



**STO: XBRANE**

July 2023

**Xbrane – a World-Leading Biosimilar Developer**



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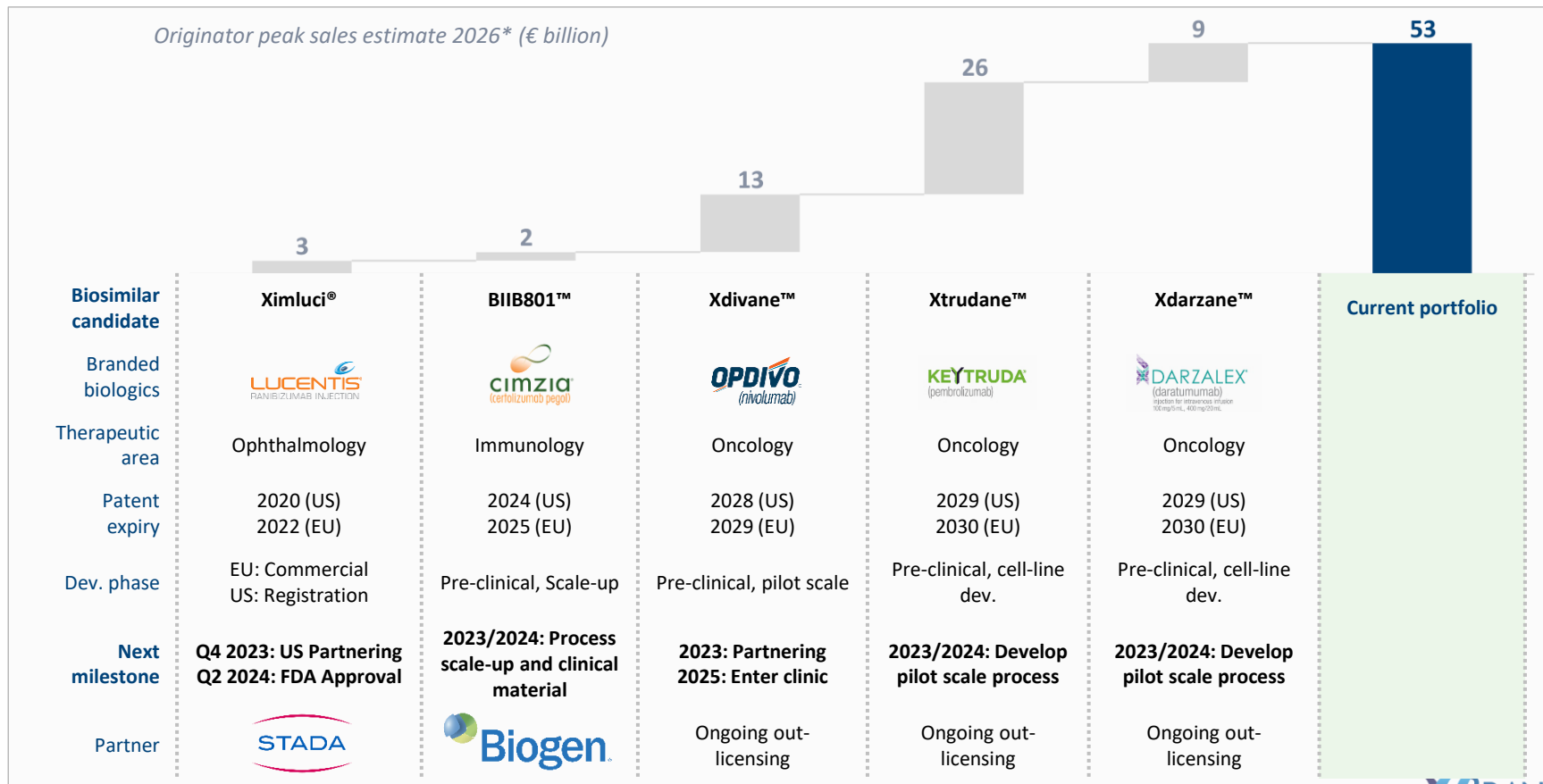
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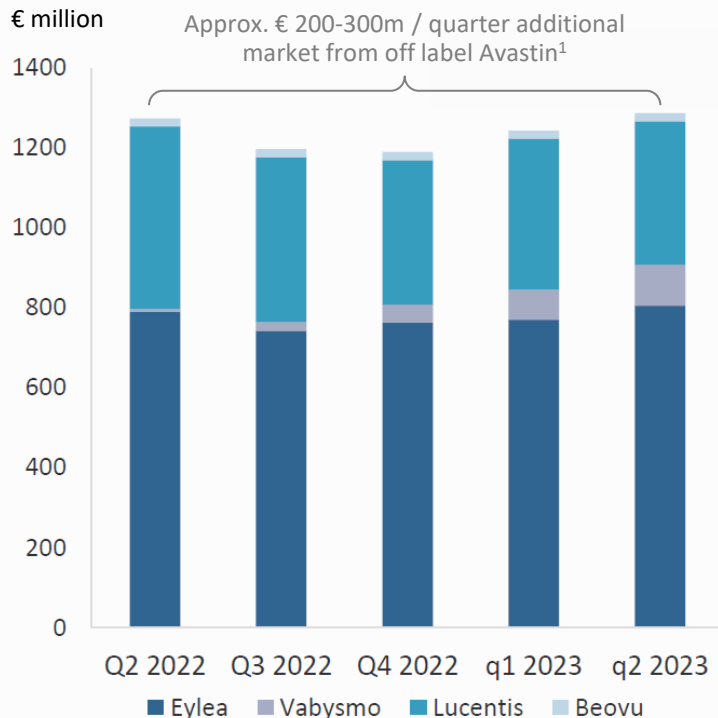
# Portfolio update

