orexo

Big step forward in launching OX124 in the US

November 2nd 2023

Orexo supports the UN's Agenda 2030 with a

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Agenda & presenters Q3 2023 Interim Report

1 Key achievements

2 Business update
- Commercial Products
- Products under Development

3 Financial & legal overview
- Financial development
- Outlook
- Legal Update

4 Future value drivers

Nikolaj Sørensen,
President and CEO

Fredrik Järrsten
Chief Financial Officer

Key achievements

Improved financials

- **OX124 refiled with the FDA and expected approval in 10-13 months**
- ✓ Continued cost reduction and positive EBITDA of SEK 13 m when excluding fee to FDA (SEK 18 m) and legal expenses (SEK 5 m)
- ✓ Overall Operating Costs reduction of 11% when excluding FDA fee (18 MSEK) OPEX reduction is 22%
- ✓ ZUBSOLV® sales slightly declining, development from Q2 primarily due to variations in inventory and declining overall market. Some market and ZUBSOLV recovery last 1½ month
- ✓ OX640 partnering process ongoing, but an unexpected CRL to a competing liquid nasal spray with epinephrine caused a delay in partner discussions

Net revenues

156 SEK M

Group EBITDA

-9.5 SEK M

Cash and invested funds

184 SEK M

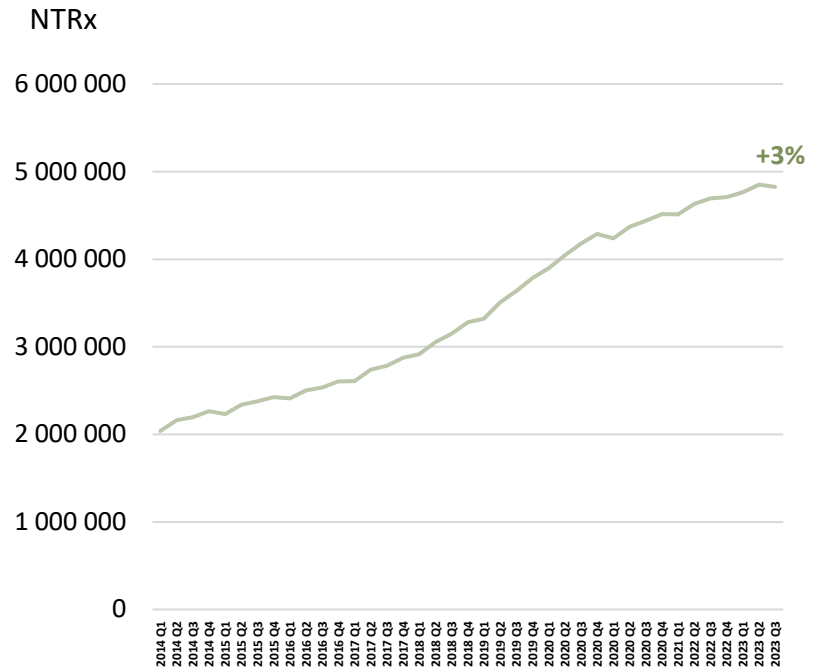
Business update

Commercial products

Unexpected market decline in Q3 impacting ZUBSOLV negatively

- ✓ Market growth of 3% vs Q3 2022 and 1% decline vs Q2 2023
  - Largest segment - Medicaid declined with 3%, while Commercial and Medicare grew slightly
- ✓ ZUBSOLV declined in Q3 with 6% and 3% versus Q2
  - United Health Group declined in line with overall ZUBSOLV decline while Humana had minimal decline
- ✓ ZUBSOLV outperformed the Medicaid segment both YoY and QoQ. E.g.
  - Continued strong growth in new Medicaid contracts, NY (+52% YoY) and Kentucky (+26% YoY) and Indiana (112% YoY)
- ✓ **Some rebound in market and ZUBSOLV growth in late Q3 and continuing into Q4, both growing compared to Q3 average[1]**

