Advancing the pipeline facilitating future growth

November 3rd 2022

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

Agenda & presenters Q3 2022 Interim Report

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Nikolaj Sørensen,
President and CEO

Robert Rönn
Head of R&D

Fredrik Järrsten
Chief Financial Officer

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Q3 Key achievements

Making progress

HQ & Pipeline

- ✓ OX124 proceeded as planned towards a NDA filing with FDA expected Q4
- ✓ OX640 –successful 1st human trial
- ✓ amorphOX® successfully tested in several large molecules

US Pharma

- ✓ ZUBSOLV® continues with stabilized demand QoQ
- ✓ NY and Kentucky Medicaid with strong growth QoQ
- ✓ Strong financial performance, despite investment in increased field force in NY

Digital Therapeutics

- ✓ Trinity Health (ND) first patients on deprexis® and successful billing tests
- ✓ More than 1200 modiaONE patients in Q3 an increase of 130% from Q2
- ✓ First patients received MODIA® in early Q4 following the reimbursement pathway

Aiming at profitability

- ✓ Total revenues grew in SEK due to ZUBSOLV® revenue growth explained by FX tailwinds
- ✓ ZUBSOLV® sales stabilized during 2022
- ✓ ~75 percent reduction in direct expenses in DTx compared to Q3 2021 through focused commercialization and increased synergies with US Pharma
- ✓ EBITDA profitability when excl. legal costs and non-repeating expenses for clinical studies

ZUBSOLV® net revenues▲

10 %

US Pharma EBIT

70 SEK M

Cash and invested funds

444 SEK M

Business update

US Pharma

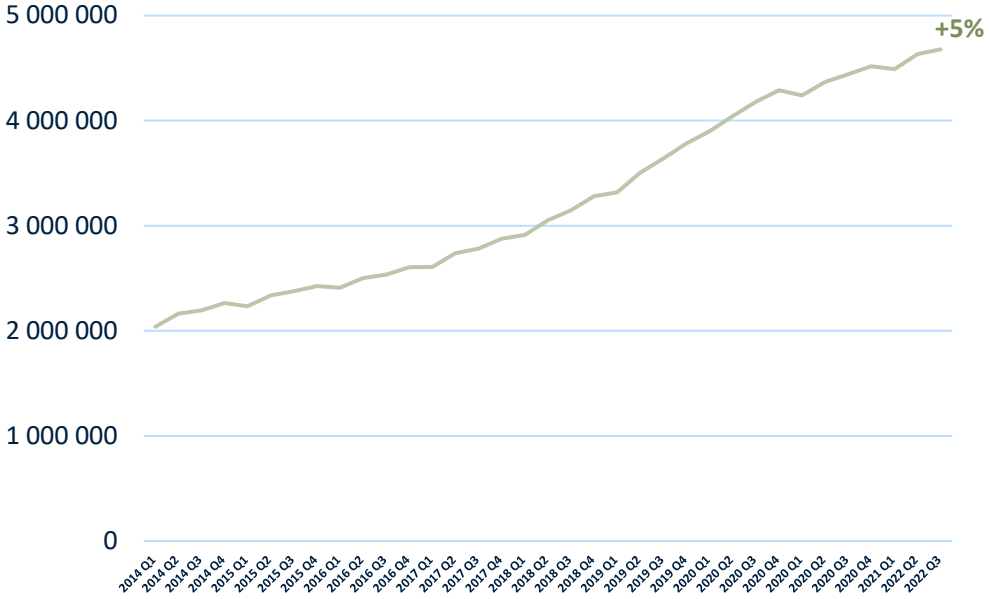
ZUBSOLV® volume stabilizing

- ✓ Stable market share and volume and from Q2 (-1%)
  - NY (16%) and Kentucky (18%) Medicaid being prime growth drivers
  - Continued slow decline in UHG and Humana (-5%)
- ✓ Increased investment in field force NY with full effect in Q3 and vacancies from Covid-19 filled
- ✓ Some improvement in field force productivity, but still below pre-Covid levels
- ✓ ZUBSOLV® access maintained on all published formularies for 2023

[1] Where ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics

Continued slow market growth

5% total market growth Q322 vs Q321[1]



Fentanyl crisis – a new inhibitor for treatment

- Fentanyl addicted patients, more difficult to treat resulting in increased rate of relapse
- Fentanyl causes increased mortality among patients
- Covid-19 effects from less access to treatment, high overdose rate etc
- Few counsellors and access to full MAT treatment

Improved funding will create new opportunities

- **USD 54 billion[2]** in settlements in the "opioid litigation" expected to accelerate access to treatment
- First funds available during Q3 to support specific projects and programs in several states
  - ➢ **Orexo is actively pursuing opportunities involving all elements of our treatment offerings in OUD and mental health**

[1] Volume sales, quarterly NTRx

Business update

HQ & Pipeline

Good progress in pipeline

OX124 – overdose rescue medication based on amorphOX®

- OX124 on track to be filed with FDA Q4 2022
- All data collected to date support filing with current FDA requirements

OX640 – adrenaline rescue medication based on amorphOX®

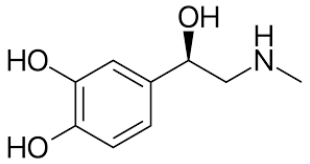
- Successful phase I exploratory study
- Orexo are exploring product development and commercialization partnerships

Prioritization of pipeline to focus resources on main opportunities

- OX125 continues with low level activities
- OX338 stopped

Note: product images are prototypes

OX640: A significant opportunity for Orexo



The epinephrine auto-injector market <u>today</u>

Projected Growth YoY: 9% (next 6 years)

