

Dear Shareholders,

Since the communication regarding the delay in FDA approval for Lucamzi (Ximluci in the US) and the Q3 report, Xbrane has received many questions. As many stakeholders are asking similar questions, we have done our best to answer them below.

Lucamzi FDA Review

Q: What caused the delays with the FDA?

A: The latest “Complete Response Letter” we received from the FDA referred to unresolved observations from their most recent inspection of one of our contract manufacturers. It’s important to note that this was the only issue raised by the FDA and thus constituted the barrier to approval. After a Complete Response Letter is issued, the FDA sends separate communication directly to the production site (as it is a contract manufacturer and the FDA cannot share what is classified as confidential site-specific information with the applicant company, i.e., Xbrane). We are currently awaiting this communication.

Q: I read that the site receiving the observations had no prior FDA inspection experience. How did management and the board assess this?

A: The site had successfully undergone an FDA inspection just before we selected them as a contract manufacturer and has since been supplying a commercial product to the U.S. However, FDA’s assessment of GMP compliance can be stricter when approving new products than when reviewing already approved ones. Additionally, Lucamzi is an intravitreally injected product, which sometimes requires stricter aseptic filling procedures. That said, the FDA has not revoked the site’s approval for its existing product, and the site has successfully passed SwissMedic inspections for many years (the site is based in Switzerland). Based on this, the board and management assessed that the site would pass an FDA inspection. Xbrane has worked closely with the site, which has also engaged consultants including former FDA inspectors to prepare thoroughly. The second site in Lucamzi’s manufacturing chain lacked FDA approval initially but has now successfully passed an FDA inspection. We take this very seriously and will minimize future delay risks due to FDA inspections at contract manufacturers. For Xdivane, we are working with one of the top 10 global contract manufacturers, where both involved sites have many successful FDA inspections and routinely produce for the U.S. market.

Q: Will you provide more information once you receive feedback from the contract manufacturer?

A: Yes.

Q: If FDA gives the green light in Q3–Q4 2026, how quickly can Valorum begin sales in the U.S.?

A: Sales can begin as soon as approval is granted. For buyers to receive Medicare reimbursement upon purchase, a so-called Q-code is needed, which takes about 6 months to apply for and obtain. However, it may be possible to start sales immediately after approval.

Ximluci Sales in Europe

Q: Can you explain the revenue recognition flow for Ximluci with Stada?

A: Revenue recognition principles for Ximluci product sales

When Xbrane delivers product to Stada, it recognizes revenue consisting of:

A) Number of units delivered × agreed sales price (aligned with Xbrane's production cost), and

B) Expected profit share of 50% of the profit margin (Stada's average net sales price minus production cost minus sales cost).

Xbrane invoices directly for A and receives payment within 30 days. At the end of each quarter, Xbrane receives a sales report showing how many units Stada sold and the generated profit margin, after which Xbrane invoices and receives payment within 30 days (C).

Since Stada holds inventory of finished product, the product delivered by Xbrane is not sold in the same quarter. Revenue B is recognized based on historical data on Stada's average net sales price and sales costs, and may be revised if conditions change in future quarters.

For example, in the Q3 2025 report, Xbrane reported Ximluci sales of 10.8 MSEK. A small delivery to Stada generated revenue of approx. 20 MSEK (A and B above). At the same time, a revision of approx. –10 MSEK was made to the expected profit share from already delivered product, due to a lower observed average net sales price from Stada to end customers in Q3. Additionally, as shown in slide 15 of the Q3 presentation, Xbrane received 9 MSEK in cash, which was invoiced for profit share generated from Stada's Q2 sales.

Q: Xbrane reported approx. 10 MSEK in revenue. Adjusting for approx. 10 MSEK in inventory valuation on Stada's side gives approx. 20 MSEK in revenue; minus 15 MSEK in COGS gives a gross profit of 5 MSEK. You have approx. 8% market share in Europe ("Ximluci® share of the ranibizumab market in launched European countries was 8.0% in volume in August 2025"), which implies that if this is a "normal" quarterly delivery level to Stada, the annual profit from Europe should be $4 \times 5 \text{ M} = 20 \text{ MSEK}$. Looking at your April presentation assumptions, where 5% market share would yield 71.7 MSEK, I assume 8% should mean $>100 \text{ MSEK}$ ($5 \times 20 \text{ MSEK}$). I understand "shipping" sales to Stada and sell-through are not exactly the same, but the figures should converge. Even assuming lower prices and less favorable product mix this quarter, how can the difference be fivefold?

