

# Year-end Report 2018

## The fourth quarter in summary

- » Revenue amounted to SEK 4,896 thousand (9,535).
- » Gross margin amounted to 25% (24).
- » Other operating income amounted to SEK 1,305 thousand (1,788).
- » EBITDA amounted to SEK -30,336 thousand (-17,992).
- » R&D expenses amounted to SEK -25,533 thousand (-17,531), corresponding to 78% (79) of total operating expenses.
- » Loss amounted to SEK -32,423 thousand (-19,157).
- » Earnings per share amounted to a SEK -5.12 (-3.22).
- » Cash and cash equivalents amounted to SEK 100,972 thousand (7,903) at the end of the year.

## Significant events during quarter

- » In October, Xbrane presented the results of an in-vivo study in rabbits, demonstrating tolerability and a pharmacokinetic profile for Xlucane equivalent to Lucentis®.
- » Application has been filed with the FDA (Food and Drug Administration) in US, for the initiation of the pivotal clinical trial with Xlucane.

## Full year summary

- » Revenue amounted to SEK 20,485 thousand (20,771).
- » Gross margin amounted to 22% (24).
- » Other operating income amounted to SEK 99,742 thousand (2,515), of which SEK 77,325 thousand was an up-front payment for the co-development agreement with STADA for Xlucane and SEK 13,008 thousand was a milestone payment for the out-licensing of Spherotide to CR Pharma.
- » EBITDA amounted to SEK -6,079 thousand (-41,988).
- » R&D expenses amounted to SEK -85,827 thousand (-37,982), corresponding to 78% (79) of total operating expenses.
- » Loss amounted to SEK -13,236 thousand (-44,935).
- » Earnings per share amounted to SEK -2.13 (-8.28).

## Significant events after the end of the year

- » Approval for the initiation of the clinical trial with Xlucane, has been obtained from FDA in US.
- » Martin Åmark, CEO, was appointed to also be the Head of IR. Xbrane's previous Head of IR and CFO, Susanna Helgesen, will be on parental leave on a part-time basis. During the parental leave, Susanna will remain as CFO. The finance team has therefore been expanded with a Group Financial Controller.
- » Board members Alessandro Sidoli and Saeid Esmailzadeh decline re-election for 2019.

## Financial summary for the Group

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full Year	2017 Full Year
Revenue	4,896	9,535	20,485	20,771
Research and development expenses	-25,533	-17,531	-85,827	-37,982
R&D expenses as a percentage of operating expenses	78%	79%	78%	79%
EBITDA	-30,336	-17,992	-6,079	-41,988
Operating profit/loss	-32,156	-19,118	-11,415	-44,718
Profit/loss for the period	-32,423	-19,157	-13,236	-44,935
Cash and cash equivalents	100,972	7,903	100,972	7,903
Equity ratio, %	33%	80%	33%	80%
Number of shares at the end of the period before dilution	6,329,239	5,956,770	6,329,239	5,956,770
Number of shares at the end of the period after dilution*	6,329,239	5,956,770	6,329,239	5,956,770
Average number of shares before dilution	6,329,239	5,956,770	6,213,927	5,425,656
Average number of shares after dilution*	6,329,239	5,956,770	6,213,927	5,425,656
Earnings per share before dilution (SEK)	-5.12	-3.22	-2.13	-8.28
Earnings per share after dilution (SEK)*	-5.12	-3.22	-2.13	-8.28

\* Dilution not taken into account where earnings per share are negative. If converted to shares, convertible loans outstanding as per December 31, 2018, would be equivalent to 132,323 shares. If converted to shares, warrants for share savings programs for employees would be equivalent to 192,338 shares. This would total 324,571 shares on conversion.



Pioneering biosimilar development

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



## CEO's comments

### Dear shareholders,

As we now leave 2018 behind us, we can conclude that this year was the most successful year in Xbrane's history! We generated total revenue of SEK 120 million from co-development and outlicensing agreements as well as from sales of Spherotide. Furthermore, we reached important milestones for the Company, especially the signing of agreements with STADA and CR Pharma and the timely development of Xlucane obtained the approval for initiation of the pivotal phase III trial. The approval was received during the beginning of 2019.

### Authority approval for initiation of clinical trial with Xlucane

It is with great pride that we could communicate that we in January 2019 received approval from the FDA and the Central Ethics Committee in US to initiate the Xplore Phase III trial with the objective to confirm biosimilarity for Xlucane

compared to Lucentis®. The study will include about 600 patients at approximately 150 clinics in 16 countries and support marketing authorization of Xlucane in most of the world. The study is now initiated, and we expect to be able to present results on the primary endpoint during the second quarter of 2020.

The importance of the co-development agreement that we have with STADA for the development and commercialization of Xlucane cannot be underestimated. The co-development is based on that the companies will share development costs and profits generated from the sale of the product.

In parallel with the clinical trial, we are preparing together with STADA, for the launch of Xlucane. The patent on the original drug Lucentis® expires second quarter 2022 in Europe, which coincides with the planned launch of Xlucane. The competitive situation looks promising since

*“As we now leave 2018 behind us, we can conclude that this was the most successful year in Xbrane’s history”*

Xbrane is one of three companies that has a biosimilar of Lucentis® in clinical phase targeting Europe and US. It is a very favorable situation considering that Lucentis® has annual sales of 32 billion SEK<sup>1&2</sup> and, according to our estimates, only 1 out of 18 million individuals affected by these serious eye diseases receive treatment with approved drugs (Lucentis® or Eylea®).

#### **Active development of the pre-clinical portfolio**

Concerning Spherotide, the Company’s ambition is to find one partner who can fund most of the clinical program. From a development perspective the preparatory work to be able to initiate the pivotal clinical trial for the one-month formulation is expected to be finalized Q2 2019.

Xbrane works actively pre-clinical with the development of biosimilars on Oncaspar®, Cimzia® and two mammalian cells based products. To achieve success as a biosimilar developer, it is absolutely critical to choose the right products to develop. Oncaspar® and Cimzia® are two niche biological drugs with annual sales of approximately EUR 200 million and EUR 1.4 billion respectively. We expect no or limited competition, from other biosimilar developers for these products. For Oncaspar®, there is only one public pre-clinical biosimilar program apart from Xbrane’s targeting the Europe and US markets despite the fact that the patent has already expired. For Cimzia® there is no public biosimilar program other than Xbrane’s. For these products, we consider Xbrane to be able to have a significant cost advantage with our patented production technology.

#### **Strengthening the development team**

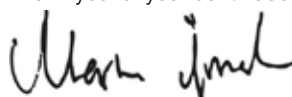
In recent months, Xbrane has completed strategic recruitments of new members into its research and development team. Through the recruitments we have added critical competence and experience from other prominent pharmaceutical companies within regulatory strategy, supply chain and quality, protein characterization, process development and cell line development. When publishing this Year-end report, there are now 32 employees in Xbrane and I believe that we have the skills and the internal resources required to implement our strategy and plans for coming years, above all, when it comes to achieving market approval for Xlucane and Spherotide, as well as pushing the development of our pre-clinical portfolio forward.

#### **Financial position**

At the end of 2018, Xbrane had a cash position of just over SEK 100 million. As stated earlier, the Company has a future capital need, especially in regarding to the clinical trial for Xlucane. Clinical trials of similar size have historically cost SEK 300-350 million (equivalent to about 500-600 thousand SEK per patient). According to the co-development agreement with STADA, the companies share all development-related costs for Xlucane equally. Therefore, the financing need for Xbrane is about SEK 150-175 million for the clinical trial for Xlucane.

Xbrane works actively to meet with institutional investors who are interested in being part of a long-term journey of the Company. During the autumn and winter, Xbrane has participated at capital market days held by DnB in New York, Jefferies in London and Redeye and Financial Hearings/Börsveckan in Stockholm. In the coming weeks, Xbrane will also participate at Nordea’s Life Science day on March 4 and at Vator Securities’ Unicorn Summit March 21. I hope to see you at any of the above-mentioned events.

