

# Interim report July – September 2018

## The third quarter in summary

- » Revenue amounted to SEK 2,441 thousand (-).
- » Gross margin amounted to 21% (-).
- » Other operating income amounted to SEK 84,041 thousand (331), of which SEK 77,325 thousand was revenue for the initial co-development agreement with STADA for Xlucane.
- » EBITDA amounted to SEK 62,054 thousand (negative 8,180).
- » R&D expenses amounted to SEK 12,069 thousand (6,620), corresponding to 54% (80) of total operating expenses.
- » Profit for the period amounted to SEK 60,096 thousand (loss 9,092).
- » Earnings per share amounted to SEK 9.49 (negative 1.53).
- » Cash and cash equivalents amounted to SEK 64,311 thousand (23,624) at the end of the period.

## Significant events during quarter

- » A co-development agreement was signed with STADA for Xlucane, with STADA acquiring 50% of the project. Accordingly, the parties will share development, marketing and distribution expenses and income equally in the future. The income received for the co-development agreement amounted to SEK 77,325 thousand.

## First nine months of the year in summary

- » Revenue amounted to SEK 15,589 thousand (11,236).
- » Gross margin amounted to 21% (24).
- » Other operating income amounted to SEK 98,437 thousand (727), of which SEK 77,325 thousand was revenue for the initial 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 24,257 thousand (negative 23,535).
- » R&D expenses amounted to SEK 60,294 thousand (20,450), corresponding to 78% (76) of total operating expenses.
- » Profit for the period amounted to SEK 19,187 thousand (loss 25,778).
- » Earnings per share were SEK 3.11 (negative 4.91).

## Significant events after the end of the period

- » In October, Xbrane presented the results of an in-vivo study in rabbits, demonstrating tolerability and a pharmacokinetic profile for Xlucane equivalent to Lucentis®.

## Financial summary for the Group

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Revenue	2,441	-	15,589	11,236	20,771
Research and development expenses	-12,069	-6,620	-60,294	-20,450	-37,982
R&D expenses as a percentage of operating expenses	54%	80%	78%	76%	79%
Operating profit/loss	60,850	-8,839	20,741	-25,415	-44,718
EBITDA	62,054	-8,180	24,257	-23,535	-40,726
Profit/loss for the period	60,096	-9,092	19,187	-25,778	-44,935
Cash and cash equivalents	64,311	23,624	64,311	23,624	7,903
Equity ratio, %	42%	90%	42%	90%	80%
Number of shares at the end of the period before dilution	6,329,239	5,956,770	6,329,239	5,956,770	5,956,770
Number of shares at the end of the period after dilution*	6,852,170	5,956,770	6,852,170	5,956,770	5,956,770
Average number of shares before dilution	6,329,239	5,941,346	6,175,067	5,246,673	5,425,656
Average number of shares after dilution*	6,852,170	5,941,346	6,697,998	5,246,673	5,425,656
Earnings per share before dilution (SEK)	9.49	-1.53	3.11	-4.91	-8.28
Earnings per share after dilution (SEK)*	8.77	-1.53	2.86	-4.91	-8.28

\* Dilution not taken into account where earnings per share are negative. If converted to shares, convertible loans outstanding as per September 30, 2018, would be equivalent to 330,593 shares. If converted to shares, warrants for share savings programs for employees would be equivalent to 192,338 shares. This would total 522,931 shares on conversion.



Pioneering biosimilar development



## CEO's comments

**Dear shareholder,**

**Focus on biosimilars**

In September 2018, the Board of Directors of Xbrane Biopharma decided to focus the activities of the company on development of biosimilars.

Following a thorough analysis of the market, competitive situation and the company's technological strengths, the natural decision to make was for Xbrane to focus on becoming a world-leading developer of biosimilars. In our assessment, the market for biosimilars offers clear future potential.

It is inevitable that this market will grow rapidly over the next few decades, as there is a large and growing market for biological drugs, patents are expiring and pressure from regulatory authorities and payers are driving up use of biosimilars. There are numerous attractive opportunities to be addressed, many more than Xbrane can handle. High entry barriers remain and competition is relatively limited, offering opportunities for high margins. Xbrane also considers itself to enjoy a clear competitive advantage in the market through its patented technology platform, with which the company is able to reduce production expenses significantly.

*“In the future, Xbrane will focus on becoming a world-leading developer of biosimilars.”*

#### **Development of Xlucane**

The development of Xlucane is progressing as planned. Xbrane has prepared commercial-scale process production and demonstrated a high degree of analytical similarity to Lucentis® based on a panel of more than 30 analytical methods in accordance with the requirements of the EMA (European Medicines Agency) and FDA (US Food and Drug Administration). In a comparative trial in rabbits, Xlucane has also demonstrated tolerability and a pharmacokinetic profile equivalent to Lucentis®. The next stage of development is the pivotal clinical trial that Xbrane intends to initiate in the first quarter of 2019. An experienced global CRO (Contract Research Organization) is in full swing with the preparatory process of selecting clinical centers for the trial. The design of the trial has been agreed with regulatory authorities in Europe (EMA) and the US (FDA). The study is an equivalence trial where Xlucane is compared with Lucentis® considering vision improvement two months after initiation of the treatment.

The trial is expected to include some 600 patients with age-related macular degeneration globally.

#### **Development of Spherotide**

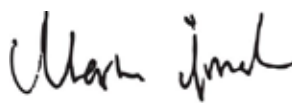
As previously communicated, Xbrane is in the process to find a commercialization partner for Spherotide, particularly in Europe. The company is currently in dialogue with a variety of interested parties for various forms of cooperation. The company's ambition is to find one partner who can fund most of the clinical program for Spherotide. 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.

#### **Financial position**

At the end of the third quarter of 2018, Xbrane had a cash position of SEK 64 million. As previously communicated the company has financing needs, above all concerning the clinical study for Xlucane. Clinical studies of similar size have typically cost around SEK 300-350 million (equivalent to about SEK 500–600 thousand per patient). According to the co-development agreement with STADA the parties share all development-related expenses for Xlucane going forward. Thus, for Xbrane, there is a financing need of approximately SEK 150–175 million for the clinical study for Xlucane. The company's ambition is to first finalize the previously mentioned partnership regarding Spherotide, and then if there still is a financing need, turn to the capital markets.

