comprises structuring prepayments, during and after delivery of products, and careful planning with the counterparty on how orders and payments are to be made.

The Group had no due accounts receivable on the balance sheet date.

*Capital management*

According to the Board's policy, the Group's financial objective is to maintain a good financial position, which helps to maintain investor confidence, creditors' and market confidence and provide a foundation for further development of business operations; while the long-term return generated to the shareholders is satisfactory. Until the Company has achieved long-term and sustainable profitability, the company's policy is to maintain low debt and high equity.

Amounts in SEK thousands	2017	2016
<b>Capital</b>		
Total equity	88,405	113,901
<b>Net debt ratio</b>		
Financial liabilities	1,119	1,726
Less cash and cash equivalents	7,903	31,338
<b>Net liabilities</b>	<b>-6,784</b>	<b>-29,612</b>
Net indebtedness (Net liabilities / Total equity)	-7.6%	-26.0%

On the balance sheet date the Company had negative net liabilities, i.e. net cash, and net indebtedness was thus negative.

**NOTE 24** Pledged assets, contingent liabilities and contingent assets

Amounts in SEK thousands	Group		Parent Company	
	31/12/2017	31/12/2016	31/12/2017	31/12/2016
Pledged assets	351	351	-	-
Contingent liabilities	-	-	-	-
	<b>351</b>	<b>351</b>	<b>-</b>	<b>-</b>

In 2017 pledged assets consisted of a leased car for a bank loan.

**NOTE 25** Distribution of the Company's profit or loss**Proposed distribution of the Company's profit or loss****Amounts in SEK thousands**

Share premium reserve	180,560
Profit/loss brought forward	-40,070
Profit/loss for the year	-37,553
<b>Total</b>	<b>102,937</b>
To be carried forward:	102,937

**NOTE 26** Transactions with closely related parties

The Parent Company has a relationship with its subsidiaries, see note 32.

**Group**

Amounts in SEK thousands	Year	Purchase of goods/ services from affiliates	Interest costs	Provision for affiliates as of 31 December*
<b>Relationship</b>				
Other closely related parties	2017	930	45	3,157
Other closely related parties	2016	578	64	3,182

*One-off payment on termination of employment refers to employees in Primm Pharma s.r.l. in accordance with Italian legislation.*

**Parent Company**

Amounts in SEK thousands	Year	Purchase of goods/ services from affiliates	Interest costs
<b>Relationship</b>			
Other closely related parties	2017	348	45
Other closely related parties	2016	578	64

Transactions with closely related parties are priced on market terms.

Remuneration to senior executives and Board of Directors is presented in Note 5.

**Transactions with closely related parties**

Closely related parties include the Group's management, board members and their relatives, as well as companies where the above mentioned have a leading position or have an ownership connection. Since 31 December 2015 there is a provision for the Italian subsidiary Primm Pharma's CEO/ Head of Long-Acting Injectables which on the balance sheet date of 31 December 2017 amounted to SEK 3,157 thousand. The provision relates to one-off payment on termination of employment in accordance with Italian legislation and is not interest-bearing.

Xbrane acquired consultancy services during 2017 of SEK 48 thousand from Edman Life Science, which is owned by Peter Edman, who is a member of Xbrane's board of directors.

Xbrane procured legal services during 2017 from S. Legal AB for SEK 154 thousand, accounting and administration services from Juno Ekonomi AB for SEK 135 thousand, and communication services from Serendipity Communication AB for SEK 11 thousand. All companies are 100 per cent owned by Sdipitech

AB which is own by 76 per cent by Serendipity Group AB, which in turn is 50 per cent owned by Saeid Esmaeilzadeh, who is Chairman of the Board of Xbrane.

During 2017 Primm Pharma s.r.l. has purchased administration and accounting services, and also rented premises from Primm s.r.l. at a cost of SEK 582 thousand. Primm s.r.l. is 56 procent per cent owned by Paolo Sarmientos, CEO/ Head of Long-Acting Injectables for Primm Pharma, and 10 per cent by Alessandro Sidoli, member of Xbrane's board of directors.

