

Making progress, while the OX124 review time extended

Interim Report Q2 2024, July 17 2024



Legal disclaimer

- This presentation, which is personal to the recipient, has been prepared and produced by Orexo AB (publ) ("Orexo") solely for the benefit of investment analysis and may not be used for any purpose other than assessment of investments concerning Orexo. Unless otherwise stated, Orexo is the source for all data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form the basis of, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of Orexo
- The shares of Orexo have not been registered under the U.S. Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States (as such term is defined in Regulation S under the Securities Act) except pursuant to an exemption from, or a transaction not subject to, the registration requirements of the Securities Act or unless registered under the Securities Act.
- The information in this presentation has not been independently verified. No representation or warranty, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy or completeness of the information or opinions contained herein. None of Orexo, any of its shareholders, or any of their respective subsidiary undertakings or affiliates or any of such person's directors, officers or employees, advisers or other representatives, accepts any liability whatsoever (whether in negligence or otherwise) arising, directly or indirectly, from the use of this presentation or otherwise arising in connection therewith.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and Orexo expressly disclaim any obligation or undertaking to release any update of, or revisions to, any forward-looking statements in this presentation as a result of any change in our expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation is not a prospectus in accordance with the Swedish Financial Instruments Trading Act (Sw. lagen (1991:981) om handel med finansiella instrument) or any other Swedish laws or regulations. Neither the Swedish Financial Supervisory Authority (Sw. Finansinspektionen) nor any other Swedish regulatory body has examined, approved or registered this presentation.

Agenda & presenters

1

Key achievements

2

Business update

- US Commercial
- Products under Development

3

Financial & legal overview

- Financial development
- Outlook 2024
- Legal update

4

Future value drivers



Nikolaj Sørensen,
President and CEO



Fredrik Järsten
EVP and Chief Financial Officer



Key achievements

Strong Zubsolv® recovery and focus on getting OX124 to the US market

- ✓ Positive EBITDA in Q2 (SEK 5.0 m) despite headwind from adjustment in Abstral® royalties, a new human factor study for OX124 and increased legal expenses in the US
- ✓ Zubsolv revenue growth in both USD and SEK, with significant rebound from Q1 with >14% revenue growth
- ✓ OX124 approval will be delayed, but successful improvement in Instructions for Use documented in a new Human Factor study
- ✓ Good progress in AmorphOX pipeline with continued strong data on stability in both small and large molecules, including partnered projects.
- ✓ Orexo AB's sustainability work ranked among the top 5% of all 70' businesses worldwide reviewed by EcoVadis
- ✓ Some tractions for Zubsolv Europe, which will be needed to replace Abstral royalties over time

Net revenues

154 SEK M

Group EBITDA

5 SEK M

Cash

140 SEK M

A middle-aged man with short, graying hair is smiling broadly, looking slightly to his right. He is wearing a dark blue quilted vest over a blue and white plaid shirt. He has a dark backpack on his shoulders and is adjusting a strap with both hands. The background is a soft-focus outdoor scene with trees and a bright sky, suggesting a natural, possibly hiking, environment.