Thank you for your continued support,



Martin Åmark  
CEO

#### **References:**

- 1) Novartis, Year-end report 2018
- 2) Roche, Year-end report 2018

## About Xbrane

Xbrane Biopharma AB (publ.) is a biotechnology company that develops and manufactures biosimilars and long-acting injectable pharmaceuticals. The Company's objective is to make difficult-to-manufacture pharmaceuticals available for the global population based on unique technology platforms enabling cost-efficient production. Xbrane has a patented protein production platform with up to eight times higher productivity compared with standard systems in *E.coli*.

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. Lucentis® has annual sales of approximately SEK 32 billion<sup>1&2</sup>.

Xbrane's leading product candidate within the segment of long-acting injectable drugs is Spherotide. Spherotide is a long-acting formulation with the active ingredient triptorelin which is used primarily in the treatment of prostate cancer, endometriosis, breast cancer and myoma. For all its formulations combined, the originator drug addressed by Spherotide has total annual sales of approximately SEK 4.5 billion<sup>3</sup>.

### Organization

The Xbrane Group comprises the Parent Company, Xbrane Biopharma AB, and the wholly-owned Italian subsidiary, Primm Pharma s.r.l.. The Parent Company focuses on research and development of biosimilars with Xlucane as the leading product candidate, while Primm Pharma focuses on long-acting injectable drugs with Spherotide as the leading product candidate.



#### References:

- 1) Novartis, Year-end report 2018
- 2) Roche, Year-end report 2018
- 3) IMS Health



## Shareholders

As per December 31, 2018, Xbrane had a total of approximately 2,700 shareholders. The number of shares outstanding amounted to 6,329,239. The ten largest shareholders at the end of the year are presented below<sup>1</sup>.

Name	Number of shares	Holding, %
Serendipity Group AB	683,329	10.80%
Paolo Sarmientos	395,919	6.26%
Försäkringsaktiebolaget Avanza pension	343,879	5.43%
Nordnet Pensionsförsäkring AB	193,060	3.05%
Swedbank försäkring	140,070	2.21%
Martin Åmark	111,890	1.77%
Christer Skogum	111,800	1.77%
Siavash Bashiri	87,294	1.38%
Jan-Willem De Gier	84,083	1.33%
Magnus Tillberg	77,000	1.22%
<b>Total, 10 largest shareholders</b>	<b>2,228,324</b>	<b>35.21%</b>
<b>Total, other shareholders</b>	<b>4,100,915</b>	<b>64.79%</b>
<b>Total</b>	<b>6,329,239</b>	<b>100.00%</b>
Shares via number of options outstanding	324,571	
<b>Total number of shares including options</b>	<b>6,653,810</b>	



*References:*

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

## Operational update

### Xlucane

Xbrane has finalized the development of the production process for Xlucane in commercial scale and has been able to demonstrate a high level of similarity compared with the originator drug Lucentis® based on a panel of more than 30 in-vitro analysis methods in accordance with EMA (European Medicines Agency) and FDA guidelines. Xlucane has also demonstrated tolerability and a pharmacokinetic profile equivalent to Lucentis® in an in-vivo study comprising 16 rabbits.

Xbrane has signed a co-development agreement with STADA for the development and commercialization of Xlucane in Europe, the US and a number of markets in the Middle East and the Asia-Pacific region. In accordance with the agreement, Xbrane and STADA will share 50/50 the upcoming development expenses for Xlucane and earnings generated through sales. Xbrane is responsible for the development of the product until it achieves market approval, while STADA is responsible for sales and marketing.

The next stage of development is initiating the pivotal phase III trial comprising some 600 patients with wet form age-related macular degeneration. The primary aim of the trial is to evaluate efficacy in terms of improved eyesight with Xlucane compared with the originator drug Lucentis®. Approval for initiation of the study was obtained from FDA in January 2019 and the first patient is expected to be recruited in March 2019.

Xbrane has approval for the trial design from both EMA and FDA and the trial will also be able to provide approval for Xlucane within the additional indications for which the originator drug is approved: macular edema and diabetic retinopathy.

### LEADING 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), and retinal vein occlusion (RVO). The originator product generated annual sales during 2018 of approximately SEK 32 billion<sup>1,2</sup> and will lose its patent protection in 2020 in the US and in 2022 in Western Europe.



#### SPHEROTIDE

Spherotide is a long-acting injectable drug 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 encapsulating the active substance in biologically 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 had an annual sales of approximately SEK 4.5 billion<sup>3</sup> in 2017.

#### References:

- 1) Novartis, Year-end report 2018
- 2) Roche, Year-end report 2018
- 3) IMS Health

### Spherotide

Development efforts continue to focus on preparations for pivotal confirmatory clinical trials in Europe and the US for the one-month formulation. Xbrane intends to initiate two clinical trials, 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 levels in patients following treatment, compared with the originator drug. Xbrane is also developing the 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 pivotal confirmatory clinical trial in prostate cancer patients will then be conducted.

Xbrane currently has commercial partners for Spherotide in China (CR Pharma), South Korea (BL&H), Israel (Bioavenir) and Iran (Pooyesh Darou). Spherotide received market approval in Iran in July 2017 through its local partner under the Microrelin® brand. 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 larger pharmaceutical companies are currently undergoing an evaluation of Spherotide for, above all, the European market, which is the largest potential market for the product.

Xbrane produces Spherotide in a production facility installed within premises owned by the pharmaceuticals company 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. Finchimica's subsidiary ICI has been subject to a reconstruction process due to economic difficulties. In December 2018, ICI agreed with their creditors on a reconstruction plan that has been decided upon in court and ICI executes now in accordance with this plan.

US maintains continued sanctions on Iran. Pharmaceuticals are excluded from these sanctions but nevertheless monetary transactions with the country are more difficult even for those involved in the sales of pharmaceutical products. Most European banks only accept monetary transactions through approved local banks in foreign currency exchanged via Iran's Central Bank. Xbrane's partner in Iran is currently in queue at the Central Bank to make payment of outstanding invoices to Xbrane's subsidiary Primm Pharma.

### Pre-clinical biosimilar portfolio

The work with the four pre-clinical biosimilars is beginning to ramp up and Xbrane have strengthened its team during the beginning of 2019 with important skills within protein characterization, process development and cell line development. Even if this is still at an early stage, dialogues have been initiated with potential partners.

Xbrane will communicate the development of the pre-clinical portfolio, especially when the following important milestones are achieved; completion of production process in pilot scale and detection of analytical similarity, upscaling to commercial scale with contract manufacturers, entering into agreements with commercialization partners as well initiation of clinical trials.



## Financial overview

### The Co-development agreement with STADA's effect on income statement and balance sheet

Since the co-development agreement with STADA was entered in July 2018, research and development expenses for Xlucane are accounted for as net expenses in the profit and loss statement, which means 50 percent of the expenses for the total project. At the balance sheet, the assets and liabilities attributable to the project are accounted for in full (i.e. 100 percent) and then STADA's share of these (i.e. 50 percent) are accounted for as an asset or liability between Xbrane and STADA. This means that the balance sheet has expanded as a result of the STADA agreement while research and development expenses in the profit and loss statement has decreased with 50 percent. This concerns both the Consolidated Group financials and the Parent Company.

### Consolidated profit or loss October-December 2018

Consolidated revenue amounted to SEK 4,896 thousand (9,535), pertaining to revenues from sales of Spherotide. The sales can vary widely between the quarters as there are a few batches sold during the year rather than a steady sales flow. This explains the halving of sales during the quarter compared with the same quarter last year, while sales for the year have remained relatively unchanged. Cost of goods sold amounted to SEK -3,655 thousand (-7,257). The gross margin amounted to 25 percent (24).

Other operating income amounted to SEK 1,305 thousand (1,788) and includes tax relief for the subsidiary, exchange rate gains on operating receivables and other license revenue. Cost of sales amounted to SEK -196 thousand (-310). Administration expenses amounted to SEK -6,858 thousand (-4,358), with the increase compared to same period last year relating primarily to an expanded administrative department and expenses associated with the Company's planned market listing. Research and development expenses amounted to SEK -25,533 thousand (-17,531), of which SEK -22,030 thousand (-12,739) pertained to biosimilars, primarily Xlucane, and SEK -3,502 thousand (-4,792) to long-acting injectable drugs, that being Spherotide exclusively. The increase that has occurred is attributable to development work, primarily for Xlucane has reached a more cost intense phase as well as the preparations for the clinical trials is ongoing. During the quarter, all development expenses has been charged to the income statement. Other operating expenses amounted to SEK -2,114 thousand (-985), primarily comprising exchange rate losses on accounts receivables and payables.

