During the first quarter of 2020, 50 percent of patients were recruited in the Xplore study. The study is continuing despite the ongoing COVID-19 pandemic and Xbrane is following the guidelines of local authorities as well as those of the FDA and EMA.

## Financial summary first quarter 2020

- » Revenue amounted to SEK 0 M (0).
- » The gross margin amounted to 0 percent (0).
- » Other operating income amounted to SEK 4.9 M (1.2).
- » EBITDA was SEK -47.0 M (-31.2).
- » R&D expenses amounted to SEK 44.6 M (26.5) representing 86 percent (82) of total operating expenses.
- » The loss for the period was SEK 48.9 M (-33.3).
- » Earnings per share was SEK -3.17 (-5.26).
- » Cash and cash equivalents at the end of the period amounted to SEK 84.5 M (44.3).

# Significant events during the first quarter 2020

- » In February, 50 percent of the patients in the Xplore study had been recruited, which represents an important milestone.
- » To better equip the management group for the upcoming commercialization of our biosimilars, it has been strengthened with the addition of Maria Edebrink, Head of Regulatory Affairs and Anders Wallström, Head of Manufacturing and Supply Chain, both of whom have been employed at Xbrane since early 2019. Furthermore, Xiaoli Hu has been recruited to the position of Head of Business Development and is a part of the management as of May 1, 2020. As a result of Xbrane's strategic focus on biosimilars, Paolo Sarmientos, Head of Long-acting injectables, is no longer part of the management group.
- » Finchimica S.p.A., parent company of the contract manufacturer ICI S.p.A, which Primm Pharma uses to manufacture Spherotide, went bankrupt in early 2020. Primm Pharma is taking the appropriate action to safeguard its interests in the future production of Spherotide.
- » Board member Maris Hartmanis has announced that he has declined re-election in 2020.

### Significant events after the end of the quarter

- » In April the company announced how the ongoing COVID-19 pandemic, had affected Xbrane's operations. Xbrane has adapted its operations to comply with local government health guidelines. This has resulted in cancelled trips, switching to digital meetings and that the majority of employees are working from home. The Xplore study remains open for recruiting new patients and treating patients already included in the study. The work on Xplore follows local authority guidelines as well as those from the European Medicines Agency ("EMA") and the US Food and Drug Administration ("FDA"). Safety for patient and clinical staff is our first priority. The rapid development of the COVID-19 pandemic makes it difficult to predict future recruitment rates at this stage. Although we expect Xplore be fully recruited by third quarter 2020 and thereby still moving towards market approval before Lucentis® loses its patent protection in the EU in July 2022.
- » In May, Xbrane and STADA announced that they had formed a partnership with Bausch + Lomb for the commercialization of Xlucane in the United States and Canada. Under the agreement, Bausch + Lomb will pay a license fee consisting of a mid single-digit million USD up-front payment upon signing and milestone payments at regulatory approval and launch as well as sharing the gross profits from sales with Xbrane and STADA. Xbrane and STADA will equally share all income from Bausch + Lomb from the commercialization of Xlucane in the United States and Canada.



# Financial summary for the Group

Amounts in SEK thousand	2020 Q1	2019 Q1	2019 Full year
Revenue	-	-	-
Research and development (R&D)	-44,597	-26,523	-115,713
R&D expenses as a percentage of operating expenses	86%	82%	78%
Operating loss	-48,681	-32,932	-164,620
EBITDA	-47,027	-31,236	-140,487
Loss for the period	-48,887	-33,313	-166,037
Cash and cash equivalents	84,470	44,317	164,197
Equity/assets ratio	45%	34%	54%
Number of shares at end of period before dilution	15,415,199	6,329,239	15,415,199
Number of shares at end of period after dilution	15,415,199	6,329,239	15,415,199
Average number of shares before dilution	15,415,199	6,329,239	11,190,591
Average number of shares after dilution	15,415,199	6,329,239	11,190,591
Earnings per share before dilution (SEK)	-3.17	-5.26	-14.84
Earnings per share after dilution (SEK)	-3.17	-5.26	-14.84

# About Xbrane

Xbrane Biopharma AB develops biological drugs based on a patented platform technology that leads to significantly lower production costs compared to competing systems. Xbrane's leading product candidate Xlucane is a biosimilar of the original drug Lucentis®, a VEGFa inhibitor used in the treatment of a number of serious eye diseases. A global

registration-based phase III study is underway for Xlucane and the launch of the product is expected in mid-2022. Xbrane's head office is in Solna, just outside Stockholm. Xbrane is listed on Nasdaq Stockholm under the ticker XBRANE.



Martin Åmark, CEO.

# CEO letter

### Dear shareholder

The first quarter of 2020 was a very special quarter due to the COVID-19 pandemic, which of course also affected Xbrane. Despite the circumstances, we have manage to continue discussions and negotiations with partners and therefore together with our partner STADA we have been able to establish a partnership with Bausch + Lomb for the United States and Canada.