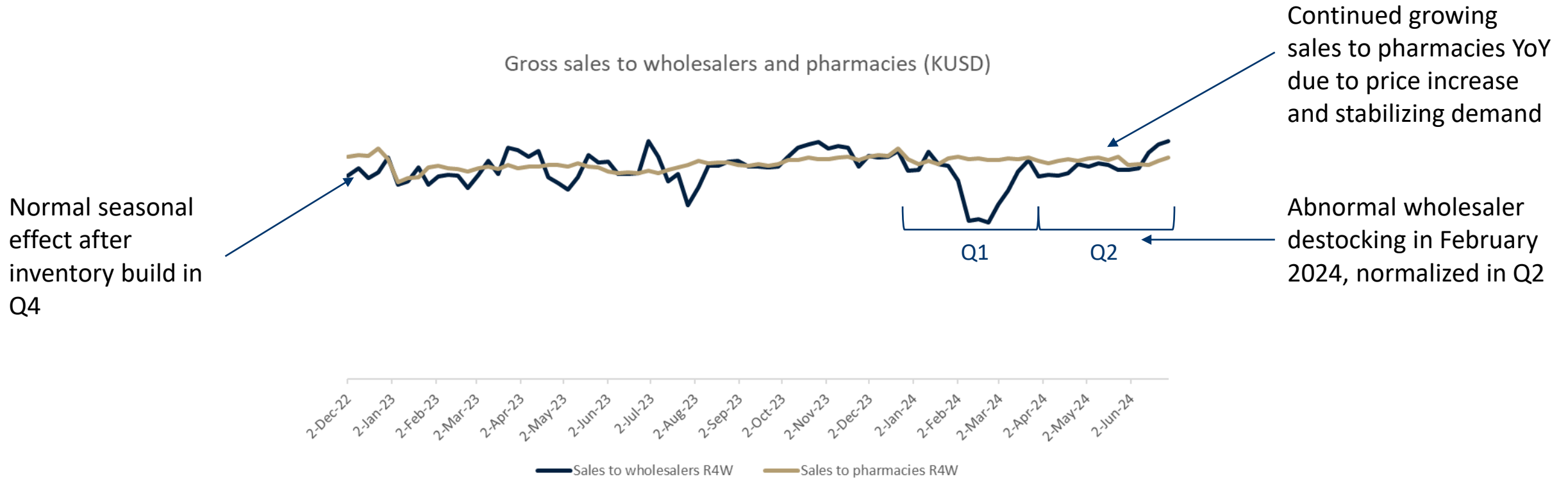
Business update
US
Commercial

Bup/Nal market events in Q1 partly solved

- Following the reduction in inventory levels at wholesalers in Q1, the inventory level has stabilized, but at a lower level than Q4
 - Increased hesitance to carry inventory of control substance
 - High cost of capital
- Continued disenrollment in Medicaid (-9%) starting Q3 2023 followed by significant increase in Commercial Insurance (+19%)
 - Removal of Covid-19 emergency measures with automatic renewal of Medicaid enrollment
 - Reduction in state subsidies following Covid-19



Stable Zubsolv[®] sales to pharmacies, but significant drop in wholesaler inventory in Feb/March 2024

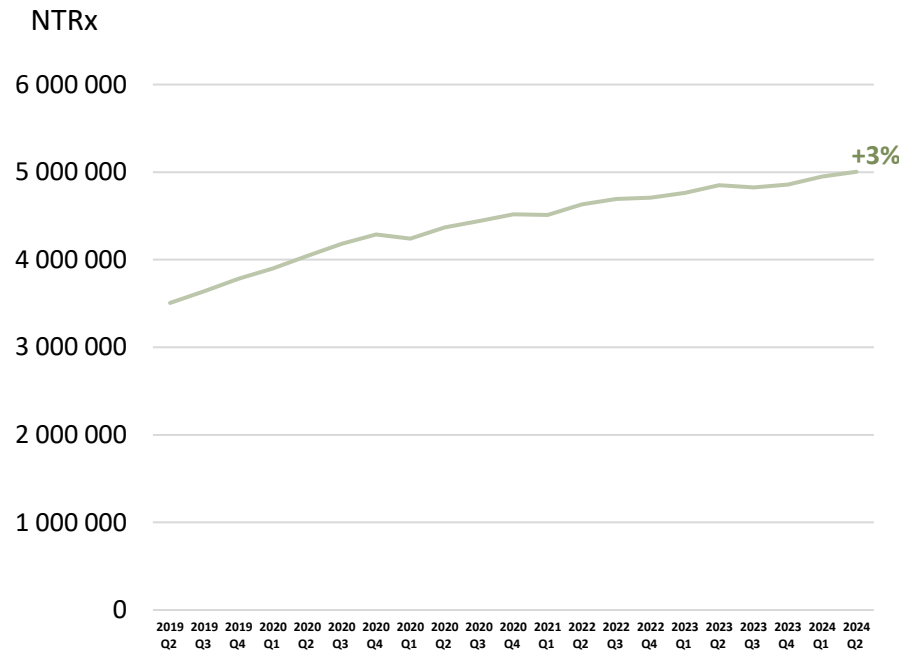


¹ Gross sales is before deduction of rebates to payers, wholesalers and accruals for returns

