

Positive EBITDA in H2 setting the target for FY 2024

February 8th 2024

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



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Future value drivers



Nikolaj Sørensen,
President and CEO



Fredrik Järsten
EVP and Chief Financial Officer



Key achievements

Strong recovery in financial results and FDA initiated review of OX124

- ✓ Positive EBITDA in Q4 (SEK 12 m) and H2 (SEK 3 m) despite headwind from USD depreciation in Q4
- ✓ Zubsolv growth in USD and SEK with more than 6% YoY and 8% from Q3
- ✓ Continued cost reduction with 23% from Q4 2022
- ✓ US Commercial EBIT (Digital Mental Health Programs, former DTx, integrated into US Pharma) improved 65% from Q4 last year
- ✓ Vorvida and Modia added to VA Federal Supply Schedule and will be reimbursed from Jan 1, 2024
- ✓ Zubsolv will be reimbursed in New Hampshire from Jan 1, 2024
- ✓ FDA review of OX124 initiated with ongoing audits of our external contract manufacturers during Q1.

Net revenues

166 SEK M

Group EBITDA

12 SEK M

Cash and invested funds

171 SEK M

2023 the start of a financial turn around towards profitability

- ✓ Net revenues grew 2.3% due to favourable exchange rates and stabilization of Zubsolv revenues
- ✓ Gross margin improved from 83.6% to 86.1%
- ✓ OPEX reduced with 6.5% (SEK 46 m) following integration of Digital Mental Health Programs into US Pharma and less non-repetitive expenses H2
- ✓ Group EBITDA improved SEK 82.7 m (SEK -32.5 m)
 - EBITDA profitable in last three quarters Q2-Q4 when excluding FDA submission fee in Q3
- ✓ Expect full year positive EBITDA 2024

ABGSC and Carnegie appointed financial advisors to evaluate refinancing of the bond during 2024

Net revenues

639

SEK M

OPEX reduction

46

SEK M

EBITDA improvement

83

SEK M

Financial outlook 2023 - all metrics met with strong ending of Q4

Metric	Outlook 2023	Outcome	
Key market development	The buprenorphine/naloxone market will grow 4-7 percent. Due to the slowdown in the growth rate in Q3, the uncertainty in the full-year guidance has increased.	Market growth 2023: +4%	✓
Lead product net sales	Group revenues will increase, with Zubsolv US revenues being in line with 2022	Group revenues SEK 639 m (624) Zubsolv US SEK 578 m (571)	✓
Group OPEX	Reduced OPEX in H2 compared to H1, which amounted to SEK 343 million including depreciation of SEK 37 million	H2: SEK 316 m (-8%)	✓
Group EBITDA	EBITDA in balance in H2	EBITDA H2: SEK 3 m (11 at constant USD/SEK)	✓

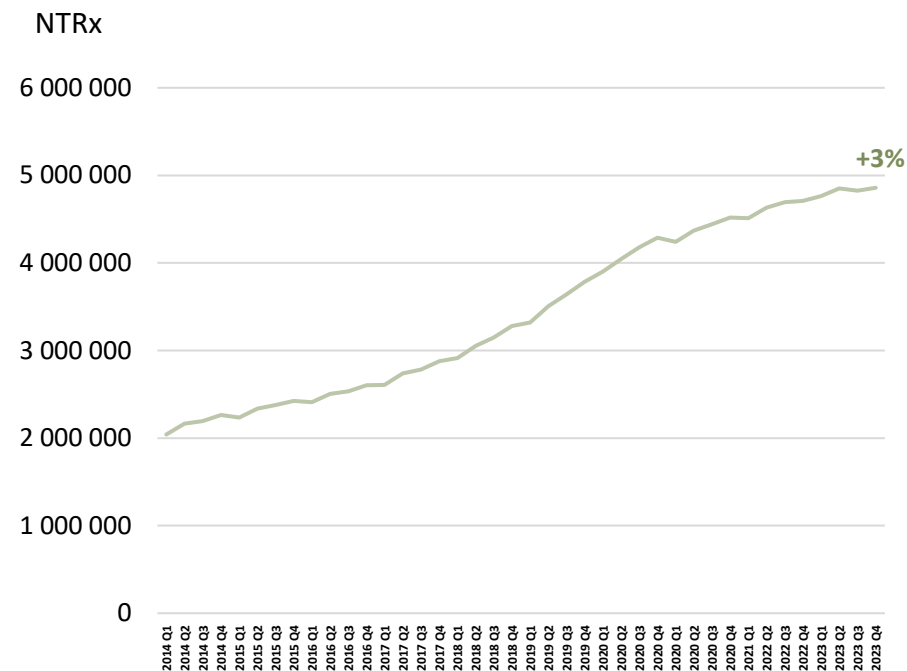
A middle-aged man with short, graying hair is smiling broadly, looking slightly to his right. He is wearing a dark blue quilted vest over a blue and white plaid shirt. He has a dark backpack on his shoulders and is adjusting a strap with both hands. The background is a soft-focus outdoor scene with green foliage and a warm, golden light, suggesting a sunset or sunrise.