On 22 December 2017 Serendipity Group AB issued a credit facility to Xbrane Biopharma AB of SEK 50,000 thousand with a duration of 18 months. Interest is charged at 3% of the total credit facility regardless of utilisation, and is paid on repayment of the loan. During 2017, the interest charges for the credit facility amounted to SEK 45 thousand. The credit facility should be viewed as bridge loan for the Company that can be utilised until a long-term financing solution is in place.



**NOTE 27** Group companies

Holdings in subsidiary companies	Subsidiary's registered office, country	Equity interest in %
Primm Pharma s.r.l.	Italy	100
<b>Parent Company</b>		
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>
<b>Accumulated historical cost</b>		
At the start of the year	88,335	62,775
Shareholder contribution made	5,756	25,560
<b>Closing balance 31 December</b>	<b>94,092</b>	<b>88,335</b>
<b>Accumulated revaluations</b>		
At the start of the year	-	-
<b>Closing balance 31 December</b>	<b>-</b>	<b>-</b>
<b>Accumulated impairments</b>		
At the start of the year	-	-
<b>Closing balance 31 December</b>	<b>-</b>	<b>-</b>
<b>Reported value 31 December</b>	<b>94,092</b>	<b>88,335</b>

**NOTE 28** Specifications for cash flow statements**Cash and cash equivalents****Group**

Amounts in SEK thousands	31/12/2017	31/12/2016
<i>The following sub-components are included in cash and cash equivalents</i>		
Cash and bank balances	7,903	31,338
<i>Total as per the balance sheet</i>	7,903	31,338
<i>Total as per the cash flow statements</i>	7,903	31,338

**Parent Company**

Amounts in SEK thousands	31/12/2017	31/12/2016
<i>The following sub-components are included in cash and cash equivalents</i>		
Cash and bank balances	6,483	30,512
<i>Total as per the balance sheet</i>	6,483	30,512
<i>Total as per the cash flow statements</i>	6,483	30,512

**Reconciliation of liabilities which derive from the financing operation**

Group	OB 2017	Cash flows	Changes that do not affect cash flow		CB 2017
Amounts in SEK thousands			Change in leasing contract	Exchange rate differences	
Bank loans	384	-120		10	273
Leasing liabilities	1,342	-137	-392	32	846
<b>Total liabilities deriving from the financing operation</b>	<b>1,726</b>	<b>-257</b>	<b>-392</b>	<b>42</b>	<b>1,119</b>

The Parent Company had no liabilities which derive from the financing operation on the balance sheet date or the balance sheet date of the comparison period.

**NOTE 28** Specifications for cash flow statements, cont.

<b>Interest paid and dividends received</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Interest received	-	-	0	-
Interest paid	-95	-	-11	-
<b>Adjustment for items not included in cash flow</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Depreciation	3,992	2,060	1,372	1,206
Expenses for equity-related remuneration	313	-	313	-
Other	-501	-1,319	-	-
<b>Cash flows in operational activities divided according to operating segment</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Biosimilars	-23,045	-16,270	-23,045	-13,963
Long-acting Injectables	-1,683	-19,392	-	-2,307
Administration and unallocated	-12,120	-3,481	-10,228	-4,220
<b>Total cash flows in operational activities</b>	<b>-36,848</b>	<b>-39,143</b>	<b>-33,273</b>	<b>-20,489</b>
<b>Cash flows in investing activities divided according to operating segment</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Biosimilars	-1,985	-7,793	-7,742	-33,353
Long-acting Injectables	-1,362	-4,972	-	-
Administration and unallocated	-	-	-	-
<b>Total cash flows in operational activities</b>	<b>-3,347</b>	<b>-12,766</b>	<b>-7,742</b>	<b>-33,353</b>
<b>Cash flows in financing activities divided according to operating segment</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Biosimilars	-	-	-	-
Long-acting Injectables	-257	-1,628	-	-
Administration and unallocated	16,985	82,157	16,985	82,157
<b>Total cash flows in operational activities</b>	<b>16,728</b>	<b>80,529</b>	<b>16,985</b>	<b>82,157</b>
<b>Investments</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Investment that have been made in order to maintain the capacity level	-	-	-	-
Investments that can be regarded as raising the operation's capacity level	-3,347	-12,766	-7,742	-33,353
<b>Total investments</b>	<b>-3,347</b>	<b>-12,766</b>	<b>-7,742</b>	<b>-33,353</b>
<b>Unutilised credits</b>				
	<b>Group</b>		<b>Parent Company</b>	
<b>Amounts in SEK thousands</b>	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Unutilised credits amount to	50,000	-	50,000	-

