

# Starting 2024 with a positive EBITDA

May 8<sup>th</sup> 2024

Orexo supports  
the UN's Agenda  
2030 with a  
focus on:



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# Agenda & presenters

## Q1 2024 Interim Report

**1**

Key achievements

**2**

Business update

- Commercial Products
- 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

# Creating a stable financial platform

- ✓ Positive EBITDA in Q1 (SEK 16 m) despite headwind from abnormal trade destocking and no supply of Zubsolv<sup>®</sup> to Accord in Europe
- ✓ Zubsolv decline due to significant wholesaler destocking and slight negative development in demand
- ✓ Significant cost reduction with 31% from Q1 2023
- ✓ Corporate bond refinanced under a sustainability framework and oversubscribed
- ✓ FDA review of OX124 ongoing with most proceeding according to plan, but delay in approval post PDUFA date likely
- ✓ Partnership with SOBI and a vaccine company to continue developing AmorphOX<sup>®</sup> with large molecules

Net revenues

**139** SEK M

Group EBITDA

**16** SEK M

Cash

**198** SEK M

A middle-aged man with short, graying hair is smiling broadly. 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 holding the straps with both hands. The background is a blurred natural landscape with trees and a bright sky, suggesting an outdoor setting like a hike or a walk in a park.

**Business update**  
**US**  
**Commercial**

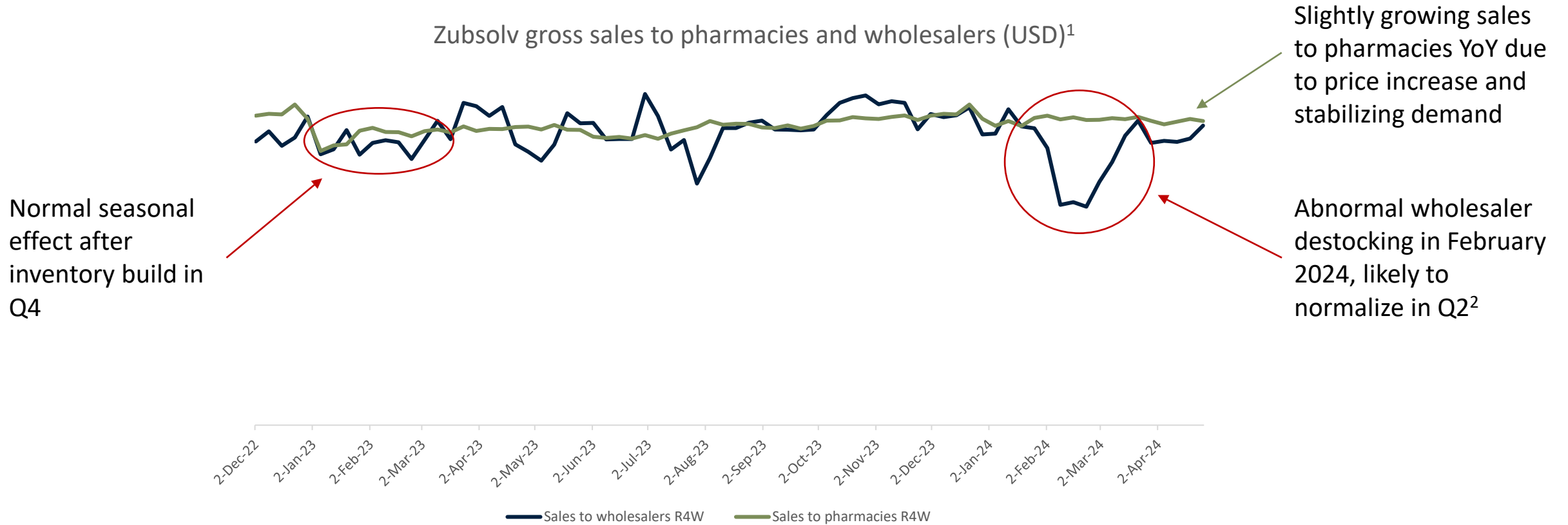
# Three major events with impact on Zubsolv<sup>®</sup> and market performance in Q1

