

# Agenda & presenters Q3 2021



Q3 Key achievements

2

Business update

- US Pharma
- Digital Therapeutics
- Pipeline & HQ

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Financial overview

- Financial development
- Outlook
- Legal update

4

Future value drivers

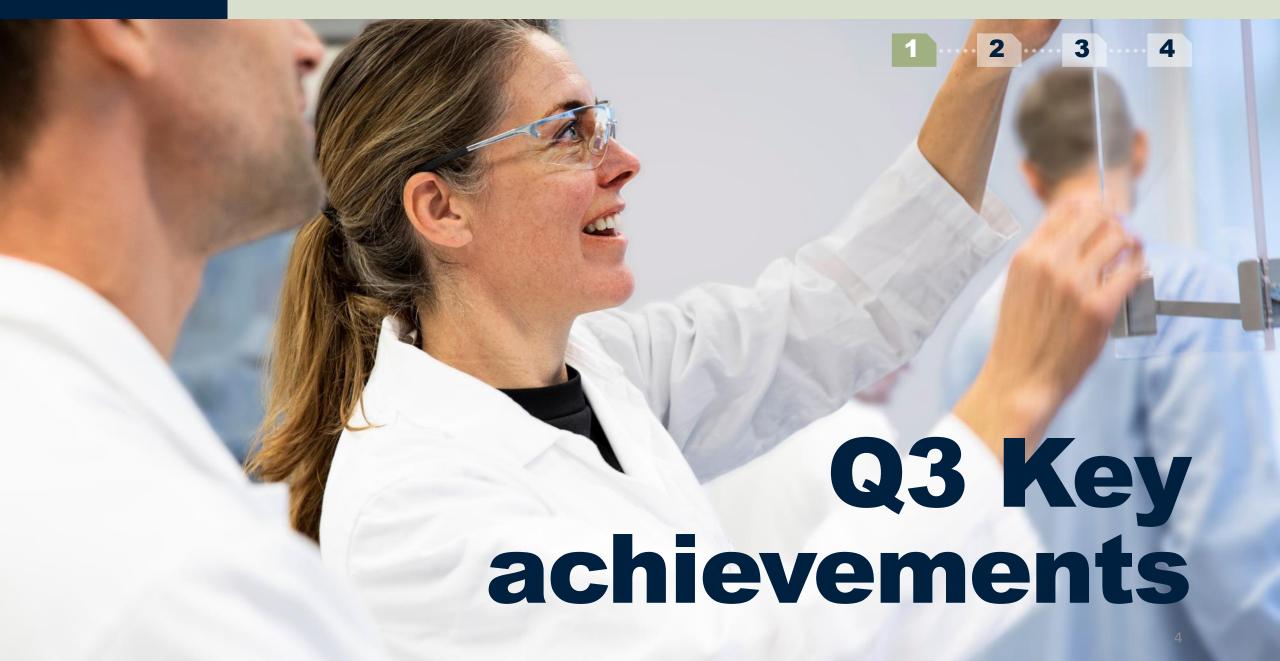






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# Steady progression on our journey to build a broader and stronger Orexo

- ✓ ZUBSOLV® returned to revenue and profit growth from Q2
- ✓ DTx commercial partnership signed with Benefis Health System, Justmine and Sober Grid
- ✓ DTx commercialization strategy will increase its focus on the B2B segment
- ✓ OX124, a rescue medication for overdoses, entered a pivotal bridging study. US launch expected in 2023
- ✓ New R&D technology platform emerging, details to be communicated shortly





#### **Group cash position**

**588** ½



# Stable development in Q3 when impact from formulary changes in 2019 decelerated

#### **Operational update**

- ✓ Overall market access improved especially in Medicaid
- ✓ ZUBSOLV®
  reimbursed by
  Kentucky Medicaid
  as of 7.1.2021
- ✓ Field force will start promotion of modia™ and Zubsolv® from November
- ✓ Sales force access to prescribers continues to improve, but not yet on pre-Covid levels