**NOTE 29** Effects of transition to International Financial Reporting Standards (IFRS)

The annual report for the 2017 financial year is the Xbrane Group's first financial annual report prepared in accordance with International Financial Reporting Standards (IFRS), issued by the International Accounting Standards Board (IASB) as adopted by the EU. Before the transition to IFRS, the Group applied K3. The date of the Xbrane Group's transition to IFRS was 1 July 2017. Up to and including the financial year 30 June 2017, the Group has prepared the consolidated financial statements in accordance with the Annual Accounts Act and the recommendations of the Swedish Financial Accounting Standards Council and accompanying statements.

The transition to IFRS is reported in accordance with IFRS 1, "First time Adoption of International Financial Reporting Stand-

ards". Previously published financial information for the 2016 financial year, prepared according to the Annual Accounts Act and the recommendations of the Swedish Financial Accounting Standards Council, have been converted to IFRS. The general rule is that all applicable IFRS and statements, which have entered into force and were approved by the EU, shall be applied with retroactive effect. However, IFRS 1 includes transitional provisions which give companies a certain limitation of the retroactive conversion. The following presents the changes in accounting principles that the introduction of IFRS entails, as well as the transitional effects on the Xbrane Group's earnings, comprehensive income, balance sheet and equity. No IFRS adjustments have affected the Group's cash flow statement.

**The effect of application of IFRS on the Xbrane Group's consolidated statement of profit and loss 2016**

Amounts in SEK thousands		Operating profit	Total comprehensive income
<b>According to previously applied principles</b>		<b>-33,222</b>	<b>-33,289</b>
Goodwill	a)	5,446	8,232
Start-up expenses	b)	62	62
Net present value of liability	c)	13	13
Other adjustments	d)	135	-
Total adjustments of earnings		5,655	8,306
<b>According to IFRS</b>		<b>-27,567</b>	<b>-24,983</b>

**The effects of application of IFRS on the Xbrane Group's equity 2016**

Amounts in SEK thousands		01/01/2016	31/12/2016
<b>Equity according to previously applied principles according to approved consolidated statement of financial position</b>		<b>47,509</b>	<b>107,301</b>
Effects in opening balances			
Goodwill	a)	1,063	1,063
Convertible loan	e)	-54,550	-54,550
Net present value of liability	c)	3	3
<b>Effects during the period of transition to IFRS</b>			
Goodwill	a)		5,457
Convertible debt	e)		54,550
Start-up expenses	b)		63
Net present value of liability	c)		13
<b>Equity according to IFRS</b>		<b>-5,975</b>	<b>113,901</b>

**NOTE 29 Effects of transition to International Financial Reporting Standards (IFRS), cont.**

- a) Goodwill is not written off according to IFRS IAS 38 Intangible assets. Depreciation previously made has thus been reversed. The add-back of goodwill affects the "Goodwill" asset item by SEK 6,520 thousand, "Operating profit/loss" 2016 by SEK 5,446 thousand, other comprehensive income by SEK 2,786 thousand, "Retained earnings including profit/loss for the year" by SEK 6,505 thousand as of the end of 2016.
- b) Start-up expenses should not be capitalized according to IFRS. Reversal of depreciation affects operating profit by SEK 62 thousand and equity by SEK 63 thousand, of which Retained earnings including the period's profit by SEK 62 thousand.
- c) Net present value of liabilities. According to IFRS, certain liabilities, such as provision for severance pay for employees, shall be computed at present value. The present value computation affected the operating profit by SEK 13 thousand and equity by SEK 13 thousand.
- d) Other adjustments. Relates to corrections from the IFRS bridge which was presented in connection with the Q3 report compared with the interim report.
- e) For a convertible loan to be classified as equity according to IFRS requires that the company's shares are available for trading on a regulated or unregulated exchange such as Nasdaq First North. At the beginning of 2016, the company's shares were not yet available for trading on Nasdaq First North and the entire convertible loan of SEK 54,550 thousand is thereby reclassified from equity to current liability. This changed when the Company's shares were accepted for trading on Nasdaq First North on 3 February 2016.