During the quarter, the number of employees has been unchanged at 27 employees.

Consolidated operating loss amounted to SEK -32,156 thousand (-19,118).

Net financial items amounted to SEK -375 thousand (-39) and refer entirely to financial expenses consisting primarily of interest expenses for credit facilities and leases.

Consolidated loss before tax amounted to SEK -32,531 thousand (-19,157). Income tax amounted to SEK 108 thousand (-) and relates to the subsidiary.

Consolidated loss after tax amounted to SEK -32,423 thousand (-19,157).

### Consolidated cash flow October-December 2018

Cash flow from operating activities amounted to SEK 37,787 thousand (-12,125). The change of operating receivable and payables can vary widely between the quarters, as a result of the re-invoicing to STADA concerning the development expenses, including the clinical trial, for Xlucane. The change in operating receivables and liabilities amounted to SEK 59,921 thousand (-2,788) respectively SEK 9,943 thousand (10,938).

Cash flow from investing activities amounted to SEK -184 thousand (-3,270), comprising investments in property, plant and equipment.

Cash flow from financing activities amounted to SEK -95 thousand (-30) and pertains amortization of loans and leasing liabilities of SEK -33 thousand (0) and SEK -62 thousand (-22) respectively.

### Consolidated profit or loss January-December 2018

Consolidated revenue amounted to SEK 20,485 thousand (20,771), pertaining to revenues from sales of Spherotide. Cost of goods sold amounted to SEK -15,907 thousand (-15,829). The gross margin amounted to 22 percent (24).

Other operating income amounted to SEK 99,742 thousand (2,515), of which SEK 77,325 thousand pertained to the up-front payment received when entering the co-development agreement with STADA for Xlucane, SEK 13,375 thousand for one of the potential several milestone payments for the license agreements with CR Pharma regarding Spherotide, SEK 2,463 thousand in tax relief for the subsidiary, SEK 4,681 thousand for exchange rate gains on operating receivables and the remaining SEK 1,899 thousand for other license revenue. Selling and distribution expenses amounted to SEK -933 thousand (-1,381), consisting of personnel expenses. Administration expenses amounted to



SEK -23,347 thousand (-11,567), and the increase compared to last year relating primarily to expenses associated with entering the agreements with STADA and CR Pharma, expenses associated with the Company's planned market listing as well as an expanded administration department. Research and development expenses amounted to SEK -85,827 thousand (-37,982), of which SEK -74,443 thousand (-27,326) pertained to biosimilars, primarily Xlucane, and SEK -11,385 thousand (-10,656) to long-acting injectable drugs, that being Spherotide exclusively. The increase that has occurred is attributable to development work, primarily for Xlucane, has reached a more cost intensive phase as the preparations for the clinical trial is ongoing. During the year, all development expenses has been charged to the income statement. Other operating expenses amounted to SEK -5,629 thousand (-1,245), primarily comprising exchange losses on accounts receivables and payables.

During the year, the number of employees has increased from 24 to 27.

Consolidated operating loss amounted to SEK -11,415 thousand (-44,718).

Net financial items amounted to SEK -1,700 thousand (-217) and refer entirely to financial expenses consisting primarily of interest expenses for credit facilities and leases.

Consolidated loss before tax amounted to SEK -13,115 thousand (-44,935). Income tax amounted to SEK -121 thousand (-) and relates to the subsidiary.

Consolidated loss after tax amounted to SEK -13,236 thousand (-44,935).

### **Consolidated cash flow January-December 2018**

Cash flow from operating activities amounted to SEK 46,707 thousand (-36,848). The change of operating receivable and payables can vary widely, as a result of the re-invoicing to STADA concerning the development expenses, including the clinical trial, for Xlucane. Change in operating receivables and liabilities amounted to SEK -46,360 thousand (-7,441) and SEK 103,509 thousand (12,292) respectively.

Cash flow from investing activities amounted to SEK -1,598 thousand (-3,347), comprising investments in property, plant and equipment.

Cash flow from financing activities amounted to SEK 47,730 thousand (16,728) and pertains to loans raised of SEK 45,000 thousand (-), amortization of loans and leasing liabilities of SEK -131 thousand (-) and

SEK -377 thousand (-257) respectively, issue of shares and warrants that raised SEK 2,549 thousand (20,004) and SEK 701 thousand (-) respectively, as well as transaction expenses of SEK -12 thousand (-3,019) for the share issue.

### **Financial position and going concern**

Consolidated cash and cash equivalents at the end of the year amounted to SEK 100,972 thousand (7,903). During the year, the Company raised loans of SEK 45,000 thousand from the credit facility it acquired from its largest shareholder, the Serendipity Group, at the end of 2017. There is a financing gap of approximately SEK 150-175 million for the Company's share of the cost for the clinical trial for Xlucane. In addition, there are further development expenses for Xlucane, expenses for continued operations, and working capital. The Company is assessing various financing options with their financial advisors and keeping a dialogue with investors.

The equity ratio amounted to 33 percent (80).

Non-current receivables amounted to SEK 8,871 thousand (635) and consisted primarily of a pre-payment to the CRO (Contract Research Organization) conducting the clinical trial for Xlucane.

As per the balance sheet date, accounts receivables amounted to SEK 10,489 thousand (8,072) and pertained mainly to receivables from the Company's distribution partner in Iran. See page 22 for more information about the effect of the implementation of IFRS 9 that affect write downs of accounts receivables. According to the Company's current assessment, no specific write down has been done for the receivables from Iran taking the country specific risk due to US's ongoing sanctions into consideration. See page 12 for description of risks and uncertainties concerning the sanction for Iran.

Prepaid expenses and accrued income amounted to SEK 34 240 thousand (1,018), pertaining primarily prepayment of expenses for Xlucane.

Non-current, non-interest-bearing liabilities amounted to SEK 4,118 thousand (-) and pertain to a liability to STADA for its share of the prepayment to the CRO described above. Accounts payable amounted to SEK 30,908 thousand (10,541) with the increase being explained by the fact that Xlucane has reached a more cost intensive phase of the development program, including test production and preparing for clinical trials. Accrued expenses and prepaid income amounted to SEK 83,970 thousand (6,488) where prepayments from STADA for their share of future expenses for Xlucane amounted to SEK 58,131 thousand.

**Intangible assets**

Intangible assets amounted to SEK 5,772 thousand (6,297) and consist of capitalized development expenditures. No development expenditures have been capitalized during 2018. Goodwill amounted to SEK 59,838 thousand (57,360) and changes from last year is entirely attributable to changes in exchange rate.

**Changes in equity**

In the second quarter, a new share issue was implemented directed at certain Board members, raising at net SEK 2,537 thousand. Warrants were also issued to certain Board members and members of management, raising SEK 701 thousand. Both issues were implemented on market terms, with the subscription price for the shares corresponding to the volume weighted average share price ten days prior to decision to implement the issue, and the warrants were priced in accordance with the Black and Scholes option pricing model. Expenses for share savings programs had effect of SEK 978 thousand.

**Parent Company income statement  
October-December 2018**

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 operating income amounted to SEK 1,441 thousand (253), comprising of exchange rate gains on operating receivables, other license revenue as well as intra-Group income. Administration expenses amounted to SEK -5,618 thousand (-4,091). The increase in expenses primarily relates to an expanded administrative department and expenses associated with the Company's planned market listing. Research and development expenses amounted to SEK -22,845 thousand (-12,739) where the increase primarily concerns the production of test batches of Xlucane as well as start-up costs for the clinical trial. During the quarter, all development expenses has been charged to the income statement.

Other operating expenses amounted to SEK -1,659 thousand (-924) and primarily pertains to exchange losses on accounts receivables and payables.

During the quarter, the number of employees has been unchanged at 18 employees.

Operating loss amounted to SEK -28,681 thousand (-17,500).

Net financial items amounted to SEK -461 thousand (-25) and refer entirely to financial expenses consisting primarily of interest expenses for the credit facility.

The loss after tax amounted to SEK -29,142 thousand (-17,526).

