

The marketing authorization application for Xlucane™ in Europe initiates the process for the upcoming launch

Financial summary third quarter 2021

- Revenue amounted to SEK 0.0m (0,0).
- Other operating income was SEK 3.5m (4.9).
- EBITDA was SEK -39.5m (-54.2).
- R&D costs amounted to SEK -36.5m (-50.5), representing 79 percent (84) of total operating costs.
- The loss for the period was SEK -45.5m (-57.7).
- Earnings per share amounted to SEK -1.83 (-2.99).
- Cash and cash equivalents at the end of the period amounted to SEK 383.4m (123.8).

Financial summary first nine months 2021

- Revenue amounted to SEK 0.0m (0.0).
- Other operating income was SEK 11.1m (14.4).
- EBITDA was SEK -140.1m (-151.5).
- R&D costs amounted to SEK -131.7m (-139.7), representing 83% (83) of total operating costs.
- The loss for the period was SEK -155.9m (-163.0).
- Earnings per share amounted to SEK -6.75 (-9.49).
- Cash and cash equivalents at the end of the period amounted to SEK 383.4m (123.8).

Numbers in parentheses refer to the corresponding period last year.

Significant events during the third quarter 2021

- In September, the company's partner STADA submitted a marketing authorization application for Xlucane™ to the European Medicines Agency (EMA), which was later validated by the agency.
- In July, a directed new issue of SEK 380m before estimated transaction costs was registered, which Xbrane announced and implemented at the end of June. After the issue, the total number of shares and votes in the company amounts to 25,039,906. The company's registered share capital amounts to around SEK 5,613,598.
- Xbrane Biopharma was officially certified as a Great Place to Work® by the Great Place to Work® institute.

Significant events after the end of the quarter

- In October, the company signed a cooperation agreement with AGC Biologics, with effective date September 30, 2021, for upscaling the established manufacturing process of Xcimzane™ and manufacture the majority of commercial scale batches for the upcoming Phase 1 and Phase 3 studies, and also comparative quality studies (CAA) to demonstrate biosimilarity, required for the marketing authorization application.
- In October, Xbrane was granted six new patents by the Patent and Registration Office (PRV).
- In October, the Nomination Committee for the 2022 Annual General Meeting was established and announced.

More detailed information on the above events can be found on pages 8-9.

Financial summary for the Group

	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Revenue (SEK 000)	–	–	–	–	–
Research and development expenses (SEK 000)	–36,472	–50,497	–131,729	–139,736	–197,284
R&D expenses as percentage of total costs	79	84	83	83	84
Operating profit/loss (SEK 000)	–42,703	–55,303	–148,442	–154,708	–217,436
EBITDA (SEK 000)	–39,497	–54,208	–140,117	–151,451	–213,066
Profit/loss for the period (SEK 000)	–45,470	–57,742	–155,905	–162,973	–226,026
Cash and cash equivalents (SEK 000)	383,435	123,768	383,435	123,768	243,139
Equity ratio (%)	66	43	66	43	56
Number of shares at the end of period	25,039,906	19,280,707	25,039,906	19,280,707	22,200,415
Number of shares at the end of period after dilution	25,039,906	19,280,707	25,039,906	19,280,707	22,200,415
Average number of shares	24,886,770	19,280,707	23,105,787	17,177,891	18,113,313
Average number of shares after dilution	24,886,770	19,280,707	23,105,787	17,177,891	18,113,313
Earnings per share before dilution (SEK)	–1,83	–2,99	–6,75	–9,49	–12,48
Earnings per share after dilution (SEK)	–1,83	–2,99	–6,75	–9,49	–12,48
Number of employees on balance sheet date	56	41	56	41	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

During Q3, our work continued to become a leading global biosimilar developer. The most important milestones were that our partner STADA submitted and received an application for market authorization for Xlucane™ validated by the European Medicines Agency (EMA), we signed an agreement with the contract manufacturer AGC Biologics for upscaling and manufacturing Xcimzane™ and strengthened our IP portfolio.

Marketing authorization application for Xlucane™

The marketing authorization application for Xlucane™ was submitted by our partner STADA to the EMA in September and was validated shortly thereafter by the Agency. The approval process therefore formally began at the end of September and is expected, depending on the time needed to answer questions during the process, to take up to 12 months. The corresponding application to the US Food and Drug Administration (FDA) is expected to be submitted during Q4 2021, or Q1 2022 and the work prior to this is proceeding according to plan. We intend to announce when we submit the application and once FDA considers it complete to start the review.

Upscaling and commercial manufacturing of Xcimzane™

The development of Xcimzane™ is progressing according to plan. We have signed an agreement with the contract manufacturer AGC Biologics for upscaling and manufacturing of Xcimzane™ for future clinical studies. The plan is that we will be able to manufacture clinical batches on a commercial scale during the second half of 2022 and then be able to start clinical studies in 2023. We continue to assess that Xcimzane™ is the only biosimilar candidate of Cimzia® in development globally. Potentially a consequence of difficulties in achieving sufficiently high productivity to secure a commercially viable gross margin. We have succeeded in this thanks to our unique patented platform technology, which is very suitable for this product.