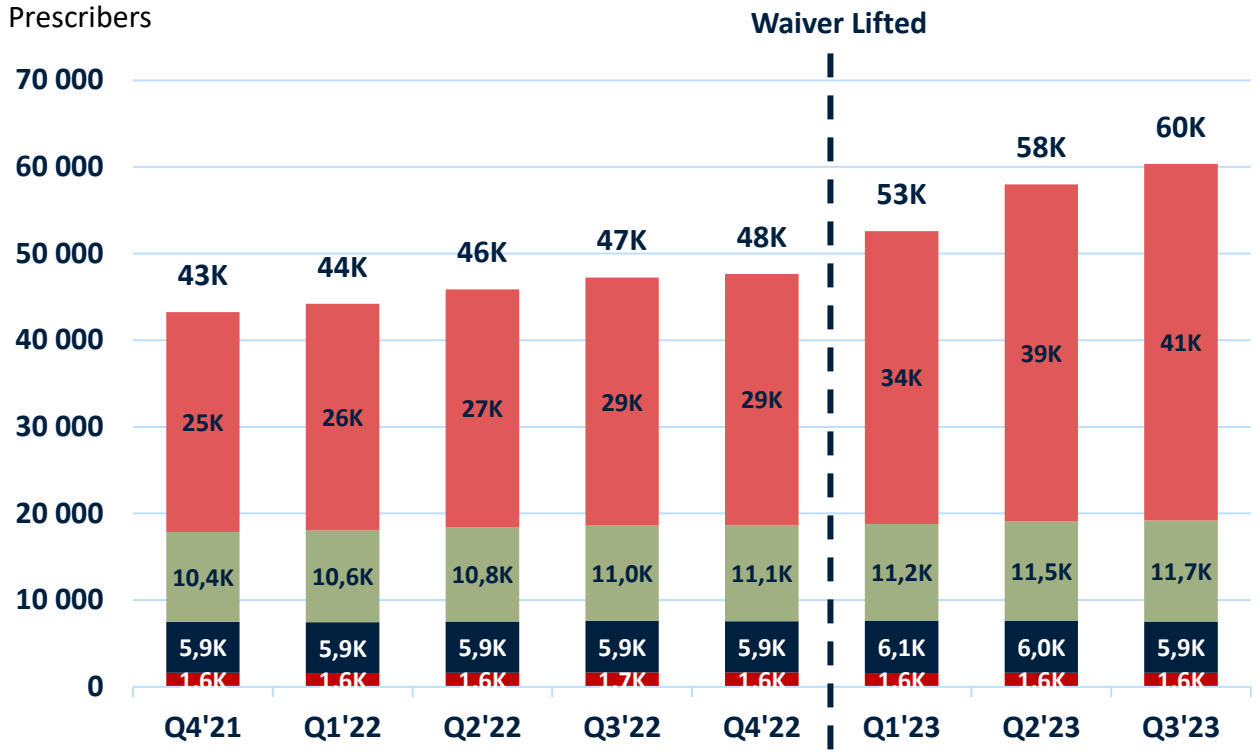
3% total market growth Q3 23 vs Q3 22[1]



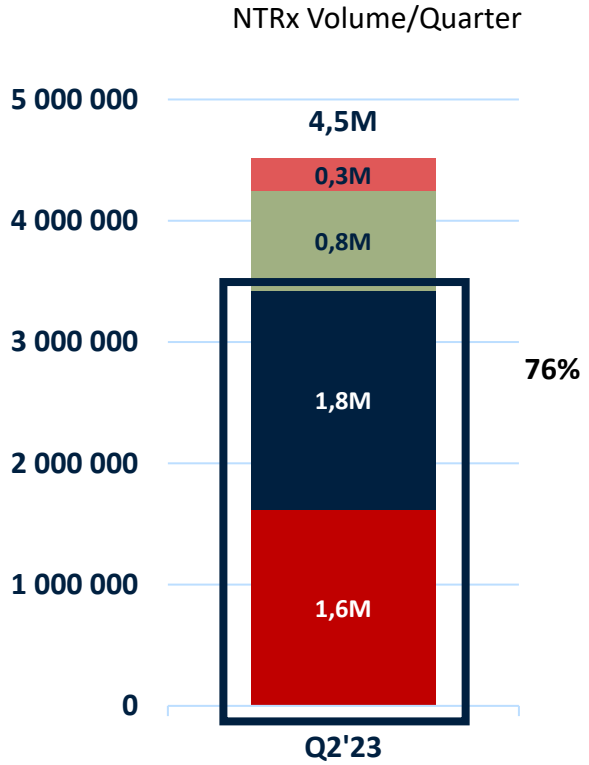
[1]Based on last 4w and 6w average NTRx volume. Note weekly prescription data is volatile and is influenced by public holidays, weather and changes to reimbursement.

New legislation increases number of prescribers, but with limited impact on market growth

Bup/Nal market - Prescribers grouped by segment



Volume by segment



Source: IQVIA XPO

[1]Based on 60 tablets or films per patient per month

Several initiatives to grow the market, but new drivers behind market dynamic makes impact harder to predict

- Significant legislative activity continues to attempt expanding OUD treatment & reduce overdose deaths, but increase in number of buprenorphine prescribers has so far limited impact on volume
  - Base is growing and new prescribers likely to expand patient volume over time
- 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
  - States and counties receiving abatement funds have an obligation to invest majority of the USD 54 billion in treatment and prevention
- Market is impacted by injectable depot formulations (Sublocade®, 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