As previously communicated, the company has an ambition to move to Nasdaq Stockholm in order to be able to attract institutional capital. The company's ambition is that the change of listing to Nasdaq Stockholm can be completed in 2019. Xbrane actively meets institutional investors and participates at various conferences and Capital Markets Days. During this week the company has participated in Jefferies healthcare conference in London and later in November, the company will present at DnB's Capital Markets Day in New York and Redeyes Capital Market Day in Stockholm.

Thank you for your continued support,



Martin Åmark  
CEO

## 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*, 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. Lucentis® has annual sales of approximately SEK 28 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., which was acquired on September 30, 2015. 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. Primm Pharma holds fixed assets related to its production line for Spherotide located outside Naples, Italy.



#### References:

- 1) Novartis Annual Report 2017
- 2) Roche Annual report 2017
- 3) IMS Health

## Shareholders

As per September 30, 2018, Xbrane had a total of approximately 2,600 shareholders. The number of shares outstanding amounted to 6,329,239. The ten largest shareholders at the end of the period 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	310,424	4.90%
Nordnet Pensionsförsäkring AB	186,340	2.94%
Swedbank insurance	148,070	2.34%
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>2,196,149</b>	<b>34.70%</b>
<b>Total, other shareholders</b>	<b>4,133,090</b>	<b>65.30%</b>
<b>Total</b>	<b>6,329,239</b>	<b>100.00%</b>
Shares via number of options outstanding	522,931	
<b>Total number of shares including options</b>	<b>6,852,170</b>	



*References:*

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

## Operational update

### Xlucane

Xbrane has completed its development of the commercial scale production process for Xlucane 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 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 further 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 I/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®. The application for the trial will be submitted in December 2018 and the first patient is expected to be recruited in the first quarter of 2019.

Xbrane has acceptance for the trial design from both the 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.

### 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

## LEADING PRODUCT CANDIDATES



### 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 has an annual sales of about SEK 4.5 billion.



### 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 2017 of approximately SEK 28 billion and will lose its patent protection in 2020 in the US and in 2022 in Western Europe.

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 large pharmaceutical companies are currently conducting an evaluation of Spherotide, primarily for Europe, which is the largest potential market for the product. The objective is to find a partner for Spherotide that can also fund most of the clinical trial.

Xbrane produces Spherotide in a production facility installed within premises owned by 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. 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 steps to ensure that the supply of Spherotide continues without any material interference, including by increasing safety stocks of the product.

Xbrane is reviewing carefully the emerging situation with the re-introduced US sanctions on Iran and their potential impact on Xbrane. Since pharmaceutical products are currently exempt from such sanctions, it is therefore more a matter of how sanctions on the financial system affect opportunities to conduct financial transactions with companies in Iran. Xbrane is maintaining a close dialogue with its partner in Iran to minimize the impact on the company's operations.



## Financial overview

### Consolidated profit for the period

#### July – September 2018

Consolidated revenue amounted to SEK 2,441 thousand (-), pertaining to revenues from sales of Spherotide. The cost of goods sold amounted to SEK 1,929 thousand (192), comprising raw materials, manufacturing expenses from the contract manufacturer, leasing expenses for production equipment, salaries and depreciation. Both raw materials and manufacturing expenses are affected by economies of scale, meaning that the gross margin, which amounted to 21 percent (-) during the period, is expected to increase with increased production.

Other operating income amounted to SEK 84,041 thousand (331), of which SEK 77,325 thousand pertains to the income that the company received in connection with signing the co-development agreement with STADA for Xlucane, SEK 3,137 thousand in tax relief for the subsidiary, SEK 2,986 thousand for exchange rate gains on operating receivables and the remaining SEK 593 thousand for other license income. Differences in selling and distribution expenses, that was a net income during the third quarter, amounted to SEK 135 thousand (284) and results from adjustments of expenses from the first and the second quarter of 2018. Administration expenses amounted to SEK 8,807 thousand (1,975), with the increase compared with the previous period relating primarily to an expanded administrative department, expenses associated with the co-development agreement with STADA and expenses associated with the company's planned market listing. Research and development expenses amounted to SEK 12,069 thousand (6,620), of which SEK 9,243 thousand (1,917) pertained to *biosimilars*, primarily Xlucane, and SEK 2,826 thousand (4,703) to *long-acting injectable drugs*, that being Spherotide exclusively. The increase that has occurred is attributable to development work, primarily for Xlucane, progressing and being intensified. The greatest increase in expenses involves the production of test batches of Xlucane and preparations for clinical trials. All development expenses are charged to the income statement. Other operating expenses amounted to SEK 2,961 thousand (98), primarily comprising exchange rate losses on accounts receivable and payable.

During the period, the number of employees increased from 23 to 25.

Consolidated operating profit amounted to SEK 60,850 thousand (loss 8,839) .

Net financial items amounted to a negative SEK 526 thousand (253) and refer entirely to financial expenses consisting primarily of interest expenses for credit facilities

and leases. Income tax amounted to SEK 229 thousand (-) and relates to the subsidiary.

Profit after tax for the period amounted to SEK 60,096 thousand (loss 9,092).

### Consolidated cash flow for the period

#### July – September 2018

Cash flow from operating activities amounted to SEK 35,138 thousand (8, 338). The negative change in operating receivables of SEK 106,641 thousand (1,177) and operating liabilities of a positive SEK 81 439 thousand (negative 1,443) relates largely to the Xlucane development program, which has been intensified and reached a more costly phase, as well as the co-development on Xlucane signed with STADA. Cash flow was affected positively by the income item of SEK 77,325 thousand received by the company on the signing of the agreement.

Cash flow from investing activities was negative in the amount of SEK 731 thousand (279), comprising investments in property, plant and equipment.

Cash flow from financing activities amounted to SEK 9,850 thousand (negative 124) and pertains to loans raised of SEK 10,000 thousand (-), amortization of loans and leasing liabilities of SEK 79 thousand (30) and a total of SEK 60 thousand (85) respectively, as well as transaction expenses of SEK 11 thousand (10) for a share issue earlier in the year).