**Parent Company cash flow  
October-December 2018**

Cash flow from operating activities amounted to SEK 46,025 thousand (-13,994). The change of operating receivable and payables can vary widely between the quarters, as a result of the re-invoicing to STADA concerning the development expenses, including the clinical trial, for Xlucane. The change in operating receivables amounted to SEK 64,789 thousand (-2,628), which is mainly due to the advanced payments from STADA. The change in operating liabilities amounted to SEK 4,269 thousand (5,594).

Cash flow from investing activities amounted to SEK -35 thousand (-2,531), comprising smaller investments in property, plant and equipment.

Cash flow from financing activities amounted to SEK -5,130 thousand (-9) and pertains amortization of loans towards the subsidiary Primm Pharma.

**Parent Company income statement  
January-December 2018**

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 operating income amounted to SEK 97,149 thousand (838), of which SEK 77,325 thousand pertained to the up-front payment received when entering the co-development agreement with STADA for Xlucane, SEK 13,375 thousand for one of the potential several milestone payments for the license agreements with CR Pharma regarding Spherotide, SEK 4,681 thousand for exchange rate gains on operating receivables and remaining SEK 1,768 thousand for other license income and intra-Group income. Administration expenses amounted to SEK -19,074 thousand (-9,841), with the increase compared to the same quarter previous year relating primarily to an expanded administrative department, expenses associated with entering the agreements with STADA and CR Pharma and expenses associated with the Company's planned market listing. Research and development expenses amounted to SEK -75,257 thousand (-27,326), with the increase primarily relates to production of test batches of Xlucane and preparations for the clinical trial. During the year, all development expenses has been charged to the income statement. Other operating expenses amounted to SEK -18,192 thousand (-1,169) and primarily per-

tains re-invoicing of income for the Spherotide agreement in China to the subsidiary as well as exchange losses on accounts receivables and payables.

During the year, the number of employees has increased from 17 to 18.

Operating loss amounted to SEK -15,375 thousand (-37,498).

Net financial items amounted to SEK -1,690 thousand (-56) and pertain entirely to financial expenses consisting of interest expenses.

The loss after taxes for the year amounted to SEK -17,065 thousand (-37,553).

### **Parent Company cash flow January-December 2018**

Cash flow from operating activities amounted to SEK 51,505 thousand (-33,273). The change of operating receivable and payables can vary widely, as a result of the re-invoicing to STADA concerning the development expenses, including the clinical trial, for Xlucane. The change in operating receivables of SEK -38,319 thousand (-2,761) and operating liabilities of SEK 99,962 thousand (5,312) relates largely to the Xlucane development program, which has been intensified and reached a more cost intensive phase, as well as the co-development agreement on Xlucane signed with STADA.

Cash flow from investing activities amounted to SEK -6,801 thousand (-7,742) and pertains to a shareholder contribution of SEK -6,691 thousand (-5,756) to the subsidiary as well as investments in property, plant and equipment of SEK -110 thousand (-1,985).

Cash flow from financing activities amounted to SEK 51,280 thousand (16,985). Loans raised amounted to SEK 55,000 thousand (-), of which SEK 45,000 thousand derived from the credit facility that the Company received from its major shareholder, the Serendipity Group, at the end of 2017 as well as a loan of SEK 10,000 thousand issued by the subsidiary Primm Pharma. The amortization of the loan towards the subsidiary amounted to SEK -6,958 thousand (-). A new issue of shares and warrants raised a net SEK 2,537 thousand (16,895) and SEK 701 thousand (-) respectively after transaction costs.

### **Parent Company financial position and going concern**

At the end of the period, the Parent Company's cash and balances amounted to SEK 100,380 thousand (6,483). For description of going concern financing need see description for the Group on page 9 that also concerns the Parent Company.

Non-current receivables amounted to SEK 8,871 thousand (635) and consisted largely of a prepayment to the CRO that conducts the clinical trial for Xlucane. Accounts receivables amounted to SEK 196 thousand (-). Other receivables amounted to SEK 1,018 thousand (278) and consist of tax receivables. Prepaid expenses and accrued income amounted to SEK 33,596 thousand (814), pertaining primarily to prepayment of expenses for Xlucane.

Non-current, non-interest-bearing liabilities amounted to SEK 4,118 thousand (-) and pertain to a liability to STADA for their share of the prepayment to the CRO described above. Accounts payable amounted to SEK 23,709 thousand (3,359) and the increase is primarily due to the test production and preparatory work for the clinical trial. Accrued expenses and prepaid income amounted to SEK 81,934 thousand (4,812) with the increase being explained by the advancement from STADA towards their upcoming cost in 2019 of SEK 58,131 thousand as well as provisions of SEK 17,595 thousand regarding not invoiced cost related to the clinical trial and other development costs for Xlucane.

### **Parent Company changes in equity**

The same changes as stated in consolidated changes in equity apply to the Parent Company.

### **Share Information**

Xbrane's share capital at the end of the year amounted to SEK 1,419 thousand (1,335) divided between 6,329,239 shares (5,956,770). The quota value of all shares is SEK 0.224 and all shares bear equal entitlement to participate in the Company's assets and profits. Since February 3, 2016, Xbrane's share has been listed on Nasdaq First North and Xbrane had approximately 2,700 shareholders as per the balance sheet date. The closing price for the share on the balance sheet date was SEK 45.9, generating a market capitalization of SEK 291 million.

### **Share-based incentive programs**

#### *Share savings program for employees*

The Annual General Meeting of 24 May 2018 approved the long-term incentive program for employees that comprise the 2017 and 2018 share savings programs. To assure the supply of shares, a decision was made to issue 192,338 warrants. Accordingly, expenses for the Company's share savings program consist of cost of the acquisition of shares and social security expenses amounting to SEK -1,212 thousand for the fourth quarter and SEK -978 thousand for the year respectively to SEK -212 thousand for the quarter and SEK 212 thousand for the year.

*Warrant program for executives and directors*

The Extraordinary General Meeting of April 3, 2018 adopted three warrant programs, two of which were directed at certain Board members and mature in 2021, and one directed at certain senior executives and maturing in 2022. In total, the programs comprise 141,785 warrants which, if all are converted, would entail a dilution of 2.19 percent.

**Risks and uncertainties**

Risks and uncertainties are described in the 2017 Annual report, which is available from the Company's website. Risks that have changed or that have been incurred during the year are described below.

*Sanctions against Iran*

Xbrane conduct sales of the pharmaceutical product Spherotide in Iran. In July 2018, US reinstated certain sanctions against Iran. Pharmaceuticals are excluded from these sanctions, but despite this, monetary transactions with the country complicates the sale of pharmaceutical products. Monetary transactions are now accepted by most European banks only through authorized local banks in foreign currency exchanged via the Iranian central bank. Xbrane's partner in Iran is currently queuing at the central bank to make payment of outstanding invoices to Xbrane's subsidiary Primm Pharma, which at the balance sheet date amounted to SEK 10,489 thousand. There is, however, a risk that existing sanctions may be extended or that new sanctions may be imposed, including sanctions against pharmaceuticals or the pharmaceutical industry which could affect the possibility of importing and exporting pharmaceuticals to and from Iran and affecting Xbrane's market approval. The availability and sale of pharmaceuticals in Iran could thus be reduced or absent. Furthermore, there is a risk that partners choose to terminate or not initiate co-operation with Xbrane in light of the fact that the Company has sales in Iran. The reintroduced and possibly extended sanctions against Iran can have a negative impact on the Company's operations, financial position or results.

*Unforeseen production stoppages disturbing the value chain*

The sale of Spherotide is dependent on the production plant in Naples, Italy. The production line owned by Xbrane's subsidiary Primm Pharma s.r.l is installed within a production facility owned by the Italian pharmaceutical company ICI. ICI has been the subject of a reconstruction process due to financial difficulties. In December 2018, ICI agreed with its creditors on a reconstruction plan, which since it was resolved in the Naples court and ICI is now executing in accordance with this plan. There is still a risk that ICI's financial difficulties would affect Xbrane's ability

to produce products in the production plant to the extent that Xbrane and its customers expect. In the event that the production plant will not be able to be used wholly or partly in the future or would have to be closed, the production and distribution of the Company's products may be prevented or interrupted. Interruptions in production can also damage Xbrane's reputation among current and potential customers, which can lead to a deterioration in customer relations and lower sales. To the extent that unforeseen production interruptions, damage to property or other events that interfere with the value chain are not fully covered by insurance, it may also have a material adverse effect on the Company's business, financial position or results.