# Impact on Xbrane's operations due to the COVID-19 pandemic

The safety of our employees, partners and patients participating in the Xplore study is of the highest priority. We have continuously followed and continue to follow local health guidelines from the authorities at the locations where Xbrane's operations are ongoing. During the first quarter, we quickly changed our working methods to provide a safe working environment, while minimizing disruptions in the operation. In addition to trips being canceled and meetings taking place digitally, the majority of employees have been working from home since mid-March. For those employees who need access to the laboratory, we have offered a safe way of travel as well as scheduled work in order to comply with guidelines about social distancing. Absence due to illness has been relatively low. Together we have found effective ways of working and an even stronger cohesion that allows us to be sustainable in this

situation and put our employees', partners' and patients' health and safety as first priority.

# Partnership with Bausch + Lomb in the United States and Canada

In May 2020, Xbrane and STADA started a partnership with Bausch + Lomb for the sale and marketing of Xlucane in the United States and Canada. We are very happy to have entered this partnership, which has great strategic value. Bausch + Lomb is one of the leading companies in the field of eye products and ophthalmic medicines in North America. Bausch + Lomb has an established sales force with good relationships with around 2,500 eye clinics who will prescribe Xlucane. They have a strong and well-known brand in ophthalmic drugs and good relationships with private and public insurers and payers. I am convinced that Bausch + Lomb will be able to establish a strong market position for Xlucane in the United States and Canada and realize the commercial potential we see in the product. Xbrane and STADA's assessment is that we have found the right partner for Xlucane and we are very pleased with the agreement. In accordance with the agreement, license payments and profit sharing will be paid to Xbrane and STADA, which, in accordance with the co-development agreement are equally divided between the companies.

# Target of generating revenue of at least EUR 100 M annually three years after the launch of Xlucane remains

In April 2019, Xbrane announced a target for Xlucane to reach annual net sales of EUR 350 M three years after launch, thus generating EUR 100 M in annual net revenue to Xbrane. The strength of a partner like Bausch + Lomb means that we are now seeing greater potential in terms of sales than we previously expected in the United States and Canada. All in all, this means that our target of reaching annual net revenue of at least EUR 100 M three years after launch is still in place despite that profit sharing will be with an additional partner. This is also supported by the strong growth we have seen in recent years in the market for ophthalmic VEGFa inhibitors, which in 2019 had sales of more than EUR 10 billion 1, 2, 3.

# Xlucane on its way to market approval before Lucentis® loses patent protection in the EU in July 2022

Since April 2019, the pivotal phase III study named Xplore is ongoing with the aim of demonstrating equivalence between Xlucane and the originator drug Lucentis®. In beginning of May 2020, 381 of the planned 580 patients had been recruited to Xplore. The recruitment rate significantly reduced as the COVID-19 pandemic broke out. However, we are now seeing certain countries that adopted strict quarantine rules are opening up again. Based on this, our assessment is that the recruitment rate will gradually increase and we are counting on finalize recruitment by third quarter 2020.

This schedule is what is required to apply for and obtain marketing approval before Lucentis® loses its patent protection in the EU in July 2022.

# Important milestones in the next 12 months

Xbrane has many important milestones to deliver in the next 12 months, mainly to:

· License out the rights to sell and promote Xlucane, especially in Latin America and Japan together with STADA.

- · Complete patient recruitment for Xplore and communicate top-line data from the interim analysis conducted after last patient concluded six months treatment.
- · Apply for marketing approval in Europe and the United States.

In addition, our ambition is to form further partnerships, primarily for Xcimzane and Xdivane, our biosimilar candidates for Cimzia® and Opdivo®, and to further strengthen our platform technology and IP-protection.

We continue to meet specialists around the world and meet investors at various events to present Xbrane, the Nordic Region's only listed biosimilar developer. In February, Xbrane was one of 16 companies presenting at Swiss Nordic Bio organized by Business Sweden and Vator Securities in Zurich. Investors from Europe with a focus on healthcare took part in the event.

Finally, I would like to extend my sincere thanks to my employees who have made it possible for Xbrane to take these important steps in our development. We all feel great enthusiasm towards Xbrane's journey to becoming a leading global biosimilar developer and, with our unique patented production platform, be able to develop cost-effective biosimilars for the benefit of the world's patients.