### Consolidated profit for the period

#### January – September 2018

Consolidated revenue amounted to SEK 15,589 thousand (11,236), pertaining to revenues from sales of Spherotide. The cost of goods sold amounted to SEK 12,251 thousand (8,573), comprising raw materials, manufacturing expenses from the contract manufacturer, leasing expenses for production equipment, salaries and depreciation. Both raw materials and manufacturing expenses are affected by scale, which means that the gross margin, which amounted to 21 percent (24) during the period, is expected to increase with increased production.

Other operating income amounted to SEK 98,437 thousand (727), of which SEK 77,325 thousand pertained to the income that the company received in connection with signing the co-development agreement with STADA for Xlucane, SEK 13,375 thousand for one of the potential several milestone payments for license agreements with CR Pharma regarding Spherotide, SEK 3,595 thousand in tax relief for the subsidiary, SEK 3,193 thousand for exchange rate gains on



operating receivables and the remaining SEK 949 thousand for other license income. Selling and distribution expenses amounted to SEK 737 thousand (1,071), consisting of personnel expenses. Administration expenses amounted to SEK 16,489 thousand (7,209), with the increase compared with the previous period relating primarily to an expanded administrative department, expenses associated with the agreements with STADA and CR Pharma and expenses associated with the company's planned market listing. Research and development expenses amounted to SEK 60,294 thousand (20,450), of which SEK 51,597 thousand (12,175) pertained to *biosimilars*, primarily Xlucane, and SEK 8,697 thousand (8,275) to *long-acting injectable drugs*, that being Spherotide exclusively. The increase that has occurred is attributable to development work, primarily for Xlucane, progressing and being intensified. The greatest increase in expenses involves the production of test batches of Xlucane and preparations for clinical trials. All development expenses are charged. Other operating expenses amounted to SEK 3,514 thousand (75), primarily comprising exchange losses on accounts receivable and payable.

During the period, the number of employees increased from 20 to 25.

The consolidated operating loss amounted to SEK 20,741 (25,415) thousand.

Net financial items were negative in the amount of SEK 1,325 (363) and refer entirely to financial expenses consisting primarily of interest expenses for credit facilities and leases.

Income tax amounted to SEK 229 thousand (-) and relates to the subsidiary.

The loss after tax for the period amounted to SEK 19,187 thousand (25,778).

#### **Consolidated cash flow for the period January – September 2018**

Cash flow from operating activities amounted to SEK 8, 920 thousand (24, 005). The negative change in operating receivables of SEK 106,281 thousand (4,653) and operating liabilities of a positive SEK 93,566 thousand (1,412) relates largely to the Xlucane development program, which has been intensified and reached a more costly phase, as well as the co-development agreement on Xlucane signed with STADA. Cash flow was affected positively by the net income item of SEK 77,325 thousand received by the company on the signing of the agreement.

Cash flow from investing activities was negative in the amount of SEK 1,414 thousand (358), comprising investments in property, plant and equipment.

Cash flow from financing activities amounted to SEK 47,825 thousand (16,648) and pertains to loans raised of SEK 45,000 thousand (-), amortization of loans and leasing liabilities of SEK 98 thousand (88) and a total of SEK 315 thousand (258) respectively, an 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 (3,010) for the share issue).

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

Consolidated cash and cash equivalents at the end of the period amounted to SEK 64,311 thousand (23,624). During the first nine months of the year, the company raised loans of SEK 45,000 thousand from the credit facility it acquired from its principal owner, the Serendipity Group, at the end of 2017. As described in the CEO's comments, approximately SEK 150-175 million will be needed to finance the company's share of 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 where a transaction for Spherotide, if implemented, would help cover the company's financing needs. Following that, if financing is still needed, the company intends to look to the capital market.

The equity ratio amounted to 42 (90) percent.

Non-current receivables amounted to SEK 18,888 thousand (635) and consisted largely of a prepayment to the CRO (Contract Research Organization) that will conduct the clinical trial for Xlucane. As per the balance sheet date, accounts receivable amounted to SEK 68,595 thousand (6,788) and pertained mainly to receivables from STADA for its share of development expenses for Xlucane, as well as receivables from the company's distribution partner in Iran. Prepaid expenses and accrued income amounted to SEK 25,497 thousand (1,306), pertaining primarily to prepayment of expenses for Xlucane. Non-current, non-interest-bearing liabilities amounted to SEK 9,127 thousand (-) and pertain to a liability to STADA for its share of the prepayment to the CRO described above. As per the balance sheet date, accounts payable and accrued expenses and prepaid income amounted to SEK 47,255 thousand (3,538) and SEK 53,202 thousand (2,632) respectively, with the increase being explained by the fact that Xlucane has reached the more costly phase of the development program, including

test production and preparing for clinical trials as well as STADA's share of the prepayment.

#### **Intangible assets**

Intangible assets amounted to SEK 5,983 thousand (6,617) and consist of capitalized development expenditure. No development expenditure has been capitalized during 2018. Goodwill amounts to SEK 59,950 thousand (55,712) and changes from the preceding period are attributable entirely to exchange rate fluctuations.

#### **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 a negative effect of SEK 235 thousand.

#### **Parent company profit for the period July – September 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 81,357 thousand (285), comprising SEK 77,325 thousand for a non-recurring income from the co-development agreement with STADA for Xlucane, SEK 2,985 thousand in exchange rate gains on operating receivables, SEK 593 thousand in other license income, and the remaining SEK 454 thousand for intra-Group income. The parent company has no selling and distribution expenses. Administration expenses amounted to SEK 7,547 thousand (5,751), with the increase compared with the previous period primarily relates to an expanded administrative department, expenses associated with the agreement with STADA and expenses associated with the company's planned change of listing. Research and development expenses amounted to SEK 10,057 thousand (1,917). The increase concerns the development of Xlucane is proceeding and being intensified. In particular it is the expense of producing test batches of Xlucane and preparations for clinical trials that is increasing expenses. All development expenses are charged to the income statement. Other operating expenses amounted to SEK 2,869 thousand (-)

and primarily pertains to exchange losses on accounts receivable and payable.

During the period, the number of employees increased from 15 to 17.

The parent company's operating profit amounted to SEK 60,885 thousand (loss 7,383).