**Organization and employees**

The headquarters of Xbrane are located 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 characterization of proteins. Xbrane acquired the Italian company Primm Pharma s.r.l. in 2015 with offices in Milan, which develops and produces microsphere products. The Company had 27 employees on the balance sheet date, 18 of which are located in Sweden and 9 in Italy.

**Annual General Meeting**

The Annual General Meeting was held on May 24, 2018. The Annual General Meeting for 2019, will be held on May 16, 2019.

**Certified adviser**

Xbrane's Certified Adviser at Nasdaq First North is Avanza Bank AB, with the following contact information:  
Email: corp@avanza.se  
Phone: +46 8 409 421 20

**Dividend**

The Board of Directors proposes that no dividend be paid for the financial year 01/01/2018 - 12/31/2018. The Board of Directors proposes that the Company's accumulated loss be carried forward.

**Annual report**

The annual report for the fiscal year 01/01/2018 - 12/31/2018 will be published at the 26th of April 2019, at Xbrane's website and as a press release.

**Auditors review**

This Year-end report has been subject to review by the Company's auditor.



## Consolidated statement of profit or loss

Amounts in SEK thousand	Notes	2018 Q4	2017 Q4	2018 Full year	2017 Full year
Revenue	2, 3	4,896,	9,535	20,485	20,771
Cost of goods sold		-3,655	-7,257	-15,907	-15,829
<b>Gross profit/loss</b>		<b>1,240</b>	<b>2,278</b>	<b>4,578</b>	<b>4,942</b>
Other operating income	2, 3, 6	1,305	1,788	99,742	2,515
Selling and distribution expenses		-196	-310	-933	-1,381
Administrative expenses		-6,858	-4,358	-23,347	-11,567
Research and development expenses		-25,533	-17,531	-85,827	-37,982
Other expenses		-2,114	-985	-5,629	-1,245
<b>Operating profit/loss</b>	2	<b>-32,156</b>	<b>-19,118</b>	<b>-11,415</b>	<b>-44,718</b>
Financial income		44	-	44	-
Financial expenses		-419	-39	-1,744	-217
<b>Net financial items</b>	2	<b>-375</b>	<b>-39</b>	<b>-1,700</b>	<b>-217</b>
<b>Profit/loss before tax</b>		<b>-32,531</b>	<b>-19,157</b>	<b>-13,115</b>	<b>-44,935</b>
Income tax expense	7	108	-	-121	-
<b>Profit/loss for the period</b>		<b>-32,423</b>	<b>-19,157</b>	<b>-13,236</b>	<b>-44,935</b>
<b>Profit/loss for the period attributable to:</b>					
– Parent Company shareholders		-32,423	-19,157	-13,236	-44,935
– Non-controlling interest		-	-	-	-
<b>Profit/loss for the period</b>		<b>-32,423</b>	<b>-19,157</b>	<b>-13,236</b>	<b>-44,935</b>
<b>Earnings per share</b>					
– Before dilution (SEK)		-5.12	-3.22	-2.13	-8.28
– After dilution (SEK)*		-5.12	-3.22	-2.13	-8.28
<b>Number of shares outstanding at end of period</b>					
– Before dilution		6,329,239	5,956,770	6,329,239	5,956,770
– After dilution*		6,329,239	5,956,770	6,329,239	5,956,770
<b>Average number of outstanding shares</b>					
– Before dilution		6,329,239	5,956,770	6,213,927	5,425,656
– After dilution*		6,329,239	5,956,770	6,213,927	5,425,656

\* Dilution not taken into account where earnings per share are negative. If converted to shares, convertible loans outstanding as per December 31, 2018, would be equivalent to 132,233 shares. If converted to shares, warrants for share savings programs for employees would be equivalent to 192,338 shares. This would total 324,571 shares on conversion.

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

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
<b>Profit/loss for the period</b>	-32,423	-19,157	-13,236	-44,935
<b>Other comprehensive income</b>				
<b>Items that have been transferred or can be transferred to profit/loss for the period</b>				
Translation differences for the period from translation of foreign operations	-251	3,860	3,686	2,218
<b>Other comprehensive income for the period</b>	<b>-251</b>	<b>3,860</b>	<b>3,686</b>	<b>2,218</b>
<b>Comprehensive income for the period attributable to:</b>				
– Parent Company shareholders	-32,674	-15,297	-9,551	-42,716
– Non-controlling interest	-	-	-	-
<b>Comprehensive income for the period</b>	<b>-32,674</b>	<b>-15,297</b>	<b>-9,551</b>	<b>-42,716</b>

## Consolidated statement of financial position

Amounts in SEK thousand	12/31/2018	12/31/2017
<b>ASSETS</b>		
Goodwill	59,838	57,360
Intangible assets	5,772	6,297
Property, plant and equipment	16,745	18,569
Non-current receivables	8,871	635
<b>Total non-current assets</b>	<b>91,226</b>	<b>82,860</b>
Inventories	5,525	3,065
Income taxes recoverable	10,427	8,043
Accounts receivable	10,489	8,072
Other receivable	5	-
Prepaid expenses and accrued income	34,240	1,018
Cash and cash equivalents	100,972	7,903
<b>Total current assets</b>	<b>161,659</b>	<b>28,100</b>
<b>TOTAL ASSETS</b>	<b>252,885</b>	<b>110,960</b>
<b>EQUITY</b>		
Share capital	1,419	1,335
Other capital contributions	184,007	179,874
Reserves	5,548	1,862
Retained earnings including profit/loss for the year	-107,903	-94,667
<b>Equity attributable to owners of the Company</b>	<b>83,070</b>	<b>88,405</b>
<b>Non-controlling interest</b>	<b>-</b>	<b>-</b>
<b>Total equity</b>	<b>83,070</b>	<b>88,405</b>
<b>LIABILITIES</b>		
Non-current interest-bearing liabilities	41	1,119
Non-current non-interest-bearing liabilities	4,118	-
Provisions	4,275	3,545
<b>Total non-current liabilities</b>	<b>8,433</b>	<b>4,664</b>
Current interest-bearing liabilities	45,561	-
Accounts payable	30,908	10,541
Current tax liabilities	123	-
Other liabilities	820	863
Accrued expenses and prepaid income	83,970	6,488
<b>Total current liabilities</b>	<b>161,382</b>	<b>17,892</b>
<b>TOTAL LIABILITIES</b>	<b>169,816</b>	<b>22,555</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>252,885</b>	<b>110,960</b>

## Consolidated statement of cash flows

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
<b>Cash flows from operating activities</b>				
Profit/loss before tax	-32,531	-19,157	-13,115	-44,935
Adjustment for non-cash items	3,275	676	4,953	3,803
Paid income tax	-	-	-	-
	<b>-29,256</b>	<b>-18,481</b>	<b>-8,162</b>	<b>-41,131</b>
Increase (-)/decrease (+) in inventories	-2,821	-1,793	-2,280	-568
Increase (-)/decrease (+) in operating receivables	59,921	-2,788	-46,360	-7,441
Increase (-)/decrease (+) in operating liabilities	9,943	10,938	103,509	12,292
<b>Cash flow from current operations</b>	<b>37,787</b>	<b>-12,125</b>	<b>46,707</b>	<b>-36,848</b>
<b>Investing activities</b>				
Acquisition of property, plant and equipment	-184	-3,270	-1,598	-3,347
<b>Cash flow from investing activities</b>	<b>-184</b>	<b>-3,270</b>	<b>-1,598</b>	<b>-3,347</b>
<b>Financing activities</b>				
New share issue	-	-	2,549	20,004
Transaction expenses	-	-9	-12	-3,019
Warrants issue	-	-	701	-
Loans raised	-	-	45,000	-
Amortization of loan	-33	-	-131	-
Amortization of lease liability	-62	-22	-377	-257
<b>Cash flow from financing activities</b>	<b>-95</b>	<b>-30</b>	<b>47,730</b>	<b>16,728</b>
Cash flow for the period	37,508	-15,426	92,839	-23,468
Cash and cash equivalents at beginning of period	64,311	23,297	7,903	31,338
Exchange rate differences in cash and cash equivalents	-847	33	230	33
<b>Cash and cash equivalents at end of period</b>	<b>100,972</b>	<b>7,903</b>	<b>100,972</b>	<b>7,903</b>