Martin Åmark, CEO

Source:

- Novartis Year-end report 2019
- Roche Year-end report 2019 Regeneron Year-end report 2019

# Product portfolio

Product	Biosimilar to	Primary indication	Sales originator drug, 2019 (SEK billion)*	Patent expire date for originator drug	Phase of development
Xlucane	Ranibizumab (Lucentis®)	Wet age-related mac- ular degeneration, di- abetic related macular edema, and retinal vein occlusion.	371.2	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.	2 4	Expired	Pre-clinical phase
Xdivane	Nivolumab (Opdivo®)	Melanoma, lung cancer, renal cell carcinoma, head- and neck cancer, bladder and urinary tract cancer.	68 <sup>5</sup>	2026-2031 Depending on country	Pre-clinical phase
Spherotide	Triptorelin (Decapeptyl®)	Prostate cancer, breast cancer, endometriosis, and myoma	4 <sup>6</sup>	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

- \* 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 billion<sup>1,2</sup>. The market has grown by about 11 percent per year over the past three years 1,2,3. 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 with no safety concerns raised. In the beginning of May 2020, 381 of the planned 580 patients had been recruited to the Xplore study. Xbrane will, as per agreement with EMA and FDA, submit Marketing Authorization application ("MAA")/Biologics License Application ("BLA") for Xlucane in Europe and United States, on the basis of six months treatment data from Xplore. Given that the recruitment is finalized no later than by the end of the third quarter of 2020, market authorization of Xlucane is expected to be in place in order to launch in Europe and the United States upon Lucentis® patent expiration in the EU in 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. In May 2020, the commercialization rights for the United States and Canada were licensed to Bausch + Lomb, for more information see pages 3 and 10.

# 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 20196. 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 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), 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:

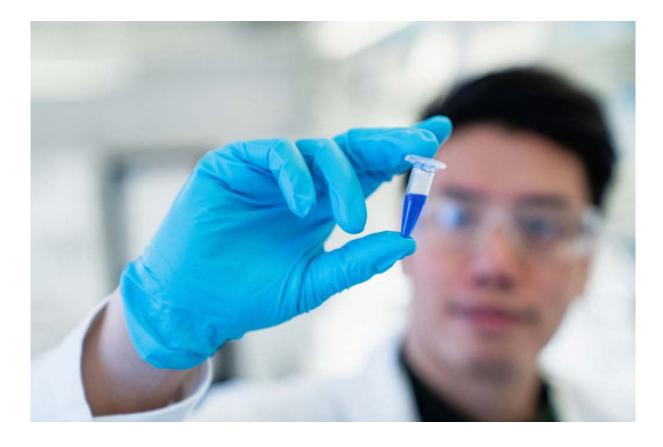
- 1) Novartis Year-end report 2019
- 2) Roche Year-end report 2019
- 3) Regeneron Year-end report 2019
- 4) Research and markets Global Tumor Necrosis Factor (TNF) Inhibitors Market 2018-2026: A \$181.13 Billion Market Opportunity by 2026
- 5) UCB Year-end report 2019
- 6) BMS Year-end report 2019
-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

# Shareholders

As per March 31, 2020, Xbrane had approximately 3,600 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	14.6%
STADA Arzneimittel AG	1,256,792	8.2%
Swedbank Robur Fonder	1,009,693	6.5%
Bengt Göran Westman	962,909	6.2%
Avanza Pension	902,746	5.9%
Futur Pension	516,760	3.4%
Nordnet Pensionsförsäkring	405,851	2.6%
Swedbank Försäkring	313,384	2.0%
Paolo Sarmientos	296,939	1.9%
Iraj Arastoupour	252,411	1.6%
Ten largest shareholders in total	8,173,459	53.0%
Other Swedish shareholders	6,169,930	40.0%
Other foreign shareholders	1,071,810	7.0%
Total outstanding shares	15,415,199	100.0%

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 January - March 2020

During the first quarter, no sales were made, and thus no cost of goods sold were incurred (SEK 0.0 M and SEK 0.0 M in the same period last year for net sales and cost of goods sold).

Other operating income amounted to SEK 4.9 M (1.2) relating to gains on currency derivatives, exchange rate gains on operating receivables and liabilities and license income from non-core operations.

No sales costs occurred in the first quarter (SEK -0.2 M) relating to personnel costs in the subsidiary during the comparison period). Administrative expenses amounted to SEK -7.0 M (-2.9) and the increase is explained by an expanding organization.

Research and development costs amounted to SEK -44.6 M (-26.5), of which SEK -42.5 M (-23.0) refers to biosimilars and primarily Xlucane and SEK -2.0 M (-3.4) to the long-acting injectable drug Spherotide. Most of the costs are related to the ongoing Xplore study for Xlucane, the parallel regulatory work and the establishment of a production chain. Costs for the preclinical portfolio of biosimilars account for SEK -7.4 M (-0.4).

Other operating expenses amounted to SEK -2.0 M (-4.5) and relate primarily to exchange rate losses on receivables and liabilities of an operating nature as well as realized and unrealized losses on currency price hedges.

The operating loss was SEK 48.9 M (32.9). Net financial items amounted to SEK -0.2 M (-0.4) and primarily relate to financial expenses of SEK -0.2 M (-0.4) regarding leasing agreements. The loss before tax amounted to SEK -48.9 M(-33.3). 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 period was SEK 48.9 M (33.3).