Originator peak sales estimate 2026\* (€ billion)



# Ximluci® non-US update – Ximluci® launched across 35-40% of the market

## Retinal anti-VEGF sales (ex US)



## Commentary on Q2 2023

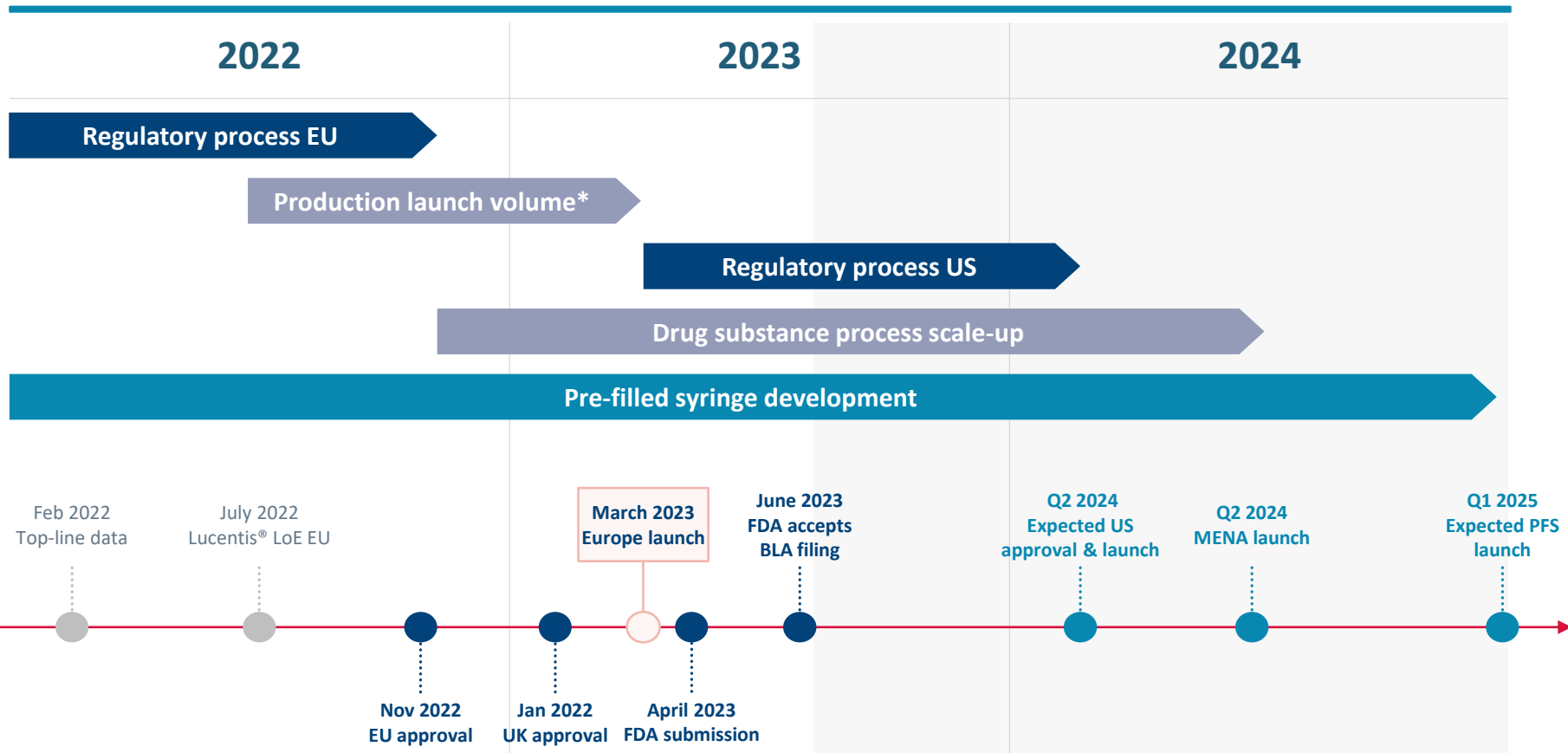
- Q2 2023 revenue from Ximluci® amounted to SEK 37 million<sup>2</sup>:
  - SEK 0.4 million profit sharing
  - STADA Sales & Marketing expenses remain high as percentage of net sales, as volumes still relatively low
- Ximluci® launched as vial in Croatia, the Czech Republic, Germany, Greece, Lithuania, Norway, Poland, Portugal, Spain and the UK (approx. 35-40% of non-US market)
- Non-US market for retinal anti-VEGFs approx. € 5 billion annually
