

Agreement with Biogen positions Xbrane as a leading global biosimilar developer

Financial overview first quarter 2022

- Revenue amounted to SEK 7.2 m (2.5).
- Other operating income was SEK 6.2 m (2.1).
- EBITDA was SEK –32.9 m (–46.8).
- R&D costs amounted to SEK –35.9 m (–45.4) representing 72 percent¹⁾ (84) of total operating costs.
- The net result for the period was SEK –36.1 m (–51.3).
- Earnings per share amounted to SEK –1.50 (–2.31).
- Cash and cash equivalents at the end of the period amounted to SEK 301.5 m (239.2).

Figures in parentheses refer to the corresponding period last year.

Significant events in the first quarter 2022

- In February, an agreement was signed with Biogen Inc. to be a development and commercialization partner for Xcimzane™, a biosimilar candidate for Cimzia®. According to the agreement, Xbrane will be responsible for the preclinical development, after which Biogen will take over and run and finance the remaining development, including clinical studies. Biogen will pay an up-front fee of USD 8 m, milestone payments of USD 80 m and royalties on future sales.
- Complete top-line data was also published from the Xplore clinical equivalence study for Xlucane™, a biosimilar candidate for Lucentis®. By Xbrane's assessment, Xlucane™ met the primary outcome measure and no clinically significant differences were observed regarding secondary efficacy and safety measures.
- Furthermore, the company announced in February that its subsidiary Primm Pharma had a positive cash flow through royalties from the licensing of IP and production equipment to its production partner ICI. Attempts to divest the subsidiary continue and dialogue with stakeholders is ongoing.

Significant events after the end of the quarter

- There were no significant events after the end of the quarter.

1) See page 9 for more information on research and development costs.

Financial summary for the Group

	2022 Jan – Mar	2021 Jan – Mar	2021 Jan – Dec
Revenue (SEK 000)	7,190	2,545	10,611
Research and development expenses (SEK 000)	-35,949	-45,363	-160,619
R&D expenses as percentage of total costs	72%	84%	82%
Operating profit/loss (SEK 000)	-36,782	-49,249	-180,583
EBITDA (SEK 000)	-32,898	-46,832	-168,366
Profit/loss for the period (SEK 000)	-36,122	-51,267	-188,376
Cash and cash equivalents (SEK 000)	301,459	239,244	295,180
Equity ratio (%)	59%	44%	63%
Number of shares at the end of period	25,039,906	22,200,415	25,039,906
Number of shares at the end of period after dilution	25,039,906	22,200,415	25,039,906
Average number of shares	25,039,906	22,200,415	23,593,291
Average number of shares after dilution	25,039,906	22,200,415	23,593,291
Earnings per share before dilution (SEK)	-1.50	-2.21	-7.77
Earnings per share after dilution (SEK)	-1.50	-2.21	-7.77
Number of employees on balance sheet date	64	42	58

About the operations

Xbrane Biopharma AB develops biological drugs based on a patented platform technology that provides significantly lower production costs compared to competing systems. Xbrane has a portfolio of biosimilar candidates that corresponds to SEK 332 bn¹⁾ in estimated annual sales of each reference drug.

Our leading product Xlucane™ is in the registration phase. Xbrane's head office is in Solna just outside Stockholm. Xbrane is listed on Nasdaq Stockholm under the ticker XBRANE. For more information, go to: www.xbrane.com.

1) See "Product candidate portfolio"



CEO's letter

Dear shareholders,

The focus of Q1 2022 was to complete and submit the Biologics License Application for Xlucane™ to the FDA, to respond to questions received from the EMA, and the licensing agreement with Biogen for Xcimzane™.

Regulatory process for Xlucane™

The Biologics License Application for Xlucane™ was submitted to the FDA at the end of March 2022. We are now closely following the regulatory processes for Xlucane™ in both Europe and the US. We will communicate if the FDA, after the validation process, accepts the application including and the so called PDUFA date, which is the date when the FDA is expected to decide on potential approval of the application. The Marketing Authorization Application was submitted to the EMA in September 2021, and we have now, in April, responded to the questions that were addressed to us as scheduled after day 120 of the registration process.

Biogen as partner in the development and commercialization of Xcimzane™

In Q1 we entered into a licensing agreement with Biogen for Xcimzane™. In accordance with the agreement, Xbrane will be responsible for running pre-clinical development, after which Biogen will take over and run and finance the remaining development, including the clinical studies and commercialization. The value of the deal with Biogen amounts to USD 80 m in milestone payments and a further USD 8 m paid upon signing the contract, as well as future royalties on sales. As the investment in the pre-clinical phase is limited, the deal is particularly attractive in terms of return on invested capital. Second, the deal allows us to focus on what we are best at, applying our patented platform technology in developing cost-effective biosimilar candidates. The agreement also validates, once again, our business model in pursuing high return on investments through similar licensing deals. We can now free-up resources for the oncology portfolio pushing the programs towards clinical development.

Key milestones in the coming 12-month period

We are in a very exciting position with the potential marketing authorization and launch of Xlucane™. Below are three of the most important milestones we look forward to reaching over the next 12 months:

- Obtain marketing authorization and launch Xlucane™ in Europe and the US
- Enter into further partnership agreements for the sales and marketing of Xlucane™
- Scale up the production process for Xcimzane™ and, in cooperation with Biogen, prepare for the start of clinical trials

With this significant agreement with Biogen, Xbrane has received further external validation of our unique patented platform technology for the development of cost-effective biological drugs, and we have established ourselves as one of the world's leading developers of biosimilars.

Finally, I want to thank my employees for a highly eventful quarter.

Thank you for your continued support.

