

# Interim report January – September 2019

#### Xbrane secures financing for the Xplore study up until top-line data is received from all patients

#### Financial summary third quarter 2019

- » Revenue amounted to SEK 0.0 M (2.4).
- » The gross margin amounted to 0% (21).
- » Other operating income amounted to SEK 1.4 M (84.0).
- » EBITDA amounted to SEK -30.0 M (62.1).
- » R&D expenses amounted to SEK -25.8 M (-12.1) representing 80% (54) of total operating expenses.
- » The loss for the period was SEK 32.4 M (60.1).
- » Earnings per share were SEK -2.24 (9.49).
- » Cash and cash equivalents at the end of the period amounted to SEK 162.2 M (64.3).

#### Financial summary for first nine months of 2019

- » Revenue amounted to SEK 0.0 M (15.6).
- » The gross margin amounted to 0% (21).
- » Other operating income amounted to SEK 4.4 M (98.4).
- » EBITDA amounted to SEK -103.4 M (24.3).
- » R&D expenses amounted to SEK -90.1 M (-60.3) representing 84% (78) of total operating expenses.
- » The loss for the period was SEK 110.1 M (19.2).
- » Earnings per share was SEK -11.27 (3.11).

#### Significant events during the third quarter 2019

- » A rights issue that began in the second quarter was completed and brought in SEK 91.1 M to the company before transaction costs.
- » The company completed a change of trading site for its shares from the Nasdaq First North Growth Market to the Nasdaq Stockholm main list where the shares started trading on September 23, 2019.

#### Significant events after the end of the quarter

» No significant events happened after the end of the quarter.



### Financial summary for the Group

Amounts in SEK thousand	2019 Q 3	2018 Q 3	2019 Q 1–3	2018 Q 1–3	2018 Full year
Revenue	-	2,441	-	15,589	20,485
Research and development expenses (R&D)	-25,750	-12,069	-90,115	-60,294	-85,827
R&D expenses as percentage of total costs	80%	54%	84%	78%	78%
Operating profit/loss	-32,127	60,851	-109,046	20,741	-11,415
EBITDA	-30,013	62,055	-103,388	24,257	-6,079
Profit/loss for the period	-32,398	60,096	-110,111	19,187	-13,236
Cash and cash equivalents	162,195	64,311	162,195	64,311	100,972
Equity ratio, %	59%	42%	59%	42%	33%
Number of shares at end of period before dilution	15,415,199	6,329,239	15,415,199	6,329,239	6,329,239
Number of shares at end of period after dilution	15,415,199	6,852,170	15,415,199	6,852,170	6,329,239
Average number of shares before dilution	14,468,999	6,329,239	9,766,913	6,175,067	6,213,927
Average number of shares after dilution	14,468,999	6,852,170	9,766,913	6,697,998	6,213,927
Earnings per share before dilution (SEK)	-2.24	9.49	-11.27	3.11	-2.13
Earnings per share after dilution (SEK)	-2.24	8.77	-11.27	2.86	-2.13

### **About Xbrane**

Xbrane Biopharma is a biotechnology company that develops and manufactures biosimilars. Xbrane has a patented protein production platform in *E.coli* and world leading expertise within development of biosimilars.

Xbrane's leading product candidate in the biosimilar segment is Xlucane. Xlucane is a ranibizumab biosimilar (originator drug Lucentis®) used in the treatment of various eye diseases, mainly in the wet form of age-related macular degeneration. Lucentis® has annual sales of approximately EUR 3.5 billion¹.².

#### Organization

The Xbrane Group consists of the parent company, Xbrane Biopharma AB, and the wholly-owned Italian subsidiary, Primm Pharma s.r.l. The parent company focuses on research and the development of biosimilars with Xlucane as a leading product candidate, while Primm Pharma is focused on long-term injectables with Spherotide as the leading product candidate.

Sources:

Novartis, Annual Report 2018

<sup>2)</sup> Roche, Annual Report 2018



Martin Åmark, CEO, at the listing ceremony at Nasdaq Stockholm.

## Comments from the CEO

Xbrane took a step up to the Nasdaq Stockholm main list in September, after strengthening its financial position earlier this year. The seal of approval that it means to be listed on Nasdaq is very important to us as it gives us access to an ever-wider group of investors while increasing awareness and knowledge of our company

# Aiming to become a world-leading biosimilar developer

The market for biosimilars in 2018 had a turnover of around SEK 58 billion and is expected to grow to SEK 230 billion a year by 20231. It is the fastest growing segment in the pharmaceutical industry. Xbrane's goal is to become a world-leading developer in this market. We will develop and market a wide portfolio of high-quality biosimilars at the lowest cost based on our unique patented production platform, which will benefit patients with a major need for cost-effective alternatives. We are well positioned in this market. We are working actively to build our IP portfolio around our production platform - all to ensure that we have the lowest production costs on the market. We have also strengthened our team and now have 34 employees, most of whom have extensive experience in drug development. We now believe that we have the in-house expertise in the areas required to take our biosimilars all the way to the market.

#### We are now stronger than ever

During the first nine months of the financial year, Xbrane raised new capital from existing and new investors. The list of owners includes institutional investors such as Swedbank Robur Medica, Nyenburgh Investment Partners in the Netherlands and Belsize in the UK, as well as our partner, the pharmaceutical company STADA. Furthermore, we have started an in-depth collaboration with STADA under which we now are evaluating several biosimilars.

# Preparing the application for market approval of Xlucane

The registration-based phase III study with Xlucane, Xplore, is underway with the aim of demonstrating equivalence compared to Lucentis®. Xbrane intends to report data on the primary endpoint, improving visual acuity after eight weeks, in mid-2020. In the blinded follow-up conducted for the study's patients for ethical reasons, no indications of discrepancies in the study compared to normal use of Lucentis® have been identified, and consequently no indications of different safety or efficacy profile for Xlucane compared to Lucentis®. For us, this is reassuring for the completion of the study.

During the quarter we participated in the leading conferences for ophthalmologists globally: EURETINA in Europe

Source:

<sup>1)</sup> MarketsandMarkets, Biosimilars Market by Disease - Global Forecast to 2023

and AAO in the US. We have spoken with ophthalmologists from all over the world, many of whom are now participating in our clinical study Xplore. It is important to build this network of future prescribers of Xlucane and to increase awareness of the product.

We are also preparing applications for market approval that we intend to submit to the European Medicines Agency (EMA) and to the US FDA during the second half of 2020. This includes preparing the commercial supply chain for Xlucane, as well as completion of the Chemistry, Manufacturing and Controls documentation (CMC). We have held scientific advisory meetings with both the EMA and the FDA to ensure that the Marketing Authorization Application shall meet the authorities' requirements. With the EMA, thanks to the authority's tailor-made program for biosimilars, we have the opportunity for more frequent and in-depth discussions than usual. We also held consultative meetings with the PMDA and NMPA during the year to clarify the local regulatory requirements in Japan and China, respectively.

#### Pre-clinical development of Xcimzane and Xdivane

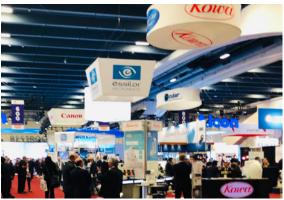
As Xlucane is leaving the pre-clinical phase, our R&D team has accelerated the exciting work with Xcimzane (biosimilar on Cimzia®) and Xdivane (biosimilar on Opdivo®). We are now establishing cost-effective pilot-scale production processes for these products. Our goal is for both products to be launched in conjunction with the respective original drugs losing their patent protection. Furthermore, the development of Xoncane (Oncaspar® biosimilar) and Spherotide continues.

