XBRANE BIOPHARMA

**STO: XBRANE**

April 2025

# Company Presentation

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# Agenda

Overview

Ximluci® / Lucamzi™

Xdivane™

Financial outlook

# Xbrane – Investment highlights

## Xbrane is a derisked opportunity in the biosimilar space

- Xbrane is a late-stage biosimilar developer set to capitalize on one commercial and one Phase 3 asset
- Ximluci® (Lucentis biosimilar ex-US) approved and marketed in Europe by STADA under 50/50 profit split, generating SEK 57m in profit-sharing 2024 with average quarterly growth of 23%*
- Lucamzi™ (Lucentis biosimilar US) under FDA review, expected to be approved in 2025 and launched in 2026 by partner Valorum with potential to generate SEK 150-250m in annual royalties to Xbrane
- Xdivane™ (Opdivo biosimilar) under pivotal Phase 3 trial together with partner Intas/Accord, on path to be one of frontrunners to lunch upon Opdivo's loss of exclusivity in early 2029, addressing expected originator sales of SEK 140bn

| | Ximluci® (ex-US) | Lucamzi™ | Xdivane™ |
|---|---|---|---|
| **Partner** | STADA | STADA, Valorum | Intas / Accord |
| **Status** | Commercial | Registration | Start of pivotal clinical trial |

## Portfolio & Company highlights

| Headquarters | Listing | Market Cap |
|---|---|---|
| Stockholm | NASDAQ Stockholm | SEK 304m |
| | | As of 1 April 2025 |

**SEK 180 million**

**Worth of Ximluci® inventory** to be deployed over 2026-2028
Does **not include profit share** from sales
**No additional investments required**

**SEK 40 million**

**Anticipated annual fixed costs** after divestment of XB003 and part of Xbrane's organization to Alvotech
Expected to be **realized in 2026**

**+**

**Positive operational cash-flow** from 2026 onwards

**SEK >1 billion**

**Revenue potential** following Xdivane™'s launch in the US
Expected to be realized in 2030

**Post restructuring, Xbrane becomes a commercial and late-stage development play with select de-risked opportunities**



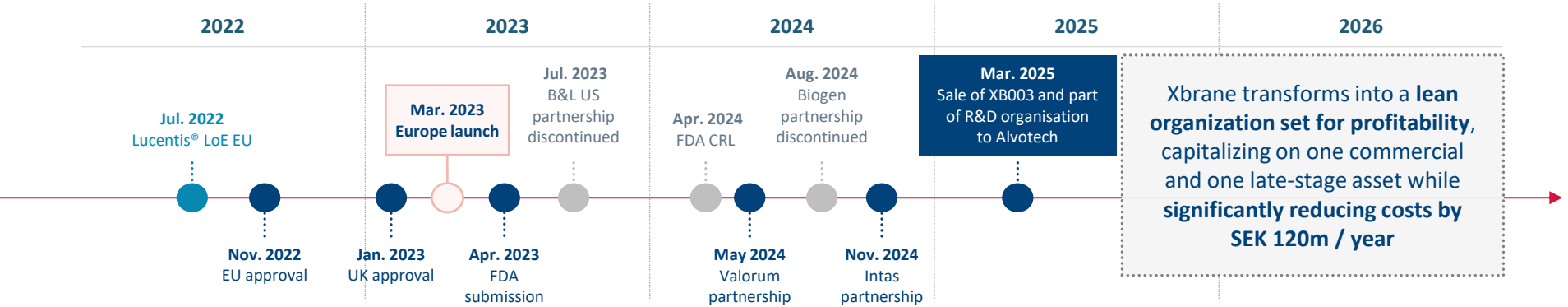
*Note (*): Average quarterly growth over last four quarters.*

# Transformative sale for Xbrane of XB003 to Alvotech

**On 20 March 2025, Xbrane announced that it had entered into an agreement to sell XB003 and parts of its organization to Alvotech for a total consideration of SEK 275 million, marking a transformational transaction for the Company**

- Sale of XB003 represents approx. 25% of competitively adjusted addressable market
- Sale of parts of R&D organization and laboratory equipment reduces Xbrane's annual fixed costs by approx. SEK 120 m
- Convertible bond with outstanding debt of SEK 150m overtaken and hence settled in their entirety
- Accounts payables reduced by SEK 40m (SEK 20m overtaken and rest reduced via agreed haircut)
- Cash proceeds of SEK 105m with which remaining outstanding accounts payables can be settled