↑ global prevalence

Projected Global Market Size: > USD 4 bn

Largest market: US

2nd largest market: Europe

Global Market Leader today: EpiPen®

No meaningful innovation for decades

OX640 with clear differentiation from other competing pipeline projects

Current unmet needs

Needle-free anaphylaxis rescue

While still fast acting

Chemically stable and more robust formulation

Oxidation & Light

Extended storing and better handling

Optimized manufacturing

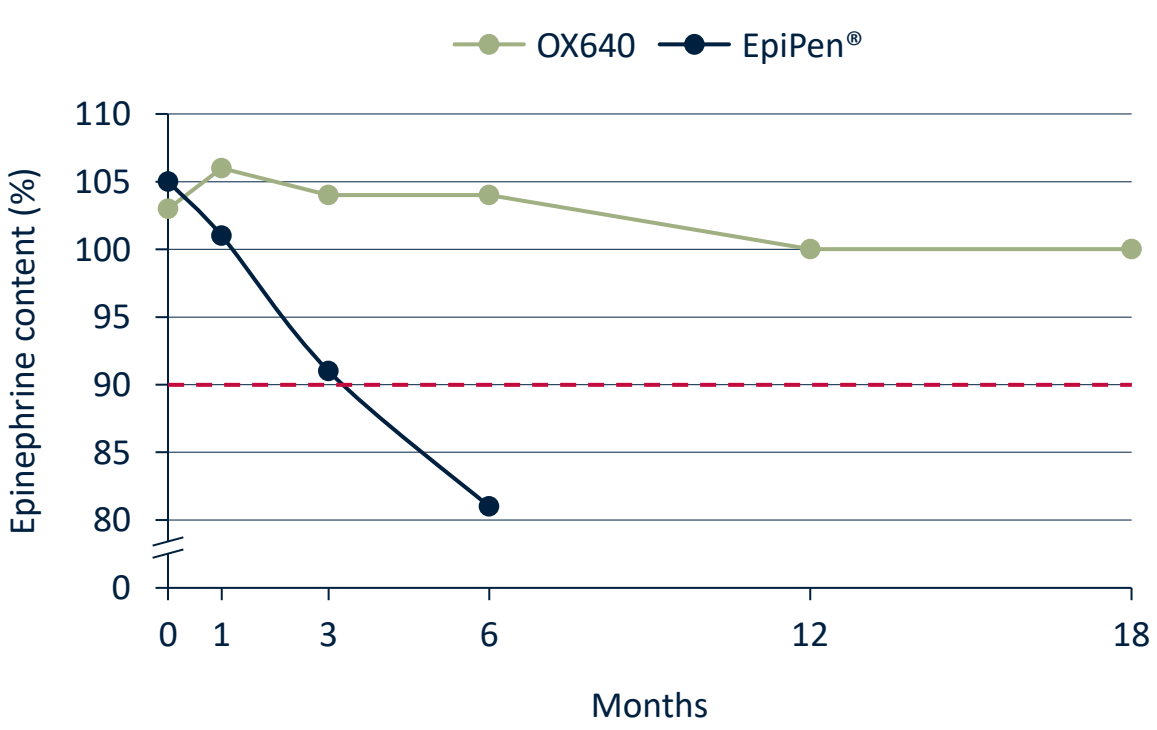
w/o using nitrogen

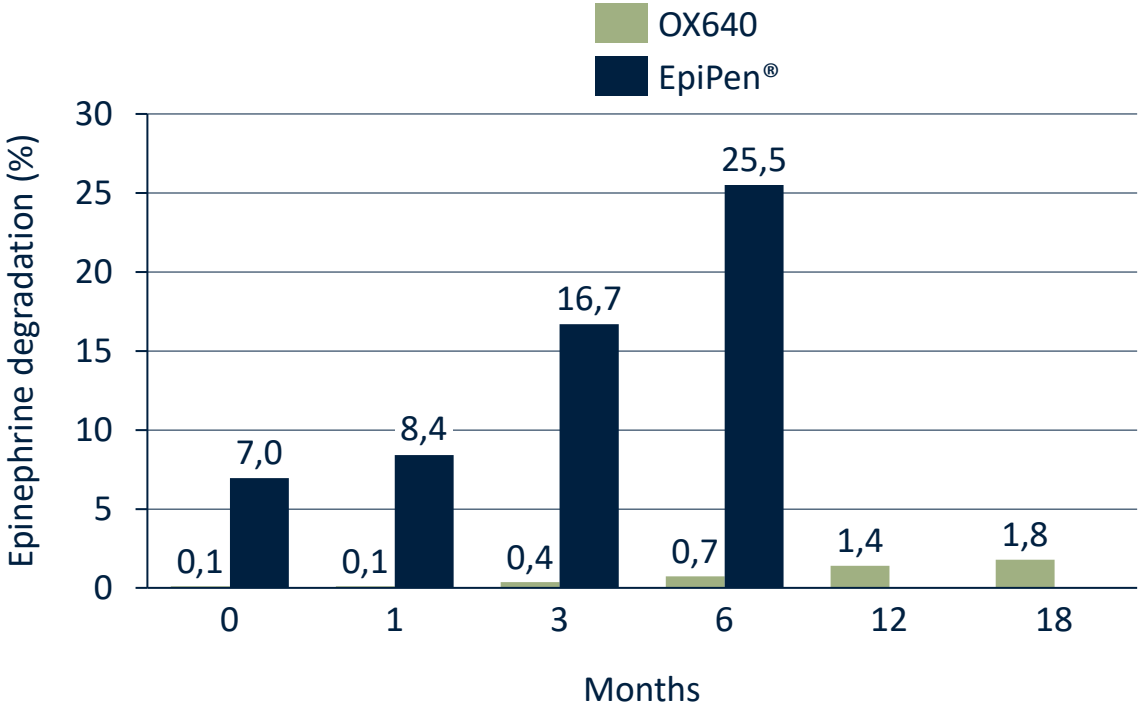
w/o protecting from light

Free of antioxidants or preservatives

OX640: Outstanding stability

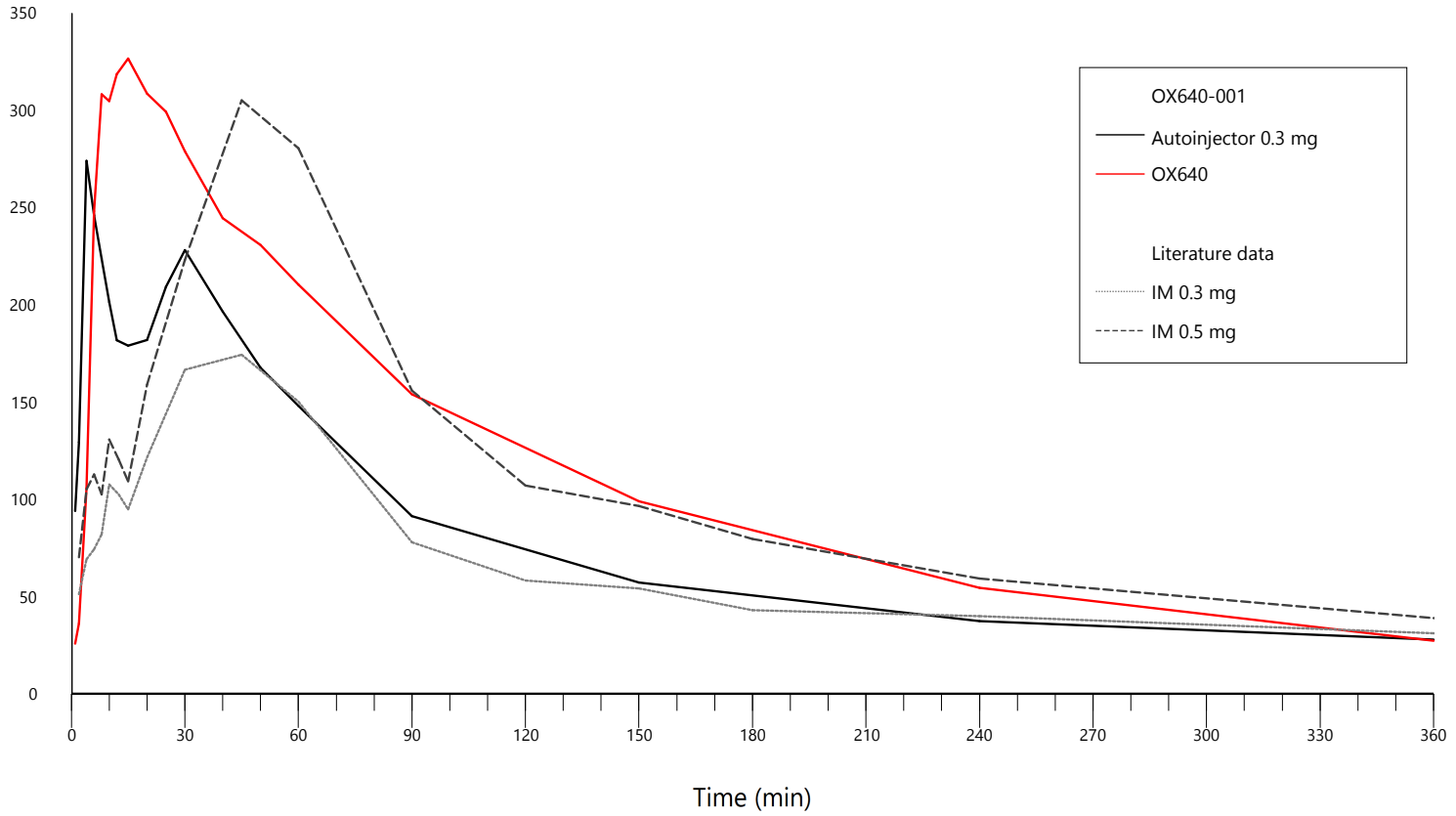
Comparative stability studies @ 40°C/75% RH





OX640 shows superior stability – even after 18 months of accelerated conditions

OX640: Excellent bioavailability



Strategy and target

To obtain pharmacokinetic parameters for OX640 within the space for already approved epinephrine products, e.g.

- Total exposure (AUC_t)
- Peak exposure (C_{max})
- Early exposure ($AUC_{0\text{-}20min}$)

OX640: Short development time

2022

Clinical Phase I (PK) study

2023

Pharmaceutical development

- Upscaling of manufacturing capitalizing on OX124 supply chain

2024

Clinical studies

- Healthy volunteers and volunteers with seasonal allergies

2025

NDA submission

Orexo is exploring potential partnering opportunities for OX640, while continuing to advance the project

Business update

Digital Therapeutics (DTx)

Fast growth in MODIA® awareness and trial

>3700 users of one of the DTx in Orexo sponsored early access programs

- Healthcare staff at large healthcare providers e.g. Trinity Health and Benefis
- Nurses through nurse associations
- Medical students through collaboration with universities
- Consumers buying access to vorvida® or deprexis®
- modiaONE and clinical trial

