

Year-end report 2019

Xbrane took major steps forward in 2019, in the development of Xlucane towards launch in 2022 in connection with the patent expiration of the original drug Lucentis<sup>®</sup>.

### Financial summary fourth quarter 2019

- » Revenue amounted to SEK 0.0 M (4.9).
- » Write-downs of inventories and production equipment for Spherotide amounted to SEK -16.8 M (-).
- » The gross margin amounted to 0 percent (25).
- » Other operating income amounted to SEK 2.0 M (1.3).
- » EBITDA amounted to SEK -37.1 M (-30.3).
- » R&D expenses amounted to SEK -25.6 M (-25.5) representing 67 percent (78) of total operating expenses.
- » The loss for the period was SEK 55.9 M (32.4).
- » Earnings per share were SEK -5.00 (-5.12).
- » Cash and cash equivalents at the end of the period amounted to SEK 164.2 M (101.0).

#### Financial summary full year 2019

- » Revenue amounted to SEK 0.0 M (20.5).
- » Write-downs of inventories and production equipment for Spherotide amounted to SEK -16.8 M (-).
- » The gross margin amounted to 0 percent (22).
- » Other operating income amounted to SEK 6.4 M (99.7).
- » EBITDA amounted to SEK -140.5 M (-6.1).
- » R&D expenses amounted to SEK -115.7 M (-85.8) representing 78 percent (78) of total operating expenses.
- » The loss for the period was SEK 166.0 M (13.2).
- » Earnings per share was SEK -14.84 (-2.13).

#### Significant events during fourth quarter 2019

» No significant events to report.

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

- » In February, the milestone of 50 percent of patients in the Xplore study recruited, was acheived.
- » To better equip the company for upcoming filing and commercialization of our biosimilars, the management team has been strengthened with Maria Edebrink, Head of Regulatory Affairs and Anders Wallström, Head of Manufacturing and Supply Chain. Both has worked in Xbrane since beginning of 2019. In addition, Xiaoli Hu has been recruited to Head of Business Development and will join the management team as of 1 May 2020. Due to Xbrane's strategic focus on biosimilars, Paolo Sarmientos, Head of long-term injectables, will no longer be a part of the management team.
- » Finchimica S.p.A., parent company of contract manufacturer ICI S.p.A., which Primm Pharma uses for the manufacture of Spherotide, was declared bankrupt in early 2020. Primm Pharma is now taking appropriate action to safeguard its interests in the future production of Spherotide. Related to this, write-downs regarding stock and production equipment for Spherotide amounting to SEK -16.8 M (-) have been made.
- » Board member Maris Hartmanis has informed that he declines re-election for 2020.



# Financial summary for the Group

Amounts in SEK thousand	2019 Q 4	2018 Q 4	2019 Full Year	2018 Full Year
Revenue	-	4,896	-	20,485
Research and development expenses (R&D)	-25,598	-25,533	-115,713	-85,827
R&D expenses as percentage of total costs	67%	78%	78%	78%
Operating profit/loss	-55,573	-32,156	-164,620	-11,415
EBITDA	-37,098	-30,336	-140,487	-6,079
Profit/loss for the period	-55,926	-32,423	-166,037	-13,236
Cash and cash equivalents	164,197	100,972	164,197	100,972
Equity ratio, %	54%	33%	54%	33%
Number of shares at end of period before dilution	15,415,199	6,329,239	15,415,199	6,329,239
Number of shares at end of period after dilution	15,415,199	6,329,239	15,415,199	6,329,239
Average number of shares before dilution	11,190,591	6,329,239	11,190,591	6,213,927
Average number of shares after dilution	11,190,591	6,329,239	11,190,591	6,213,927
Earnings per share before dilution (SEK)	-5.00	-5.12	-14.84	-2.13
Earnings per share after dilution (SEK)	-5.00	-5.12	-14.84	-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 SEK 37 billion<sup>1,2</sup>.

Sources:
1) Novartis, Year-end report 2019
2) Roche, Year-end report 2019



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

# **CEO** letter

2019 was a very positive year for Xbrane and the biosimilar market. The strong market growth demonstrates how the reception may be for our leading biosimilar candidate Xlucane at expected launched in 2022:

- » Biosimilars in Europe are taking increasing market share. For example, biosimilars of Infliximab, Rituximab and Etanercept have taken between 83-95 percent of the market of the original drugs in volume terms in the five largest EU countries¹.
- We are starting to see positive signs from the US. For example, biosimilars of Pegfilgrastim have achieved 25 percent market share in volume terms just over a year after a launch<sup>2</sup>.
- » The EMA and the FDA approved five and ten new biosimilars, respectively, and adopted new guidelines to facilitate biosimilar developments, such as those applying to interchangeability in the US<sup>3,4</sup>.

# $\label{positive market growth for VEGFa-inhibitors} \textbf{Positive market growth for VEGFa-inhibitors}$

The direct market that Xlucane addresses - the market for VEGFa- inhibitors for ophthalmic use - continues to grow strongly with ten percent growth in 2019 and sales of SEK 109 billion<sup>5,6,7</sup>. This supports our previously communicated sales targets to be able to generate annual total sales

of Xlucane of at least EUR 350 M, which is expected to result in EUR 100 M annually in revenue from Xlucane after costs and profit sharing three years after launch.

#### Xlucane phase III trial Xplore progresses well

Xplore is progressing well with no safety concerns raised. In February, more than 50 percent of the patients had already been recruited into the trial and the 130 currently active clinics are now recruiting approx. 60-80 patients on a monthly basis. Xbrane will, as per agreement with EMA and FDA, submit Marketing Authorization application ("MAA")/ Biologics License Application ("BLA") for Xlucane on the basis of six months treatment data from Xplore. Regulatory submission is expected to take place well in time to allow for approval of Xlucane and subsequent launch in Europe and US in connection with Lucentis® patent expiration in EU July 2022.

