XBRANE BIOPHARMA

Science for high quality biosimilars

Interim report January – September 2022

Positive opinion from CHMP[1)] paves the way for launch of Ximluci®

Financial overview third quarter 2022

- Revenue amounted to SEK 13.9 m (2.3).
- Other operating income was SEK 6.3 m (1.2).
- EBITDA amounted to SEK –37.6 m (–39.5).
- R&D costs amounted to SEK –51.2 m (–36.5), corresponding to 82 percent[2)] (79) of total operating costs.
- The loss for the period was SEK –41.9 m (–45.5).
- Earnings per share was SEK –1.67 (–1.83).
- Cash and cash equivalents at the end of the period amounted to SEK 165.2 m (383.4).

Financial overview first nine months 2022

- Revenue amounted to SEK 36.8 m (7.6).
- Other operating income was SEK 23.9 m (3.5).
- EBITDA amounted to SEK –98.9 m (–140.1).
- R&D costs amounted to SEK –140.1 m (–131.7) corresponding to 82 percent[2)] (83) of total operating costs.
- The loss for the period was SEK –111.8 m (–155.9).
- Earnings per share was SEK –4.45 (–6.75).
- Cash and cash equivalents at the end of the period amounted to SEK 165.2 m (383.4).

Figures in parentheses refer to the corresponding period last year.

Significant events during the third quarter of 2022

- Xbrane announced in September that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) had adopted a positive opinion for Ximluci®, which was developed under the name Xlucane™, a Lucentis® (ranibizumab) biosimilar candidate. The opinion recommends approval of Ximluci® throughout the EU and has been referred to the European Commission (EC), which will decide on a marketing authorization. Approval can be expected by the end of November.
- Due to the imminent launch of Ximluci®, the company held a capital markets day at the end of September, where there was an update on Xbrane's long-term strategy, product portfolio, platform technology and an in-depth look at the imminent launch of Ximluci® in Europe.

Significant events after the end of the quarter

- With the support of authorization from the annual general meeting on May 5, 2022, the company announced and carried out a directed new issue in mid-October, of around SEK 170 m at a subscription price of SEK 72 per share. Effects in the balance sheet and cash flow will become visible in the upcoming interim report for October–December 2022.

1) European Medicines Agency's (EMA's) committee for Medicinal Products for Human Use (CHMP).
2) See page 9 for more information on research and development costs.

Financial summary for the Group

	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Revenue (SEK 000)	13,935	2,303	36,756	7,635	10,709
Research and development expenses (SEK 000)	–51,239	–36,472	–140,101	–131,729	–160,619
R&D expenses as percentage of total costs	82%	79%	82%	83%	82%
Operating profit/loss (SEK 000)	–41,992	–42,703	–111,176	–148,442	–180,583
EBITDA (SEK 000)	–37,637	–39,497	–98,904	–140,117	–168,366
Profit/loss for the period (SEK 000)	–41,884	–45,470	–111,780	–155,905	–188,376
Cash and cash equivalents (SEK 000)	165,235	383,435	165,235	383,435	295,180
Equity ratio (%)	56%	66%	56%	66%	63%
Earnings per share before dilution (SEK)	–1.67	–1.83	–4.45	–6.75	–7.98
Earnings per share after dilution (SEK)	–1.67	–1.83	–4.45	–6.75	–7.98
Number of employees on balance sheet date	74	56	74	56	58

CEO's letter

Dear shareholders
In September, we received a positive opinion from the European Medicines Agency's (EMA's) committee for Medicinal Products for Human Use (CHMP), which recommended approval of our Lucentis biosimilar candidate, which is now called Ximluci®. This was of course fantastic news for us and paves the way for a formal approval in November and launch in Europe in Q1 2023.

Towards the launch of Ximluci® in Europe
Therefore, we are moving towards the important launch of Xbrane's first drug candidate, Ximluci®, for the treatment of serious eye diseases. Like other product candidates in our portfolio, this is a biosimilar, i.e. a biological drug that has existing drugs on the market as a reference and can be sold when the patent has expired. We thus offer cost-effective treatment options for a wider target group.

During Q3, we received a positive opinion from the European Medicines Agency's (EMA's) committee for Medicinal Products for Human Use (CHMP), which recommended approval of Ximluci® in Europe. In parallel, we have started production so our partner STADA can launch the product in Europe during Q1 2023. We have also worked on completing our application to the Food and Drug Administration (FDA) in the US, which we intend to submit during Q4 2022. We can therefore expect approval in the US in Q4 2023, which could enable a launch in North America by our partner Bausch + Lomb shortly thereafter.

Meets large and untreated market
Ximluci® targets the market for VEGFa inhibitors for ophthalmic use, which has global sales of around SEK 120 bn, of which around SEK 40 bn is in Europe. The product therefore addresses a significant market. We also expect further growth for Xbrane in connection with more cost-effective biosimilars coming to the market, as there is still a large proportion of untreated and undertreated patients due to high drug costs and limited subsidies. We have seen this in similar situations before, for example when biosimilars came to the market for TNFalpha inhibitors in the treatment of autoimmune diseases. In that case, in Europe it led to a doubling of the number of treatment days per capita in just a couple of years.

Development of the biosimilar portfolio
Work on the biosimilar portfolio continues. Preparations for scaling-up to a commercial scale for the manufacture of clinical material regarding BIIB801 (a biosimilar candidate for Cimzia®) are underway in close collaboration with Biogen. For Xdivane™, process development is ongoing as well as trying to find a cooperation partner on the manufacturing side. We now have five approved patents for Xdivane™, regarding DNA constructs that are used to achieve as high productivity as possible and therefore the lowest production costs. For Xdarzane™ and Xtrudane™, cell line development is underway using the same patented technology used for Xdivane™. Our ambition is to find a commercialization partner in 2023 for these three biosimilar oncology candidates.

Financing
During October, we carried out a directed share issue of SEK 170 m. With this addition, coupled with cash of SEK 165 m as of the end of September, we go into 2023 strengthened.

Key milestones for the next 12 months
In summary, we are in a very exciting position ahead of the imminent launch of Ximluci® in Europe. Some of the key milestones we see ahead of us over the next 12 months are:

- Launching of Ximluci® in Europe in Q1 2023
- Submit a Biologics license application for Ximluci® in the US
- Submit a marketing authorization application for Ximluci® in selected countries outside Europe and the US
- Scale up the production process and prepare clinical studies for BIIB801 with our partner Biogen
- Establish commercialization partner for the oncology portfolio

We look forward confidently to strengthening our position as a world-leading biosimilar developer over the next 12 months.

Thank you for your continued support.

Solna, October 28, 2022

Martin Åmark
CEO

Product candidate portfolio

Xbrane has a portfolio of five product candidates in active development for a range of treatment areas. This includes several serious eye diseases, several different types of cancer and, among others, rheumatoid arthritis, psoriasis and Crohn's disease. Of the candidates, Ximluci® is the closest to marketing authorization.

