

The positive interim read-out from the phase III study Xplore paves way for marketing authorization application submission of Xlucane™ in 2021

Financial summary second quarter 2021

- Revenue amounted to SEK 2.5m (0,0).
- Other operating income was SEK 3.6m (5.3).
- EBITDA was SEK -54.8m (-51.6).
- R&D costs amounted to SEK -51.7m (-45.1), representing 83% (77) of total operating costs.
- The loss for the period was SEK -59.2m (-53.4).
- Earnings per share amounted to SEK -2.67 (-3.11).
- Cash and cash equivalents at the end of the period amounted to SEK 129.3m (232.5).

Financial summary first six months 2021

- Revenue amounted to SEK 2.5m (0.0).
- Other operating income was SEK 7.7m (10.2).
- EBITDA was SEK -103.8m (-101.5).
- R&D costs amounted to SEK -97.8m (-92.6), representing 83% (81) of total operating costs.
- The loss for the period was SEK -110.4m (-105.2).
- Earnings per share amounted to SEK -4.97 (-6.12).
- Cash and cash equivalents at the end of the period amounted to SEK 129.3m (232.5).

Significant events during the second quarter 2021

- Xbrane held a virtual capital markets day in May and announced its ambition of generating a positive operating cash flow monthly through the net income from Xlucane™ at the end of 2023/beginning of 2024 and to initiate one new development project per year.
- In June, top-line data was obtained from an interim read-out of the ongoing Phase III equivalence study Xplore with the Lucentis® biosimilar candidate Xlucane™. Xlucane™ reached the primary endpoint and demonstrated equivalent efficacy with Lucentis® in terms of change of BCVA (Best Corrected Visual Acuity) at the eighth week of treatment. The company then confirmed the plan to submit the marketing authorization application to the European Medicines Agency (EMA) during Q3 2021 and to the US Food and Drug Administration (FDA) in Q4 2021 on the basis of the interim read-out.
- With the support of the authorization at the Annual General Meeting on May 6, 2021, Xbrane announced and implemented a directed new issue of SEK 380m at a subscription price of SEK 135 per share, at the end of June. The shares were registered and payment received in July, so the effects in the balance sheet and cash flow will not be seen until the next interim report for July-September 2021.

More detailed information on the above events can be found on page 7.

Significant events after the end of the quarter

- Xbrane Biopharma was officially certified as a Great Place to Work® by the Great Place to Work® Institute.

Financial summary for the Group

	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Revenue (SEK 000)	2,486	–	2,486	–	–
Research and development expenses (SEK 000)	–51,749	–45,099	–97,769	–92,642	–203,301
R&D expenses as percentage of total costs	83	77	83	81	83
Operating profit/loss (SEK 000)	–58,413	–53,197	–109,823	–104,825	–225,257
EBITDA (SEK 000)	–54,788	–51,573	–103,781	–101,547	–218,691
Profit/loss for the period (SEK 000)	–59,168	–53,397	–110,435	–105,231	–226,026
Cash and cash equivalents (SEK 000)	129,332	232,506	129,332	232,506	243,139
Equity ratio (%)	39	44	39	44	56
Number of shares at the end of period	22,222,206	19,280,707	22,222,206	19,280,707	22,200,415
Number of shares at the end of period after dilution	22,222,206	19,280,707	22,222,206	19,280,707	22,200,415
Average number of shares	22,200,654	17,195,806	22,200,535	17,195,806	18,113,313
Average number of shares after dilution	22,200,654	17,195,806	22,200,535	17,195,806	18,113,313
Earnings per share before dilution (SEK)	–2.67	–3.11	–4.97	–6.12	–12.48
Earnings per share after dilution (SEK)	–2.67	–3.11	–4.97	–6.12	–12.48
Number of employees on balance sheet date	60	42	60	42	42

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's leading product Xlucane™ is a biosimilar candidate to the original drug Lucentis® aimed at the market for ophthalmic VEGFa-inhibitors which amounts to around SEK 106bn^{1,2,3}. Marketing authorization for Xlucane™ is expected for the second half of 2022. Xbrane has a further two biosimilar candidates in the pipeline aimed at a market where sales of the original product are worth SEK 80bn.

1) Novartis Annual Report 2020 (Lucentis® and Beovu®)

2) Roche Annual Report 2020 (Lucentis®)

3) Regeneron Annual Report 2020 (Eylea®)

CEO's letter



Dear shareholders,

The second quarter of 2021 was an eventful quarter for Xbrane. We received positive top-line data from the interim read-out of Xplore - the ongoing phase III study with Xlucane™ - and thus confirmed the timetable for submitting the marketing authorization application to the EMA (Europe) and FDA (USA) in the third and fourth quarters of 2021. We also carried out a directed share issue of SEK 380m, with strong support from our largest shareholders. This enables us to drive the business forward in line with our strategy.

Positive top-line data from the interim read-out of Xplore

During Q2, an interim read-out was carried out from the ongoing phase III study Xplore, aimed at demonstrating the equivalent efficacy and safety of Xlucane™ compared to Lucentis®. The interim read-out includes data from all patients with up to six months of treatment. We were pleased to note that Xlucane™ achieved the primary endpoint and showed equivalent efficacy measured in best corrected visual acuity (BCVA) at week eight compared with Lucentis®. Equivalence was shown when the two-sided 95% confidence interval around the difference in the improvement of BCVA at week eight between Xlucane™ and Lucentis® was within the predefined equivalence margin agreed with the EMA and FDA. Furthermore, no clinically meaningful differences between Xlucane™ and Lucentis® were observed in secondary measures at month six.