Continued slow, but some operational progress in digital health

MODIA® study failed to meet primary end-points, but promising explorative data

- Both treatment arms with better effect on illicit drug use than any previous study in OUD
- No statistical difference between the MODIA population and Care-As-Usual
- Patients completing all MODIA modules has significantly better outcome than those who completed less than 50% of the MODIA modules (explorative analysis)
- First customer discussions about the results with no negative reaction

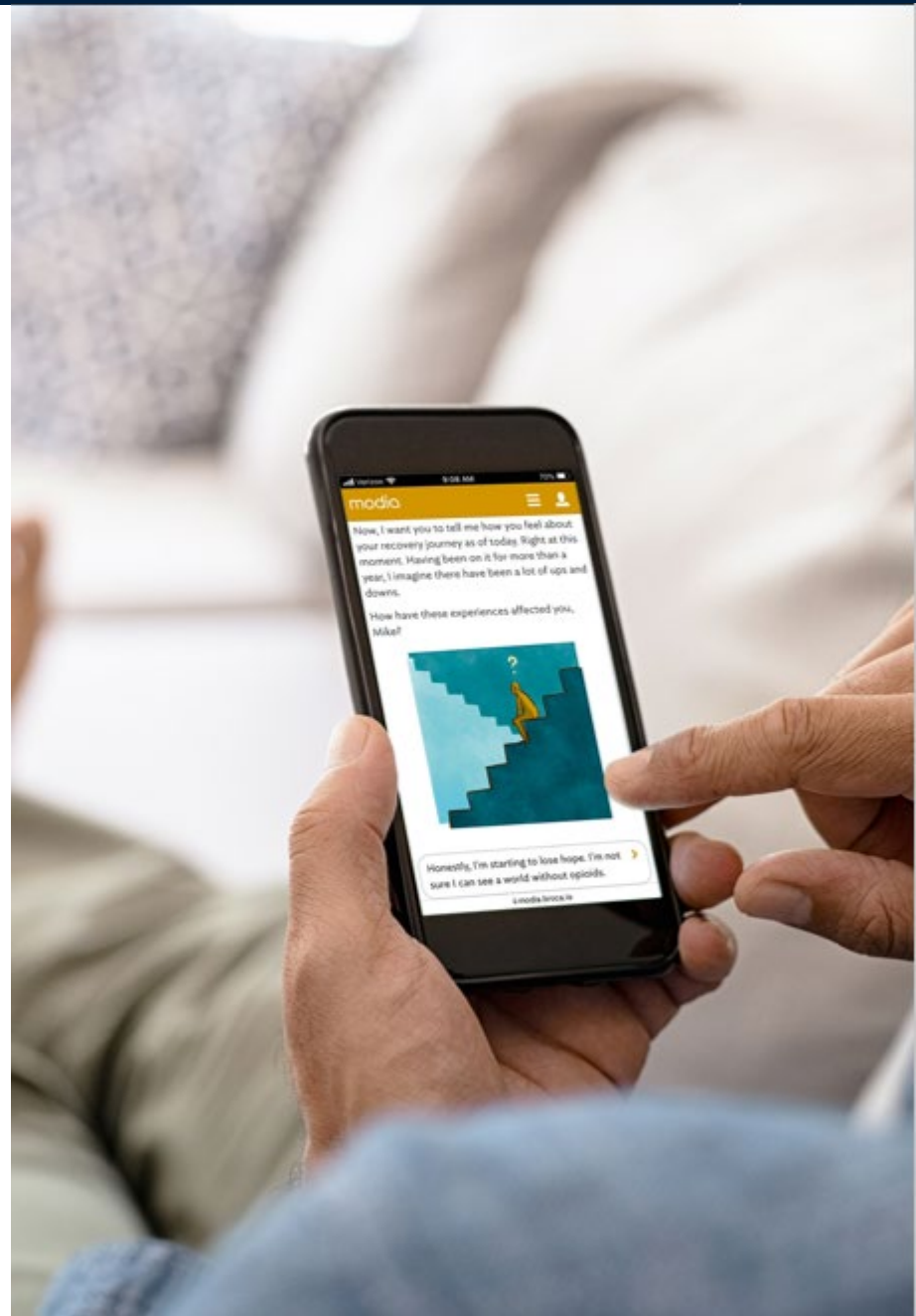
MODIA will be available through FDAs enforcement discretion for mobile medical devices

- New regulatory status require some updates to MODIA to reflect the new instruction for use, which are being implemented by our partner GAIA AG

MODIA functionality will be expanded to improve HCPs ability to monitor patient progress and utilization of MODIA, to improve patient benefits and to improve access to reimbursement