Ximluci®

Ximluci® is a biosimilar candidate to ranibizumab (original drug Lucentis®), a VEGFa inhibitor used in the treatment of several serious eye diseases. The market for VEGFa inhibitors saw sales of over SEK 119 bn[1,2,3] in 2021 and has grown by 8–10 percent per year in recent years[1,2,3]. In Europe, the market had sales of around SEK 40 bn (IQVIA) and has grown in line with the global market.

The European Medicines Agency's (EMA) Scientific Committee (CHMP) recommended in September 2022 that the European Commission approve Ximluci® for the treatment of wet age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (PDR), retinal vein occlusion (RVO) and visual impairment due to choroidal neovascularization (CNV) in Europe. Ximluci® will be launched by Xbrane's partner STADA Arzneimittel AG (STADA) in Q1 2023.

Xbrane intends to submit a Biologics license application to the Food and Drug Administration (FDA) in the US in Q4 2022, which is expected to lead to approval in Q4 2023 and a launch by Bausch+Lomb, Xbrane's and STADA's partner in North America. Ximluci® is expected to be initially approved as a vial of the active substance, which the ophthalmologist extracts into a syringe for injecting into the eye. Xbrane is also developing Ximluci® as a prefilled syringe, for which additional approval will be sought in future.

BIIB801

BIIB801 is a biosimilar candidate to certolizumab pegol (original drug Cimzia®), a TNF-alpha inhibitor particularly used in the treatment of rheumatoid arthritis and psoriasis. The TNF-alpha inhibitor market saw sales of about SEK 365 bn[4] in 2021 and Cimzia® saw sales of SEK 19 bn[5] in 2021.The patent protection of Cimzia® is expected to expire in 2024 in the US and 2025 in Europe.

BIIB801is undergoing preclinical 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 BIIB801 for future clinical studies. Xbrane has signed a development and commercialization agreement with Biogen in which Biogen obtains global rights to the product. The agreement means that Biogen makes an up-front payment of USD 8 m and an additional USD 80 m in development and sales-based payments as well as royalties on sales.

Xdivane™

Xdivane™ is a biosimilar candidate to nivolumab (original drug Opdivo®), a PD-1-inhibitor for the treatment of different types of cancer with sales of around SEK 68 bn[6] in 2021. Opdivo® is expected to lose its patent protection between 2026 and 2031, depending on the country.

Xdivane™ is at the preclinical development stage, with a focus on developing a cost-effective production process and demonstrating a biochemical similarity to the original drug. After that, upscaling with a production partner will follow, after which the product can be taken into clinical trials.

Sources:
1) Novartis Annual Report 2021
2) Roche Annual Report 2021
3) Regeneron Year-End Report 2021
4) TNF-Alpha Inhibitors Global Market Report 2021: COVID-19 Growth and Change to 2030
5) UCB Annual Report 2021 (extrapolated)
6) BMS Year-end report 2021

Xtrudane™

Xtrudane™ is a biosimilar candidate to pembrolizumab (original drug Keytruda®), a PD-1 inhibitor for the treatment of various types of cancer, with sales of around SEK 155 bn in 2021. The patent protection of Keytruda® is expected to expire during 2029–2031 depending on the country. Xtrudane™ is at the preclinical development stage with a focus on developing a cost-effective production process and demonstrating a biochemical similarity to the original drug. After that, upscaling with a production partner will follow, after which the product can begin clinical trials.

Xdarzane™

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

Xdarzane™ is at the preclinical development stage with a focus on developing a cost-effective production process and demonstrating a biochemical similarity to the original drug. After that, upscaling with a production partner will follow, after which the product can begin 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 3 bn. Xbrane is not currently actively developing Xoncane™ but is looking for a partner who can drive the development further.

Spherotide™*)

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

Xbrane is not currently actively developing Spherotide™ but is working to divest Primm Pharma.

*) Products where no active development is being carried out

Product portfolio

Product	Original drug	Primary indication	Estimated annual peak sales of original drug	Patent expiry of original drug	Development phase
Ximluci®	Ranibizumab (Lucentis®)	Wet age-related macular degeneration, diabetes-related eye damage and retinal vein occlusion	EUR 3 bn[1)]	2022 (Europe) 2020 (USA)	Registration phase
BIIB801	Certolizumab pegol (Cimzia®)	Rheumatoid arthritis, axial spondylarthrosis, psoriatic arthritis, and psoriasis	EUR 2 bn[1)]	2024 (USA) 20259 (Europe)	Preclinical phase
Xdivane™	Nivolumab (Opdivo®)	Melanoma, lung cancer, kidney cell cancer, head and neck cancer and bladder and urinary tract cancer.	EUR 13 bn[1)]	2026–2031 depending on country	Preclinical phase
Xtrudane™	Keytruda®	Brain cancer, melanoma, lung cancer, kidney cell cancer, head and neck cancer and bladder and urinary tract cancer.	EUR 26 bn[1)]	2029–2031 depending on country	Preclinical phase
Xtrudane™	Darzalex®	Multiple melanoma	EUR 9 bn[1)]	2029–2031 depending on country	Preclinical phase
			EUR 53 bn		

***) Products where no further development is being carried out**

Xoncane™	Pegaspargase (Oncaspar®)	Acute lymphomatic leukemia.	Not applicable	Expired	Preclinical phase
Spherotide™	Triptorelin (Decepeptyl®)	Prostate cancer, breast cancer, endometriosis and fibroids.	Not applicable	Expired	Clinical phase

Source
1) Evaluate Pharma: "Originator Peak Sales Estimate 2026"

Patent protection

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

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

Expanding patent portfolio

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

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

The most important regions for patents are Europe and the US, but patent applications may also be filed in Canada, China, South Korea, India, Japan and Australia if our products and methods have a market there.

Xbrane's LEMO™ technology platform is patent protected in Europe and the US until 2029. Between 2020 and Q3 2022, the two patents, which were filed in 2009, were complemented by 32 patent applications for a total of 34 applications "harvested" from five different development programs. A total of eleven patent applications were filed in 2020, twelve patent applications in 2021 and nine patent applications in the first three quarters of 2022.

Strengthen the Xbrane brand

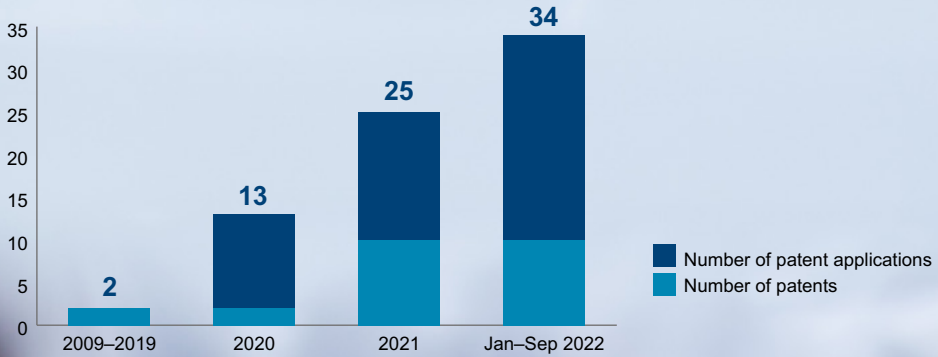
The Swedish Intellectual Property Office (PRV) granted eight patents in 2021. Three relate to DNA constructs for the regulation of protein production and were co-filed with CloneOpt AB. Five of the patents resulted from the development of Xdivane™ and form the foundation for the emerging high-yield expression platform in mammalian cells. A large part of the upcoming development of the biosimilar candidates Xtrudane™ and Xdarzane™ is based on this platform. The five Swedish patents were followed up, via an international patent application, with applications in the US, Canada, India, China, Singapore and Japan during Q3. During Q4, the scope of protection will be extended to South Korea, Australia and Europe.

