Focusing operations on Orexo's strengths

April 27

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Agenda & presenters Q1 2023 Interim Report

1 Key achievements

2 Business update
- Commercial
- 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

Navigating troubled waters

- ✓ Net revenues similar to Q1 2022 supported by currency and ZUBSOLV® sales slightly above Q4 2022 in USD
- ✓ Continued positive EBITDA when excl. legal costs and non-repeating clinical trials
  - District court hearing finalized and decision expected during the summer
  - MODIA® study ending in April
- ✓ Consolidation of the US organization completed in Q1
  - Review of barriers to commercial traction and potential efficiency improvements led to new approach to reimbursement
- ✓ OX124 filing completed in February, but need to be refiled later this year due to issues in outsourced packaging line

Net revenues

159 SEK M

US Pharma EBIT

74 SEK M

Cash and invested funds

279 SEK M

Business update

Commercial

ZUBSOLV® volume stabilizing in open & non-reimbursed

- ✓ Market growth of 6%
  - Slight improvement from previous quarters
  - Public segment continue to be main growth driver
- ✓ ZUBSOLV® demand decline slow down and with to 2% versus Q4 and 4% versus Q1 2022
  - Stable development in Open segment
  - NY and Kentucky Medicaid continue to be prime growth drivers
  - UHG and Humana main drivers of overall decline
- ✓ ZUBSOLV® Commercial market access formulary levels maintained for 2023
  - Commercial access of 98%
  - Public access of 47%

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

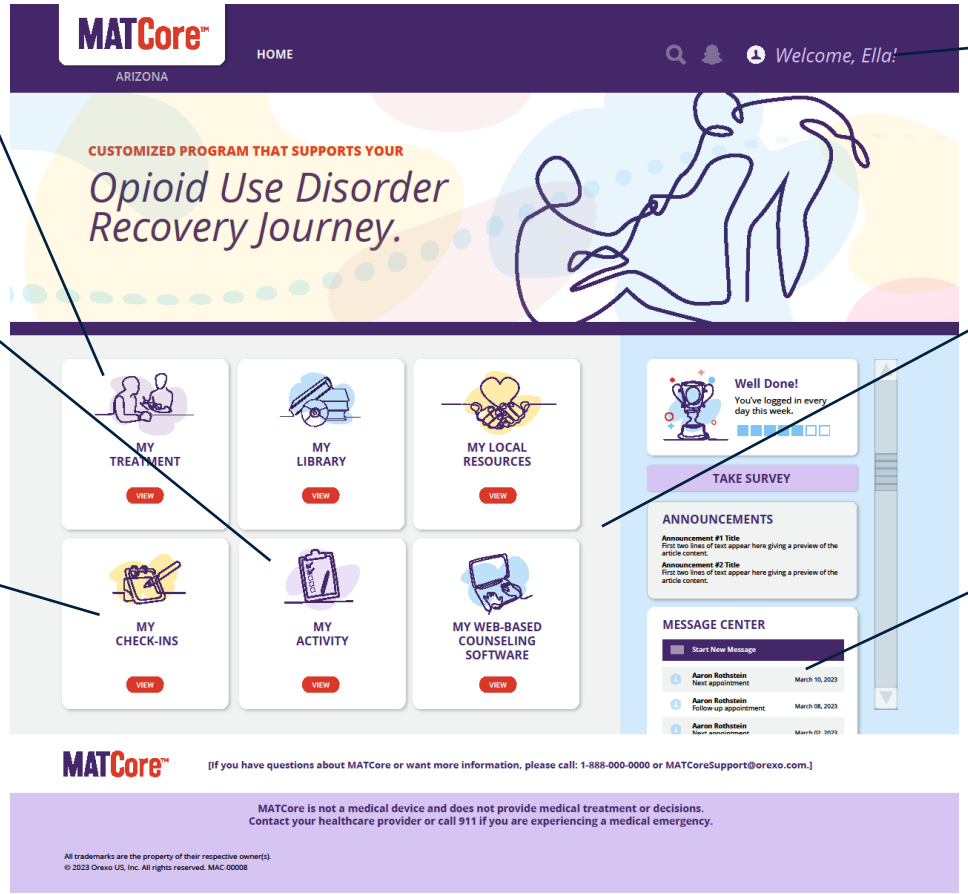
First steps taken to test MATCore™ concept in Arizona and first income recognized