Business update
Commercial
products

Market and Zubsolv recovered from negative Q3 development

- ✓ Market growth in prescriptions of 3% vs Q4 2022 and 1% vs Q3 2023
 - Medicaid continue to decline while Commercial and Medicare grow
- ✓ Zubsolv was stable compared to Q3 and declined 4% versus Q4 2024
 - Decline due to United Health Group (UHG) and Humana
 - Growth in Medicaid and Commercial (excl UHG and Humana)
- ✓ Zubsolv outperformed the Medicaid segment both YoY +4% and QoQ +1%. E.g.
 - Continued strong growth in new Medicaid contracts YoY, NY (+33%) and Kentucky (+19%) and Indiana (196%)
- ✓ Maintained market access in commercial segment in 2024 (98%) and public segment 50%
 - New Hampshire Medicaid adding Zubsolv from Jan 1, compensating from decline in overall Medicaid share of public segment
- ✓ Price increased 4% from January 1st
 - Slight increase in overall rebates

3% total market growth Q4 23 vs Q4 22¹



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.

The start of 2024 in line with the ending of 2023, and no dramatic changes are expected

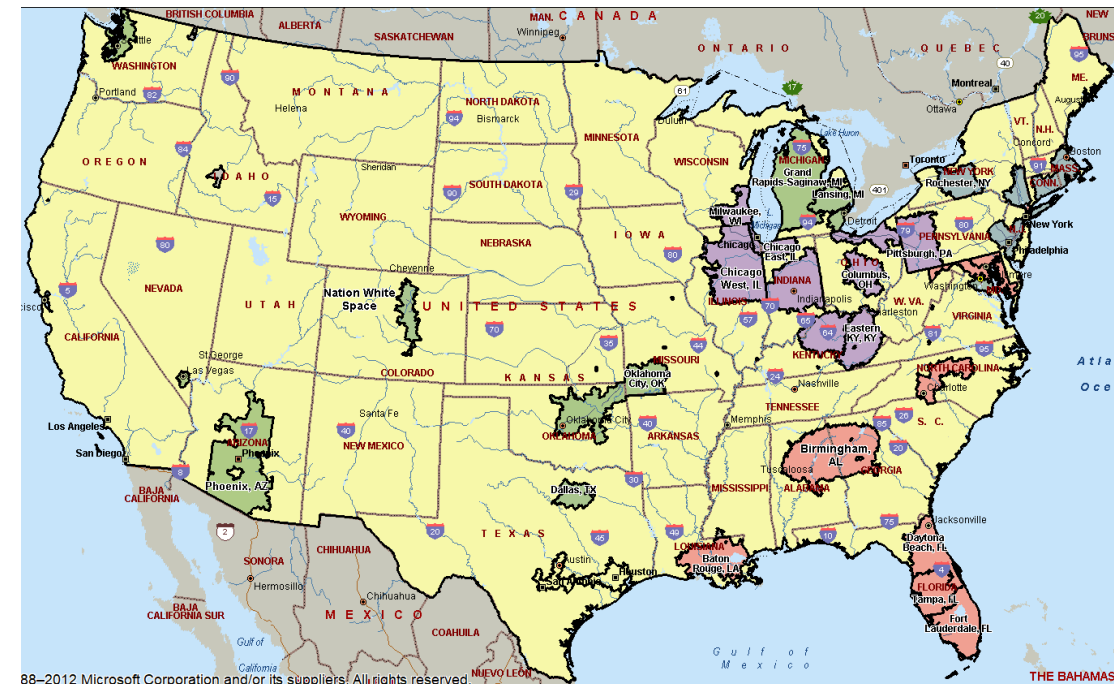
- First few weeks of 2024 with a market growth of 3% YoY and Zubsolv keeping pace with the market
- 2024 is an election year and currently focus is at other issues than the OUD epidemic reducing probability of material political initiatives to improve access to treatment
- Significant reduction in hurdles for physicians to prescribe Zubsolv and similar products from start of 2023
 - However, 76% of prescriptions are made by 12.5% of active physicians¹ and no increase in high prescribers post Covid-19
- Significant inflow of new funds to finance treatment initiatives from USD 54 billion abatement funds, but the processes to allocate the funds are slow and bureaucratic
 - First allocations appears to be smaller local initiatives
- Market is impacted by injectable depot formulations (Sublocade[®] and Brixadi[®] introduction), but volume share of depot formulations is limited with about ~4.5% market share today of volume
 - Large share of volume in institutional settings such as correction facilities
 - Significant increase in cost to treatment may change dynamics if payer reacts
- Increase in fentanyl utilization makes treatment more difficult, but physicians are learning and refining their treatment approach e.g. different titration of medication