#### **Development NTRx QoQ**

Overall -2%

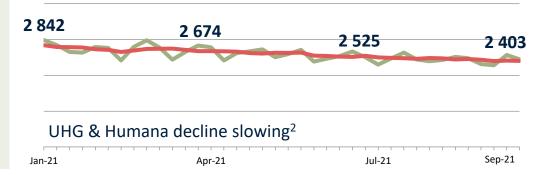
Open segment<sup>1</sup> 0%

UHG & Humana -4%

Non-reimbursed -1%

#### High level comments +/-

- + 85% growth in Kentucky during Q3
- + Good QoQ growth in several Medicaid accounts
- + YoY growth in large PBMs (CVS, ESI)
- Continued slow market growth especially in commercial segment



<sup>&</sup>lt;sup>1</sup> Where ZUBSOLV® is reimbursed and competes on equal terms with both branded products and/or generics

<sup>&</sup>lt;sup>2</sup> R4W Average NTRx in Bold Color; Single Week NTRx in Lighter Shade. Period 01.08.21-09.24.21

## Multiple drivers for future growth

#### 6% total market growth Q321 vs Q320

Driven primarly by Public payer segment, although the growth is lower than recent years, and Commercial payer segment also contributing



Market volume sales development<sup>1</sup>

1

Covid-19 effects likely to diminish improving patient access to care and Orexo access to customers

2

Multiple comprehensive activities on-going on federal and state levels will increase access to treatment

3

Overall improved market access for Zubsolv with Public payer access improving from 34% to 42% and Commercial declining slightly from 99% to 98%

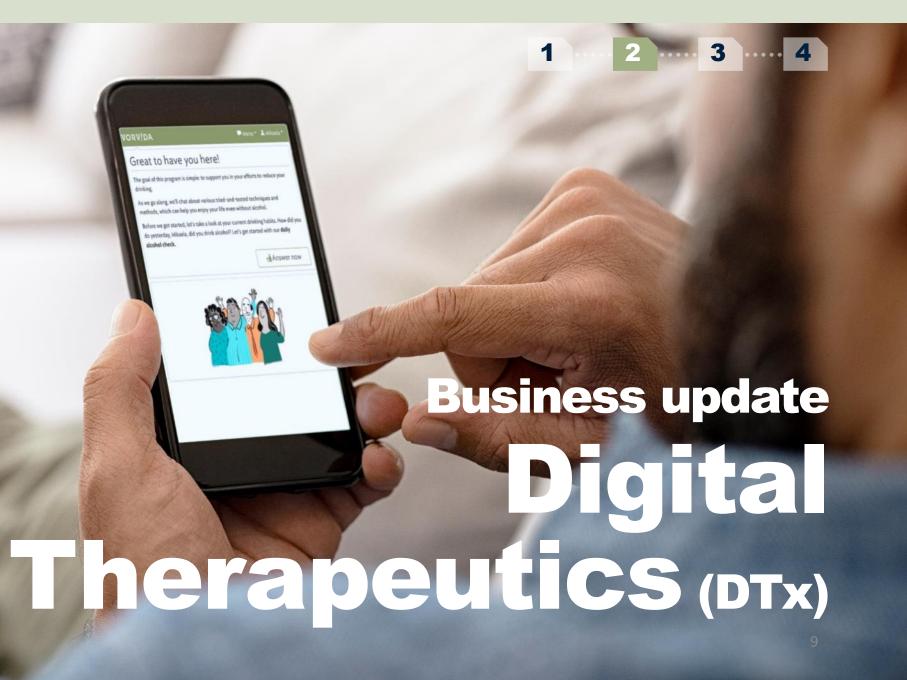
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The launch of MODIA™ as a treatment compliment to ZUBSOLV® will open up for new sales routes and market segments

<sup>&</sup>lt;sup>1</sup> Volume sales, quarterly NTRx

#### DTx in brief

- ✓ 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



## 21.3 BUSD invested in digital health YTD 2021<sup>1</sup>

"In sum, it is not hard to imagine the emergence of a very different healthcare system powered by digital technologies within ten years."

The promise of digital therapeutics, McKinsey &Co

Despite significant lobbying efforts from DTx manufacturers, the Centers for Medicaid and Medicaid Services (CMS) has not yet issued clear guidance for reimbursement of DTx.

Characteristics and challenges of the clinical pipeline of digital therapeutics, NPJ Digital Medicine article 159 (2020)



## Strong underlying trends will force the DTx market to gain traction

#### Healthcare systems challenged

treatments with access 24/7.