- Abnormal decline in inventory from large wholesalers February-March, significantly impacting Zubsolv and other products in the category
- Significant and accelerating disenrollment in Medicaid starting Q3 2023 and accelerating in Q1 2024 impacting the overall market and Zubsolv
- Cyberattack<sup>1</sup> on United Health Group's subsidiary Change Health impacting the claims processes between payers, physicians, patients and pharmacies

<sup>1</sup> [www.wsj.com/articles/change-healthcare-hack-what-you-need-to-know-45efc28c](https://www.wsj.com/articles/change-healthcare-hack-what-you-need-to-know-45efc28c)

# Stable Zubsolv<sup>®</sup> sales to pharmacies, but significant drop in wholesaler inventory in February/March 2024

Zubsolv gross sales to pharmacies and wholesalers (USD)<sup>1</sup>



Normal seasonal effect after inventory build in Q4

Slightly growing sales to pharmacies YoY due to price increase and stabilizing demand

Abnormal wholesaler destocking in February 2024, likely to normalize in Q2<sup>2</sup>

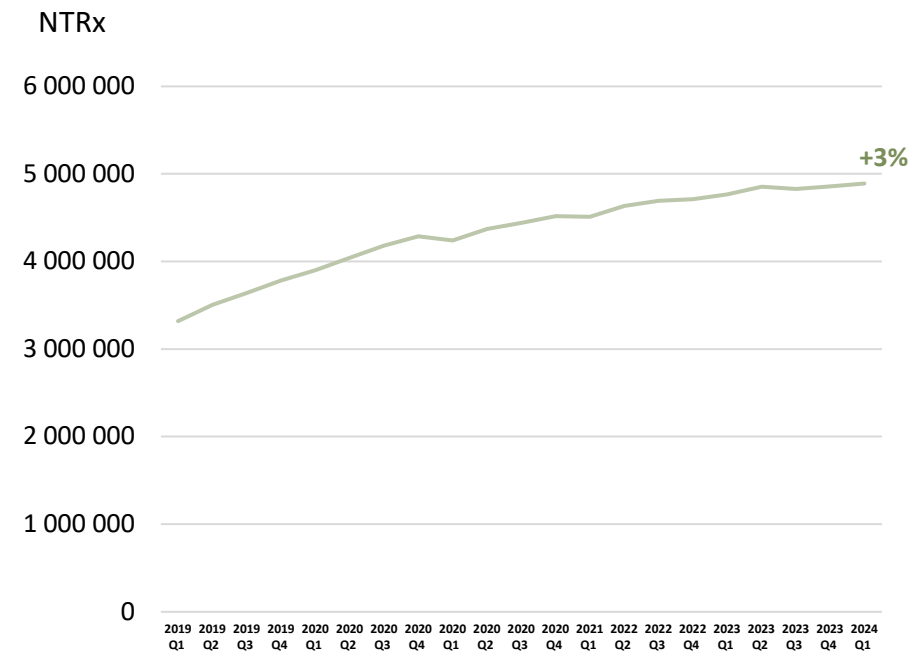
<sup>1</sup> Gross sales is before deduction of rebates to payers, wholesalers and accruals for returns

<sup>2</sup> Orexo has no influence on wholesaler inventory levels



# Zubsolv<sup>®</sup> gain share in a declining Medicaid segment

**3% total market growth Q1 24 vs Q1 23<sup>1</sup>**



**Low market growth** in prescriptions of 3% vs Q1 2023 and 1% vs Q4 2023

- **Significant decline in Medicaid** with minus 9% YoY following Medicaid disenrollment
- **Commercial growth** of 9% YoY
- Medicaid remain the largest market segment with 41% of patients followed by commercial with 32%

**Zubsolv declined slightly** with 4% versus Q1 2023 and 2% vs Q4

- Decline explained by United Health Group (UHG) and Humana and Medicaid market decline