**NOTE 30 Events after the balance sheet date****Out-licensing agreement for Spherotide in China**

Xbrane entered into an out-licensing agreement after the balance sheet date with CR Pharma for sales and marketing of Spherotide in China.

**Election of new chairman of board of directors**

The extraordinary general meeting on 3 April 2018 elected Anders Tullgren as Chairman of the Board of Xbrane Biopharma.

**Issue of warrants and shares**

Following the decision of the Extraordinary General Meeting on 3 April 2018, the following directed issues of shares and warrants were implemented:

- 32,857 shares at subscription price of SEK 60.87 and 49,285

warrants with maturity in 2021 priced according to Black & Schole's option pricing model for Chairman of the Board Anders Tullgren.

- A total of 9,000 shares at an subscription price of SEK 61.04 plus a total of 13,500 warrants with maturity in 2021 priced according to Black & Schole's option pricing model which were subscribed by the following board members: Maris Hartmanis, Peter Edman, Karin Wingstrand, Alessandro Sidoli and Giorgio Chirivi.

- A total of 79,000 warrants with maturity in 2022 priced according to Black & Schole's option pricing model which were subscribed by the following persons from the management: Martin Åmark, Susanna Helgesen, Siavash Bashiri and David Viklund.

**NOTE 31 Significant estimates and assessments**

The management has discussed with the Audit Committee the development, selection and information in relation to the Group's important accounting principles and estimates, as well as the application of these principles and estimates.

**Important sources of uncertainty in the estimates**

The sources of uncertainty in the estimates indicated below refer to aspects which entail a significant risk that assets' or liabilities' value might need to be adjusted significantly during the forthcoming financial year.

**Impairment testing of goodwill**

When calculating cash generative units' recovery value for assessment of any impairment of goodwill, several assumptions regarding future circumstances and estimates of parameters have been made. There is an account of them in note 11. As is clear from the description in note 11, changes in the conditions for these assumptions and estimates during 2017 could have a material effect on the value of goodwill for the subsidiary Primm Pharma.

**NOTE 32 Information about the Parent Company**

Xbrane Biopharma AB (publ), Corp ID no. 556749-2375, is a Swedish-registered limited company with registered office in Solna. The Parent Company's shares are registered on NASDAQ First North Stockholm. The address of the head quarter is Banvaktsvä-

gen 22, 171 48 Solna. The consolidated financial statements for 2017 consist of the Parent Company and its subsidiary, together with the named Group. The Group also includes Primm Pharma, Corp ID no. MI - 2075109 with registered office in Milan, Italy.

## Signatures

The income statement and balance sheet will be presented to the AGM on May 24, 2018 for adoption. The Board of Directors and the CEO certify that the consolidated accounts have been prepared in accordance with IFRS and give a true and fair view of the Group's financial position and results. The annual financial statements have been prepared in accordance with generally accepted accounting principles

and give a true and fair view of the Parent Company's financial position and results. The Administration Report for the Group and Parent company provides a fair review of the development of the Group and the Parent Company's operations, position and results and describes significant risks and uncertainty factors that the Parent Company and the companies included in the Group face.

Stockholm 27 April 2018

---

Anders Tullgren  
*Chairman*

---

Saeid Esmailzadeh  
*Director*

---

Peter Edman  
*Director*

---

Maris Hartmanis  
*Director*

---

Karin Wingstrand  
*Director*

---

Giorgio Chiviri  
*Director*

---

Alessandro Sidoli  
*Director*

---

Martin Åmark  
*CEO*

Our audit report was presented on 27 April 2018  
KPMG AB

---

Duane Swanson  
*Authorised Public Accountant*



## Auditor's report

To the general meeting of the shareholders of Xbrane Biopharma AB (publ), corp. ID no. 556749-2375.