Through the sale and restructuring, Xbrane transforms into a biosimilar asset company **set to generate dividends** from two **highly derisked assets** while maintaining a **low cost-base and high degree of optionality** from the remaining competence and know-how in the Company



# Derisked biosimilar portfolio set to generate profitability

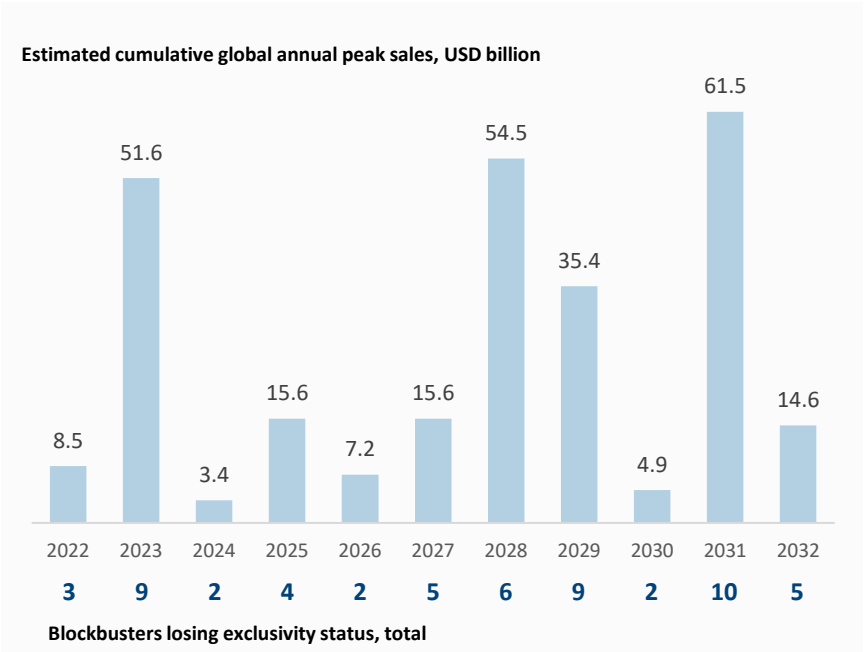
| Biosimilar candidate | Ximluci® (ex-US) | Lucamzi™ (US) | Xdivane™ |
|---|---|---|---|
| Reference product | LUCENTIS RANIBIZUMAB INJECTION | | OPDIVO (nivolumab) |
| Therapeutic area | Ophthalmology | | Oncology |
| Patent expiry | 2022 (EU) | 2020 (US) | Dec 2028 (US)<br>June 2030 (EU) |
| Development phase | Commercial (Europe, MENA) | Registration | Entering pivotal clinical trials |
| Next milestone | **2025: PFS regulatory submission** | **2025: FDA approval** | **2025: Enter clinic** |
| Partner | STADA | STADA, VALORUM BIOSIMILARS | INTAS, accord Make it better |
| Market size[1] | EUR 5 billion | USD 10 billion | USD 40 billion |
| Organisation | **Lean organisation with 25 employees and approx. SEK 40m in annual fixed costs** | | |
| Business model | **Late-stage biosimilar development and de-risked partnering strategy for commercialisation** | | |



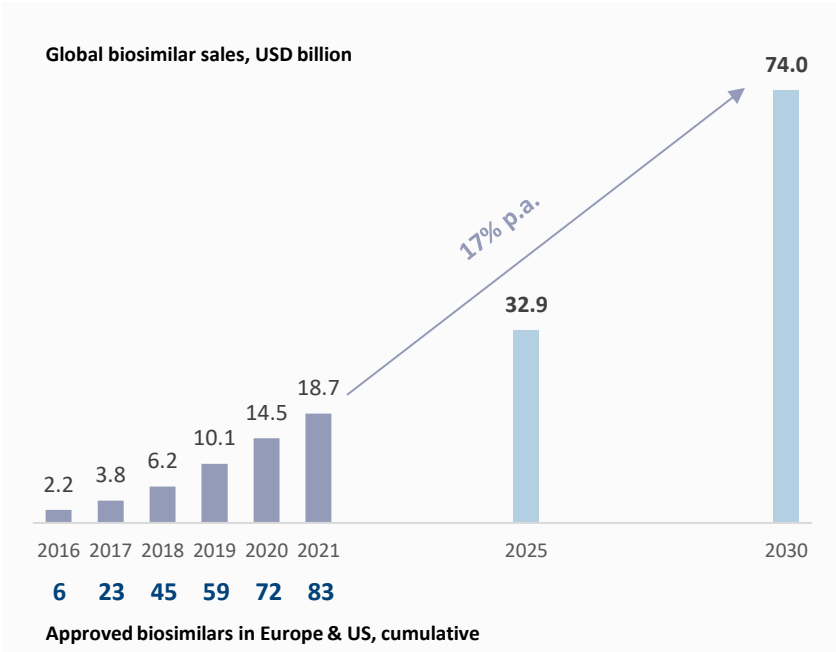
*Source: Evaluate pharma. Notes: (1) Market for respective class of drugs, anti-VEGFs for retinal disorders and PD1s respectively*