# The Group's cash flow for January - March 2020

The cash flow from operating activities amounted to SEK -83.3 M (-53.2). Change in inventories amounted to SEK 0.0 M (-3.3), as the stock that previously referred to Spherotide has been written down since last year. Changes in operating receivables and operating liabilities, respectively, amounted to SEK -49.2 M(-40.0) and SEK -17.3 M(18.7), respectively. Changes in working capital can vary greatly between quarters, primarily as a

result of advance payments from STADA regarding the development work for Xlucane and costs for the clinical study.

The cash flow from investment activities consisted of smaller investments in tangible fixed assets that rounded amounted to SEK 0.0 M (-0.4).

The cash flow from financing activities amounted to SEK -0.8 M (-0.3) and refers to minor repayment of loans that rounded amounted to SEK 0.0 M (0.0) and repayment of a leasing liability of SEK -0.8 M (-0.3).

# The Group's financial position and continued operations

On the balance sheet date, cash and cash equivalents amounted to SEK 84.5 M (44.3).

Besides the revenues that partnerships are expected to bring in in the near future, among others through the transaction with Bausch + Lomb described on pages 3 and 10, Xbrane is expected to need additional capital to finance the next 12 months of operations. Additional financing is also expected to be needed until 2022, when the company is expected to generate sales revenue from Xlucane. The company continues to evaluate a range of financing options together with its financial advisors and dialogues with investors.

## Goodwill

Goodwill amounted to SEK 64.5 M (60.7) on the balance sheet date and the increase of SEK 3.8 M compared with the previous year is due to exchange rate changes.

# Tangible fixed assets

Tangible fixed assets amounted to SEK 6.6 M (14.2) on the balance sheet date and changes relate to depreciation and the previous year's impairment of production equipment in the subsidiary.

# Inventories

As sales of Spherotide have been put on hold, inventories have been written down and thus amounted to SEK 0.0 M (SEK 8.9 M).

# Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 84.8 M (79.5), of which SEK 45.1 M (49.2) refers to purchases and packaging costs of reference drugs for the ongoing Phase III study that will be used on an ongoing basis, SEK 17.9 M (16.1) refers to the advance payment to the CRO (Contract Research Organization)

conducting the clinical study and the remaining SEK 21.8 M (14.3) refers to other prepaid expenses and accrued income.

### Changes in equity

Equity amounted to SEK  $3.5\,\mathrm{M}$  (1.4) on the balance sheet date. Other capital contributions amounted to SEK  $448.3\,\mathrm{M}$  (174.7) and during the quarter were impacted by SEK  $0.2\,\mathrm{M}$  in reserved share-related remuneration to employees. Total equity amounted to SEK  $139.5\,\mathrm{M}$  (101.1). The equity ratio was  $45\,\mathrm{percent}$  (34).

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

On the balance sheet date, there were no long-term interest-bearing liabilities (SEK 45.0 M in the comparison period) and no short-term interest-bearing liabilities (SEK 0.1 M in the comparison period). The former credit facility from the Serendipity Group, which constituted long-term interest-bearing loans during the comparison period, was fully settled by converting loans of SEK 45.0 M to shares in connection with issues during last year.

### Leasing liabilities

Long- and short-term interest-bearing leasing liabilities amounted to SEK 5.6 M (2.5) and SEK 3.1 M (1.9), respectively. The increase from the previous year is explained by newly signed leasing contracts relating to laboratory equipment.

### Accounts payable

Accounts payable amounted to SEK 43.7 M (36.2). The increase from the previous period is mainly explained by fluctuations in payment flows for the clinical study and development work for Xlucane.

# Accrued expenses and prepaid income

Accrued expenses and prepaid revenues amounted to SEK 108.7 M (97.6) and primarily relate to advance payments of SEK 84.4 M (72.1). from STADA relating to Xlucane. Of the remaining SEK 24.4 M (25.3), the majority of the reserved expenses relate to the product development of Xlucane.

# Impact of the joint development agreement with STADA on the results and balance sheet

Since the joint development agreement with STADA for Xlucane was concluded in July 2018, Xbrane's net costs for the research and development attributable to the 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 closing date, Xbrane had a long-term non-interest-bearing debt to STADA amounting to SEK 4.4 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 84.4 M (72.1), of which SEK 22.6 M (25.0) refers to the purchase of the reference drug Lucentis®, SEK 9.0 M (8.0) refers to the short-term portion of the prepayment to CRO and the remaining SEK 52.8 M (39.1) refers to 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 would provide no further information than described in the report. Hence, this is only presented in reporting format on pages 17-19.

#### Risks and uncertainties

Risks and uncertainties are described in the 2019 Annual Report on pages 27-29. This is available on the company's website. With regard to risks related to the ongoing COVID-19 pandemic, these are described in the annual report and at the time of publishing this interim report, these have not changed.