Deprexis and vorvida focused on the VA short term

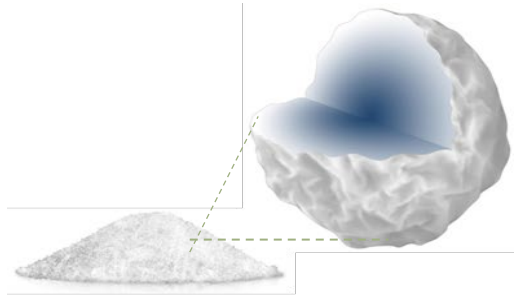
- Efficient distribution and reimbursement process within the VA is complex for a new category of products and launch success depends on ability to remove all large hurdles
- Contract signed with established VA distributor to leverage their existing infrastructure and expertise



Business update

Products under development

R&D – Next product refiled with the FDA



amorphOX® - a scalable drug delivery platform

- Continued positive stability data from explorative studies in e.g. biological drugs and vaccines conducted with external partners

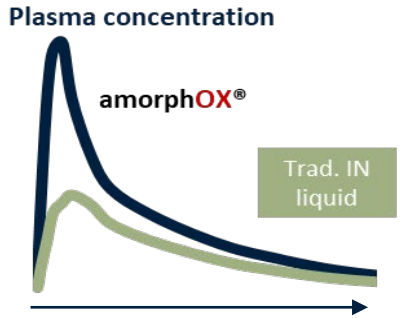
amorphOX® OX124 – high-dose rescue medication for opioid overdose

- Filing completed in September and approval expected in 10-13 month, but final PDUFA date will be received during November
- Launch expected Q4 2024 or early 2025, dependent on PDUFA date and outcome of FDA review

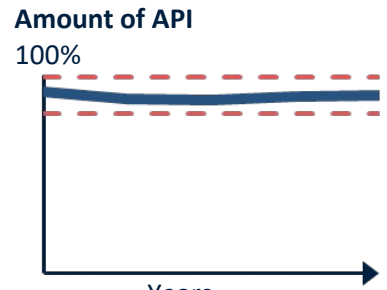
amorphOX® OX640 – epinephrine rescue medication for allergic reactions

- Intensive partner discussions and due diligence during Q3
- Significant focus on required clinical development and investment to get approval
- Unexpected Complete-Response-Letter for competing liquid nasal spray reduced uncertainty of a valid regulatory pathway to the US, but increased uncertainty on required investment
- Orexo is seeking FDA advice on the required development program