A: There are significant quarterly fluctuations in the cash profit share Xbrane receives (C). Market share has been around 8% during the first three quarters of 2025, and Xbrane has received approx. 39 MSEK in cash from profit share (C) during these quarters (including Q3 profit share paid in Q4). With a similar level in Q4, we reach approx. 52 MSEK, which compares to the scenario analysis where 5% market share yields 71 MSEK. In the last two quarters, we've observed a lower average net sales price from Stada, slightly higher sales costs as a percentage of sales, and a decline in the ranibizumab market (Lucentis and biosimilars) in favor of Vabysmo. These factors explain the difference.

Q: Why did "accumulated profit share to Xbrane per quarter" decrease (what was the relevant revenue increase and why didn't the 50% profit share lead to higher revenue)?

A: Accumulated profit share includes expected profit share to be received. Due to falling prices, the expected profit share is reduced and adjusted accordingly. Of the approx. 115 MSEK in profit share, approx. 85 MSEK has been received in cash, and the rest is expected profit share for already delivered product to Stada.

Q: How much did STADA's revenue from Ximluci sales increase in Q3 (sell-through)?

A: It was more or less constant compared to Q2 2025.

Q: Why was there no growth in sell-through this quarter? Any signs of improvement?

A: We still believe the expected market share of 20% can be achieved, and Stada is actively working toward this. We know Stada is participating in various tenders and working on new accounts, which we believe will lead to growth in 2026 compared to 2025, although quarterly fluctuations may occur.

Q: Does the adjustment for falling prices also affect cash flow from Stada, or is it independent?

A: They are linked, i.e., it also affects cash flow.

Cash and Liquidity

Q: How much cash did Xbrane have as of September 30, 2025, before the loan?

A: Approx. 94 MSEK. The loan was taken after the end of the quarter.

Q: How much of the proceeds from the rights issue remained at that date?

A: See slide 15 in the Q3 presentation: [Microsoft PowerPoint - xbrane Biopharma Q3 2025](#)

Q: What were the main uses of the proceeds from the rights issue (e.g., production and consulting costs, STADA-related costs, R&D)?

A: All of the above, as well as repayment of accumulated supplier debt. See slide 15 in the Q3 presentation.

Q: Since the loan was announced on October 16–17, i.e., two days before the FDA decision, how did the board reason about the need for external financing before the FDA decision?

A: The board wanted to proactively address the company's capital needs in case of a delay in FDA approval of Lucamzi, as such a delay could result in significant share price movements, making financing much harder to arrange in that scenario. For example, the lender Xbrane signed with does not issue loans exceeding 10% of the company's market value. The cost of this "insurance" was a setup fee of 2.4 MSEK, which the board deemed worth paying. No information regarding the Complete Response Letter had been received from the FDA at the time the loan was signed.

Q: How were the July rights issue proceeds used, or why was a new loan needed already in October?

A: Please see the presentation where the use of proceeds is clearly shown: [Microsoft PowerPoint - xbrane Biopharma Q3 2025](#)

Q: Xdivane – What investments remain in the Xdivane project from Xbrane's side after Q3? What % of these costs are planned for Q4 2025, FY 2026, and FY 2027 respectively?

A: Net of sellable manufactured material, development costs amount to approx. 200 MSEK. These are mainly distributed over 2026–2027 based on development pace and are intended to be financed with Ximluci inventory valued at 170 MSEK, which will be converted to cash during the same period as deliveries to Stada resume.

Q: CTA approval with a milestone of 2 MEUR was mentioned in the Q2 report, and it was said that approval would occur in Q3. Was it delayed?

A: No, the milestone was met and we received the payment as planned.

Q: What exactly was the increase (+)/decrease (–) in accounts payable and other liabilities of –74,805?

A: Please refer to [Microsoft PowerPoint - xbrane Biopharma Q3 2025](#)

91 MSEK are accumulated accounts payable from our three largest CMOs that has been accumulated since 2024 and were settled in July in accordance with the agreement between the parties.