Marketing authorization application to the EMA in September

The marketing authorization application for Xlucane™ is largely complete and will be submitted to the EMA (Europe) in September. The application to the FDA (USA) is expected to be submitted during Q4, but the schedule will be confirmed in a meeting with the FDA later in August. The application will be supplemented with the full study report, including 12 months of treatment data from all patients, which is expected to be completed during Q1 2022.

Ambition to become a world-leading biosimilar developer

The biosimilar market is one of the most rapidly expanding segments in the pharmaceutical industry with a number of important patents expiring in the coming decade. We have a unique opportunity with our patented platform technology, dedicated team and newly-established development lab, to become a world-leading developer of biosimilars. At our capital markets day in May, we announced that our plan is to start one new development program per year and generate a positive operating cash flow towards the end of 2023/ beginning of 2024 based on the expected income generated from Xlucane™.

Key milestones in the coming 12-month period

Xbrane has many key milestones to deliver over the next 12-month period, mainly to:

- Apply for marketing authorization in Europe and the US for Xlucane™
- Sign agreements with additional partners for the sales and marketing of Xlucane™
- Upscale the production process for Xcimzane™ and prepare for the start of clinical trials
- Establish partners for the commercialization of Xcimzane™ in Europe and/or the US.

Finally, I would like to say a big thank you to our employees and shareholders who have made it possible for Xbrane to take these important steps in its development. We are all very enthusiastic about Xbrane's journey towards becoming a world-leading biosimilar developer and with our unique patented platform technology, will develop cost-effective biosimilars for the benefit of patients around the world.

Thank you for your continued support,

Martin Åmark, CEO

Solna, August 12, 2021

Product candidate portfolio

Xlucane™

Xlucane™ is a biosimilar candidate to ranibizumab (original drug Lucentis®), known as 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 saw sales of over SEK 106bn^{1,2,3} in 2020 and has grown by over 10% annually in recent years^{1,2,3}, although a marginal decline was noted in 2020 due to Covid-19.

In April 2019, Xbrane initiated the pivotal phase III study Xplore, a randomized, double-blind multicenter study evaluating the efficacy, safety, pharmacokinetics and immunogenicity of Xlucane™ in patients with wAMD compared to Lucentis®. The primary endpoint in the study is a change in BCVA (Best Corrected Visual Acuity) at week eight. wAMD patients were randomized (1: 1) and receive monthly injections of Xlucane™ into the eye, or the reference product Lucentis® for one year. The study, which is being conducted in 15 countries at around 140 clinics, was fully recruited with 583 patients in November 2020, despite the ongoing Covid-19 pandemic. Xlucane™ showed positive phase III top-line data from a completed interim read-out in June. Xbrane will, in agreement with the EMA and FDA, submit a marketing authorization application for Xlucane™ in Europe and the US on the basis of the interim read-out and will be supplemented later with full data from the study during the registration procedure.

Xbrane has a collaboration agreement with STADA GmbH for the development, sales and marketing of Xlucane™ in Europe and a number of markets in the Middle East and Asia-Pacific region. Last year, Xbrane and STADA signed an agreement with Bausch + Lomb, which will commercialize Xlucane™ in North America.

Xcimzane™

Xcimzane™ is a biosimilar candidate to certolizumab pegol (original drug Cimzia®), a so-called TNF-inhibitor particularly

used in the treatment of rheumatoid arthritis, psoriasis and Crohn's disease. The TNF-inhibitor market saw sales of about SEK 240bn⁴ in 2018 and Cimzia® saw sales of SEK 19bn⁵ in 2020. The patent protection of Cimzia® is expected to expire in 2024 in the US and 2025 in Europe. Xcimzane™ is undergoing pre-clinical development and a cost-effective production process has been established. Then, upscaling and planning with a production partner will follow, after which the product can commence clinical trials.

Xdivane™

Xdivane™ is a biosimilar candidate to nivolumab (original drug Opdivo®), a PD1-inhibitor for the treatment of different types of cancer with a turnover of around SEK 64bn in 2020⁶. Opdivo® is expected to lose its patent protection between 2026 and 2031, depending on the country. Xdivane™ is at the pre-clinical development stage, with a focus on developing a cost-effective production process and demonstrating a biochemical similarity to the original drug. Then, upscaling with a production partner will follow, after which the product can be taken into clinical trials.

Xoncane™

Xoncane™ is a biosimilar candidate to pegaspargase (original drug Oncaspar®), used in the treatment of acute lymphocytic leukemia. In 2018, sales of Oncaspar® were around SEK 2bn⁷. Xoncane™ is now undergoing pre-clinical development.

Spherotide

Xbrane has agreed on a non-binding letter of intent with New FaDem regarding the divestment of the subsidiary Primm Pharma. The purchase price will amount to €14.0m and must be paid upon signing and at various development and sales milestones. The parties intend to complete the transaction in 2021.

Product	Original drug	Primary indication	Estimated sales of originator 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 32bn ^{1,2}	2022 (Europe) 2020 (USA)	Phase III
Xcimzane™	Certolizumab pegol (Cimzia®)	Rheumatoid arthritis, axial spondylarthritis, psoriatic arthritis, psoriasis and Crohn's disease.	SEK 19bn ⁵	2024 (USA) 2025 ⁹ (Europe)	Pre-clinical phase
Xdivane™	Nivolumab (Opdivo®)	Melanoma, lung cancer, kidney cell cancer, head and neck cancer and bladder and urinary tract cancer.	SEK 64bn ⁶	2026–2031 depending on country	Pre-clinical phase
Xoncane™	Pegaspargase (Oncaspar®)	Acute lymphocytic leukemia.	SEK 2bn ⁷	Expired	Pre-clinical phase
Spherotide	Triptorelin (Decapeptyl®)	Prostate cancer, breast cancer, endometriosis and fibroids.	SEK 4bn ⁸	Expired	Pre-clinical phase

1) Novartis Annual report 2020

2) Roche Annual report 2020

3) Regeneron Annual report 2020

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 2020

6) BMS Annual report 2020

7) Evaluate Pharma 2018

8) IQVIA 2018

9) Includes six months patent extension due to pediatric indication

Shareholders

As of June 30, 2021, Xbrane had around 6,100 shareholders. The number of outstanding shares totaled 22,222,206. The ten largest shareholders at the end of the period are shown in the table below¹.