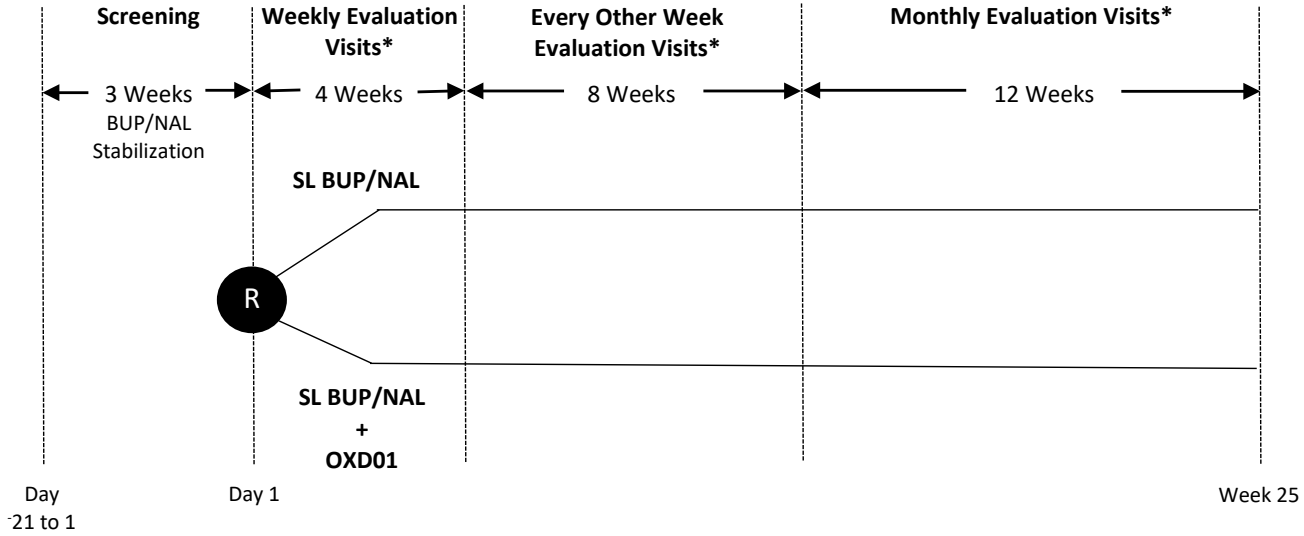
Nearly 1200 users of MODIA® through modiaONE in Q3

- 130% increase from Q2
- First patients received MODIA® through the reimbursement pathway in October

Last patient recruited in MODIA® clinical trial

modia

- 437 randomized patients with moderate to severe OUD[1]
- Primary endpoint: Treatment success, defined as ≥ 80% of urine drug tests negative for opioids plus negative self-reports for illicit opioid use from Week 6 to Week 25
- 510 K approval provide access to broader reimbursement as a prescription digital therapy



[1] Opioid use disorder

Final result expected Q2 2023 enabling a 510 K application with the FDA

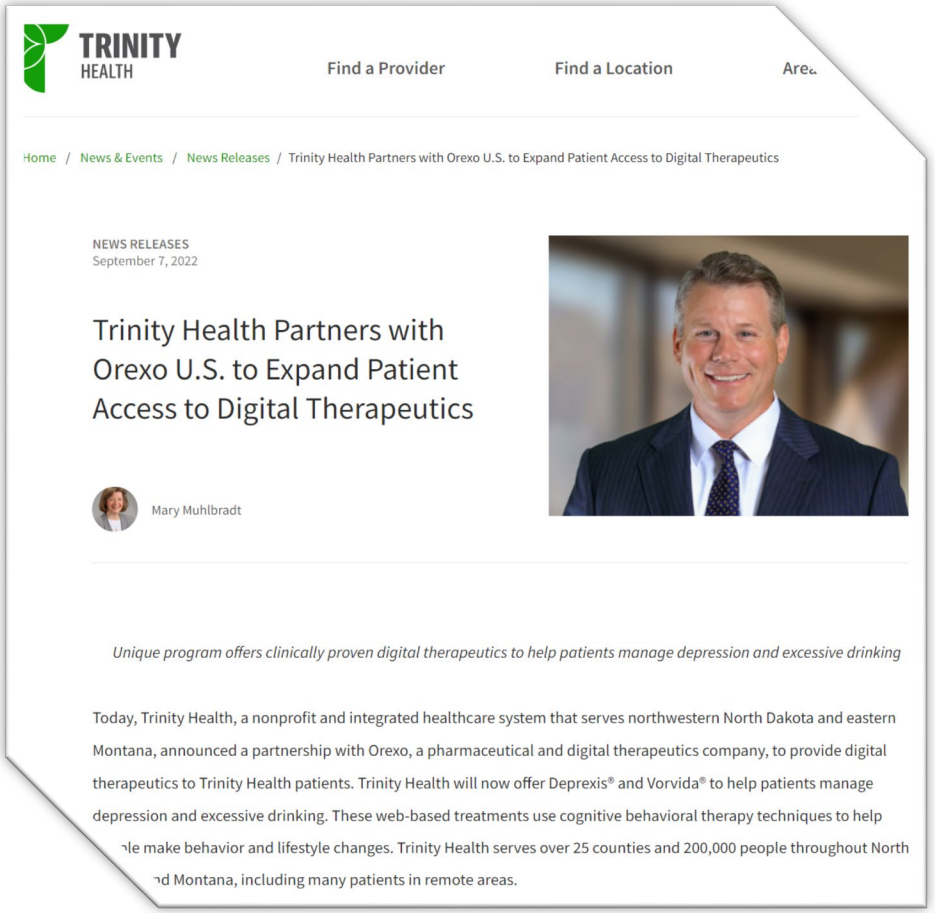
Trinity Health is ready to expand, but new tools and processes slow down implementation