# Biosimilar market expected to grow to USD 74bn by 2030

## Biologics with >USD 260bn in sales lose exclusivity by 2032




## Biosimilar market to grow by 17% per year through to 2030




**Biosimilars significantly increase accessibility with treatment days per capita, realizing significant savings for healthcare systems. Biosimilars show continuous momentum in the past years and are set to grow to USD 74bn by 2030 as blockbuster biologic patents expire.**



*Source: Three imperatives for R&D in biosimilars, Mckinsey & Company 2022*

# Agenda

Overview

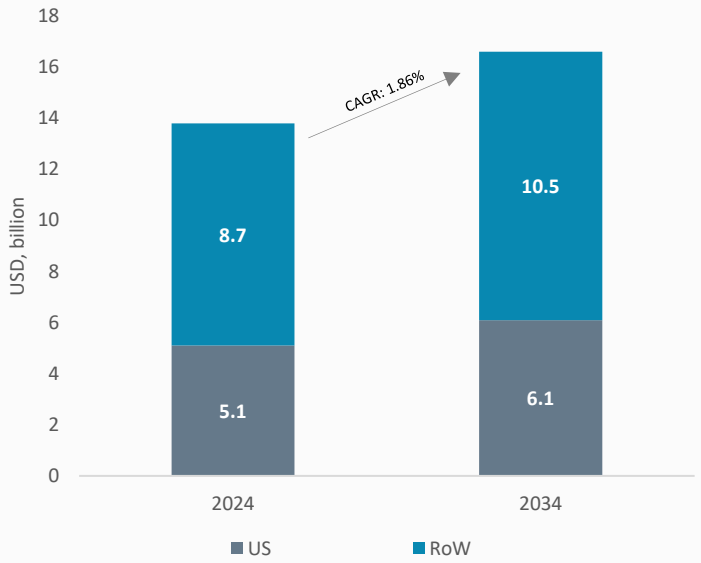
**Ximluci® / Lucamzi™**

Xdivane™

Financial outlook

# Ximluci® / Lucamzi™ – Market & landscape

## Global anti-VEGF therapeutics market




*Includes Lucentis, Beovu, Vabysmo, Eylea and other products. Excludes off-label Avastin, which is used significantly.*

## Landscape & Commentary

- Ximluci® is one of 3 Lucentis (ranibizumab) biosimilars currently available:
  - Byooviz – Biogen
  - Cimerli – Sandoz US / Ranvisio – Teva Europe
- In the US biosimilars have now claimed a 57% share of the ranibizumab market by volume. In Europe biosimilars are estimated to have claimed an approx. 20% share of the ranibizumab market by volume
- In the US, the Average Sales Price (ASP*) of ranibizumab biosimilars is USD 810 per vial
- Only one Eylea biosimilar, Pavblu (Amgen), launched so far, the others currently expected to launch mid 2027 upon expiry of formulation patents
- High dose Eylea launched and captured 20% of US Eylea sales
- About 40% of all doses in US are off-label Avastin, with potential of further conversion to biosimilars
- First Avastin biosimilar, Lytenava (Outlook), expected to launch in Europe in 2025 and is pending BLA decision from FDA in the US

*Source: GM Insights – Anti-VEGF Therapeutics Market 2025; Samsung Bioepis Biosimilar Market Report; Company estimates. Note: (*) Average Sales Price, calculated as the revenue for units sold per quarter divided by the units sold per quarter.*

# Ximluci® – Commercial status Europe & RoW

## Ximluci® launched by STADA in 22 countries

- Global generics and biosimilar specialist with sales in over 100 countries
- Sales: EUR 4,059m (2024)
- Employees: 11,649 (2024)

- Additionally launched in Bahrain and Uzbekistan

## Co-Development & Commercialization Partnership with STADA

Partnership with STADA signed in 2018. STADA are granted the commercial rights to Ximluci® globally including Europe, the US, several countries in the Middle East and North Africa and selected markets in Asia Pacific. Xbrane retains responsibility for development.