Solna, May 5, 2022

Martin Åmark
CEO

Portfolio of product candidates

Xbrane has a portfolio of five active product candidates for a range of treatment areas. This includes a number of serious eye diseases, several different types of cancer and, among others, rheumatoid arthritis, psoriasis and Crohn's disease. Of the candidates, Xlucane™ is the closest to market approval.

Xlucane™

Xlucane™ is a biosimilar candidate for ranibizumab (original drug Lucentis®), a 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) and retinal vein occlusion (RVO). The VEGFa-inhibitors market had sales of more than SEK 119 bn^{1,2,3} in 2021 and grew by more than 14 percent^{1,2,3} this year.

In April 2019, Xbrane started the registration-based phase III trial, Xplore, a randomized, double-blind multi-center trial to assess the efficacy, safety, pharmacokinetics and immunogenicity of Xlucane™ for patients with wAMD compared with Lucentis®. The trial's primary measure of efficacy was the change in Best Corrected Visual Acuity (BCVA) at week eight. wAMD patients were randomized (1:1) and received monthly intravitreal injections of Xlucane™ or the reference product Lucentis® for one year. The trial, which was carried out in 15 countries at approximately 140 clinics, was fully recruited with 583 patients in November 2020, despite the ongoing pandemic.

Xlucane™ met the primary endpoint of efficacy in Xplore and showed equivalent efficacy measured in vision improvement at week eight after beginning treatment compared with the reference product Lucentis®. According to Xbrane's assessment, no clinically significant differences between Xlucane™ and Lucentis® could be observed in secondary measures of efficiency and safety.

Xbrane has signed a co-development agreement with STADA AG on the development and commercialization of Xlucane™ in Europe as well as a number of markets in the Middle East and the Asia-Pacific region. In 2020, Xbrane and STADA AG also signed an agreement with Bausch + Lomb that will commercialize Xlucane™ in North America.

STADA AG submitted an application for market approval to the EMA in September 2021.

Xcimzane™

Xcimzane™ is a biosimilar to certolizumab pegol (original drug Cimzia®), a TNF inhibitor used primarily in the treatment of rheumatoid arthritis and psoriasis. The market for TNF inhibitors had sales of around SEK 365 bn⁴ in 2021 and Cimzia® SEK 19 bn⁵ in 2021. Cimzia® patent protection is expected to expire in 2024 in the US and 2025 in Europe.

Xcimzane™ is now undergoing preclinical development, and a cost-efficient production process has been established. As the next step in production and upscaling, an agreement has been made with AGC Biologics Inc. to produce Xcimzane™ ahead of upcoming clinical trials. Xbrane has entered into a development and commercialization agreement with Biogen, in which Biogen receives full global rights to the product. The agreement requires that Biogen pay USD 8 m up front and a further USD 80 m in development and sales-based payments, in addition to royalties on the sales.

Xdivane™

Xdivane™ is a biosimilar to nivolumab (original drug Opdivo®), a PD1-inhibitor for the treatment of various cancers with sales of around SEK 68 bn⁶ in 2021. Opdivo® patent protection is expected to expire during 2026–2031, depending on the country.

Xdivane™ is undergoing preclinical 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.

Sources:

- 1) Novartis Annual Report 2021
- 2) Roche Annual Report 2021
- 3) Regeneron Year-end report 2021
- 4) Research and markets Global Tumor Necrosis Factor (TNF) Inhibitors Market 2018-2026: A \$181.13 Billion Market Opportunity by 2026
- 5) UCB Annual Report 2021
- 6) BMS Year-end report 2021
- 7) Merck Year-end report 2021

Xtrudane™

Xtrudane™ is a biosimilar candidate for pembrolizumab (original drug Keytruda®), a PD1-inhibitor for the treatment of various cancers with sales of around SEK 155 bn⁷⁾ in 2021. Keytruda® patent protection is expected to expire during 2029–2031, depending on the country. Xtrudane™ is undergoing preclinical 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.

Xdarzane™

Xdarzane™ is a biosimilar candidate for daratumumab (original drug Darzalex®), an antibody that binds to CD38 for the treatment of multiple myeloma with sales of around SEK 55 bn⁷⁾ in 2021. Darzalex® patent protection is expected to expire during 2029–2031, depending on the country.

Xdarzane™ is undergoing preclinical 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, sold for about SEK 3 bn⁹⁾. Xbrane is not actively developing Xoncane™ at present but is seeking a partner that can drive the development forward.

Spherotide

Spherotide is a long-acting formulation of triptorelin, a GnRH analog used in the treatment of prostate cancer, endometriosis, fibroids and breast cancer. The rights to Spherotide are owned by Xbrane's subsidiary Primm Pharma.

Xbrane is not actively developing Spherotide at present but is working to divest Primm Pharma.

Product portfolio

Produkt	Original drug	Primary indication	Estimated sales of original drug	Patent expiry of original drug	Development phase
Xlucane™	Ranibizumab (Lucentis®)	Wet age-related macular degeneration, diabetes-related eye damage and retinal vein occlusion.	SEK 33 bn ^{1,2,3)}	2022 (Europe) 2020 (USA)	Registration phase
Xcimzane™	Certolizumab pegol (Cimzia®)	Rheumatoid arthritis, axial spondylarthritis, psoriatic arthritis, psoriasis and Crohn's disease.	SEK 19 bn ⁴⁾	2024 (USA) 2025 ⁹⁾ (Europe)	Preclinical phase
Xdivane™	Nivolumab (Opdivo®)	Melanoma, lung cancer, kidney cell cancer, head and neck cancer and bladder and urinary tract cancer.	SEK 68 bn ⁵⁾	2026–2031 depending on country	Preclinical phase
Xtrudane™	Keytruda®	Brain cancer, melanoma, lung cancer, kidney cell cancer, head and neck cancer and bladder and urinary tract cancer.	SEK 155 bn ⁶⁾	2029–2031 depending on country	Preclinical phase
Xdarzane™	Darzalex®	Multipelt Myelom	SEK 55 bn ⁷⁾	2029–2031 depending on country	Preclinical phase