amorphOX® - an amorphous powder

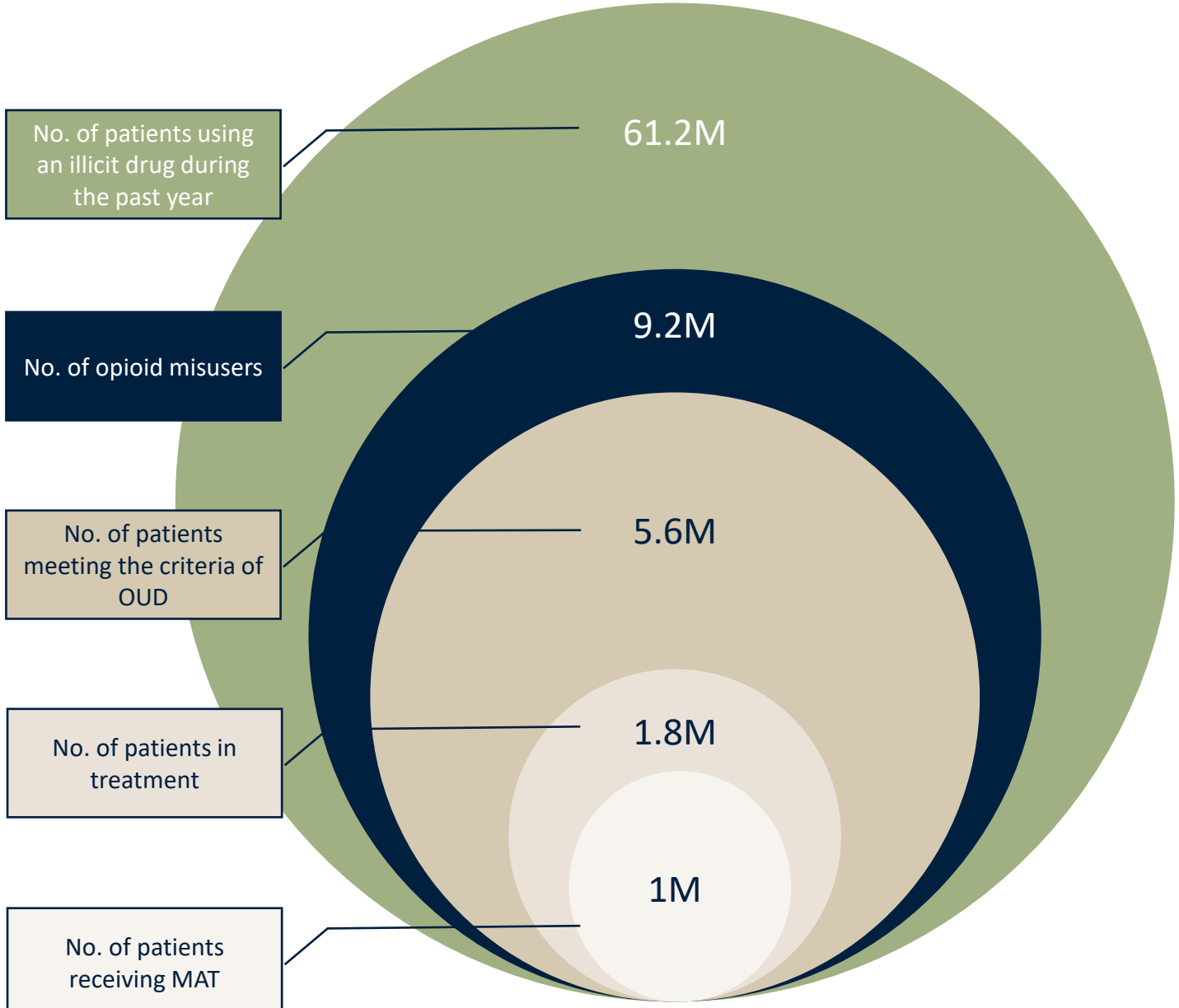


Comparison to liquid nasal sprays



Excellent stability

With 9.2M people at *immediate* risk of an opioid overdose, 1 out of 5 above the age of 12 years risking their lives by using any illicit drug* during the past year (2021)[1]



The number of misusers and OUD patients is most likely underestimated

The real number may be as high as **4.49x** the reported and documented number of opioid misuse and use disorder patients[2]

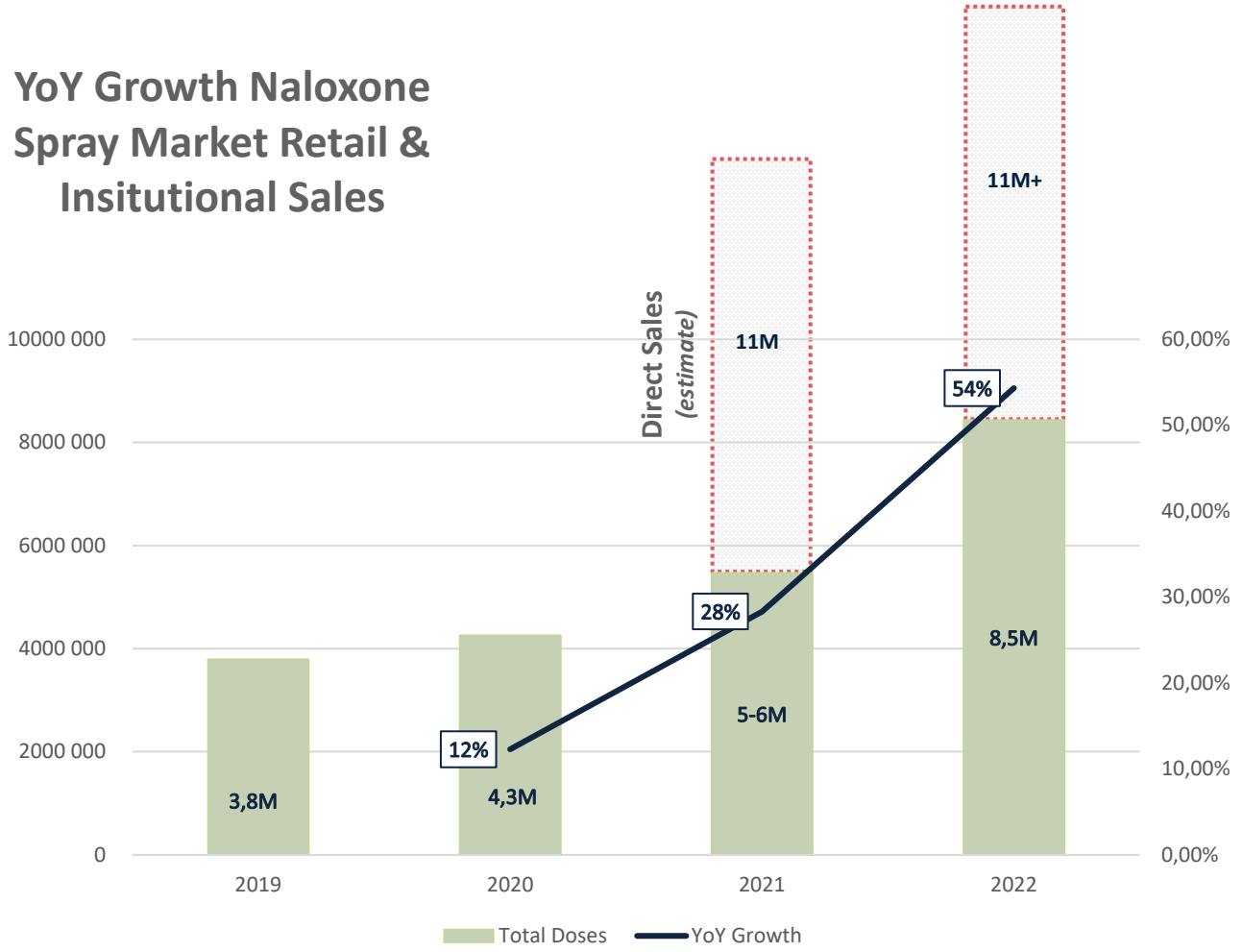
* Illicit drugs may be laced with fentanyl and pose an ever growing risk of experiencing an accidental opioid overdose