¹ Measured as one prescription within last 12 months

Orexo continuously work to optimize the sales force and commercial efforts

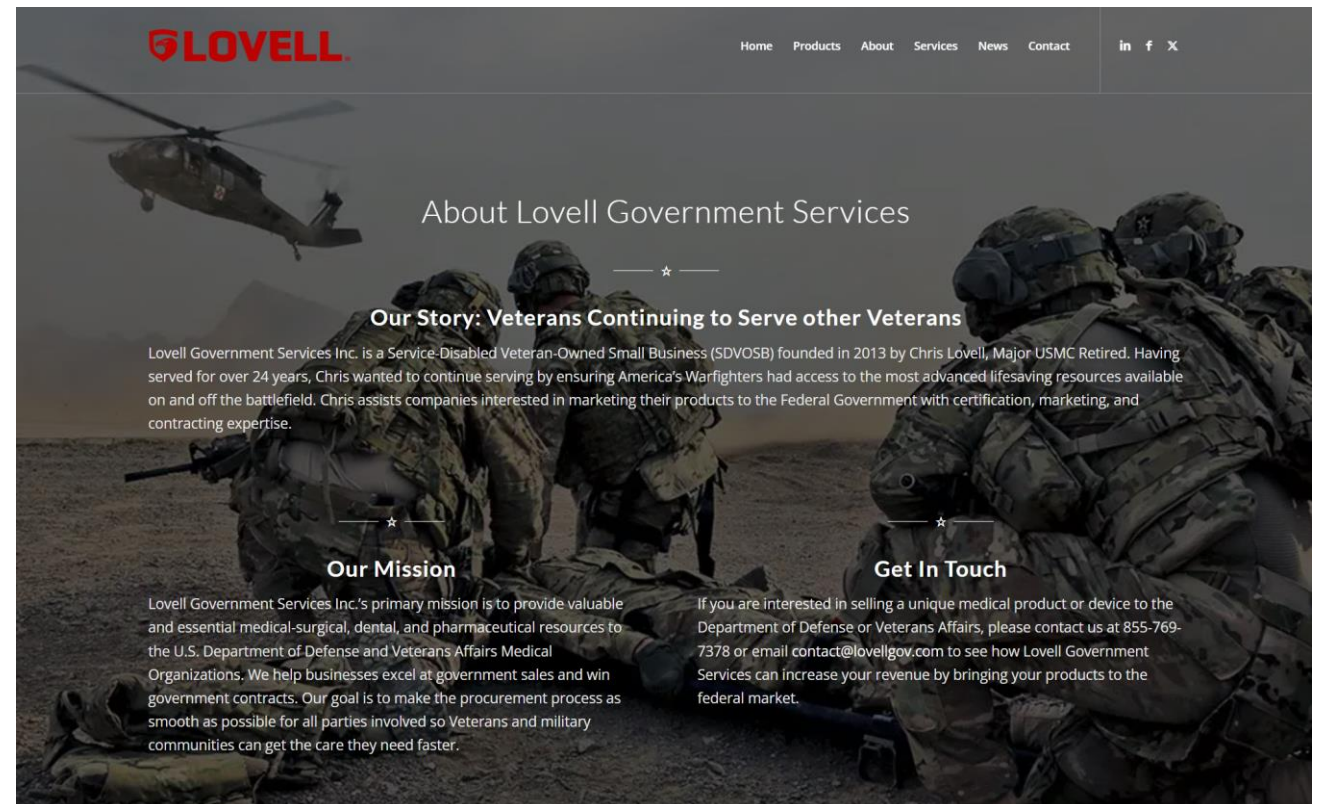
- Orexo field force size maintained into 2024, but improved reimbursement in New Hampshire will increase focus on North East
- Orexo field force coverage highly dependent on regional market access, market growth and potential ROI for each sales representative
- Orexo field force cover ~50% of the market and ~70% of the Zubsolv volume
 - Average market share of ~3.5% in sales territories with active promotion
- Integration of Digital Therapeutics (now Digital Mental Health Programs) into US Pharma has been managed by re-organizing responsibilities for tenured US Pharma colleagues