| Up-front | Milestones / cost-coverage | Profit Sharing |
|---|---|---|
| EUR 7.5m | EUR 40-50m | 50% of EBITDA |

### Economics & Mechanics

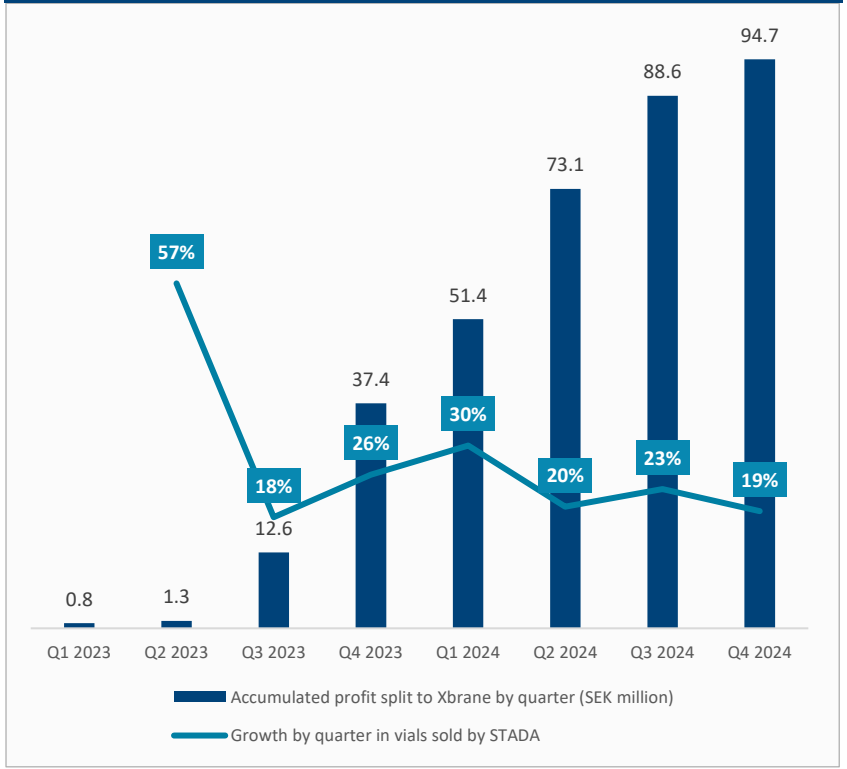
1. Xbrane produce Ximluci® basis STADA forecasts (12-month binding / semi-binding)
2. Xbrane sells Ximluci® to STADA at cost as per forecast
3. STADA sells Ximluci® in launched markets
4. Xbrane receives its share of profit contribution after production and S&M expenses every quarter

### STADA Activities & Commitment

- Dedicated biosimilars team within STADA global speciality care
- Dedicated KAMs to target KOLs / compounders
- Dedicated ophthalmology field force for specific markets
- Experienced local tender teams in all countries for bidding and participation in key tenders
- Ximluci® is the sixth approved biosimilar in STADA's specialty care portfolio. Strong track record of commercializing biosimilars: Retacrit® epoetin alfa-epbx, Movymia®, OYAVAS®, Hukyndra® adalimumab
- Pre-filled syringe version to be launched in Europe in 2025

# Ximluci® – Performance in launched markets & opportunity

## Profit split to Xbrane and growth in vials sold by STADA




## Commentary

- Current inventory with value of SEK 180m to be converted into cash during 2026-2028 as more product is delivered to STADA
- Total profit sharing to Xbrane since launch of SEK 95m with average quarterly growth of 23%*
- Ximluci® average volume market share in Europe during 2024 was approx. 2.5% of the ranibizumab (Lucentis and Lucentis biosimilars) market by volume
- Ximluci® share of ranibizumab market across launched countries in Europe was 5.0% by volume in January 2025

**Annual profit share scenario table in launched markets basis claimed ranibizumab market share****

| | | | | |
|---|---|---|---|---|
| **Claimed market share by volume** | 2.5% | 5.0% | 10.0% | 25.0% |
| **Estimated annual profit share to Xbrane (SEK, million)** | 36.4 | 71.7 | 144.4 | 360.5m |



*Note: (*) Average quarterly growth over last four quarters.; (**) Scenario table assumes current NSP and profitability on Ximluci®.*

# Lucamzi™ – Status US

## Xbrane & STADA partner with Valorum

VALORUM BIOLOGICS

- Biosimilar commercialization specialist founded by several industry veterans
- Johnson & Johnson, Merck and Roche.