**Zubsolv outperformed the Medicaid segment** both YoY +0% and QoQ -2%.

- Continued strong growth in new Medicaid contracts YoY, NY (+16%) and Kentucky (+10%) and Indiana (244%)

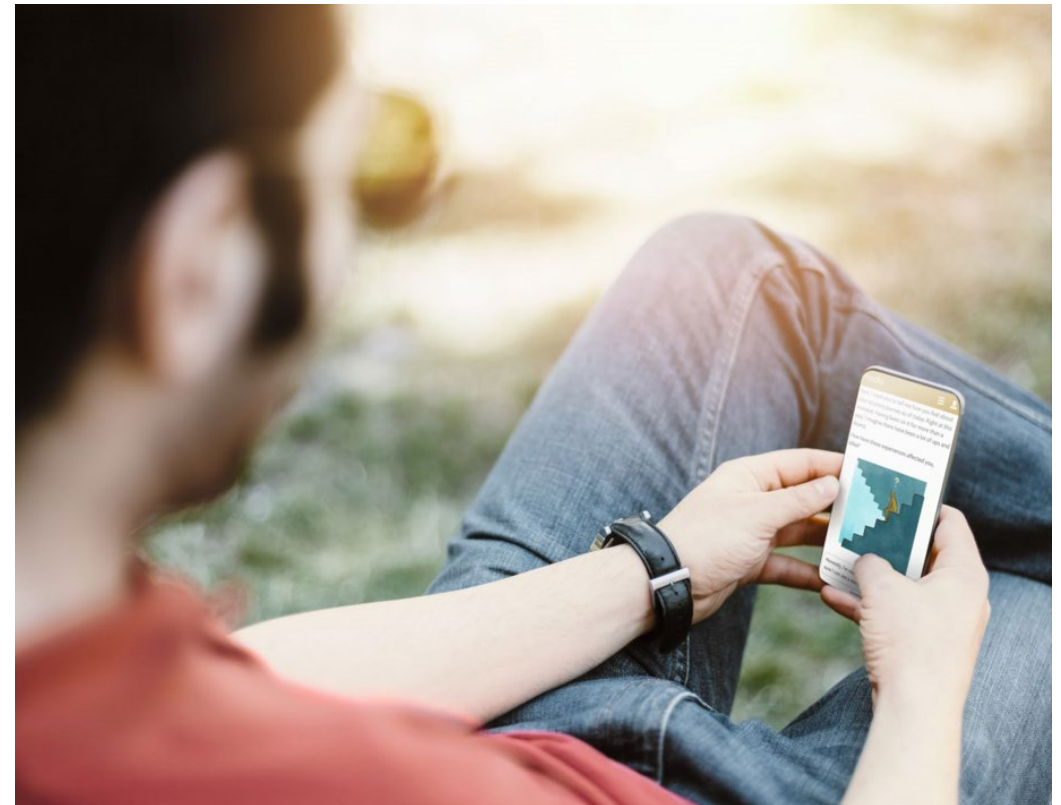
**Price increased 4%** from January 1<sup>st</sup>

- Small increase in overall rebates

<sup>1</sup>Based 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.

# Digital Mental Health Programs navigating a difficult market

- All leading competitors experience continued issues establishing scalable reimbursement and distribution solutions
- Center for Medicaid Services (CMS) with an ongoing initiative to establish a reimbursement and distribution model for digital health products in Medicaid and Medicare
- Orexo continue with a cost-conscious approach to commercialization
  - VA focus on pilot programs in selected states
  - Collaborations in several states with health care providers to access opioid abatement funds through grant applications





**Business update**  
**Products under development**

# R&D – New collaboration and OX124 FDA review progressing

## amorphOX® - a scalable drug delivery platform

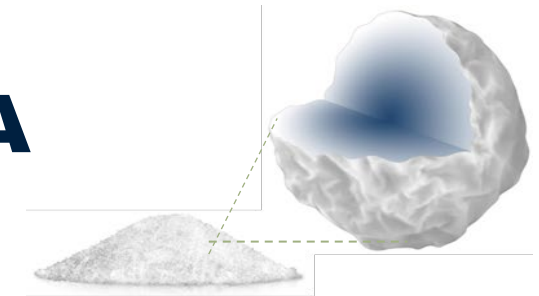
- Exploratory collaboration with Sobi advancing into next phase to further optimize the formulation, extend stability studies and review optimal route of administration
- New collaboration with a vaccine development company

