#### Q1 2022 INTERIM REPORT

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## **Promising start to 2022**

April 28<sup>th</sup> 2022

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



### **Agenda &** presenters Q1 2022 **Interim Report**

3 2 4 Q1 Key **Business update Financial** Future value drivers achievements overview • US Pharma • Pipeline & HQ • Financial development • Digital Therapeutics

- Legal Update
- Outlook

Joseph DeFeo, EVP & **Chief Financial Officer** 

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## Q1 Key achievements

### **Making progress – key business achievements**



#### HQ & Pipeline

 $\checkmark$ 

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- OX124 approaching NDA filing with FDA expected Q4
- OX640 on track to initiate 1<sup>st</sup>
   human trial starting Q3 and
   continued improving stability
- First shipment of ZUBSOLV<sup>®</sup> EU to Accord Healthcare



#### **US Pharma**

- JZUBSOLV® reimbursed by NY<br/>Medicaid as of March 22
- Access to the fastest growing Public segment increased, from 42% in Q4 to 48%
- modia<sup>™</sup> enable our sales force to improve quality and length of sales calls with ZUBSOLV<sup>®</sup> customers



#### **Digital Therapeutics**



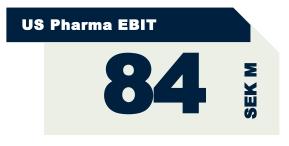
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- Continued, but slow, progress in prioritized accounts
- Monitoring & adaption to increased legislative reimbursement actions
- 250 modiaONE patients since start in late February and total DTx users now exceed 1,800

## Making progress – key financial achievements

- Revenues grew across the line of all drugs, supported by FX tailwinds
   & favorable price development
- ✓ Good cost control and increased synergies between US Pharma & DTx
- Improved profitability led by US Pharma and increased revenues from partners
- ✓ Continued solid cash position, SEK 438 m with negative cash flow primarily from changes in working capital
- ✓ 2022 outlook updated, incl. lower FY OPEX

## Group revenues A





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## Business update US Pharma

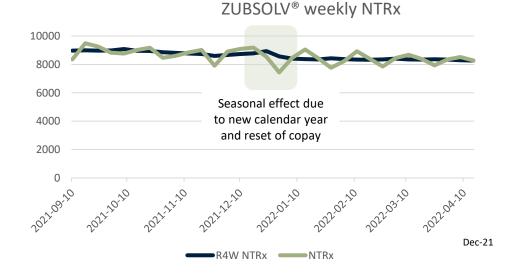
## ZUBSOLV® new market access agreement in NY Medicaid

#### **Operational update**

- ✓ ZUBSOLV<sup>®</sup> added to preferred NY Medicaid formulary from March 22<sup>nd</sup> increasing access in public segment to 48%
- ✓ Commercial market share in NY in Q1 was 10.2%<sup>1</sup> compared to Medicaid with ~0.5%
- Increased investment in FF from April in NY
- ✓ Field force continue with MODIA<sup>™</sup> awareness campaign and initiated modiaONE trial campaign to ZUBSOLV<sup>®</sup> customers in February
- Continued limitations in access to physicans compared with pre-covid levels

#### High level comments to demand

- Demand declined with 3.6%<sup>2</sup> QoQ, with nearly all decline during the first weeks of 2022
- Commercial segment and UHG & Humana in particular continues to impact overall demand negatively
- Several growing accounts in Q1 e.g. Caremark (5%), Ascent Medicare (ESI & Cigna) (11%), Kentucky (5%)



<sup>1</sup> Includes UHG and Humana, 7.2% marketshare if these are excluded

<sup>2</sup> Weekly trend, decline is 5% when including impact from two less calendar days in Q1 compared to Q4

### Multiple drivers for future growth

### 6% total market growth YoY, but slight negative development QoQ

Q1 seasonal effect due to reset of co-pay and fewer calendar days



Volume sales, quarterly NTRx

## 1

Covid-19 effects likely to diminish improving patient access to care and Q2-Q4 historically with improving growth rates Multiple comprehensive activities on-going on federal and state levels to enable more patients access to treatment

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Improved market access for ZUBSOLV<sup>®</sup> with Public access increasing to 48%(42%) and a slight decrease in Commercial at 98% (99%) The launch of MODIA<sup>™</sup> will

open up new market segments and is highly complementary to ZUBSOLV<sup>®</sup>

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## Business update HQ & Pipeline

## An exciting pipeline materializing....

#### **Opioid overdose rescue medication, OX124 and OX125**

- Significant health issue in the US with >105.000 deaths from overdose last 12 months
- Current US market exceeding 400 MUSD
- OX124 clinically differentiated to market leader and Gx of market leader
- OX124 on track to be filed with FDA H2 2022