Name	Number of shares	Ownership, %
Serendipity Group	2,819,967	12.7
Swedbank Robur Fonder	2,156,022	9.7
Bengt Göran Westman	1,820,393	8.2
STADA Arzneimittel AG	1,570,989	7.1
Futur Pension	1,201,637	5.4
TIN Fonder	1,200,000	5.4
Avanza Pension	965,037	4.3
Nordnet Pensionsförsäkring	389,896	1.8
Swedbank Försäkring	355,362	1.6
Paolo Sarmientos	296,939	1.3
Ten largest shareholders in total	12,776,242	57.5
Other Swedish shareholders	7,567,578	34.0
Other foreign shareholders	1,878,386	8.5
Total outstanding shareholders	22,222,206	100.0

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



Financial overview

The Group's results for April – June 2021

The Group's net sales amounted to SEK 2.5m (0.0) and relates to license revenue to Xbrane's subsidiary Primm Pharma from the contractor ICI regarding sales of Spherotide. The cost of goods sold was SEK 2.5m (0.0), which consists of production costs.

Other operating income amounted to SEK 3.6m (5.3) and relates mainly to the licensing of the American and Canadian rights for Xlucane™ to Bausch + Lomb, which will accrue over two years. Other operating income also includes license income from non-core operations as well as exchange rate gains on operating receivables and liabilities.

Administrative expenses amounted to SEK -9.3m (-9.7).

Research and development costs amounted to SEK -51.7m (-45.1), of which SEK -50.0m (-43.8) relates to biosimilars, primarily Xlucane™ and SEK -1.6m (-1.3) relates to the long-acting injectable drug Spherotide. The majority of the R&D costs relates to the ongoing Xplore study for Xlucane™, the parallel regulatory work and the establishment of a production chain. The Xplore study was fully recruited at the end of 2020 and positive top-line data was announced at the interim read-out in June 2021, where Xlucane™ reached the primary endpoint.

Other operating expenses amounted to SEK -0.1m (-3.6) and consisted of exchange rate losses on operating receivables and liabilities. The operating loss amounted to SEK -58.4m (-53.2). The loss before tax was SEK -59.2m (-53.4). During the quarter, there was no taxable profit and thus no tax expense (0.0). The loss after tax for the quarter was SEK -59.2m (-53.4) and earnings per share was SEK -2.67 (-3.11).

The Group's cash flow for April – June 2021

Cash flow from operating activities amounted to SEK -104.9m (15.8). Changes in operating receivables and operating liabilities amounted to SEK -19.3m (14.0) and SEK -22.2m (48.5), respectively. Changes in working capital can vary greatly between the periods, mainly as a result of re-invoicing to STADA regarding the development work for Xlucane™ and costs for the clinical study Xplore.

The cash flow from investment activities amounted to SEK -5.2m (0.0) and consisted of investments in tangible fixed assets in R&D.

The cash flow from financing activities amounted to SEK -1.5m (135.3), and mainly related to amortization of leasing liabilities. The item also includes the payment of the new directed share issue for the outcome of the warrant program and LTIP of SEK 0.4m.

The Group's results for January – June 2021

The Group's net sales amounted to SEK 2.5m (0.0) and relates to license revenue to Xbrane's subsidiary Primm Pharma from the contractor ICI regarding sales of Spherotide. The cost of goods sold was SEK 2.5m (0.0), which consists of production costs.

Other operating income amounted to SEK 7.7m (10.2) and relates mainly to the licensing of the American and Canadian rights for Xlucane™ to Bausch + Lomb, which will accrue over two years. Other operating income also includes license income from non-core operations as well as exchange rate gains

on operating receivables and liabilities.

Administrative expenses amounted to SEK -18.1m (-16.8). The change relates to a planned expansion of the organization and non-recurring costs in connection with moving to new premises.

R&D costs amounted to SEK -97.8m (-92.6), of which SEK -95.2m (-89.2) relates to biosimilars and primarily Xlucane™ and SEK -2.5m (-3.4) relates to the long-acting injectable drug Spherotide. The majority of the R&D costs relates to the ongoing Xplore study for Xlucane™, the parallel regulatory work and the establishment of a production chain. The Xplore study was fully recruited at the end of 2020 and positive top-line data was announced at the interim read-out in June 2021, where Xlucane™ reached the primary end-point.

Other operating expenses amounted to SEK -1.6m (-5.6) and consist of exchange rate losses on operating receivables and liabilities. The operating loss was SEK -109.8m (-104.8). The loss before tax was SEK -110.4m (-105.2). During the first six months, there was no taxable profit and thus no tax expense (0.0). The loss after tax for the period was SEK -110.4m (-105.2) and earnings per share was SEK -4.97 (-6.12).

The Group's cash flow for January – June 2021

The cash flow from operating activities amounted to SEK -96.9m (-67.4). Changes in operating receivables and operating liabilities amounted to SEK 18.7m (35.2) and SEK -3.1m (68.7), respectively. Changes in working capital can vary greatly between periods, mainly as a result of re-invoicing to STADA regarding the development work for Xlucane™ and costs for the clinical study Xplore.