The patent applications protect new DNA sequences in genes that are introduced into host cells and instruct the cells to express the protein of interest. These DNA sequences have resulted in a significant increase in yield and can also be applied to future biosimilar candidates to be expressed in mammalian cells. A large portion of the rest of the patent applications relate to DNA constructs, host cells and/or methods for producing Ximluci® (three patent applications) and BIB801 (eleven patent applications).

The patent applications to protect Ximluci® have been filed together with STADA.

The expanding patent portfolio will strengthen Xbrane's brand, protect our own and our partners' products and enable more outlicensing of IP in the future.

Number of patents and patent applications (accumulated)



Shareholders

As of September 30, 2022, Xbrane had around 6,200 shareholders. The number of outstanding shares amounted to 25,144,906. The ten largest shareholders at the end of the period are shown in the table below[1].

Name	Number of shares	Ownership, %
Serendipity Group	3,177,367	12.6%
Bengt Göran Westman	2,106,552	8.4%
Swedbank Robur Fonder	2,022,275	8.0%
STADA Arzneimittel AG	1,570,989	6.3%
Futur Pension	1,569,755	6.2%
TIN Fonder	1,435,000	5.7%
Avanza Pension	904,725	3.6%
Nordnet Pensionsförsäkring	407,718	1.6%
Swedbank Försäkring	365,638	1.5%
Clearstream Banking S.A	197,000	1.3%
Ten largest shareholders in total	**13,879,499**	**55.2%**
Other Swedish shareholders	**7,466,509**	**29.7%**
Other foreign shareholders	**3,798,898**	**15.1%**
Total outstanding shares	**25,144,906**	**100%**

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 2022

The Group's revenue amounted to SEK 13.9 m (2.3) and consisted partly of income from the out-licensing of the American and Canadian rights for Ximluci®, to Bausch + Lomb and the agreement signed with Biogen regarding BIIB801. The agreement with Biogen started during Q1 2022. Revenues attributable to the agreements are accrued until May 2022 and June 2023, respectively. Similar agreements were previously deemed to constitute other operating income for the Group. Since January 1, 2022, however, this type of income is deemed to form part of the Group's main business and is thus reported as revenue. Previous periods have therefore been reclassified, which means that comparative figures are no longer in line with previous reports. See also Note 1 for further information regarding the reclassification.

The cost of goods sold amounted to SEK 0.0 m (0.0).

Other operating income amounted to SEK 6.3 m (1.2) and consisted mainly of exchange rate gains on operating receivables and liabilities as well as license income from sources other than the core business itself.

Research and development costs amounted to SEK –51.2 m (–36.5) and mainly relate to Ximluci®, where the main cost-drivers are the regulatory work and establishing a production chain for Ximluci®. Additional factors are the continuing work on BIIB801 which has intensified and the work on developing new biosimilars. All development costs for Ximluci® have been recognized as intangible assets in the balance sheet and amounted to SEK 89.1 m (26.9) for the period. The gross effect of research and development costs for the period was SEK –54.9 m (–49.9). The capitalization of development costs also affects the comparative figures for research and development costs, which decreased compared with previous periods.

Administrative expenses amounted to SEK –6.6 m (–8.8), and the decrease is due to the change of premises during the comparison period. Furthermore, work continues to strengthen the organization prior to commercialization and continued growth.

Other operating expenses amounted to SEK –4.4 m (–1.0) and consisted of exchange rate losses on operating receivables and liabilities.

The operating loss was SEK –42.0 m (–42.7). The loss before tax was SEK –42.6 m (–44.0). During Q3, no taxable profit arose and thus no tax expense (0.0). The loss for the quarter after tax from remaining operations amounted to SEK –42.6 m (–44.0) and loss for the quarter was SEK –33.8 m (–59.2). Earnings per share for remaining operations amounted to SEK –1.69 (–1.77) per share and earnings per share amounted to SEK –1.67 (–1.83).

The Group's cash flow July – September 2022

Cash flow from operating activities amounted to SEK –38.0 m (–42.3). The change in operating receivables and operating liabilities was SEK 23.2 m (–24.1) and SEK –60.1 m (4.1), respectively, of which asset out for sale SEK –0.3 m (–1.5) (Primm Pharma) The change in working capital can vary greatly between periods, mainly due to the re-invoicing to STADA for the development work for Ximluci®, i.e. establishing a production chain and the regulatory work. The continuing work on BIIB801 has also intensified and is part of the change.

Cash flow from investment activities amounted to SEK –11.5 m (–37.5) and included investments in tangible assets for the internal laboratory and capitalization of research and development costs. Cash flow from financing activities amounted to SEK –11.5m (–37.5) and relates to leasing of machines and premises.

The Group's results for January – September 2022

The Group's revenue amounted to SEK 36.8 m (7.6) and consisted partly of income from the out-licensing of the American and Canadian rights for Ximluci®, to Bausch + Lomb and the agreement signed with Biogen regarding BIIB801. The agreement with Biogen started during Q1 2022. Revenues attributable to the agreements are accrued until May 2022 and June 2023, respectively. Similar agreements were previously deemed to constitute other operating income for the Group. Since January 1, 2022, however, this type of income is deemed to form part of the Group's main business and is thus reported as revenue. Previous periods have therefore been reclassified, which means that comparative figures are no longer in line with previous reports. See also Note 1 for further information regarding the reclassification.

The cost of goods sold amounted to SEK 0.0 m (0.0).

Other operating income amounted to SEK 23.9 m (3.5) and consisted mainly of exchange rate gains on operating receivables and liabilities as well as license income from sources other than the core business itself.

Research and development costs amounted to SEK –140.1 m (–131.7) and mainly relate to Ximluci®, where the main cost-drivers are the regulatory work and establishing a production chain for Ximluci®. Additional factors are the continuing work on BIIB801 which has intensified and the work on developing new biosimilars. All development costs for Ximluci® have been recognized as intangible assets in the balance sheet and amounted to SEK 89.1 m (26.9) for the period. The gross effect of research and development costs for the period was SEK –179.5 m (–158.6). The capitalization of development costs also affects the comparative figures for research and development costs, which decreased compared with previous periods.