## FDA status

- BLA resubmitted December 2024
- Additional documents requested from one CMO for FDA to determine need for re-inspection
- Review to be initiated and BsUFA date to be set in April 2025
- Expected review timing 2-5 months from initiation dependent on need for re-inspection

## US Commercialization Partnership

Xbrane and STADA license US commercial rights to Valorum Biologics. Valorum will be responsible for sales, marketing and commercial efforts in the US after approval. STADA are responsible for completing the regulatory approval process. Xbrane are responsible for commercial manufacturing and supply.

| Milestones | Royalties | Supply |
|---|---|---|
| Upon regulatory approval & launch | on net sales of Lucamzi™, shared equally by STADA & Xbrane | Xbrane to supply Lucamzi™ at a double-digit mark-up to COGS |

### Economics & Mechanics

1. Xbrane produce Lucamzi™ on basis of Valorum forecast (2 years binding/semi-binding)
2. Xbrane sell Lucamzi™ to Valorum with double-digit mark-up as per forecast
3. Valorum sells Lucamzi™ in US
4. Xbrane receives its share of royalty in line with agreement on quarterly basis

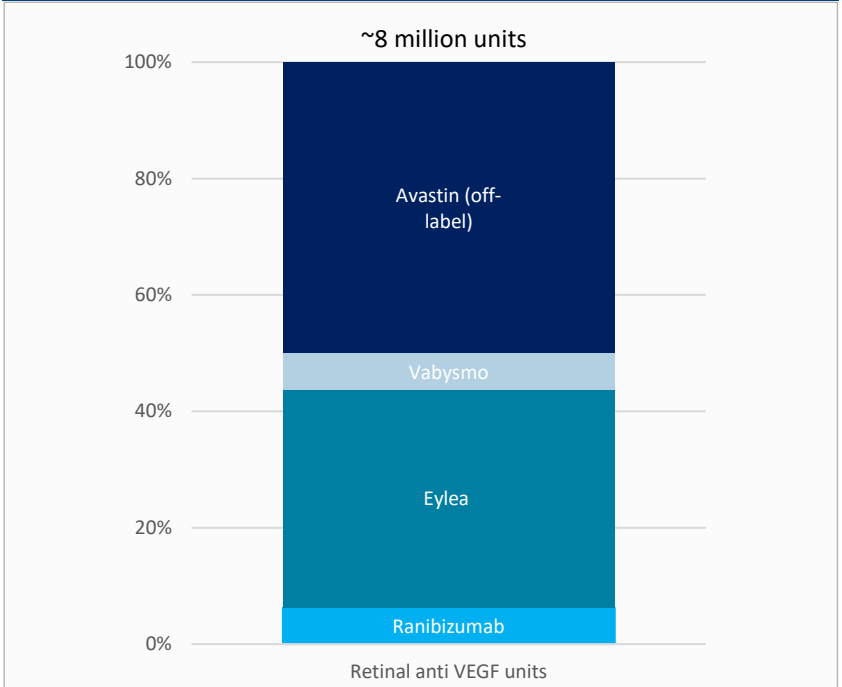
### Valorum Activities & Commitment

Current activities that Valorum are engaging in for swift launch upon approval:

- Set up commercialisation team
- Market Lucamzi™ to key accounts (mainly larger PE owned retinal chains)
- Apply for Q-code (post approval)
- Contract distributors and list product with Medicare and private insurance companies

# Lucamzi™ – US opportunity

## US retinal anti VEGF: USD 10 billion market




## Commentary

- Lucentis biosimilars covered under Medicare Part B with 20% patient co-payment
- Reimbursement based on ASP* + 6-8% of originator ASP
- Dynamic which favors new biosimilar entrants starting from high WAC** forming the basis for reimbursement until ASP is established after 12 months
- Sandoz withdrew its Lucentis biosimilar Cimerli to “wash out” ASP and re-launch at fresh WAC / ASP after 12 months
- Lucamzi™ to benefit from this dynamic, Valorum forecast to reach SEK 1 billion in annual sales (1% of total retinal anti-VEGF market) which would generate SEK 150-250m in royalties for Xbrane

| Annual profit share scenario table in the US basis claimed ranibizumab market share | | | |
|---|---|---|---|
| **Claimed market share by volume** | 10% | 20% | 30% |
| **ASP (USD / Unit)** | 1,000 | 800 | 600 |
| **Estimated annual profit share for Xbrane (SEK. million)** | SEK 122 million | SEK 196 million | SEK 220 million |