² Orexo has no influence on wholesaler inventory levels

Stabilizing Zubsolv[®] demand

3% total market growth Q2 24 vs Q2 23¹



Low market growth in prescriptions of 3% vs Q2 2023 and 1% vs Q1 2023

- **Significant decline in Medicaid** with minus 9% YoY following Medicaid disenrollment
- **Commercial growth** of 19% YoY
- Medicaid remain the largest market segment with 38% of patients followed by Commercial with 33%

Zubsolv stable with 0% versus Q1 2024 and -4% vs Q2 2023

- Growth in Commercial segment, excl. United Health Group (UHG)
- The previous exclusive payers (UHG) grew 1% from Q1, while lower volume YoY

Zubsolv outperformed the Medicaid segment both YoY -5% and QoQ 0%

- Continued strong growth in new Medicaid contracts YoY, NY (+13%)

¹Based on last 4w and 6w average NTRx volume. Note weekly prescription data is volatile and is influenced by public holidays, weather and changes to reimbursement.



Business update

**Products under
development and
partnered products**

OX124 approval and launch extended

Issue with Instructions for Use successfully addressed..

- Following FDA concerns raised late April the team has successfully updated the Instructions for Use and documented the positive impact in a new Human Factor study completed in early July

...but a new concern has been raised requesting for additional technical data

- A CRL issued, as expected, on July 15th requesting additional technical data related to the device and packaging
- Requested data has been shown from a pilot scale manufacturing, but more data is requested to bridge to the final commercial scale process
- The CRL does not indicate a need for additional clinical or non-clinical studies

Orexo will now seek guidance on the scope of the data requested

- Orexo will submit a response to FDA within 30 days and have a meeting to agree on the response to the FDA concerns
- Orexo will need to respond to the concerns, but do not need to submit a new NDA



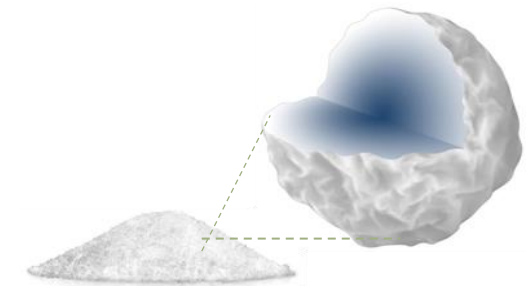
R&D pipeline advancing

amorphOX® - a scalable drug delivery platform

- Continued good progress in showing stability in partnered large molecules, with retained activity in after room temperature storage for molecules otherwise requiring cold chain

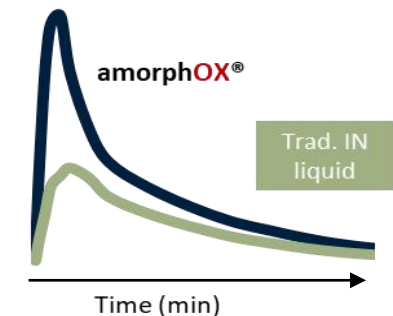
amorphOX® OX640 – epinephrine rescue medication for allergic reactions

- Continued work on formulation and preparation of moving manufacturing to commercial scale
- Smaller exploratory study planned for Q4 in patients with allergic rhinitis to ensure optimal dosing and maintained clinical differentiation in this patient segment
- Competing product receive positive opinion for nasal delivery of epinephrine in Europe reducing the regulatory uncertainty for OX640 in Europe
- Partnering discussions continue with constructive dialog based on the updated development plan following the briefing book accepted by the FDA