Net financial items amounted to SEK -467 thousand (-273) and refer entirely to financial expenses consisting primarily of interest expenses for credit facilities.

Profit after tax for the period amounted to SEK 60,418 thousand (loss 7,657).

#### **Parent company cash flow for the period July – September 2018**

Cash flow from operating activities amounted to SEK 36,929 thousand (6,844). The negative change in operating receivables of SEK 106,201, thousand (1,810) and operating liabilities of a positive SEK 83,161 thousand (282) relates largely to the Xlucane development program, which has been intensified and reached a more costly phase, as well as the co-development agreement on Xlucane signed with STADA. Cash flow is affected positively by the net income item of SEK 77,325 thousand received by the company on the signing of the agreement.

Cash flow from investing activities was negative in the amount of SEK 60 thousand (1,944), comprising investments in property, plant and equipment.

Cash flow from financing activities amounted to SEK 8,161 thousand (negative 68) and pertains to loans of SEK 8,172 thousand raised by the subsidiary Primm Pharma and minor transaction expenses of SEK 11 thousand from a previous issue of shares and warrants (-).

#### **Parent company earnings for the period January – September 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 95,708 thousand (585), of which SEK 77,325 thousand pertained to the income that the company received in connection with signing the co-development agreement with STADA for Xlucane, SEK 13,375 thousand for one of potentially several milestone payments for license agreements with

China Resources Pharmaceuticals regarding Spherotide, SEK 3,188 thousand for exchange rate gains on operating receivables, SEK 949 thousand for other license income and the remaining SEK 871 thousand pertained to intra-Group income. The parent company has no selling and distribution expenses. Administration expenses amounted to SEK 13,456 thousand (5,751), with the increase compared with the previous period relating primarily to an expanded administrative department, expenses associated with the agreements with STADA and CR Pharma and expenses associated with the company's planned market listing. Research and development expenses amounted to SEK 52,412 thousand (14,587), with the increase that has occurred being attributable to the fact that the development of Xlucane is proceeding and being intensified. In particular it is the expense of producing test batches of Xlucane and preparations for clinical trials that is increasing expenses. All development expenses are charged to the income statement. Other operating expenses amounted to SEK 16,534 thousand (-) and primarily pertains to onward invoicing of income for the Spherotide agreement in China and exchange losses on accounts receivable and payable.

During the period, the number of employees increased from 15 to 17.

The parent company's operating profit amounted to SEK 13,307 thousand (loss 19,753).

Net financial items were negative in the amount of SEK 1,229 thousand (275) and pertain entirely to financial expenses consisting primarily of interest expenses for credit facilities.

The loss after tax for the period amounted to SEK 12,078 thousand (20,028).

#### **Parent company cash flow for the period January – September 2018**

Cash flow from operating activities amounted to SEK 5,480 thousand (negative 19,221). The negative change in operating receivables of SEK 103,108 thousand (88) and operating liabilities of a positive SEK 95,693 thousand (negative 282) relates largely to the Xlucane development program, which has been intensified and reached a more costly phase, as well as the co-development agreement on Xlucane signed with STADA. The positive cash flow is affected by the net income item of SEK 77,325 thousand received by the company on the signing of the co-development agreement.

Cash flow from investing activities was negative in the amount of SEK 6,766 thousand (5,211) and pertains to a shareholder contribution of SEK 6,691 thousand (5,756) to the subsidiary and investments in property, plant and equipment of SEK 75 thousand (546).

Cash flow from financing activities amounted to SEK 56,410 thousand (16,936). Loans raised amounted to SEK 53,172 thousand (-), of which SEK 45,000 thousand derived from the credit facility that the company received from its principal owner, the Serendipity Group, at the end of 2017 and a loan of SEK 8,172 thousand issued by the subsidiary Primm Pharma. A new issue of shares and warrants raised a net SEK 2,537 thousand (16,936) 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 63,052 thousand (23,016).

Non-current receivables amounted to SEK 18,888 thousand (635) and consisted largely of a prepayment to the CRO that conducts the clinical trial for Xlucane. As per the balance sheet date, accounts receivable amounted to SEK 63,035 thousand (-) and pertained mainly to receivables from STADA for its share of development expenses for Xlucane. Prepaid expenses and accrued income amounted to SEK 25,400 thousand (742), pertaining primarily to prepayment of expenses for Xlucane. Non-current, non-interest-bearing liabilities amounted to SEK 9,127 thousand (-) and pertain to a liability to STADA for its share of the prepayment to the CRO described above. As per the balance sheet date, accounts payable and accrued expenses and prepaid income amounted to SEK 44,848 thousand (1,252) and SEK 50,992 thousand (1,057) respectively, with the increase being explained by the fact that Xlucane has reached the more costly phase of the development program, including test production and preparing for clinical trials as well as STADA's share of the prepayment.

#### **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 period amounted to SEK 1,419 thousand (1,336) 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

### **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 only of social security expenses, which amounted to SEK 57 thousand for the third quarter and totaled SEK 105 thousand for the first nine months of the year.

#### *Warrant program*

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.

#### *Unforeseen production stoppages disturbing the value chain*

Sales of Spherotide are 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 is undergoing reconstruction in accordance with a reconstruction plan to be formally adopted by creditors in November 2018. There is a risk that the court ruling could affect the company's ability to produce products at the production facility at the level expected by the company and its customers. If the production facility cannot be used following the ruling in the reconstruction process, or if it were to be completely or partially destroyed, need to be closed, or if any equipment at the facilities were to be seriously damaged, the production and distribution of the company's products could be impeded or discontinued. Interruptions to production could also damage Xbrane's reputation among current and potential customers, which could lead to poorer customer relations and reduced sales. To the extent that unforeseen production interruptions, damage to property or other events disturbing the value chain are not fully covered by insurance, this could also have a material adverse effect on the company's operations, financial position or earnings.