Illustrative and not final version

Access to MODIA® and medication

Monitor progress

Upcoming meetings with HCPs



Personalized portal

Access to providers and local support resources in AZ

Newsflow and access to HCP

MODIA® with continued high demand, but commercial launch delayed

MODIA® continues according to either through modiaONE™ trial program or as a part of a "billing tests"

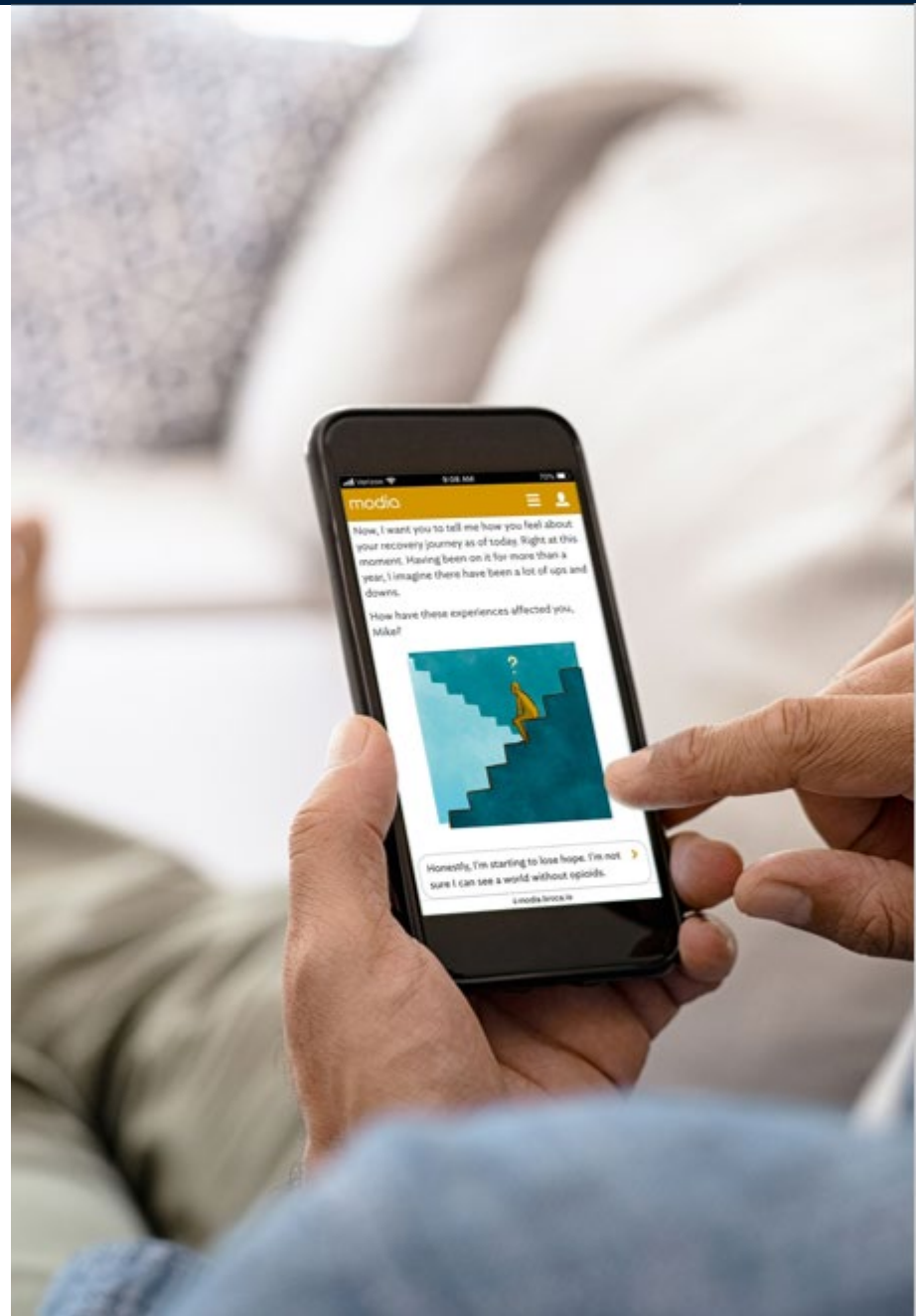
- Orexo has delayed move from "billing test" to invoice due to need for additional documentation on patient utilization
- MODIA® is included in the MATCore™ platform to be implemented in Arizona
- modiaONE™ program has been stopped during April to fully focus on commercial contracts