Strengthening the IP portfolio

We have recently further developed our platform technology and strengthened its IP protection. Xbrane now has eight approved patents and 14 patent applications were filed, one of which is expected to be approved in November 2021. Six new patents were approved during Q3. Two of these relate to DNA constructs for regulating protein production and were submitted together with CloneOpt AB. The remaining four are a broadening of our original platform technology, from the production of proteins in host cells of the E.coli form to mammalian cells. The patents protect new DNA sequences we have used as part of how we instruct the host cells to produce the protein of interest and resulted in a significant increase in the productivity of Xdivane™. This is incredibly important to us as a large part of our future portfolio of biosimilars will be manufactured in mammalian cells.

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 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.
- Begin the development of another biosimilar candidate.

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 and also, in a relatively short time, broadened the base of our product portfolio. We are all very confident and enthusiastic about Xbrane's continued journey to fulfill the ambition of becoming a leading, global, biosimilar developer for the benefit of patients around the world.

Thank you for your continued support,

Martin Åmark, CEO

Solna, October 28, 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 and in September the partner STADA submitted a marketing authorization application to the EMA, which was later validated by the authority. This means that the EMA has now started the review process for approval, which is expected to take up to a year.

Xbrane will also, in agreement with the FDA, submit a marketing authorization application for Xlucane™ in the US. Both applications will later be supplemented with full data from the study during the registration process.

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. As the next step in manufacturing and upscaling, an agreement has been signed with AGC Biologics for the manufacture of Xcimzane™ for future clinical studies.

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 EUR 14.0 m and must be paid upon signing and at various development and sales milestones. The usual due diligence and negotiations are continuing.

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

Patent protection

An expanding patent portfolio provides possibilities for entering strategic partnerships and strengthens the Xbrane brand

Xbrane has a team of innovative scientists within biochemistry, molecular biology, fermentation, protein-purification, and analytics as well as professionals with extensive experience from the pharmaceutical industry in regulatory affairs, clinical affairs, manufacturing and supply chains. Since Xbrane is an innovative drug development company, which invests heavily in R&D, Xbrane's goal is to file strategically important patent applications to protect its core technologies and products.

Growing patent portfolio

Xbrane's expanding patent portfolio will provide opportunities which will facilitate the implementation of Xbrane's business strategies. Such opportunities include licensing and various types of strategic business partnerships, or alliances in commercializing Xbrane's biosimilars and biosimilar production platforms.

It is important to note that Xbrane seeks to file patent applications protecting a broad spectrum of technologies covering everything from core protein production or purification technologies to novel formulations of biosimilars.

Although Xbrane's primary regions of patent focus are Europe and the USA, patent applications may also be filed in Canada, China, South Korea, India, Japan and Australia, if Xbrane's products and methods have a market in these jurisdictions. Moreover, Xbrane will make use of international patent applications to have further strategic options of creating patent protection in a large number of countries.

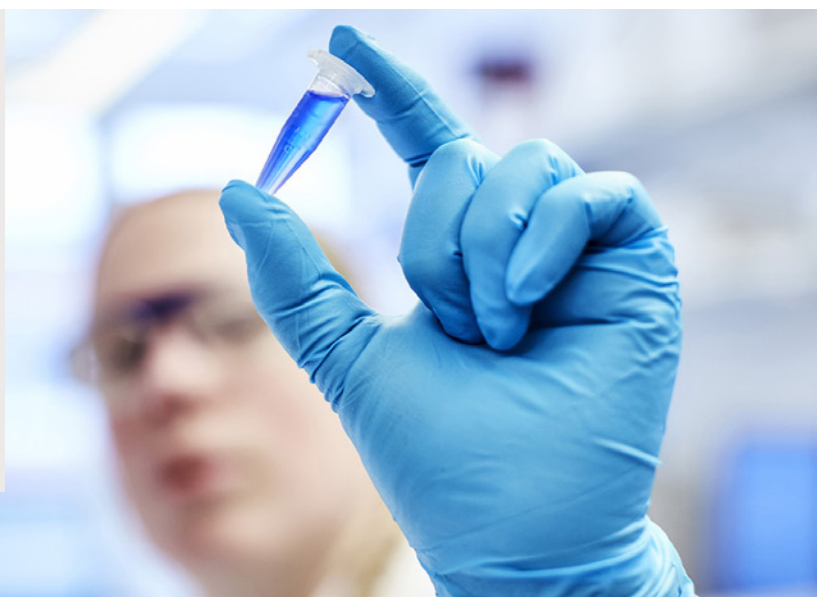
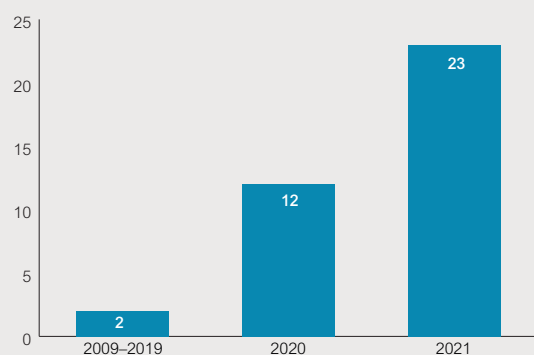
Xbrane's LEMO™ technology platform is patent protected in Europe and the USA until 2029. In 2020 and 2021, these two patents which had been filed in 2009 were complemented with a total of twenty-one pending patent applications "harvested" from five different development programs. Ten of these patent applications were filed in 2020 and four of them were filed in 2021, each followed-up with an international patent application which provides provisional protection in 153 countries. The Swedish Intellectual Property Office (PRV) granted six patents in October 2021. Moreover, the same patent office has notified the intention of granting a further patent in November 2021.