- Uptake of all ranibizumab biosimilars slower than anticipated due to requirements for education of stakeholders
  - Ximluci #2 amongst ranibizumab biosimilars in Europe
- Registration processes ongoing in Saudi Arabia (KSA) and the United Arab Emirates (UAE)
- Long term view of Ximluci sales potential remains

Sources: Novartis, Roche and Regeneron quarterly reports

1) Assuming cost of compounded offlabel Avastin of €100 per unit and a 30% volume market share

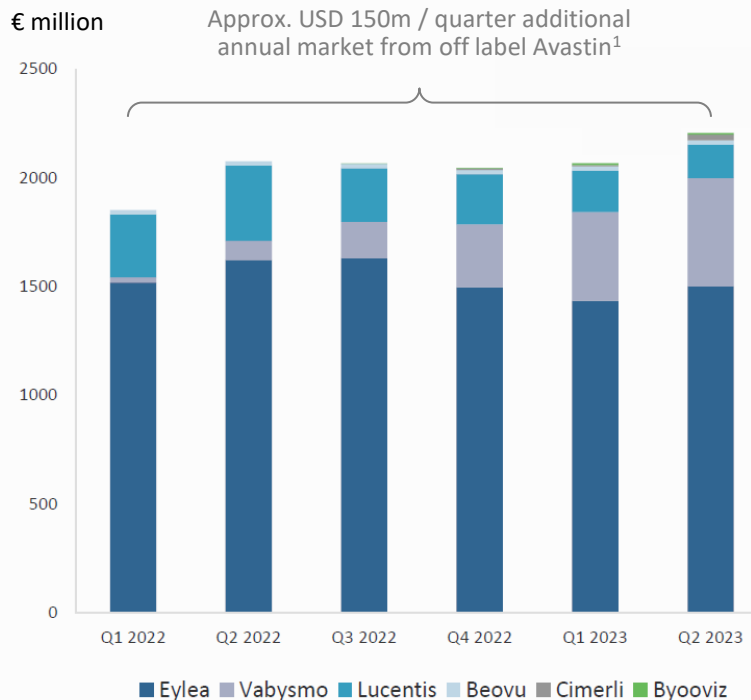
2) Xbrane generates revenue from Ximluci through: (i) sales of Finished Goods to its partner STADA at cost and; (ii) STADA sharing 50% of contribution (net sales less COGs less S&M expenses) from Ximluci sales