Aging population and sky-rocketing costs are forcing the healthcare providers to rethink how to deliver healthcare to increase efficiency and value.

Consumers (patients) in the center
Patients want to be seen as consumers
and requires holistic and customized



#### Widespread technology acceptance

Covid-19 has further pushed forward the ongoing tech revolution and the use of telemedicine is pervasive.

#### Value-based care

Providers will be rewarded based on the ability to add patient value. Analyzing RWE data pave the way for efficient allocation of resources.

# Orexo is at the leading edge of digitalization in the pursuit to take DTx from its infancy to become a natural part of healthcare

"In less than a decade, DTx companies have completely disrupted the healthcare scene for the better."

The Future of Digital Therapeutics and The Impact On Care, The Linus Group, May 2021

- ✓ Establishing Reimbursement

  Orexo working in tight collaboration
  with world leaders in digital health to
  make DTx accessible to all patients.

  However, universal reimbursement
  processes still to be established
- ✓ **Disruptive technology**Through pilot programs, trials and real world evidence collection, Orexo is working with payers and leading healthcare organizations to build confidence in the value of our DTx to healthcare.

### At the forefront of addressing hurdles for reimbursement and commercial sales

#### **Reimbursement Route**

The Prescription Model

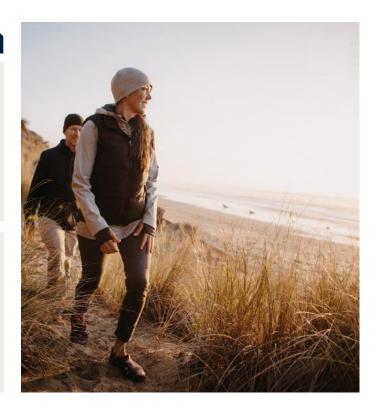
The Medical Benefit Model

#### Requirement

- FDA approval as a prescription digital therapy (PDT)
- Pharmacy benefit coverage pathway
- HCPs integrate DTx in treatment programs
- CPT codes defined by AMA/CMS

#### **Orexo's Activities**

- ✓ Active member in the DTx alliance to enable change in Washington
- ✓ Randomized clinical trial for modia underway, early market entry via FDA EUA
- ✓ Partnership with IDNs such as Trinity Health, Benefis Health System
- ✓ Engagement of payers and generation of RWE e.g.
   Magellan



# Clinically proven DTx in collaboration with GAIA AG

Rooted in cognitive behavioral therapy techniques and based on AI technology offering a highly individualized intervention.

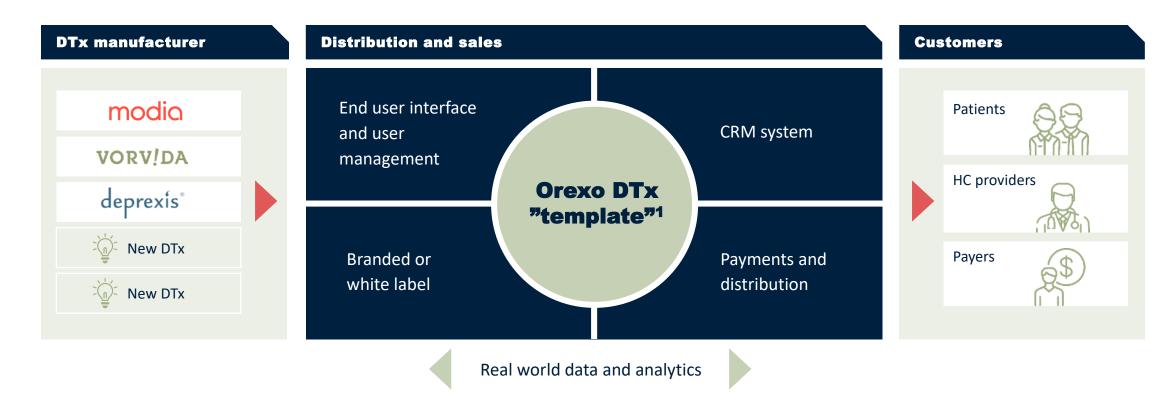
	modia	VORV!DA	deprexis
Instructions for use	Opioid dependence	Alcohol misuse	Depression
Clinical evidence <sup>1</sup>	Ongoing randomized clinical trial, 400 patients	Evaluated in 1 randomized clinical trial, > 600 patients	Evaluated in 13 randomized clinical trials, > 2.800 patients
Length of treatment	6 months	6 months	3 months
Treatment method	Along with current standard of care including medication	Standalone or as a complement to current standard of care	Standalone or as a complement to current standard of care
FDA clearance	Will apply for a 510 k clearance, meanwhile launched under FDA's Public Health Emergency Use Authorization (EUA)	FDA cleared under the Emergency Use Authorization	FDA cleared under the enforcement disctretion