#### **Emergency treatment of allergic reactions, OX640**

• >2 BUSD global market and growing

<sup>1</sup> Based on publicly available data

- Market dominated by expensive auto-injectors like EpiPen<sup>®</sup>
- OX640 with excellent stability data compared to all other products<sup>1</sup>
- First clinical trial on track to be initiated in Q3 2022



## **....latest with OX-MPI granted orphan drug designation**

#### Systemic sclerosis, OX-MPI (GS-248)

- 2.5 million patients globally lacking access to effective treatment
- OX-MPI(GS-248) granted orphan drug status for treatment of systemic sclerosis
- Phase II clinical trial expected to finalize during 2022
- Gesynta Pharma acquired all rights to the project in 2017, but Orexo maintain right to a tiered double digit share of future revenues<sup>1</sup>



## OX124 – continue to progress towards planned filing with the FDA H2 2022



- Commercial supply chain established
- 12-month stability study initiated
- Pivotal study

Positive outcome from pivotal trial – study met primary endpoints



- Based on the novel proprietary powder technology 4-period cross-over, comparative bioavailability study
- Showed a significantly faster & higher absorption of naloxone vs intramuscular dosing with a injection reference product

- Stability study finalized (H2)
- Filing New Drug Application with FDA (H2)



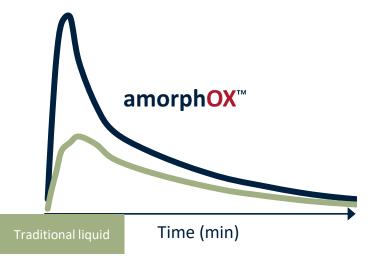
US launch late H2



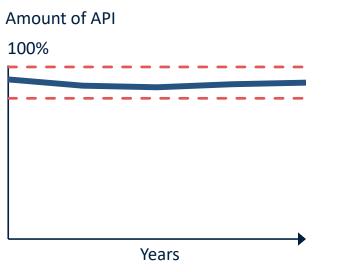
## Orexo internal platform building on the amorphOX<sup>™</sup> technology

 Superior pharmacokinetic properties with more rapid onset, higher peak and overall exposure, lower variability

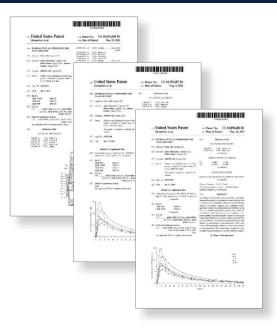
Plasma concentration from clinical trial



 Excellent stability even under accelerated conditions and proven to work on a broad scope of API's



 Three granted US patents and several patent applications have been filed with potential protection until 2042



#### Q1 2022 INTERIM REPORT

#### DTx in brief

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- ✓ Subsection of digital health
- Evidence-based therapeutic intervention
- Prevent, manage, or treat a medical disorder or disease
- Particularly applicable in the mental illness & addiction space
- Standalone or along with pharma treatment
- ✓ Available 24/7

#### TORVEDA Letters" Lotants" Great to have you here! The goal of this program is simple to support you in your efforts to reduce you chrolog. More go long, we'll chat shout valous tried-and tested suchriques and methods, which can help you ming your like new without alcohol. Before we get started, let's take a look at your current einsing habits. How did you do getterday, Mikania, did you divis alcoholi Let's get started with our daily alcohol derek.

## Business update Digital Therapeutics (DTx)

### Good progress on federal level to improve access and reimbursement of DTx

Remote Therapeutic monitoring code and CPT code Q4 2021

- Code enabling reimbursement of certain DTx allowing remote monitoring of patients
- Approved for reimbursement by CMS (Medicaid and Medicare)
- Implementation January 2023

Healthcare Common Procedure Coding System (HCPCS)

Q1 2022

- HCPCS code enable reimbursement of FDA cleared prescription digital therapies (510K approved)
- HCPCS code is available now, but require reimbursement decisions by individual insurance companies
- Relevant for modia<sup>™</sup> when 510K approval is obtained

The Access to Prescription Digital Therapeutics Act

Q1 2022

- Bi-partisan proposed bill introduced to both chambers of the US congress
- If receiving sufficient support the bill will enable coverage of prescription digital therapeutics (510K approved) for Medicare and Medicaid patients
- Relevant for modia<sup>™</sup> when 510K approval is obtained

### Orexo has worked intensively to gain awareness and experience from physians, clinic staff and patients of our DTx

>1800 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<sup>®</sup> or DEPREXIS<sup>®</sup>

>500 users of modia<sup>™</sup> through modiaONE and clinical trial

- >250 users of modia from OUD clinics in the modiaONE program since launch in late February
- 268 enrolled patients in modia clinical trial



### **DTx establishing a platform for commercial success**

## 2021

- Developing proprietary backoffice system to manage reimbursement and payment processes
- ✓ Initiating modia™ clinical trial
- Partnering with Trinity Health (ND) to develop treatment program and reimbursement pathways
- ➤ Unsuccessful test of direct to consumer marketing in social media
- Individual clinics found reimbursement pathways too complex