MODIA® trial completed with last patient out in April

- Trial involving 437 patients
- Primary endpoint is reduction in illicit drug use
- Final results expected in Q3 and if successful will trigger a 510k application

Main competitor, Pear Therapeutics entered Chapter 11 procedure in April

- Lack of reimbursement and efficient distribution model claimed to be main hurdles for commercial success
- Orexo is investigating implications on MODIA® in terms of both learnings from failed efforts and business opportunities



Steady progress in VA, but Trinity Health is stalling

VA | U.S. Department of Veterans Affairs

- Working on ordering pathway for deprexis® within VA system
  - Work with NCOs (Network Contract Organizations) in selected regions to ensure deprexis is on Purchase Ordering system
  - Identifying which department will manage ordering process in each region
- Establish contacts with KOL(s) to create deprexis® demand
  - Work with VA peer counselor program
- Vorvida® registration under FDA Enforcement Discretion has enabled process to include vorvida® in agreement with the VA

TRINITY HEALTH

- Trinity Health is prioritizing move to new facilities in April before additional steps can be taken in the implementation
- Fragmented reimbursement and ordering process needs to be reconstructed
  - Reimbursement pathway works, but TH clinical staff find the process complex
- Continued support from top management and commitment to facilitate a restart after completion of move
  - Working with clinic managers to agree on implementation pathway

Consolidation of organization and review of reimbursement and ordering process has caused delay in implementation

Business update

Products under development

R&D – taking two steps forward and one step back

amorphOX® - a scalable drug delivery platform

- Feasibility studies with partners in biomolecules ongoing
- Successful feasibility study with US pharmaceutical company, now proceeding into additional in vivo testing

OX124 – overdose rescue medication based on amorphOX®

- Filing completed in February, but re-filing is needed due to issues with an outsourced secondary packaging
- New filing expected in Q3, subject to successful qualification of packaging equipment at the contract manufacturer
- Ordinary approval timeline of 10 month after filing, but recent approvals in the category has been up to 13 months