<sup>&</sup>lt;sup>1</sup> View study results in Appendix

# Many affected and few are treated

	US Market	Patients in treatment	Potential USD net sales 5–10 yrs post launch
modia Opioid dependence	10m are misusing opioids	1.3m	~150-225 m
VORV!DA Alcohol misuse	17m heavy alcohol users	1.5m	~120-200 m
deprexis® Depression	20m  are suffering from at least one major depression annually	10m	>150-225 m

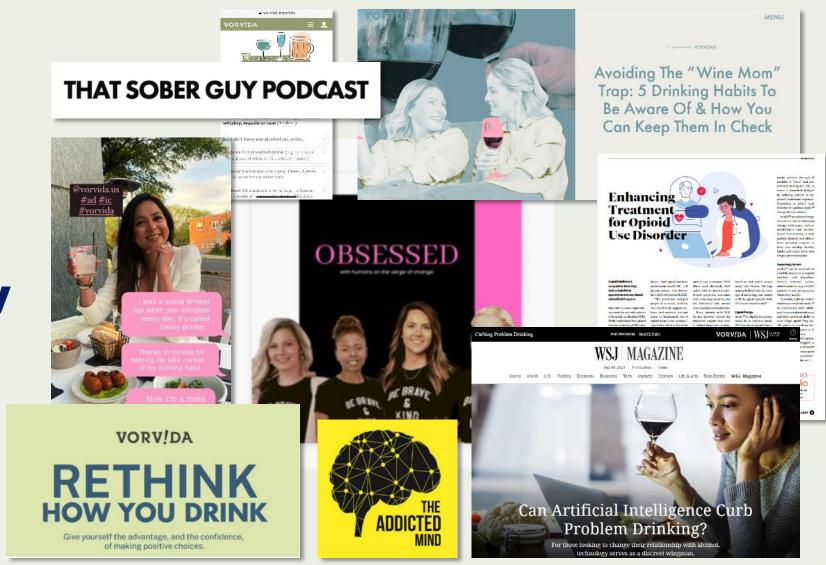
## A scalable full-service platform for bringing digital therapies to the US market



<sup>&</sup>lt;sup>1</sup> Developed for Orexo by Accenture on their INTIENT™ Platform, the solution is proprietary for Orexo.

# Marketing campaigns & PR activities to drive awareness and credibility

With improving access to healthcare providers, activities direct to consumers will be reduced from Q4 and beyond



# Partnering with health network systems and healthcare providers is expected to be the primary sales channel

#### **Examples of announced partnerships**



~3000 employees Serving residents in ND and Montana

- ✓ Magellan (RWE study)
- ✓ NYC clinic
- Mental health hospital in St Louis

#### New partnerships evolving in Q3



>300,000 users
The largest global social media network for people in recovery from addiction



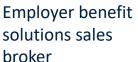
~3300 employees Serving residents in Montana