The cash flow from investment activities amounted to SEK -13.9m (0.1) and consisted of investments in tangible fixed assets in R&D.

The cash flow from financing activities amounted to SEK -2.7m (134.5), and mainly related to amortization of leasing liabilities. The item also includes the payment of the new directed share issue for the outcome of the warrant program and LTIP of SEK 0.4m.

The Group's financial position and continued operations

On the balance sheet date, cash and cash equivalents amounted to SEK 129.3m (232.5).

The capital raise in June raised a total of SEK 380.3m before transaction costs and thus significantly strengthened the company's financial position. The effects in the balance sheet and cash flow will first be seen in the third quarter, July-September 2021, as the shares were registered and payment received in the beginning of July. Xbrane now possesses the necessary funds to develop the business according to the business plan for the coming 12 months.

Assets held for sale

During Q1 2021, a non-binding letter of intent was signed with New FaDem regarding the divestment of the subsidiary Primm Pharma. During Q2, the usual due diligence and negotiations continued. In the Q1 report, Primm Pharma's assets and liabilities were reclassified to "Assets held for sale" in the consolidated balance sheet. The reclassification created some

minor effects from a number of items in the balance sheet and the significant change that was shown related to the item "Goodwill" as described below. Other balance sheet items for the Group showed a minor effect from the reclassification, which is expected as Primm Pharma is a smaller part of the Group and its composition.

Goodwill

Goodwill amounted to SEK 0.0m (61.0) on the balance sheet date and the decrease compared with the previous year is entirely attributable to the reclassification to "Assets held for sale" described above.

Accounts receivable

Accounts receivable amounted to SEK 24.4m (21.2) and relate to receivables from our partner STADA

Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 76.8m (86.6), of which SEK 2.4m (38.7) relates to the purchase and pack-aging costs of reference medicines for the ongoing phase III study that are used on an ongoing basis, SEK 47.8m (34.3) relates to an advance payment to the CRO (Contract Research Organization) which performs the clinical study, and the remaining SEK 26.6m (13.6) relates to other prepaid expenses and accrued income.

Changes in equity

Equity amounted to SEK 5.0m (4.3) on the balance sheet date. Other capital contributions amounted to SEK 775.7m (584.4) and during the period were affected by the private placement and by share-based payments to employees of SEK 1.5m (1.0). Total equity amounted to SEK 149.7m (191.3). The equity ratio was 39% (44).

Accounts payable

Accounts payable amounted to SEK 21.4m (36.2). The reduction is partly due to naturally declining activities for Xlucane™, which is now entering a preparatory commercialization phase.

Accrued expenses and prepaid income

Accrued expenses and prepaid income amounted to SEK 158.4m (191.9) and primarily relates to advance payments of SEK 99.6m (130.6) from STADA for Xlucane™.

Impact of the cooperation agreement with STADA on the income statement and balance sheet

Since the cooperation agreement with STADA for Xlucane™ started in July 2018, Xbrane's net costs for the research and development of Xlucane™ have been reported in the results, i.e. 50% of the total cost of the project. With regard to the balance sheet, assets and liabilities attributable to the development of Xlucane™ are reported in their entirety, i.e. 100%, and then STADA's share of these, i.e. 50% is reported additionally as the receivable or liability arising between Xbrane and STADA.

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 amounting to SEK 0.0m (4.2) as well as deferred income from STADA amounting to SEK 99.6m (103.6).

Parent company

Xbrane's core business, which is the development of biosimilars, is run by the parent company. As announced, the Group has begun the sale of the subsidiary Primm Pharma, which is expected to be completed during 2021. As a result, shares in subsidiaries have been written down by SEK 48.0m. 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 does not lead to any further information than that described in the report on the Group. Therefore, this is only presented in report format on pages 14–16.

SIGNIFICANT EVENTS DURING THE SECOND QUARTER

Virtual capital markets day

Xbrane held a virtual capital markets day in May and announced its ambition of generating a positive operating cash flow monthly through the net income from Xlucane™ at the end of 2023/beginning of 2024 and to initiate one new development project per year. The biosimilar market is one of the most rapidly expanding segments in the pharmaceutical industry with a number of important patents expiring in the coming decade. The company's plan is to start one new development program per year and thereby build a broader portfolio of products that can come to market in 2025 and beyond.

Xlucane™

In June, top-line data was obtained from an interim read-out of the ongoing Phase III equivalence study Xplore with the Lucentis® biosimilar candidate Xlucane™. Xlucane™ reached the primary endpoint and demonstrated equivalent efficacy with Lucentis® in terms of change of BCVA (Best Corrected Visual Acuity) at the eighth week of treatment. The company then confirmed the plan to submit the marketing authorization application to the European Medicines Agency (EMA) during Q3 2021 and to the US Food and Drug Administration (FDA) in Q4 2021 on the basis of the interim read-out.

Xplore is a randomized, double-blind multicenter study evaluating the efficacy, safety, pharmacokinetics and immunogenicity of Xlucane™ in patients with wAMD compared to Lucentis®. The primary measure of effectiveness in the study is a change in BCVA (Best Corrected Visual Acuity) at week eight. wAMD patients were randomized (1: 1) and received monthly injections into the eye of Xlucane™ or the reference product Lucentis® for one year. The study, which is being conducted in 15 countries at around 140 clinics, with 583 patients fully recruited by November 2020 despite the ongoing Covid-19 pandemic. Following the positive interim read-out, Xbrane will, as planned, submit a marketing authorization application to the EMA during the third quarter of 2021 and the submittance to the FDA is expected during the fourth quarter of 2021.