#### Higher sales potential for biosimilars

Since I started at Xbrane in 2015, several new sales records for biosimilars have been set. For example, Eli Lilly's insulin biosimilar Abasalgar® 2019 became the first biosimilar to pass USD 1 billion in annual sales¹. For each launch of a new biosimilar, the impact becomes faster and stronger. Particularly for biosimilars that are sold to, and administered in a hospital environment. The penetration for biosimilars such as , Infliximab, Rituximab and Etanercept have reached as high as between 83-95% in comparisons between the five largest EU countries in just a few years². Our goal of reaching sales with Xlucane, which is sold to and administered in a hospital environment, of EUR 350 million annually three years after launch is fully realistic, given the positive development we see for biosimilars.

# Financing in place up until top line data from Xplore study is available

At the end of the third quarter, our cash and cash equivalents amounted to SEK 162 million, which will finance the Xplore study up until top line result is available, other development activities in order to apply for market approval for Xlucane as well as development of our pre-clinical biosimilars up until end of third quarter 2020. In 2018, revenue from commercial agreements amounted to approximately



Participants at the American Academy of Ophthalmology's annual congress in San Francisco.

SEK 100 million from Xlucane and Spherotide, both then in pre-clinical development. We expect to be able to generate additional revenue from commercial agreements up untill 2022. If no further commercial agreements take place up until the end of third quarter 2020 the company would need additional capital to fund the coming 12 months operations.

Furthermore, to finance the company up until 2022 when Xlucane is expected to generate sales, additional capital will be needed. This is expected to be generated from commercial agreements for our product candidates potentially in combination with additional financing from investors. Xbrane is working actively to meet investors that are interested to be a part of the long-term building of the company.

#### Capital market activities during autumn and winter

During the autumn, Xbrane participated in a number of capital market days in Vienna, Stockholm and Lund organized by LSX, Biostock and Vator Securities. In the coming months, we will be attending Jefferies' Global Healthcare conference in London on November 20, Vator Unicorn Summit in Stockholm on November 27, an event in Tel Aviv organized by Vator Securities in December and the JP Morgan Healthcare conference in San Francisco in January 2020.

Finally, I would like to extend a big thank you to our employees who have made it possible for us to take these important steps in our development. Thanks to our listing on Nasdaq's main list, we now have a channel to market in a completely different way than before. We feel very enthusiastic about our building of Xbrane to become a world-leading biosimilar developer with a unique technological platform and with the ambition of developing future cost-effective biosimilars that will benefit the patients of the world.

Martin Åmark, CEO

4

XBRANE BIOPHARMA

<sup>2)</sup> IQVIA

## Product portfolio

Product	Biosimilar to	Primary indication	Sales of original drug 2018 (SEK bn)	Patent expiry date for original drug	Development phase
Xlucane	Ranibizumab (Lucentis®)	Wet age-related macular degeneration, diabetic related macular edema, and retinal vein occlusion.	351,2	2022 (Europe) 2020 (US)	Phase III
Xcimzane	Certolizumab pegol (Cimzia®)	Rheumatoid arthritis, axial spondylarthro- sis, psoriatic arthritis, psoriasis and Crohn disease.	14 <sup>3</sup>	2024 (US) 2025* (Europe)	Pre-clinical phase
Xoncane	Pegaspargase (Oncaspar®)	Acute lymphocytic leukemia.	24	Expired	Pre-clinical phase
Spherotide	Triptorelin (Decapeptyl®)	Prostate cancer, breast cancer, endometriosis, and myoma	4 <sup>5</sup>	Expired	Pre-clinical phase
Xdivane	Nivolumab (Opdivo®)	Melanoma, lung cancer, renal cell carcinoma, hhead- and neck cancer, bladder and urinary tract cancer.	54 <sup>6</sup>	2026-2031 Predepending on country	Pre-clinical phase

Source:
1) Novartis Annual Report 2018.
2) Roche Annual Report 2018.
3) UCB Annual Report 2018.
4) EvaluatePharma
5) IQVIA
6) BMS Annual Report 2018

 $<sup>\</sup>ensuremath{^{\star}}$  Includes six months patent extension due to pediatric indication.

#### Xlucane

Xlucane is a biosimilar to ranibizumab (original drug Lucentis®), and it is used to treat wet age-related macular degeneration and other eye diseases such as diabetic retinopathy, diabetic macular edema and macular edema following retinal vein occlusion. The market for VEGF inhibitors for ophthalmic use had sales of SEK 94 billion in 2018, of which Lucentis® accounted for SEK 35 billion¹¹². The market has grown by about 10% per year over the past three years and is growing at the same rate on a quarterly basis during 2019³³⁴. Lucentis® main patent protection will expire in 2020 in the US and 2022 in Europe.

Xlucane is undergoing a pivotal phase III study, Xplore, to demonstrate equivalence compared to Lucentis<sup>®</sup>. The study started in April 2019 and data on the primary endpoint for all patients is expected to be presented in mid-2020. Preparatory regulatory work for the marketing authorization application is being done in parallel with work on designing the pre-filled syringe and establishing a logistics chain. The marketing authorization application is planned to be submitted second half of 2020.

Xbrane has a co-development agreement with STADA for the development, sale and marketing of Xlucane, which means that STADA and Xbrane are splitting the development costs and future profits for Xlucane equally.

### Xcimzane

Xcimzane is a biosimilar to certolizumab pegol (original drug Cimzia®), a TNF inhibitor used in the treatment of rheumatoid arthritis and Crohn's disease in particular. The market for TNF inhibitors had a turnover of approximately SEK 240 billion in 2018<sup>5</sup> and Cimzia® sold for SEK 14 billion in 2018<sup>6</sup>. Cimzia® patent protection is expected to expire in 2024 in the US and 2025 in Europe.

Xcimzane is now undergoing pre-clinical development with a focus on developing a cost-efficient production process and demonstrating analytical similarity to the original drug. When this step is completed, upscaling along with a production partner will follow, after which the product can be used for clinical trials.

#### Xdivane

Xdivane is a biosimilar to nivolumab (original drug Opdivo®), a PD1 inhibitor for the treatment of various cancers with a turnover of approximately SEK 72 billion over the last 12-month period<sup>7</sup>. Opdivo® patent protection is expected to expire during 2026-2031, depending on the country.

Xdivane is undergoing pre-clinical development with a focus on developing a cost-efficient production process and demonstrating analytical similarity to the original drug. When this step is completed, upscaling with a production partner will follow, after which the product can be used in clinical trials.

#### Xoncane

Xoncane is a biosimilar to pegaspargase (original drug Oncaspar®), used in treatment for Acute Lymphatic Leukemia. In 2018, Oncaspar® sold for about SEK 2 billion8. Xoncane is now undergoing pre-clinical development.

### Spherotide

Spherotide is a long-acting injectable drug with the active substance triptorelin, used primarily in the treatment of prostate cancer, breast cancer, endometriosis and myoma. In 2018, Triptorelin sold for about SEK 4 billion<sup>9</sup>, and although patents expired several years ago, there are still no generics on the long-term formulations.