#### *Sanctions against Iran*

Xbrane conducts sales of the drug Spherotide in Iran. In July 2018, the US reintroduced certain sanctions against Iran. Initially, the sanctions are not expected to include drugs or the pharmaceutical industry. Other societal functions, however, including the banking system and payment functions are expected to be encompassed by the new sanctions. Sanctions against the banking system and payment functions could cause Xbrane difficulties in receiving payments from Iran, which could affect sales of the company's products. There is also a risk that existing sanctions could be extended or that new sanctions could be imposed, including sanctions on drugs or the pharmaceutical industry, which could affect opportunities to import and export medicines to and from Iran and affect Xbrane's market approval. Accordingly, access to, and sales of, drugs in Iran could be reduced or disappear entirely. There is also a risk that collaborative partners will choose to terminate or not initiate cooperation with Xbrane in view of the fact that the company has sales in Iran. The reintroduced and possibly extended sanctions against Iran could adversely affect the company's operations, financial position or earnings.

### **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 25 employees on the balance sheet date, 17 of which are located in Sweden and eight in Italy.

### **Annual General Meeting**

The Annual General Meeting was held on May 24, 2018.

### **Certified adviser**

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

## Consolidated statement of profit or loss

Amounts in SEK thousand	Notes	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Revenue	2, 3	2,441	-	15,589	11,236	20,771
Cost of goods sold		-1,929	-192	-12,251	-8,573	-15,829
<b>Gross profit/loss</b>		<b>512</b>	<b>-192</b>	<b>3,338</b>	<b>2,664</b>	<b>4,942</b>
Other operating income	2, 3, 6	84,041	331	98,437	727	2,515
Selling and distribution expenses		135	-284	-737	-1,071	-1,381
Administrative expenses		-8,807	-1,975	-16,489	-7,209	-11,567
Research and development expenses		-12,069	-6,620	-60,294	-20,450	-37,982
Other expenses		-2,961	-98	-3,514	-75	-1,245
<b>Operating profit/loss</b>	2	<b>60,850</b>	<b>-8,839</b>	<b>20,741</b>	<b>-25,415</b>	<b>-44,718</b>
Financial income		-	-18	-	0	0
Financial expenses		-526	-235	-1,325	-363	-217
<b>Net financial items</b>	2	<b>-526</b>	<b>-253</b>	<b>-1,325</b>	<b>-363</b>	<b>-217</b>
<b>Profit/loss before tax</b>		<b>60,325</b>	<b>-9,092</b>	<b>19,416</b>	<b>-25,778</b>	<b>-44,935</b>
Income tax expense	7	-229		-229	-	
<b>Profit/loss for the period</b>		<b>60,096</b>	<b>-9,092</b>	<b>19,187</b>	<b>-25,778</b>	<b>-44,935</b>
<b>Profit/loss for the period attributable to:</b>						
– Parent Company shareholders		60,096	-9,092	19,187	-25,778	-44,935
– Non-controlling interest		-				
<b>Profit/loss for the period</b>		<b>60,096</b>	<b>-9,092</b>	<b>19,187</b>	<b>-25,778</b>	<b>-44,935</b>
<b>Earnings per share</b>						
– Before dilution (SEK)		9.49	-1.53	3.11	-4.91	-8.28
– After dilution (SEK)*		8.77	-1.53	2.86	-4.91	-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	5,956,770
– After dilution*		6,852,170	5,956,770	6,852,170	5,956,770	5,956,770
<b>Average number of outstanding shares</b>						
– Before dilution		6,329,239	5,941,346	6,175,067	5,246,673	5,425,656
– After dilution*		6,852,170	5,941,346	6,697,998	5,246,673	5,425,656

\* Dilution not taken into account where earnings per share are negative. If converted to shares, convertible loans outstanding as per September 30, 2018, would be equivalent to 330,593 shares. If converted to shares, warrants for share savings programs for employees would be equivalent to 192,338 shares. This would total 522,931 shares on conversion.

## Summary consolidated statement of profit/loss and other comprehensive income

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
<b>Profit/loss for the period</b>	60,096	-9,092	19,187	-25,778	-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	-1,148	50	3,936	276	2,218
<b>Other comprehensive income for the period</b>	<b>-1,148</b>	<b>50</b>	<b>3,936</b>	<b>276</b>	<b>2,218</b>
<b>Comprehensive income for the period attributable to:</b>					
– Parent Company shareholders	58,948	-9,042	23,123	-25,502	-42,716
– Non-controlling interest	-	-	-	-	-
<b>Comprehensive income for the period</b>	<b>58,948</b>	<b>-9,042</b>	<b>23,123</b>	<b>-25,502</b>	<b>-42,716</b>

## Summary consolidated statement of financial position

Amounts in SEK thousand	9/30/18	9/30/17	12/31/17
<b>ASSETS</b>			
Goodwill	59,950	55,712	57,360
Intangible assets	5,983	6,617	6,297
Property, plant and equipment	17,553	15,373	18,569
Non-current receivables	18,888	635	635
<b>Total non-current assets</b>	<b>102,373</b>	<b>78,337</b>	<b>82,860</b>
Inventories	2,651	1,271	3,065
Income taxes recoverable	11,703	6,250	8,043
Accounts receivable	68,595	6,788	8,072
Prepaid expenses and accrued income	25,497	1,306	1,018
Cash and cash equivalents	64,311	23,624	7,903
<b>Total current assets</b>	<b>172,756</b>	<b>39,239</b>	<b>28,100</b>
<b>TOTAL ASSETS</b>	<b>275,129</b>	<b>117,576</b>	<b>110,960</b>
<b>EQUITY</b>			
Share capital	1,419	1,336	1,335
Other capital contributions	182,794	179,814	179,874
Reserves	5,798	-81	1,862
Retained earnings including profit/loss for the year	-75,480	-75,511	-94,667
<b>Equity attributable to owners of the company</b>	<b>114,532</b>	<b>105,558</b>	<b>88,405</b>
<b>Non-controlling interest</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total equity</b>	<b>114,532</b>	<b>105,558</b>	<b>88,405</b>
<b>LIABILITIES</b>			
Non-current interest-bearing liabilities	155	1,213	1,119
Non-current non-interest-bearing liabilities	9,127	-	-
Provisions	4,135	3,510	3,545
<b>Total non-current liabilities</b>	<b>13,417</b>	<b>4,723</b>	<b>4,664</b>
Current interest-bearing liabilities	45,593	-	-
Accounts payable	47,255	3,538	10,541
Current tax liabilities	234	-	-
Other liabilities	898	1,126	863
Accrued expenses and prepaid income	53,202	2,632	6,488
<b>Total current liabilities</b>	<b>147,181</b>	<b>7,296</b>	<b>17,892</b>
<b>TOTAL LIABILITIES</b>	<b>160,598</b>	<b>12,018</b>	<b>22,555</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>275,129</b>	<b>117,576</b>	<b>110,960</b>