## Consolidated statement of changes in equity

Amounts in SEK thousand	Share capital	Other capital contributions	Translation reserve	Retained earnings including profit/loss for the period	Total	Non-controlling interest	Total equity
<b>Equity at January 1, 2018</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>
<b>Comprehensive income for the period</b>							
Profit/loss for the period	-	-	-	-13,236	-13,236	-	-13,236
Other comprehensive income for the period	-	-	3,686	-	3,686	-	3,686
<b>Comprehensive income for the period</b>	<b>-</b>	<b>-</b>	<b>3,686</b>	<b>-13,236</b>	<b>-9,551</b>	<b>-</b>	<b>-9,551</b>
<b>Transactions with Group shareholders</b>							
<b>Contributions from and distributions to shareholders</b>							
New share issue	9	2,528	-	-	2,537	-	2,537
– Issue of ordinary shares	9	2,540	-	-	2,549	-	2,549
– Transaction expenses	-	-12	-	-	-12	-	-12
Conversion of debentures	74	-74	-	-	-	-	-
Warrants issue	-	701	-	-	701	-	701
Share savings program	-	978	-	-	978	-	978
<b>Total contributions from and distributions to shareholders</b>	<b>84</b>	<b>4,132</b>	<b>-</b>	<b>-</b>	<b>4,216</b>	<b>-</b>	<b>4,216</b>
<b>Equity at December 31, 2018</b>	<b>1,419</b>	<b>184,007</b>	<b>5,548</b>	<b>-107,903</b>	<b>83,070</b>	<b>-</b>	<b>83,070</b>

## Consolidated statement of changes in equity, cont.

Amounts in SEK thousand	Share capital	Other capital contributions	Translation reserve	Retained earnings including profit/loss for the period	Total	Non-controlling interest	Total equity
<b>Equity at January 1, 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>Comprehensive income for the period</b>							
Profit/loss 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 period</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 Group shareholders</b>							
<b>Contributions from and distributions to shareholders</b>							
New share issue	151	16,835	-	-	16,985	-	16,985
– Issue of ordinary shares	151	19,853	-	-	20,004	-	20,004
– Transaction expenses	-	-3,019	-	-	-3,019	-	-3,019
Conversion of debentures	118	-118	-	-	-	-	-
Share savings program	-	235	-	-	235	-	235
<b>Total contributions from and distributions to shareholders</b>	<b>269</b>	<b>16,951</b>	<b>-</b>	<b>-</b>	<b>17,220</b>	<b>-</b>	<b>17,220</b>
<b>Equity at December 31, 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>

## Parent Company Income Statement

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
Revenue	-	-	-	-
Cost of goods sold	-	-	-	-
<b>Gross profit/loss</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Other operating income	1,441	253	97,149	838
Administrative expenses	-5,618	-4,091	-19,074	-9,841
Research and development expenses	-22,845	-12,739	-75,257	-27,326
Other expenses	-1,659	-924	-18,192	-1,169
<b>Operating profit/loss</b>	<b>-28,681</b>	<b>-17,500</b>	<b>-15,375</b>	<b>-37,498</b>
<b>Profit/loss from financial items</b>				
Financial income	-	-	-	-
Financial expenses	-461	-25	-1,690	-56
<b>Net financial items</b>	<b>-461</b>	<b>-25</b>	<b>-1,690</b>	<b>-56</b>
<b>Profit/loss before tax</b>	<b>-29,142</b>	<b>-17,526</b>	<b>-17,065</b>	<b>-37,553</b>
Income tax expense	-	-	-	-
<b>Profit/loss for the period</b>	<b>-29,142</b>	<b>-17,526</b>	<b>-17,065</b>	<b>-37,553</b>

## Parent Company Income statement and other comprehensive income

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
Profit/loss for the period	-29,142	-17,526	-17,065	-37,553
Other comprehensive income	-	-	-	-
<b>Comprehensive income for the period</b>	<b>-29,142</b>	<b>-17,526</b>	<b>-17,065</b>	<b>-37,553</b>

## Parent Company Balance sheet

Amounts in SEK thousand	12/31/2018	12/31/2017
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property, plant and equipment	5,014	6,725
<b>Financial non-current assets</b>		
Shares in Group companies	100,783	94,092
Non-current receivables	8,871	,635
<b>Total financial non-current assets</b>	<b>109,654</b>	<b>94,727</b>
<b>Total non-current assets</b>	<b>114,667</b>	<b>101,451</b>
<b>Current assets</b>		
Current receivables		
Accounts receivable	196	-
Receivables from Group companies	-	4,178
Other receivables	1,018	278
Prepaid expenses and accrued income	33,596	814
<b>Total current receivables</b>	<b>34,810</b>	<b>5,269</b>
Cash and bank	100,380	6,483
<b>Total current assets</b>	<b>135,190</b>	<b>11,752</b>
<b>TOTAL ASSETS</b>	<b>249,857</b>	<b>113,204</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Restricted equity		
Share capital	1,419	1,335
Unrestricted equity		
Share premium	184,693	,180,560
Retained earnings	-77,623	-40,070
Profit/loss for the period	-17,065	-37,553
<b>Total equity</b>	<b>91,424</b>	<b>104,273</b>
<b>Non-current liabilities</b>		
Non-current non-interest-bearing liabilities	4,118	-
<b>Total non-current liabilities</b>	<b>4,118</b>	<b>-</b>
<b>Current liabilities</b>		
Current interest-bearing liabilities	45,000	-
Liabilities to Group companies	3,042	-
Accounts payable	23,709	3,359
Other liabilities	630	760
Accrued expenses and prepaid income	81,934	4,812
<b>Total current liabilities</b>	<b>154,316</b>	<b>8,931</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>249,857</b>	<b>113,204</b>



## Parent Company's cash flow statement

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
<b>Cash flows from operating activities</b>				
Profit/loss before tax	-29,143	-17,526	-17,065	-37,553
Adjustments for non-cash items	6,110	565	6,927	1,685
Paid income tax	-	-	-	-
	<b>-23,033</b>	<b>-16,960</b>	<b>-10,138</b>	<b>-35,869</b>
Increase (-)/decrease (+) in operating receivables	64,789	-2,628	-38,319	-2,716
Increase (-)/decrease (+) in operating liabilities	4,269	5,594	99,962	5,312
<b>Cash flow from current operations</b>	<b>46,025</b>	<b>-13,994</b>	<b>51,505</b>	<b>-33,273</b>
<b>Investing activities</b>				
Investments in subsidiaries	-	-	-6,691	-5,756
Acquisition of property, plant and equipment	-35	-2,531	-110	-1,985
<b>Cash flow from investing activities</b>	<b>-35</b>	<b>-2,531</b>	<b>-6,801</b>	<b>-7,742</b>
<b>Financing activities</b>				
New share issue	-	-	2,549	20,004
Transaction expenses	-	-9	-12	-3,019
Warrants issue	-	-	701	-
Loans raised	-	-	55,000	-
Amortization	-5,130	-	-6,958	-
<b>Cash flow from financing activities</b>	<b>-5,130</b>	<b>-9</b>	<b>51,280</b>	<b>16,985</b>
Cash flow for the period	40,860	-16,533	95,984	-24,029
Cash and cash equivalents at beginning of period	63,052	23,016	6,483	30,512
Exchange rate differences in cash and cash equivalents	-3,532	-	-2,087	-
<b>Cash and cash equivalents at end of period</b>	<b>100,380</b>	<b>6,483</b>	<b>100,380</b>	<b>6,483</b>

## Notes

### General information

Xbrane Biopharma AB (publ), Corp ID No. 556749-2375, is a Swedish-registered limited company with registered offices in Solna. The address of the headquarters is Banvaktsvägen 22, 171 48 Solna, Sweden.

### Note 1 Accounting principles

This interim report has been prepared in accordance with IAS 34, Interim Financial Reporting, and applicable provisions in the Annual Accounts Act. The consolidated accounts have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and the Swedish Annual Accounts Act. The Group applies IFRS effective from July 1, 2017 and the comparative figures for 2017 have been recalculated. Bridges for the IFRS conversion are available on the Company's website. The interim report for the Parent Company has been prepared in accordance with the Annual Accounts Act. The Parent Company applies the same accounting principles as in the most recent Annual Report.