# Ximluci® development update – FDA BsUFA date in April 2024



# Ximluci® – US market update

## Retinal anti-VEGF sales (US)



## Commentary on Q2 2023

- Ongoing process to identify commercialization partner following the mutual decision to discontinue the commercial license agreement with Bausch + Lomb
- FDA has set a BsUFA date for Ximluci® in April 2024
- US market for retinal anti-VEGFs approx. \$8 billion annually
- Ranibizumab biosimilar value market share 1.5% in overall retinal anti VEGF market and 18% in ranibizumab market (combined biosimilar sales \$33.7m)

# Plan to positive operating cash flow on a monthly basis

		Key operating cash flow components q2 2023 (SEK million)		Plan to positive operating cash flow before end of q1 2025
Negative cash-flow impact	Development organization	35	<ul style="list-style-type: none"> <li>Capacity to develop one new biosimilar candidate per year</li> </ul>	<ul style="list-style-type: none"> <li>Capacity is calculated under the current set-up at around SEK 140 m per year but is to some extent flexible and can be matched to different development activities</li> </ul>
	Ximluci®	65	<ul style="list-style-type: none"> <li>Process scale-up ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Completed</li> </ul>
	BIIB01™		<ul style="list-style-type: none"> <li>Process scale-up ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Completed and handed over to Biogen</li> </ul>
	Xdivane™		<ul style="list-style-type: none"> <li>Process scale-up ongoing</li> </ul>	<ul style="list-style-type: none"> <li>Co-funding from commercialization partner</li> </ul>
	Ximluci inventory	41	<ul style="list-style-type: none"> <li>Ongoing build-up of inventory of commercial material for Europe and US</li> </ul>	<ul style="list-style-type: none"> <li>Reduced</li> </ul>
Positive Cash-flow impact	Ximluci® ex-US	0.4	<ul style="list-style-type: none"> <li>Profit sharing from STADA</li> </ul>	<ul style="list-style-type: none"> <li>Increased income expected as ranibizumab biosimilars gain momentum</li> <li>Improved profitability with increased scale</li> </ul>
	Ximluci® US	n/a		<ul style="list-style-type: none"> <li>Upfront and milestones from new US partner and profit sharing post launch</li> </ul>
	BIIB01™	n/a		<ul style="list-style-type: none"> <li>Income from sales of clinical material and milestone payments from Biogen</li> </ul>

} Expected to generate income to cover cost of the dev- organization

## Upcoming key milestones

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- Ximluci<sup>®</sup> out-licensing of North American rights
- Ximluci<sup>®</sup> FDA approval and launch
- BIIB801 scale up of production process and production of clinical material triggering milestone payments as per agreement with Biogen
- Xdivane<sup>™</sup> out-licensing
- Reaching positive operating cash-flow on a monthly basis





# Jan-Jun Interim Report 2023

## Financials

# Ximluci<sup>®</sup> generates revenue from three main revenue streams

## Supply of Finished Goods to partners “at cost”

- Sales of Finished Goods to STADA under Supply Agreements “at cost”
- Products delivered & invoiced every 2-3 months
- Products delivered during Q2 generated about 37 SEK m in revenue