1:https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFFRRev010323.pdf (2022),
https://reader.elsevier.com/reader/sd/pii/S0955395922002031?token=5D5617AEA3177C1C8F5AC974A5EF26813F23E56F3127AC06C99B21118E682746BCB55057E6AD83CA5AA510CDF945C683&originRegion=eu-west-1&originCreation=20230131161824 (2022)

Significant need for rescue medication reflected in rapid market growth

Institutional sales i.e. hospital, medical college, corporate organisations, centralized institutions like group practices, integrated delivery networks (IDNs) and **market retail** i.e. pharmacy sales together cover the large majority of all sales of the naloxone spray market.

The total distribution is however, much larger with recorded figures around **17 million doses**[1] of naloxone distributed in 2021. Only ~5-6 million of which were distributed to retail pharmacies and other health care facilities, respectively, indicating **both stockpiling, direct sales (federal, hospitals etc.) and the effect of standing orders.**



Source: Bloomberg

Source: 1. Regall Undall Foundation for the Food and Drug Aministration, 2023, "Summary Report Naloxone Economic View"

US opioid rescue market is in a very dynamic situation currently

Current Naloxone Market:
Narcan Switches to OTC in Q3

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
- Anticipated launch Q4 2023
- Price: WAC of USD 98/2 pack (Rx)
- The company expects peak annual net revenue of USD 150-250 million

Synthetic Surge Impact

- 107,000 drug overdose deaths in 2021, 80,000 attributable to opioids
- Trending higher for 2022 & 2023, with approx. 88% linked to synthetic opioids
- Growing need for effective agents and stronger doses

* Estimated market size based on historical data purchased from IQVIA inc. 2022

Attractive business case for OX124, but we enter a dynamic market

- **Significant market need** for more effective treatment of overdose
  - Low-dose OTC alternatives **not strong enough to sustain reversal** in many overdoses with fentanyl **(deaths are driven by synthetic opioids)**
  - 80% 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	✓
Use below 39°F/ Does not freeze	✓
Long Shelf-Life	✓