Directed new share issue

With the support of the authorization at the Annual General Meeting on May 6, 2021, Xbrane announced and implemented a directed new issue of SEK 380m at a subscription price of SEK 135 per share, at the end of June. Through this, the company has secured financing for the continued development of the biosimilar portfolio and marketing authorization of Xlucane™.

Significant events after the end of the reporting period

Xbrane Biopharma was officially certified as a Great Place to Work® by the Great Place to Work® Institute.

Risks and uncertainties

Risks and uncertainties are described on pages 26–28 of the Annual Report of 2020, 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.

Impact of Covid-19

Xbrane has adapted its operations to comply with local government health guidelines. The inauguration of the new premises on Campus Solna has made it possible for some company-critical physical meetings to be held, but the majority of the employees continue to work from home. The company continues to follow local health guidelines from authorities at the places where Xbrane's operates. Sick leave has been relatively low. The company has a strong cohesion and together has found effective working methods that make the company sustainable. Xbrane will continue to put the health and safety of staff, partners and patients first.

Share information

Xbrane's share capital at the end of the period was SEK 5.0m (4.3) divided into 22,222,206 shares (19,280,707). 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 6,100 shareholders on the balance sheet date. The closing price of the share on the balance sheet date was SEK 147.60 generating a market capitalization of SEK 3,280m.

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 above, the sale of the subsidiary is ongoing. On the balance sheet date, the Group had 60 (42) employees, 55 (35) of whom were employed by the parent company and 5 (7) by the subsidiary.

Annual General Meeting

The 2021 Annual General Meeting was held on May 6, 2021 in Baker McKenzie's premises at Vasagatan 7, Stockholm.

Auditor's review

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

Consolidated income statement

Amounts in SEK thousand	Notes	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Revenues	2,3	2,486	–	2,486	–	–
Cost of goods sold		–2,520	–	–2,520	–	–
Gross profit		–34	–	–34	–	–
Other income	2,3	3,596	5,283	7,678	10,185	20,652
Selling and distribution expenses		–	–	–	–	–
Administrative expenses		–9,301	–9,742	–18,141	–16,777	–31,189
Research and development expenses		–51,749	–45,099	–97,769	–92,642	–203,301
Other expenses		–926	–3,640	–1,557	–5,592	–11,419
Operating profit/loss	2	–58,413	–53,197	–109,823	–104,825	–225,257
Financial income		–	–	506	–	–
Financial costs		–754	–200	–1,119	–406	–769
Net financial costs	2	–754	–200	–612	–406	–769
Profit/loss before tax		–59,168	–53,397	–110,435	–105,231	–226,026
Income tax expense		–	–	–	–	–
Profit/loss for the period		–59,168	–53,397	–110,435	–105,231	–226,026
Profit/loss attributable to:						
– Owners of the Company		–59,168	–53,397	–110,435	–105,231	–226,026
– Non-controlling interests		–	–	–	–	–
Total comprehensive income f or the period		–59,168	–53,397	–110,435	–105,231	–226,026
Earnings per share						
– Basic earnings per share (SEK)		–2.67	–3.11	–4.97	–6.12	–12.48
– Diluted earnings per share (SEK)		–2.67	–3.11	–4.97	–6.12	–12.48
Number of outstanding shares at the end of the reporting period						
– Before dilution		22,222,206	19,280,707	22,222,206	19,280,707	22,200,415
– After dilution		22,222,206	19,280,707	22,222,206	19,280,707	22,200,415
Average number of outstanding shares						
– Before dilution		22,200,654	17,195,806	22,200,535	17,195,806	18,113,313
– After dilution		22,200,654	17,195,806	22,200,535	17,195,806	18,113,313

Consolidated income statement and other comprehensive income

Amounts in SEK thousand	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Total comprehensive income for the period	-59,168	-53,397	-110,435	-105,231	-226,026
Other comprehensive income					
Items that have been transferred and can be transferred to profit/loss for the period					
Reclassification of foreign currency translation differences	-738	-3,742	520	78	-2,774
Comprehensive income for the period	-738	-3,742	520	78	-2,774
Total comprehensive profit/loss attributable to:					
– Owners of the Company	-56,906	-57,139	-109,915	-105,153	-228,801
– Non-controlling interests	–	–	–	–	–
Total comprehensive income for the period	-59,906	-57,139	-109,915	-105,153	-228,801

Consolidated statement of financial position

Amounts in SEK thousand	06-30-2021	06-30-2020	12-31-2020
ASSETS			
Goodwill	–	61,033	58,453
Intangible assets	–	4,669	4,083
Property, plant and equipment	17,736	9,235	8,166
Right of use assets	45,308	7,600	5,969
Trade and other receivables	12,680	9,019	12,610
Non-current assets	75,723	91,556	89,281
Trade receivables	24,413	21,210	51,384
Other receivables	7,180	5,692	6,981
Prepaid expenses and accrued income	76,826	86,559	72,978
Cash and cash equivalents	129,332	232,506	243,139
Assets held for sale	70,330	–	–
Current assets	308,081	345,968	374,482
TOTAL ASSETS	383,804	437,524	463,763
EQUITY			
Share capital	4,982	4,322	4,977
Share premium	775,665	584,369	773,724
Reserves	4,465	6,797	3,945
Retained earnings including the loss of the period	–635,373	–404,142	–524,938
Equity attributable to owners of the Company	149,739	191,347	257,708
Non-controlling interests	–	–	–
Total equity	149,739	191,347	257,708
LIABILITIES			
Leasing liability	39,019	4,918	3,995
Non-current non-interest-bearing liabilities	4,050	4,192	8,257
Provisions	–	4,931	4,810
Non-current liabilities	43,069	14,042	17,062
Trade and other payables	21,370	36,167	29,546
Other current liabilities	1,314	1,107	1,328
Leasing liability	6,940	2,947	2,265
Deferred income/revenue	158,371	191,915	155,853
Assets held for sale	3,002	–	–
Current liabilities	190,996	232,136	188,993
TOTAL LIABILITIES	234,065	246,178	206,055
TOTAL EQUITY AND LIABILITIES	383,804	437,524	463,763