- Work with federal initiatives to expand access to digital therapies
- Continue to work with Trinity Health (ND) to address administrative hurdles
- Expand customer pipeline of health distribution networks and payers
- ✓ Initiate modiaONE and modia™ awareness campaign explaining majority of OPEX
- All direct to consumer promotion stopped and reduction in admin support

## Q2

- First commercial patients processed by Trinity Health (ND)
- Leverage Trinity Health treatment programs and reimbursement model to onboard more customers
- Continue the effort to secure feasible reimbursement pathways
- Work with selected OUD clinics to test reimbursement model for modia<sup>™</sup>
- Continue to develop collaboration with Sober Grid, Justmiine and E-HBS

## H2

- Pull-through customer partnerships with Trinity Health and other new customers i.e. local promotion
- Expand pipeline of customers
- Continued focus on evolving and broadening of reimbursement pathways
- Finalization of modia<sup>™</sup> trial

## Financial & legal

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VORV/DA That's hard, but it's good to recognize this. So, we've already gone through a ton ~ your drinking behavior, the pros and consult drinking some of the possible consequences of excessive alcohol consumption, Now all of that leads to our next big questions: What obstacles might you face if

..... 4

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## **ZUBSOLV®** sales grew 9.7 percent YoY

Net revenues per segment SEK m	Q1 2022	Q1 2021	Jan - Dec 2021	Comments	
ZUBSOLV <sup>®</sup> US	139.1	126.8	522.7	✓ ZUBSOLV <sup>®</sup> Net sales grew YoY with	
US Pharma – Total	139.1	126.8	522.7	-	
DTx	0.2	0.2	1.1	9.7% primarily due to positive	
DTx — Total	0.2	0.2	1.1	payer mix and favorable GTN	
Abstral <sup>®</sup> royalties	12.4	2.7	32.1	supported by FX	
Edluar <sup>®</sup> royalties	3.2	2.6	9.1	✓ First shipment to	
ZUBSOLV <sup>®</sup> – ex US	4.6	_	-	Accord Healthcare	
HQ & Pipeline – Total	20.1	5.3	41.2	Accord Healthcare	
TOTAL	159.4	132.3	565.0		
				139.1	
133.6 Pharma					4.1%
revenue					
22 vs Q421					
-3.4% in	-0.5% in demand	-2.5% in Higher who		Payer mix and Positive FX	
demand i	-	demand in inventory	adjustment,	favorable GTN, impact:	
segment	reimbursed	UHG & destocking Humana 3.8 million		impact SEK 6.3 USD/SEK AVG:	
		5.0 [[]]]U		• Q4/21: 8.9	
←		-1.6% growth in currency	local	• Q1/22: 9.4	
Q4 2021 Open	<sup>1</sup> Non-reimbursed <sup>1</sup> U	IHG & Humana <sup>1</sup> Stocking	g Adjustments Ne	t Price/Mix/GTN FX Q1 2022	_

<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

### **Investing in future growth drivers**

Income statement SEK m	Q1 2022	Q1 2021	Jan - Dec 2021
Net revenues	159.4	132.3	565.0
Cost of goods sold (COGS)	-27.5	-19.2	-78.9
Gross Profit	131.9	113.1	486.1
Selling expenses	-41.6	-68.7	-280.4
Administrative expenses	-33.0	-28.6	-151.5
Research & development expenses	-72.0	-55.6	-272.3
Other operating income & expenses	1.5	3.0	4.0
Operating Costs	-145.1	-149.9	-700.2
EBIT	-13.2	-36.8	-214.1
Net financial items	-1.9	4.7	-8.4
EBT	-15.1	-32.1	-222.5
Тах	-8.5	0.6	-1.0
Net profit/loss	-23.6	-31.5	-223.5
EBITDA	2.8	-23.9	-161.0

	Comments
.0	
.9	ZUBSOLV <sup>®</sup> COGS higher due to a negative FX impact
.1 .4 .5 .3	<ul> <li>OPEX lower due to</li> <li>decreased selling expenses in US Pharma &amp; in DTx</li> <li>lower legal expenses</li> <li>above partly offset by costs for MODIA<sup>™</sup> study &amp; OX124 development</li> </ul>
.2	ZUBSOLV <sup>®</sup> US EBIT contribution of USD 8.9 m (7.9)
.4 .5 .0 .5 .0	<ul> <li>EBIT Margin of 60.4% (52.2%) supported by increased allocation of resources to DTx for MODIA<sup>™</sup></li> </ul>