### Strengthening our technological platform

We are continuing to develop our IP-portfolio around our technological platform. Only during last months, we have submitted three patent applications covering new innovative aspects of our technological platform further strengthening the competitive advantage in terms of low-cost production of recombinant proteins. With our newly

Sources:

1) IQVIA

2) IQVIA

3) European Medical Agency (EMA)

4) Food and Drug Administration (FDA)

5) Novartis Year-end report 2019

6) Roche Year-end report 2019

7) Regeneron Year-end report 2019

established IP-department we expect to file more patent applications during 2020 with the ambition to build a strong IP-portfolio around our platform technology.

#### Advancing our pre-clinical portfolio

Furthermore, we advanced our portfolio of pre-clinical biosimilars in 2019, especially our biosimilar candidates to Cimzia® (Xcimzane) and Opdivo®(Xdivane.) We are very excited about both these programs. Xcimzane is the only known biosimilar targeting Cimzia® - a niche TNF-inhibitor used for treatment of rheumatoid arthritis, psoriasis and Crohn disease with annual sales of SEK 18 bn in 2019 and annual growth of 18 percent. Xdivane is one of the frontrunner biosimilars targeting Opdivo®, a leading revolutionary immunoncology product with annual sales of SEK 68 bn and annual growth of seven percent.

#### Capital market acitvities

Through the capital raises during 2019 we increased the shareholder list with institutional investors such as Swedbank Robur Medica and our partner STADA. Since September 2019, the company's shares have been traded on Nasdaq Stockholm. We are working actively to meet investors globally who are interested in joining and building the company with us. In recent months we have met with a

large number of investors at the JP Morgan conference in San Francisco, the Jefferies conference in London and the Vator Securities events in Tel Aviv, Vienna and Zürich.

#### An exciting 2020

We are looking forward enthusiastically to 2020, when several important activities for Xlucane are expected to take place. We will prepare MAA and BLA filings and together with STADA, and we will intend to sign up additional partners for the sale and marketing of Xlucane, and thereby generate additional license income.

Finally, I would like to extend a huge thank you to my co-workers who have made it possible for us to take these important steps in our development. We all feel enthusiasm for Xbrane's journey to become a leading global biosimilar developer with a unique patented production platform, and with the ambition of developing future cost-effective biosimilars that will benefit the world's patients.

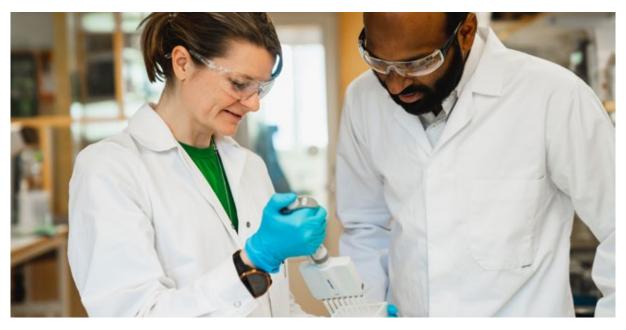
Martin Åmark, CEO



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

# Product portfolio

Product	Originator	Primary indication	Sales of original drug 2019 (SEK billion)*	Patent expiry date for original drug	Development phase
Xlucane	Ranibizumab (Lucentis®)	Wet age-related mac- ular degeneration, di- abetic related macular edema, and retinal vein occlusion.	37 <sup>1,2</sup>	2022 (Europe) 2020 (US)	Phase III
Xcimzane	Certolizumab pegol (Cimzia®)	Rheumatoid arthritis, axial spondylarthro- sis, psoriatic arthritis, psoriasis and Crohn disease.	18 <sup>3</sup>	2024 (US) 2025** (Europe)	Pre-clinical phase
Xoncane	Pegaspargase (Oncaspar®)	Acute lymphocytic leukemia.	24	Expired	Pre-clinical phase
Xdivane	Nivolumab (Opdivo®)	Melanoma, lung cancer, renal cell carcinoma, head- and neck cancer, bladder and urinary tract cancer.	685	2026-2031 Depending on country	Pre-clinical phase
Spherotide	Triptorelin (Decapeptyl®)	Prostate cancer, breast cancer, endometriosis, and myoma	46	Expired	Pre-clinical phase



- Sources:
  1) Novartis Year-end report 2019
  2) Roche Year-end report 2019
  3) UCB Year-end report 2019
  4) EvaluatePharma 2018
  5) BMS Year-end report 2019
  6) IQVIA 2018

<sup>\*</sup> If sales figures for the full year 2019 are not available, sales figures for 2018 have been used. \*\* Includes six months patent extension due to pediatric indication.

### Xlucane

Xlucane is a biosimilar to ranibizumab (original drug Lucentis®), a so-called VEGFa-inhibitor, and it is used to treat a number of serious eye diseases: wet age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), as well as retinal vein occlusion (RVO. The market for VEGFa-inhibitors for ophthalmic use had sales of SEK 109 billion<sup>1,2,3</sup> in 2019, of which Lucentis® accounted for SEK 37 billion1,2. The market has grown by about 11 percent per year over the past three years<sup>1,2,3</sup>. Lucentis® main patent protection will expire in 2020 in the US and 2022 in Europe.

A pivotal phase III study, Xplore, is being conducted to demonstrate equivalence compared to Lucentis®. The study is progressing well with no safety concerns raised. More than 50 percent of the patients have already been recruited into the trial and the 130 currently active clinics are now recruiting approx. 60-80 patients on a monthly basis. Xbrane will, as per agreement with EMA and FDA, submit Marketing Authorization application ("MAA")/Biologics License Application ("BLA") for Xlucane on the basis of six months treatment data from Xplore. Regulatory submission is expected to take place well in time to allow for approval of Xlucane and subsequent launch in Europe and US in connection with Lucentis® patent expiration in EU July 2022.

Xbrane has a co-development agreement with STADA for the development, sale and marketing of Xlucane, which means that STADA and Xbrane are sharing 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>4</sup> and Cimzia<sup>®</sup> sold for SEK 18 billion<sup>5</sup> in 2019<sup>6</sup>. Cimzia<sup>®</sup> 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 biochemical similarity to the original drug. When this step is completed, upscaling along with a production partner will follow, after which the product can be taken into 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 68 billion in 20196. 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 biochemical similarity to the original drug. When this step is completed, upscaling with a production partner will follow, after which the product can be taken into 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 billion7. Xoncane is now undergoing pre-clinical development.