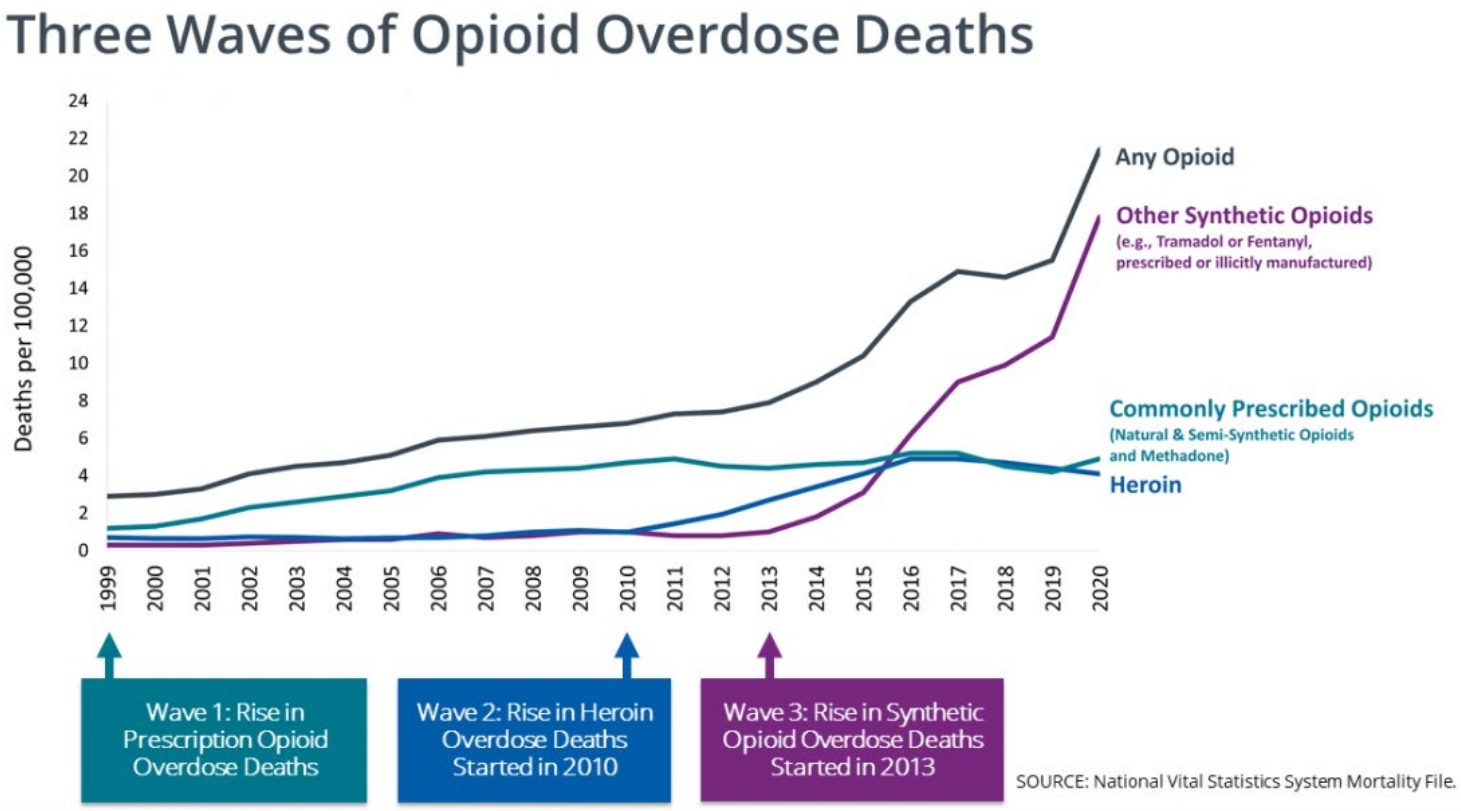
OX640 – adrenaline rescue medication based on amorphOX®

- Ongoing discussions with potential partners for co-development and commercialization
- Orexo proceed preparing manufacturing for pivotal trials

Note: product images are prototypes

Fentanyl and Covid-19 have propelled the acceleration of the Opioid Epidemic in the US

- The prevalence of highly potent, **synthetic opioids like fentanyl** has led to a significant increase in opioid-induced overdoses in the US
- The Covid-19 pandemic has affected the deadly epidemic even further leading to an **increase in reported 12-months opioid-induced overdoses from ~510k in Jan 2020 to ~81,000 in Jan 2022**



https://www.cdc.gov/opioids/basics/epidemic.html
https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

Naloxone OTC switch: Market development predictions

- NARCAN® (4mg naloxone) is the 1st ever rescue medication making an OTC switch in the US.
- The opioid crisis was declared a public health emergency (Opioid PHE) and the FDA has repeatedly asked for development / applications of OTC naloxone to combat the crisis.
- Naloxone is considered a safe rescue medication with minimal to zero abuse potential.

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

Out-of-pocket costs increase *if* OTC naloxone is **not longer reimbursed**: decreased spending power in vulnerable population

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

Naloxone-opioid co-prescr. requirements: As higher doses of opioids require higher doses of naloxone → pot. increased high dose naloxone products usage

Market division into high dose Rx vs. Low dose OTC market and most likely resulting in different sales channels and price

THN: Take-Home-Naloxone
HDN: High-Dose Naloxone

High-dose alternatives such as OX124 may be required to adress overdoses with synthetic opioids