As communicated in June, the focus of the continued development for Spherotide is to be able to initiate a pivotal phase III trial with endometriosis patients, which support the market authorization in Europe and China. This step can be taken after 1) signing of a binding agreement with STADA, 2) approval of the design for the clinical trial from the Chinese authorities and 3) completion of the ongoing upgrade of the quality system at Xbrane's contract manufacturer ICI.

STADA is now conducting a due diligence on Spherotide. Signing of a binding agreement will not, as earlier communicated, happen in 2019 but is rather expected during 2020. Xbrane has had an advisory meeting with the Chinese authorities. A follow-up meeting is being planned

#### Source:

- 1) Novartis Annual Report 2018.
- Roche Annual Report 2018.
- 3) Novartis Interim report January-June 2019.
- 4) Roche Interim report January-June 2019.
- 5) Research and markets Global Tumor Necrosis Factor (TNF) Inhibitors Market 2018-2026: A \$181.13 Billion Market Opportunity by 2026
- 6) UCB Annual Report 2018.
- 7) BMS Interim report January-September 2019
- 8) EvaluatePharma
- 9) IQVIA

during the current year where outstanding questions regarding the study will be resolved. ICI has completed the upgrade of their quality system, which was initiated based on few deviations identified by AIFA, the Italian regulatory authority, during an inspection of the production facility earlier this year. ICI is, for the moment, awaiting approval of the update from AIFA. Further, as communicated in the previous interim report of 2019, Xbrane has, as a precaution,

temporarily stopped all sales and deliveries to Iran, due to the geopolitical situation. Nothing has changed concerning that decision and no sales should be expected during fourth quarter 2019.



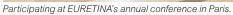
Top: Dina Jurman, Head of Clinical Affairs, presenting the Xplore study for ophthalmologist at investigator meeting in Madrid. Bottom left: Dina Jurman, Head of Clinical Affairs, visiting a clinic participating in the study in Hyderabad, India. Middle right: Martin Åmark, CEO, at the listing cermony at Nasdaq Stockholm. Bottom right: Siavash Bashiri, Head of Biosimilar, and Maria Edebrink, Head of CMC Regulatory affairs, at a meeting with PMDA (Pharmaceuticals and Medical Devices Agency) in Japan.

### Shareholders

As per September 30, 2019, Xbrane had a total of approximately 3,300 shareholders distributed over 15,415,199 shares. The ten largest shareholders by the end of this report's period are shown in the table below<sup>1</sup>.

Name	Number of shares	Ownership, %
Serendipity Group	2,255,974	14.63%
STADA Arzneimittel AG	1,256,792	8.15%
Avanza Pension	989,631	6.42%
Swedbank Robur Fonder	910,713	5.91%
Bengt Göran Westman	641,540	4.16%
Nordnet Pensionsförsäkring	528,849	3.43%
Paolo Sarmientos	395,919	2.57%
Swedbank Försäkring	253,709	1.65%
Iraj Arastoupour	248,011	1.61%
Nyenburgh Holding B.V.	223,880	1.45%
Ten largest shareholders in total	7,705,018	49.98%
Other Swedish shareholders	6,462,244	41.92%
Other foreign shareholders	1,247,937	8.10%
Total outstanding shares	15,415,199	100.00%







Martin Åmark, CEO, before the bell ringing at the Nasdaq Stockholm listing ceremony.

Source:
1) Modular Finance. Based on a complete list of shareholders including directly registered and nominee registered shareholders.

### Financial overview

#### The Group's results for July - September 2019

During the third quarter, no sales were made (SEK 2.4 M in the same period last year) and thus no cost of goods sold (SEK -1.9 M) was reported. The reduced sales is a direct consequence of the geopolitical situation in Iran. The Company has, as communicated earlier, decided to temporarily stop all sales and deliveries of Spherotide to Iran.

Other operating income amounted to SEK 1.4 M (84.0) and relates to license revenue from non-core operations and exchange rate gains on receivables and liabilities. During the comparison period, exceptional income of SEK 77.3 M occurred from the cooperation agreement for Xlucane with STADA.

Sales expenses amounted to SEK 0.1 M (0.1) and had a positive effect of SEK 0.4 M regarding a reversal of the provision for customer credit losses. Administrative expenses amounted to SEK -7.0 M (-8.8). During the comparison period, there were exceptional transaction costs of SEK -3.8 M relating to the STADA agreement. Adjusted for this, administrative expenses have increased compared with the previous year due to the administrative function expanding, as well as costs related to the listing on Nasdaq Stockholm's main list.

Research and development costs amounted to SEK -25.8 M (-12.1), of which SEK -22.0 M (-9.2) refers to biosimilars and primarily Xlucane, and SEK -3.8 M (-2.8) to the long-acting injectable drug Spherotide. The increase compared to the previous year is mainly due to costs related to the Xplore study that started this year and the parallel regulatory work. In addition, costs for the pre-clinical portfolio of biosimilars of SEK -2.8 M (-)\* have been added.

Other operating expenses amounted to SEK -0.9 M (-3.0) and primarily consist of exchange rate losses on receivables and liabilities.

The operating loss amounted to SEK 32.1 M (60.9). Net financial items amounted to SEK -0.3 M (-0.5) and primarily relate to financial expenses of SEK -0.2 M (-0.5) relating to the now fully repaid credit facility, leasing agreements and marginal interest income SEK 0 M (-). The loss before tax was SEK 32.4 M (60.3). During the quarter there was no taxable profit and thus no tax expense (-0.2 M).

The loss after tax for the quarter was SEK 32.4 M (60.1).

#### The Group's cash flow for July - September 2019

The cash flow from operating activities amounted to SEK -83.9 M (35.1). Changes in operating receivables and liabilities amounted to SEK -45.4 M (-106.6) and SEK -7.9 M (81.4), respectively. Changes in working capital can vary greatly between quarters, primarily as a result of further invoicing to STADA regarding the development work for Xlucane as well as costs for the clinical study.

The cash flow from investment activities amounted to SEK -0.2 M (-0.7) and consists of investments in property, plant and equipment. Cash flow from financing activities amounted to SEK 75.1 M (9.9) and refers to the second rights issue which brought in SEK 91.1 M before additional transaction costs of SEK -15.2 M, of which guarantee commitments accounted for SEK -8.4 M, as well as amortization of a leasing liability of SEK -0.8 M (-0.1).

#### The Group's results for January - September 2019

During the first nine months, no sales were made (SEK 15.6 M in the same period last year), and thus no cost of goods sold (SEK -12.3 M) were reported. The lack of sales is a direct consequence of the geopolitical situation in Iran. As previously communicated, the company has decided to tem-porarily suspend the sale and delivery of Spherotide to Iran.

Other operating income amounted to SEK 4.4 M (98.4) and refers to license revenue from non-core operations and exchange rate gains on receivables and liabilities. During the comparative pe-riod, exceptional income was reported from the licensing of Spherotide of SEK 13.4 M and SEK 77.3 M for the signed cooperation agreement for Xlucane with STADA.