# Spherotide

Spherotide is a long-acting formulation with the active substance triptorelin, which is mainly used for the treatment of prostate cancer, breast cancer, endometriosis and myoma. Triptorelin had annual sales of SEK 4 billion<sup>8</sup> in 2018, and despite the fact that the patents expired several years ago, there are still no generics within long-acting formulations.

Preparations for being able to initiate a pivotal phase III trial with endometriosis patients, which support the market authorization in Europe and China, is ongoing.

In January 2020, Finchimica S.p.A., parent company of contract manufacturer International Chemical Industry S.p.A. (ICI), who is the contract manufacturer of Spherotide, was declared bankrupt by the Milan court. Primm Pharma is closely following the process and is taking appropriate measures to protect its interests in future production of Spherotide. However, this may delay the continued development of Spherotide.

#### Sources:

- Novartis Year-end report 2019
- Roche Year-end report 2019
- Regeneron Year-end report 2019
- Research and markets Global Tumor Necrosis Factor (TNF) Inhibitors Market 2018-2026: A \$181.13 Billion Market Opportunity by 2026
- UCB Year-end report 2019
- BMS Year-end report 2019
- Evaluate Pharma
- IQVIA

# Shareholders

As per December 31, 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 AB	2,255,974	14.63%
STADA Arzneimittel AG	1,256,792	8.15%
Swedbank Robur Medica	1,009,693	6.55%
Avanza Pension Försäkringsaktiebolaget	988,478	6.41%
Bengt Göran Westman	763,070	4.95%
Nordnet Pensionsförsäkring AB	510,900	3.31%
Paolo Sarmientos	296,939	1.93%
Swedbank Försäkring AB	257,783	1.67%
Iraj Arastoupour	242,411	1.57%
Neyenburgh Holding B.V.	132,836	0.86%
Ten largest shareholders in total	7,714,876	50.05%
Other Swedish shareholders	6,672,485	43.29%
Other foreign shareholders	1,027,838	6.67%
Total outstanding shares	15 415 199	100,00%

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 October - December 2019

During the fourth quarter, no sales were made (SEK 4.9 M in the same period last year). The lack of sales is a direct consequence of the geopolitical situation in Iran. As previously communicated, the company has decided to temporarily suspend the sale and delivery of Spherotide to Iran. Cost of goods sold amounted to SEK -18.3 M (-3.7) and refers mainly to the write-downs regarding stock and production equipment for Spherotide. The write-down is a result of the bankruptcy of the parent company of the contract manufacturer, in whose facilities the equipment is located.

Other operating income amounted to SEK 2.0 M (1.3) and relates to exchange rate gains on receivables and liabilities and license revenue from non-core operations.

Sales expenses amounted to SEK -0.2 M (-0.2) and relate to personnel costs in the subsidiary. Administrative expenses amounted to SEK -8.3 M (-6.9) and this increase is explained by a growing organization as well as costs related to the listing on Nasdaq Stockholm.

Research and development costs amounted to SEK -25.6 M (-25.5), of which SEK -23.6 M (-22.8) refers to biosimilars - primarily Xlucane and SEK -2.0 M (-2.7) to long-acting injectable drug Spherotide. The research and development costs were in line with same period previous year and mainly consist of costs for the Xplore study, the parallel regulatory work and establishment of manufacturing and supply chain. Costs for the pre-clinical portfolio of biosimilars amounts to SEK -3.3 M (-0.3)\*.

Other operating expenses amounted to SEK -5.2 M (-2.1) and primarily relate to exchange rate losses on receivables and liabilities of an operating nature as well as realized and unrealized losses on currency hedges.

The operating loss was SEK 55.6 M (32.2). Net financial items amounted to SEK -0.4 M (-0.4) and primarily relate to financial expenses of SEK -0.4 M (-0.4) regarding leasing agreements and marginal interest income of SEK 0.0 M (0.0). The loss before tax was SEK 55.9 M (32.5). During the quarter there was no taxable profit and thus no tax expense (SEK 0.0 M in the same period last year).

The loss after tax for the quarter totaled SEK 55.9 M (32.4).

# The Group's cash flow for October - December 2019

The cash flow from operating activities amounted to SEK 6.3 M (37.8). Changes in inventories amounted to SEK 0.0 M (-2.8) as the write-down of the entire stock of Spherotide does not affect the cash flow. Changes in

operating receivables and operating liabilities, respectively, amounted to SEK 46.9 M (59.9) and SEK -7.7 M (9.9). Changes in working capital can vary greatly between quarters, primarily as a result of advance payments from STADA in relation to the development work for Xlucane and costs for the clinical study.

The cash flow from investment activities amounted to SEK -0.2 M (-0.2) and consists of investments in property, plant and equipment.

The cash flow from financing operations amounted to SEK -0.8 M (-0.1) and contains repayment of loans of SEK -0.0 M (-0.0) and amortization of a leasing liability of SEK -0.8 M (-0.1).

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

No sales were made during the year (SEK 20.5 M in the same period last year). The lack of sales is a direct consequence of the geopolitical situation in Iran. As previously communicated, the company has decided to temporarily suspend the sale and delivery of Spherotide to Iran. Cost of goods sold amounted to SEK -18.3 M (-15.9) and refers mainly to the write-downs regarding stock and production equipment for Spherotide. The write-down is a result of the bankruptcy of the parent company of the contract manufacturer, in whose facilities the equipment is located.

Other operating income amounted to SEK 6.4 M (99.7) and relates to exchange rate gains on receivables and liabilities as well as license income from non-core operations. During the comparison period, income affecting comparability 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 -0.5 M (-0.9), the fall of which is directly attributable to the lack of sales. Administrative costs amounted to SEK -26.4 M (-23.3) and the increase is explained by a growing organization, as well as costs related to the listing on Nasdaq Stockholm.