- Synthetic opioids like fentanyl are present in almost 90% of all opioid-involved overdoses in the US today
- A recent study has shown that **brain damage and death occur within 6 min** of an opioid overdose.[1]
- Simulations of fentanyl overdoses suggest that **current standard dose may be inadequate for a rapid, successful reversal**.
- **43-83% of lay people administer more than 1 dose of 4mg naloxone**.[2]
- **90%** of laypeople that have administered Narcan in the last year **worry that 1 box is not enough**. 86% reported more confidence in 8mg.[2]

1: PLOS ONE, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0234683#pone-0234683-t001
2: Pubmed, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9122081/

Financial & legal overview

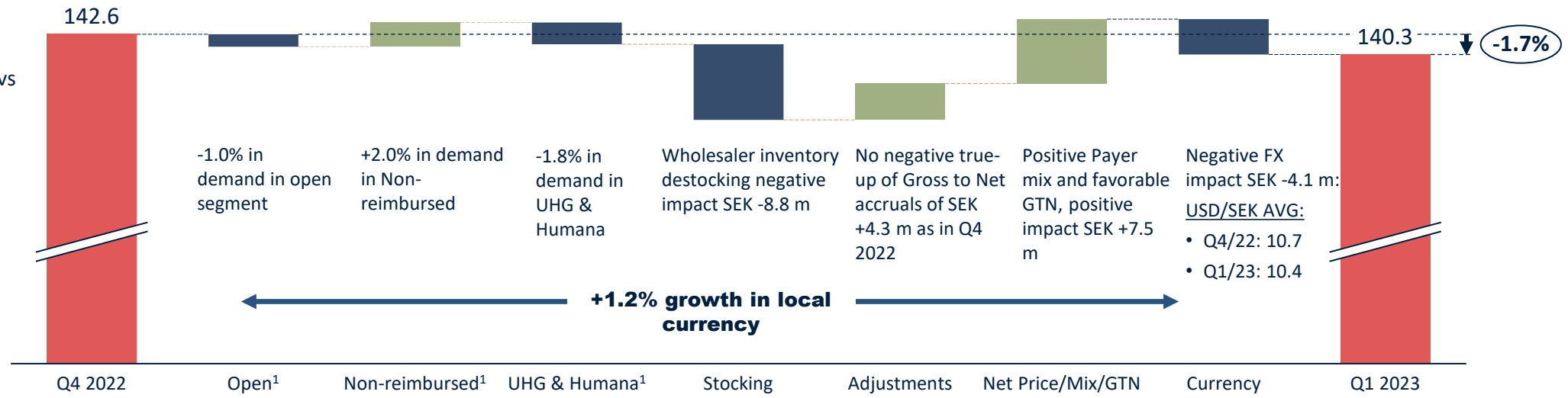
ZUBSOLV® net revenue grew 1% in Q1

Net revenue per segment SEK m	Q1 2023	Q1 2022	Jan – Dec 2022
ZUBSOLV® US	140.3	139.1	571.4
US Pharma – Total	**140.3**	**139.1**	**571.4**
DTx	0.0	0.2	0.4
DTx – Total	**0.0**	**0.2**	**0.4**
Abstral® royalties	6.2	12.4	30.4
Edluar® royalties	1.3	3.2	10.4
ZUBSOLV® – ex US	10.9	4.6	11.8
HQ & Pipeline – Total	**18.5**	**20.1**	**52.6**
TOTAL	**158.8**	**159.4**	**624.3**

Comments Q1

- ✓ ZUBSOLV® Net revenue grew YoY with 0,9 % primarily due to stronger USD vs SEK US impact of SEK 14.1 m
- ✓ Partly offset by lower demand and Gross to Net items - wholesaler destocking and absence of positive return adjustment

US Pharma net revenue Q123 vs Q422



[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

Continued strong EBIT contribution from US Pharma

Income statement SEK m	Q1 2023	Q1 2022	Jan – Dec 2022
Net revenues	158.8	159.4	624.3
Cost of goods sold (COGS)	-28.7	-27.5	-102.6
Gross Profit	**130.1**	**131.9**	**521.7**
Operating Costs	**-189.4**	**-145.1**	**-705.6**
EBIT	**-59.3**	**-13.2**	**-183.9**
Net financial items	-9.1	-1.9	13.5
EBT	**-68.5**	**-15.1**	**-170.4**
Tax	4.6	-8.5	-7.2
Net profit/loss	**-63.9**	**-23.6**	**-177.6**
EBITDA	**-41.1**	**2.8**	**-115.2**