Administrative expenses amounted to SEK –20.6 m (–25.4), and the decrease is due to the change of premises during the comparison period. Furthermore, work continues to strengthen the organization prior to commercialization and continued growth.

Other operating expenses amounted to SEK –11.2 m (–2.4) and consisted of exchange rate losses on operating receivables and liabilities.

The operating loss was SEK –111.2 m (–148.4). The loss before tax was SEK –113.2 m (–150.3). During the period, no taxable profit arose and thus no tax expense (0.0). The loss for the period after tax from remaining operations amounted to SEK –113.2 m (–150.3) and loss for the period was SEK –111.8 m (–155.9). Earnings per share for remaining operations amounted to SEK –4.51 (–6.50) per share and earnings per share amounted to SEK –4.45 (–6.75).

The Group's cash flow January – September 2022

Cash flow from operating activities amounted to SEK –102.6 m (–154.9). The change in operating receivables and operating liabilities was SEK 19.7 m (–5.4) and SEK –5.7 m (1.1), respectively, of which asset out for sale SEK 0.4 m (–11.2) (Primm Pharma). The change in working capital can vary greatly between periods, mainly due to the re-invoicing to STADA for the development work for Ximluci®, i.e. establishing a production chain and the regulatory work. The continuing work on BIIB801 has also intensified and is part of the change.

Cash flow from investment activities amounted to SEK –50.7 m (–51.5) and included investments in tangible assets for the internal laboratory and capitalization of research and development costs. Development costs for Xlucane™ are reported as intangible assets, which for the period affected cash flow by SEK –40.8 m (–26.9). Cash flow from financing activities amounted to SEK –6.1 m (351.7) and relates to leasing of machines and premises.

The Group's financial position and continued operations

The capital raising carried out in October brought in around SEK 170 m before transaction costs and thereby strengthened the company's financial position. The effects in the balance sheet and cash flow will only become visible in the coming interim report, October–December 2022.

The Board and management continuously monitor the Group's current and forecast cash flows according to the decided business plan. The stock build-up of Ximluci® to support a launch, and the further development of the product portfolio, will require capital in 2023. As previously announced, the company has the aim to out-license the biosimilar candidates in oncology in 2023 and assuming that this is carried out on time, the Board assesses that the Group has the necessary financial resources to run the business according to the decided business plan for the next 12 months. To create additional flexibility around when a potential out-licensing deal for the oncology portfolio needs to be carried out, the company is continually looking at alternative ways to finance the business, including continuous dialogues with investors on both the equity and debt side, as well as with partners for co-financing the stock build-up of Ximluci®.

Fixed assets

Fixed assets amounted to SEK 166.7 m (103.3), where the change is largely explained by capitalization of research and development costs, amounting to SEK 89.1 m (26.9). Capitalization of research and development costs began on July 1, 2021. Remaining changes to the item consist of the acquisition of laboratory equipment, machinery, equipment for the office premises and customary monthly depreciation.

Other receivables

Other receivables amounted to SEK 7.8 m (25.5) which last year included a receivable from STADA of SEK 11.7 m. Customer invoices to STADA have been reclassified since January 1, 2022, as "other receivables", instead of "accounts receivable" as this is considered to reflect the business more accurately. Previous periods have therefore been reclassified, which means that comparative figures are no longer in line with previous reports. See also Note 1 for further information regarding the reclassification.

Prepaid expenses and accrued income

Prepaid expenses and accrued income amounted to SEK 164.3 m (115.1). The significant items relate in part to an advance payment SEK 16.7 m (22.8) to CRO (Contract Research Organization) which is carrying out the clinical study of Ximluci®. An advance payment was made to CMO (Contract Manufacturing Organization) of SEK 89.8 m (85.1), of which SEK 35.1 m (6.3) relates to future upscaling activities. The increase is explained by the fact that the expected delivery times at the suppliers have become longer and thus there is a longer initial process before the work can begin. SEK 45.5 m (0.0) refers to an advance for the collaboration with AGC Biologics Inc. for continued work with the manufacturing process. The remaining part refers to customary and recurring items amounting to SEK 14.3 m (7.2).

Changes in equity

The share capital on the balance sheet date amounted to SEK 5.6 m (5.6). Other contributed capital amounted to SEK 1,136.4 m (1,132.7), the change in which mainly relates to share-related remuneration. Total equity amounted to SEK 326.8 m (462.4) and the equity ratio was 56% (66).

Accounts payable

Accounts payable amounted to SEK 30.6 m (29.2). The change partly refers to increased activity with BIIB801 and activities linked to establishing a production chain for Ximluci®.

Accrued expenses and prepaid income

Accrued expenses and prepaid income amounted to SEK 178.2 m (143.2) and partly relate to advance payments from STADA for Ximluci® of SEK 58.7 m (73.0). Furthermore, SEK 46.0 m (47.9) relates to work carried out that has not yet been invoiced, regarding the Ximluci® project. Other items amounted to SEK 31.7 m (23.3), of which the up-front payment from Biogen, which has been accrued until the end of Q2 2023, was SEK 41.8 m (0.0).

Significant events during the third quarter

- Xbrane announced in September that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Ximluci®, which was developed under the name Xlucane™ a Lucentis® (ranibizumab) biosimilar candidate. The positive opinion recommends EU-wide approval of Ximluci® for the treatment of wet age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (PDR), retinal vein occlusion (RVO) and visual impairment due to choroidal neovascularization (CN). The opinion has been referred to the European Commission (EC), which will decide on a marketing authorization. Approval can be expected by the end of November.
- Due to the imminent launch of Ximluci®, the company held a capital market day at the end of September, where they gave an update on Xbrane's long-term strategy, product portfolio, technology platform and an in-depth look at the imminent launch of Ximluci® in Europe.

Significant events after the end of the quarter

- With the support of authorization from the annual general meeting on May 5, 2022, the company announced and carried out a directed new issue in mid-October, of SEK 170 m at a subscription price of SEK 72 per share. Effects in the balance sheet and cash flow will become visible in the upcoming interim report for October–December 2022.

Effects of the cooperation agreement with STADA

The collaboration agreement started in July 2018 with STADA regarding projects for research and development of Ximluci® meant that STADA and Xbrane would equally share (50/50) research and development costs attributable to the project. This meant that until June 1, 2021, Xbrane reported its share of 50 percent of the total costs for the project in the income statement. After June 1, 2021, when clinical trials showed that the primary endpoint for efficacy for Ximluci® had been reached, the project was judged to meet the criteria for capitalization of research and development costs and is subsequently reported as an intangible asset in the balance sheet and thus does not continue to be reported in the income statement.

Receivables and liabilities attributable to the project are reported in full in Xbrane's balance sheet with a settlement of 50 percent for STADA's share. This applies to both the Group and the Parent Company.

On the balance sheet date, Xbrane had accrued expenses and prepaid income from STADA amounting to SEK 58.7 m (73.0).

Effects of the planned sale of Primm Pharma

Assets held for sale

Xbrane's intention is to continue to work towards divesting the subsidiary Primm Pharma in accordance with previously taken decisions. Negotiations are continuing and the conditions for a divestment are still considered to be good. In the 2021 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 of several items in the balance sheet which is expected as Primm Pharma is a smaller part of the Group.