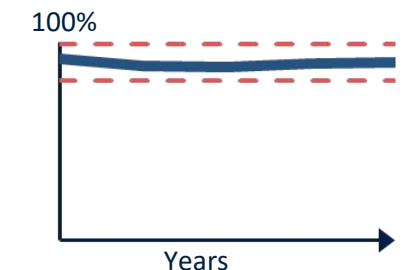
amorphOX® - an amorphous powder

Plasma concentration



Comparison to liquid nasal sprays

Amount of API



Excellent stability

Zubsolv Europé gaining some traction, but Abstral royalties expected to decline

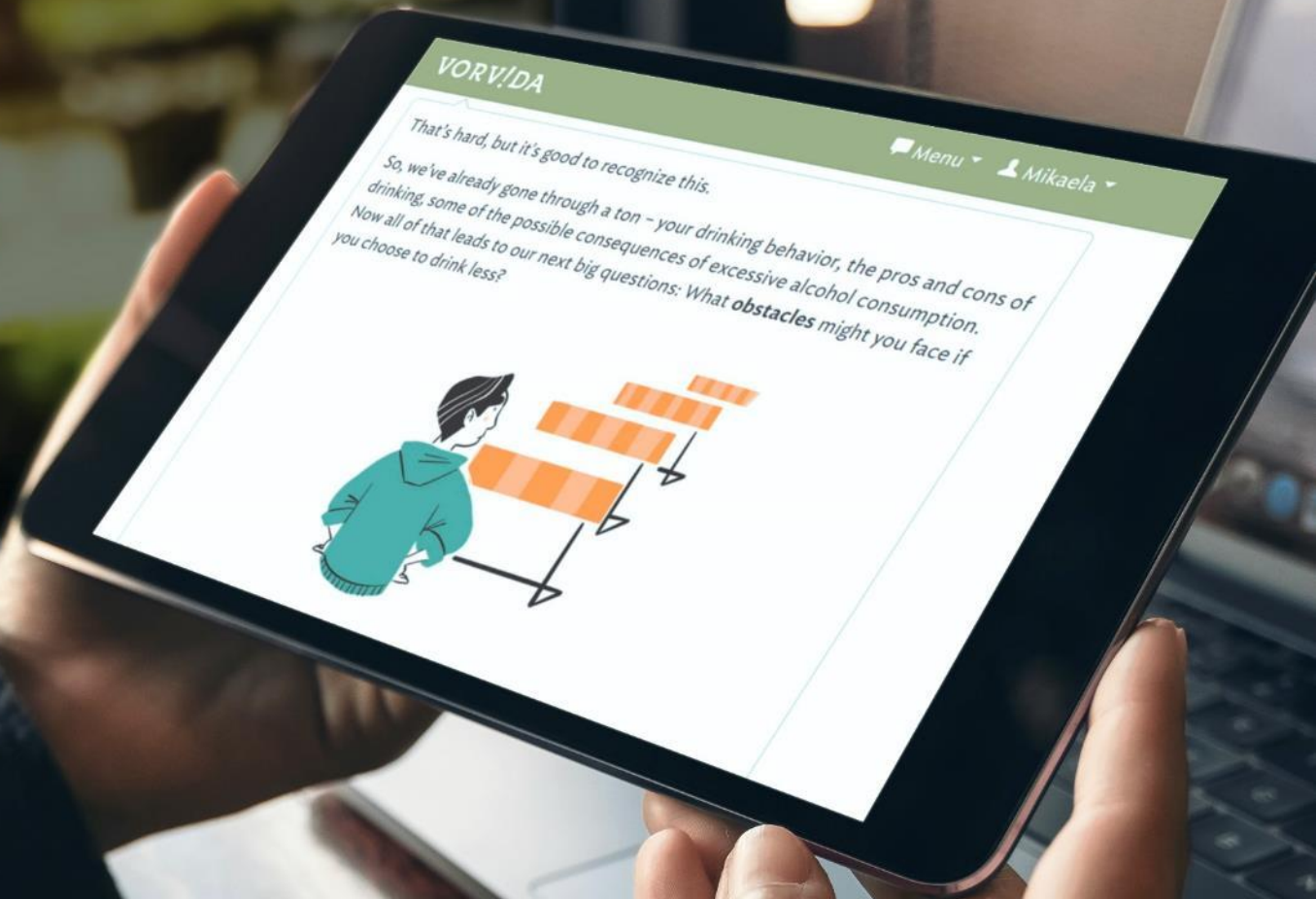
Zubsolv gaining traction in Europé

- Some good progress in a few countries during the quarter making Zubsolv a preferred choice
- In partnership with Accord Healthcare Orexo has worked intensively to reduce COGS to ensure price competitiveness in Europé
- Current material is sourced from the US at a significantly higher price than Zubsolv US material
- Accord Healthcare has shown high commitment in improving the supply chain and are ready to broaden launch, when new European supply is ready

Abstral royalties will decline

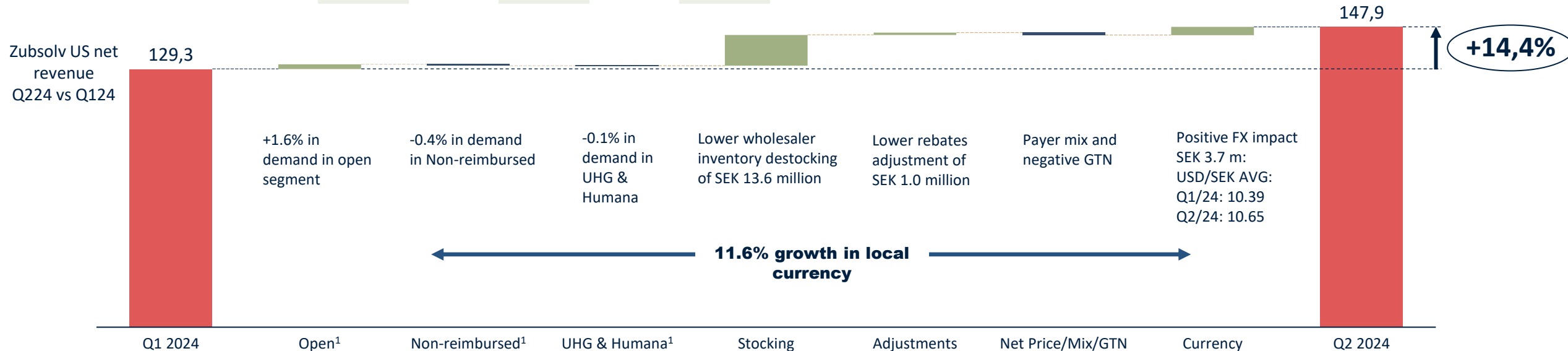
- Contract Grünenthal Meds (acquired Kyowa Kirin in Europé 2023) has ended for the first launch countries and will expire for additional countries during 2024-2025