Financial & legal

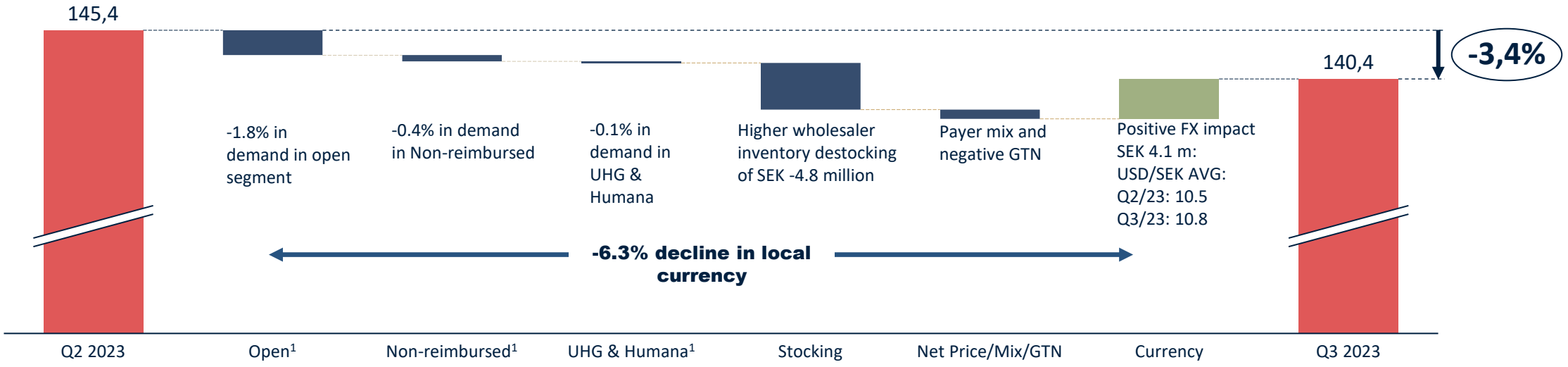
Net revenue declined 3% in Q3

Net revenue per segment SEK m	Q3 2023	Q3 2022	Jan - Sep 2023	Jan - Sep 2022	Jan – Dec 2022
ZUBSOLV US	140.4	150.1	426.3	428.8	571.4
US Pharma – Total	**140.4**	**150.1**	**426.3**	**428.8**	**571.4**
DTx	0.0	0.0	0.1	0.3	0.4
DTx – Total	**0.0**	**0.0**	**0.1**	**0.3**	**0.4**
Abstral® royalties	7.7	7.5	21.9	24.9	30.4
Edluar® royalties	3.5	2.9	8.8	7.7	10.4
ZUBSOLV – ex US	4.5	0.4	15.6	6.5	11.8
HQ & Pipeline – Total	**15.7**	**10.8**	**46.4**	**39.1**	**52.6**
TOTAL	**156.1**	**161.0**	**472.8**	**468.3**	**624.3**

Comments Q3

- ✓ ZUBSOLV US Net revenue declined YoY with 6,5 % primarily due to loss of market share in previous exclusive contracts in previous quarters and lack of market growth to compensate.
- ✓ ZUBSOLV reduction compared to Q2 primarily due to inventory and market decline in the quarter.
- ✓ ZUBSOLV US net revenues partly compensated by sales of tablets ex-US and some royalties.
- ✓ USD vs SEK US with a slight positive impact of SEK 3.5 m YoY.

US Pharma net revenue Q323 vs Q223



[1]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

Significantly lower OPEX

Income statement SEK m	Q3 2023	Q3 2022	Jan - Sep 2023	Jan - Sep 2022	Jan – Dec 2022
Net revenues	156.1	161.0	472.8	468.3	624.3
Cost of goods sold (COGS)	-22.8	-28.0	-68.8	-76.7	-102.6
Gross Profit	**133.3**	**133.0**	**404.1**	**391.5**	**521.7**
Operating Costs	**-161.9**	**-182.8**	**-505.0**	**-504.3**	**-705.6**
EBIT	**-28.6**	**-49.8**	**-100.9**	**-112.8**	**-183.9**
Net financial items	-7.9	27.4	-19.9	37.8	13.5
EBT	**-36.6**	**-22.4**	**-120.8**	**-74.9**	**-170.4**
Tax	3.3	-4.1	11.1	-10.9	-7.2
Net profit/loss	**-33.3**	**-26.5**	**-109.7**	**-85.8**	**-177.6**
EBITDA	**-9.5**	**-32.4**	**-44.8**	**-62.1**	**-115.2**

Comments Q3

OPEX significantly lower mainly due to

- Lower expenses for IP litigation and no clinical trials
- New DTx organization
- Partly offset by OX124 filing fee of SEK 18 m and negative impact from stronger USD
- Operating cost >20% below Q3 2022, when excluding filing fee

ZUBSOLV® US EBIT contribution of SEK 62 m (70)

- EBIT Margin for the quarter 44% (47%)