#### just **miine**

Telehealth and established clinic in Chicago

#### E-HBS

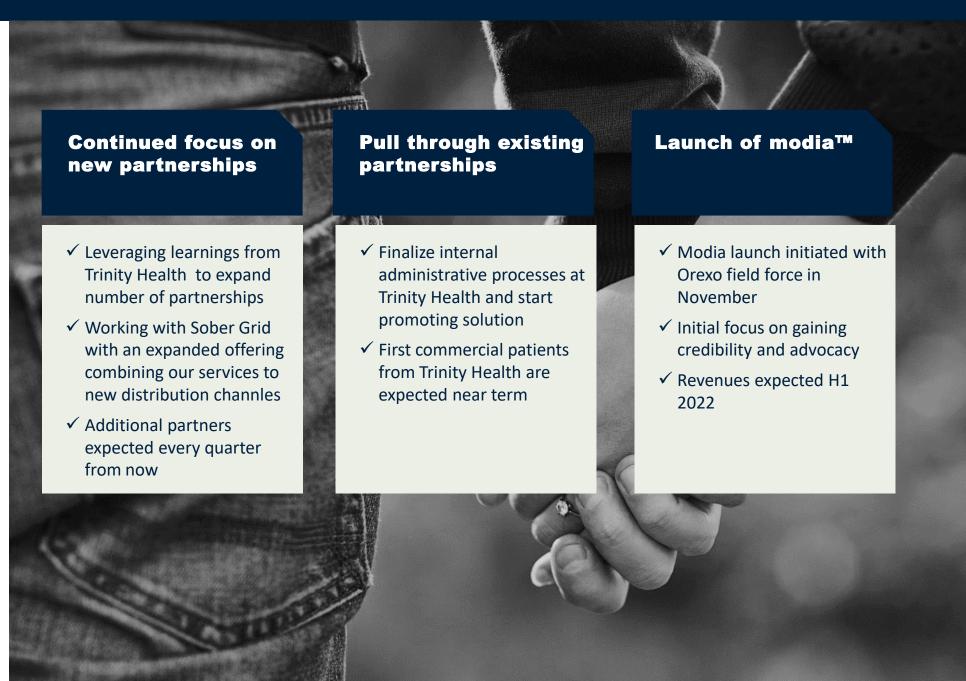
Employer health Business Solutions Providing the Bridge to Employers





# What to expect from DTx?

Digital Therapies are a new disruptive tool in healthcare and while significant interest exist and viable reimbursement pathways are evolving the development of the overall market is still in its infancy





A new, stronger rescue medication (OX124) designed to reverse the effect of overdoses caused by the most powerful synthetic opioids

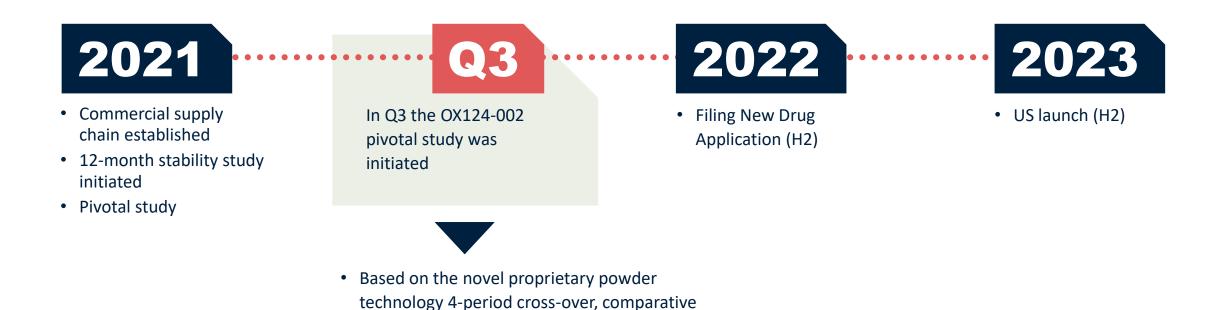


#### **OX124 entered a pivotal study**

bioavailability study

Tested in healthy volunteers

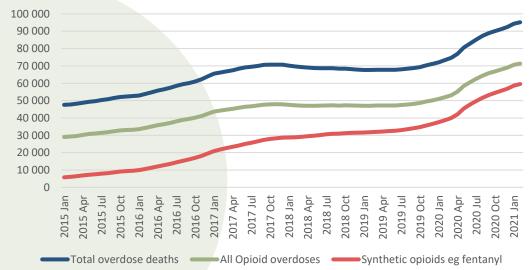
Results expected in Q4 2021



# Annual overdose deaths in the US are approaching 100 000

75% are caused by opioids, of which 84% can be attributed to use of synthetic opioids such as fentanyl.





<sup>1</sup>Center of Disease Control



"Giana made the switch to heroin, and it was all downhill from there."