- Contract remain for several countries, but most are lower volume countries

Financial & legal



Zubsolv® net revenue in Q2 rebound significantly from Q1

Net revenue per segment SEK m	Q2 2024	Q2 2023	H1 2024	H1 2023	Jan - Dec 2023	Comments Q2
Zubsolv US	147.9	145.4	277.2	286.0	577.7	<ul style="list-style-type: none"> ✓ Zubsolv US Net revenue grew YoY with 1,7 % primarily due to favorable payer mix and stronger USD vs SEK US impact of SEK 1.9 m partly offset by lower demand ✓ Lower Abstral ROW royalties due to a negative true-up of Q1 2024 accrued royalties based on Orexo's partner Grünenthal Meds reporting ✓ Higher Zubsolv ex-US revenues related to royalties and sales of tablets to Orexo's partner Accord Healthcare
Digital Mental Health Programs (DMHP)	0.0	0.0	0.0	0.1	0.0	
US Commercial – Total	147.9	145.4	277.2	286.1	577.7	
Abstral® royalties	1.3	8.0	8.4	14.2	31.9	
Edluar® royalties	3.3	4.0	6.0	5.3	10.8	
Zubsolv – ex US	1.5	0.2	1.7	11.2	18.4	
HQ & Pipeline – Total	6.0	12.3	16.1	30.8	61.1	
TOTAL	154.0	157.7	293.2	316.8	638.8	