Consolidated cash flow statement

Amounts in SEK thousand	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Cash flow from operating activities					
Profit/loss before tax	-59,168	-53,397	-110,435	-105,231	-226,026
Adjustments for items not included in cash flow	-4,246	6,738	-2,160	4,267	6,247
Paid income taxes	-	-	-	-	-
Total	-63,414	-46,659	-112,595	-100,964	-219,779
Increase (-)/Decrease (+) of trade and other receivables	-19,316	14,020	18,713	-35,207	-51,325
Increase (+)/Decrease (-) of trade and other payables	-22,152	48,486	-3,054	68,740	32,697
Cash flow from current operations	-104,882	15,847	-96,936	-67,431	-238,407
Cash flow from investing activities					
Acquisition of property, plant and equipment	-5,177	-34	-13,924	-76	-3,855
Cash flow from investing activities	-5,177	-34	-13,924	-76	-3,855
Cash flow from financing activities					
Proceeds from exercise of share options	-	3	-	3	3
New share issue	425	146,444	425	146,444	346,444
Transaction expense	-	-10,337	-	-10,337	-20,584
Amortization of loan	-	-	-	-12	-12
Amortization of lease liability	-1,952	-766	-3,096	-1,564	-3,127
Cash flow from financing activities	-1,527	135,344	-2,671	134,534	322,724
Cash flow for the period	-111,586	151,157	-113,531	67,027	80,461
Cash and cash equivalents in assets held for sale	-535	-	-535	-	-
Cash and cash equivalents at beginning of period	240,141	84,471	243,139	164,197	164,197
Exchange rate differences in cash and cash equivalents	1,312	-3,120	259	1,282	-1,520
Cash and cash equivalents at end of period	129,332	232,506	129,332	232,506	243,139

Consolidated statement of changes in equity

Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total equity
Balance at January 1, 2021	4,997	773,724	3,945	-524,938	257,708
Total comprehensive income for the period					
Profit/loss for the period	-	-	-	-110,435	-110,435
Other comprehensive income for the period	-	-	520	-	520
Total comprehensive income for the period	-	-	520	-110,435	-109,915
Transactions with group shareholder					
New share issue	1	479	-	-	480
Issue expenses	-	-60	-	-	-60
Share savings program	4	1,522	-	-	1,526
Total contributions from and distributions to shareholders	5	1,941	-	-	1,946
Balance at June 30, 2021	4,982	775,665	4,465	-635,373	149,739
Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total equity
Balance at January 1, 2020	3,456	448,089	6,719	-273,941	184,323
Recalculation*	-	-	-	-24,970	-24,970
Balance at January 1, 2020 after recalculation	3,456	448,089	6,719	-298,911	159,352
Total comprehensive income for the period					
Profit/loss for the period	-	-	-	-105,231	-105,231
Other comprehensive income for the period	-	-	78	-	78
Total comprehensive income for the period	-	-	78	-105,231	-105,153
Transactions with group shareholder					
New share issue	867	145,580	-	-	146,447
Issue expenses	-	-10,337	-	-	-10,337
Share savings program	-	1,037	-	-	1,037
Total contributions from and distributions to shareholders	867	136,280	-	-	137,147
Balance at June 30, 2020	4,322	584,369	6,797	-404,142	191,347
Amounts in SEK thousand	Share capital	Share premium	Translation reserve	Retained earnings	Total equity
Balance at January 1, 2020	3,456	448,089	6,719	-273,941	184,323
Recalculation*	-	-	-	-24,970	-24,970
Balance at January 1, 2020 after recalculation	3,456	448,089	6,719	-298,911	159,352
Total comprehensive income for the period					
Profit/loss for the period	-	-	-	-226,026	-226,026
Other comprehensive income for the period	-	-	-2,774	-	-2,774
Total comprehensive income for the period	-	-	-2,774	-226,202	-228,801
Transactions with group shareholder					
New share issue	1,519	344,926	-	-	346,444
Issue expenses	-	-20,584	-	-	-20,584
Share savings program	3	1,293	-	-	1,296
Total contributions from and distributions to shareholders	1,521	325,635	-	-	327,156
Balance at December 31, 2020	4,997	773,724	3,945	-524,938	257,708

*) This period has been recalculated due to restatement, see Year-end report 2020, Appendix 1 for the effects.