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 influences previously reported periods, which is why comparative figures no longer correspond to previous reports. In the cash flow, Primm Pharma's share of each activity is reported in the item "Of which from discontinued operations."

Parent company

The core business in Xbrane, which is developing biosimilars, is run by the parent company. The Group has continued working on divesting the subsidiary Primm Pharma and the conditions are assessed as still good. Xbrane has previously written down the shares in the subsidiary by SEK 49.0 m and the impairment assessment is not considered to have changed during Q3 2022.

As the parent company constitutes such a large part of the Group, an account in text format of the parent company's earnings, financial position and cash flow would not provide any further information to that described in the report on the Group. Therefore, this is only presented in report format on pages 15–17.

Risks and uncertainties

Due to the ongoing conflict in Ukraine, the Board and management are closely following developments in the area. The company currently has no supplier or customer contacts in the affected areas but may be affected in future by the high-cost situation.

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

Share information

Xbrane's share capital at the end of the period was SEK 5.6 m (5.6) divided into 25,144,906 shares (25,039,906). The quota value of all shares is SEK 0.224, and all the shares have equal rights to the company's assets and earnings. Since September 23, 2019, Xbrane's shares have been listed on the Nasdaq OMX main list under the XBRANE ticker. Xbrane had around 6,200 shareholders on the balance sheet date. The closing price of the share on the balance sheet date was SEK 78.6 generating a market capitalization of SEK 1,976 m.

Organization and employees

Xbrane is headquartered at Campus Solna, outside of Stockholm, Sweden, where the company also has a laboratory for the research and development of biosimilars. The wholly-owned subsidiary, Primm Pharma, is in Milan, Italy. As mentioned above, the sale of the subsidiary is in progress. On the balance sheet date, the Group had 70 (60) employees, of which 70 (55) in the parent company and 0 (5) in the subsidiary Primm Pharma.

Nomination committee

During October, the nomination committee for the 2023 annual general meeting was decided and presented and consists of the following people who together represent around 30 percent of the number of shares and votes in the company as of September 30, 2022:

- Saeid Esmaeilzadeh appointed by Serendipity Group AB, the company's largest shareholder
- Bengt Göran Westman, the company's second largest shareholder
- Oscar Bergman appointed by Swedbank Robur Fonder, the company's third largest shareholder
- Anders Tullgren, Xbrane's chairman of the board.

Saeid Esmaeilzadeh has been appointed chairman of the nomination committee.

Shareholders can submit proposals to the nomination committee for the annual general meeting on May 4, 2023, until January 20, 2023. The proposals can be sent to the following address: Xbrane Biopharma AB Valberedning, c/o Xbrane Biopharma AB, Retzius väg 8, 171 65 Solna, Sweden, or via e-mail: valberedning@xbrane.com.

Presentation of the interim report

Presentation of the interim report for January to September 2022 will take place digitally on October 28, at 14.00 CET, where CEO Martin Åmark and CFO Anette Lindqvist will present the report. The presentation will be held in English and is expected to last about 20 minutes, after which there will be an opportunity for questions.

To take part in the presentation, *follow the link below:* https://register.vevent.com/register/BId0340ab2f-d9846138cce38859079d156

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	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Revenues	2, 3	13,935	2,303	36,756	7,635	10,709
Cost of goods sold		–	–	–	–	–
Gross profit		**13,935**	**2,303**	**36,756**	**7,635**	**10,709**
Other operating income	2, 3	6,317	1,206	23,916	3,455	4,848
Administrative expenses		–6,558	–8,768	–20,563	–25,361	–31,395
Research and development expenses		–51,239	–36,472	–140,101	–131,729	–160,619
Other operating expenses		–4,447	–971	–11,183	–2,442	–4,126
Operating profit/loss	2	**–41,992**	**–42,703**	**–111,176**	**–148,442**	**–180,583**
Financial income		0	–506	0	–	–
Financial expenses		–623	–754	–2,006	–1,855	–2,643
Net financial costs	2	**–623**	**–1,260**	**–2,006**	**–1,855**	**–2,643**
Profit/loss before tax		**–42,614**	**–43,964**	**–113,181**	**–150,297**	**–183,226**
Tax			–	–	–	–
Profit/loss for the period from continuing operations		**–42,614**	**–43,964**	**–113,181**	**–150,297**	**–183,226**
Profit/loss from discontinued operations		730	–1,506	1,401	–5,607	–5,150
Profit/loss for the period		**–41,884**	**–45,470**	**–111,780**	**–155,905**	**–188,376**
Profit/loss for the period attributable to:						
– Owners of the Company		–41,884	–45,470	–111,780	–155,905	–188,376
– Non-controlling interests			–		–	–
Total comprehensive income for the period		**–41,884**	**–45,470**	**–111,780**	**–155,905**	**–188,376**
Earnings per share from continuing operations						
– Before dilution (SEK)		–1.69	–1.77	–4.51	–6.50	–7.77
– After dilution (SEK)		–1.69	–1.77	–4.51	–6.50	–7.77
Earnings per share						
– Before dilution (SEK)		–1.67	–1.83	–4.45	–6.75	–7.98
– After dilution (SEK)		–1.67	–1.83	–4.45	–6.75	–7.98
Number of outstanding shares at the end of the reporting period						
– Before dilution		25,144,906	25,039,906	25,144,906	25,039,906	25,039,906
– After dilution		25,144,906	25,039,906	25,144,906	25,039,906	25,039,906
Average number of outstanding shares						
– Before dilution		25,144,906	24,886,770	25,103,138	23,105,787	23,593,291
– After dilution		25,144,906	24,886,770	25,103,138	23,105,787	23,593,291

Consolidated income statement and other comprehensive income

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Profit/loss for the period	–41,884	–45,470	–111,780	–155,905	–188,376
Other comprehensive income					
Items that have been transferred to, or can be transferred to, the profit/loss for the year					
Reclassification of foreign currency translation differences	1,614	516	4,650	1,036	1,220
Comprehensive income for the period	**1,614**	**516**	**4,650**	**1,036**	**1,220**
Total comprehensive profit/loss attributable to:					
– Owners of the Company	–40,270	–44,954	–107,130	–154,869	–187,156
– Non-controlling interests					–
Total comprehensive income for the period	**–40,270**	**–44,954**	**–107,130**	**–154,869**	**–187,156**