TRINITY HEALTH

Billing test and training of health care staff successfully completed in Q3

First patients have received deprexis®, but revenue recognition will come when first invoice is paid by the payers in Q4

DTx and the reimbursement pathway are new to the healthcare staff and continuous education is needed to get started



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NEWS RELEASES
September 7, 2022

Trinity Health Partners with Orexo U.S. to Expand Patient Access to Digital Therapeutics

Mary Muhlbradt

Unique program offers clinically proven digital therapeutics to help patients manage depression and excessive drinking

Today, Trinity Health, a nonprofit and integrated healthcare system that serves northwestern North Dakota and eastern Montana, announced a partnership with Orexo, a pharmaceutical and digital therapeutics company, to provide digital therapeutics to Trinity Health patients. Trinity Health will now offer Deprexis® and Vorvida® to help patients manage depression and excessive drinking. These web-based treatments use cognitive behavioral therapy techniques to help ple make behavior and lifestyle changes. Trinity Health serves over 25 counties and 200,000 people throughout North nd Montana, including many patients in remote areas.

Strong belief in digital therapeutics (DTx), but adopting expenses to slow implementation

DTx works & will grow in importance…

- Patient feedback generally very positive according to their caregiver (Orexo has no direct contact with patients)
- Large share of clinics testing MODIA® through the trial program modiaONE are interested in a commercial contract
- Digital therapies seen as a tool for multiple healthcare networks and several networks follow implementation at Trinity Health

….but adoption takes time

- Collaborative care model implemented at Trinity Health is new and require training
- Digital therapies are new to patients and their physician, creating uncertainty in when and how to use these new tools
- Patients use of digital therapies not always aligned with the healthcare program and improved education is needed

Focus resources on best opportunities

- Prioritization and focus of DTx activities:
  - Trinity Health implementation and expansion of concept to new health systems
  - VA implementation
  - MODIA® commercial contracts
- 75 percent reduction in direct expenses within DTx and more reliance on shared resources with US Pharma
- Increase in expenses will be triggered by confirmed business opportunities

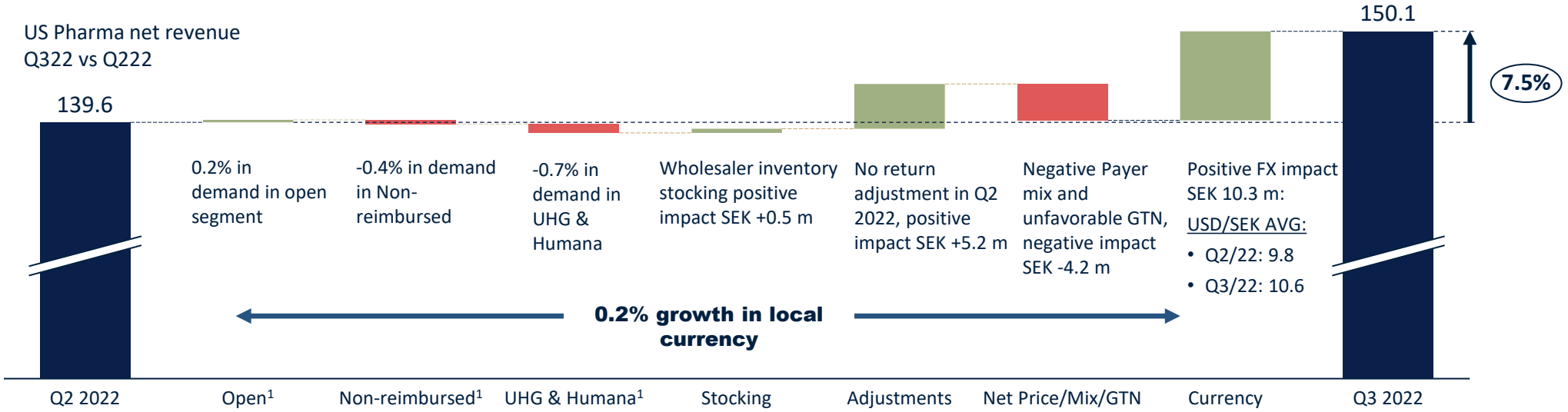
Financial & legal

ZUBSOLV® net revenue grew 10% YoY

Net revenue per segment SEK m	Q3 2022	Q3 2021	Jan – Sep 2022	Jan – Sep 2021	Jan - Dec 2021
ZUBSOLV® US	150.1	136.4	428.8	389.2	522.7
US Pharma – Total	**150.1**	**136.4**	**428.8**	**389.2**	**522.7**
DTx	0.0	0.4	0.3	0.8	1.1
DTx – Total	**0.0**	**0.4**	**0.3**	**0.8**	**1.1**
Abstral® royalties	7.5	6.8	24.9	23.8	32.1
Edluar® royalties	2.9	2.4	7.7	7.2	9.1
ZUBSOLV® – ex US	0.4	—	6.5	—	—
HQ & Pipeline – Total	**10.8**	**9.2**	**39.1**	**31.0**	**41.2**
TOTAL	**161.0**	**145.9**	**468.3**	**421.0**	**565.0**

Comments

- ✓ ZUBSOLV® Net revenue grew YoY with 10 % primarily due to stronger USD vs SEK
- ✓ Good growth in NY and Kentucky Medicaid volume



[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

Limited USD FX impact on EBIT due to natural hedge from balanced USD income and costs