Orexo sales force coverage in 2023



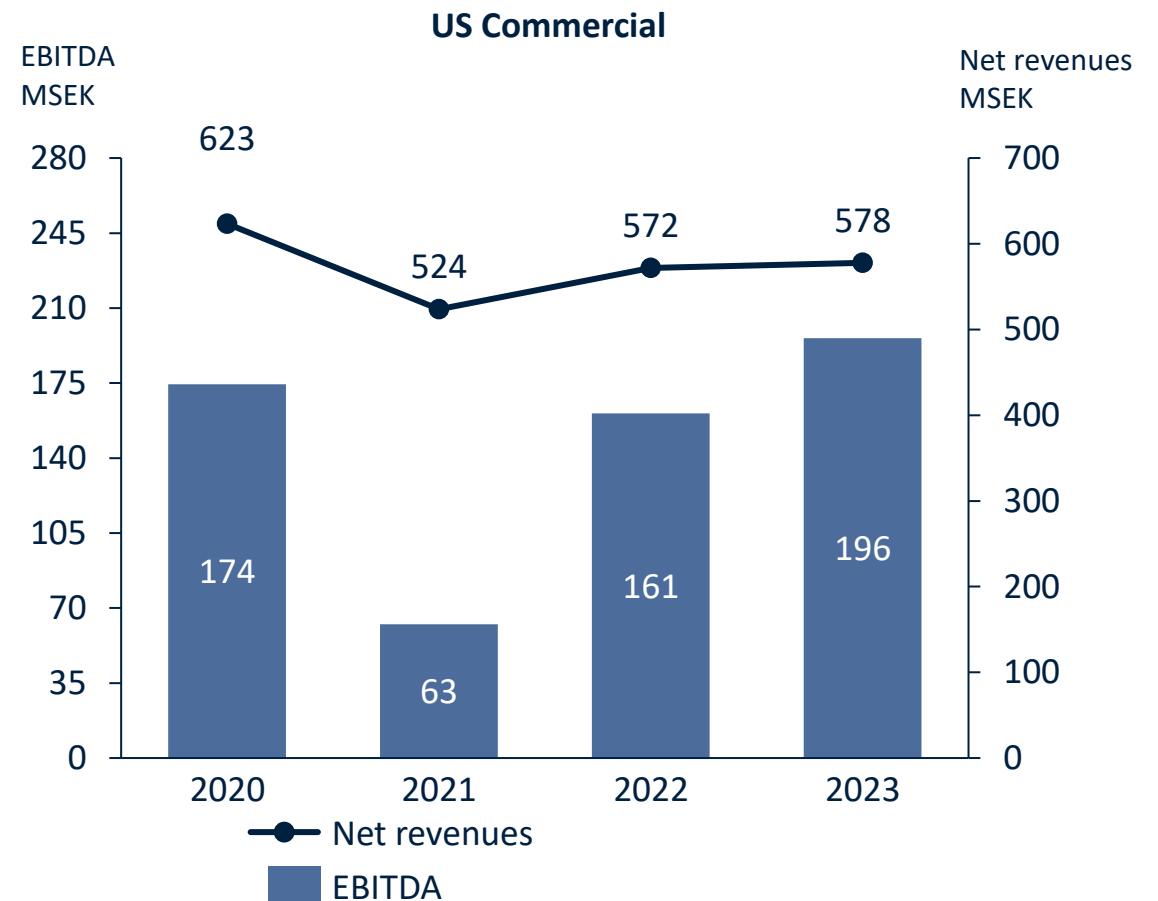
All Digital Mental Health Programs now listed on the VA Federal Supply Schedule

- Signed distribution contract with Lovell Government Services who will manage distribution and reimbursement of Orexo's digital mental health programs within Veterans Affairs (VA)
- Vorvida® and MODIA® both added to the VA list from January as a result of the collaboration with Lovell
- Initial focus on on selected VA healthcare providers in the North East before expanding geographic reach and commercial resources
- MODIA upgrade will be completed in Q1 with additional functionality for the healthcare provider to monitor progress and to align with new regulatory status



US Pharma and DTx organizations merged in H1 2023 and from Q1 2024 to be reported as one business unit

- Starting Q1 2024, all US commercial operations will be reported as one business unit
- Digital Mental Health Programs (former DTx) increasingly reliant on shared resources with US Pharma, with more than 75% of OPEX (excl depreciations) allocated from US Pharma in Q4
- Leadership for Digital Mental Health Programs under Bob DeLuca, President Orexo US Inc. and US Pharma





Business update
**Products under
development**

R&D – OX124 review initiated and PDUFA date in July 2024

amorphOX® - a scalable drug delivery platform

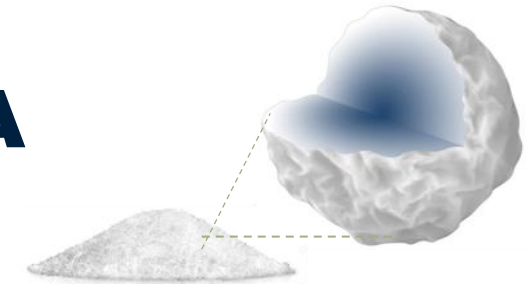
- Orexo has tested enzymes, peptides and proteins in AmorphOX and seen retained activity and significant improvement in stability compared to other formulations in a wide range of storage temperatures
- Ongoing discussions to advance initial partnered feasibility studies to next development phase