## Summary consolidated statement of cash flows

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
<b>Cash flows from operating activities</b>					
Profit/loss before tax	60,325	-9,092	19,416	-25,778	-44,935
Adjustment for non-cash items	-1,443	674	1,678	3,789	3,803
Paid income tax	-	-	-	-	-
	<b>58,882</b>	<b>-8,418</b>	<b>21,094</b>	<b>-21,989</b>	<b>-41,131</b>
Increase (-)/decrease (+) in inventories	1,458	347	541	1,226	-568
Increase (-)/decrease (+) in operating receivables	-106,641	1,177	-106,281	-4,653	-7,441
Increase (-)/decrease (+) in operating liabilities	81,439	-1,443	93,566	1,412	12,292
<b>Cash flow from current operations</b>	<b>35,138</b>	<b>-8,338</b>	<b>8,920</b>	<b>-24,005</b>	<b>-36,848</b>
<b>Investing activities</b>					
Acquisition of property, plant and equipment	-731	-279	-1,414	-358	-3,347
<b>Cash flow from investing activities</b>	<b>-731</b>	<b>-279</b>	<b>-1,414</b>	<b>-358</b>	<b>-3,347</b>
<b>Financing activities</b>					
New share issue	-	-	2,549	20,004	20,004
Transaction expenses	-11	-10	-12	-3,010	-3,019
Warrants issue	-	-	701	-	-
Loans raised	10,000	-	45,000	-	-
Amortization of loan	-79	-30	-98	-88	-
Amortization of lease liability	-60	-85	-315	-258	-257
<b>Cash flow from financing activities</b>	<b>9,850</b>	<b>-124</b>	<b>47,825</b>	<b>16,648</b>	<b>16,728</b>
Cash flow for the period	44,257	-8,741	55,331	-7,714	-23,468
Cash and cash equivalents at beginning of period	19,255	32,365	7,903	31,338	31,338
Exchange rate differences in cash and cash equivalents	798	-	1,075	-	33
<b>Cash and cash equivalents at end of period</b>	<b>64,311</b>	<b>23,624</b>	<b>64,311</b>	<b>23,624</b>	<b>7,903</b>



## Summary 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	-	-	-	19,187	19,187	-	19,187
Other comprehensive income for the period	-	-	3,936	-	3,936	-	3,936
<b>Comprehensive income for the period</b>	<b>-</b>	<b>-</b>	<b>3,936</b>	<b>19,187</b>	<b>23,123</b>	<b>-</b>	<b>23,123</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	-	-235	-	-	-235	-	-235
Total contributions from and distributions to shareholders	84	2,920	-	-	3,003	-	3,003
<b>Equity at September 30, 2018</b>	<b>1,419</b>	<b>182,794</b>	<b>5,798</b>	<b>-75,480</b>	<b>114,531</b>	<b>-</b>	<b>114,531</b>

## Summary 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	-	-	-	-25,778	-25,778	-	-25,778
Other comprehensive income for the period	-	-	276	-	276	-	276
<b>Comprehensive income for the period</b>	<b>-</b>	<b>-</b>	<b>276</b>	<b>-25,778</b>	<b>-25,502</b>	<b>-</b>	<b>-25,502</b>
<b>Transactions with Group shareholders</b>							
<b>Contributions from and distributions to shareholders</b>							
New share issue	151	16,843	-	-	16,994	-	16,994
– Issue of ordinary shares	151	19,853	-	-	20,004	-	20,004
– Transaction expenses	-	-3,010	-	-	-3,010	-	-3,010
Conversion of debentures	118	-118	-	-	-	-	-
Share Savings Program	-	166	-	-	166	-	166
Total contributions from and distributions to shareholders	269	16,891	-	-	17,159	-	17,160
<b>Equity at September 30, 2017</b>	<b>1,335</b>	<b>179,814</b>	<b>-81</b>	<b>-75,511</b>	<b>105,557</b>	<b>-</b>	<b>105,558</b>

## Summary 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 year	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>113,901</b>
<b>Comprehensive income for the year</b>							
Profit/loss for the year	-	-	-	-44,935	-44,935	-	-44,935
Other comprehensive income for the year	-	-	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 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	-	-	-	-	-
Provision for incentive program	-	235	-	-	235	-	235
Total contributions from and distributions to shareholders	269	16,951	-	-	17,220	-	17,220
<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 Summary Income Statement

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Revenue	-	-	-	-	-
Cost of goods sold	-	-	-	-	-
<b>Gross profit/loss</b>	-	-	-	-	-
Other operating income	81,357	285	95,708	585	838
Administrative expenses	-7,547	-5,751	-13,456	-5,751	-9,841
Research and development expenses	-10,057	-1,917	-52,412	-14,587	-27,326
Other expenses	-2,869	-	-16,534	-	-1,169
<b>Operating profit/loss</b>	60,885	-7,383	13,307	-19,753	-37,498
<b>Profit/loss from financial items</b>					
Financial income	-	-	-	-	-
Financial expenses	-467	-273	-1,229	-275	-56
<b>Net financial items</b>	<b>-467</b>	<b>-273</b>	<b>-1,229</b>	<b>-275</b>	<b>-56</b>
<b>Profit/loss before tax</b>	<b>60,418</b>	<b>-7,657</b>	<b>12,078</b>	<b>-20,028</b>	<b>-37,553</b>
Income tax expense	-	-	-	-	-
<b>Profit/loss for the period</b>	<b>60,418</b>	<b>-7,657</b>	<b>12,078</b>	<b>-20,028</b>	<b>-37,553</b>

## Parent Company summary statement of profit/loss and other comprehensive income

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Profit/loss for the period	60,418	-7,657	12,078	-20,028	-37,553
Other comprehensive income	-	-	-	-	-
<b>Comprehensive income for the period</b>	<b>60,418</b>	<b>-7,657</b>	<b>12,078</b>	<b>-20,028</b>	<b>-37,553</b>