Sales costs amounted to SEK -0.3 M (-0.7), the decrease of which is directly attributable to the lack of sales. Administrative costs amounted to SEK -18.1 M (-16.5). The comparative period con-tains exceptional transaction costs related to the conclusion of the STADA agreement of SEK -3.8 M. Adjusted for this, the increase compared to the previous year is even greater and is explained by a larger administrative function, as well as costs related to the listing on Nasdaq Stockholm's main list. Research and development costs amounted to SEK -90.1 M (-60.3), of which SEK-80.3 M (-51.6) concerns biosimilars and primarily Xlucane and SEK -9.8 M (-8.7) the long-term impact injectable drug Spherotide. The increase in costs is mainly attributable to the ongoing Xplore study that started this year and the parallel regulatory work. In addition, costs have been added related to the pre-clinical portfolio of biosimilars of SEK -4.2 M (-)\*.

Other operating expenses amounted to SEK -4.9 M (-3.5) and primarily consist of exchange rate losses on receivables and liabilities.

The operating loss was SEK 109.0 M (20.7).

Net financial items amounted to SEK -1.0 M (-1.3) and relate to financial income of SEK 0.1 M (-) from interest income and financial expenses of SEK -1.1 M (-1.3), which primarily consist of interest expenses related to the now fully repaid credit facility and leasing agreements.

<sup>\*</sup> Other biosimilars in addition to Xlucane were added as a sub-segment of biosimilars in 2019. Previously, costs have been marginal and separate accounts have not been considered relevant.

The loss before tax was SEK 110.1 M (19.4). During the period, no taxable income and no tax expenses (SEK -0.2 M) were incurred. The loss after tax was SEK 110.1 M (19.2).

#### The Group's cash flow for January - September 2019

The cash flow from operating activities amounted to SEK -154.8 M (8.9). Changes in operating receivables and operating liabilities were SEK -75.1 M (-106.3) and SEK 28.7 M (93.6), respectively. Changes in working capital can vary greatly between periods, primarily as a result of further invoicing to STADA regarding the development work for Xlucane as well as costs for the clinical study.

The cash flow from investment activities amounted to SEK -1.0 M (-1.4) and consisted of investments in property, plant and equipment.

The cash flow from financing activities amounted to SEK 217.0 M (47.8) and refers to the two rights issues and the directed issue totaling SEK 252.5 M with additional transaction costs of SEK -33.4 M, of which guarantee commitments accounted for SEK -12.5 M. In addition, amortization of loans and leasing debt accounted for SEK -0.1 M (-0.1) and SEK -2.0 M (-0.3) respectively.

#### The Group's financial position and going concern

During the first nine months, three issues were completed, which in total brought the company SEK 219.0 M after transaction costs and loan conversions. On the balance sheet date, cash and cash equivalents amounted to SEK 162.2 M (64.3). Existing cash is expected to fund Xbrane's participation in the ongoing Xplore phase III study up until top line result from all patients is available, other ongoing development activities for Xlucane, and parts of the continued development of the company's pre-clinical biosimilars, until the end of Q3 2020. If no commercial deals were to take place until the third quarter of 2020, the company would need additional funding to cover the next 12 months of financing the business.

#### Inventory

Inventory amounted to SEK 10.1 M (2.7) and the increase is explained by the temporary cessation in sales of Spherotide.

#### Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 88.4 M (25.5), of which SEK 52.2 M (-) refers to the purchase of reference drugs for the ongoing Phase III study that will be used on an ongoing basis, SEK 27.4 M refers to the advance payment to the CRO (Contract Research Organization) which performs the clinical trial and the remaining SEK 8.8 M refers to other prepaid costs and accrued income.

#### Changes in equity

The share capital amounted to SEK 3.5 M (1.4) on the balance sheet date. Other capital contributions amounted to SEK 446.9 M (182.8) and was affected by SEK 295.4 M in issue liquidity, SEK -33.4 M in transaction costs and SEK 0.9 M in reserved share-related compensation for employees during the first nine months. Total equity amounted to SEK 241.7 M (114.5).

The equity ratio was 59% (42).

#### Long-term interest-bearing liabilities

On the balance sheet date, there were no long-term interest-bearing liabilities (SEK 0.2 M), but a smaller short-term interest-bearing loan of SEK 0.1 M (45.6). The former Serendipity Group credit facility was fully settled by converting it into shares during the year.

#### Leasing liabilities

Long- and short-term interest-bearing leasing liabilities amounted to SEK 7.1 M (-) and SEK 3.2 M (-), respectively. Comparative figures are missing as new accounting principles for leasing were introduced on January 1, 2019.

#### Accounts payable

Accounts payable amounted to SEK 18.9 M (47.3). The decrease compared to the previous year is mainly explained by advance payments to the CRO, which were initially larger when work for the Xplore study began.

#### Accrued expenses and prepaid income

Accrued expenses and prepaid income amounted to SEK 125.4 M (53.2) and primarily relate to advance payments from STADA for Xlucane of SEK 95.8 M (39.1).

Out of the remaining SEK 29.6 M (14.1), most of the related expenses relate to Xlucane.

# The co-development agreement with STADA's impact on results and the balance sheet

Since the co-development agreement with STADA for Xlucane was concluded in July 2018, Xbrane's net costs for research and development of Xlucane have been reported in the results i.e. 50% of the total cost of the project. With regard to the balance sheet, assets and liabilities attributable to the development of Xlucane are reported in their entirety, i.e. 100%, and STADA's share of these, i.e. 50%, is reported in addition as the receivable or liability arising between Xbrane and STADA. This applies to both the Group and the parent company. On the balance sheet date, Xbrane had an account receivable with STADA of SEK 37.9 M. Furthermore, Xbrane had a long-term non-interest-bearing debt to STADA amounting to SEK 4.3 M, as well as accrued expenses and prepaid income from STADA amounting to SEK 95.8 M

#### Parent company

The core business at Xbrane, which is the development of biosimilars, is run by the parent company. As the parent company constitutes the major part of the Group, further presentation in text format of the parent company's results, financial position, going concern and cash flow is deemed unnecessary. Therefore, the parent company is only presented in reporting format on pages 19-21.

#### Risks and uncertainties

Risks and uncertainties are described in the annual report of 2018 on pages 32-34, which is available on the company's website. The annual report 2018 describes the risks involving sanctions against Iran that could lead to aggravated opportunities to sell goods and receive payments from Iran. Due to the difficult geopolitical situation, Xbrane has decided to temporarily stop all sales and deliveries of Spherotide to Iran.

The annual report 2018 also described the risk that the company will not be able to finance the remaining SEK 100-150 M required up until top line result of the clinical study. Since then, Xbrane has, by raising capital, strengthened its financial position and, at the time of publication of this report, has capital up until top line data from the clinical study is available and to finance its operations until the end of the third quarter 2020.

Apart from the comments above, no new factors or changed assumptions have arisen during the first nine months that could have a significant impact on the previously made risk and uncertainty assessment.

#### **Share information**

Xbrane's share capital at the end of the period amounted to SEK 3.5 M (1.4) divided among 15,415,199 shares (6,329,239). The quota value of all shares is SEK 0.224, and all the shares have equal rights to the company's assets and earnings. Since September 23, 2019, Xbrane's shares have been listed on the Nasdaq OMX main list and Xbrane had approximately 3,300 shareholders as per the balance sheet date. The closing price of the shares on the balance sheet date was SEK 33.3 generating a market capitalization of SEK 513.3 M.