Research and development costs amounted to SEK -115.7 M (-85.8), of which SEK -103.9 M (-75.3) concerns biosimilars and primarily Xlucane and SEK -11.8 M (-10.6) to the long-term injectable drug Spherotide. The increase in costs is mainly attributable to the ongoing Xplore study, the parallel regulatory work and establishment of manufacturing and supply chain. In addition, costs related to the pre-clinical portfolio of biosimilars of SEK -7.4 M (-0.4)\* have been added.

<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.

Other operating expenses amounted to SEK -10.1 M (-5.6) primarily from exchange rate losses on receivables and liabilities as well as realized and unrealized losses on currency hedges.

The operating loss was SEK 164.6 M (11.4).

Net financial items amounted to SEK -1.4 M (-1.7) and relate to financial income of SEK 0.1 M (0.0) from interest income and financial expenses of SEK -1.5 M (-1.7), which primarily consist of interest expenses regarding the now fully repaid credit facility of SEK -0.7 M (-1.5), interest expenses for leasing agreements of SEK -0.4 M (0.0) and other interest expenses of SEK -0.3 M (-0.2).

The loss before tax was SEK 166.0 M (13.1). During the period, no taxable income and no tax expenses arose (SEK -0.1 M in the same period last year).

The loss after tax was SEK 166.0 M (13.2).

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

The cash flow from operating activities amounted to SEK -148.6 M (46.7). Changes in inventories were SEK 0.0 M (-2.8) as the write-down of the entire stock of Spherotide does not affect the cash flow. Changes in operating receivables and operating liabilities were SEK -28.3 M (-46.4) and SEK 21.0 M (103.5), respectively. Changes in working capital can vary greatly between periods, primarily as a result of advance payments from STADA in relation to the development work for Xlucane and costs for the clinical study.

The cash flow from investment activities amounted to SEK -1.2 M (-1.6) and consisted of investments in property, plant and equipment.

The cash flow from financing activities amounted to SEK 216.0 M (47.7) and covers 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 liabilities accounted for SEK -0.1 M (-0.1) and SEK -2.8 M (-0.4) respectively.

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

During the year, 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 164.2 M (101.0).

In addition to the revenues that potential partnerships are expected to generate in the near future, Xbrane is expected

to need additional capital to finance the next 12 months of operations. In addition, capital to finance the business up until 2022 will be required, when the company is expected to generate revenue from Xlucane. The Company is assessing various financing options with their financial advisors and holding discussions with investors.

#### Tangible fixed assets

Tangible fixed assets on the balance sheet date amounted to SEK 7.0 M (16.7). New acquisitions during the year amounted to SEK 1.2 million (1.6), depreciation to SEK -3.9 million (-4.2), write-downs to SEK -5.1 million (-) and translation differences to SEK 0.1 M (0.4). Write-downs refers to a production facility for the subsidiary Primm Pharma. Since the production plant is located in the contract manufacturer's ICI premises and is run by its staff, write-downs have been made as a result of the bankruptcy proceedings of ICI's parent company.

#### Inventory

Inventories, which consisted of Spherotide, have been written down in their entirety during the year and amount to SEK 0.0 M (5.5) as sales to Iran have ceased as a result of the complicated geopolitical situation.

#### Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 77.8 M (34.2), of which SEK 51.5 M (-) covers the purchase and packaging costs of reference drugs that will be used on an ongoing basis for the ongoing Phase III study, SEK 14.5 M (21,8) refers to the prepayment to the CRO (Contract Research Organization) which is conducting the clinical study and the remaining SEK 11.8 M (12.4) refers to other prepaid expenses and accrued income.

#### Changes in equity

Share capital amounted to SEK 3.5 M (1.4) on the balance sheet date. Other capital contributions amounted to SEK 448.1 M (184.0) and during the year were impacted by SEK 295.4 M in issue liquidity, SEK -33.4 M in transaction costs and SEK 2.1 M (0.7) in reserved share-related payments to employees. Total equity amounted to SEK 184.3 M (83.1).

The equity ratio was 54 percent (33).

#### Long-term and short-term interest-bearing liabilities

On the balance sheet date, there were no long-term interest-bearing liabilities (SEK 0.0 M in the comparative period) but a smaller short-term interest-bearing liability of SEK 0.0 M (45.1). The former credit facility from the Serendipity Group, which constituted short-term interest-bearing loans, was fully settled by converting loans of SEK 45.0 M to shares from issues during the year.

#### Leasing liabilities

Long- and short-term interest-bearing leasing liabilities amounted to SEK 6.3 M (0.0) and SEK 3.1 M (0.4), respectively. Comparative figures are missing as new accounting principles for leasing were introduced on January 1, 2019.

#### Accounts payable

Accounts payable amounted to SEK 21.1 M (30.9). The decrease from the previous year is mainly explained by fluctuations in payment flows for the clinical study and the development work for Xlucane.

#### Accrued expenses and prepaid income

Accrued expenses and prepaid income amounted to SEK 112.5 M (84.0) and primarily relate to advance payments of SEK 85.2 M (58.1) from STADA for Xlucane. Out of the remaining SEK 27.3 M (25.9), most of the related expenses relate to Xlucane's product development.

# The co-development agreement with STADA's impact on the results and 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 percent 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 percent and then STADA's share of these, i.e. 50 percent, is reported 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 a long-term non-interest-bearing debt to STADA of SEK 4.2 M (4.1) relating to STADA's share of the long-term advance payment to CRO. In addition, accrued expenses and prepaid income from STADA amounted to SEK 85.2 M (58.1), of which SEK 22.0 M (-) covers the purchase of the reference drug Lucentis®, SEK 7.3 M (-) covers the short-term portion of the prepayment to CRO and the remaining SEK 55.9 M (58.1) covers other prepaid expenses and accrued income for the clinical trial and development program.

#### Parent company

The core business of Xbrane, which is the development of biosimilars, is run by the parent company. As the parent company constitutes the major part of the Group, a statement in text format of the parent company's earnings, financial position and cash flow creates no further information than described in the report. Hence, this is only presented in reporting format on pages 18-20.