Elise discovered her daughter's opioid addiction months before she died from an overdose.

Read more at the Orexo blog

#### **OX124**

OX 124 Overdose rescue medication Rescue drug market in the US (USD)

 $320_{\rm m}$ 

**Yearly growth** 

10%

Potential USD net sales 5-10 yrs post launch

~70-110<sub>m</sub>



#### **Initiatives for expanding access**

- ✓ Mandatory co-prescription legislation when treated for pain
- ✓ Standing orders at the pharmacy
- ✓ Distribution of naloxone upon leaving emergency room
- ✓ Expand availablity in communities



**A transformative** 12-month period **building for** future growth

**Group net revenues1** 

**580** %

US Pharma net revenues<sup>1</sup>

532 ×

**EBITDA** 

**-112 EXECUTE** 

US Pharma EBIT<sup>1</sup>

301 ×

**Cash position** 

**US Pharma EBIT margin** 

**57**%

<sup>&</sup>lt;sup>1</sup> LTM, Last Twelve Months, Q4 2020-Q3 2021

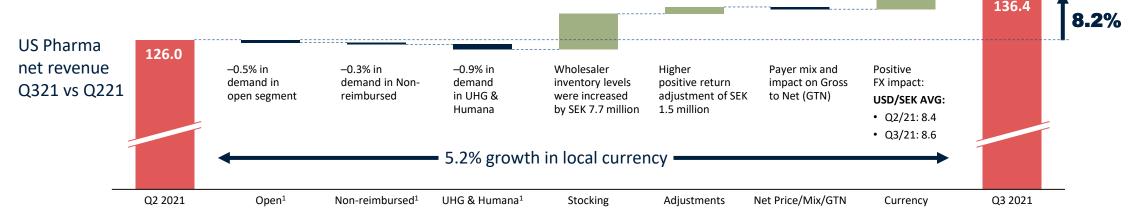
## Growth of 8% QoQ, but lower ZUBSOLV® US net revenues YoY

Net revenue per segment

SEK m	Q3 2021	Q3 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
ZUBSOLV® US	136.4	143.8	389.2	480.2	623.3
US Pharma – Total	136.4	143.8	389.2	480.2	623.3
DTx	0.4	_	0.8	_	0.0
DTx – Total	0.4	_	0.8	_	0.0
Abstral® royalties	6.8	2.5	23.8	14.6	29.7
Edluar® royalties	2.4	4.0	7.2	9.5	10.4
ZUBSOLV® – ex US	_	_	_	0.1	0.1
HQ & Pipeline – Total	9.2	6.5	31.0	24.2	40.2
TOTAL	145.9	150.3	421.0	504.4	663.6

#### **Comments**

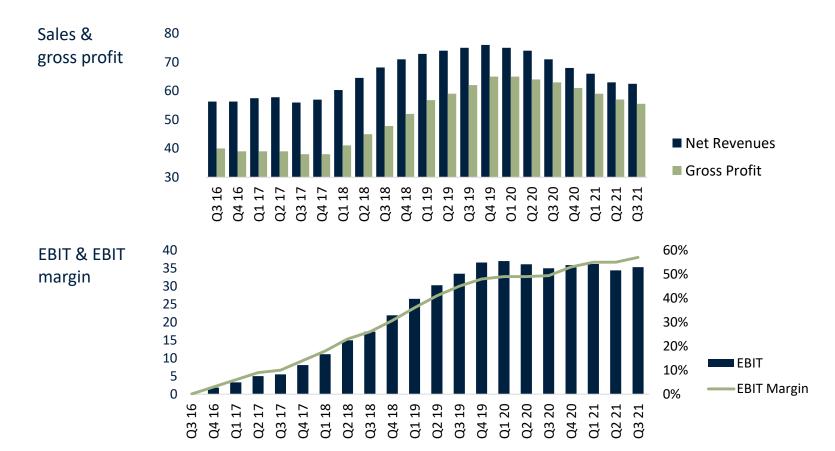
- ✓ ZUBSOLV® Net sales
  declined YoY with 2.9%
  primarily due to
  competition in previously
  exclusive plans
- ✓ Q3 supported by additional selling days



<sup>&</sup>lt;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

#### **US Pharma Operating Margin (LTM) 56.5%**

US Pharma segment, sales & profitability, LTM USD m



#### **Comments**

- ✓ Improved EBIT SEK 35.3m (34.4)
- ✓ Higher EBIT margin 56.5% (54.6%)
- ✓ Some reduction in FTE during Covid-19 due to less access to HCPs
- ✓ Significant synergies between US Pharma and DTx business

Note: COGS converted from SEK to USD using monthly average exchange rates for the period.