The 2019 Annual Report describes the risk that Xbrane and its partner STADA not succeeding in reaching agreements with a third-party distributors for major markets, for example the United States and LATAM. After the end of the reporting period, this risk has been altered by the fact that Xbrane and STADA have signed an agreement with Bausch + Lomb to obtain the rights to distribute Xlucane in the United States and Canada. The agreement is described in more detail on pages 3 and 10

Apart from the change described above, no new factors or changed assumptions have arisen that could have a material impact on the previously compiled 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 was around 3,600 on the balance sheet date. The closing price of the shares on the balance sheet date was SEK 31.7 (38.2),

generating a market capitalization of SEK 488.7 M (241,6).

### 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 40 (35) employees.

# **Annual General Meeting (AGM)**

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

#### Auditor's review

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

## Events after the end of the quarter

In April the company announced how the ongoing COVID-19 pandemic, had affected Xbrane's operations. Xbrane has adapted its operations to comply with local government health guidelines. This has resulted in cancelled trips, switching to digital meetings and that the majority of employees are working from home. The Xplore

study remains open for recruiting new patients and treating patients already included in the study. The work on Xplore follows local authority guidelines as well as those from the European Medicines Agency ("EMA") and the US Food and Drug Administration ("FDA"). Safety for patient and clinical staff is our first priority. The rapid development of the COVID-19 pandemic makes it difficult to predict future recruitment rates at this stage. Although we expect Xplore be fully recruited by third quarter 2020 and thereby still moving towards market approval before before Lucentis® loses its patent protection in the EU in July 2022.

In May, Xbrane and STADA announced that they had formed a partnership with Bausch + Lomb for the commercialization of Xlucane in the United States and Canada. Under the agreement, Bausch + Lomb will pay a license fee consisting of a mid single-digit million USD up-front payment upon signing and milestone payments at regulatory approval and launch as well as sharing the gross profits from sales with Xbrane and STADA. Xbrane and STADA will equally share all income from Bausch + Lomb from the commercialization of Xlucane in the United States and Canada. For more information see page 3.



# Consolidated income statement

		2020	2019	2019
Amounts in SEK thousand	Notes	Q1	Q1	Full year
Revenues	2,3	-	-	-
Cost of goods sold		-	-	-18,271
Gross profit		-	-	-18,271
Other income	2,3	4,902	1,201	6,355
Selling and distribution expenses		-	-232	-454
Administrative expenses		-7,035	-2,883	-26,415
Research and development expenses		-44,597	-26,523	-115,713
Other expenses		-1,952	-4,495	-10,122
Operating profit/loss	2	-48,681	-32,932	-164,620
Financial income		-	51	51
Financial costs		-206	-432	-1,468
Net financial costs	2	-206	-381	-1,417
Profit/loss before tax		-48,887	-33,313	-166,037
Income tax expense		-	-	-
Profit/loss for the period		-48,887	-33,313	-166,037
Profit/loss attributable to:				
- Owners of the Company		-48,887	-33,313	-166,037
- Non-controlling interests		-	-	-
Total comprehensive income for the period		-48,887	-33,313	-166,037
Earnings per share				
- Basic earnings per share (SEK)		-3.17	-5.26	-14.84
- Diluted earnings per share (SEK)		-3.17	-5.26	-14.84
Number of outstanding shares at the end of the reporting period				
- Before dilution		15,415,199	6,329,239	15,415,199
- After dilution		15,415,199	6,329,239	15,415,199
Average number of outstanding shares				
- Before dilution		15,415,199	6,329,239	11,190,591
- After dilution		15,415,199	6,329,239	11,190,591

# Consolidated income statement and other comprehensive income

Amounts in SEK thousand	<b>2020</b> Q1	<b>2019</b> Q1	<b>2019</b> Full year
Total comprehensive income for the period	-48,887	-33,313	-166,037
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	3,820	1,289	1,171
Comprehensive income for the period	3,820	1,289	1,171
Total comprehensive profit/loss attributable to:			
- Owners of the Company	-45,067	-32,024	-164,866
- Non-controlling interests	-	-	-
Total comprehensive income for the period	-45,067	-32,024	-164,866