## amorphOX® OX124 – high-dose rescue medication for opioid overdose

- Review ongoing with promising results from audit of supply chain
- FDA requires changes to be made on the device and instructions for use, which needs to be tested and documented and will cause a delay beyond the current PDUFA date
- Ambition remain to launch OX124 late 2024/early 2025

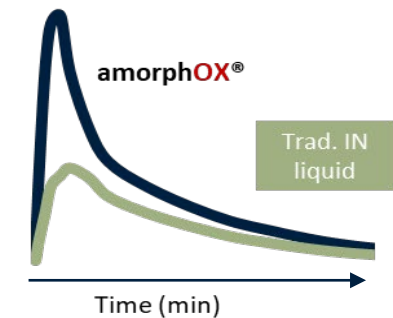
## amorphOX® OX640 – epinephrine rescue medication for allergic reactions

- Positive feedback from FDA briefing book outlining the clinical development program
- Orexo's OX640 clinical results were presented at the 2024 AAAAI Annual Meeting in Washington, DC and received positive feedback on the unique product properties
- Continued discussions with potential partners following feedback from FDA



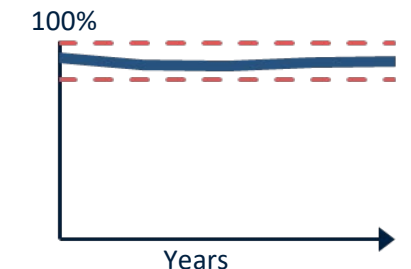
amorphOX® - an amorphous powder

Plasma concentration



Comparison to liquid nasal sprays

Amount of API



Excellent stability

# OX124 has unique properties and is progressing towards launch late 2024/early 2025

## INTRANASAL POWDER DELIVERY OF NALOXONE & NALMEFENE

**OX124**  
**amorphOX®**

High-dose rescue medication containing naloxone, designed to reverse the effect of the most powerful synthetic opioids, such as fentanyl

Filed with the FDA in Q3 2023



Small in size, easy to carry

Built-in desiccant to protect the powder from any moisture

The usage and application of a potentially life-saving dose of naloxone in case of an accidental opioid overdose event is simple, fast and most of all: high-dose

Product	Indication	Exploratory	Preclinical	Phase			Registration	Approved/Launched			Expected launch
				1	2	3		US	EU	RoW	
OX124	Naloxone	[Progress bar showing completion of Phase 1, 2, and 3]									2024 / 2025
OX125	Nalmefene	[Progress bar showing completion of Phase 1]									

*OX125 (incl. nalmefene) is similar to OX124 – to be used in acute situations where the treatment effect needs to be long-lasting while also being powerful and fast-acting. Nalmefene has a half-life of 8-11 hours in the body versus 1-2 hours for naloxone*

## OX124 DIFFERENTIATION & COMPETITIVE ADVANTAGES



Differentiation formulations of OX124 have shown **more rapid absorption and substantially higher plasma concentrations of naloxone compared to the current market leader** – critical in avoiding brain damages and saving lives as well as preventing re-intoxification during the revival process



In addition, OX124 has unique properties compared with existing products i.e., **being a powder-based product** while other products are liquid-based



The amorphOX powder-based technology provides for **longer shelf-life and makes it less vulnerable to temperature changes**



**Easy to carry** as OX124 comes in a unique device that is less bulky



OX124 has **patents protecting the product until 2039**

*If approved, OX124 will be the only product on the market that does not freeze at temperatures below zero degrees*

<sup>1</sup> Estimated market size based on historical data and company financial reports <sup>2,3</sup> Center of Disease Control and Prevention