Strengthen Xbrane's brand

Two of the above-mentioned patents granted relate to DNA constructs for regulation protein production and were co-filed with CloneOpt AB. Four of the above-mentioned patents granted 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 novel sequences have resulted in a significant yield increase 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™ and Xcimzane™. The patent applications for the protection of Xlucane™ have been co-filed with STADA.

The expanding patent portfolio will strengthen Xbrane's brand, provide protection for our own and our investors' products, and enable more out-licensing of IP in the future.

Number of patents and patent applications:



Shareholders

As of September 30, 2021, Xbrane had around 6,500 shareholders. The number of outstanding shares totaled 23,039,906. 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	2,429,322	9.7
Bengt Göran Westman	1,919,261	7.7
Futur Pension	1,575,900	6.3
STADA Arzneimittel AG	1,570,989	6.3
TIN Fonder	1,435,000	5.7
Avanza Pension	1,226,609	4.9
Swedbank Försäkring	359,478	1.4
Nordnet Pensionsförsäkring	348,901	1.4
Paolo Sarmientos	296,939	1.2
Ten largest shareholders in total	14,339,766	57.3
Other Swedish shareholders	8,471,644	33.8
Other foreign shareholders	2,228,496	8.9
Total outstanding shareholders	23,039,906	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 July – September 2021

From Q1 2021, the subsidiary Primm Pharma is reported as an "asset held for sale". This means that Primm Pharma's revenues and expenses are reported net on a separate item - "Profit/loss from discontinued operations". This also has an effect on previously reported periods, which means that all comparative figures and notes linked to the data have been adjusted.

The Group's net sales amounted to SEK 0.0m (0.0) and cost of goods sold amounted to SEK 0.0m (0.0).

Other operating income amounted to SEK 3.5m (4.9) 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 -8.8m (-6.1). The change refers to a planned expansion of the organization and non-recurring costs in connection with moving to new premises.

Research and development costs amounted to SEK -36.5m (-50.5), which relate to biosimilars, primarily Xlucane™. From July 1, 2021, development costs for Xlucane™ are reported as intangible fixed assets in the balance sheet, which for the period amounted to SEK 26.9m (0.0). The largest part of the research and development costs relate to the regulatory work and the establishment of a production chain.

Other operating expenses amounted to SEK -1.0m (-3.5) and consisted of exchange rate losses on operating receivables and liabilities.

The operating loss amounted to SEK -42.7m (-55.3). The loss before tax was SEK -44.0m (-55.5). During the quarter, there was no taxable profit and thus no tax expense (0.0). The loss after tax for the quarter was SEK -45.5m (-57.7) and earnings per share was SEK -1.83 (-2.99).

The Group's cash flow for July – September 2021

Cash flow from operating activities amounted to SEK -62.3m (-103.4). Changes in operating receivables and operating liabilities amounted to SEK -24.1m (17.3) and SEK 4.1m (-61.1), 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 -37.5m (-3.8) and consisted of investments in tangible fixed assets in R&D. During the quarter, the company invested SEK -6.8m to be able to begin the upscaling of drug substance from 300 L to 3,000 L. From July 1, 2021, development costs for Xlucane™ are reported as intangible fixed assets, which for the period had an effect on cash flow of SEK -26.9m (0.0).

The cash flow from financing activities amounted to SEK 354.4m (-0.8). The item mainly includes the net payment of the directed share issue in June, where the shares were registered and the payment was not received until the beginning of July, as well as amortization of lease liabilities.

The Group's results for January – September 2021

From Q1 2021, the subsidiary Primm Pharma is reported as an "asset held for sale". This means that Primm Pharma's revenues and expenses are reported net on a separate item - "Profit/loss from discontinued operations". This also has an effect on previously reported periods, which means that all comparative figures and notes linked to the data have been adjusted.

The Group's net sales amounted to SEK 0.0m (0.0) and cost of goods sold amounted to SEK -0.0m (0.0).

Other operating income amounted to SEK 11.1m (14.4) 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 -25.4m (-20.3). The change refers to a planned expansion of the organization and non-recurring costs in connection with moving to new premises.

Research and development costs amounted to SEK -131.7m (-139.7), which relate to biosimilars and primarily Xlucane™. From July 1, 2021, development costs for Xlucane™ are reported as intangible fixed assets in the balance sheet, which for the period amounted to SEK 26.9m (0.0). The largest part of the research and development costs relate 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 -2.4m (-9.0) and consist of exchange rate losses on operating receivables and liabilities. The operating loss was SEK -148.4m (-154.7). The loss before tax was SEK -150.3m (-155.3). During the first nine months, there was no taxable profit and thus no tax expense (0.0). The loss after tax for the period was SEK -155.9m (-163.0) and earnings per share was SEK -6.75 (-9.49).