## Summary balance sheet, Parent Company

Amounts in SEK thousand	9/30/18	9/30/17	12/31/17
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment	5,437	4,613	6,725
<b>Financial non-current assets</b>			
Shares in Group companies	100,783	94,092	94,092
Non-current receivables	18,888	635	635
<b>Total financial non-current assets</b>	<b>119,671</b>	<b>94,727</b>	<b>94,727</b>
<b>Total non-current assets</b>	<b>125,108</b>	<b>99,339</b>	<b>101,451</b>
<b>Current assets</b>			
Current receivables			
Accounts receivable	63,035	-	-
Receivables from Group companies	-	955	4,178
Other receivables	1,679	946	278
Prepaid expenses and accrued income	25,400	742	814
Total current receivables	90,114	2,642	5,269
Cash and bank	63,052	23,016	6,483
<b>Total current assets</b>	<b>153,166</b>	<b>25,659</b>	<b>11,752</b>
<b>TOTAL ASSETS</b>	<b>278,274</b>	<b>124,998</b>	<b>113,204</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Restricted equity			
Share capital	1,419	1,335	1,335
Unrestricted equity			
Share premium	183,480	180,500	180,560
Retained earnings	-77,623	-40,070	-40,070
Profit/loss for the period	12,078	-20,028	-37,553
<b>Total equity</b>	<b>119,354</b>	<b>121,738</b>	<b>104,273</b>
<b>Non-current liabilities</b>			
Non-current non-interest-bearing liabilities	9,127	-	-
<b>Total non-current liabilities</b>	<b>9,127</b>	<b>-</b>	<b>-</b>
<b>Current liabilities</b>			
Current interest-bearing liabilities	45,000	-	-
Liabilities to Group companies	8,172	-	-
Accounts payable	44,848	1,252	3,359
Other liabilities	782	950	760
Accrued expenses and prepaid income	50,992	1,057	4,812
<b>Total current liabilities</b>	<b>149,794</b>	<b>3,259</b>	<b>8,931</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>278,274</b>	<b>124,997</b>	<b>113,204</b>

## Parent Company's cash flow statement

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
<b>Cash flows from operating activities</b>					
Profit/loss before tax	60,419	-5,637	12,078	-20,028	-37,553
Adjustments for non-cash items	-450	320	817	1,177	1,684
Paid income tax	-	-	-	-	-
	<b>59,969</b>	<b>-5,317</b>	<b>12,895</b>	<b>-18,851</b>	<b>-35,869</b>
Increase (-)/decrease (+) in operating receivables	-106,201	-1,810	-103,108	-88	-2,716
Increase (-)/decrease (+) in operating liabilities	83,161	282	95,693	-282	5,312
<b>Cash flow from current operations</b>	<b>36,929</b>	<b>-6,844</b>	<b>5,480</b>	<b>-19,221</b>	<b>-33,273</b>
<b>Investing activities</b>					
Investments in subsidiaries	-	-1,910	-6,691	-5,756	-5,757
Acquisition of property, plant and equipment	-60	-35	-75	546	-1,985
<b>Cash flow from investing activities</b>	<b>-60</b>	<b>-1,944</b>	<b>-6,766</b>	<b>-5,211</b>	<b>-7,742</b>
<b>Financing activities</b>					
New share issue	-	-68	2,549	16,936	20,004
Transaction expenses	-11	-	-12	-	-3,019
Warrants issue	-	-	701	-	-
Loans raised	8,172	-	53,172	-	-
<b>Cash flow from financing activities</b>	<b>8,161</b>	<b>-68</b>	<b>56,410</b>	<b>16,936</b>	<b>16,985</b>
Cash flow for the period	45,030	-8,856	55,124	-7,496	-24,030
Cash and cash equivalents at beginning of period	16,744	31,873	6,483	30,512	30,512
Exchange rate differences in cash and cash equivalents	1,278	-	1,445	-	-
<b>Cash and cash equivalents at end of period</b>	<b>63,052</b>	<b>23,016</b>	<b>63,052</b>	<b>23,016</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 Stockholm. 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 3.

### 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 the extent that the Parent Company applies 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 58 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 supersedes the current IAS 17 Leases and IFRIC 4 Determining Whether an Arrangement Contains a Lease and related rules. Application of the standard is mandatory from January 1, 2019. With the exception of contracts for a maximum 12-month period 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. Accordingly, agreements currently constituting opera-

tional leases will be reported in the balance sheet, with the result that the current operating expense, the leasing fee for the period, is replaced by amortization and interest expense in the income statement. As an operational lessee, it is mainly the Group's rental agreement that is affected, with the effect that the balance sheet total, operating profit and financial expenses increase. The effect on the consolidated accounts is not expected to be material, although the calculation of amounts and the choice of transition method have yet to be fully implemented.

## Note 2 Segment reporting

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

Amounts in SEK thousand	2018 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
<b>Income per segment</b>					
Biosimilars	77,325	-	77,325	-	-
Long-acting injectable drugs	2,441	-	28,964	11,236	22,447
Unallocated income	6,716	331	7,737	727	838
<b>Total income</b>	<b>86,482</b>	<b>331</b>	<b>114,027</b>	<b>11,963</b>	<b>23,285</b>
<b>Profit/loss by segment</b>					
Biosimilars	68,082	-1,917	25,727	-927	-27,326
Long-acting injectable drugs	-386	-4,703	20,268	10,454	-5,419
Administration and unallocated profit/loss	-6,846	-2,219	-25,254	-34,941	-11,973
<b>Operating profit/loss</b>	<b>60,850</b>	<b>-8,839</b>	<b>20,741</b>	<b>-25,415</b>	<b>-44,718</b>
<b>Net financial items</b>					
Biosimilars					
Long-acting injectable drugs	-10	-16	-36	-54	-69
Administration and unallocated profit/loss	-515	-236	-1,289	-309	-147
<b>Total</b>	<b>-526</b>	<b>-253</b>	<b>-1,325</b>	<b>-363</b>	<b>-217</b>
<b>Profit/loss before tax</b>	<b>60,325</b>	<b>-9,092</b>	<b>19,416</b>	<b>-25,778</b>	<b>-44,935</b>
<b>Depreciation</b>					
Biosimilars	449	349	1,340	946	1,362
Long-acting injectable drugs	796	120	2,124	708	2,555
Administration and unallocated profit/loss	-41	190	52	226	75
<b>Total</b>	<b>1,204</b>	<b>659</b>	<b>3,516</b>	<b>1,880</b>	<b>3,992</b>