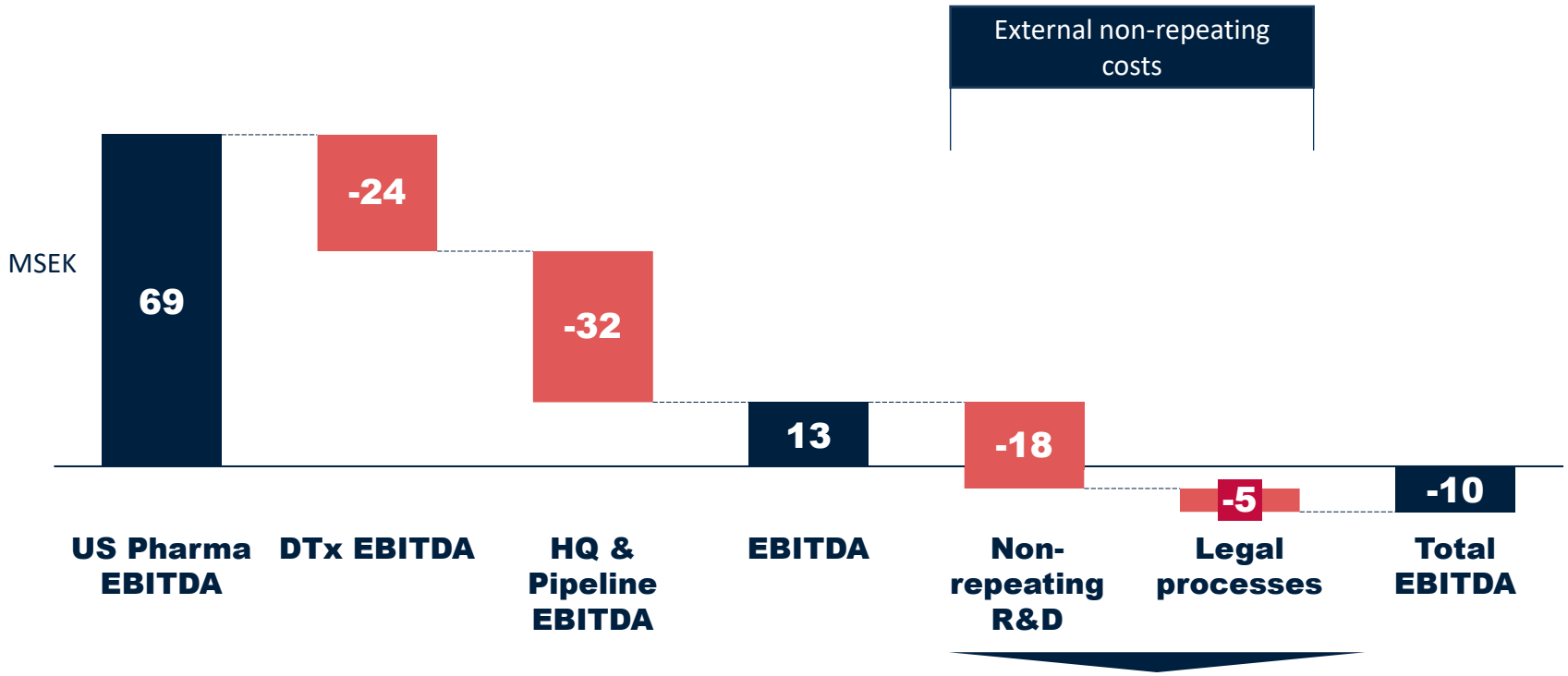
EBITDA of SEK -9.5 m (-32.4)

- Exclusion of costs for legal processes and external non-repeating costs for the FDA filing fee, would result in an EBITDA of SEK 13 m (14) for Q3.

NET FINANCIAL ITEMS of SEK -7.9 m (27.4)

- Lower positive unrealized exchange rate impact of SEK 0.8 m (33.2) derived from the parent company's foreign currency bank accounts mainly in USD
- Higher interest rate for corporate bonds of SEK -9.7 m (-6.7).
- Partly offset by interest income of SEK 1.3 m (1.2) from bank accounts.

Q3 EBITDA positive SEK 13 m, excluding non-recurring expenses



- OX124 project, filing with the FDA 18 MSEK
- Sun Litigation
- Subpoena

* DTx EBITDA including internal allocations from US Pharma

Sufficient cash position enables continued R&D investments for growth

Cash Flow SEK m	Q3 2023	Q3 2022	Jan - Sep 2023	Jan - Sep 2022	Jan - Dec 2022
Cash flow from operating activities	-21.9	-60.7	-92.4	-107.8	-156.6
Investment activities	-6.6	-69.0	201.7	-300.9	-234.7
Financing activities	-39.1	-5.0	-64.6	-15.6	-21.4
Cash flow (excl. exchange rate differences)	-67.6	-134.7	44.7	-424.3	-412.8
Exchange-rate differences in cash and cash equivalents	0.7	12.9	7.2	42.6	40.9
Add back short-term investments	0.0	321.5	0.0	321.5	219.6
Cash and cash equivalents at the beginning of the period	251.1	244.2	132.2	504.1	504.1
Liquid funds	**184.2**	**443.9**	**184.2**	**443.9**	**351.9**
Net cash position including short-term investments	-263.6	-50.3	-263.6	-50.3	-142.9

Comments Q3

- ✓ Liquid funds (SEK 184 m) decreased with SEK 67 m from Q2 2023 (SEK 251 m)
  - ✓ SEK 22 m negative contribution from operating activities primarily impacted by negative operating earnings mainly due to payment of OX124 filing fee of SEK 18 m
  - ✓ Investment activities had a negative impact of SEK 7 m on cash flow primarily from investments in equipment for the development organisation
  - ✓ Financing activities had a negative impact of SEK 39 m on cash flow primarily from buy back of the corporate bond with a nominal value of SEK 33.5 m

Financial outlook

Metric	Outlook 2023	Reaffirmed/revised
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.	Reaffirmed
Lead product net sales	Group revenues will increase, with ZUBSOLV US revenues being in line with 2022	Reaffirmed
Group OPEX	Reduced OPEX in H2 compared to H1, which amounted to SEK 343 million including depreciation of SEK 37 million	Reaffirmed
Group EBITDA	EBITDA in balance in H2	Reaffirmed

Q3 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

- ✓ 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

Thanks

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