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

#### Income statement

SEK m	Q3 2021	Q3 2020	Jan - Sep 2021	Jan - Sep 2020	Jan - Dec 2020
Net revenues	145.9	150.3	421.0	504.4	663.6
Cost of goods sold (COGS)	-21.3	-14.5	-58.6	-54.3	-65.6
Gross Profit	124.7	135.8	362.4	450.1	598.0
Selling expenses	-79.0	-83.3	-209.5	-207.7	-286.6
Administrative expenses	-42.4	-26.4	-112.4	-83.0	-102.8
Research & development expenses	-63.5	-50.3	-192.4	-165.9	-224.9
Other operating income & expenses	1.3	-5.4	1.9	-2.5	-3.6
Operating Costs	-183.7	-165.4	-512.4	-459.0	-617.9
EBIT	-59.0	-29.6	-150.0	-8.9	-19.9
Net financial items	-0.1	-10.8	-6.3	10.9	-18.4
ЕВТ	-59.1	-40.5	-156.3	2.0	-38.3
Tax	7.1	-44.4	-1.3	-36.8	-46.1
Net profit/loss	-52.0	-84.9	-157.6	-34.8	-84.4
EBITDA	-47.4	-20.9	-112.6	17.9	19.0

#### **Comments**

- ✓ Gross Profit below prior year due to:
  - Lower Zubsolv US sales
  - Higher COGS due to production variations
  - Technical infrastructure costs for the DTx product portfolio
- ✓ Operating Costs above prior year explained by:
  - Higher legal expenses
  - OX124 development expenses
  - DTx associated expenses



### Sufficient Cash Position to continue investments in DTX and OX124

#### Cash flow

SEK m	Q3 2021	Q3 2020	Jan - Sep 2021	Jan - Sep 2020	Jan - Dec 2020
Cash flow from operating activities	-79.7	-12.9	-148.4	28.0	16.8
Investment activities	-20.7	-50.2	-50.0	-160.1	-189.2
Financing activities	-2.0	-4.2	256.1	-106.9	-111.3
Cash flow (excl exchange rate differences)	-102.4	-67.4	57.7	-239.1	-283.7
Liquid funds	588.1	593.3	588.1	593.3	505.3
Net cash position	96.3	369.1	96.3	369.1	280.8

#### **Comments**

- ✓ SEK 79.7 m negative contribution from operating activities
- ✓ Investment activities had a negative impact of SEK 20.7 m primarily due to purchase of equipment for the development organization and investments in DTx enterprise platform

## Legal update

### ZUBSOLV® patent dispute vs Sun Therapueutics

#### No changes in Q3

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

### Subpoena with regards to ZUBSOLV®

#### No changes in Q3

✓ No additional information received since issuance of subpoena July 2020

## Financial outlook

Based on USD/SEK exchange rate as of Sep 2021

Metric	Outlook 2021	Reaffirmed/revised
Overall Covid-19 impact and mitigation	With the Covid-19 pandemic continuing, the financial outlook is associated with increased uncertainties	Reaffirmed
Key market development	The buprenorphine/naloxone market will continue with a 5-8 percent growth rate in Q4	Revised
Lead product net sales	ZUBSOLV® US net sales in Q4 is expected to be in line with Q3, and net sales for 2021 will decline compared to 2020	Revised
Group OPEX	OPEX for Q4 will be in line with Q3	Revised
US Pharma EBIT	US Pharma EBIT will exceed 50 percent	Revised



# Strong value drivers for long-term growth

1

Product portfolio addressing large and growing markets



2

Leveraging our US commercial excellence



3

Pharma pipeline targeting unmet medical needs

4

Strong cash position to support growth and continuous strong cash flow from US Pharma 5

Entering digital therapeutics, a new evidence-based frontier in patient care