### Report on the annual accounts and consolidated accounts

#### *Opinions*

We have audited the annual accounts and consolidated accounts of Xbrane Biopharma AB for the year 2017. Annual accounts and consolidated accounts of Xbrane Biopharma AB includes on the pages 30-74 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2017 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2017 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

#### *Basis for Opinions*

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they

give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

#### *Auditor's responsibility*

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's, use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

## **Report on other legal and regulatory requirements**

### *Opinions*

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Xbrane Biopharma AB for the year 2017 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### *Basis for Opinions*

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Managing Director shall manage the ongoing administration according to the Board of Directors'

guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### *Auditor's responsibility*

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company,

or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

#### *Other matters*

The company has on several occasions failed to pay of taxes on a timely basis.

Stockholm 27 April 2018  
KPMG AB

---

Duane Swanson  
*Authorised Public Accountant*

# Annual General Meeting

## 2018 Annual General Meeting

Annual General Meeting in Xbrane Biopharma AB (publ) will be held on Thursday 24 May 2018 at 17.30 in Baker & McKenzie Advokatbyrå's premises, Vasagatan 7, 101 23 Stockholm

### To participate

Shareholders who want to participate in the meeting must be registered in the share register kept by Euroclear Sweden AB on Friday 18 May 2018. Registration is to be made no later than Friday 18 May 2018 in one of the following ways:

- via website, [www.xbrane.com](http://www.xbrane.com)
- by telephone: +46 708 27 86 36
- by post: Xbrane Biopharma AB (publ), "Annual General Meeting", Bankvaktsvägen 22, 171 48 Solna

### When registering, shareholders must state:

- name
- social security number/corporate identity number
- daytime address and telephone number
- number of shares
- where appropriate details of any agent/assistant

### Nominee registered shares

Shareholders who have their shares registered in the name of a nominee at a bank or other manager must, to be entitled to participate in the general meeting of shareholders, register their shares in their own name, so that the person in question is registered in the share register kept by Euroclear Sweden AB on Friday

18 May 2018. Shareholders who wish to register their shares in their own name should notify the nominee in good time before this date. Such registration can be temporary.

### Agents

Shareholders who are to be represented through an agent must issue written and dated power of attorney for the agent. If the power of attorney is issued by a legal entity, a certified copy of a registration certificate or corresponding "certificate" for such legal entity must be attached. Power of attorney applies for one year from issuance or the longer period of validity set out on the power of attorney, though a maximum of five years. Certificate of registration shall indicate the circumstances which apply on the date of the general meeting of shareholders and should in any event not be older than one year at the time of the annual general meeting. The original power of attorney plus any certificate of registration should be submitted by letter to the company to the address indicated above in good time before the meeting. Form for power of attorney is available on the Company's website [www.xbrane.com](http://www.xbrane.com) and can also be sent to shareholders who so request.

### Contact information

Xbrane Biopharma AB (publ)  
171 48 Stockholm, Sweden  
Visitors: Bankvaktsvägen 22, 171 48 Solna  
Tel: +46 708 27 86 36  
E-mail: [info@xbrane.com](mailto:info@xbrane.com)  
Website: [www.xbrane.com](http://www.xbrane.com)

## Alternative key indicators

The company presents certain financial key indicators in the Annual Report that are not defined according to IFRS. The company considers that these key indicators provide valuable supplementary information to investors and the company's management as they enable evaluation of the company's performance. As not all companies calculate financial key indicators in the same way, they are not always comparable with key indicators that are used by other companies. These financial key indicators should therefore not be viewed as a replacement for key indicators that are defined according to IFRS. The tables below present key indicators that are not defined according to IFRS.

### Gross margin

The gross margin is calculated as gross result in relation to the net sales. The gross margin is net sales minus cost of goods sold.

Amounts in SEK thousands	2017	2016
Gross profit	4,942	-
Divided by net sales	20,771	-
Gross margin	24%	-

### EBITDA

Shows the operation's earning power from operational activities without taking into account capital structure and tax situation, with the aim of facilitating comparisons with other companies in the same industry.