#### Raising capital

During the first nine months, three issues were completed. Vator Securities acted as financial advisor and Baker McKenzie acted as legal advisor to the company in all issues and also in the list change to Nasdaq Stockholm's main list.

#### Rights issue I

At the beginning of the second quarter, a rights issue was completed, after a mandate from the annual general meeting in May 2018. The issue brought in SEK 59.5 M before issue costs. The subscription price was SEK 30 per share, which represented a discount of 23% compared to

the theoretical price following the separation of subscription rights, based on the closing price of Xbrane's shares on March 28, 2019 at Nasdaq First North Growth Market. Transaction costs amounted to SEK -9.5 M and included costs for guarantee commitments of SEK -4.1 M and the remaining SEK -5.4 M related to costs for financial and legal advisers, marketing and administration. The Serendipity Group set off its subscription corresponding to SEK 8.0 M against the issued credit facility to Xbrane. Through the private placement, Xbrane's share capital increased by SEK 0.4 M to SEK 1.9 M and the number of shares increased by 1,977,887 shares to 8,307,126 shares.

#### Directed share issue

At the end of the second quarter, a directed share issue was concluded, with mandate from the Extra General Meeting in June 2019. The directed share issue amounted to SEK 147 M before transaction costs.

The subscription price was SEK 33,5 per share which corresponds to a discount of 10 percent compared to the closing price for the Xbrane share at the 29th of May 2019 at Nasdaq First North. The transaction costs amounted to SEK -7,7 M and includes costs for guarantors, financial and legal advisors, marketing as well as administration.

The Serendipity Group set off its subscription of SEK 37.0 M against the remaining part of the credit facility issued to Xbrane, which after the directed issue was thus fully settled. Through the private placement, Xbrane's share capital increased by SEK 1.0 M to SEK 2.8 M, the total number of shares increased by 4,387,745 to 12,694,871.

#### Rights issue II

At the beginning of the third quarter, a rights issue was completed, supported by a mandate from the extraordinary general meeting in June 2019. The rights issue brought in SEK 91.1 M before issue costs. The subscription price was SEK 33.5 per share, which corresponds to a 10% discount based on the volume-weighted closing price of Xbrane's shares on May 29, 2019 at Nasdaq First North Growth Market. Transaction costs amounted to SEK -16.2 M and includes costs for guarantee commitments of SEK -8.4 M and the remaining SEK -7.8 M related to costs for financial and legal advisers, marketing and administration. Through the rights issue, Xbrane's share capital increased by SEK 0.6 M to SEK 3.5 M, the total number of shares increased by 2,720,328 to 15,415,199.

#### Organization and employees

Xbrane is headquartered in Solna, outside of Stockholm, Sweden, where the company also has a laboratory for research and development of biosimilars. Xbrane has one wholly-owned subsidiary, Primm Pharma, located in Milan, Italy. At the end of the period the company had 34 (25) employees.

### Annual general meeting

The AGM was held on May 16, 2019. The AGM for 2020 will be held on May 14, 2020.

### **Nomination Committee**

In accordance with the principles for nomination committee adopted at the Annual General Meeting on May 16, 2019, a nomination committee has been established. The Nomination Committee consists of Xbrane's Chairman of the

Board and three representatives nominated by the following shareholders; Serendipity Group AB, STADA Arzneimittel AG and Swedbank Robur Fonder.

#### Auditor's review

This interim report has been subject to a review by the company's auditor.



Dina Jurman, Head of Clinical Affairs, represented Xbrane at EURETINA's annual conference in Paris.

## Consolidated income statement

Amounts in SEK thousand Notes	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Revenues 2	-	2,441	-	15,589	20,485
Cost of goods sold	-	-1,929	-	-12,251	-15,907
Gross profit	-	512	-	3,338	4,578
Other income 2	1,373	84,041	4,369	98,437	99,742
Selling and distribution expenses	111	135	-271	-737	-933
Administrative expenses	-6,998	-8,807	-18,115	-16,489	-23,347
Research and development expenses	-25,750	-12,069	-90,115	-60,294	-85,827
Other expenses	-864	-2,961	-4,914	-3,514	-5,629
Operating profit/loss 2	-32,127	60,851	-109,046	20,741	-11,415
Financial income	0	-	52	-	44
Financial costs	-272	-526	-1,116	-1,325	-1,744
Net financial costs 2	-271	-526	-1,064	-1,325	-1,700
Profit/loss before tax	-32,398	60,325	-110,111	19,416	-13,115
Income tax expense	-	-229	-	-229	-121
Profit/loss for the period	-32,398	60,096	-110,111	19,187	-13,236
Profit/loss attributable to:					
- Owners of the Company	-32,398	60,096	-110,111	19,187	-13,236
- Non-controlling interests	-	-	-	-	-
Total comprehensive income for the period	-32,398	60,096	-110,111	19,187	-13,236
Earnings per share					
- Basic earnings per share (SEK)	-2.24	9.49	-11.27	3.11	-2.13
- Diluted earnings per share (SEK)	-2.24	8.77	-11.27	2.86	-2.13
Number of outstanding shares at the end of the reporting period					
- Before dilution	15,415,199	6,329,239	15,415,199	6,329,239	6,329,239
- After dilution	15,415,199	6,852,170	15,415,199	6,852,170	6,329,239
Average number of outstanding shares					
- Before dilution	14,468,999	6,329,239	9,766,913	6,175,067	6,213,927
- After dilution	14,468,999	6,852,170	9,766,913	6,697,998	6,213,927

# Consolidated income statement and other comprehensive income

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Total comprehensive income for the period	-32,399	60,096	-110,111	19,187	-13,236
Other comprehensive income					
Items that have been transferred and can be transferred to profit/loss for the period					
Reclassification of foreign currency translation differences	1,382	-1,148	3,815	3,936	3,686
Comprehensive income for the period	1,382	-1,148	3,815	3,936	3,686
Total comprehensive profit/loss attributable to:					
- Owners of the Company	-31,017	58,948	-106,296	23,123	-9,551
- Non-controlling interests	-	-	-	-	-
Total comprehensive income for the period	-31,017	58,948	-106,296	23,123	-9,551

# Consolidated statement of financial position

Amounts in SEK thousand	2019-09-30	2018-09-30	2018-12-31
ASSETS			
Goodwill	62,479	59,950	59,838
Intangible assets	5,403	5,983	5,773
Property, plant and equipment	25,163	17,553	16,744
Trade and other receivables	9,218	18,888	8,871
Non-current assets	102,263	102,373	91,226
Inventories	10,102	2,651	5,525
Current tax assets	5,204	11,703	10,427
Trade and other receivables	38,180	68,595	10,489
Other receivables	89	-	5
Prepaid expenses and accrued income	88,376	25,497	34,240
Cash and cash equivalents	162,195	64,311	100,972
Current assets	304,147	172,756	161,659
TOTAL ASSETS	406,410	275,129	252,885
EQUITY			
Share capital	3,456	1,419	1,419
Non-registered equity			-
Share premium	446,915	182,794	184,007
Reserves	9,363	5,798	5,548
Retained earnings	-218,014	-75,480	-107,903
Equity attributable to owners of the Company	241,719	114,532	83,070
Non-controlling interests	-	-	-
Total equity	241,719	114,532	83,070
LIABILITIES			
Non-current interest-bearing liabilities	-	155	41
Leasing	7,149	-	29
Non-current non-interest-bearing liabilities	4,291	9,127	4,118
Provisions	4,667	4,135	4,275
Non-current liabilities	16,107	13,417	8,433
Current interest-bearing liabilities	49	45,593	45,561
Trade and other payables	18,818	47,255	30,908
Current tax liabilities	-	234	123
Other current liabilities	1,085	898	820
Leasing	3,235	-	422
Deferred income/revenue	125,396	53,202	83,970
Current liabilities	148,584	147,181	161,382
TOTAL LIABILITIES	164,691	160,598	169,816
TOTAL EQUITY AND LIABILITIES	406,410	275,129	252,885