# Consolidated statement of financial position

Amounts in SEK thousand	03-31-2020	03-31-2019	12-31-2019
ASSETS			
Goodwill	64,543	60,693	60,760
Intangible assets	5,153	5,653	5,053
Property, plant and equipment	6,612	14,210	7,004
Right of use	8,471	6,056	9,204
Trade and other receivables	9,501	8,871	8,982
Non-current assets	94,280	95,482	91,003
Inventories	-	8,912	-
Trade and other receivables	42,886	1,463	-
Other receivables	4,893	64,445	5,889
Prepaid expenses and accrued income	84,825	79,546	77,850
Cash and cash equivalents	84,470	44,317	164,197
Current assets	217,074	198,683	247,937
TOTAL ASSETS TOTAL ASSETS	311,354	294,165	338,940
EQUITY			
Share capital	3,456	1,419	3,456
Non-registered equity	-	59,337	-
Share premium	448,331	174,742	448,089
Reserves	10,539	6,837	6,719
Retained earnings	-322,827	-141,216	-273,941
Equity attributable to owners of the Company	139,499	101,118	184,323
Non-controlling interests			
Total equity	139,499	101,118	184,323
LIABILITIES			
Non-current interest-bearing liabilities	_	45,000	_
Leasing	5,644	2,512	6,281
Non-current non-interest-bearing liabilities	4,433	4,118	4,173
Provisions	5,021	4,475	4,547
Non-current liabilities	15,098	56,105	15,001
Current interest-bearing liabilities	-	119	12
Trade and other payables	43,650	36,227	21,097
Current tax liabilities	-	125	-
Other current liabilities	1,321	1,011	2,903
Leasing	3,063	1,896	3,144
Deferred income/revenue	108,724	97,564	112,460
Current liabilities	156,758	136,942	139,615
TOTAL LIABILITIES	171,856	193,047	154,617
TOTAL EQUITY AND LIABILITIES	311,354	294,165	338,940

# Consolidated cash flow statement

Amounts in SEK thousand	<b>2020</b> Q1	<b>2019</b> Q1	<b>2019</b> Full year
Cash flow from operating activities	QT	Qı	i uli yeai
· · · ·	40.007	00.040	400.007
Profit/loss before tax	-48,887	-33,313	-166,037
Adjustments for items not included in cash flow	-2,471	4,654	24,718
Paid income taxes	-	-	-
Total	-51,357	-28,659	-141,319
Increase (-)/Decrease (+) of inventories	-	-3,285	-
Increase (-)/Decrease (+) of trade and other receivables	-49,227	-39,965	-28,286
Increase (-)/Decrease (+) of trade and other payables	17,307	18,709	21,016
Cash flow from current operations	-83,277	-53,200	-148,589
Cash flow from investing activities			
Acquisition of property, plant and equipment	-42	-357	-1,187
Cash flow from investing activities	-42	-357	-1,187
Cash flow from financing activities			
New share issue	-	-	252,457
Transaction expense	-	-25	-33,430
Amortization of loan	-12	-35	-140
Amortization of lease liability	-798	-282	-2,846
Cash flow from financing activities	-810	-342	216,041
Cash flow for the period	-84,129	-53,899	66,265
Cash and cash equivalents at beginning of period	164,197	100,972	100,972
Exchange rate differences in cash and cash equivalents	4,402	-2,757	-3,039
Cash and cash equivalents at end of period	84,471	44,317	164,197

# Consolidated statement of changes in equity

Amounts in SEK thousand	Share capital	None -registered shares	Share premium	Translation reserve	Retained earnings	Total	Total equity
Balance at January 1,2020	3,456	-	448,089	6,719	-273,941	184,323	184,323
Total comprehensive income for the period							
Profit/loss for the period	-	-	-	-	-48,887	-48,887	-48,887
Other comprehensive income for the period	-	-	-	3,820	-	3,820	3,820
Total comprehensive income for the period	-	-	-	3,820	-48,887	-45,067	-45,067
Transactions with group shareholder							
Share savings program	-	-	242	-	-	242	242
Total contributions from and distributions to shareholders	-	-	242	-	-	242	242
Balance at March 31, 2020	3,456	-	448,331	10,539	-322,827	139,499	139,499

Amounts in SEK thousand	Share capital	None -registered shares	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	-	-	-	-	-33,313	-33,313	-33,313
Other comprehensive income for the period	-	-	-	1,289	-	1,289	1,289
Total comprehensive income for the period	-	-	-	1,289	-33,313	-32,024	-32,024
Transactions with the group's owner							
New share issue	-	59,337	-9,486	-	-	49,851	49,851
- New share issue	-	443	-	-	-	443	443
- Unregistered rights issue	-	58,893	-	-	-	58,893	58,893
- Transaction expenses	-	-	-9,486	-	-	-9,486	-9,486
Share savings program	-	-	221	-	-	221	221
Total contributions from and distributions to sharehol-							
ders	-	59,337	-9,265	-	-	50,072	50,072
Balance at March 31, 2019	1,419	59,337	174,742	6,837	-141 216	101,118	101,118

# Consolidated statement of changes in equity, cont.

	Share	None -registered	Share	Translation	Retained		Total
Amounts in SEK thousand	capital	shares	premium	reserve	earnings	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	-	-	-	-	-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 the group's owner							
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	-	-	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