The Group's cash flow for January – September 2021

The cash flow from operating activities amounted to SEK -159.2m (-170.8). Changes in operating receivables and operating liabilities amounted to SEK -5.4m (-17.9) and SEK 1.1m (7.7), 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 -51.5m (-3.9) and consisted of investments in tangible fixed assets in R&D. During the quarter, the company invested SEK -6.8m to be able to begin the upscaling of drug substance from 300 L to 3,000 L. From July 1, 2021, development costs for Xlucane™ are reported as intangible fixed assets, which for the period had an effect on cash flow of SEK -26.9m (0.0).

The cash flow from financing activities amounted to SEK 351.7m (133.7). The item mainly includes the net payment of the directed share issue in June, where the shares were registered and the payment was not received until the beginning of July, as well as amortization of lease liabilities.

The Group's financial position and continued operations

On the balance sheet date, cash and cash equivalents amounted to SEK 383.4 m (123.8). The company thus has the capital to finance the development of the business in accordance with the business plan for the next 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" and "Liabilities attributable to assets held for sale" respectively, 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 demonstrated 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.

In the income statement, Primm Pharma's results are reported separately as "Profit/loss from discontinued operations". The reclassification gives the effect that Primm Pharma's previous income and expenses have been reversed and reported net as "Profit/loss from discontinued operations". This also has an effect on previously reported periods, which is why comparative figures no longer correspond to previous reports. A consequence of this is that notes have also been adjusted and the segment "Long-acting injectable drugs" (notes 2 and 3) no longer exists.

In the cash flow, Primm Pharma's share of each activity is reported in the item "Of which from discontinued operations".

Goodwill

Goodwill amounted to SEK 0.0m (61.4) 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 12.4m (0.0) and relate to receivables from our partner STADA.

Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 115.1m (90.0), of which SEK 0.0m (28.1) relates to the purchase and pack-aging costs of reference medicines for the ongoing phase III study that is used on an ongoing basis, SEK 22.1m (51.5) relates to advance payment to the CRO (Contract Research Organization) which performs the clinical study and SEK 71.1m relates to advance payment for consumables for upscaling drug substances to ensure that materials are in place for future upscaling activities. This is because supplier times have been extended with the suppliers and because advance payments are now common in the prevailing circumstances with COVID-19. The remaining SEK 21.9m (10.4) refers to other prepaid expenses and accrued income.

Changes in equity

Equity amounted to SEK 5.6m (4.3) on the balance sheet date. Other capital contributions amounted to SEK 1,132.7m (585.3) and during the period were affected by the directed issue and

share-based payments to employees of SEK 3.0m (2.0). Total equity amounted to SEK 462.4m (135.0). The equity ratio was 66% (44).

Accounts payable

Accounts payable amounted to SEK 29.2m (16.1).

Accrued expenses and prepaid income

Accrued expenses and prepaid income amounted to SEK 143.2m (147.2) and primarily relates to advance payments of SEK 73.0m (90.4) 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 73.0m (90.4).

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 shortly. As a result, shares in subsidiaries have been written down by SEK 49.0 m.

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 15–17.

Significant events during the third quarter

Xlucane™

In September, the company's partner STADA submitted a marketing authorization application for Xlucane™ to the European Medicines Agency (EMA), which was later validated by the agency. The EMA validation confirms that the application is complete enough to initiate a formal review process. The company expects an EMA review for the biosimilar candidate, developed under the name Xlucane™, in accordance with the standard timeline. Xlucane™ will, subject to approval, be marketed under a brand name which will be published during the regulatory process.

Directed share issue

In July, a directed new issue of SEK 380m before estimated issue expenses was registered, which Xbrane announced and implemented at the end of June. After the issue, the total number of shares and votes in the company amounts to 25,039,906. The company's registered share capital amounts to

around SEK 5,613,598. Through this, the company has secured financing for the continued development of the company's product portfolio and the marketing authorization application for Xlucane™.

Great Place to Work®

Xbrane Biopharma was officially certified as a Great Place to Work® by the independent institute Great Place to Work®, a global player working with workplace culture and leadership. The certification is based on the results of an anonymous survey Trust Index™, to which Xbrane's employees responded. This evaluates three perspectives: leadership, pride and team spirit. 95% of Xbrane's employees took part in the survey. The company's culture is based on cornerstones such as: "Make it happen", "Beat yesterday", "Impossible is nothing" and "We win as one".

Significant events after the end of the reporting period

Xcimzane™

In October, the company signed a cooperation agreement with AGC Biologics, with effective date September 30, 2021, for upscaling the established manufacturing process of Xcimzane™ and manufacture the majority of commercial scale batches for the upcoming Phase 1 and Phase 3 studies, and also comparative quality studies (CAA) to demonstrate biosimilarity, required for the marketing authorization application.

Patent protection

In October, Xbrane was granted six new patents by the Patent and Registration Office (PRV). Two of the patents relate to new methods of using signal peptides to increase the production yield and thereby reduce the production cost of recombinant proteins expressed in *E. coli*. The patents are jointly owned, in equal parts, by Xbrane Biopharma AB and CloneOpt AB, a spin-out from Stockholm University. Four of the patents came as a result of the development of Xdivane™ and form the basis for a broadening of the platform technology for high-yield antibody production in mammalian cells on which Xbrane will base much of its future development of biosimilar candidates. The patents are important additional components for Xbrane's platform technology that aim to enable the development of biosimilars at the lowest possible production cost.