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

- PDUFA date in July 2024 and expected approval during Q3
- FDA review ongoing with audits scheduled with contract manufacturers during Q1

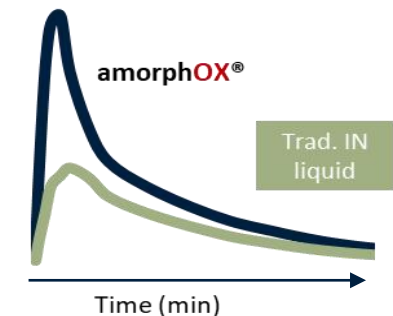
amorphOX® OX640 – epinephrine rescue medication for allergic reactions

- FDA briefing book submitted and Orexo expects FDA feedback late Q1/early Q2 on proposed development program
- Orexo's OX640 development results to be presented at the 2024 AAAAI Annual Meeting in Washington, DC, on February 23-26



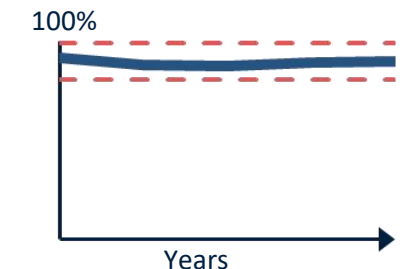
amorphOX® - an amorphous powder

Plasma concentration



Comparison to liquid nasal sprays

Amount of API



Orexo's next product, OX124, enters a dynamic and growing market

Current Naloxone Market:

~\$500 m market¹

Narcan switched to OTC in Q3 2023

New Nalmefene Market:

OPVEE® as the 1st nasal nalmefene product for regular people / non-medical personnel

Increase of Fentanyl/Synthetic Opioids:

Fentanyl has Propelled the Acceleration of the opioid epidemic in the US

OTC Switch

- First naloxone Rx-to-OTC switch approved March 2023 (Narcan)
- Low dose (OTC) vs high dose (Rx)
- Specific shift dynamics unknown
- Downward pricing pressure
 - Narcan price reduction: USD 120/2 pack (Rx) → USD 50/2 pack (OTC)

Nasal Nalmefene Market

- First nasal nalmefene rescue medication
- Launched in Q4 2023
- Price: WAC of USD 98/2 pack (Rx)
- The company expects peak annual net revenue of USD 150-250 m

Synthetic Surge Impact

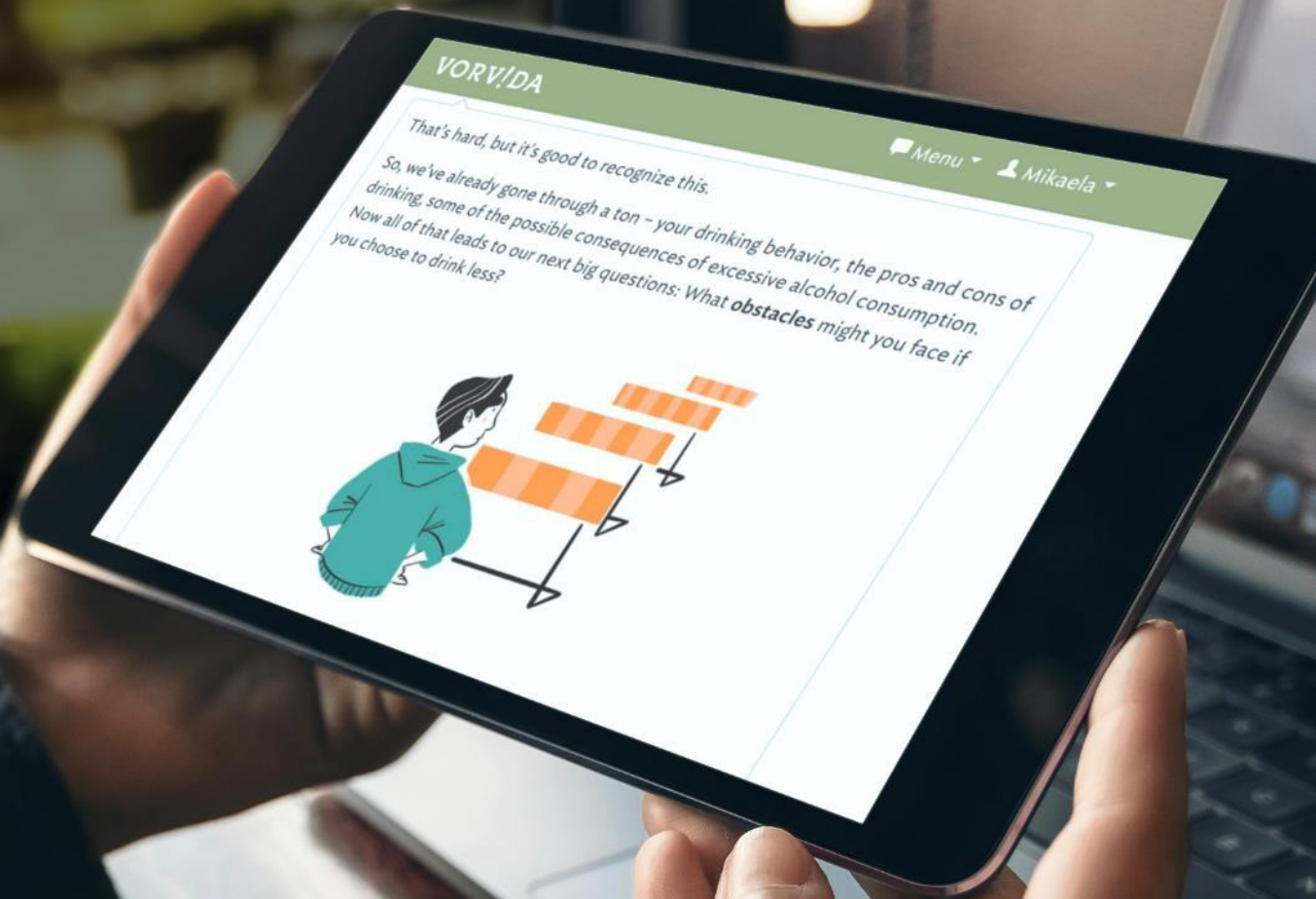
- Despite increase access to overdose rescue medications, reported fatal overdoses still on a high level²
- 76% of fatal overdoses caused by synthetic opioids³
- Growing need for effective agents and stronger doses