*Source: Sources: Quarterly reports, , IQVIA, Company estimates. Note: (*) Average Sales Price, calculated as the revenue for units sold per quarter divided by the units sold per quarter; (**) Wholesale Acquisition Cost.*

# Agenda

Overview

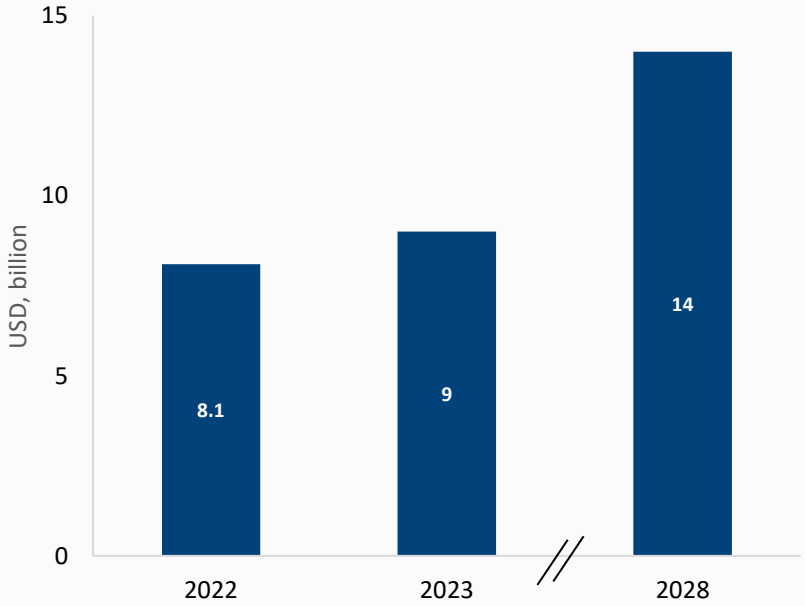
Ximluci® / Lucamzi™

**Xdivane™**

Financial outlook

# Xdivane™ – Market & landscape

## Opdivo® expected to generate net-sales of $14b globally in 2028




## Landscape & Commentary

- Opdivo is an immuno-oncology drug (PD1 inhibitor) used in treatment of several cancers including melanoma and lung cancer
- The total global market for PD1/PDL1 inhibitors is estimated to €40bn
- Opdivo is the first PD1 inhibitor to lose exclusivity (Dec 2028 in US/June 2030 in Europe) creating an opportunity for Opdivo biosimilars to take market share from other novel PD1/PDL1s
- Xdivane™ is expected to be one out of 4-5 biosimilars to Opdivo in regulated markets
  - Sandoz and Amgen have biosimilar candidates currently undergoing clinical trial
  - Teva in-licensed an Opdivo biosimilar from Mabxience
- Expected uptake by BMS Opdivo follow on product Opdualag (combination of nivolumab and relatlimab) reduced due to recently failed Phase 3 in stage III-IV melanoma


*Source: BMS annual reports, Global Data*

# Xdivane™ – Global partnership with Intas

## Partnership with Intas

- Growing at ~22% CAGR
- >10,000 product registrations globally
- >15 biosimilars marketed
- >19,000 employees
- Vertically integrated pharmaceutical player with vast experience in formulation development, manufacturing and commercialisation

accord
Make it better

- Global presence in >85 markets
- Accord Healthcare has presence across North America, Europe, Central & Latin America and Asia Pacific, with robust sales, marketing and distribution infrastructure

## Global License & Co-Development Agreement

Exclusive agreement with Intas signed in 2024. Intas will finance and oversee clinical and regulatory development activities as well as global manufacturing and commercialization through its subsidiary Accord Healthcare. Xbrane are responsible for CMC related development.

| Up-front | Clinical trial cost assumed by Intas | Development milestone | Royalties |
|---|---|---|---|
| EUR 10m | Approx. EUR 50m | EUR 3m | Double-digit on profit contribution |