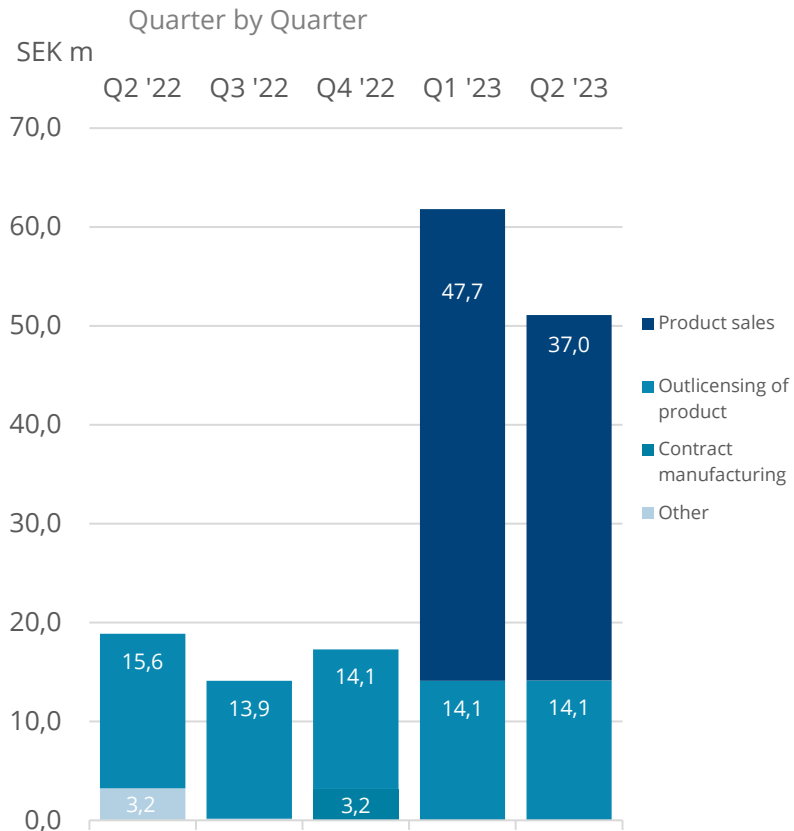
## Profit sharing with partners

- Profit split with STADA calculated as:
  - *STADA product net-sales*
  - *minus production costs*
  - *minus Sales and Marketing expenses*
  - *50/50 split of contribution*
- Large part of Sales & Marketing expenses are fixed, hence still significantly higher as % of net sales in Q2 than expected at scale