### Consolidated cash flow statement

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Cash flow from operating activities					
Profit/loss before tax	-32,398	60,325	-110,111	19,416	-13,115
Adjustments for items not included in cash flow	1,786	-1,443	5,965	1,678	4,953
Paid income taxes	-	-	-	-	-
Total	-30,613	58,882	-104,146	21,094	-8,162
Increase (-)/Decrease (+) of inventories	-21	1,458	-4,242	541	-2,280
Increase (-)/Decrease (+) of trade and other receivables	-45,378	-106,641	-75,144	-106,281	-46,360
Increase (-)/Decrease (+) of trade and other payables	-7,865	81,439	28,687	93,566	103,509
Cash flow from current operations	-83,877	35,138	-154,845	8,920	46,707
Cash flow from investing activities					
Acquisition of property, plant and equipment	-209	-731	-1,017	-1,414	-1,598
Cash flow from investing activities	-209	-731	-1,017	-1,414	-1,598
Cash flow from financing activities					
New share issue	91,131	0	252,457	2,549	2,549
Transaction expense	-15,199	-11	-33,430	-12	-12
Warrants issue	-	-	-	701	701
Loan and borrowings	0	10,000	-	45,000	45,000
Amortization of loan	-36	-79	-106	-98	-131
Amortization of lease liability	-846	-60	-2,037	-315	-377
Cash flow from financing activities	75,050	9,850	216,884	47,825	47,730
Cash flow for the period	-9,036	44,257	61,022	55,331	92,839
Cash and cash equivalents at beginning of period	171,410	19,255	100,972	7,903	7,903
Exchange rate differences in cash and cash equivalents	-178	798	202	1,075	230
Cash and cash equivalents at end of period	162,195	64,311	162,195	64,311	100,972

# Consolidated statement of changes in equity

Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total	Total equity
Balance at January 1, 2019	1,419	184,007	5,548	-107,903	83,070	83,070
Total comprehensive income for the period						
Profit/loss for the period	-	-	-	-110,111	-110,111	-110,111
Other comprehensive income for the period	-	-	3,815		3,815	3,815
Total comprehensive income for the period	-	-	3,815	-110,111	-106,296	-106,296
Transactions with group shareholder						
New share issue	2,037	261,990	-	-	264,027	264,027
- New share issue	2,037	295,420			297,457	297,457
- Transaction expenses	-	-33,430	-	-	-33,430	-33,430
Share savings program	-	918	-	-	918	918
Total contributions from and distributions to shareholders	2,037	262,908	-	-	264,945	264,945
Balance at September 30, 2019	3,456	446,915	9,363	-218,014	241,719	241,719

Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total	Total equity
Balance at January 1, 2018 Total comprehensive income for the period	1,335	179,874	1,862	-94,667	88,405	88,405
Profit for the period						
Other comprehensive in-come for the period	-	-	-	19,187	19,187	19,187
Total comprehensive income for the period	-	-	3,936	-	3,936	3,936
Total comprehensive income for the period	-	-	3,936	19,187	23,123	23,123
Transactions with group shareholder						
New share issue	9	2,528	-	-	2,537	2,537
- New share issue	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	-	2,920	-	-	3,003	3,003
Balance at September 30.2018	1.419	182,794	5,798	-75,480	114,532	114,532

# Consolidated statement of changes in equity, cont.

Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total	Total equity
Balance at January 1, 2018	1,335	179,874	1,862	-94,667	88,405	88,405
Total comprehensive in-come for the period						
Profit/loss for the period	-	-	-	-13,236	-13,236	-13,236
Other comprehensive income for the period	-	-	3,686	-	3,686	3,686
Total comprehensive income for the period	-	-	3,686	-13,236	-9,551	-9,551
Transactions with group shareholder						
New share issue	9	2,528	-	-	2,537	2,537
- New share issue	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
Total contributions from and distributions						
to shareholders	83	4,132	-	-	4,216	4,216
Balance at December 31, 2018	1,419	184,007	5,548	-107,903	83,070	83,070

# Income statement, Parent company

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Revenues	-	-	-	-	-
Cost of sales	-	-	-	-	-
Gross profit	-	-	-	-	-
Other income	1,039	81,357	3,238	95,708	97,149
Selling and distribution expenses	-	-	-	-	-
Administrative expenses	-5,945	-7,547	-14,632	-13,456	-19,074
Research and development expenses	-22,299	-10,057	-80,653	-52,412	-75,257
Other expenses	-860	-2,869	-4,886	-16,534	-18,192
Operating profit/loss	-28,064	60,885	-96,932	13,307	-15,375
Financial items					
Financial income	-	-	-	-	-
Financial expenses	-110	-467	-880	-1 229	-1 690
Net finance costs	-110	-467	-880	-1 229	-1 690
Profit/loss before tax	-28,174	60,418	-97,812	12,078	-17,065
Income tax expense	-	-	-	-	-
Total comprehensive income for the period	-28,174	60,418	-97,812	12,078	-17,065

# Parent company statement of comprehensive income

	2019	2018	2019	2018	2018
Amounts in SEK thousand	Q3	Q3	Q 1–3	Q 1–3	Full year
Profit/loss for the period	-28,174	60,418	-97,812	12,078	-17,065
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	-28,174	60,418	-97,812	12,078	-17,065

# Balance Sheet, Parent company

Amounts in SEK thousand	2019-09-30	2018-09-30	2018-12-31
ASSETS			
Non-current assets Property, plant and equipment			
Financial non-current assets	3,995	5,437	5,014
Shares in group companies	100,783	100,783	100,783
Other non-current receivables	9,218	18,888	8,871
Total financial non-current assets	110,001	119,671	109,654
Total non-current assets	113,996	125,108	114,667
Current assets			
Current receivables			
Trade and other receivables	38,180	63,035	196
Receivables from group company	83	-	-
Other receivables	2,203	1,679	1,018
Prepaid expenses and accrued income	88,344	25,400	33,596
Total current receivables	128,810	90,114	34,810
Cash and bank	159,386	63,052	100,380
Current assets	288,196	153,166	135,190
TOTAL ASSETS	402,192	278,274	249,857
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	3,456	1,419	1,419
Unrestricted equity			
Share premium	447,601	183,480	184,693
Retained earnings	-94,688	-77,623	-77,623
Profit/loss for the period	-97,812	12,078	-17,065
Total equity	258,557	119,354	91,424
Non-current liabilities			
Non-current non-interest-bearing liabilities	4,291	9,127	4,118
Non-current liabilities	4,291	9,127	4,118
Current liabilities			
Current interest-bearing liabilities	-	45,000	45,000
Liabilities to subsidiaries	-	8,172	3,042
Trade and other payables	17,212	44,848	23,709
Other current liabilities	958	782	630
Deferred income/revenue	121,174	50,992	81,934
Current liabilities	139,344	149,794	154,316
TOTAL LIABILITIES	143,635	158,921	158,434
TOTAL EQUITY AND LIABILITIES	402,192	278,274	249,857