Comments Q1

COGS in line with 2022, despite short term high COGS for supply to Europe, compensated by positive variance in US supply

OPEX higher mainly due to the increase in non-repeating expenses

- Higher expenses for IP litigation and subpoena
- Significant reduction in direct DTx expenses
- Negative impact from stronger USD

ZUBSOLV® US EBIT contribution of SEK 74 m (84)

- EBIT Margin for the quarter 53% (60%)

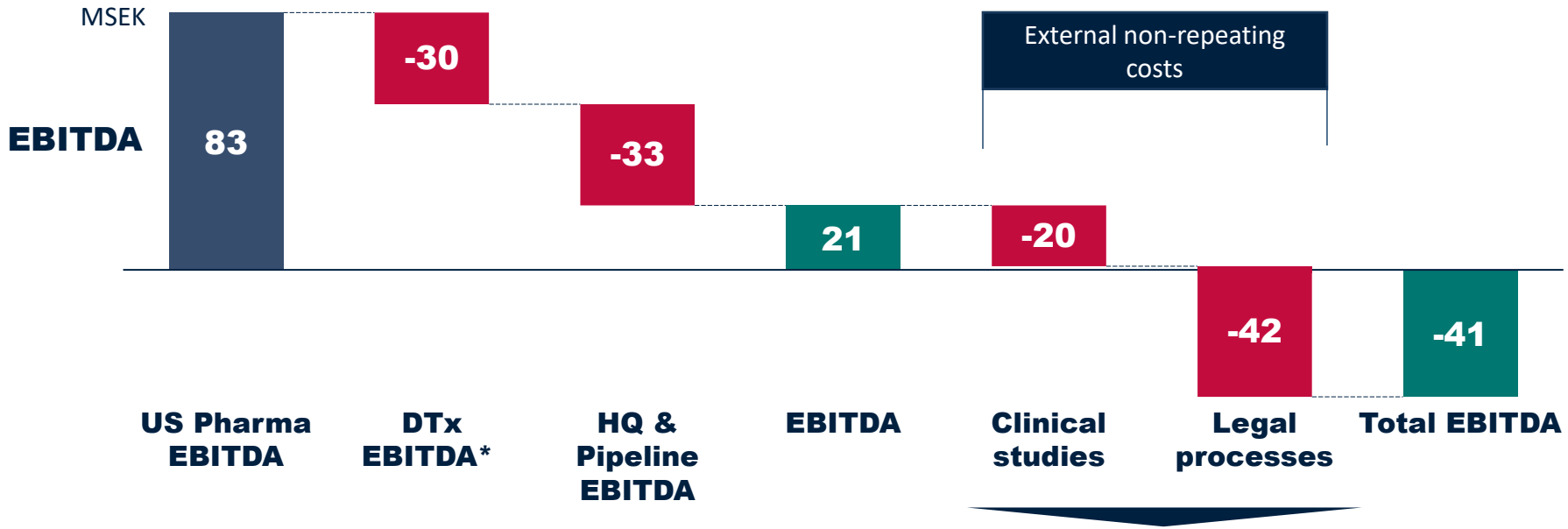
EBITDA of SEK -41 m (3)

- Exclusion of costs for legal processes and external non-repeating costs for clinical studies, would result in an EBITDA of SEK 21 m (32) for Q1.
- Minimal negative impact from currency of SEK 0.2 m

NET FINANCIAL ITEMS of SEK -9 m (-2)

- Negative unrealized exchange rate impact of SEK -1.5 m (4.0) derived from the parent company's foreign currency bank accounts mainly in USD
- Higher interest rate for corporate bonds of SEK -8.0 m (-4.7).
- Partly offset by interest income of SEK 1.6 m (-) from short-term cash investments.