Products where no further development is being carried out

Xoncane™	Pegaspargase (Oncaspar®)	Acute lymphocytic leukemia.	SEK 3 bn ⁹⁾	Expired	Preclinical phase
Spherotide	Triptorelin (Decepeptyl®)	Prostate cancer, breast cancer, endometriosis and fibroids.	SEK 5 bn ⁹⁾	Expired	Preclinical phase

Sources:

- 1) Novartis Annual Report 2021
- 2) Roche Annual Report 2021
- 3) Regeneron Year-end report 2021
- 4) UCB Annual Report 2021
- 5) BMS Year-end report 2021
- 6) Merck Year-end report 2021
- 7) Johnson & Johnson Year-end report 2021
- 8) SERVIER Group financial year 2020 / 2021
- 9) Ipsen Year-end report 2021

Patent protection

An expanding patent portfolio provides opportunities to enter into strategic partnerships and strengthens the Xbrane brand. The most important regions for the protection of intellectual property (IP) are Europe and the US, but applications may also be made in other countries.

As Xbrane is an innovative Company that invests significantly in R&D, our goal is to file strategically important patent applications to protect its core technologies and products.

Expanding patent portfolio

The expanding patent portfolio will facilitate the implementation of our business strategies, such as licensing and strategic business partnerships or alliances to commercialize biosimilars and biosimilar production platforms.

Xbrane plans to file patent applications that protect a wide range of technologies, from protein production and purification to novel formulations of biosimilars.

The most important regions for patents are Europe and the US, but patent applications may also be filed in Canada, China, South Korea, India, Japan and Australia if

our products and methods have a market there. We are also applying for international patents to have further strategic alternatives in a large number of countries.

Xbrane's LEMO™ platform technology is patent protected in Europe and the US until 2029. In 2020 and 2021, the two patents which were filed in 2009 were complemented with a total of 23 pending patent applications "harvested" from five different development programs. Eleven of these patent applications were filed in 2020 and four of them were followed up in 2021 with international patent applications which provide provisional protection in 153 countries.

Strengthen the Xbrane brand

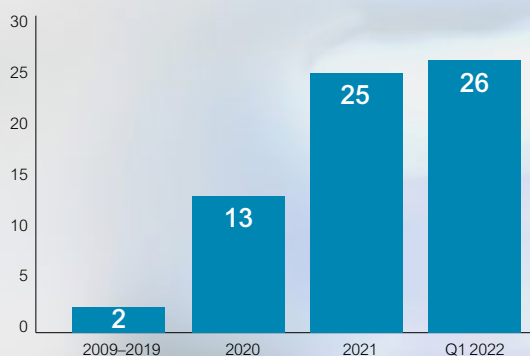
The Swedish Intellectual Property Office (PRV) granted eight patents in 2021. Three relate to DNA constructs for regulation protein production and were co-filed with CloneOpt AB. Five of the patents resulted from the

development of Xdivane™ and form the foundation for the emerging high-yield expression platform in mammalian cells upon which Xbrane will base much of its upcoming development of biosimilar candidates.

The patent applications protect certain novel sequences in the gene construct introduced in the host cells, instructing them to express the target protein. These DNA sequences have resulted in a significant increase in yield and can be applied for future biosimilar candidates expressed in mammalian cells. The rest of the patent applications relate primarily to DNA constructs, host cells and/or methods of producing Xlucane™ (2 patent applications) and Xcimzane™ (8 patent applications). The patent applications for the protection of Xlucane™ have been co-filed with STADA AG.

In the first quarter of 2022, another patent application was filed within the Xlucane project together with STADA AG. The expanding patent portfolio will strengthen Xbrane's brand, protect our own and our partners' products and enable more outlicensing of IP in the future.

Number of patents and patent applications (accumulated)



Shareholders

As of March 31, 2022, Xbrane had around 6,200 shareholders. The number of outstanding shares totaled 25,039,906. The ten largest shareholders at the end of the period are shown in the table below¹⁾.

Name	Number of shares	Ownership, %
Serendipity Group	3,177,367	12.7%
Swedbank Robur Fonder	2,313,881	9.2%
Bengt Göran Westman	2,035,416	8.1%
Futur Pension	1,587,991	6.3%
STADA Arzneimittel AG	1,570,989	6.3%
TIN Fonder	1,435,000	5.7%
Avanza Pension	811,433	3.2%
Swedbank Försäkring	365,138	1.5%
Nordnet Pensionsförsäkring	359,620	1.4%
Lancelot Asset Management AB	285,000	1.1%
Ten largest shareholders in total	13,941,835	55.7%
Other Swedish shareholders	8,631,307	34.5%
Other foreign shareholders	2,466,764	9.9%
Total outstanding shareholders	25,039,906	100%

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



Financial overview

Significant events first quarter

- In February, an agreement was signed with Biogen Inc. to be a development and commercialization partner for Xcimzane™, a biosimilar candidate for Cimzia®. According to the agreement, Xbrane will be responsible for the preclinical development, after which Biogen will take over and run and finance the remaining development, including clinical studies. Biogen will pay an up-front fee of USD 8 m, milestone payments of USD 80 m and royalties on future sales.
- Complete top-line data was also published from the Xplore clinical equivalence study for Xlucane™, a biosimilar candidate for Lucentis®. According to Xbrane's assessment, Xlucane™ met the primary outcome measure and no clinically meaningful differences were observed regarding secondary efficacy and safety measures.
- Furthermore, the company announced in February that its subsidiary Primm Pharma had a positive cash flow through royalties from the licensing of IP and production equipment to its production partner ICI. Attempts to divest the subsidiary continue and dialogue with stakeholders is ongoing.