#### Risks and uncertainties

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

The annual report 2018 also described the risk that the company will not be able to finance the remaining SEK 100-125 M required up until top line result of the clinical study Xplore and communication of it. Furthermore, since the risk description in the 2018 Annual Report was published, Xbrane has strengthened its financial position through capital raising. When publishing this report, there is a continued need for capital for the next 12 months.

The annual report 2018, also described the risk of unfore-seen production stoppages that disrupt the value chain: the production plant in Italy where Spherotide is produced was highlighted. The production plant is owned by International Chemical Industry S.p.A. (ICI,), whose parent company Finchimica S.p.A. was declared bankrupt by a Milan court in early 2020. Primm Pharma is closely following the process and is taking appropriate measures to secure its interests in the future production of Spherotide. Write-downs of SEK 7.1 M have been made on tangible assets relating to production placed in ICI's production facilities as a result of the bankruptcy.

In addition to the above comment, the following risk has occured:

The risk of not tying in a European partner for Spherotide and financing further development

Xbrane and its subsidiary Primm Pharma, have been actively working for a couple of years to tie in an European commercialization partner for Spherotide. Such a partner would be responsible for marketing and distributing the finished product and share, or fully finance, continued development costs for Spherotide. Xbrane has not ruled out other forms of operational/financial cooperation, or even if divesting the entire subsidiary could be relevant. Xbrane has had rewarding conversations with potential partners. If no agreement could be reached, Xbrane needs to decide whether the further development and initiation of the Phase III clinical trial will be funded by Xbrane in its entirety, or whether project development should be put on hold. As Xbrane does not currently have this capital available for Spherotide, there is a financing risk.

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

#### **Share information**

Xbrane's share capital amounted to SEK 3.5 M (1.4) at the end of the period, divided among 15,415,199 shares (6,329,239). The quota value of all shares is SEK 0.224 and all shares have equal rights to the company's assets and earnings. Xbrane's shares have been listed on Nasdaq Stockholm since September 23, 2019 and the number of shareholders in Xbrane amounted to about 3,300 on the balance sheet date. The closing price of the shares on the balance sheet date was SEK 34.6 M (45.9), generating a market capitalization of SEK 533.4 M (290.5).

#### Raising capital

Three issues were completed in 2019. 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.

## 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 percent compared to the theoretical price following the separation of subscription rights, based on the closing price of Xbrane's shares on March 28, 2019 on the Nasdag 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 a 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 Xbrane's shares at May 29, 2019 on Nasdag First North. The transaction costs amounted to SEK -7.7 M and includes costs for guarantors, financial and legal advisors, marketing and 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 percent discount based on the volume-weighted closing price of Xbrane's shares on May 29, 2019 on the 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 Stockholm, Sweden, where the company also has a laboratory for the research and development of biosimilars. Xbrane has one wholly-owned subsidiary, Primm Pharma, located in Milan, Italy. On the balance sheet date, the company had 37 (27) employees.

#### **Annual General Meeting (AGM)**

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 the nomination committee adopted at the AGM 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.

#### Dividend

The Board of Directors proposes that no dividend be paid for the fiscal year 01-01-2019 - 12-31-2019. The Board of Directors proposes that the company's accumulated loss be transferred to a new account.

#### **Annual report**

The annual report for the fiscal year 2019 will be published on April 16, 2020 on the company's website and through a press release.

#### Auditor's review

This report has not been subject to a review by the company's auditor.

### Events after the end of the reporting period

In February, the milestone of 50 percent of patients in the Xplore study recruited, was acheived.

To better equip the company for upcoming filing and commercialization of our biosimilars, the management team has been strengthened with Maria Edebrink, Head of Regulatory Affairs and Anders Wallström, Head of Manufacturing and Supply Chain. Both has worked in Xbrane since beginning of 2019. In addition, Xiaoli Hu has been recruited to Head of Business Development and will join the management team as of 1 May 2020. Due to Xbrane's strategic focus on biosimilars, Paolo Sarmientos, Head of long-term injectables, will no longer be a part of the management team.

Finchimica S.p.A., parent company of contract manufacturer ICI S.p.A., which Primm Pharma uses for the manufacture of Spherotide, was declared bankrupt in early 2020. Primm Pharma is now taking appropriate action to safeguard its interests in the future production of Spherotide. Related to this, write-downs regarding stock and production equipment for Spherotide amounting to SEK -16.8 M (-) have been made.

Board member Maris Hartmanis has informed that he declines re-election for 2020.



From left: Siavash Bashiri, Head of Biosimilars, David Vikström, CTO and Håkan Yildirim, Head of Intellectual Property, in a discussion.

# Consolidated income statement

Amounts in SEK thousand	Notes	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Revenues	2,3	-	4,896	-	20,485
Cost of goods sold		-18,271	-3,655	-18,271	-15,907
Gross profit		-18,271	1,240	-18,271	4,578
Other income	2,3	1,987	1,305	6,355	99,742
Selling and distribution expenses		-183	-196	-454	-933
Administrative expenses		-8,301	-6,858	-26,415	-23,347
Research and development expenses		-25,598	-25,533	-115,713	-85,827
Other expenses		-5,208	-2,114	-10,122	-5,629
Operating profit/loss	2	-55,573	-32,156	-164,620	-11,415
Financial income		0	44	51	44
Financial costs		-353	-419	-1,468	-1,744
Net financial costs	2	-353	-375	-1,417	-1,700
Profit/loss before tax		-55,926	-32,531	-166,037	-13,115
Income tax expense		-	108	-	-121
Profit/loss for the period		-55,926	-32,423	-166,037	-13,236
Profit/loss attributable to:					
- Owners of the Company		-55,926	-32,423	-166,037	-13,236
- Non-controlling interests		-	-	-	
Total comprehensive income for the period		-55,926	-32,423	-166,037	-13,236
Earnings per share					
- Basic earnings per share (SEK)		-5.00	-5.12	-14.84	-2.13
- Diluted earnings per share (SEK)		-5.00	-5.12	-14.84	-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
- After dilution		15,415,199	6,329,239	15,415,199	6,329,239
Average number of outstanding shares					
- Before dilution		11,190,591	6,329,239	11,190,591	6,213,927
- After dilution		11,190,591	6,329,239	11,190,591	6,213,927