¹Estimated change in demand by segment, based on Net Sales development during the quarter, IQVIA demand data, institutional sales and claims data from insurance companies

Positive EBITDA for the third consecutive quarter

Income statement SEK m	Q2 2024	Q2 2023	H1 2024	H1 2023	Jan - Dec 2023
Net revenues	154.0	157.7	293.2	316.8	638.8
Cost of goods sold (COGS)	-16.3	-17.2	-29.6	-46.0	-88.9
Gross Profit	137.7	140.5	263.7	270.8	550.0
Operating Costs	-153.5	-153.4	-284.2	-343.0	-659.5
EBIT	-15.8	-12.9	-20.5	-72.3	-109.5
Net financial items	-21.5	-2.9	-26.6	-12.0	-30.8
EBT	-37.3	-15.8	-47.1	-84.3	-140.3
Tax	1.4	3.2	2.3	7.8	12.0
Net profit/loss	-35.9	-12.6	-44.8	-76.5	-128.3
EBITDA	5.0	5.6	20.9	-35.4	-32.5

Comments Q2

OPEX on par with prior year

- Higher expenses in US Commercial for OX124 launch preparation
- Higher administrative expenses for DOJ investigation in US Commercial
- Lower R&D costs in HQ & Pipeline due to finalized MODIA® study in Q3 2023 partly offset by higher costs for OX124

US Commercial EBIT contribution of SEK 36.0 m (37.6)

- EBIT Margin for the quarter 24.4% (25.8%)

EBITDA of SEK 5.0 m (5.6)

- Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 12.6 m (30.3) for Q2

NET FINANCIAL ITEMS of SEK -21.5 m (-2.9)

- Higher bond loan costs of SEK -21.4 m (-9.3) in relation to final transaction costs and higher interest expense for the new corporate bond loan
- Negative unrealized exchange rate impact of SEK -0.8 m (5.3) derived from the parent company's foreign currency bank accounts mainly in USD
- Lower interest income from bank accounts of SEK 1.1 m (1.5) explained by absence of short-term investments

Cash position

Cash Flow SEK m	Q2 2024	Q2 2023	H1 2024	H1 2023	Jan - Dec 2023
Cash flow from operating activities	-6.5	-12.7	-25.4	-70.5	-95.0
Investment activities	-2.7	125.1	-3.8	208.3	200.8
Financing activities	-48.0	-14.0	-4.7	-25.5	-70.1
Cash flow (excl. exchange rate differences)	-57.1	98.5	-34.0	112.3	35.7
Exchange-rate differences in cash and cash equivalents	-1.2	10.1	2.6	6.5	3.1
Cash and cash equivalents at the beginning of the period	198.0	142.2	171.0	132.2	132.2
Cash and cash equivalents at the end of period	139.7	251.1	139.7	251.1	171.0
Net cash position	-318.8	-229.9	-318.8	-229.9	-277.4

Comments Q2

- ✓ **Cash and cash equivalents (SEK 140 m) decreased with SEK 58 m from Q1 2024 (SEK 198 m)**
 - ✓ Orexo completed and fully recognized the transaction for issued senior secured callable floating rate social bonds of SEK 500 in the quarter
 - ✓ SEK -6.5 m negative contribution from operating activities primarily impacted by negative impact on interest paid of SEK -7.7 m (0.0) from transaction costs for the refinancing of the old corporate bond loan and a positive impact on receivables of SEK 25.0 m (0.0) reversing the prepayment of own purchase of the new bond loan of SEK -25 m in Q1
 - ✓ Investment activities had a negative impact of SEK -2.7 m on cash flow primarily from investments in equipment for the development organisation
 - ✓ Financing activities had a negative impact of SEK -48.0 m mainly due to the closure of the purchase of new Orexo owned bonds of SEK 30.0 m (0.0) and issuance costs for the new bond loan of SEK 12.3 m (0.0)