# OX124, enters a dynamic and growing market requiring new competences and experiences

## YOY GROWTH OF THE NALOXONE SPRAY MARKET (RETAIL AND INSTITUTIONAL SALES)

The majority of sales in the naloxone spray market are covered by:



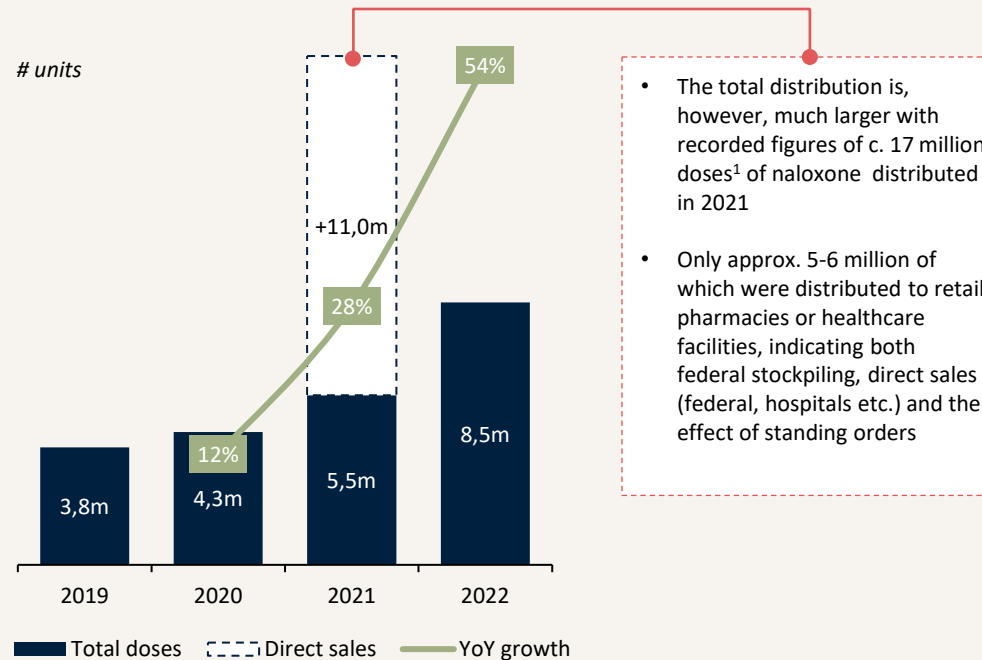
### Institutional sales

*i.e., hospitals, medical colleges, corporate organisations, centralised institutions like group practices, integrated delivery networks*



### Market retail

*i.e., pharmacy sales*



## NALOXONE OTC SWITCH: MARKET DEVELOPMENT PREDICTIONS



**Access to life-saving naloxone is expected to increase:** Easier way of buying naloxone for families, bystanders, employers, state institutions



**Out-of-pocket costs increase if OTC naloxone is no longer reimbursed:** decreased spending power in vulnerable population (Albeit Narcan at \$50/box)



**Reduced stigma and fear of judgement by doctors and pharmacists as identified barriers today:** more patients might be willing to purchase naloxone. However, expensive product is likely to go behind the counter still