Orexo's long presence in the OUD market and OX124 differentiation are key success factors

- **Significant market need** for more effective treatments of overdose
 - Low-dose OTC alternatives **not strong enough to sustain reversal** in many overdoses with fentanyl (**deaths are driven by synthetic opioids**)
 - 85% of all lethal overdoses are fentanyl related (synthetic opioids)
- **Commercial synergies** with existing organization and capabilities
 - **Orexo field force** in 12 out of 17 states with mandatory co-prescription of naloxone with an opioid (including ZUBSOLV)
 - **Long history with largest payers** in the OUD disease space
 - **Extensive knowledge of OUD** in all parts of the organization
 - Some new capabilities needed in marketing and institutional sales in 2024
- **A dynamic market** with several interesting market drivers to monitor
 - **Pricing dynamic** after launch of OTC products and lowering price to 50 USD/2 pack
 - **Traction for high-dose Kloxxado**
 - **Potential switch to Nalmefene** for high risk patients (fentanyls/synthetics)

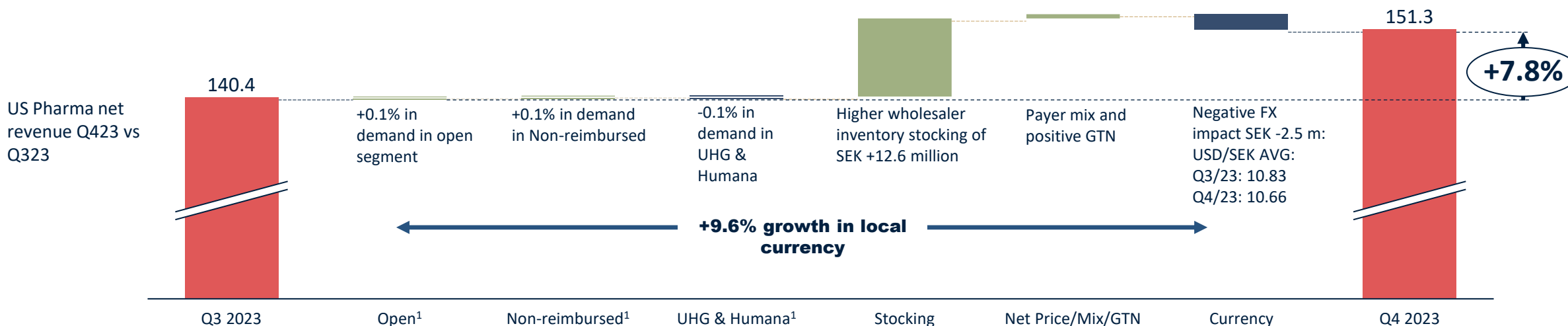
	OX124 (High-dose naloxone)
Naloxone “Gold Standard”	✓
High-Dose Naloxone	✓
Powder	✓
Unique Device	✓
Does not freeze	✓
Long Shelf-Life	✓