Significant events after the end of the quarter

- There were no significant events after the end of the quarter.

Impact of the cooperation agreement with STADA AG

The cooperation agreement with STADA AG which started in July 2018 regarding the research and development of Xlucane™ entails that STADA AG and Xbrane will be equally responsible (50/50) for the research and development costs attributable to the project.

This means that until June 1, 2021, Xbrane reported its share of 50 percent of the total costs of the project in the balance sheet. After July 1, 2021, when the primary endpoint for efficacy was reached, Xlucane™ was deemed to meet the criteria for the capitalization of research and development costs. These are thereafter reported as intangible fixed assets in the balance sheet and thus are not charged to the income statement.

Assets and liabilities attributable to the project are reported in their entirety in Xbrane's balance sheet with a deduction of 50 percent for STADA AG's share of these. This applies to both the Group and parent company.

On the balance sheet date, Xbrane had a non-current non-interest-bearing liability to STADA AG amounting to SEK 0.0 m (4.2) as well as accrued expenses and deferred income from STADA AG amounting to SEK 63.1 m (107.0).

Impact of planned sale of Primm Pharma

Assets held for sale

Xbrane continues to work towards a sale of our subsidiary Primm Pharma. In the Q1 2021 report, Primm Pharma's assets and liabilities were reclassified respectively to "Assets held for sale" and "Liabilities attributable to assets held for sale" in the consolidated balance sheet.

The reclassification had some minor effects on a number of items in the balance sheet, which is expected as Primm Pharma is a minor part of the Group.

In the income statement, Primm Pharma's results are reported separately as "Profit/loss from discontinued operations". The reclassification has the effect of reversing Primm Pharma's previous income and reported net as "Profit/loss from discontinued operations". This also has an effect on previous reporting periods, which is why comparative figures no longer correspond to previous reports. In the cash flow, Primm Pharma's contribution to each activity is reported in the item "Of which from discontinued operations".

The Group's results for January – March 2022

The group's net sales amounted to SEK 7.2 m (2.5) and consists partly of income from the licensing of the American and Canadian rights for Xlucane™ to Bausch + Lomb as well as the newly signed agreement with Biogen regarding Xcimzane™. The income attributable to these agreements is accrued until May 2022 and June 2023, respectively. Similar agreements were classified as "other income" in previous periods, but since January 1, 2022, have been classified as "net sales" as this is seen as a more accurate reflection of the business. See Note 1 for more information about the reclassification.

Cost of goods sold amounted to SEK 0.0 m (0.0).

Other operating income amounted to SEK 6.2 m (2.1) and consists of license income from non-core operations and exchange rate gains on operating receivables and liabilities.

Research and development costs amounted to SEK -35.9 m (-45.4) and is primarily related to Xlucane™, wherein the biggest cost-drivers are the regulatory work and the establishment of a production chain for Xlucane™. Additional factors are the ongoing work with Xcimzane™, which has intensified, and work towards the development of new biosimilars. From July 1, 2021, all development costs for Xlucane™ have been capitalized as intangible fixed assets in the balance sheet, which for the period amounted to SEK 29.9 m (0.0). The gross effect of research and development costs for the period amounted to SEK -65.8 m (-45.4). The capitalization of development costs also has an effect on the comparative figures for research and development costs, which fell compared with previous periods. No retroactive capitalization was done relating to research and development costs accrued prior to July 1, 2021.

Administrative expenses amounted to SEK -7.9 m (-8.0).

Other operating expenses amounted to SEK -6.3 m (-0.5) and consisted of exchange rate losses on operating receivables and liabilities.

The operating loss amounted to SEK -36.8 m (-49.2). The loss before tax amounted to SEK -37.5 m (-49.1). During the quarter, there was no taxable profit and thus no tax expense (0.0). The loss after tax from continuing operations for the quarter amounted to SEK -37.5 m (-49.1) and the loss for the quarter amounted to SEK -36.1 m (-51.3). Earnings per share for continuing operations amounted to SEK -1.50 (-2.21) per share and earnings per share amounted to SEK -1.44 (-2.31).

The Group's cash flow January – March 2022

Cash flow from operating activities amounted to SEK 45.5 m (7.9). Changes in operating receivables and operating liabilities amounted to SEK 47.9 m (38.0) and SEK 26.8 m (19.1), respectively. Changes in working capital can vary greatly between the periods, mainly as a result of re-invoicing to STADA AG regarding development work for Xlucane™, including the ongoing clinical study, establishing a production chain and regulatory work. The ongoing work with Xcimzane™ has also intensified and therefore represents a portion of the change.

Cash flow from investment activities amounted to SEK –31.6 m (–8.8) and consisted partly of investments in tangible fixed assets for the internal laboratory as well as capitalization of research and development costs. From July 1, 2021 (see above) development costs for Xlucane™ have been reported as intangible fixed assets, which for the period had an effect on cash flow of SEK –29.9 m (0.0). Cash flow from financing activities amounted to SEK –1.9 m (–1.1) and relates to leasing of machines and premises.

The Group's financial position and continued operations

The Board and management continually monitor the Group's existing and projected cash flow to ensure that the Company has the financial resources needed to run the business according to the agreed plan, in a way that is optimal for both the Group and the shareholders.

On the balance sheet date, the Group's cash and cash equivalents amounted to SEK 301.5 m. Together with the up-front payment from Biogen of USD 8m and other liquidity-enhancing measures that are deemed possible if necessary, the Board considers that the Group has financing for at least 12 months ahead according to the current business plan.