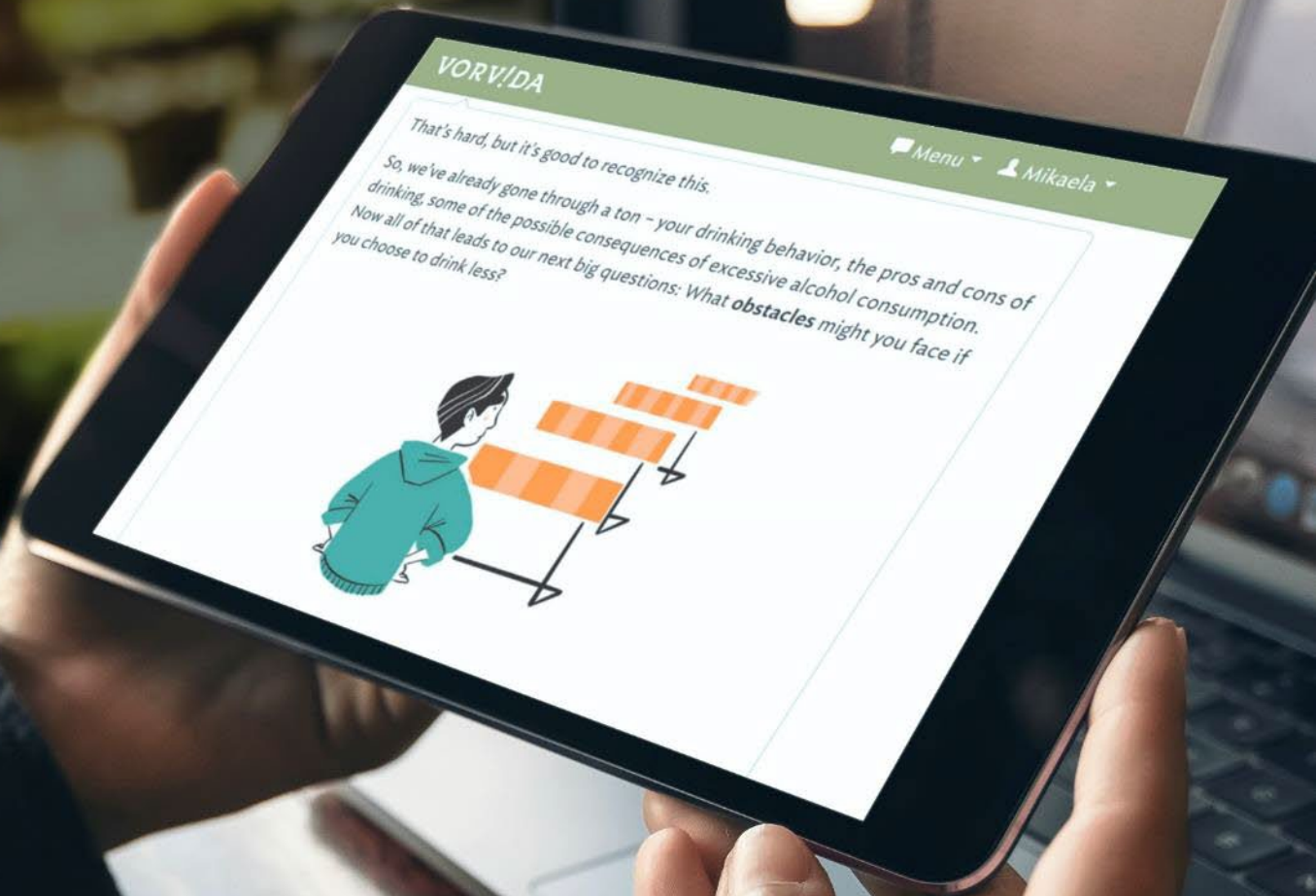
**Co-dependent relationship of Naloxone prescriptions and opioid strength:** Higher doses of opioids require higher doses of naloxone – potentially increased usage of high-dose naloxone products



**Division of the market:** Market division into RX (prescription drugs) and OTC, with different sales channel and pricing characteristics