## License proceeds from partners

- License proceeds expected from new partner in US

# Net revenue (Q by Q)



## Commentary on q2 2023

### Revenues in Q2

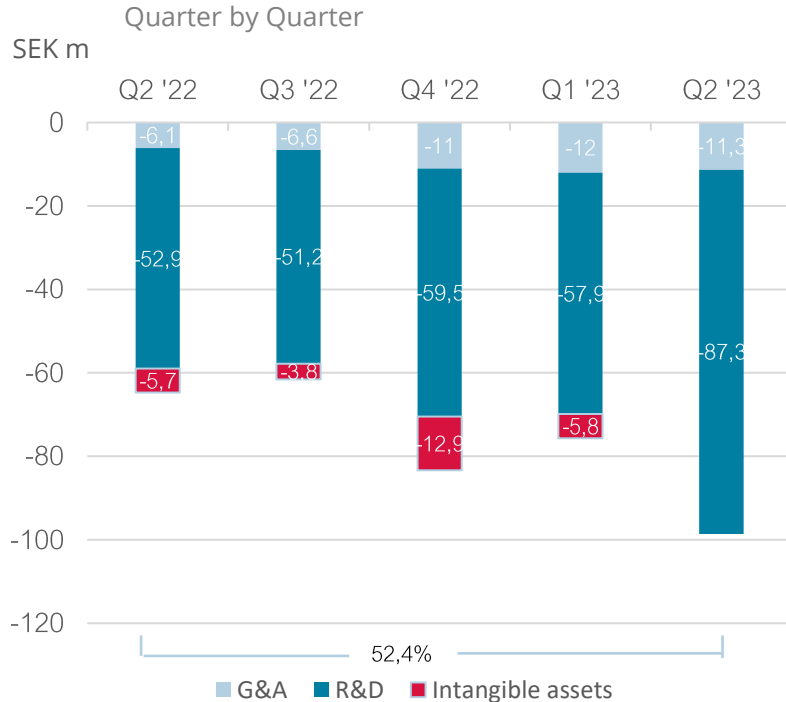
#### Product sales

- Supplies to STADA "at cost" of 36,6 SEK m
- Positive profit split of 0,4 SEK m

#### Outlicensing

- Accrued income for BIIB801 from Biogen Inc. 14 SEK m

# Total Company Expenses (G&A and R&D)



## Commentary on q2 2023

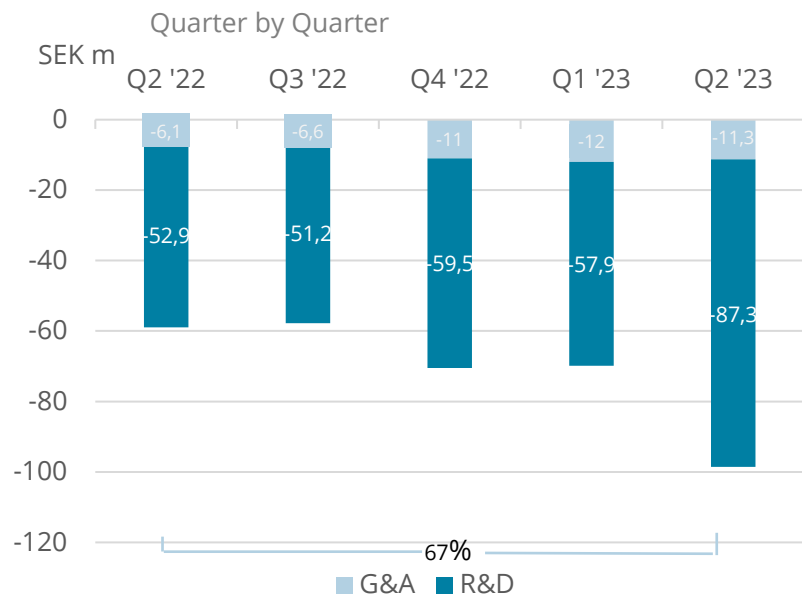
Comparing "like-for-like" year-on-year, total Operating Costs have increased by 52.4% mainly as a result of scale-up activities for Ximluci<sup>®</sup>, BIIB801 and Xdivane<sup>™</sup>

Expenses expected to be reduced in 2024 when completed (Ximluci<sup>®</sup> and BIIB801) and co-funded by commercialization partner (Xdivane<sup>™</sup>)

The total R&D costs (incl. Intangible Asset of 0.0 SEKm) amounted to 87.3 SEK m. ~89%. Total G&A amounted to 11 SEK m. ~11% of total operational costs in the second quarter.

Reclassification of the development costs for Ximluci<sup>®</sup> in accordance with IAS 38 started July 1st, 2021 and ended in connection with the commercialization in March 2023. As of June 2023, 105 SEK m is capitalized on the Balance Sheet related to Ximluci<sup>®</sup>.

# Net Company Expenses (G&A and R&D) as reported in P&L



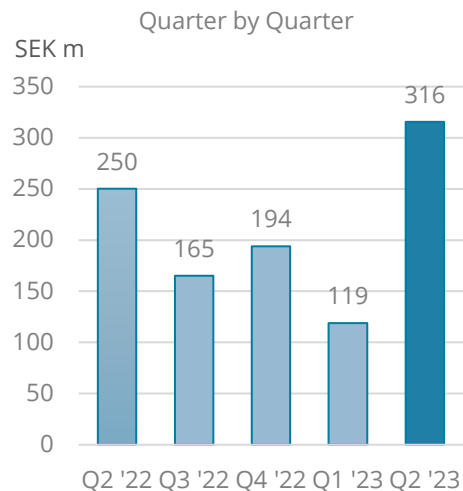
## Commentary on q2 2023

Total Company Expenses expensed in the P&L and as reported in the Q2 Interim Report have increased by 40 SEK m:

1. All of the expenses related to Ximluci® are commercial/launch activities - not capitalized vs Q2, 2022.
2. Production of clinical material for BIIB 801.
3. Progressing pre-clinical development for Xdivane™, Xtrudane™ and Xdarzane™.