# Consolidated income statement and other comprehensive income

Amounts in SEK thousand	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Total comprehensive income for the period	-55,926	-32,423	-166,037	-13,236
Other comprehensive income				
Items that have been transferred and can be transferred to profit/loss for the period to profit/loss for the period				
Reclassification of foreign currency translation differences	-2,790	-251	1,171	3,686
Comprehensive income for the period	-2,790	-251	1,171	3,686
Total comprehensive profit/loss attributable to:				
- Owners of the Company	-58,716	-32,674	-164,866	-9,551
- Non-controlling interests	-	-	-	-
Total comprehensive income for the period	-58,716	-32,674	-164,866	-9,551

# Consolidated statement of financial position

Amounts in SEK thousand	2019-12-31	2018-12-31
ASSETS		
Goodwill	60,760	59,838
Intangible assets	5,053	5,772
Property, plant and equipment	7,004	16,745
Right of use	9,204	-
Trade and other receivables	8,982	8,871
Non-current assets	91,003	91,226
Inventories		- 5,525
Trade and other receivables		10,489
Other receivables	5,889	10,432
Prepaid expenses and accrued income	77,850	34,240
Cash and cash equivalents	164,197	100,972
Current assets	247,937	161,659
TOTAL ASSETS TOTAL ASSETS	338,940	252,885
EQUITY		
Share capital	3,456	1,419
Non-registered equity		
Share premium	448,089	184,007
Reserves	6,719	5,548
Retained earnings	-273,941	-107,903
Equity attributable to owners of the Company	184,323	83,070
Non-controlling interests		
Total equity	184,323	83,070
LIABILITIES		
Non-current interest-bearing liabilities		- 12
Leasing	6,281	29
Non-current non-interest-bearing liabilities	4,173	4,118
Provisions	4,547	4,275
Non-current liabilities	15,001	8,433
Current interest-bearing liabilities	12	45,139
Trade and other payables	21,097	30,908
Current tax liabilities		- 123
Other current liabilities	2,903	820
Leasing	3,144	422
Deferred income/revenue	112,460	83,970
Current liabilities	139,615	161,382
TOTAL LIABILITIES	154,617	169,816
TOTAL EQUITY AND LIABILITIES	338,940	252,885

# Consolidated cash flow statement

Amounts in SEK thousand	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Cash flow from operating activities				
Profit/loss before tax	-55,926	-32,531	-166,037	-13,115
Adjustments for items not included in cash flow	22,996	3,275	24,718	4,953
Paid income taxes	-	-	-	-
Total	-32,931	-29,256	-141,319	-8,162
Increase (-)/Decrease (+) of inventories	-	-2,821	-	-2,280
Increase (-)/Decrease (+) of trade and other receivables	46,858	59,921	-28,286	-46,360
Increase (-)/Decrease (+) of trade and other payables	-7,671	9,943	21,016	103,509
Cash flow from current operations	6,256	37,787	-148,589	46,707
Cash flow from investing activities				
Acquisition of property, plant and equipment	-170	-184	-1 187	-1,598
Cash flow from investing activities	-170	-184	-1,187	-1,598
Cash flow from financing activities				
New share issue	-	-	252,457	2,549
Transaction expense	-	-	-33,430	-12
Warrants issue	-	-	-	701
Loan and borrowings	-	-	-	45,000
Amortization of Ioan	-34	-33	-140	-131
Amortization of lease liability	-809	-62	-2,846	-377
Cash flow from financing activities	-843	-95	216,041	47,730
Cash flow for the period	5,244	37,508	66,265	92,839
Cash and cash equivalents at beginning of period	162,195	64,311	100,972	7,903
Exchange rate differences in cash and cash equivalents	-3,241	-847	-3,039	230
Cash and cash equivalents at end of period	164,197	100,972	164,197	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	1419	184,007	5,548	-107,903	83,070	83,070
Total comprehensive income for the period						
Profit/loss for the period	-	-	-	-166,037	-166,037	-166,037
Other comprehensive income for the period	-	-	1,171	-	1,171	1,171
Total comprehensive income for the period	-	-	1,171	-166,037	-164,866	-164,866
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	-	-	-33,340	-33,430
Share savings program	-	2,092	-	-	2,092	2,092
Total contributions from and distributions to shareholders	2,037	264,082	-	-	266,119	266,119
Balance at December 31, 2019	3,456	448,089	6,719	-273,941	184,323	184,323

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 income 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 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	84	4,123	-	-	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	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Revenues	-	-	-	-
Cost of goods sold	-	-	-	-
Gross profit	-	-	-	-
Other income	1,178	1,441	4,416	97,149
Selling and distribution expenses	-	-	-	-
Administrative expenses	-6,962	-5,618	-21,595	-19,074
Research and development expenses	-23,904	-22,845	-104,557	-75,257
Other expenses	-5,204	-1,659	-10,090	-18,192
Operating profit/loss	-34,893	-28,681	-131,825	-15,375
Financial items				
Financial income	4	-	4	-
Financial expenses	-115	-461	-995	-1,690
Net finance costs	-110	-461	-990	-1,690
Profit/loss before tax	-35,003	-29,142	-132,815	-17,065
Income tax expense	-	-	-	-
Total comprehensive income for the period	-35,003	-29,142	-132,815	-17,065

# Parent company statement of comprehensive income

Amounts in SEK thousand	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Profit/loss for the period	-35,003	-29,142	-132,815	-17,065
Other comprehensive income	-	-	-	
Total comprehensive income for the period	-35,003	-29,142	-132,815	-17,065