Nomination Committee

In October, the Nomination Committee for the 2022 Annual General Meeting was established and announced. See press release on website: https://xbrane.com/en/mfn_news_en/xbrane-biopharma-presents-nomination-committee-4/

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 5.6m (4.3) divided into 25,039,906 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 6,500 shareholders on the balance sheet date. The closing price of the share on the balance sheet date was SEK 136.20 generating a market capitalization of SEK 3,410m.

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 56 (41) employees, 54 (35) of whom were employed by the parent company and 2 (6) by the subsidiary Primm Pharma.

Annual General Meeting

The next Annual General Meeting will be held on May 5, 2022 in Stockholm.

Auditor's review

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

Consolidated income statement

Amounts in SEK thousand	Notes	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Revenues	2,3	–	–	–	–	–
Cost of goods sold		–	–	–	–	–
Gross profit		–	–	–	–	–
Other income	2,3	3,509	4,857	11,090	14,359	17,557
Selling and distribution expenses		–	–	–	–	–
Administrative expenses		–8,768	–6,124	–25,361	–20,305	–26,505
Research and development expenses		–36,472	–50,497	–131,729	–139,736	–197,284
Other expenses		–971	–3,539	–2,442	–9,026	–11,203
Operating profit/loss	2	–42,703	–55,303	–148,442	–154,708	–217,436
Financial income		–506	–	–	–	–
Financial costs		–754	–210	–1,855	–567	–690
Net financial costs	2	–1,260	–210	–1,855	–567	–690
Profit/loss before tax		–43,964	–55,512	–150,297	–155,275	–218,126
Income tax expense		–	–	–	–	–
Profit/loss for the period from continuing operations		–43,964	–55,512	–150,297	–155,275	–218,126
Profit/loss from discontinued operations		–1,506	–2,230	–5,607	–7,698	–7,900
Profit/loss for the period		–45,470	–57,742	–155,905	–162,973	–226,026
Profit/loss attributable to:						
– Owners of the Company		–45,470	–57,742	–155,905	–162,973	–226,026
– Non-controlling interests		–	–	–	–	–
Total comprehensive income for the period		–45,470	–57,742	–155,905	–162,973	–226,026
Earnings per share						
– Basic earnings per share (SEK)		–1.83	–2.99	–6.75	–9.49	–12.48
– Diluted earnings per share (SEK)		–1.83	–2.99	–6.75	–9.49	–12.48
Number of outstanding shares at the end of the reporting period						
– Before dilution		25,039,906	19,280,707	25,039,906	19,280,707	22,200,415
– After dilution		25,039,906	19,280,707	25,039,906	19,280,707	22,200,415
Average number of outstanding shares						
– Before dilution		24,886,770	19,280,707	23,105,787	17,177,891	18,113,313
– After dilution		24,886,770	19,280,707	23,105,787	17,177,891	18,113,313

Consolidated income statement and other comprehensive income

Amounts in SEK thousand	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Total comprehensive income for the period	-45,470	-57,742	-155,905	-162,973	-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	516	398	1,036	476	-2,774
Comprehensive income for the period	516	398	1,036	476	-2,774
Total comprehensive profit/loss attributable to:					
– Owners of the Company	-44,954	-57,345	-154,869	-162,498	-228,801
– Non-controlling interests	–	–	–	–	–
Total comprehensive income for the period	-44,954	-57,345	-154,869	-162,498	-228,801

Consolidated statement of financial position

Amounts in SEK thousand	09-30-2021	09-30-2020	12-31-2020
ASSETS			
Goodwill	–	61,386	58,453
Intangible assets	26,922	4,492	4,083
Property, plant and equipment	28,467	8,983	8,166
Right of use assets	43,342	6,800	5,969
Trade and other receivables	4,580	13,013	12,610
Non-current assets	103,310	94,673	89,281
Trade receivables	12,390	–	51,384
Other receivables	13,777	7,658	6,981
Prepaid expenses and accrued income	115,144	89,985	72,978
Cash and cash equivalents	383,435	123,768	243,139
Assets held for sale	68,938	–	–
Current assets	593,684	221,441	374,482
TOTAL ASSETS	696,994	316,083	463,763
EQUITY			
Share capital	5,614	4,322	4,977
Share premium	1,132,678	585,343	773,724
Reserves	4,981	7,194	3,945
Retained earnings including the loss of the period	–680,842	–461,885	–524,938
Equity attributable to owners of the Company	462,431	134,976	257,708
Non-controlling interests	–	–	–
Total equity	462,431	134,976	257,708
LIABILITIES			
Leasing liability	37,219	4,419	3,995
Non-current non-interest-bearing liabilities	2,462	4,216	8,257
Provisions	–	5,046	4,810
Non-current liabilities	39,681	13,681	17,062
Trade and other payables	29,157	16,111	29,546
Other current liabilities	13,180	1,431	1,328
Leasing liability	7,043	2,665	2,265
Deferred income/revenue	143,206	147,219	155,853
Assets held for sale	2,296	–	–
Current liabilities	194,882	167,426	188,993
TOTAL LIABILITIES	234,563	181,108	206,055
TOTAL EQUITY AND LIABILITIES	696,994	316,083	463,763