Fixed assets

Fixed assets amounted to SEK 155.9 m (73.6), where the change is in large part explained by capitalization of research and development costs amounting to SEK 79.6 m (0.0). Capitalization of research and development costs was begun on July 1, 2021; no retroactive capitalization occurred for earlier periods. The remaining change to this item consists of acquisition of laboratory equipment, machines and inventory for the new office as well as typical monthly write-downs.

Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 133.8 m (79.4). The main items relate partly to advance payment to the CRO (Contract Research Organization) performing the clinical study of Xlucane™, amounting to SEK 27.0 m (42.9). Advance payment to the CMO (Contract Manufacturing Organization) which amounted to SEK 73.9 m (10.7) of which SEK 61.8 m (8.5) relates to upcoming upscaling activities. The reason for this increase is that lead times have increased with the suppliers, making for a longer initial process before work can begin. SEK 24.8 m (0.0) relates to an advance payment for collaboration with AGC Biologics Inc. to establish a manufacturing process.

Changes in equity

The share capital on the balance sheet date amounted to SEK 5.6 (5.0). Other capital contributions capital amounted to SEK 1,134.2 m (774.4). The change relates primarily to a share issue carried out in mid-2021, amounting to about SEK 380 m before transaction costs and share-based compensation. Total equity amounted to SEK 396.2 m (208.4) and the equity ratio was 59 percent (44).

Accounts payable

Accounts payable amounted to SEK 23.1 m (49.3) and the change is partly attributable to reduced activity in the clinical study and lower development costs relating to Xlucane™, as most of these costs were already recovered in previous periods.

Accrued expenses and prepaid income

Accrued expenses and prepaid income amounted to SEK 203.9 m (150.8) and partly relates to advance payments from STADA AG for Xlucane™ of SEK 63.1 m (107.0). Furthermore, SEK 49.8 m (21.6) relates to work performed that has not yet been invoiced, regarding the Xlucane™ project. The up-front payment from Biogen has been accrued until the end of Q2 2023 and amounts to SEK 69.7 m (0.0). The remaining portion relates to other items amounting to SEK 21.3 m (22.2).

Parent company

Xbrane's core business, which is the development of biosimilars, is run by the parent company. The Group is still working on the ongoing divestment of the subsidiary Primm Pharma. Xbrane has already written down shares in the subsidiary by SEK 49.0 m and the impairment assessment is not considered to have changed during the current financial period.

As the parent company constitutes such a large part of the Group, an account in text format of the parent company's earnings, financial position and cash flow would not provide any further information to that described in the report on the Group. Therefore, this is only presented in report format on pages 18–20.

Risks and uncertainties

Risks and uncertainties are described on pages 29–30 of the Annual Report of 2021, which is available on the company's website, www.xbrane.com. At the time of publication of this interim report, these have not changed significantly.

Share information

Xbrane's share capital at the end of the period was SEK 5.6 m (5.0) divided into 25,039,906 shares (22,200,415).

The quota value of all shares is SEK 0.224, and all the shares have equal rights to the company's assets and earnings. Since September 23, 2019, Xbrane's shares have been listed on the Nasdaq OMX main list under the XBRANE ticker. Xbrane had around 6,200 shareholders on the balance sheet date. The closing price of the share on the balance sheet date was SEK 103.8 generating a market capitalization of about SEK 2,599 m.

Organization and employees

Xbrane is headquartered at Campus Solna, outside of 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. As mentioned earlier, the sale of the subsidiary is ongoing. On the balance sheet date, the Group had 64 (51) employees, 64 (45) of whom were employed by the parent company and 0 (6) by the subsidiary Primm Pharma.

Presentation of interim report

Presentation of the interim report for January–March 2022 will take place digitally on May 5 at 11:00 CET, where CEO Martin Åmark and CFO Anette Lindqvist will present the interim report. The presentation will be held in English and is expected to last about 20 minutes, after which there will be an opportunity for questions.

To take part in the presentation, follow the link below:

<https://edge.media-server.com/mmc/p/phmnzgvw>

Annual General Meeting

The Annual General Meeting 2022 will be held on May 5, 2022, in Baker McKenzie's premises at Vasagatan 7 in Stockholm. The Board proposes that no dividend be paid for the financial year 2021.

Auditor's review

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

Consolidated income statement

Amounts in SEK thousand	Notes	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Revenues	2,3	7,190	2,545	10,611
Cost of goods sold		–	–	–
Gross profit		7,190	2,545	10,611
Other operating income	2,3	6,176	2,102	4,946
Administrative expenses		–7,918	–7,988	–31,395
Research and development expenses		–35,949	–45,363	–160,619
Other operating expenses		–6,281	–545	–4,126
Operating profit/loss	2	–36,782	–49,249	–180,583
Financial income		–	512	–
Financial expenses		–731	–361	–2,643
Net financial costs	2	–731	151	–2,643
Profit/loss before tax		–37,513	–49,098	–183,226
Tax		–	–	–
Profit/loss for the period from continuing operations		–37,513	–49,098	–183,226
Profit/loss from discontinued operations		1,391	–2,169	–5,150
Profit/loss for the period		–36,122	–51,267	–188,376
Profit/loss for the period attributable to:				
– Owners of the Company		–36,122	–51,267	–188,376
– Non-controlling interests		–	–	–
Total comprehensive income for the period		–36,122	–51,267	–188,376
Earnings per share from continuing operations				
– Before dilution (SEK)		–1.50	–2.21	–7.77
– After dilution (SEK)		–1.50	–2.21	–7.77
Earnings per share				
– Before dilution (SEK)		–1.44	–2.31	–7.98
– After dilution (SEK)		–1.44	–2.31	–7.98
Number of outstanding shares at the end of the reporting period				
– Before dilution		25,039,906	22,200,415	25,039,906
– After dilution		25,039,906	22,200,415	25,039,906
Average number of outstanding shares				
– Before dilution		25,039,906	22,200,415	23,593,291
– After dilution		25,039,906	22,200,415	23,593,291