Financial & legal



Zubsolv® net revenue grew 6.1% in Q4

Net revenues per segment SEK m	Q4 2023	Q4 2022	Jan - Dec 2023	Jan - Dec 2022	Comments Q4
Zubsolv US	151.3	142.6	577.7	571.4	✓ Zubsolv Net revenues grew YoY with 6.1 % in SEK and 6.7% in USD primarily due to higher wholesaler stocking and favorable payer mix ✓ Partly offset by lower demand YoY and weaker USD vs SEK US impact of SEK -1.1 m. ✓ Zubsolv – ex US, royalties increase in Q4 2023, revenues include supply of finished products and vary by quarter
US Pharma – Total	151.3	142.6	577.7	571.4	
Digital Mental Health Programs (DMHP) product Sales	0.0	0.0	0.0	0.4	
DMHP – Total	0.0	0.0	0.0	0.4	
Abstral® royalties	10.0	5.5	31.9	30.4	
Edluar® royalties	1.9	2.7	10.8	10.4	
Zubsolv – ex US	2.8	5.2	18.4	11.8	
HQ & Pipeline – Total	14.7	13.4	61.1	52.6	
TOTAL	166.0	156.1	638.8	624.3	



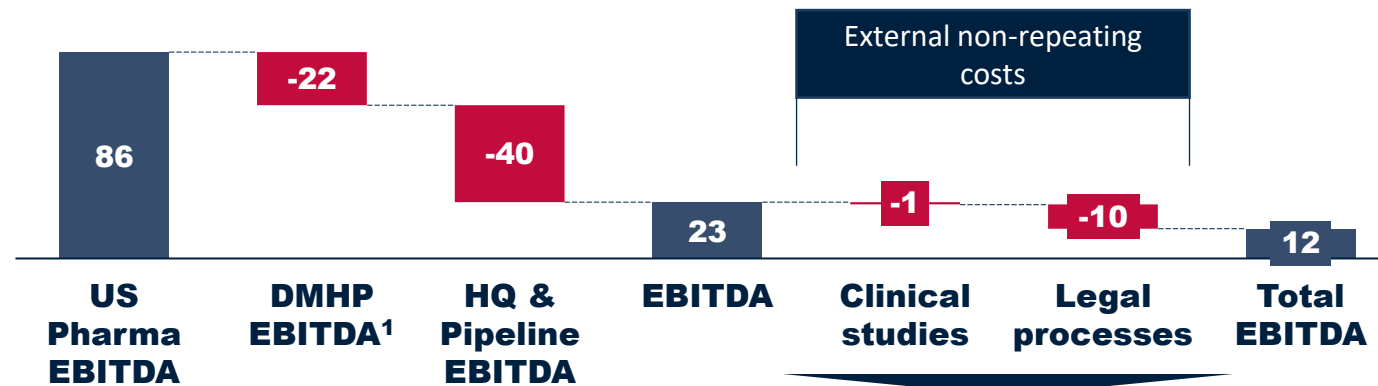
¹Estimated change in demand by segment, based on Net Sales development during the quarter, IQVIA demand data, institutional sales and claims data from insurance companies

Significantly lower OPEX

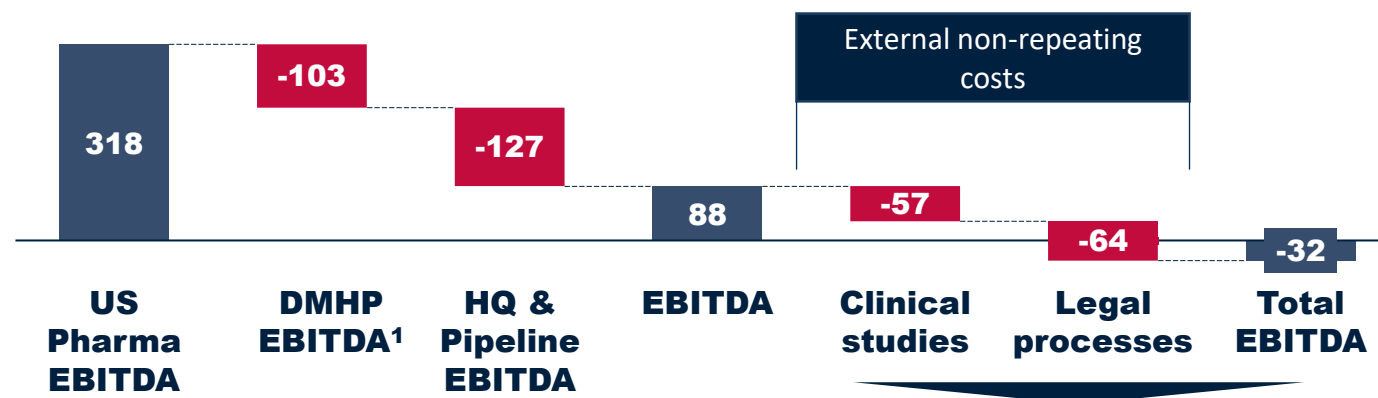
Income statement SEK m	Q4 2023	Q4 2022	Jan - Dec 2023	Jan - Dec 2022	Comments Q4
Net revenues	166.0	156.1	638.8	624.3	<p>OPEX decline 23% from Q4 2022 mainly due to</p> <ul style="list-style-type: none"> • Lower expenses for IP litigation • Lower expenses in DMHP organization • Finalized MODIA® study in Q3 2023 and lower costs for OX124 <p>Zubsolv® US EBIT contribution of SEK 75.4 m (77.0)</p> <ul style="list-style-type: none"> • EBIT margin 49.8% (54.0%) <p>EBITDA of SEK 12.4 m (-53.1)</p> <ul style="list-style-type: none"> • Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 23.4 m (-0.1) for Q4. <p>NET FINANCIAL ITEMS of SEK -10.9 m (-24.4)</p> <ul style="list-style-type: none"> • Lower negative unrealized exchange rate impact of SEK -2.0 m (-18.2) derived from the parent company's foreign currency bank accounts mainly in USD • Partly offset by lower interest income of SEK 1.1 m (2.2) from bank accounts due to no short-term investments and higher costs for corporate bonds of SEK -9.6 m (-7.8).
Cost of goods sold (COGS)	-20.1	-25.9	-88.9	-102.6	
Gross Profit	145.9	130.2	550.0	521.7	
Operating Costs	-154.5	-201.3	-659.5	-705.6	
EBIT	-8.6	-71.1	-109.5	-183.9	
Net financial items	-10.9	-24.4	-30.8	13.5	
EBT	-19.5	-95.5	-140.3	-170.4	
Tax	0.9	3.7	12.0	-7.2	
Net profit/loss	-18.6	-91.8	-128.3	-177.6	
EBITDA	12.4	-53.1	-32.5	-115.2	