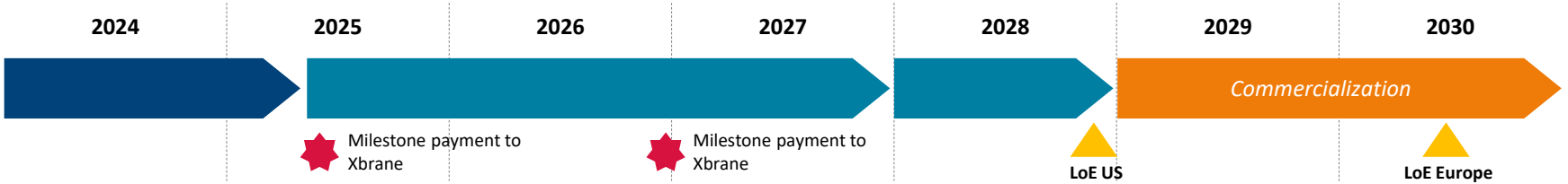
**Economics & Mechanics**

1. Xbrane finalizes process characterization and validation together with selected manufacturing partner (estimated investment of €20-25m during 2026-2027)
2. Intas conducts clinical trial during 2025-2027 (estimated investment of €50m)
3. Intas submits BLA/MAA to FDA/EMA
4. Intas manufactures and fully owned subsidiary Accord commercializes globally

**Intas Activities & Commitment**

- Partnership with Xbrane is aligned with Intas' global biosimilar strategy and commitment to expanding access worldwide
- Beyond IV formulation, Intas has full responsibility (incl. funding) of developing a SC formulation included with same profit split as the IV formulation in the agreement
- Strong track record with oncology biosimilars such as Pelgraz, Accofil and Zercepac
- 30% of all injectable oncology drugs in Europe are sold by Accord

# Xdivane™ – Streamlined development agreed with EMA & FDA




**Production of clinical material**

- Successful scale-up to commercial scale
- Conformed analytical similarity at scale
- Scientific advice meetings with EMA and FDA
- CMC development for the intravenous formulation (ongoing)

**Pivotal clinical trial**

- Single pivotal trial with ~340 patients
- Primary end-point: Comparative pharmacokinetics
- Secondary end-points: safety and immunogenicity
- No confirmatory efficacy analysis needed (as required in traditional Phase 3 for a biosimilar)
- EMA and FDA endorsed clinical development plan
- Supported by comparative analytical assessment with minimal residual uncertainty
- Timeline and budget reduced by 60%, from EUR 120m to €50m compared to traditional approach with parallel Phase 1 and Phase 3

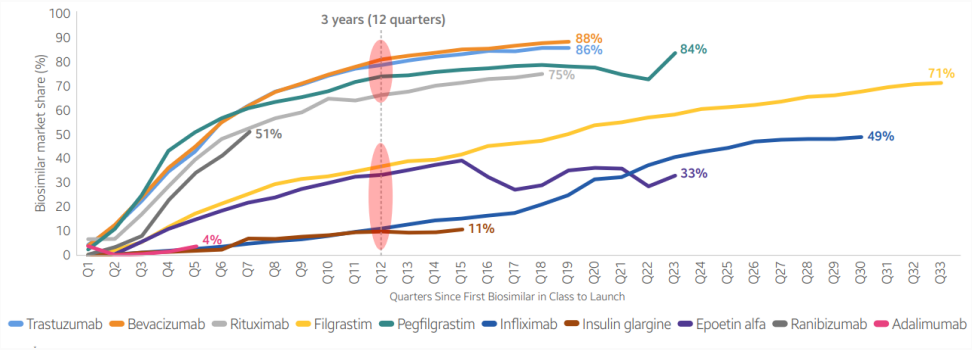
**MAA / BLA**

- Intas overall responsible for regulatory process
- Positive indications from EMA/FDA on comparative analytical assessment
- Manufacturing partner for both drug substance and product a global top 3 CMO with production sites already approved by FDA
- Intas have 5 biologics approved in EU and 2 in the US

**Xdivane™ is positioned to launch at patent expiration of Opdivo® (US – December 2028, EU – June 2030)**

# Xdivane™ – Market dynamics & opportunity

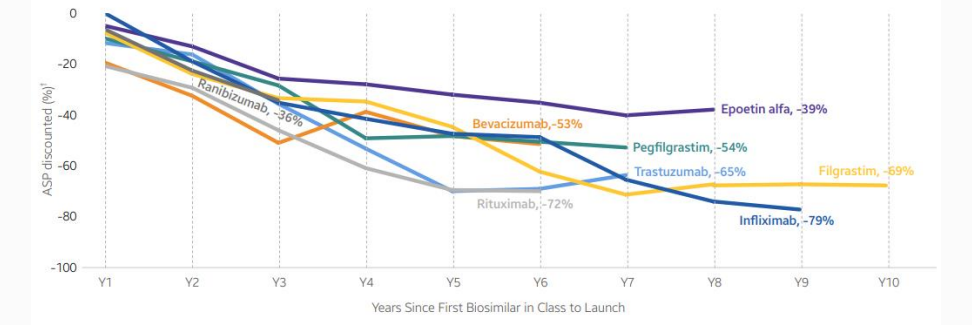
## US biosimilar volume market share vs. reference product