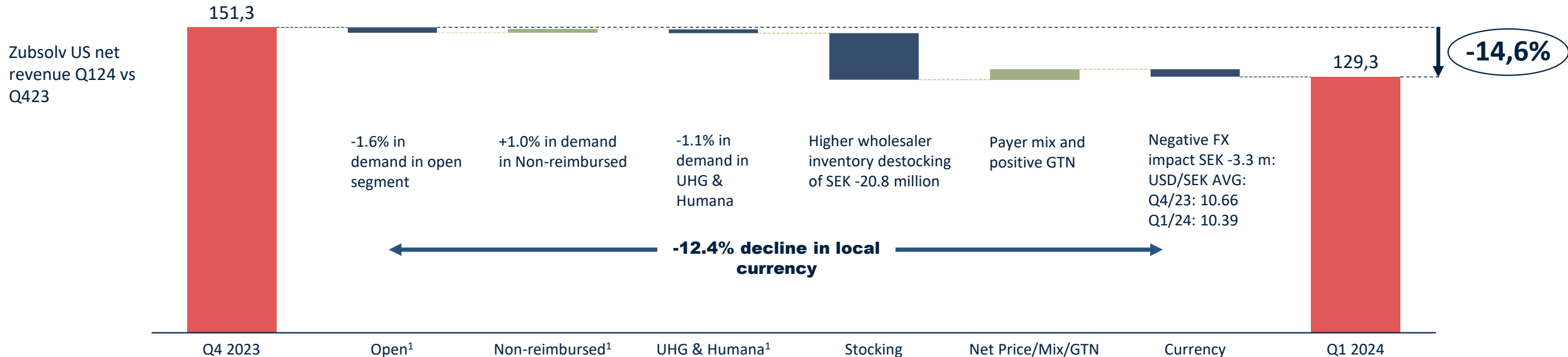
To understand market dynamics, new commercial lead for OX124 hired starting May 1

# Financial & legal



# Zubsolv<sup>®</sup> net revenue significantly impacted by inventory destocking

Net revenue per segment SEK m	Q1 2024	Q1 2023	Jan - Dec 2023	Comments Q1
Zubsolv US	129.3	140.3	577.7	✓ Zubsolv Net revenue declined YoY with 8,0 % primarily due to higher wholesaler destocking, slightly lower demand and weaker USD vs SEK US impact of SEK -0.8 m
Digital Mental Health Programs (DMHP) product Sales	0.0	0.0	0.0	
<b>US Commercial – Total</b>	<b>129.3</b>	<b>140.3</b>	<b>577.7</b>	
Abstral <sup>®</sup> royalties	7.1	6.2	31.9	✓ Partly offset by favorable payer mix
Edluar <sup>®</sup> royalties	2.7	1.3	10.8	✓ Due to previous inventory build up at Orexo’s partner Accord and some timing impact of deliveries to respective European markets – Zubsolv ex US showed no net revenue from supply of tablets to Accord this quarter
Zubsolv – ex US	0.2	10.9	18.4	
<b>HQ &amp; Pipeline – Total</b>	<b>10.0</b>	<b>18.5</b>	<b>61.1</b>	
<b>TOTAL</b>	<b>139.3</b>	<b>158.8</b>	<b>638.8</b>	



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



# Strong recovery (+57 m) in EBITDA driven by efficiency improvements and cost control

Income statement SEK m	Q1 2024	Q1 2023	Jan - Dec 2023	Comments Q1
Net revenues	139.0	158.8	638.8	<p><b>OPEX</b> significantly lower mainly due to</p> <ul style="list-style-type: none"> <li>• Lower expenses for IP litigation</li> <li>• Lower expenses in US Commercial organization</li> <li>• Finalized MODIA® study in Q3 2023 and lower costs for OX124</li> </ul> <p><b>US Commercial EBITDA contribution</b> of SEK 42.6 m (48.5)</p> <ul style="list-style-type: none"> <li>• EBITDA Margin for the quarter 33% (35%)</li> </ul> <p><b>EBITDA</b> of SEK 15.9 m (-41.1)</p> <ul style="list-style-type: none"> <li>• Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 23.5 m ( 20.9) for Q1</li> </ul> <p><b>Net financial items</b> of SEK -5.0 m (-9.1)</p> <ul style="list-style-type: none"> <li>• Higher positive unrealized exchange rate impact of SEK +2.1 m (-1.5) derived from the parent company's foreign currency bank accounts mainly in USD and lower costs of SEK -7.7 m (-8.5) for the corporate bond loan</li> <li>• Partly offset by lower interest income of SEK 0.9 m (1.4) from bank accounts due to no short-term investments</li> </ul>
Cost of goods sold (COGS)	-13.3	-28.7	-88.9	
<b>Gross Profit</b>	<b>126.0</b>	<b>130.1</b>	<b>550.0</b>	
<b>Operating Costs</b>	<b>-130.7</b>	<b>-189.4</b>	<b>-659.5</b>	
<b>EBIT</b>	<b>-4.7</b>	<b>-59.3</b>	<b>-109.5</b>	
Net financial items	-5.0	-9.1	-30.8	
<b>EBT</b>	<b>-9.8</b>	<b>-68.5</b>	<b>-140.3</b>	
Tax	0.9	4.6	12.0	
<b>Net profit/loss</b>	<b>-8.9</b>	<b>-63.9</b>	<b>-128.3</b>	
<b>EBITDA</b>	<b>15.9</b>	<b>-41.1</b>	<b>-32.5</b>	