Consolidated statement of financial position

Amounts in SEK thousand	09-30-2022	09-30-2021	12-31-2021
ASSETS			
Intangible assets	89,071	26,922	49,672
Property, plant and equipment	35,117	28,467	30,622
Right of use assets	38,568	43,342	43,180
Long-term receivables	3,945	4,580	3,945
Non-current assets	**166,702**	**103,310**	**127,418**
Accounts receivables	4,283	704	–
Other receivables	7,778	25,463	50,253
Prepaid expenses and accrued income	164,254	115,144	147,027
Cash and cash equivalents	165,235	383,435	295,180
Assets held for sale	74,206	68,938	68,548
Current assets	**415,756**	**593,684**	**561,008**
TOTAL ASSETS	**582,458**	**696,994**	**688,427**
EQUITY			
Share capital	5,640	5,614	5,614
Other contributed capital	1,136,399	1,132,678	1,134,276
Reserves	9,815	4,981	5,165
Retained earnings including profit/loss for the year	–825,094	–680,842	–713,313
Equity attributable to parent company's owners	**326,759**	**462,431**	**431,741**
Non-controlling interests	–	**–**	**–**
Total equity	**326,759**	**462,431**	**431,741**
LIABILITIES			
Leasing liabilities	31,399	37,219	36,476
Long-term non-interest-bearing liabilities	–	2,462	543
Total long-term liabilities	**31,399**	**39,681**	**37,019**
Accounts payable	30,615	29,157	41,393
Other liabilities	5,496	13,180	9,757
Leasing liabilities	9,028	7,043	7,905
Accrued expenses and prepaid income	178,236	143,206	159,355
Liabilities attributable to assets held for sale	925	2,296	1,257
Total short-term liabilities	**224,300**	**194,882**	**219,667**
TOTAL LIABILITIES	**255,699**	**234,563**	**256,686**
TOTAL LIABILITIES AND EQUITY	**582,458**	**696,994**	**688,427**

Consolidated statement of changes in equity

Amounts in SEK thousand	Share Capital	Other contributed capital	Translation reserve	Retained earnings incl. profit/loss for the period	Total
Opening balance January 1, 2022	5,614	1,134,276	5,165	–713,313	431,741
Total comprehensive income for the period					
Profit/loss for the period				–111,780	–111,780
Other comprehensive income for the period			4,650		4,650
Total comprehensive income for the period			**4,650**	**–111,780**	**–107,130**
Transactions with group shareholder					
Share savings program	24	2,123			2,146
Total contributions from and distributions to shareholders	**24**	**2,123**			**2,146**
Closing balance September 30, 2022	**5,640**	**1,136,399**	**9,815**	**–825,094**	**326,757**

Amounts in SEK thousand	Share Capital	Other contributed capital	Translation reserve	Retained earnings incl. profit/loss for the period	Total
Opening balance January 1, 2021	4,977	773,724	3,945	–524,938	257,709
Total comprehensive income for the period					
Profit/loss for the period				–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	633	380,237			380,870
New share issue		–24,244			–24,244
Share savings program	4	2,961			2,965
Total contributions from and distributions to shareholders	**637**	**358,954**	**–**	**–**	**359,591**
Closing balance September 30, 2021	**5,614**	**1,132,678**	**4,981**	**–680,842**	**462,431**

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

Consolidated cash flow statement

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Cash flow from operating activities					
Profit/loss for the period before tax	–41,884	–45,470	–111,780	–155,905	–188,376
Adjustments for items not included in cash flow	3,887	3,122	7,485	962	7,180
Paid income taxes	–	–	–	–	–
Total	**–37,997**	**–42,348**	**–104,295**	**154,943**	**–181,195**
Increase (–)/Decrease (+) of trade and other receivables	23,227	–24,097	19,722	–5,384	–61,086
Increase (+)/Decrease (–) of trade and other payables	–60,108	4,139	5,712	1,085	22,671
Cash flow from current operations	**–74,878**	**–62,306**	**–78,861**	**–159,242**	**–219,610**
Of which discontinued operations	*–330*	*–1,489*	*367*	*–11,225*	*–10,401*
Cash flow from investing activities					
Acquisition of property, plant and equipment	–6,288	–10,604	–9,936	–24,528	–27,678
Acquisition of intangible assets	–5,168	–26,922	–40,783	–26,922	–49,672
Cash flow from investing activities	**–11,455**	**–37,526**	**–50,719**	**–51,450**	**–77,350**
Of which discontinued operations	–	–	–	–	–
Cash flow from financing activities					
Stock options redeemed by staff	–	–	24	–	–
New share issue	–	380,445	–	380,870	380,870
Issue expenses	–	–24,244	–	–24,244	–24,231
Amortization of lease liability	–2,175	–1,824	–6,130	–4,920	–7,273
Cash flow from financing activities	**–2,175**	**354,376**	**–6,106**	**351,706**	**349,366**
Of which discontinued operations	–	*–129*	–	*–377*	*–529*
Cash flow for the period	**–88,508**	**254,544**	**–135,687**	**141,014**	**52,406**
Cash and cash equivalents reported in assets held for sale	–2,256	399	–2,256	–1,033	–1,758
Cash and cash equivalents at beginning of period	250,085	128,436	295,180	243,139	243,139
Cash and cash equivalents at beginning of period (reported in assets held for sale)	2,548	–	1,758	–	–
Exchange rate differences in cash and cash equivalents	3,354	56	6,239	315	1,393
Cash and cash equivalents at end of period	**165,235**	**383,435**	**165,235**	**383,435**	**295,180**

Income statement, Parent company

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Revenues	13,935	2,303	36,756	7,635	10,709
Cost of goods sold		–	–	–	–
Gross profit	**13,935**	**2,303**	**36,756**	**7,635**	**10,709**
Other operating income	6,317	1,206	23,916	3,455	4,848
Administrative expenses	–6,886	–8,962	–21,557	–26,160	–32,525
Research and development expenses	–51,295	–36,674	–140,323	–131,916	–160,916
Other operating expenses	–4,447	–971	–11,183	–2,442	–4,126
Operating profit/loss	**–42,377**	**–43,098**	**–112,391**	**–149,429**	**–182,011**
Financial items					
Financial income	–	–506	–	–	–
Impairment loss on shares in subsidiary	–	–1,015	–	–10,631	–10,631
Financial expenses	–11	–89	–133	–210	–276
Net finance costs	**–11**	**–1,610**	**–133**	**–10,841**	**–10,908**
Profit/loss before tax	**–42,388**	**–44,708**	**–112,523**	**–160,270**	**–192,918**
Tax		–		–	–
Profit/loss for the period	**–42,388**	**–44,708**	**–112,523**	**–160,270**	**–192,918**

Income statement and other comprehensive income, Parent company

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Profit/loss for the period	–42,388	–44,708	–112,523	–160,270	–192,918
Other comprehensive income	–	–	–	–	–
Comprehensive income for the period	**–42,388**	**–44,708**	**–112,523**	**–160,270**	**–192,918**