Income statement SEK m	Q3 2022	Q3 2021	Jan – Sep 2022	Jan – Sep 2021	Jan – Dec 2021
Net revenues	161.0	145.9	468.3	421.0	565.0
Cost of goods sold (COGS)	-28.0	-21.3	-76.7	-58.6	-78.9
Gross Profit	**133.0**	**124.7**	**391.5**	**362.4**	**486.1**
Operating Costs	**-182.8**	**-183.7**	**-504.3**	**-512.4**	**-700.2**
EBIT	**-49.8**	**-59.0**	**-112.8**	**-150.0**	**-214.1**
Net financial items	27.4	-0.1	37.8	-6.3	-8.4
EBT	**-22.4**	**-59.1**	**-74.9**	**-156.3**	**-222.5**
Tax	-4.1	7.1	-10.9	-1.3	-1.0
Net profit/loss	**-26.5**	**-52.0**	**-85.8**	**-157.6**	**-223.5**
EBITDA	**-32.4**	**-47.4**	**-62.1**	**-112.6**	**-161.0**

Comments

ZUBSOLV® COGS higher due to a negative FX impact

OPEX lower due to

- Significantly lower selling expenses in DTx
- Partly offset by higher expenses for IP litigation, higher OX124 and OX640 development expenses
- Negative impact from stronger USD

ZUBSOLV® US EBIT contribution of SEK 70 m (79)

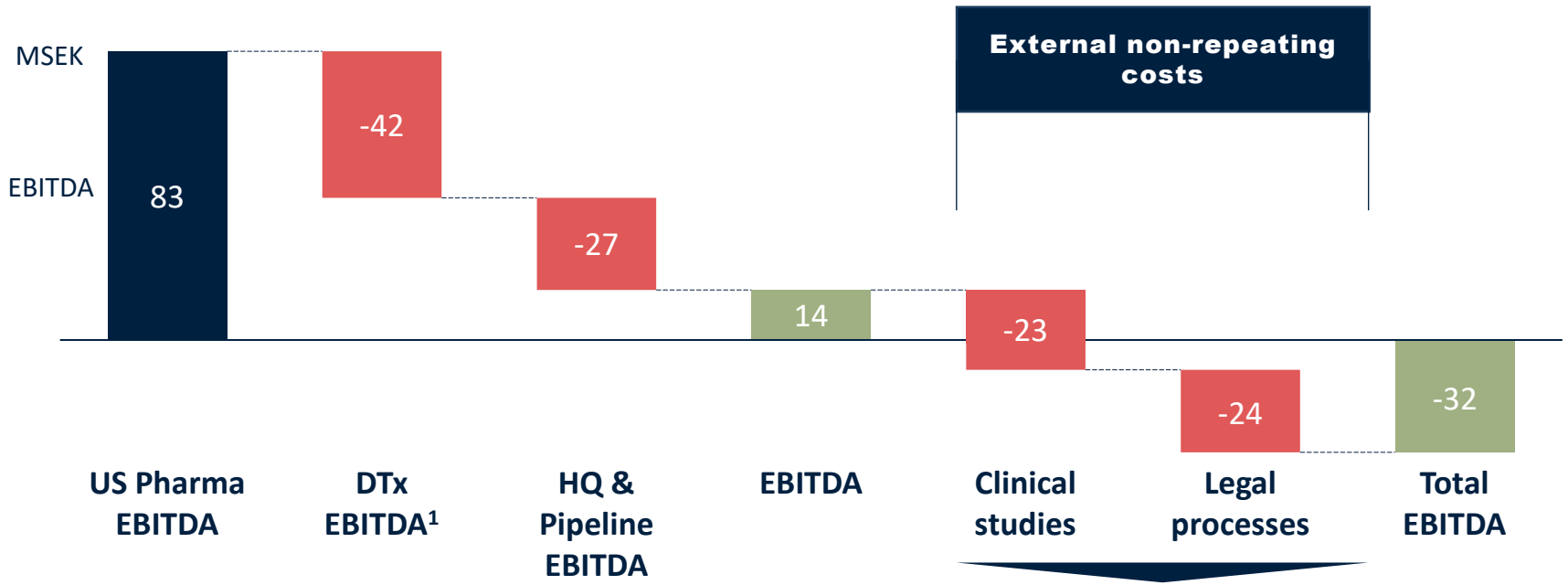
- EBIT Margin lower Q3 with 47% (58%) and 54% (53%) for the first nine months explained by increased field force and one-time adjustments

EBITDA of SEK -32 m (-47)

NET FINANCIAL ITEMS of SEK 27 m (-0.1)

- Mainly explained by positive unrealized exchange rate impact of SEK 33.2 m (6.5) derived from the parent company's foreign currency bank accounts mainly in USD
- Partly offset by higher costs for corporate bonds of SEK 6.6 m (5.8).

Orexo core EBITDA positive excl. external non-repeating costs



Completed	
• MODIA® phase III	Q2, 2023
• OX640 phase I	Q4, 2022
• OX124 HF studies	Q4, 2022
• Sun Litigation	Q1, 2023 (District Court)
• Subpoena	TBD