Consolidated cash flow statement

Amounts in SEK thousand	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Cash flow from operating activities					
Profit/loss before tax	-45,470	-57,742	-155,905	-162,973	-226,026
Adjustments for items not included in cash flow	3,122	-1,859	962	2,408	6,247
Paid income taxes	-	-	-	-	-
Total	-42,348	-59,602	-154,943	-160,556	-219,779
Increase (-)/Decrease (+) of trade and other receivables	-24,097	17,296	-5,384	-17,911	-51,325
Increase (+)/Decrease (-) of trade and other payables	4,139	-61,087	1,085	7,653	32,697
Cash flow from current operations	-62,306	-103,393	-159,242	-170,824	-238,407
<i>Of which discontinued operations</i>	<i>-1,489</i>	<i>-1,360</i>	<i>-11,225</i>	<i>-6,028</i>	<i>-8,020</i>
Cash flow from investing activities					
Acquisition of property, plant and equipment	-10,604	-3,788	-24,528	-3,864	-3,855
Acquisition of intangible assets	-26,922	-	-26,922	-	-
Cash flow from investing activities	-37,526	-3,788	-51,450	-3,864	-3,855
<i>Of which discontinued operations</i>	<i>0</i>	<i>-361</i>	<i>0</i>	<i>-361</i>	<i>-352</i>
Cash flow from financing activities					
Proceeds from exercise of share options	-	-	-	3	3
New share issue	380,445	-	380,870	146,444	346,444
Issue expenses	-24,244	-	-24,244	-10,337	-20,584
Amortization of loan	-	-	-	-12	-12
Amortization of lease liability	-1,824	-786	-4,920	-2,350	-3,127
Cash flow from financing activities	354,376	-786	351,706	133,748	322,724
<i>Of which discontinued operations</i>	<i>-129</i>	<i>-226</i>	<i>-377</i>	<i>-2,268</i>	<i>2,367</i>
Cash flow for the period	254,545	-107,967	141,014	-40,940	80,461
Cash and cash equivalents in assets held for sale	399	-	-1,033	-	-
Cash and cash equivalents at beginning of period	128,436	232,506	243,139	164,197	164,197
Exchange rate differences in cash and cash equivalents	56	-771	315	510	-1,520
Cash and cash equivalents at end of period	383,435	123,768	383,435	123,768	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	-	-	-	-155,905	-155,905
Other comprehensive income for the period	-	-	1,036	-	1,036
Total comprehensive income for the period	-	-	1,036	-155,905	-154,869
Transactions with group shareholder					
New share issue	633	380,237	-	-	380,870
Issue expenses	-	-24,244	-	-	-24,244
Share savings program	4	2,961	-	-	2,965
Total contributions from and distributions to shareholders	637	358,954	-	-	359,591
Balance at September 30, 2021	5,614	1,132,678	4,981	-680,842	462,431
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	-	-	-	-162,973	-162,973
Other comprehensive income for the period	-	-	476	-	476
Total comprehensive income for the period	-	-	476	-162,973	-162,498
Transactions with group shareholder					
New share issue	864	145,580	-	-	146,444
Issue expenses	-	-10,337	-	-	10,337
Share savings program	3	2,011	-	-	2,014
Total contributions from and distributions to shareholders	867	137,254	-	-	138,121
Balance at September 30, 2020	4,322	585,343	7,194	-461,885	134,976
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 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Revenues	–	–	–	–	–
Cost of goods sold	–	–	–	–	–
Gross profit	–	–	–	–	–
Other income	3,509	4,849	11,090	14,485	17,730
Administrative expenses	–8,962	–6,139	–26,160	–20,352	–26,567
Research and development expenses	–36,674	–45,593	–131,916	–135,036	–197,690
Other expenses	–971	–3,539	–2,442	–9,026	–11,203
Operating profit/loss	–43,098	–50,377	–149,429	–149,929	–217,730
Financial items					
Financial income	–506	–	–	11	11
Impairment loss on shares in subsidiary	–1,015	–	–10,631	–	–38,400
Financial expenses	–89	–112	–210	–261	–296
Net finance costs	–1,610	–112	–10,841	–250	–38,685
Profit/loss before tax	–44,708	–50,489	–160,270	–150,179	–256,415
Income tax expense	–	–	–	–	–
Total comprehensive income for the period	–44,708	–50,489	–160,270	–150,179	–256,415

Parent company statement of comprehensive income

Amounts in SEK thousand	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Profit/loss for the period	–44,708	–50,489	–160,270	–150,179	–256,415
Other comprehensive income	–	–	–	–	–
Total comprehensive income for the period	–44,708	–50,489	–160,270	–150,179	–256,415