Q1 EBITDA positive excluding external non-repeating costs



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

* DTx EBITDA including internal allocations from US Pharma

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

Cash Flow SEK m	Q1 2023	Q1 2022	Jan – Dec 2022
Cash flow from operating activities	-61.6	-61.6	-156.6
Investment activities	83.1	-5.6	-234.7
Financing activities	-7.8	-5.3	-21.4
Cash flow (excl. exchange rate differences)	13.7	72.5	-412.8
Add back short-term investments	136.5	—	219.6
Liquid funds	**278.9**	**437.8**	**351.9**
Net cash position including short-term investments	-210.2	-55.2	-142.9

Comments Q1

- ✓ Liquid funds (SEK 279 m) decreased with SEK 73 m from Q4 2022 (SEK 352 m)
  - ✓ SEK 62 m negative contribution from operating activities mainly due to negative operating earnings and negative changes in working capital
  - ✓ Investment activities had a positive impact of SEK 83 m on cash flow primarily from net effect of short-term investments
  - ✓ Financing activities had a negative impact of SEK 8 m on cash flow primarily from buy back of the corporate bond with nominal value of SEK 6.25 m
- ✓ Out of the total liquid funds, invested surplus cash in certificates of deposits and in US treasuries, i.e. short-term investments, amounted to SEK 137 m end of Q1.

Financial outlook

Metric	Outlook 2023	Reaffirmed/revised
Key market development	The buprenorphine/naloxone market will grow 4-7 percent, based on current growth trajectory. The new legislation, effective January 1, 2023, will have a positive effect over time, but due to uncertainty related to timeline of the implementation its impact on market growth in 2023 is excluded.	Reaffirmed
Lead product net sales	Group revenues will increase, ZUBSOLV® US net sales in line with 2022	Reaffirmed
Group OPEX	OPEX H1 2023, slightly higher than H2 2022 (SEK 385 m), but H2 2023 will decline versus the same comparison period	Reaffirmed
Group EBITDA	EBITDA will reach balance in H2	Reaffirmed

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.

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

US authorities' investigation with regards to ZUBSOLV® promotion

- ✓ In Q1 2023 additional information have been shared at the request of the authorities
- ✓ Orexo continues to cooperate with the authorities and provide the requested documentation related to the promotion of ZUBSOLV®

Future value drivers

Focusing operations on Orexo's strengths

A successful drug delivery company

Developed four commercial pharmaceuticals generating **> SEK 10 billion in global sales**

New **world leading nasal delivery technology** - amorphOX® is leading to a new wave of products

- OX124, OX125, OX640
- Patent and patent applications covering a broad range of molecules until 2039-2042

Commercial operations in the US since 2013 fighting the Opioid Use Disorder epidemic

Significant value contribution from ZUBSOLV®

- >SEK 4.7 billion in sales since launch
- Sales of SEK ~570 million 2022
- EBIT margin >50%

Pipeline of synergistic overdose rescue medications

- High dose naloxone - OX124
- Fast acting nalmefene - OX125

New complementary digital health solutions in OUD

- MODIA® a digital therapy for OUD
- MATCore™ – combining medications and digital therapies

A track record of value creating partnerships

History of partnering with significant value contributions

- Royalties and milestones from partnership on sublingual platform **> SEK 2.3 billion**

Partner opportunities emerging

- OX640 (epinephrine)
- AmorphOX® technology in biomolecules

Several significant milestones near term

- ✓ **Corporate profitability** in sight[1]
  - Main current external cost drivers will diminish during H2 2023
  - Significant reduction in direct expenses for DTx
  - No new activity driving external expenses to be initiated without certainty of associated revenues
- ✓ **ZUBSOLV® sales** stabilized and opportunities to grow
  - Settlements providing approx. USD 54 billions announced
  - New legislation open up for all physician's to prescribe ZUBSOLV®
- ✓ **R&D pipeline** is expected to result in revenue generating partnerships in 2023
  - OX640 and amorphOX® partnering discussions on-going
  - New OX124 filing with the FDA in Q3 2023
- ✓ **DTx making progress**
  - VA and restart of Trinity Health implementation
  - MODIA® study result during the summer
  - MATCore® implementation in Arizona and potentially additional states
- ✓ **Decision in SUN IP litigation during the summer of 2023**

[1] Assuming no unexpected events outside the control of Orexo e.g. legal expenses associated with the government investigation or new IP litigations

Thanks

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