# Income statement, Parent company

Amounts in SEK thousand	<b>2020</b> Q1	<b>2019</b> Q1	<b>2019</b> Full year
Revenues	-	-	-
Cost of goods sold	-	-	-
Gross profit	-	-	-
Other income	4,884	839	4,416
Selling and distribution expenses	-	-7	-
Administrative expenses	-5,769	-1,750	-21,595
Research and development expenses	-42,857	-23,082	-104,557
Other expenses	-1,899	-4,470	-10,090
Operating profit/loss	-45,641	-28,470	-131,825
Financial items			
Financial income	11	-	4
Financial expenses	-70	-414	-995
Net finance costs	-59	-414	-990
Profit/loss before tax	-45,700	-28,884	-132,815
Income tax expense	-	-	-
Total comprehensive income for the period	-45,700	-28,884	-132,815

# Parent company statement of comprehensive income

	2020	2019	2019
Amounts in SEK thousand	Q1	Q1	Full year
Profit/loss for the period	-45,700	-28,884	-132,815
Other comprehensive income	-	-	-
Total comprehensive income for the period	-45,700	-28,884	-132,815

# Balance Sheet, Parent company

Amounts in SEK thousand	03-31-2020	03-31-2019	12-31-2019
ASSETS			
Non-current assets Property, plant and equipment	3,254	4,631	3,697
Financial non-current assets			
Shares in group companies	105,638	100,783	102,319
Other non-current receivables	9,501	8,871	8,982
Total financial non-current assets	115,139	109,654	111,301
Total non-current assets	118,393	114,285	114,998
Current assets			
Current receivables			
Trade and other receivables	42,886	5	-
Receivables in group companies	-	20	-
Other receivables	2,881	60,950	2,962
Prepaid expenses and accrued income	84,710	79,473	77,752
Total current receivables	130,476	140,448	80,714
Cash and bank	83,701	36,887	163,601
Current assets	214,177	177,335	244,315
TOTAL ASSETS	332,570	291,620	359,313
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	3,456	1,419	3,456
Unregistered shares	-	59,337	-
Unrestricted equity			
Share premium	449,017	175,428	448,775
Retained earnings	-227,503	-94,688	-94,688
Profit/loss for the period	-45,700	-28,884	-132,815
Total equity	179,270	112,612	224,728
Non-current liabilities			
Non-current interest-bearing liabilities	-	45,000	-
Non-current non-interest-bearing liabilities	4,433	4,118	4,173
Non-current liabilities	4,433	49,118	4,173
Current liabilities			
Liabilities to subsidiaries	160	-	-
Trade and other payables	42,981	34,724	20,377
Other current liabilities	1,194	859	2,708
Deferred income/revenue	104,532	94,307	107,327
Current liabilities	148,867	129,890	130,412
TOTAL LIABILITIES	153,300	179,008	134,585
TOTAL EQUITY AND LIABILITIES	332,570	291,620	359,313

# Cash flow statement, Parent company

Amounts in SEK thousand	<b>2020</b> Q1	<b>2019</b> Q1	<b>2019</b> Full year
Cash flows from operating activities			
Earnings before income and tax	-45,700	-28,884	-132,815
Adjustments for items not included in cash flow	-3,829	4,104	6,706
Paid income taxes	-	-	-
Total	-49,529	-24,780	-126,109
Increase (-)/Decrease (+) of trade and other receivables	-50,282	-55,794	-46,015
Increase (-)/Decrease (+) of trade and other payables	18,811	23,267	24,510
Cash flow from current operations	-81,000	-57,307	-147,614
Cash flow from investing activities			
Investments in subsidiaries	-3,318	-	-1,536
Acquisition of property, plant and equipment	-42	-73	-565
Cash flow from investing activities	-3,360	-73	-2,101
Cash flow from financing activities			
New share issue	-	-	252,457
Transaction expense	-	-25	-33,430
Amortization of loan	-	-3,042	-3,042
Cash flow from financing activities	-	-3,067	215,985
Cash flow for the period	-84,360	-60,447	66,270
Cash and cash equivalents at beginning of period	163,601	100,380	100,380
Exchange rate differences in cash and cash equivalents	4,460	-3,046	-3,049
Cash and cash equivalents at end of period	83,701	36,887	163,601

# Noter

# Note 1 Accounting principles

This interim report 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. 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.

# Note 2 Segment reporting

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

Amounts in SEK thousand	<b>2020</b> Q1	<b>2019</b> Q1	<b>2019</b> Full year
Revenues per segment			. , ,
Biosimilars		-	-
Long-acting injectable drugs		352	-
Unallocated revenue	4,902	849	6,355
Total	4,902	1,201	6,355
Operating profit or loss per segment			
Biosimilars	-42,537	-23,082	-103,723
Long-acting injectable drugs	-2,060	-3,084	-30,261
Unallocated revenue	-4,084	-6,766	-30,637
Operating profit/loss	-48,681	-32,932	-164,620
Net finance costs			
Biosimilars	-114	-	-354
Long-acting injectable drugs	-33	-	-71
Unallocated revenue	-59	-381	-993
Total	-206	-381	-1,417
Profit/loss before tax	-48,887	-33,313	-166,037
Depreciation, amortization and write downs			
Biosimilars	1,071	680	3,624
Long-acting injectable drugs	470	910	20,068*
Unallocated revenue	113	105	441
Total	1,654	1,696	24,134