Consolidated income statement and other comprehensive income

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Profit/loss for the period	-36,122	-51,267	-188,376
Other comprehensive income			
Items that have been transferred to, or can be transferred to, the profit/loss for the year			
Reclassification of foreign currency translation differences	749	1,259	1,220
Comprehensive income for the period	749	1,259	1,220
Total comprehensive profit/loss attributable to:			
– Owners of the Company	-35,372	-50,009	-187,156
– Non-controlling interests	–	–	–
Total comprehensive income for the period	-35,372	-50,009	-187,156

Consolidated statement of financial position

Amounts in SEK thousand	03-31-2022	03-31-2021	12-31-2021
ASSETS			
Intangible assets	79,604	–	49,672
Property, plant and equipment	30,544	13,375	30,622
Right of use assets	41,020	47,421	43,180
Long-term receivables	4,725	12,770	3,945
Non-current assets	155,893	73,566	127,418
Accounts receivables	–	611	–
Other receivables	14,130	8,417	50,253
Prepaid expenses and accrued income	133,793	79,415	147,027
Cash and cash equivalents	301,459	239,244	295,180
Assets held for sale	70,453	72,501	68,548
Current assets	519,836	400,187	561,008
TOTAL ASSETS	675,729	473,754	688,427
EQUITY			
Share capital	5,614	4,977	5,614
Other contributed capital	1,134,156	774,395	1,134,276
Reserves	5,914	5,203	5,165
Retained earnings including profit/loss for the year	–749,435	–576,205	–713,313
Equity attributable to parent company's owners	396,249	208,370	431,741
Non-controlling interests	–	–	–
Total equity	396,249	208,370	431,741
LIABILITIES			
Leasing liabilities	34,426	40,793	36,476
Long-term non-interest-bearing liabilities	–	8,337	543
Total long-term liabilities	34,426	49,130	37,019
Accounts payable	23,082	49,339	41,393
Other liabilities	8,929	1,573	9,757
Leasing liabilities	8,022	6,995	7,905
Accrued expenses and prepaid income	203,989	150,764	159,355
Liabilities attributable to assets held for sale	1,032	7,583	1,257
Total short-term liabilities	245,054	216,254	219,667
TOTAL LIABILITIES	279,480	265,384	256,686
TOTAL LIABILITIES AND EQUITY	675,729	473,754	688,427

Consolidated statement of changes in equity

Amounts in SEK thousand	Share Capital	Other contributed capital	Translation reserve	Retained earnings incl. profit/loss for the period	Total
Opening balance January 1, 2022	5,614	1,134,276	5,165	-713,313	431,741
Total comprehensive income for the period					
Profit/loss for the period				-36,122	-36,122
Other comprehensive income for the period			749		749
Total comprehensive income for the period	-	-	749	-36,122	-35,372
Transactions with group shareholder					
New share issue					
Issue expenses					
Share savings program		-120			-120
Total contributions from and distributions to shareholders	-	-120	-	-	-120
Closing balance March 31, 2022	5,614	1,134,156	5,914	-749,435	396,249

Amounts in SEK thousand	Share Capital	Other contributed capital	Translation reserve	Retained earnings incl. profit/loss for the period	Total
Opening balance January 1, 2021	4,977	773,724	3,945	-524,938	257,709
Total comprehensive income for the period					
Profit/loss for the period				-51,267	-51,267
Other comprehensive income for the period			1,259		1,259
Total comprehensive income for the period	-	-	1,259	-51,267	-50,009
Transactions with group shareholder					
Share savings program		671			671
Total contributions from and distributions to shareholders	-	671	-	-	671
Closing balance March 31, 2021	4,977	774,395	5,203	-576,205	208,370

Amounts in SEK thousand	Share Capital	Other contributed capital	Translation reserve	Retained earnings incl. profit/loss for the period	Total
Opening balance January 1, 2021	4,977	773,724	3,945	-524,938	257,709
Total comprehensive income for the period					
Profit/loss for the period				-188,376	-188,376
Other comprehensive income for the period			1,220		1,220
Total comprehensive income for the period	-	-	1,220	-188,376	-187,156
Transactions with group shareholder					
New share issue	633	380,237			380,870
Issue expenses		-24,231			-24,231
Share savings program	4	4,547			4,551
Total contributions from and distributions to shareholders	637	360,552	-	-	361,189
Closing balance December 31, 2021	5,614	1,134,276	5,165	-713,313	431,741

Consolidated cash flow statement

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Cash flow from operating activities			
Profit/loss for the period before tax	–36,122	–51,267	–188,376
Adjustments for items not included in cash flow	6,921	2,086	7,180
Paid income taxes	–	–	–
Total	–29,200	–49,181	–181,195
Increase (–)/Decrease (+) of trade and other receivables	47,880	38,029	–61,086
Increase (+)/Decrease (–) of trade and other payables	26,792	19,098	22,671
Cash flow from current operations	45,472	7,946	–219,610
<i>Of which discontinued operations</i>	656	–1,992	–10,401
Cash flow from investing activities			
Acquisition of property, plant and equipment	–1,646	–8,747	–27,678
Acquisition of intangible assets	–29,932	–	–49,672
Cash flow from investing activities	–31,578	–8,747	–77,350
<i>Of which discontinued operations</i>	–	–	–
Cash flow from financing activities			
New share issue	–	–	380,870
Issue expenses	–	–	–24,231
Amortization of lease liability	–1,933	–1,144	–7,273
Cash flow from financing activities	–1,933	–1,144	349,366
<i>Of which discontinued operations</i>	–	–99	–529
Cash flow for the period	11,960	–1,945	52,406
Cash and cash equivalents reported in assets held for sale	–2,437	–896	–1,758
Cash and cash equivalents at beginning of period	295,180	243,139	243,139
Cash and cash equivalents at beginning of period (reported in assets held for sale)	1,758	–	–
Exchange rate differences in cash and cash equivalents	–5,003	–1,053	1,393
Cash and cash equivalents at end of period	301,459	239,244	295,180