Income statement, Parent company

Amounts in SEK thousand	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Revenues	–	–	–	–	–
Cost of goods sold	–	–	–	–	–
Gross profit	–	–	–	–	–
Other income	2,935	4,707	7,582	9,591	17,730
Administrative expenses	–9,052	–8,444	–17,198	–14,213	–26,567
Research and development expenses	–49,852	–43,639	–95,243	–89,443	–197,690
Other expenses	–926	–3,588	–1,471	–5,487	–11,203
Operating profit/loss	–56,896	–50,964	–106,330	–99,552	–217,730
Financial items					
Financial income	–	–	506	11	11
Impairment loss on shares in subsidiary	–5,086	–	–9,616	–	–38,400
Financial expenses	–50	–79	–121	–149	–296
Net finance costs	–5,118	–79	–9,231	–138	–38,685
Profit/loss before tax	–62,014	–51,043	–115,561	–99,960	–256,415
Income tax expense	–	–	–	–	–
Total comprehensive income for the period	–62,014	–51,043	–115,561	–99,690	–256,415

Parent company statement of comprehensive income

Amounts in SEK thousand	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Profit/loss for the period	–62,014	–51,043	–115,561	–99,690	–256,415
Other comprehensive income	–	–	–	–	–
Total comprehensive income for the period	–62,014	–51,043	–115,561	–99,690	–256,415

Balance Sheet, Parent company

Amounts in SEK thousand	06-30-2021	06-30-2020	12-31-2020
ASSETS			
Fixed assets			
Property, plant and equipment	17,736	6,206	5,212
Financial assets			
Shares in group companies	74,066	108,838	74,066
Other non-current receivables	12,680	9,019	12,610
Total financial assets	86,746	117,857	86,676
Total non-current assets	104,481	124,063	91,888
Current assets			
Current receivables			
Trade receivables	24,413	21,210	51,384
Other receivables	7,180	3,864	5,148
Prepaid expenses and accrued income	76,826	86,507	72,935
Total current receivables	108,418	111,580	129,467
Cash and bank	129,332	230,745	242,247
Current assets	237,750	342,325	371,715
TOTAL ASSETS	342,232	466,388	463,603
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	4,982	4,322	4,977
Unrestricted equity			
Share premium	776,351	585,055	774,410
Retained earnings	-508,889	-252,474	-252,474
Profit/loss for the period	-115,561	-99,690	-256,415
Total equity	156,883	237,214	270,498
Non-current liabilities			
Non-current interest-bearing liabilities	4,050	4,192	8,257
Non-current non-interest-bearing liabilities	4,050	4,192	8,257
Current liabilities			
Liabilities to subsidiaries	244	264	285
Trade and other payables	21,370	35,928	29,421
Other current liabilities	1,314	984	1,192
Deferred income/revenue	158,371	187,805	153,949
Current liabilities	181,299	224,982	184,847
TOTAL LIABILITIES	185,349	229,174	193,104
TOTAL EQUITY AND LIABILITIES	342,232	466,388	463,603

Cash flow statement, Parent company

Amounts in SEK thousand	2021 Apr – Jun	2020 Apr – Jun	2021 Jan – Jun	2020 Jan – Jun	2020 Jan – Dec
Cash flows from operating activities					
Earnings before income and tax	-62,014	-51,043	-115,561	-99,690	-256,415
Adjustments for items not included in cash flow	4,541	3,653	7,491	-176	39,601
Paid income taxes	-	-	-	-	-
Total	-57,473	-47,390	-108,070	-99,866	-216,814
Increase (-)/Decrease (+) of trade and other receivables	-19,887	38,893	20,979	-11,389	-52,381
Increase (+)/Decrease (-) of trade and other payables	-21,958	25,833	-2,765	47,591	36,709
Cash flow from current operations	-99,319	17,336	-89,856	-63,664	-232,486
Cash flow from investing activities					
Investments in subsidiaries	-5,063	-3,201	-9,616	-6,519	-10,148
Acquisition of property, plant and equipment	-5,413	-34	-14,160	-76	-3,503
Cash flow from investing activities	-10,476	-3,235	-23,776	-6,595	-13,651
Cash flow from financing activities					
Exercised share options by employees	-	3	-	3	3
New share issue	425	146,444	425	146,444	346,444
Transaction expense	-	-10,337	-	-10,337	-20,584
Cash flow from financing activities	425	136,110	425	136,110	325,863
Cash flow for the period	-109,369	150,211	-113,208	65,851	79,726
Cash and cash equivalents at beginning of period	239,244	83,701	242,247	163,601	163,601
Exchange rate differences in cash and cash equivalents	-543	-3,166	292	1,294	-1,079
Cash and cash equivalents at end of period	129,332	230,745	129,332	230,746	242,247

Notes

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 has been applied with the exception of the additional applications principles for accounting for license revenues described below on the new license agreements which is different in nature to licensing agreements previously reported. Information according to IAS 34.16A is included in these financial statements and related notes as well in other parts of this interim report.

Assets and liabilities held for sale and discontinued operations

Assets are classified as held for sale if their value, within one year, will be recovered through sale and not through continued use in the business. At the time of reclassification, assets and liabilities are valued at the lower of fair value, after deduction of selling expenses and the carrying amount. The assets are no longer depreciated after reclassification. The profit is limited to an amount corresponding to previously made write-downs. Gains and losses reported on revaluation and divestment are reported in the profit for the period.

When an independent line of business or a significant activity within a geographical area is divested, it is classified as a discontinued operation. The sale, or the time when the business meets the criteria for being classified as held for sale, determines when the business is to be classified as a discontinued business. The profit/loss after tax from discontinued operations is reported as a separate item 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	2021		2020		2020 Jan – Dec
	Apr – Jun	Apr – Jun	Jan – Jun	Jan – Jun	
Other revenues per segment					
Biosimilars	2,691	1,697	5,333	1,697	6,787
Long-acting injectable drugs	2,486	–	2,486	–	–
Unallocated revenue	906	3,586	2,345	8,489	13,865
Total	6,083	5,283	10,165	10,185	20,652
Operating profit or loss per segment					
Biosimilars	-47,404	-42,059	-89,924	-87,542	-190,497
Long-acting injectable drugs	833	-1,343	-26	-3,403	-6,017
Unallocated revenue	-11,842	-9,795	-19,873	-13,880	-28,743
Operating profit/loss	-58,413	-53,197	-109,823	-104,825	-225,257
Net finance costs					
Biosimilars	-690	-106	-980	-220	-406
Long-acting injectable drugs	-9	-27	-17	-59	-90
Unallocated revenue	-55	-68	385	-127	-274
Total	-754	-201	-612	-406	-769
Profit/loss before tax	-59,168	-53,397	-110,435	-105,231	-226,026
Depreciation, amortization and write downs					
Biosimilars	3,006	1,074	4,894	2,144	4,337
Long-acting injectable drugs	447	443	900	913	1,799
Unallocated revenue	172	107	248	220	430
Total	3,625	1,624	6,042	3,278	6,566