# Cash flow statement, Parent company

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Cash flows from operating activities					
Earnings before income and tax	-28,174	60,419	-97,812	12,078	-17,065
Adjustments for items not included in cash flow	849	-450	2,950	817	6,927
Paid income taxes	-	-	-	-	-
Total	-27,325	59,969	-94,862	12,895	-10,138
Increase (-)/Decrease (+) of trade and other receivables	-48,424	-106,201	-94,348	-103,108	-38,319
Increase (-)/Decrease (+) of trade and other payables	-8,133	83,161	32,486	95,693	99,962
Cash flow from current operations	-83,882	36,929	-156,724	5,480	51,505
Cash flow from investing activities					
Investments in subsidiaries	-	-	-	-6,691	-6,691
Acquisition of property, plant and equipment	-16	-60	-386	-75	-110
Cash flow from investing activities	-16	-60	-386	-6,766	-6,801
Cash flow from financing activities					
New share issue	91,131	-	252,457	2,549	2,549
Transaction expense	-15,199	-11	-33,430	-12	-12
Warrants issue	-	-	-	701	701
Loan and borrowings	-	8,172	-	53,172	55,000
Amortization of loan	-	-	-3,042		-6,958
Cash flow from financing activities	75,932	8,161	215,985	56,410	51,280
Cash flow for the period	-7,965	45,030	58,875	55,124	95,984
Cash and cash equivalents at beginning of period	167,429	16,744	100,380	6,483	6,483
Exchange rate differences in cash and cash equivalents	-78	1,278	131	1,445	-2,087
Cash and cash equivalents at end of period	159,386	63,052	159,386	63,052	100,380

#### Notes

#### Note 1 Accounting principles

This interim financial reporting has been prepared in accordance with IAS 34, Interim Financial Reporting, as well as applicable regulations from the annual accounts act.

The interim report for the Parent company has been prepared according to the Annual accounts act, chapter 9, Interim Report. For the Group and the Parent company the same accounting principles and calculation bases as the previous annual report have been used, with the exception from the changed accounting principles described below. Information according to IAS 34.16A is presented, except for within the financial reports and the associated notes, in other parts or the interim report as well.

The Group adopted IFRS 16 Leasing contracts from the first of January 2019. The Parent company are not applying IFRS 16 according to the exception rules within the RFR 2. Description of IFRS 16 and the effects from the transition to the standard are presented in brief below.

#### IFRS 16 Leasing agreements

IFRS 16 Leasing agreements replaced the previous IAS 17 Leasing agreements and IFRIC 4 determining whether an arrangement contains a Lease and related agreements. The new standard requires that all contracts which fulfill the definition of a leasing agreement, except contracts of less than 12 months duration and those with low values, as an asset and liability in the financial statements. The accounting according to IFRS 16 are based upon the approach that the lessee has the right to use the assets under a specific time period and simultaneously has an obligation to pay for the rights.

The assets and liabilities are accounted for as a discounted present value of the future leasing payments. The cost regarding the leased assets consists of amortization of the assets and interest cost towards the leasing liability. Contracts that earlier have been classified as operating leases will thereby be accounted for in the balance sheet with the effect that the current operating costs, leasing cost for the period, will be replaced with amortization of the right-to-use asset and interest expense in the income statement.

#### Transitional method

The implementation of IFRS 16 at Xbrane has been made by using the simplified transitional method, which means that the prior periods have not been restated.

As an operational lessee, the effect relates primarily to office premises and car rental contracts with the effect that total assets, operating profit/loss and financial costs increases as well as the related cash flows move from the operational activities to financing activities. The opening effect on the Group's balance sheet as of 1 January 2019 is estimated to SEK 4,495 thousand, consisting of a leasing asset as well as a leasing liability, within the balance sheet. The equity has not been affected.

At the closing date for the third quarter of 2019 the total leasing asset amounted to SEK 11, 965 thousand as well as a leasing liability. Which also includes a lease previously reported as a finance lease at the subsidiary.

The effect on the Group's income statement during the third quarter of 2019 amounted to SEK 148 thousand and SEK -102 thousand for interest cost and depreciation respectively. The effect on the first nine months of 2019 amounted to SEK 344 thousand and SEK -203 thousand for interest cost and depreciation respectively. The average marginal interest rate of 6% has been used as a discounting rate when calculating the transitional effects. For the Group's alternative KPI, there were no significant effects after the implementation of IFRS 16.

Effect from IFRS 16 SEK thousand	2019 Q 3 (IFRS 16)	Effect from IFRS 16	2019 Q 3 (IAS 17)
Operating profit/loss	-32,127	102	-32,229
Net finance costs	-271	-148	-123
Profit/loss before tax	-32,398	-46	-32,352
Effect from IFRS 16 SEK thousand	2019 Q 1-3 (IFRS 16)	Effect from IFRS 16	2019 Q 1-3 (IAS 17)
Operating profit/loss	-109,046	203	-109,249
Net finance costs	-1,064	-344	-720
Profit/loss before tax	-110,111	-141	-109,970

Note 2 Segment reporting

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

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Revenues per segment					
Biosimilars	-	77,325	-	77,325	77,860
Long-acting injectable drugs	467	2,441	1,324	28,964	33,561
Unallocated revenue	906	6,716	3,044	7,737	8,806
Total	1,373	86,482	4,369	114,026	120,227
Operating profit or loss per segment					
Biosimilars	-21,930	68,082	-80,283	25,727	3,497
Long-acting injectable drugs	-3,820	-386	-8,507	20,268	-27,462
Administration and unallocated profit/loss	-6,377	-6,846	-20,256	-25,254	12,550
Operating profit/loss	-32,127	60,851	-109,046	20,741	-11,415
Net finance costs					
Biosimilars	-221	-	-221	-	-
Long-acting injectable drugs	110	-10	33	-36	-
Administration and unallocated profit/loss	-160	-515	-876	-1,289	-1,700
Total	-271	-526	-1,064	-1,325	-1,700
Profit/loss before	-32,398	60,325	-110,111	19,416	-13,115
tax Depreciation					
Biosimilars	1,044	449	2,523	1,340	1,788
Long-acting injectable drugs	953	796	2,792	2,124	3,481
Administration and unallocated profit/loss	118	-41	343	52	66
Total	2,115	1,204	5,658	3,516	5,336

Note 3 Distribution of Income

Amounts in SEK thousand	Q 3 2019					
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	Group		
Middle East	-	-	-	-		
Asia	-	-	-	-		
Europe	-	467	882	1,349		
US	-	-	24	24		
Total	-	467	906	1,373		
Income per category						
Pharmaceuticals	-	-	-	-		
Milestone payments from partners	-	-	-	-		
Services and other	-	467	9061	1,373		
Total	-	467	906	1,373		

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 402 thousand in exchange rate gains.

Amounts in SEK thousand	Q 3 2018
	Long-acting

Total	77,860	2,441	6,182	86,483
Services and other	535	-	6,182¹	6,717
Milestone payments from partners	77,325	-	-	77,325
Pharmaceuticals		2,441	-	2,441
Income per category				
Total	77,860	2,441	6,182	86,482
US	-	-	53	53
Europe	77,860	-	6,129	83,988
Asia	-	-	-	-
Middle East	-	2,441	-	2,441
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	Group

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 2,986 thousand in exchange rate gains.