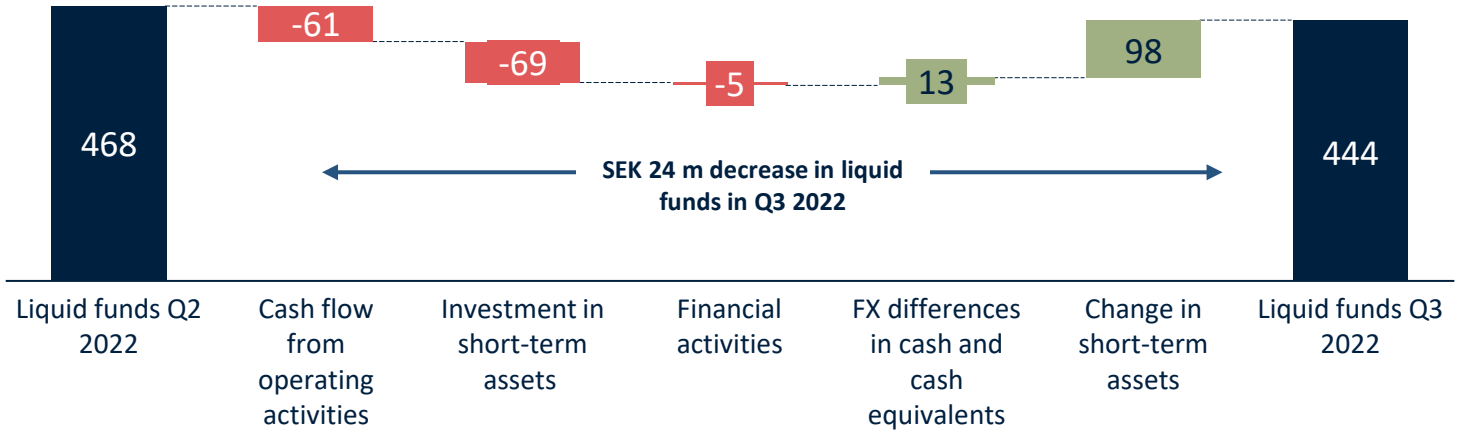
[1] Including internal allocations from US Pharma

Sufficient cash position to continue R&D investments and defend IP rights

Cash Flow SEK m	Q3 2022	Q3 2021	Jan –Sep 2022	Jan –Sep 2021	Jan - Dec 2021
Cash flow from operating activities	-60.7	-79.7	-107.8	-148.4	-229.0
Investment activities	-69.0	-20.7	-300.9	-50.0	-52.9
Financing activities	-5.0	-2.0	-15.6	256.1	250.6
Cash flow (excl. exchange rate differences)	-134.7	-102.4	-424.3	57.7	-31.2
Add back short-term investments	321.5	—	321.5	—	
Liquid funds	**443.9**	**588.1**	**443.9**	**588.1**	**504.1**
Net cash position including short-term investments	-50.3	96.3	-50.3	96.3	11.7

Comments

- ✓ Liquid funds (SEK 444 m) decreased with SEK 24 m from Q2 (SEK 468 m)
- ✓ SEK 61 m negative contribution from operating activities mainly due to negative operating earnings
- ✓ Investment activities had a negative impact of SEK 69 m on cash flow primarily due to **invested surplus cash of SEK 322 m in certificates of deposits and in US treasuries**



Financial outlook

Based on exchange rates in September 2022, if based on previous exchange rates, OPEX estimate from Q2 would still be valid

Metric	Outlook 2022	Reaffirmed/revised
Key market development	Due to the continuing pandemic the buprenorphine/naloxone market will show a growth pace in line with 2021, and reach a level of 5-8 percent	Reaffirmed
Lead product net sales	In H2 ZUBSOLV® net sales in USD will increase comparing to H1.	Reaffirmed
Group OPEX	OPEX will be SEK 700-725 m based on the appreciation of the USD during Q3	Revised
US Pharma EBIT margin	US Pharma EBIT margin will exceed 50 percent on a full year basis	Reaffirmed

Q3 legal update

ZUBSOLV® patent dispute vs Sun Pharmaceuticals

- ✓ A new patent was granted in the US
- ✓ The date for trial was rescheduled and is planned to take place during Q1.

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

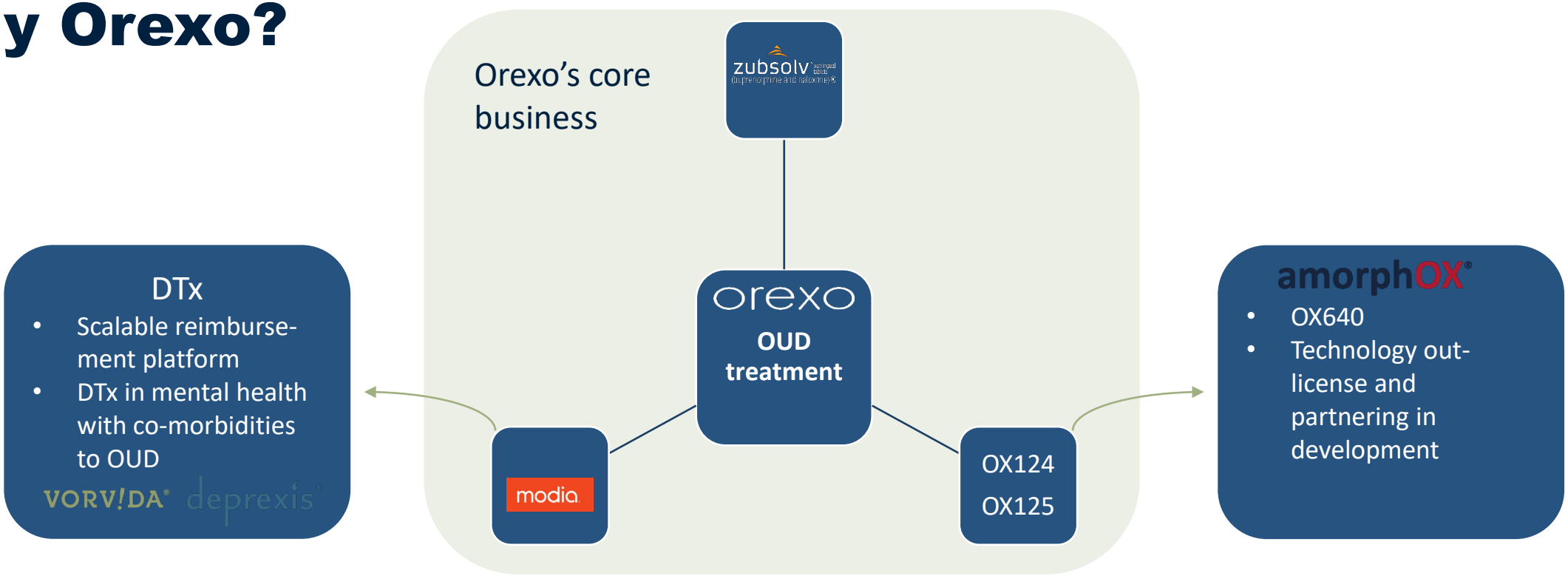
The outcome of the trial is expected during the summer of 2023

Subpoena with regards to ZUBSOLV®

- ✓ Some clarifications and complements to information previously shared with the US authorities

Future value drivers

Why Orexo?