Balance sheet, Parent company

Amounts in SEK thousand	09-30-2022	09-30-2021	12-31-2021
ASSETS			
Fixed assets			
Intangible assets	89,071	26,922	49,672
Property, plant and equipment	35,117	28,467	30,622
Financial assets			
Shares in group companies	74,066	74,066	74,066
Other non-current receivables	3,945	4,580	3,945
Total financial assets	**78,011**	**78,646**	**78,011**
Total non-current assets	**202,200**	**134,035**	**158,304**
Current assets			
Current receivables			
Accounts receivables	4,283	704	–
Other receivables	7,778	25,463	50,253
Prepaid expenses and accrued income	164,254	115,144	147,027
Total current receivables	**176,315**	**141,310**	**197,280**
Cash and bank	165,235	383,435	295,180
Current assets	**341,551**	**524,746**	**492,460**
TOTAL ASSETS	**543,750**	**658,780**	**650,764**
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	5,637	5,614	5,614
Reserve for development expenditure	89,071	26,922	49,672
Unrestricted equity			
Share premium	1,137,085	1,133,364	1,134,962
Retained earnings	–790,879	–535,811	–558,561
Profit/loss for the period	–112,523	–160,270	–192,918
Total equity	**328,391**	**469,819**	**438,769**
Long-term liabilities			
Long-term non-interest-bearing liabilities	–	2,462	543
Total long-term liabilities	**–**	**2,462**	**543**
Current liabilities			
Liabilities to subsidiaries	1,012	957	948
Accounts payables	30,615	29,157	41,393
Other current liabilities	5,496	13,180	9,757
Deferred income and prepaid revenue	178,236	143,206	159,355
Current liabilities	**215,359**	**186,500**	**211,453**
TOTAL LIABILITIES	**215,359**	**188,961**	**211,996**
TOTAL EQUITY AND LIABILITIES	**543,750**	**658,780**	**650,764**

Cash flow statement, Parent company

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Cash flows from operating activities					
Profit/loss for the period before tax	–42,388	–44,708	–112,523	–160,270	–192,918
Adjustments for items not included in cash flow	3 992	2,091	2 756	9,582	12,968
Paid income taxes	–	–	–	–	–
Total	**–38,396**	**–42,617**	**–109,767**	**–150,687**	**–179,950**
Increase (–)/Decrease (+) of trade and other receivables	21,361	–24,792	17,897	–3,813	–59,147
Increase (+)/Decrease (–) of trade and other payables	–61,028	5,208	5,172	2443	24,275
Cash flow from current operations	**–78,063**	**–62,201**	**–86,686**	**–152,057**	**–214,822**
Cash flow from investing activities					
Investments in subsidiaries	–	–1,015	–	–10,631	–10,631
Acquisition of property, plant and equipment	–6,331	–11,972	–9,979	–26,132	–29,939
Acquisition of intangible assets	–3,785	–26,922	–39,399	–26,922	–49,672
Cash flow from investing activities	**–10,116**	**–39,909**	**–49,378**	**–63,685**	**–90,243**
Cash flow from financing activities					
Stock options redeemed by staff	–	–	24	–	–
New share issue	–	380,445	–	380,870	380,870
Issue expenses	–	–24,244	–	–24,244	–24,231
Cash flow from financing activities	**–**	**356,201**	**24**	**356,626**	**356,638**
Cash flow for the period	**–88,179**	**254,091**	**–136,053**	**140,883**	**51,573**
Cash and cash equivalents at beginning of period	250,085	254,091	295,180	140,883	242,247
Exchange rate differences in cash and cash equivalents	3,328	129,331	6,096	242,247	1,360
Cash and cash equivalents at end of period	**165,235**	**383,435**	**165,235**	**383,435**	**295,180**

Notes

NOTE 1 Accounting principles

This consolidated interim report for the Group has been prepared in accordance with IAS 34, Interim Financial Reporting, as well as applicable regulations from the Annual Accounts Act. The interim report for the parent company has been prepared according to the Annual Accounts Act, chapter 9, Interim Reports. For the Group and the parent company the same accounting principles and calculation bases as the previous annual report have been applied except for the changed or additional accounting principles described below. Information according to IAS 34.16A is included in these financial statements and related notes as well in other parts of this interim report.

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

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

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

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

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

NOTE 2 Segment reporting

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

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Revenues by segment					
Commercialization	4,223	2,545	8,465	7,635	10,181
Biosimilar development	28,530	–	47,109	–	528
Unclassified[1)]	–12,500	964	5,098	3,455	4,848
Total	**20,252**	**3,509**	**60,672**	**11,090**	**15,557**
Operating profit or loss by segment					
Commercialization[2)]	–27,708	–24,714	–45,198	–76,108	–72,155
Biosimilar development	–11,332	–9,456	–55,644	–47,986	–77,755
Unclassified	–2,952	–8,534	–10,334	–24,348	–30,673
Operating profit/loss	**–41,992**	**–42,703**	**–111,176**	**–148,442**	**–180,583**
Net finance costs					
Commercialization	–122	–302	–438	–596	–852
Biosimilar development	–367	–	–1,061	–686	–1,515
Unclassified	–133	–958	–508	–572	–276
Total	**–623**	**–1,260**	**–2,006**	**–1,855**	**–2,643**
Profit/loss before tax[2)]	**–42,614**	**–43,964**	**–113,181**	**–150,297**	**–183,226**
Depreciation, amortization and write downs					
Commercialization	1,030	2,656	3,294	5,973	5,358
Biosimilar development	3,004	122	7,984	1,227	5,411
Unclassified	320	427	994	1,124	1,448
Total	**4,354**	**3,206**	**12,272**	**8,325**	**12,217**

1) Reclassifications of FX gains
2) As of July 1, 2021, parts of R&D were capitalized.

NOTE 3 Distribution of income

Amounts in SEK thousand	July – Sep 2022 Commercialization	Biosimilar development	Unclassified[1)]
Revenues by region			
Europe	1,437	–	–4,919
USA	–1,456	–3,984	–7,482
Others	–	–	–99
Total	**–19**	**–3,984**	**–12,500**
Revenues by category			
Commercial products	–	–	1,414
Outlicensing / partnership	–19	–3,984	4,892
Services and other	–	–	11
Total	**–19**	**–3,984**	**6,317**

1) Reclassifications of FX gains

Amounts in SEK thousand	July – Sep 2021 Commercialization	Biosimilar development	Unclassified
Revenues by region			
Europe	–	–	1,137
USA	2,303	2,303	69
Others	–	–	–
Total	**2,303**	**2,303**	**1,206**
Revenues by category			
Commercial products	–	–	–
Outlicensing / partnership	2,303	–	1,206
Services and other	–	–	–
Total	**2,303**	**2,303**	**1,206**

NOTE 3 Distribution of income, continued

Amounts in SEK thousand	Jan – Sep 2022 Commercialization	Biosimilar development	Unclassified[1)]
Revenues by region			
Europe	1,437	–	5,098
USA	2,786	14,595	–
Others	–	–	–
Total	**4,223**	**14,595**	**5,098**
Revenues by category			
Commercial products	–	–	–
Outlicensing / partnership	4,243	14,595	5,098
Services and other	–	–	–
Total	**4,243**	**14,595**	**5,098**

1) Reclassifications of FX gains

Amounts in SEK thousand	Jan – Sep 2021 Commercialization	Biosimilar development	Unclassified
Revenues by region			
Europe	–	–	3,123
USA	7,635	–	332
Others	–	–	–
Total	**7,635**	**–**	**3,455**
Revenues by category			
Commercial products	–	–	–
Outlicensing / partnership	7,635	–	–
Services and other	–	–	3,455
Total	**7,635**	**–**	**3,455**

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

NOTE 4 Transactions with related parties

Since 2019, STADA Arzneimittel AG has been a shareholder in Xbrane (see the list of owners on page 6). Transactions with STADA relate to shared costs for the collaboration agreement with Ximluci™.