Note 3 Distribution of Income, cont.

Amounts in SEK thousand	Q 1–3 2019				
Income per region	Biosimilars	Long-acting i njectable drugs	Unallocated/ admi- nistration	Group	
Middle East	-	-	-	-	
Asia	-	-	-	-	
Europe	-	1,324	2,974	4,299	
US	-	-	70	70	
Total			3,044	4,369	
Income per category					
Pharmaceuticals	-	-	-	-	
Milestone payments/one-off payments from partners	-	-	-	-	
Services and other	-	1,324	3,0441	4,369	
Total	-	1,324	3,044	4,369	

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 826 thousand in exchange rate gains.

### Q 1-3 2018

Total	77,860	28,964	7,202	114,026
Services and other	535	-	7,2021	7,737
Milestone payments/one-off payments from partners	77,325	13,375	-	90,700
Pharmaceuticals	-	15,589	-	15,589
Income per category	-	-	-	-
Total	77,860	28,964	7,202	114,026
US			409	409
Europe	77,860	-	6,793	84,653
Asia	-	13,375	-	13,375
Middle East	-	15,589	-	15,589
Income per region	Biosimilars	njectable drugs	Unallocated/ admi- nistration	Group
			11 11 1 1 1	

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 3,193 thousand in exchange rate gains.

### Note 3 Distribution of Income, cont.

Services and other

Total

Amounts in SEK thousand		Full year 20	018	
Income per region	Biosimilars	Long-acting i njectable drugs	Unallocated/ administration	Group
Middle East	-	20,485	-	20,485
Asia	-	13,076	-	13,076
Europe	77,860	2,463	5,918	86,241
US	-	-	425	425
Total	77,860	36,024	8,806	120,227
Income per category				
Pharmaceuticals	-	20,485	-	20,485
Milestone payments from partners	77,325	13,076	-	90,401

535

77,860

2,463

36,024

6,3441

6,344

9,341

120,227

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 3,460 thousand in exchange rate gains.

#### Note 4 Transactions with related parties

During the third quarter, preferential share rights issue II, which started during Q2, was concluded (see page 11). Several closely-related parties participated and subscribed for shares at market conditions. The following transactions with closely related persons and parties took place:

- Serendipity Group participated and subscribed for 201,465 shares.
- The following persons from the Board of Directors and Group Management participated in the issue and subscribed shares: Anders Tullgren (24,789 shares), Maris Hartmanis (2,139 shares), Peter Edman (2,247 shares), Karin Wingstrand (3,612 shares), Martin Åmark (23,502 shares), Siavash Bashiri (1,845 shares), Susanna Helgesen (2,136 shares) and David Vikström (2,026 shares).

The shares were registered and distributed to the abovementioned persons and company after the end of the second quarter. The loan from Serendipity Group was also converted into shares during the third quarter.

Since 2019, STADA Arnzeimittel AG has been a shareholder in Xbrane (see the list of owners on page 8). Transactions with STADA relate to shared costs for the collaboration agreement with Xlucane. Xbrane invoiced STADA for SEK 25,790 thousand during the third quarter, and for a total of SEK 83,741 thousand during Q1-Q3. At the end of the period, Xbrane had a trade receivable with STADA amounting to SEK 37,940 thousand.

In addition, Xbrane had a non-current non-interest-bearing liability to STADA amounting to SEK 4,291 thousand as well as deferred income/revenue from STADA amounting to SEK 95,804 thousand.

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#### Note 5 Financial instruments

The reported value of accounts receivable, other receivables, cash and cash equivalents, accounts payable and other liabilities represent a reasonable approximation of fair value.

### Certification

The Board of Directors and the CEO hereby certify that this interim report provides a true and fair view of the Parent Company and the Group's operations, position and results and describes significant risks and uncertainties faced by the Company and the companies that are part of the Group.

Stockholm, 15 November 2019

Anders Tullgren	Ivan Cohen-Tanugi
Chairman of the Board	Board member
Peter Edman Board member	Eva Nilsagård Board member
Karin Wingstrand Board member	Maris Hartmanis Board member
Giorgio Chirivì	Martin Åmark
Board member	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 2019 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 4 and 10 which describes that the company expects to generate revenues from commercial agreements with third parties to ensure continued operations over the next 12 months. The company's work with commercial agreements has not been finalized 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 15 November 2019

KPMG AB

Duane Swanson Authorized Public Accountant

### Alternative performance measures

The Company presents certain financial measures in the interim report that are not defined in accordance with IFRS. The Company believes that 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 measurements in the same way, these are not always comparable to measurements used by other companies. These financial measures should therefore not be seen as replacement for measures that are defined in accordance with IFRS. The tables below show measurements that are not defined in accordance with IFRS.

#### Gross margin

Gross margin is calculated as gross result divided by revenues. Gross result is calculated as revenues minus cost of goods sold.

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Gross profit	-	512	-	3,338	4,578
Divided by revenues	-	2,441	-	15,589	20,485
Gross margin	-	21%	-	21%	22%

#### **EBITDA**

Shows the business's earning ability from current operations without regard to capital structure and tax situation and is intended to facilitate comparisons with other companies in the same industry.

	2019	2018	2019	2018	2018
Amounts in SEK thousand	Q 3	Q3	Q 1–3	Q 1–3	Full year
Operating profit or loss	-32,127	60,851	-109,046	20,741	-11,415
Depreciation and amortization	-2,114	-1,204	-5,658	-3,516	-5,336
EBITDA	-30,013	62,055	-103,388	24,257	-6,079

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

The company's direct costs for research and development relate to personnel, materials and external services costs. Research and development expenses as a percentage of operating expenses show the proportion of operating expenses relating to research and development. This is calculated by dividing research and development expenses by total operating expenses excluding depreciation and amortization. Total operating expenses comprise of selling and distribution expenses, administrative expenses, research and development expenses and other operating expenses.

Amounts in SEK thousand	<b>2019</b> Q 3	<b>2018</b> Q 3	<b>2019</b> Q 1–3	<b>2018</b> Q 1–3	<b>2018</b> Full year
Research and development expenses	-25,750	-12,069	-90,115	-60,294	-85,827
Divided by total operating expenses minus depreciation and amortization	-32,240	-22,442	-107,757	-77,518	-110,400
Research and development expens-es as a percentage of operating expenses	80%	54%	84%	78%	78%

#### Equity ratio

Equity ratio is the proportion of assets funded by equity to show the company's long-term ability to pay, i.e. equity through total assets.

Amounts in SEK thousand	2019-09-30	2018-09-30	2018-12-31
Total equity	241,719	114,532	83,070
Divided by total assets	406,410	275,129	252,885
Equity ratio	59%	42%	33%



#### For further information

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Susanna Helgesen, CFO susanna.helgesen@xbrane.com

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### Financial calendar

Year-end report 2019 February 28, 2020
Annual report 2019 April 16, 2020
Interim report January-March 2020 May 6, 2020
Annual General Meeting 2020 May 14, 2020
Interim report January-June 2020 August 21, 2020
Interim report January-September 2020 November 13, 2020