Income statement, Parent company

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Revenues	7,190	2,545	10,611
Cost of goods sold	–	–	–
Gross profit	7,190	2,545	10,611
Other operating income	6,176	2,102	4,946
Administrative expenses	–8,249	–8,146	–32,525
Research and development expenses	–36,030	–45,391	–160,916
Other operating expenses	–6,281	–545	–4,126
Operating profit/loss	–37,195	–49,435	–182,011
Financial items			
Financial income	–	512	–
Impairment loss on shares in subsidiary	–	–4,554	–10,631
Financial expenses	–90	–71	–276
Net finance costs	–90	–4,113	–10,908
Profit/loss before tax	–37,285	–53,547	–192,918
Tax	–	–	–
Profit/loss for the period	–37,285	–53,547	–192,918

Income statement and other comprehensive income, Parent company

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Profit/loss for the period	–37,285	–53,547	–192,918
Other comprehensive income	–	–	–
Comprehensive income for the period	–37,285	–53,547	–192,918

Balance sheet, Parent company

Amounts in SEK thousand	03-31-2022	03-31-2021	12-31-2021
ASSETS			
Fixed assets			
Intangible assets	79,604	–	49,672
Property, plant and equipment	30,544	13,375	30,622
Financial assets			
Shares in group companies	74,066	74,066	74,066
Other non-current receivables	4,725	12,770	3,945
Total financial assets	78,791	86,836	78,011
Total non-current assets	188,939	100,211	158,304
Current assets			
Current receivables			
Accounts receivables	–	611	–
Other receivables	14,130	8,417	50,253
Prepaid expenses and accrued income	133,793	79,415	147,027
Total current receivables	147,924	88,443	197,280
Cash and bank	301,459	239,244	295,180
Current assets	449,383	327,687	492,460
TOTAL ASSETS	638,322	427,898	650,764
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	5,614	4,977	5,614
Reserve for development expenditure	79,604	–	49,672
Unrestricted equity			
Share premium	1,134,842	775,081	1,134,962
Retained earnings	–781,411	–508,889	–558,561
Profit/loss for the period	–37,285	–53,547	–192,918
Total equity	401,363	217,622	438,769
Long-term liabilities			
Long-term non-interest-bearing liabilities	–	8,337	543
Total long-term liabilities	–	8,337	543
Current liabilities			
Liabilities to subsidiaries	958	263	948
Accounts payables	23,082	49,339	41,393
Other current liabilities	8,929	1,573	9,757
Deferred income and prepaid revenue	203,989	150,764	159,355
Current liabilities	236,958	201,939	211,453
TOTAL LIABILITIES	236,958	210,276	211,996
TOTAL EQUITY AND LIABILITIES	638,322	427,898	650,764

Cash flow statement, Parent company

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Cash flows from operating activities			
Profit/loss for the period before tax	–37,285	–53,547	–192,918
Adjustments for items not included in cash flow Paid income taxes	4,552	2,950	12,968
Paid income taxes	–	–	–
Total	–32,733	–50,597	–179,950
Increase (–)/Decrease (+) of trade and other receivables	48,575	40,866	–59,147
Increase (+)/Decrease (–) of trade and other payables	27,062	19,193	24,275
Cash flow from current operations	42,904	9,462	–214,821
Cash flow from investing activities			
Investments in subsidiaries	–	–4,554	–10,631
Acquisition of property, plant and equipment	–1,646	–8,747	–29,939
Acquisition of intangible assets	–29,932	–	–49,672
Cash flow from investing activities	–31,578	–13,301	–90,243
Cash flow from financing activities			
New share issue	–	–	380,870
Issue expenses	–	–	–24,231
Cash flow from financing activities	–	–	356,638
Cash flow for the period	11,326	–3,839	51,573
Cash and cash equivalents at beginning of period	295,180	242,247	242,247
Exchange rate differences in cash and cash equivalents	–5,046	835	1,360
Cash and cash equivalents at end of period	301,459	239,244	295,180

Notes

NOTE 1 Accounting principles

This consolidated interim report for the Group 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 Reports. For the Group and the parent company the same accounting principles and calculation bases as the previous annual report have been applied with the exception of the changed or additional accounting principles described below. Information according to IAS 34.16A is included in these financial statements and related notes as well in other parts of this interim report.

Licensing income

In order to present relevant information that more accurately reflects Xbrane's core business, licensing income attributable to activities within biosimilars is reported as operating income in the income statement. Income from the concluded licensing agreement with Bausch + Lomb is thereby reclassified as revenue and a part of ordinary activities. In previous periods, Xbrane has reported licensing income attributable to activities within biosimilars as other operating income in the income statement. The change to this accounting principle has been applied retroactively and the comparison periods for 2021 have been recalculated for the Group. This means that comparative figures no longer align with previously published financial reports.

STADA AG

In order to present relevant information that more accurately reflects Xbrane's core business, receivables related to our partner STADA AG have been reclassified as other receivables in the balance sheet. STADA AG receivables relate primarily to ongoing research and development costs for Xlucane™. In previous periods, receivables related to STADA AG were classified as accounts receivable in the balance sheet. The change to this accounting principle has been applied retroactively and the comparison periods for 2021 have been recalculated for the Group. This means that comparative figures no longer align with previously published financial reports.