Balance Sheet, Parent company

Amounts in SEK thousand	09-30-2021	09-30-2020	12-31-2020
ASSETS			
Fixed assets			
Intangible assets	26,922	–	–
Property, plant and equipment	28,467	5,729	5,212
Financial assets			
Shares in group companies	74,066	110,391	74,066
Other non-current receivables	4,580	13,013	12,610
Total financial assets	78,646	123,404	86,676
Total non-current assets	134,035	129,133	91,888
Current assets			
Current receivables			
Trade receivables	12,390	–	51,384
Other receivables	13,777	6,164	5,148
Prepaid expenses and accrued income	115,144	89,895	72,935
Total current receivables	141,310	96,059	129,467
Cash and bank	383,435	122,326	242,247
Current assets	524,746	218,385	371,715
TOTAL ASSETS	658,780	347,518	463,603
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	5,614	4,322	4,977
Reserve for development expenditure	26,922	–	–
Unrestricted equity			
Share premium	1,133,364	586,029	774,410
Retained earnings	–535,811	–252,474	–252,474
Profit/loss for the period	–160,270	–150,179	–256,415
Total equity	469,819	187,699	270,498
Non-current liabilities			
Non-current interest-bearing liabilities	2,462	4,216	8,257
Non-current non-interest-bearing liabilities	2,462	4,216	8,257
Current liabilities			
Liabilities to subsidiaries	957	349	285
Trade and other payables	29,157	15,678	29,421
Other current liabilities	13,180	1,292	1,192
Deferred income/revenue	143,206	138,284	153,949
Current liabilities	186,500	155,603	184,847
TOTAL LIABILITIES	188,961	159,819	193,104
TOTAL EQUITY AND LIABILITIES	658,780	347,518	463,603

Cash flow statement, Parent company

Amounts in SEK thousand	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Cash flows from operating activities					
Earnings before income and tax	-44,708	-50,489	-160,270	-150,179	-256,415
Adjustments for items not included in cash flow	2,091	-1,333	9,582	-1,509	39,601
Paid income taxes	-	-	-	-	-
Total	-42,617	-51,822	-150,687	-151,688	-216,814
Increase (-)/Decrease (+) of trade and other receivables	-24,792	-7,987	-3,813	-19,376	-52,381
Increase (+)/Decrease (-) of trade and other payables	5,208	-42,994	2,443	4,597	36,709
Cash flow from current operations	-62,201	-102,803	-152,057	-166,467	-232,486
Cash flow from investing activities					
Investments in subsidiaries	-1,015	-1,554	-10,631	-8,073	-10,148
Acquisition of property, plant and equipment	-11,972	-3,427	-26,132	-3,503	-3,503
Acquisition of intangible assets	-26,922	-	-26,922	-	-
Cash flow from investing activities	-39,906	-4,981	-63,685	-11,576	-13,651
Cash flow from financing activities					
Exercised share options by employees	-	-	-	3	3
New share issue	380,445	-	380,870	146,444	346,444
Issue expenses	-24,244	-	-24,244	-10,337	-20,584
Cash flow from financing activities	356,201	-	356,626	136,110	325,863
Cash flow for the period	254,091	-107,784	140,883	-41,933	79,726
Cash and cash equivalents at beginning of period	129,331	230,746	242,247	163,601	163,601
Exchange rate differences in cash and cash equivalents	12	-636	304	658	-1,079
Cash and cash equivalents at end of period	383,435	122,326	383,435	122,326	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.

Intangible assets

Intangible assets with a limited useful life are reported at acquisition value less depreciation and any impairment. Intangible fixed assets are depreciated systematically over the asset's estimated useful life. The useful life is reconsidered at each balance sheet date and adjusted if necessary. Depreciation begins upon completion, when the product is launched on the market. When the depreciable amount of the asset is determined, the residual value of the asset is taken into account where applicable. Development expenses are capitalized when they meet the criteria in accordance with IAS 38 "Intangible assets". In other respects, development expenses are expensed on an ongoing basis as operating expenses.

The criteria for capitalizing are:

- it is technically possible to complete a useful product
- the company's intention is to complete the product and to sell it
- there are conditions to sell the product
- it can be shown how the product generates probable future financial benefits
- adequate technical, financial and other resources to complete the development and to use the product are available
- the expenses attributable to the product during its development can be calculated reliably

Directly attributable expenses that are capitalized as part of capitalized development expenses include, in addition to direct development costs, expenses for employees, external consultants, depreciation of right-of-use assets in the form of used premises and interest.

NOTE 2 Segment reporting

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

Amounts in SEK thousand	2021 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Other revenues per segment					
Biosimilars	2,303	2,545	7,635	4,242	6,787
Unallocated revenue	1,206	2,312	3,455	10,117	10,770
Total	3,509	4,857	11,090	14,359	17,557
Operating profit or loss per segment					
Biosimilars	-34,169	-47,952	-124,094	-135,494	-190,497
Unallocated revenue	-8,534	-7,351	-24,349	-19,214	-26,939
Operating profit/loss	-42,703	-55,303	-148,442	-154,708	-217,436
Net finance costs					
Biosimilars	-665	-97	-1,645	-317	-406
Unallocated revenue	-595	-112	-210	-250	-284
Total	-1,260	-210	-1,855	-567	-690
Profit/loss before tax	-43,964	-55,512	-150,297	-155,275	-218,126
Depreciation, amortization and write downs					
Biosimilars	3,080	1,087	7,974	3,231	4,337
Unallocated revenue	126	8	351	26	33
Total	3,206	1,095	8,325	3,257	4,370

As of Q1 2021, the subsidiary Primm Pharma is reported as an asset held for sale, see page 8. This means that the segment "Long-acting injectable drugs" is no longer included in the segment reporting. This also has an effect on previously reported periods.