## Cash position

Cash Flow SEK m	Q1 2024	Q1 2023	Jan - Dec 2023	Comments Q1
<b>Cash flow from operating activities before changes in working capital</b>	<b>4.3</b>	<b>-48.2</b>	<b>-41.2</b>	<ul style="list-style-type: none"> <li>✓ <b>Liquid funds (SEK 198 m) increased with SEK 27 m from Q4 2023 (SEK 171 m)</b> <ul style="list-style-type: none"> <li>✓ Orexo issued senior secured callable floating rate social bonds of SEK 500 m and recognized the first part of the transaction of in Q1</li> <li>✓ SEK -18.9 m negative contribution from operating activities primarily impacted by negative changes in working capital mainly due to prepayment of own purchase of the new bond loan of SEK -25 m</li> <li>✓ Investment activities had a negative impact of SEK -1.2 m on cash flow primarily from investments in equipment for the development organisation</li> <li>✓ Financing activities had a positive impact of SEK +43.3 m mainly due to booking of sale of the old Orexo owned bonds of SEK +48.8 m</li> </ul> </li> </ul>
Changes in working capital	-23.3	-13.4	-53.8	
<b>Cash flow from operating activities</b>	<b>-18.9</b>	<b>-61.6</b>	<b>-95.0</b>	
Investment activities	-1.2	83.1	200.8	
Financing activities	43.3	-7.8	-70.1	
<b>Cash flow (excl. exchange rate differences)</b>	<b>23.2</b>	<b>13.8</b>	<b>35.7</b>	
Exchange-rate differences in cash and cash equivalents	3.8	-3.6	3.1	
Add back short-term investments	0.0	136.5	0.0	
Cash and cash equivalents at the beginning of the period	171.0	132.2	132.2	
<b>Liquid funds</b>	<b>198.0</b>	<b>278.9</b>	<b>171.0</b>	
Net cash position including short-term investments	-299.8	-210.2	-277.4	

# 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

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.

# Q1 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 <sup>®</sup> drug delivery technology	Improving access to treatment
<i>Key milestones and focus areas going forward</i>		
<ul style="list-style-type: none"> <li>Stabilise Zubsolv<sup>®</sup> revenues and focus commercial investments in areas with growth opportunities</li> <li>Approval of OX124 by the FDA</li> <li>Hire experienced OX124 team</li> <li>Launch of OX124 in the US leveraging existing resources and focused investments into new areas</li> </ul>	<ul style="list-style-type: none"> <li>Expand reimbursement of Zubsolv in the public segment and maintain access in the commercial segment</li> <li>Secure reimbursement for OX124 at launch</li> <li>Establish collaborations with healthcare providers under MatCore</li> <li>Establish patient support programs for all Orexo's products</li> <li>Establish legislation and policies enabling access to all types of treatment of OUD and mental health</li> </ul>	<ul style="list-style-type: none"> <li>Partnering with other pharmaceutical companies to co-develop new products based on AmorphOX<sup>®</sup></li> <li>Out-license products based on the AmorphOX technology such as OX640</li> <li>Develop new products for Orexo to commercialise primarily within OUD and mental health.</li> </ul>



Responsible business	Access to healthcare	Environment & climate change	Sustainable employees
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*We empower people with  
innovative treatment solutions*

# Thanks

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