Pioneer in future growth area with proprietary reimbursement platform and products

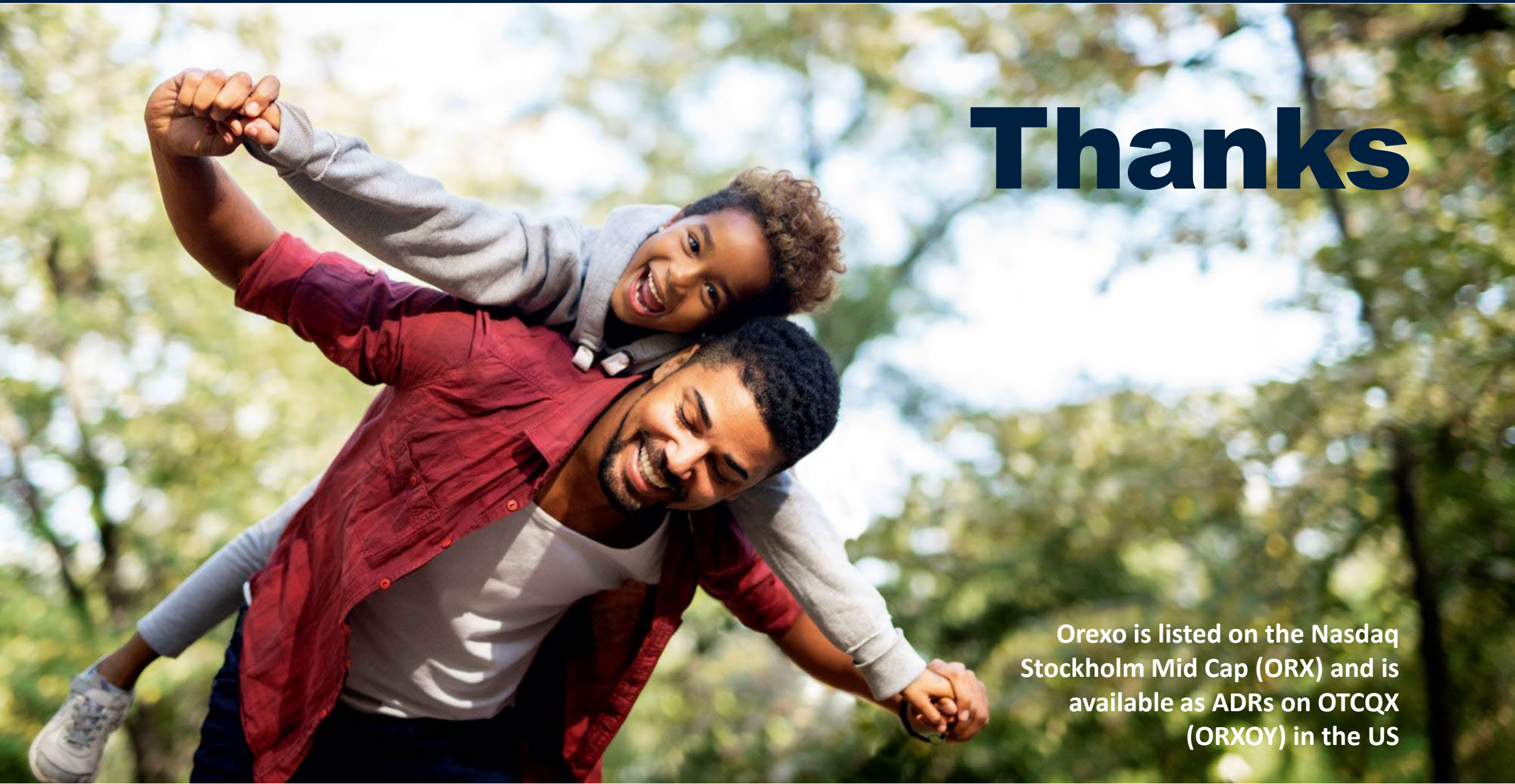
Profitable and stable US Pharma business with long presence in significantly underserved market and significant near-term milestones from MODIA® study and OX124 approval enabling a comprehensive treatment solution to OUD

World leading technology enabling new profit generating partnerships

Why Orexo?

- ✓ **Corporate profitability** in sight[1]
  - Main external cost drivers will diminish during H1 2023
  - No new activity driving external expenses to be initiated without certainty of associated revenues
  - Significant focus on cost efficiency
- ✓ **R&D pipeline** is expected to result in revenue generating partnerships during 2023
  - OX124 filing with the FDA in Q4 2022
  - OX640 and amorphOX® partnering discussions on-going
- ✓ **DTx revenues** expected to build from Q4 and beyond
  - Reimbursement model confirmed
- ✓ **ZUBSOLV® sales** stabilized and opportunities to grow
  - Settlements providing USD 54 billions announced

[1] Assuming no unexpected events outside the control of Orexo



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