The Group's accounting and valuation principles are consistent with the principles applied in the 2017 Annual Report, with the exception of the new standards IFRS 9 Financial Instruments and IFRS 15 Revenue from Contracts with Customers applied effective from January 1, 2018. The Company also applies IFRS 11 Joint Arrangements and IFRS 12 Disclosure of Interests in Other Entities with regard to the collaborative agreement with STADA Arzneimittel AG described in Note 4.

### IFRS 9 Financial Instruments

IFRS 9 replaced IAS 39 bringing together all aspects of the reporting of financial instruments, updating their classification, valuation, impairment and disclosures. In accordance with IFRS 9, the classification and valuation of financial instruments is based on the Company's business model and the contractual cash flows of the asset. The standard introduced an impairment model based on expected loan losses rather than incurred losses, which requires a more timely recognition of credit losses. The classifications in IAS 39 were replaced by three categories with valuation at fair value or at amortized cost. The Group applies IFRS 9 effective from January 1, 2018, with the practical relief rules permitted by the standard and considered applicable by Xbrane. IFRS 9 was applied without recalculated comparative figures and the comparative figures are therefore based on earlier accounting principles. The transition did not have a material impact on the Group's accounts since only accounts receivable were affected by the transition through early application of provisions in accordance with the new impairment model, which did not entail any material effects on the accounts. The Group has no significant liabilities recognized at fair value through the income statement and has no hedging relations. To that extent the Parent Company should apply IFRS 9, this has not had any effect.

#### Classification of financial assets

Effective from January 1, 2018, the Group classifies its financial assets in accordance with IFRS 9 in the following categories:

- Financial to subsequently be reported at fair value through the income statement,
- Financial assets to subsequently be reported at fair value through other comprehensive income, and
- Financial assets recognized at amortized cost.

The new categories did not materially affect the Group's accounts. At present, the Group only has assets that are reported at amortized cost. The classification is attributable to the Group's business model for managing financial assets and the contractual terms of the assets' cash flows.

In the balance sheet, financial assets and liabilities are reported at cost, which is judged to be a good approximation to the fair value of the items.

#### Impairment

In accordance with the rules in IFRS 9, the Group applies a simplified method for impairment testing of receivables, entailing expected losses being recognized when the underlying receivables are entered in the balance sheet. The Group's receivables are valued at amortized cost. In total, a credit loss provision of SEK 879 thousand was made as a consequence of the implementation of IFRS 9.

### IFRS 15 Revenue from Contracts with Customers

IFRS 15 is a comprehensive standard that sets out the accounting of the nature, size and timing of income from agreements with customers. The standard replaces IAS 18 Revenue, IAS 11 Construction Contracts and IFRIC 13 Customer Loyalty Programs. In accordance with IFRS 15, income is reported when the customer receives control of the item or service sold rather than when the material risks and benefits have passed to the customer. The Group applies IFRS 15 effective from January 1, 2018, with the total effect of the transition being reported on the first date of application. The effect of the transition to IFRS 15 amounted to SEK 0 thousand and had no impact on the Group's profit/loss statements or financial position.

#### Income

##### (i) Sales of goods

Income from sales of goods is recognized in the profit for the period when the control of the goods has been transferred to the buyer. 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 recognized at that fair value of what has been obtained, or is expected to be obtained, less discounts applied.

##### (ii) Sales of licenses

Income from sales of licenses is recognized in the same way as sales 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 recognized in the same way as sale of goods as described above.

### IFRS 16 Leases

IFRS 16 Leases replaces IAS 17 Leases and IFRIC 4 Determining whether an arrangement contains a lease and associated interpretations. Starting on January 1, 2019 application of the standard is mandatory. With the exception of contracts with a contract period of a maximum of 12 months and individual low-value contracts, the new standard requires the lessee to report all contracts meeting the definition of a lease as assets and liabilities in the statement of financial position. Contracts that were previously reported as operating leases will be reported in the balance sheet, with the effect that the current operating ex-

penses, the period's lease fee, are replaced by depreciation and interest expenses in the income statement. Xbrane applies the standard from the financial year that started on January 1, 2019 with the simplified transition method. As an operational lessee, the Group is primarily affected through its building/ car leases, with the effect of increases in the balance sheet total, operating profit and financial expenses, and that the corresponding

cash flows are transferred from operating activities to financing activities. The opening effect on the Group's balance sheet as of January 1, 2019 is that a preliminary increase of SEK 3,610 thousand, consisting of a lease asset and the corresponding lease liability, will be reported. Equity was not affected. Depreciation and interest expenses during 2019 are estimated to be affected by SEK 1,376 thousand and SEK 94 thousand, respectively.

## Note 2 Segment reporting

### Report of income, operating profit/loss and profit/loss before tax per segment

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
<b>Income per segment</b>				
Biosimilars	535	-	77,860	-
Long-acting injectable drugs	4,597	11,211	33,561	22,447
Unallocated income	1,068	112	8,806	838
<b>Total income</b>	<b>6,200</b>	<b>11,323</b>	<b>120,227</b>	<b>23,285</b>
<b>Profit/loss by segment</b>				
Biosimilars	-22,230	-12,739	3,497	-27,326
Long-acting injectable drugs	-47,730	-1,148	-27,462	-5,419
Administration and unallocated profit/loss	37,804	-5,231	12,550	-11,973
<b>Operating profit/loss</b>	<b>-32,156</b>	<b>-19,118</b>	<b>-11,415</b>	<b>-44,718</b>
<b>Net financial items</b>				
Biosimilars	-	-	-	-
Long-acting injectable drugs	36	-16	-	-69
Administration and unallocated profit/loss	-411	-23	-1,700	-147
<b>Total</b>	<b>-375</b>	<b>-39</b>	<b>-1,700</b>	<b>-217</b>
<b>Profit/loss before tax</b>	<b>-32,531</b>	<b>-19,157</b>	<b>-13,115</b>	<b>-44,935</b>
<b>Depreciation</b>				
Biosimilars	448	416	1,788	1,362
Long-acting injectable drugs	1,358	625	3,481	1,333
Administration and unallocated profit/loss	14	85	66	35
<b>Total</b>	<b>1,820</b>	<b>1,126</b>	<b>5,336</b>	<b>2,730</b>

**Note 3 Distribution of income**

Amounts in SEK thousand		Q4 2018		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	4,597	-	4,597
Asia	-	-	-	-
Europe	535	-	896	1,431
US	-	-	172	172
<b>Total</b>	<b>535</b>	<b>4,597</b>	<b>1,068</b>	<b>6,200</b>
<b>Income by category</b>				
Pharmaceutical products	-	4,597	-	4,597
Milestone payments from partners	-	-	-	-
Services and other	535	-	1,068	1,603
<b>Total</b>	<b>535</b>	<b>4,597</b>	<b>1,068</b>	<b>6,200</b>
		<b>Q4 2017</b>		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	11,211	-	11,211
Asia	-	-	-	-
Europe	-	-	20	20
US	-	-	92	92
<b>Total</b>	<b>-</b>	<b>11,211</b>	<b>112</b>	<b>11,322</b>
<b>Income by category</b>				
Pharmaceutical products	-	11,211	-	11,211
Milestone payments from partners	-	-	-	-
Services and other	-	-	112	112
<b>Total</b>	<b>-</b>	<b>11,211</b>	<b>112</b>	<b>11,322</b>

**Note 3 Distribution of income, cont.**

Amounts in SEK thousand		Full year 2018		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	20,186	-	20,186
Asia	-	13,375	-	13,375
Europe	77,860	-	8,381	86,241
US	-	-	425	425
<b>Total</b>	<b>77,860</b>	<b>33,561</b>	<b>8,806</b>	<b>120,227</b>
<b>Income by category</b>				
Pharmaceutical products	-	20,485	-	20,485
Milestone payments from partners	77,325	13,076	-	90,401
Services and other	535	-	8,806	9,341
<b>Total</b>	<b>77,860</b>	<b>33,561</b>	<b>8,806</b>	<b>120,227</b>
		Full year 2017		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	20,771	-	20,771
Asia	-	-	-	-
Europe	-	1,676	369	2,046
US	-	-	469	469
<b>Total</b>	<b>-</b>	<b>22,447</b>	<b>838</b>	<b>23,285</b>
<b>Income by category</b>				
Pharmaceutical products	-	20,771	-	20,771
Milestone payments from partners	-	-	-	-
Services and other	-	1,676	838	2,515
<b>Total</b>	<b>-</b>	<b>22,447</b>	<b>838</b>	<b>23,285</b>