# Cash Flow and Financing

## Cash and Cash Equivalents



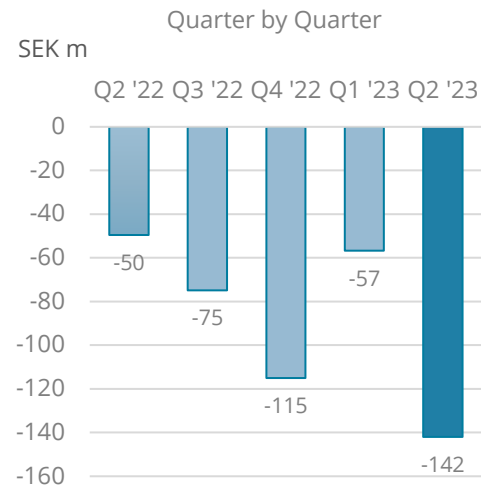
## Cash and Cash Equivalents

Amounted to ~316 SEK m end of June 30<sup>th</sup>, 2023 as a result of the capital injection in Q2, 2023.

## Operating Cash Flow

Operating cash flow of -142 SEK m in Q2 2023, is primarily a result of stock-build of Ximluci<sup>®</sup> and prepaid expenses for upscaling production processes for Ximluci<sup>®</sup> and BIIB801 and Xdivane<sup>™</sup>.

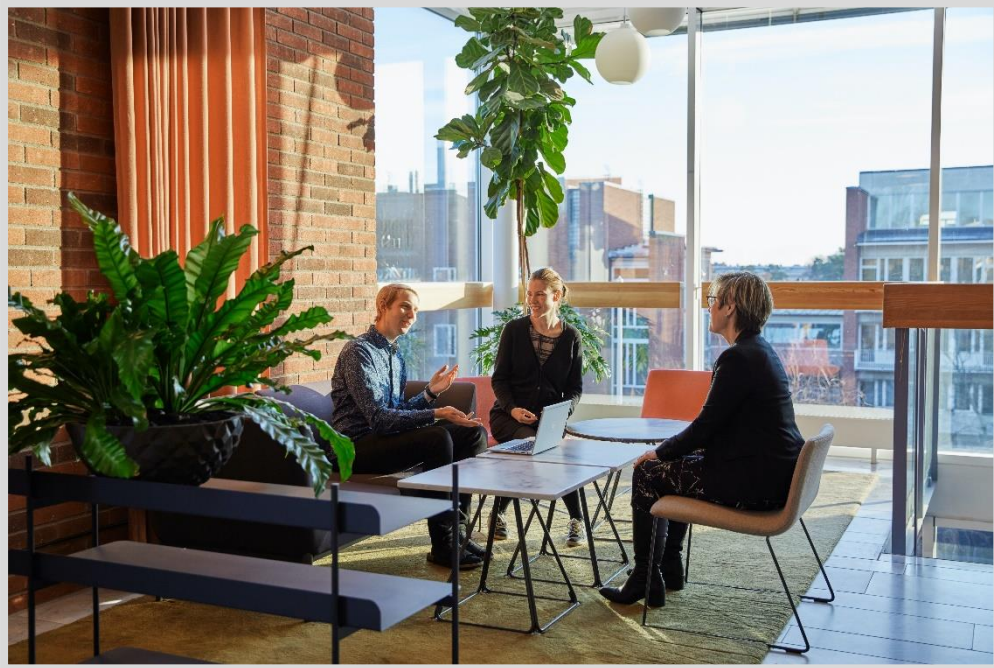
## Operating Cash Flow



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Q&A