## Commentary

- Oncology biosimilars have been well received with average penetration of 75% at year 3 post launch in US
- Sold via hospital channel in US under Medicare Part B reimbursement scheme with strong incentive to select biosimilar (e.g. +8% originator ASP vs. 6% for originator)
- Accord has strong track record in oncology biosimilars:
  - 39% market share in US peg-filgrastim market (via acquired franchise from Coherus)
  - 30% market share across oncology injectables in Europe

## ASP trend by molecule




| Annual profit share scenario table basis claimed Opdivo market share* | | | |
|---|---|---|---|
| Claimed market share by volume | 19% | 15% | 13% |
| Discount to orignator | 40% | 55% | 70% |
| Estimated profit share to Xbrane (SEK, million) | 3,000 | 2,000 | 1,000 |



*Source: Samsung Bioepis Biosimilar Market Report. Note (*): Assumptions include annual Opdivo sales of USD 14 billion at time of patent expiry, with biosimilars taking 75% of Opdivo volume at year 3. COGS are assumed basis current manufacturing partner and maximum sales and marketing allowances, as per agreement with Accord.*

# Agenda

Overview

Ximluci® / Lucamzi™

Xdivane™

**Financial outlook**

# Strong growth in product & license related gross profit in 2024

## Historical Revenue Split and P&L

| P&L Overview (SEK, million) | 2021A | 2022A | 2023A | 2024A |
|---|---|---|---|---|
| License revenues | 10.5 | 50.9 | 28.4 | 132.0 |
| Product sales to STADA at cost | - | - | 172.1 | 6.2 |
| Profit sharing | - | - | 37.4 | 57.2 |
| Other | 0.9 | 6.8 | 0.9 | 3.3 |
| **Total Revenues** | **10.7** | **57.6** | **238.7** | **198.7** |
| Cost of Goods Sold | - | - | (203.3) | (18.2) |
| **Gross Profit** | **10.7** | **57.6** | **35.4** | **180.5** |
| | | | | |
| Other Operating Income | 4.8 | 20.9 | 13.7 | 15.8 |
| Administrative Expenses | (31.4) | (31.5) | (40.0) | (40.1) |
| Research & Development Expenses | (160.6) | (199.6) | (305.8) | (312.9) |
| Other Operating Expenses | (4.1) | (13.6) | (25.4) | (61.2) |
| **Operating Profit / Loss** | **(180.6)** | **(166.2)** | **(322.2)** | **(217.9)** |

## Commentary

- In 2024, product sales mostly related to profit sharing
- In 2023, 18% of product sales was related to profit sharing and remainder was finished goods delivery at cost to partner STADA
- 2024 gross profit was SEK 180.5m compared to SEK 35.4m in 2023, a significant increase which is attributed to increased license revenue and profit sharing
- R&D expenses during 2023 and 2024 were mainly driven by pre-clinical development of Xdivane™ and XB003, including scale-up of production processes and production of clinical material with selected manufacturing partners
- With the recent divestment of XB003 and Xdivane™ soon being handed over to Intas for clinical development, **R&D expenses are expected to significantly decrease** in 2025, and even further from 2026 onwards
- With the divestment of part of Xbrane's organisation to Alvotech, the fixed cost-base is expected to significantly decrease (annual reduction of SEK 120m), resulting in a **lean organisation with anticipated fixed costs of approx. SEK 40m**
- **SEK 180m** worth of Ximluci® product inventory ready to be deployed over 2026-28 as more product is delivered to STADA

# Xbrane’s cumulative financial profile, product by product

| | Ximluci® | + | Lucamzi™ | + | Xdivane™ |
|---|---|---|---|---|---|
| **Gross Margin:** | 40-55% | | 55-65% | | +85% |
| **EBITDA Margin:** | 20-40% | | 40-50% | | +80% |
| **Assumptions:** | • Xbrane’s first commercial asset<br>• 7.5% volume market share claimed<br>• Current ASP | | • US FDA approval and launch in US in 2026<br>• 20% of ranibizumab volume market share claimed<br>• ASP of USD 800 | | • US FDA approval in December 2028<br>• Launch in US early 2029<br>• 13% nivolumab market share claimed (“fair” share assuming 6 biosimilars on market)<br>• 70% price discount to originator |

**Through the restructuring, Xbrane has the potential to become financially stable and highly profitable business**