NOTE 3 Distribution of income

Amounts in SEK thousand	Jul – Sep 2021		
	Biosimilars	Unallocated/ administration	Group
Income per region			
Middle East	–	–	–
Asia	–	–	–
Europe	–	1,137	1,137
United States	2,303	69	2,372
Total	2,303	1,206	3,509
Income per category			
Pharmaceuticals	–	–	–
Milestone payments from partners	2,303	–	2,303
Services and other	–	1,206	1,206
Total	2,303	1,206	3,509

As of Q1 2021, the subsidiary Primm Pharma is reported as an asset held for sale, see page 8. This means that the segment "Long-acting injectable drugs" is no longer included in the distribution of income. This also has an effect on previously reported periods.

NOTE 3 Distribution of income cont.

Jul – Sep 2020			
Amounts in SEK thousand	Biosimilars	Unallocated/administration	Group
Income per region			
Middle East	–	–	–
Asia	–	–	–
Europe	–	2,292	2,292
United States	2,545	19	2,565
Total	2,545	2,312	4,857
Income per category			
Pharmaceuticals	–	–	–
Milestone payments from partners	2,545	–	2,545
Services and other	–	2,312	2,312
Total	2,545	2,312	4,857

Jan – Sep 2021			
Amounts in SEK thousand	Biosimilars	Unallocated/administration	Group
Income per region			
Middle East	–	–	–
Asia	–	–	–
Europe	–	3,123	3,123
United States	7,635	332	7,967
Total	7,635	3,455	11,090
Income per category			
Pharmaceuticals	–	–	–
Milestone payments from partners	7,635	–	7,635
Services and other	–	3,455	3,455
Total	7,635	3,455	11,090

As of Q1 2021, the subsidiary Primm Pharma is reported as an asset held for sale, see page 8. This means that the segment "Long-acting injectable drugs" is no longer included in the distribution of income. This also has an effect on previously reported periods.

Jan – Sep 2020			
Amounts in SEK thousand	Biosimilars	Unallocated/administration	Group
Income per region			
Middle East	–	–	–
Asia	–	–	–
Europe	–	9,999	9,999
United States	4,242	118	4,360
Total	4,242	10,117	14,359
Income per category			
Pharmaceuticals	–	–	–
Milestone payments from partners	4,242	–	4,242
Services and other	–	10,117	10,117
Total	4,242	10,117	14,359

NOTE 3 Distribution of income cont.

Jan – Dec 2020			
Amounts in SEK thousand	Biosimilars	Unallocated/administration	Group
Income per region			
Middle East	–	–	–
Asia	–	–	–
Europe	–	10,598	10,598
United States	6,787	171	6,958
Total	6,787	10,770	17,557
Income per category			
Pharmaceuticals	–	–	–
Milestone payments from partners	6,787	–	6,787
Services and other	–	10,770	10,770
Total	6,787	10,770	17,557

NOTE 4 Transactions with related parties

Since 2019, STADA Arzneimittel AG has been a shareholder in Xbrane (see the list of owners on page 6). 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	09-30-2021 Level 2	09-30-2020 Level 2	12-31-2020 Level 2
Amounts in SEK thousand			
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, October 28, 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

Auditor's report

To the Board of Directors of Xbrane Biopharma AB (publ)
Corp. id. 556749-2375

Introduction

We have reviewed the condensed interim financial information (interim report) of Xbrane Biopharma AB (publ) as of 30 September 2021 and the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Stockholm, 28 October 2021

PricewaterhouseCoopers AB

Magnus Lagerberg
Authorized Public Accountant

Alternative performance measures

The Company presents certain financial measures in the interim report that are not defined in accordance with IFRS. The Company believes that these measures provide valuable supplementary information to investors and the Company's management as they enable evaluation of the Company's performance. Since not all companies calculate financial measurements in the same way, these are not always comparable to measurements used by other companies. These financial measures should therefore not be seen as replacement for measures that are defined in accordance with IFRS. The tables below show measurements that are not defined in accordance with IFRS.

Gross margin

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 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Gross profit	–	–	–	–	–
Net sales	–	–	–	–	–
Gross margin	–	–	–	–	–

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 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Operating profit or loss	–42,703	–55,303	–148,442	–154,708	–217,436
Depreciation, amortization and write downs	–3,206	–1,095	–8,325	–3,257	–4,370
EBITDA	–39,497	–54,208	–140,117	–151,451	–213,066

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 Jul – Sep	2020 Jul – Sep	2021 Jan – Sep	2020 Jan – Sep	2020 Jan – Dec
Research and development expenses	–36,472	–50,497	–131,729	–139,736	–197,284
Total operating expenses	–46,212	–60,160	–159,533	–169,067	–234,992
R&D expenses as a percentage of operating expenses	79%	84%	83%	83%	84%

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	09-30-2021	09-30-2020	12-31-2020
Total equity	462,431	134,976	257,708
Total assets	696,994	316,083	463,763
Equity ratio	66%	43%	56%



For further information:

Martin Åmark, CEO
martin.amark@xbrane.com
+46 76-309 37 77

Anette Lindqvist CFO/IR
anette.lindqvist@xbrane.com
+46 76-325 60 90

www.xbrane.com

Financial calendar

Year-end report 2021	February 16, 2022
Annual report 2021	March 31, 2022
Interim report January - March 2022	April 28, 2022
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



Xbrane Biopharma AB | Retzius väg 8, SE-171 65 Solna, Sweden | www.xbrane.com

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