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 27, 2022

Anders Tullgren
Chairman of the Board

Eva Nilsagård
Board member

Peter Edman
Board member

Mats Thorén
Board member

Karin Wingstrand
Board member

Kirsti Gjellan
Board member

Ivan Cohen-Tanugi
Board member

Martin Åmark
CEO

Auditor's report

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 2022 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.

Emphasis of Matter
We would like to draw attention to the section regarding the group's financial position and continued operations on page 8, which describes the board's assessment of the financing of the business going forward. We have not modified our statement in this regard.

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, 27 October 2022

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

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Gross profit	13,935	2,303	36,756	7,635	10,709
Gross margin	**100%**	**100%**	**100%**	**100%**	**100%**

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

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Operating profit / loss	–41,992	–42,703	–111,176	–148,442	–180,583
Depreciation and impairment	4,354	3,206	12,272	8,325	12,217
EBITDA	**–37,637**	**–39,497**	**–98,904**	**–140,117**	**–168,366**

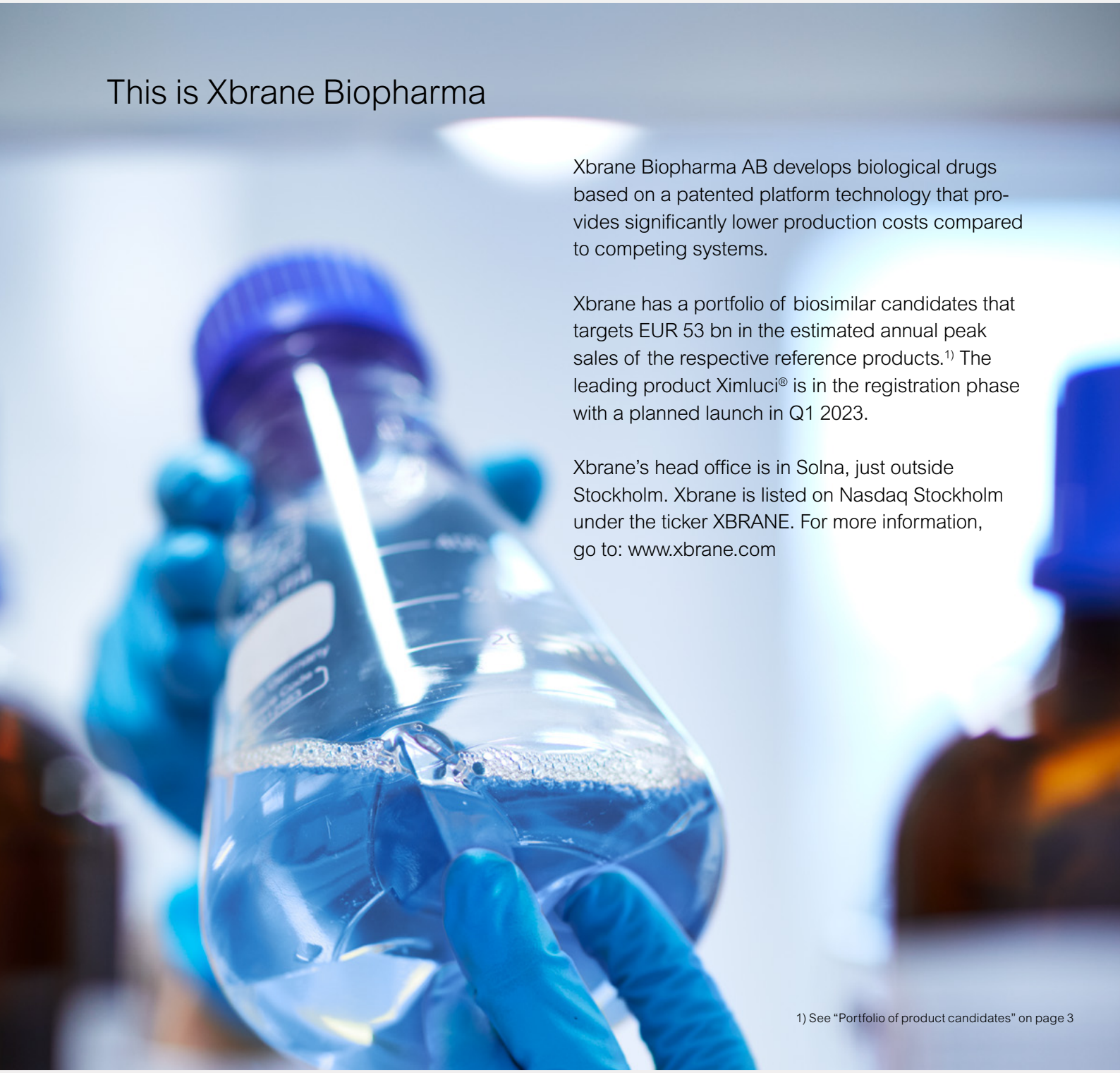
Research and development expenses as a percentage of operating expenses
The company's direct costs for research and development relate to personnel, materials and external services costs. Research and development expenses as a percentage of operating expenses show the proportion of operating expenses relating to research and development. This is calculated by dividing research and development expenses by total operating expenses. Total operating expenses comprise of selling and distribution expenses, administrative expenses, research and development expenses and other operating expenses.

Amounts in SEK thousand	2022 July – Sep	2021 July – Sep	2022 Jan – Sep	2021 Jan – Sep	2021 Full year
Research and development expenses	–51,239	–36,472	–140,101	–131,729	–160,619
Operating expenses	–62,244	–46,212	–171,847	–159,533	–196,140
Research and development expenses as a percentage of operating expenses	82%	79%	82%	83%	82%

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

Amounts in SEK thousand	09-30-2022	09-30-2021	12-31-2021
Total equity	326,759	462,431	431,741
Divided by total assets	582,458	696,994	688,427
Equity ratio	**56%**	**66%**	**63%**

This is Xbrane Biopharma



Xbrane Biopharma AB develops biological drugs based on a patented platform technology that provides significantly lower production costs compared to competing systems.

Xbrane has a portfolio of biosimilar candidates that targets EUR 53 bn in the estimated annual peak sales of the respective reference products.[1)] The leading product Ximluci® is in the registration phase with a planned launch in Q1 2023.

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

1) See "Portfolio of product candidates" on page 3

Financial calendar

Year-end report 2022	February 17, 2023
Annual report 2022	March 31, 2023
Annual General Meeting	May 4, 2023
Interim report January–March 2023	May 31, 2023
Interim report January–June 2023	August 31, 2023

For further information

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