# Balance Sheet, Parent company

Amounts in SEK thousand	2019-12-31	2018-12-31
ASSETS		
Non-current assets Property, plant and equipment		
Financial non-current assets	3,697	5,014
Shares in group companies	102,319	100,783
Other non-current receivables	8,982	8,871
Total financial non-current assets	111,301	109,654
Total non-current assets	114,998	114,667
Current assets		
Current receivables		
Trade and other receivables	-	196
Other receivables	2,962	1,018
Prepaid expenses and accrued income	77,752	33,596
Total current receivables	80,714	34,810
Cash and bank	163,601	100,380
Current assets	244,315	135,190
TOTAL ASSETS	359,313	249,857
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	3,456	1,419
Unrestricted equity		
Share premium	448,775	184,693
Retained earnings	-94,688	-77,623
Profit/loss for the period	-132,815	-17,065
Total equity	224,728	91,424
Non-current liabilities		
Non-current non-interest-bearing liabilities	4,173	4,118
Non-current liabilities	4,173	4,118
Current liabilities		
Current interest-bearing liabilities	-	45,000
Liabilities to subsidiaries	-	3,042
Trade and other payables	20,377	23,709
Other current liabilities	2,708	630
Deferred income/revenue	107,327	81,934
Current liabilities	130,412	154,316
TOTAL LIABILITIES	134,585	158,434
TOTAL EQUITY AND LIABILITIES	359,313	249,857

# Cash flow statement, Parent company

Amounts in SEK thousand	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Cash flows from operating activities				
Earnings before income and tax	-35,003	-29,143	-132,815	-17,065
Adjustments for items not included in cash flow	3,756	6,110	6,706	6,927
Paid income taxes	-	-	-	-
Total	-31,247	-23,033	-126,109	-10,138
Increase (-)/Decrease (+) of trade and other receivables	48,333	64,789	-46,015	-38,319
Increase (-)/Decrease (+) of trade and other payables	-7,976	4,269	24,510	99,962
Cash flow from current operations	9,110	46,025	-147,614	51,505
Cash flow from investing activities				
Investments in subsidiaries	-1,536	-	-1,536	-6,691
Acquisition of property, plant and equipment	-179	-35	-565	-110
Cash flow from investing activities	-1,715	-35	-2,101	-6,801
Cash flow from financing activities				
New share issue	-	-	252,457	2,549
Transaction expense	-	-	-33,430	-12
Warrants issue	-	-	-	701
Loan and borrowings	-	-	-	55,000
Amortization of loan	-	-5,130	-3,042	-6,958
Cash flow from financing activities	-	-5,130	215,985	51,280
Cash flow for the period	7,394	40,860	66,270	95,984
Cash and cash equivalents at beginning of period	159,386	63,052	100,380	6,483
Exchange rate differences in cash and cash equivalents	-3,180	-3,532	-3,049	-2,087
Cash and cash equivalents at end of period	163,601	100,380	163,601	100,380

### Notes

#### Note 1 Accounting principles

This Year-end report has been prepared in accordance with IAS 34, Interim Financial Reporting, as well as applicable regulations from the annual accounts act. The Year-end 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 year-end report as well.

The Group adopted IFRS 16 Leasing contracts from 1 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 as of 1 January 2019 has been made by using the simplified transitional method, which means that the prior periods have not been restated.

#### Transition effects

As an operational lessee, the effect relates primarily to office premises and car lease 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 2019 the total leasing asset amounted to SEK 9,204 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 fourth quarter of 2019 amounted to SEK 144 thousand and

SEK -90 thousand for interest cost and depreciation respectively. The effect on full year 2019 amounted to SEK 457 thousand and SEK -268 thousand for interest cost and depreciation respectively. The average marginal interest rate of 6 percent 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 4 (IFRS 16)	Effect from IFRS 16	2019 Q 4 (IAS 17)
Operating profit/loss	-55,573	90	-55,663
Net finance costs	-353	-144	-209
Profit/loss before tax	-55,926	-54	-55,872
Effect from IFRS 16 SEK thousand	2019 Full year (IFRS 16)	Effect from IFRS 16	2019 Full year (IAS 17)
	•		year
SEK thousand	(IFRS 16)	IFRS 16	year (IAS 17)

#### **Currency derivatives**

Since Q4 2019, Xbrane has entered into currency derivative agreements. Holding currency derivatives that show a positive fair value are reported as assets in the financial position statement, while currency derivatives with a negative fair value are reported as a liability on the balance sheet date. Hedge accounting is not applied to the entered currency derivatives and these are therefore recognized at fair value through the profit or loss.

According to the IFRS valuation hierarchy, there are three different levels of valuation at fair value:

- Level 1: Quoted prices in an active market for identical assets or liabilities
- Level 2: Observable data for the asset or liability other than quoted prices included in level 1, either directly, i.e. as price quotations or indirectly, i.e. obtained from price quotations.
- **Level 3:** Data for the asset or liability that is not entirely based on observable market data.

In accordance with the above valuation hierarchy, the fair value of all currency derivatives has been valued according to level 2. This means that the valuation is based partly on observable market value in terms of SEK against EUR and partly on the volatility of the market price in terms of SEK against EUR during the period for the closing, which takes place monthly.

The total value of the currency derivatives held shows a negative value on the balance sheet date. The outcome of the derivative is not offset in the balance sheet. During the fourth quarter there were no transfers between the three different valuation levels.

Note 2 Segment reporting

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

Amounts in SEK thousand	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Revenues per segment				
Biosimilars	-	535	-	77,860
Long-acting injectable drugs	696	4,597	2,021	33,561
Unallocated revenue	1,290	1,068	4,335	8,806
Total	1,987	6,200	6,355	120,227
Operating profit or loss per segment				
Biosimilars	-23,585	-22,230	-103,868	3,497
Long-acting injectable drugs	-2,013	-47,730	-9,824	-27,462
Unallocated revenue	-29,975	37,804	-50,928	12,550
Operating profit/loss	-55,573	-32,156	-164,620	-11,415
Net finance costs				
Biosimilars	-133	-	-354	-
Long-acting injectable drugs	-114	36	-81	-
Unallocated revenue	-106	-411	-982	-1,700
Total	-353	-375	-1,417	-1,700
Profit/loss before tax	-55,926	-32,531	-166,037	-13,115
Depreciation, amortization and write downs				
Biosimilars	1,101	448	3,624	1,788
Long-acting injectable drugs	17,275*	1,358	20,068*	3,482
Unallocated revenue	99	14	441	66
Total	18,475	1,820	24,134	5,336

 $<sup>^{\</sup>star}$  Whereof SEK 16,808 thousand relates to write down of inventory and production facilities for Spherotide.