NOTE 3 Distribution of income

Amounts in SEK thousand	Apr – Jun 2021			Group
	Biosimilars	Long-acting injectable drugs	Unallocated/administration	
Income per region				
Middle East	–	–	–	–
Asia	–	–	–	–
Europe	–	2,486	884	3,370
United States	2,691	–	22	2,712
Total	2,691	2,486	906	6,083
Income per category				
Pharmaceuticals	–	–	–	–
Milestone payments from partners	2,691	–	–	2,691
Services and other	–	2,486	906	3,392
Total	2,691	2,486	906	6,083

Amounts in SEK thousand	Apr – Jun 2020			Group
	Biosimilars	Long-acting injectable drugs	Unallocated/administration	
Income per region				
Middle East	–	–	–	–
Asia	–	–	–	–
Europe	–	–	3,541	3,541
United States	1,697	–	45	1,742
Total	1,697	–	3,586	5,283
Income per category				
Pharmaceuticals	–	–	–	–
Milestone payments from partners	1,697	–	–	1,697
Services and other	–	–	3,586	3,586
Total	1,697	–	3,586	5,283

Amounts in SEK thousand	Jan – Jun 2021			Group
	Biosimilars	Long-acting injectable drugs	Unallocated/administration	
Income per region				
Middle East	–	–	–	–
Asia	–	–	–	–
Europe	–	2,486	2,083	4,569
United States	5,333	–	263	5,596
Total	5,333	2,486	2,346	10,165
Income per category				
Pharmaceuticals	–	–	–	–
Milestone payments from partners	5,333	–	–	5,333
Services and other	–	2,486	2,346	4,832
Total	5,333	2,486	2,346	10,165

NOTE 3 Distribution of income cont.

Amounts in SEK thousand	Jan – Jun 2020			Group
	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	
Income per region				
Middle East	–	–	–	–
Asia	–	–	–	–
Europe	–	–	8,389	8,389
United States	1,697	–	99	1,796
Total	1,697	–	8,488	10,185
Income per category				
Pharmaceuticals	–	–	–	–
Milestone payments from partners	1,697	–	–	1,697
Services and other	–	–	8,488	8,488
Total	1,697	–	8,488	10,185

Amounts in SEK thousand	Jan – Dec 2020			Group
	Biosimilars	Long-acting injectable drugs	Unallocated/ administration	
Income per region				
Middle East	–	–	–	–
Asia	–	–	–	–
Europe	–	–	13,693	13,693
United States	6,787	–	171	6,958
Total	6,787	–	13,865	20,652
Income per category				
Pharmaceuticals	–	–	–	–
Milestone payments from partners	6,787	–	–	6,787
Services and other	–	–	13,865	13,865
Total	6,787	–	13,865	20,652

NOTE 4 Transactions with related parties

Since 2019, STADA Arzneimittel AG has been a shareholder in Xbrane (see the list of owners on page 5). Transactions with STADA relate to shared costs for the collaboration agreement with Xlucane.

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 25 in the 2020 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	06-30-2021	06-30-2020	12-31-2020
	Level 2	Level 2	Level 2
Financial assets			
Other current receivables	–	–	–
Whereof currency derivatives	–	–	–
Total financial assets	–	–	–
Financial liabilities			
Other current payables	–	–	–
Whereof currency derivatives	–	–	–
Total financial liabilities	–	–	–

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, August 12, 2021

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 calculated as gross result in relation to the net sales. The gross margin is net sales minus cost of goods sold.

Amounts in SEK thousand	2021		2020	
	Apr – Jun	Apr – Jun	Jan – Jun	Jan – Jun
Gross profit	–34	–	–34	–
Net sales	2,486	–	2,486	–
Gross margin	–1 %	–	–1 %	–

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.

Amounts in SEK thousand	2021		2020	
	Apr – Jun	Apr – Jun	Jan – Jun	Jan – Jun
Operating profit or loss	–58,413	–53,197	–109,823	–104,825
Depreciation, amortization and write downs	–3,625	–1,624	–6,042	–3,278
EBITDA	–54,788	–51,573	–103,781	–101,547

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	2021		2020	
	Apr – Jun	Apr – Jun	Jan – Jun	Jan – Jun
Research and development expenses	–51,749	–43,809	–97,769	–90,031
Total operating expenses	–61,976	–56,856	–117,467	–111,732
R&D expenses as a percentage of operating expenses	83 %	77 %	83 %	81 %

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	06-30-2021	06-30-2020	12-31-2020
Total equity	149,739	191,347	257,708
Total assets	383,804	437,524	463,763
Equity ratio	39 %	44 %	56 %



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Financial calendar

Interim report January–September 2021

October 29, 2021

Year-end report 2021

February 16, 2022

Annual General Meeting

May 5, 2022



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This report is a translation of the Swedish version. When in doubt, the Swedish version should prevail.