<sup>\*</sup> 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 1 2020	)	
	D: : :	Long-acting	Unallocated/	
Income per region	Biosimilars	injectable drugs	administration	Group
Middle East	-	-	-	-
Asia	-	-	-	-
Europe	-	-	4,848	4,848
United States	-	-	54	54
Total	-	-	4,902	4,902
Income per category				
Pharmaceuticals	-	-	-	-
Milestone payments from partners	-	-	-	-
Services and other	-	-	4,902	4,902
Total	-	-	4,902	4,902

Amounts in SEK thousand	Q 1 2019
	Long-acting

-	352	848	1,201
-	50	848	899
-	-	-	-
-	302	-	302
-	352	849	1,201
-	-	809	809
-	50	40	90
-	-	-	-
-	302	-	302
Biosimilars	Long-acting injectable drugs	Unallocated/ administration	Group
	- - - - -	Biosimilars injectable drugs - 302 50 352 - 302 50 - 50	Biosimilars injectable drugs administration - 302 50 40 809 - 352 849 - 302 50 848

#### Amounts in SEK thousand Full year 2019

		Long-acting	Unallocated/	
Income per region	Biosimilars	injectable drugs	administration	Group
Middle East	-	-	-	-
Asia	-	-	-39	-39
Europe	-	-	6,132	6,132
United States	-	-	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

### 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 42,883 thousand during the first quarter.

At the end of the period, Xbrane had a trade receivable towards STADA amounting to SEK 42,883 thousand, a non-current non-interest-bearing liability to STADA amounting to SEK 4,433 thousand as well as deferred income/revenue from STADA amounting to SEK 84,364 thousand.

### Note 5 Financial instruments

The below table shows the different valuation levels of the financial assets and liabilities that are reported at fair value in the consolidated balance sheet. For a description of how fair value has been calculated, see Note 26 in the 2019 Annual Report. All entries assessed at fair value are defined as being Level 2. The fair value of financial assets and liabilities to acquisition value or accrued acquisition value is estimated to correspond to book values in all material aspects.

The total value of the currency derivatives held shows a neutral value at the balance sheet date. During the first quarter, no transfers were made between the different valuation levels.

Group Amounts in SEK thousand	03-31-2020 Level 2	03-31-2019 Level 2	03-31-2019 Level 2
Financial assetss			
Other current receivables fordringar	101	-	24
Whereof currency deriatives	101	-	24
Total financial assets	101	-	24
Financial liabilities			
Other current payables	101	-	1,729
Whereof currency deriatives	101	-	1,729
Total financial liabilities	101	-	1,729

# 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, 13 May 2020

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

# 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 31 March 2020 and the three-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.

# Material uncertainty related to going concern

Without qualifying our Conclusion above, we draw attention to the company's disclosures in the quarterly report on page 8 which describes that the company expects that in addition to revenues from partnerships with third parties will also need further financing to cover financing needs of the operations over the next 12 months. As of the date of signing this report, the company was evaluting various financing alternative and as such the needed financing was not finalized. This indicates that there are material uncertainties as to the company's ability to continue as a going concern.

Stockholm 13 May 2020

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.

	2020	2019	2019
Amounts in SEK thousand	Q1	Q1	Full year
Gross profit	-	-	-18,271
Divided by revenues	-	-	-
Gross margin	N/A	N/A	N/A

#### **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.

	2020	2019	2019
Amounts in SEK thousand	Q1	Q1	Full year
Operating profit or loss	-48,681	-32,932	-164,620
Depreciation, amortization and write downs	-1,654	-1,696	-24,134
EBITDA	-47,027	-31,236	-140,487

# 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>2020</b> Q1	<b>2019</b> Q1	<b>2019</b> Full year
Research and development expenses	-44,597	-26,523	-115,713
Divided by total operating expenses minus depreciation and amortization	-51,930	-32,437	-148,627
Research and development expens-es as a percentage of operating expenses	85%	82%	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	03-31-2020	03-31-2019	12-31-2109
Total equity	139,499	101,118	184,323
Divided by total assets	311,354	294,165	338,940
Equity ratio	45%	34%	54%



# For further information

Martin Åmark, CEO/IR martin.amark@xbrane.com

Susanna Helgesen, CFO susanna.helgesen@xbrane.com

+ 46 76-309 37 77 www.xbrane.com

### Financial calendar

Annual General Meeting 2020 May 14, 2020
Interim report January-June 2020 August 21, 2020
Interim report January-September 2020 November 13, 2020
Year-end report 2020 February 26, 2021