### **Cash flow from operating activities**

Cash Flow SEK m	Q1 2022	Q4 2021	Q1 2021	Jan - Dec 2021	Comments Q1 2022
Operating earnings	-13.2	-64.1	-36.8	-214.1	✓ SEK 22.8 m negative contribution from operating
Interest received	0.0	0.0	0.0	0.0	activities before changes in working capital
Interest paid	-4.7	-4.9	-8.5	-22.9	✓ Changes in working capital had a negative impact of SEK
Income taxes paid	1.9	5.1	-1.8	8.2	38.8 m primarily due to increased A/R explained by
Adjustment for non-cash items	-6.8	26.4	-34.7	-16.8	later timing of sales to wholesalers and by decreased
Cash flow from operating activities before change in working capital	-22.8	-37.5	-81.7	-245.5	current liabilities explained by timing in payment of rebates and to lesser degree by annual bonus pay-out
Change in inventories	19.3	4.5	7.1	27.8	primarily in the US. This was partly offset by decreased inventories.
Change in receivables	-22.2	-46.1	46.2	-21.8	inventories.
Change in current liabilities	-35.9	-1.5	-19.4	10.6	
Change in working capital	-38.8	-43.1	33.9	16.5	
Cash Flow from operating activities	-61.6	-80.6	-47.8	-229.0	

### Legal update – no changes during Q1

ZUBSOLV<sup>®</sup> patent dispute vs Sun Therapueutics

#### Subpoena with regards to ZUBSOLV®

No changes in Q1

- ✓ 9 patents listed in the Orange Book
- ✓ Expiring dates Dec 2027
   Sep 2032
- Previously successfully managed to defend ZUBSOLV<sup>®</sup> IP rights in the US appeal court

#### No changes in Q1

- ✓ Very limited activities in Q1
- No additional information received since issuance of subpoena July 2020

## Updated financial outlook

Based on USD/SEK exchange rate as of March 2022

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	ZUBSOLV <sup>®</sup> net sales <b>in USD</b> will decline slightly in H1 2022 vs H2 2021. In H2 ZUBSOLV <sup>®</sup> net sales <b>in USD</b> will increase comparing to H1.	Revised
Group OPEX	OPEX will <b>decline from 2021 to 650-700 MSEK</b> with the current business plans and activity level in legal processes	Revised
US Pharma EBIT	US Pharma EBIT will exceed 50% on a full year basis	Reaffirmed

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# Future value drivers

#### OTEXO Q1 2022 INTERIM REPORT • FUTURE VALUE DRIVERS

## Why Orexo?

Profitable US Pharma	Unique pharmaceutical pipeline and technology	Pioneer in digital therapies
<ul> <li>SEK 84 m in EBIT contribution Q1 and 42 quarters left to patent expires for ZUBSOLV®</li> <li>Significantly strengthened market access last 12 month despite Gx competition</li> <li>Outstanding performance in securing market access in low priced Gx market, which is key to all future product launches</li> </ul>	<ul> <li>✓ Developed an entirely new and unique drug delivery technology, amorphOX™ attracting interest from leading biotech companies</li> <li>✓ OX124, with a clearly differentiated profile to market leader in &gt;440 MUSD opioid overdose rescue medication market</li> <li>✓ OX640 with a superior stability to any other epinephrine product<sup>1</sup> and soon clinical data</li> <li>✓ Patent protection of amorphOX<sup>™</sup> covering</li> </ul>	<ul> <li>Digital health market is in it's early stages, but significant progress in establishing reimbursement</li> <li>Established a proprietary technical infrastructure to manage reimbursement processes in the US for DTx</li> <li>Excellent customer feedback from the &gt;1800 initial users of our DTx</li> <li>Intimate partnership with large healthcare provider to develop treatment program and reimbursement pathways</li> </ul>

multiple other APIs

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## Several exciting milestones in 2022/2023

#### ✓ ZUBSOLV<sup>®</sup> launch in Europe

H1

- DTx partnering progression
- First DTx sales through Trinity Health and other large health care providers
- DTx sales progression expected in Q2

- OX124 filing of a new drug application with FDA
- OX640 first human exploratory trial

H2

- MODIA<sup>™</sup> commercial launch
- DTx partnering and sales progression
- ZUBSOLV<sup>®</sup> market access development in the US
- ZUBSOLV<sup>®</sup> sales progression in Europe

• MODIA<sup>™</sup> trial results in H1

2023

- Patent litigation trial in the District Court of NJ for ZUBSOLV<sup>®</sup> in H1
- Approval and launch of OX124 H2
- New projects based on the amorphOX<sup>™</sup> platform

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Headquarter Sweden, Orexo AB, P.O. Box 303, 751 05 Uppsala, Sweden, E-mail: info@orexo.com, Phone: +46 (0)18 780 88 00 Subsidiary US, Orexo US Inc. 150 Headquarters Plaza East Tower Morristown, New Jersey 07960 United States E-mail: infous@orexo.com, Phone: +1 (0)855 982 7658