EBITDA positive SEK 23 m in Q4 and SEK 88 m for the full year, excluding non-repeating expenses

MSEK



- OX124 project
- Sun Litigation
- Subpoena



- OX124 project
- MODIA study
- OX640
- Sun Litigation
- Subpoena

¹ DMHP EBITDA including internal allocations from US Pharma

Cash position

Cash Flow SEK m	Q4 2023	Q4 2022	Jan - Dec 2023	Jan - Dec 2022
Cash flow from operating activities	-2.6	-48.9	-95.0	-156.6
Investment activities	-0.9	66.2	200.8	-234.7
Financing activities	-5.6	-5.8	-70.1	-21.4
Cash flow (excl. exchange rate differences)	-9.1	11.5	35.7	-412.8
Exchange-rate differences in cash and cash equivalents	-4.1	-1.6	3.1	40.9
Add back short-term investments	0.0	219.6	0.0	219.6
Cash and cash equivalents at the beginning of the period	184.2	122.4	132.2	504.1
Liquid funds	171.0	351.9	171.0	351.9
Net cash position including short-term investments	-277.4	-142.9	-277.4	-142.9

- ✓ Liquid funds (SEK 171 m) decreased with SEK 13 m from Q3 2023 (SEK 184 m)
 - ✓ SEK -2.6 m negative contribution from operating activities primarily impacted by negative operating earnings and changes in working capital
 - ✓ Investment activities had a negative impact of SEK -0.9 m on cash flow primarily from investments in equipment for the development organisation
 - ✓ Financing activities had a negative impact of SEK -5.6 m on cash flow from amortization of lease liability (IFRS 16)

Financial outlook

Metric	Outlook 2024	Reaffirmed/revised
Key market development	The buprenorphine/naloxone market will grow 2-5 percent, based on current growth trajectory	N.A
Lead product net sales	Zubsolv® net sales in USD will be in line with 2023	N.A
Group OPEX	Cost control is a priority and OPEX excluding depreciation and amortization will decline from SEK 582 m in 2023 to below SEK 530 m in 2024	N.A
Group EBITDA	Positive EBITDA for the FY 2024	N.A

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.

Q4 legal update

Zubsolv® patent litigation 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

- ✓ All information requested by the authorities have been delivered. Orexo will continue to cooperate with the US authorities to ensure they receive the necessary information and to understand the scope of the investigations.



Future value drivers

Creating a solid ground for 2024 and beyond

- Strong focus on cost control and EBITDA balance
- Approval and launch of OX124
- Zubsolv sales stabilization
- Partnering of pipeline projects and the AmorphOX technology
- Focus digital health on Orexo's strongholds in OUD and confirmed contracts such as the contract with Veterans Affairs
- Resolution of legal processes



A photograph of a man and a young girl in a park. The man is wearing a red jacket and a white t-shirt, and the girl is wearing a grey hoodie. They are both smiling and holding hands, suggesting a joyful moment. The background is a blurred green forest.

Thanks

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Stockholm Main List (ORX) and is
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(ORXOY) in the US