**Note 4 Co-development agreement**

On July 12, 2018, Xbrane signed a co-development agreement with German STADA Arzneimittel AG ("STADA") regarding Xlucane, a biosimilar of Lucentis®. Within the co-development agreement, a joint controlling influence applies, according to which both parties contribute to development costs and share equally in the profits from the commercialization of Xlucane. Xbrane is responsible for the development of the product until the market approval applications have been submitted to the EMA and FDA and for providing the completed pharmaceutical product. STADA will hold the market approval and will be responsible for selling and marketing the product in all territories included in the agreement. The co-development agreement covers Europe, the US and parts of the markets in the Middle East and North Africa and the Asia Pacific region. The co-development is reported as a joint venture in accordance with IFRS 11 Joint Arrangements and recognized in the consolidated accounts in accordance with the proportional method. As per December 31, 2018, the joint venture had no common assets, liabilities or income. In the fourth quarter, Xbrane's share of the development expenses amounted to SEK 26,234 thousand. For the full year of 2018 the expenses amounted to SEK 40,555 thousand.

**Note 5 Transactions with related parties**

Since December 31, 2015 a provision has been in place for the CEO/Head of Long-Acting Injectables of the Italian subsidiary Primm Pharma, amounting on December 31, 2018 to SEK 3,638 thousand. The provision relates to a non-recurring payment on termination of employment in accordance with Italian legislation and is not interest-bearing.

During 2018, up until December 31, Primm Pharma s.r.l. has purchased administration and accounting services and rented premises from Primm s.r.l. at an expense of SEK 684 thousand. Primm s.r.l. is 56 percent per cent owned by Paolo Sarmientos, CEO/ Head of Long-Acting Injectables for Primm Pharma, and 10 percent by Alessandro Sidoli, member of Xbrane's Board of Directors.

On the balance sheet date of December 31, 2018, Xbrane had utilized SEK 45,000 thousand of the credit facility issued by Serendipity Group AB at the end of 2017. Interest during 2018 amounted to SEK 1,500 thousand as per December 31. The debt is classified as current.

On the balance sheet date of December 31, 2018, the Parent Company Xbrane held a loan of SEK 3,042 thousand issued by the subsidiary Primm Pharma. Interest during 2018 amounted to SEK 125 thousand as per December 31.

In 2018, up until December 31, the Parent Company Xbrane had invoiced the subsidiary Primm Pharma SEK 56 thousand for administrative services related to the agreement for the out-licensing of Spherotide to the Chinese market, and had onward invoiced Xbrane Biopharma AB a total of SEK 985 thousand in external expenses, although these pertained to Primm Pharma. Primm Pharma has, in turn, onward invoiced Xbrane Biopharma SEK 377 thousand for external costs relating to Xbrane. These are eliminated in the consolidated accounts.

In 2018, up until December 31, Xbrane had purchased consulting services from Edman Life Science AB for a total SEK 42 thousand, including travel expenses related to this work. Edman Life Science AB is owned 100 percent by Peter Edman, Board member of Xbrane.

**Note 6 Significant transactions**

In the third quarter, Xbrane entered into a collaborative agreement with STADA as described in Note 4. In connection with the signing of the agreement, Xbrane received an income item of SEK 77,325 thousand.

**Note 7 Tax**

The Group's effective tax rate for the nine months ending December 31, 2018 was 1 percent (0). The change in the effective tax rate is due to tax expenses in the Italian subsidiary.



## Statement of assurance

The Board of Directors and the CEO hereby certify that this interim report provides a true and fair view of the operations, position and earnings of the Parent Company and the Group, and describes the material risks and uncertainties facing the Company and the companies within the Group.

Solna, February 22, 2019

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Anders Tullgren  
*Chairman of the Board*

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Saeid Esmailzadeh  
*Board member*

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Peter Edman  
*Board member*

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Alessandro Sidoli  
*Board member*

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Karin Wingstrand  
*Board member*

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Maris Hartmanis  
*Board member*

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Giorgio Chirivi  
*Board member*

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Martin Åmark  
*CEO*

## Review report

### Review report

To the Board of Directors of Xbrane Biopharma AB (publ)  
Corp. id. 556749-2375

### Introduction

We have reviewed the condensed interim financial information (Year-end report 2018) of Xbrane Biopharma AB (publ) as of 31 December 2018 and the twelve-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of review

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

### Conclusion

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

### Uncertainties regarding going concern assumption

Without affecting our Conclusion above, we draw attention to the company's disclosures in the quarterly report on pages 3 and 9 which describes that the company is evaluating various financing options to ensure continued operations over the next 12 months. No financing agreement is in place at the date of signing this report. This indicates that there are uncertainties that about the company's ability to continue as a going concern.

Stockholm 22 February 2019

KPMG AB

Duane Swanson

Authorized Public Accountant

## Alternative performance measures

In the interim report, the Company presents certain financial measures not defined under applicable accounting regulations such as IFRS and the Annual Accounts Act. In the Company's view, these measures provide valuable supplementary information to investors and the Company's management as they enable evaluation of the Company's performance. Since not all companies calculate financial measures in the same way, they are not always comparable with the measures used by other companies. Accordingly, these financial measures should not be viewed as a replacement for those defined in accordance with IFRS. The measures not defined in accordance with IFRS are presented in the tables below.

### Gross margin

Gross margin is a measure that the Group considers important in understanding the profitability of its products. The gross margin is calculated as gross profit/loss in relation to revenue. Gross profit/loss is revenue minus cost of goods sold.

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
Gross profit/loss	1,240	2,278	4,578	4,942
Divided by revenue	4,896	9,535	20,485	20,771
<b>Gross margin</b>	<b>25%</b>	<b>24%</b>	<b>22%</b>	<b>24%</b>

### EBITDA

EBITDA is a measure the Group considers relevant to investors seeking to understand profit generation before investments in fixed assets. EBITDA shows the operation's earning power from operating activities without taking into account capital structure and tax situation, with the aim of facilitating comparisons with other companies in the same sector.

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
Operating profit/loss	-32,156	-19,118	-11,415	-44,718
Depreciation	-1,820	-1,126	-5,336	-2,730
<b>EBITDA</b>	<b>-30,336</b>	<b>-17,992</b>	<b>-6,079</b>	<b>-41,988</b>

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

Research and development expenses (R&D) as a percentage of operating expenses are a measure that the Group considers important in understanding the proportion of research and development expenses that can be considered to generate value for a company. 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 operating expenses are calculated by dividing research and development expenses by total operating expenses less depreciation and impairment. Total operating expenses comprise selling expenses, administrative expenses, research and development expenses and other operating expenses.

Amounts in SEK thousand	2018 Q4	2017 Q4	2018 Full year	2017 Full year
Research and development expenses	-25,533	-17,531	-85,827	-37,982
Divided by operating expenses less depreciation and impairment	-32,881	-22,058	-110,400	-48,182
<b>Research and development expenses as a percentage of operating expenses</b>	<b>78%</b>	<b>79%</b>	<b>78%</b>	<b>79%</b>

### Equity ratio

The equity ratio is a measure the Group considers relevant to investors seeking to understand the distribution between equity and liabilities. The equity ratio represents the proportion of assets funded by equity to show the Company's long-term payment capacity, that is equity divided by total assets.

Amounts in SEK thousand	12/31/2018	12/31/2017
Total equity	83,070	88,405
Divided by total assets	252,885	110,960
<b>Equity ratio</b>	<b>33%</b>	<b>80%</b>



**For further information**

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**Financial calendar**

Annual Report	April 26, 2019
Interim Report Jan-Mar	May 14, 2019
Annual General Meeting 2019	May 16, 2019
Interim Report Apr-Jun	August 23, 2019
Interim Report Jul-Sep	November 15, 2019
Year-end report 2019	February 28, 2020