**Note 3 Distribution of income**

Amounts in SEK thousand		Q3 2018		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	2,441	-	<b>2,441</b>
Asia	-	-	-	-
Europe	77,860	-	6,129	<b>83,988</b>
US	-	-	53	<b>53</b>
<b>Total</b>	<b>77,860</b>	<b>2,441</b>	<b>6,181</b>	<b>86,482</b>
<b>Income by category</b>				
Pharmaceutical products	-	2,441	-	<b>2,441</b>
Milestone payments/non-recurring compensation from partners	77,325	-	-	<b>77,325</b>
Services	535	-	6,181	<b>6,716</b>
<b>Total</b>	<b>77,860</b>	<b>2,441</b>	<b>6,181</b>	<b>86,482</b>
		Q3 2017		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	-	-	-
Asia	-	-	-	-
Europe	-	-	319	<b>319</b>
US	-	-	12	<b>12</b>
<b>Total</b>	<b>-</b>	<b>-</b>	<b>331</b>	<b>331</b>
<b>Income by category</b>				
Pharmaceutical products	-	-	-	-
Milestone payments/non-recurring compensation from partners	-	-	-	-
Services	-	-	331	<b>331</b>
<b>Total</b>	<b>-</b>	<b>-</b>	<b>331</b>	<b>331</b>

Amounts in SEK thousand		Q1-3 2018		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	15,589	-	<b>15,589</b>
Asia	-	13,375	-	<b>13,375</b>
Europe	77,860	-	6,793	<b>84,653</b>
US	-	-	409	<b>409</b>
<b>Total</b>	<b>77,860</b>	<b>28,964</b>	<b>7,202</b>	<b>114,027</b>
<b>Income by category</b>				
Pharmaceutical products	-	15,589	-	<b>15,589</b>
Milestone payments/non-recurring compensation from partners	77,325	13,375	-	<b>90,700</b>
Services	535	-	7,202	<b>7,737</b>
<b>Total</b>	<b>77,860</b>	<b>28,964</b>	<b>7,202</b>	<b>114,027</b>
		<b>Q1-3 2017</b>		
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/administration	Group
Middle East	-	11,236	-	<b>11,236</b>
Asia	-	-	-	<b>-</b>
Europe	-	-	685	<b>685</b>
US	-	-	42	<b>42</b>
<b>Total</b>	<b>-</b>	<b>11,236</b>	<b>727</b>	<b>11,963</b>
<b>Income by category</b>				
Pharmaceutical products	-	11,236	-	<b>11,236</b>
Milestone payments/non-recurring compensation from partners	-	-	-	<b>-</b>
Services	-	-	727	<b>727</b>
<b>Total</b>	<b>-</b>	<b>11,236</b>	<b>727</b>	<b>11,963</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 (European Medicines Agency) and FDA (US Food and Drug Administration) 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 (MENA) and the Asia Pacific region (APAC). 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 September 30, 2018, the joint venture had no assets, liabilities or income. In the third quarter, Xbrane's share of the development expenses amounted to SEK 14,321 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 September 30, 2018 to SEK 3,560 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 September 30, Primm Pharma s.r.l. has purchased administration and accounting services and rented premises from Primm s.r.l. at an expense of SEK 363 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 September 30, 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 1,125 thousand as per September 30. The debt is classified as current.

On the balance sheet date of September 30, 2018, the Parent Company Xbrane held a loan of SEK 8,172 thousand issued by the subsidiary Primm Pharma. Interest during 2018 amounted to SEK 82 thousand as per September 30.

In 2018, up until September 30, 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 4,038 thousand in external expenses, although these pertained to Primm Pharma. Primm Pharma has, in turn, onward invoiced Xbrane Biopharma SEK 188 thousand for external costs relating to Xbrane. These are eliminated in the consolidated accounts.

In 2018, up until September 30, Xbrane had purchased consulting services from Edman Life Science AB (org nr: 559034-7265) for a total SEK 40 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 September 30, 2018 was 1.3 percent (for the 2017 financial year, 0 percent). 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.

Stockholm, November 16, 2018

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Anders Tullgren  
*Chairman*

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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  
*Director*

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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

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

### Introduction

We have reviewed the condensed interim financial information (interim report) of Xbrane Biopharma AB (publ) as of 30 September 2018 and the nine-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 2 and 9 which describes the company's plans to find a co-financer for development of Spherotide or raise funds in the capital markets to ensure continued operations over the next 12 months. No co-financing agreement or share issue is in place at the date of signing this report. This indicates that there are uncertainties about the company's ability to continue as a going concern.

Stockholm 16 November 2018

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 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Gross profit/loss	512	-192	3,338	2,664	4,942
Divided by revenue	2,441	-	15,589	11,236	20,771
<b>Gross margin</b>	<b>21%</b>	<b>-</b>	<b>21%</b>	<b>24%</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 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Operating profit/loss	60,850	-8,839	20,741	-25,415	-44,718
Depreciation	-1,204	-659	-3,516	-1,880	-3,992
<b>EBITDA</b>	<b>62,054</b>	<b>-8,180</b>	<b>24,257</b>	<b>-23,535</b>	<b>-40,726</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 Q3	2017 Q3	2018 Q1-3	2017 Q1-3	2017 Full-year
Research and development expenses	-12,069	-6,620	-60,294	-20,450	-37,982
Divided by operating expenses less depreciation and impairment	-22,499	-8,318	-77,518	-26,925	-48,182
<b>Research and development expenses as a percentage of operating expenses</b>	<b>54%</b>	<b>80%</b>	<b>78%</b>	<b>76%</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	9/30/18	9/30/17	12/31/17
Total equity	114,532	105,558	88,405
Divided by total assets	275,129	117,576	110,960
<b>Equity ratio</b>	<b>42%</b>	<b>90%</b>	<b>80%</b>



**For further information**

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**Financial calendar**

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