Operating segment

In Q1 2022 Xbrane carried out a strategic review with the result that segment reporting was updated and will include the segment "Commercialization, Biosimilar development and Unclassified." The segment was identified based on the internal reporting presented to the Company's chief operating decision-maker. The segments are defined according to the following:

- **Commercialization:** Developed biosimilars that are in a commercialization phase and have thus undergone the development stage and requisite clinical trials.
- **Biosimilar development:** Comprises biosimilars that have not yet undergone the requisite development phases and clinical trials.
- **Unclassified:** The segment comprises other activities within the company that are not included in the above segments.

Monitoring of the segment is not carried out for assets and liabilities at the segment level but instead appears in the income statement.

NOTE 2 Segment reporting

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

Amounts in SEK thousand	2022	2021	2021
	Jan – Mar	Jan – Mar	Full year
Revenues by segment			
Commercialization	2,545	2,545	10,181
Biosimilar development	4,645	–	528
Unclassified	6,176	2,102	4,848
Total	13,366	4,647	15,557
Operating profit or loss by segment			
Commercialization*	–4,201	–29,501	–78,780
Biosimilar development	–25,529	–15,738	–71,130
Unclassified	–7,052	–4,010	–30,673
Operating profit/loss	–36,782	–49,249	–180,583
Net finance costs			
Commercialization	–160	–87	–852
Biosimilar development	–352	–203	–1,515
Unclassified	–219	441	–276
Total	–731	151	–2,643
Profit/loss before tax*	–37,513	–49,098	–183,226
Depreciation, amortization and write downs			
Commercialization	–1,107	1,309	5,358
Biosimilar development	–2,435	436	5,411
Unclassified	–342	208	1,448
Total	–3,884	1,952	12,217

* From 1 July 2021, parts of Research & Development were activated.

NOTE 3 Distribution of income

Amounts in SEK thousand	Jan – Mar 2022		
	Commercialization	Biosimilar development	Unclassified
Revenues by region			
Europe	–	–	804
USA	2,545	4,645	5,372
Others	–	–	–
Total	2,545	4,645	6,176
Revenues by category			
Commercial products	–	–	–
Outlicensing / partnership	2,545	4,645	–
Services and other	–	–	6,176
Total	2,545	4,645	6,176

NOTE 3 Distribution of income cont.

Amounts in SEK thousand	Jan – Mar 2021		
	Commercialization	Biosimilar development	Unclassified
Revenues by region			
Europe	–	–	1,861
USA	2,545	–	–
Others	–	–	241
Total	2,545	–	2,102
Revenues by category			
Commercial products	–	–	–
Outlicensing / partnership	–	–	–
Services and other	2,545	–	2,102
Total	2,545	–	2,102

Amounts in SEK thousand	Full year 2021		
	Commercialization	Biosimilar development	Unclassified
Revenues by region			
Europe	–	–	4,848
USA	10,181	528	–
Others	–	–	–
Total	10,181	528	4,848
Revenues by category			
Commercial products	–	–	–
Outlicensing / partnership	10,181	–	–
Services and other	–	528	4,848
Total	10,181	528	4,848

NOTE 4 Transactions with related parties

Since 2019, STADA Arzneimittel AG has been a shareholder in Xbrane (see the list of owners on page 8). Transactions with STADA relate to shared costs for the collaboration agreement with Xlucane™.

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, May 5, 2022

Anders Tullgren
Chairman of the Board

Eva Nilsagård
Board member

Peter Edman
Board member

Mats Thorén
Board member

Karin Wingstrand
Board member

Giorgio Chirivi
Board member

Ivan Cohen-Tanugi
Board member

Martin Åmark
CEO

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

The gross margin is a measure that the Group considers important for understanding the products' profitability. The gross margin is calculated as gross profit in relation to the Revenue. The gross profit is Revenue minus cost of goods sold.

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Gross profit	7,190	2,545	10,611
Gross margin	100%	100%	100%

EBITDA

EBITDA is a measure that the Group considers relevant for an investor who wants to understand profit generation before investing in fixed assets. EBITDA shows the business's earning capacity from cash flow from operating activities without regard to capital structure and tax situation and is intended to facilitate comparisons with other companies in the same industry.

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Operating profit / loss	-36,782	-49,249	-180,583
Depreciation and impairment	-3,884	-2,416	-12,217
EBITDA	-32,898	-46,832	-168,366

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. Total operating expenses comprise of selling and distribution expenses, administrative expenses, research and development expenses and other operating expenses.

Amounts in SEK thousand	2022 Jan – Mar	2021 Jan – Mar	2021 Full year
Research and development expenses	-35,949	-45,363	-160,619
Operating expenses	-50,148	-53,896	-196,140
Research and development expenses as a percentage of operating expenses	72%	84%	82%

Equity ratio

The equity ratio is a measure that the Group considers relevant for an investor who wants to understand the distribution between equity and liabilities. The equity ratio consists of the proportion of assets that are financed with equity to show the company's long-term ability to pay, i.e., equity through total assets.

Amounts in SEK thousand	03-31-2022	03-31-2021	12-31-2021
Total equity	396,249	208,370	431,741
Divided by total assets	675,729	473,754	688,427
Equity ratio	59%	44%	63%



For further information

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Financial calendar

Annual General Meeting 2022	May 5, 2022
Interim report January – June 2022	July 22, 2022
Interim report January – September 2022	October 28, 2022
Year-end report 2022	February 17, 2023
Annual report 2022	March 31, 2023



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This information is information that Xbrane Biopharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the CEO, for publication on 02-24-2022, 08:00 CEST.