Financial outlook

Metric	Outlook 2024	Reaffirmed/revised
Key market development	The buprenorphine/naloxone market will grow 2-5 percent, based on current growth trajectory	Reaffirmed
Lead product net sales	Zubsolv net sales in USD will be in line with 2023	Reaffirmed
Group OPEX	Cost control is a priority and OPEX excluding depreciation and amortization will decline from SEK 582 m in 2023 to below SEK 520 m in 2024	Reaffirmed
Group EBITDA	Positive EBITDA for the FY 2024	Reaffirmed

Note: The financial outlook for 2024 is based on current circumstances as of July 2024. However, there is an increased risk in the Zubsolv net sales guidance due to the wholesaler inventory adjustment in Q1 2024. In addition, a potential settlement of the ongoing DOJ investigation (see note 4), and increased R&D expenses, related to the OX124 resubmission, may affect our cost projections and financial results. The financial outlook 2024 is based on a forward looking assumption of a USD/SEK exchange rate of 10,28 calculated as an average of December 2023 by the Riksbanken.

Q2 legal update

Zubsolv® patent dispute vs Sun Pharmaceuticals

- ✓ In Q1 2023 the trial was conducted in the US District Court for the District of New Jersey.
- ✓ On June 30 (US Time Zone) the District Court for the District of New Jersey ruled in favor of Orexo against Sun. The district court found that Orexo's patents are valid and infringed by Sun
- ✓ In July 2023, Sun appealed the District Court decision to the US Court of Appeals for the Federal Circuit. A briefing schedule has been set by the Federal Circuit and an oral hearing is expected to take place during 2024

Overall strong IP rights for Zubsolv:

- In total 10 patents listed in the Orange Book
- Patent expiring dates Dec 2027 – Sep 2032
- Previously successfully managed to defend ZUBSOLV® IP rights in the US appeal court

US government agency investigation related to Zubsolv

- ✓ On July 14, 2020, Orexo became aware of an investigation by the US authorities which is ongoing
- ✓ Based on communications from the US authorities, the company believes it refers to certain historic marketing messaging campaigns
- ✓ Orexo's position to the government has been that its investigation concerns have no merit, but Orexo is also seeking to negotiate a settlement of the matter.



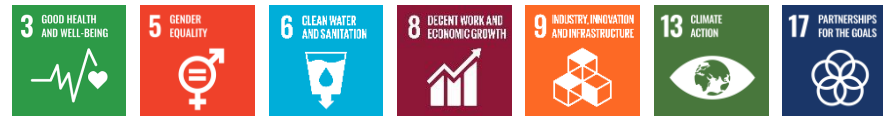
Future value drivers

Strategic initiatives going forward

Growing commercial revenues and profit contributions	Capitalising on the amorphOX [®] drug delivery technology	Improving access to treatment
<i>Key milestones and focus areas going forward</i>		
<ul style="list-style-type: none"> Stabilise Zubsolv[®] revenues and focus commercial investments in areas with growth opportunities Approval of OX124 by the FDA Hire experienced OX124 team Launch of OX124 in the US leveraging existing resources and focused investments into new areas 	<ul style="list-style-type: none"> Expand reimbursement of Zubsolv in the public segment and maintain access in the commercial segment Secure reimbursement for OX124 at launch Establish collaborations with healthcare providers under MatCore Establish patient support programs for all Orexo's products Establish legislation and policies enabling access to all types of treatment of OUD and mental health 	<ul style="list-style-type: none"> Partnering with other pharmaceutical companies to co-develop new products based on AmorphOX[®] Out-license products based on the AmorphOX technology such as OX640 Develop new products for Orexo to commercialise primarily within OUD and mental health.



Responsible business	Access to healthcare	Environment & climate change	Sustainable employees
----------------------	----------------------	------------------------------	-----------------------





Thanks

www.orexo.com

You can also follow Orexo on LinkedIn, X and YouTube and also read our blog



blog.orexo.com