Amounts in SEK thousands	2017	2016
Operating profit	-44,718	-27,567
Depreciation	-3,992	-2,069
EBITDA	-40,726	-25,497

### Research and development expenses as a percentage of operating expenses.

The company's direct expenses for research and development relate to expenses for personnel, materials and external services. Research and development expenses as a percentage of business expenditure show how great a proportion of the business expenditure relates to research and development. This is calculated by dividing research and development expenses by total business expenditure minus depreciation and write-downs. Total business expenditure comprises selling expenses, administrative expenses, research and development expenses and other business expenses.

Amounts in SEK thousands	2017	2016
Research and development expenses	-37,982	-23,858
Divided by operating expenses minus depreciation and write-downs	-48,182	-30,321
Research and development expenses as a percentage of operating expenses.	79%	79%



## Glossary

**Age-related macular degeneration (AMD)** – Changes in the macula due to aging, also called age-related macular degeneration (AMD), is condition that results in permanent damage to the macula. The first changes that a person notices is that the vision becomes blurred, straight lines become crooked and some letters disappear when you try reading. Colors often become less clear than normal. The central field of vision is weakened, but the peripheral vision is retained. Macular degeneration is the most common cause of blindness or serious vision impairment in the developed world. If the disease is allowed to continue, the patient loses central vision, but maintains a certain amount of peripheral vision.

**AIFA** – Italian Medicines Agency (Agenzia Italiana del Farmaco).

**BfArM** – German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte).

**Biosimilar** – The term biosimilar was introduced in law in 2004 and is a biologic drug that is similar to an approved biologic drug (the biological reference drug). In order for a biosimilar drug to be approved, it must be comparable with the reference drug in terms of chemical properties (e.g. molecular structure and impurities), biologic activity, and it must also have similar properties in terms of pharmacokinetics and pharmacodynamics as well as equal safety and efficacy.

**CFDA** – China Food and Drug Administration.

**Diabetes-related macular edema (DME)** – Macular edema results in fluid collecting in the outer layer of the macula in the middle of the retina. Cyst-like blisters are formed, which can cause macular depression or holes. The edema may be associated with background illnesses, but often appears in patients with diabetes.

**Diabetic retinopathy (DME)** – A change in the blood vessel in the retina, e.g. bleeding, which can occur amongst diabetes patients.

**EMA** – European Medicines Agency

**Endometriosis** – Endometriosis involves the endometrium growing outside of the uterus. Roughly one in ten people who menstruate have this disease.

**FDA** – US Food and Drug Administration.

**Generic** – Generic drugs are medically interchangeable drugs with the same function, quality and safety as an original drug. A generic drug can be sold at a lower price since the production has limited costs for research and development. In 2018, generic medicines make up 60% of the volume and 19% of the value on the Swedish pharmaceutical market.

**GMP certification** – Certification that the production is performed according to good manufacturing practices.

**GnRH analog** – A hormone-inhibiting medicine that reduces the production of sex hormones in the body, testosterone in men and estrogen in women, and is used primarily in men to treat prostate cancer and in women to treat endometriosis, breast cancer and myoma.

**In-vitro** – a term that refers to studying a living microorganism, cell or biomolecule outside of its normal biological context.

**MHRA** – UK Medicines and Healthcare products Regulatory Agency.

**Myoma** – Myoma are muscle nodules that can develop inside or outside of the uterus.

**Off-label use** – Using a medical product to treat a disease for which the medicine is not approved.

**PMDA** – Japanese Pharmaceuticals and Medical Devices Agency.

**Retinal venous occlusion (RVO)** – RVO is a blood clot (thrombosis) in one of the eye's blood vessels (a vein). This is a common vascular disease, which if left untreated, can lead to blindness.

**Statistical power** – Indicates the risk taken in a study of making a so-called type 2 error, i.e. in the case of equivalency tests, of accepting the hypothesis that there is a difference between the drugs even if there isn't. With a statistical strength of 90%, there is a 10% risk of making a type 2 error.

**VEGF-A** – Vascular endothelial growth factor which, among other things, stimulates the growth of abnormal blood vessels in patients with AMD, DME and RVO.

**VEGF-inhibitors** – Drugs that act by binding to VEGF-A and thereby inhibit its ability to stimulate growth of e.g. abnormal blood vessels in the eye.