## Note 3 Distribution of Income

Amounts in SEK thousand	Q 4 2019				
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	Group	
Middle East	-	-	-	-	
Asia	-	-	-39	-39	
Europe	-	-1,324	3,158	1,833	
US	-	-	192	192	
Total	-	-1,324	3,311	1,987	
Income per category					
Pharmaceuticals	-	-	-	-	
Milestone payments from partners	-	-	-	-	
Services and other	-	-1,324	3,311	1,987	
Total	-	-1,324	3,311	1,987	

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 1,045 thousand in exchange rate gains.

#### Amounts in SEK thousand Q 4 2018

		Long-acting	Unallocated/	
Income per region	Biosimilars	injectable drugs	administration	Group
Middle East	-	4,597	-	4,597
Asia	-	-	-	-
Europe	535	-	896	1,431
US	-	-	172	172
Total	535	4,597	1,068	6,200
Income per category				
Pharmaceuticals	-	4,597	-	4,597
Milestone payments from partners	-	-	-	-
Services and other	535	-	1,068	1,603
Total	535	4,597	1,068	6,200

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 1,529 thousand in exchange rate gains.

Note 3 Distribution of Income, cont.

Amounts in SEK thousand	Full year 2019				
Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	Group	
Middle East	-	-	-	-	
Asia	-	-	-39	-39	
Europe	-	-	6,132	6,132	
US	-	-	262	262	
Total	-	-	6,355	6,355	
Income per category					
Pharmaceuticals	-	-	-	-	
Milestone payments from partners	-	-	-	-	
Services and other	-	-	6,355	6,355	
Total	-	-	6,355	6,355	

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 3,461 thousand in exchange rate gains.

#### Amounts in SEK thousand Full year 2018

Income per region	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	Group
Middle East	-	20,186	-	20,186
Asia	-	13,375	-	13,375
Europe	77,860	-	8,381	86,241
US	-	-	425	425
Total	77,860	33,561	8,806	120,227
Income per category				
Pharmaceuticals	-	20,485	-	20,485
Milestone payments from partners	77,325	13,076	-	90,401
Services and other	535	-	8,806	9,341
Total	77,860	33,561	8,806	120,227

<sup>1)</sup> Out of which unallocated/administration amounts to SEK 4,730 thousand in exchange rate gains.

#### Note 4 Transactions with related parties

Since 2019, STADA Arnzeimittel AG has been a shareholder in Xbrane (see the list of owners on page 7). Transactions with STADA relate to shared costs for the collaboration agreement with Xlucane. Xbrane invoiced STADA for SEK 26,253 thousand during the fourth quarter, and for a total of SEK 140,713 thousand for the

At the end of the period, Xbrane had a non-current non-interest-bearing liability to STADA amounting to SEK 4,173 thousand as well as deferred income/revenue from STADA amounting to SEK 85.177 thousand.

#### Note 5 Financial instruments

The book value of account receivables, other receivables, cash and cash equivalents, accounts payable and other liabilities is a reasonable approximation of fair value.

#### Financial assets and liabilities are measured at fair value.

The Group's financial instruments that have been valued at fair value are the currency derivatives holdings. The fair value of the Group's currency derivatives is based on the observable market value of SEK against the EUR exchange rate and volatility at the market price with respect to SEK against the EUR exchange rate. The valuation is thus considered to fall under category 2, in the valuation hierarchy below, which shows the different valuation levels for the financial assets and financial liabilities that are reported at fair value in the consolidated balance sheet. The breakdown of how fair value is determined is based on the 3 levels below:

Level 1: Quoted prices in an active market for identical assets or

Level 2: Observable data for the asset or liability other than quoted prices included in level 1, either directly, i.e. as price quotations or indirectly, i.e. obtained from price quotations. Level 3: Data for the asset or liability that is not entirely based on observable market data.

The total value of the currency derivatives held shows a negative value on the balance sheet date. During the fourth quarter, there were no transfers between the different valuation levels. The fair value of financial assets and liabilities, reported at cost and amortized cost, is estimated in all material corresponds to book values.

Group Amounts in SEK thousand	2019 Q 4 Level 2	2018 Q 4 Level 2	2019 Full year Level 2	2018 Full year Level 2
Financial assetss				
Other current receivables fordringar	24	-	24	-
Whereof currency deriatives	24	-	24	-
Total financial assets	24	-	24	-
Financial liabilities				
Other current payables	1,729	-	1,729	-
Whereof currency deriatives	1,729	-	1,729	-
Total financial liabilities	1,729	-	1,729	-

# Certification

The Board of Directors and the CEO hereby certify that this Year-end 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, 28 February 2020

Anders Tullgren	Ivan Cohen-Tanugi
Chairman of the Board	Board member
Peter Edman	Eva Nilsagård
Board member	Board member
Karin Wingstrand	Maris Hartmanis
Board member	Board member
Giorgio Chirivì	Martin Åmark
Board member	CEO

# Alternative performance measures

The Company presents certain financial measures in the Year-end 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	2019 Q 4	2018 Q 4	2019 Full year	2018 Full year
Gross profit	-18,271	1,240	-18,271	4,578
Divided by revenues	-	4,896	-	20,485
Gross margin	-	25%	-	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
Amounts in SEK thousand	Q 4	Q 4	Full year	Full year
Operating profit or loss	-55,573	-32,156	-164,620	-11,415
Depreciation, amortization and write downs	-18,475	-1,820	-24,134	-5,336
EBITDA	-37,098	-30,336	-140,487	-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.

	2019	2018	2019	2018
Amounts in SEK thousand	Q 4	Q 4	Full year	Full year
Research and development expenses	-25,598	-25,533	-115,713	-85,827
Divided by total operating expenses minus depreciation and amortization				
	-37,974	-32,881	-148,627	-110,400
Research and development expens-es as a percentage of operating expenses	67%	78%	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	2019-12-31	2018-12-31
Total equity	184,323	83,070
Divided by total assets	338,940	252,885
Equity ratio	54%	33%



### For further information

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#### Financial calendar

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

