



Develops and commercializes improved pharmaceuticals and digital therapies –  
with the aim of becoming a leader within the treatment of addiction



**Stockholm Corporate Finance Life Science Seminar, March 11, 2020**

Nasdaq Stockholm: ORX US OTC Market: ORXOY (ADR)

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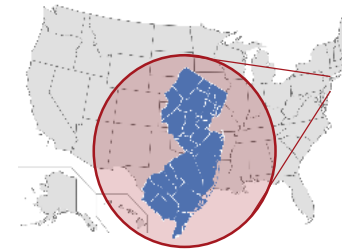
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# Orexo develops and commercializes pharmaceuticals and digital therapies

- Focuses on **treatment of addiction** in all phases, from prevention to treatment
- Broad pipeline with multiple assets based on innovative **drug delivery technologies** or **digital therapeutics (DTx)**
- Developed **four commercial products** with worldwide approval
- Direct presence in the **US opioid dependence market**, one of the largest health crises in US history, with lead asset **Zubsolv®**
- Strategic focus on **portfolio expansion** through development and licensing/M&A
- **Profitable** company with **strong financial position** to support future growth
- Top two largest shareholders<sup>1</sup>: **Novo Holdings** (27.7%) and **HealthCap** (10.2%)



**Corporate Headquarters**  
(Uppsala, Sweden)  
Corporate functions and Development



**US Headquarters**  
(Morristown, New Jersey)  
Commercial subsidiary incl. fully owned field force

**Net revenues**  
SEK, 2019

**845** m

**EBITDA**  
SEK, 2019

**272** m

**Cash position**  
SEK, Dec. 31, 2019

**817** m

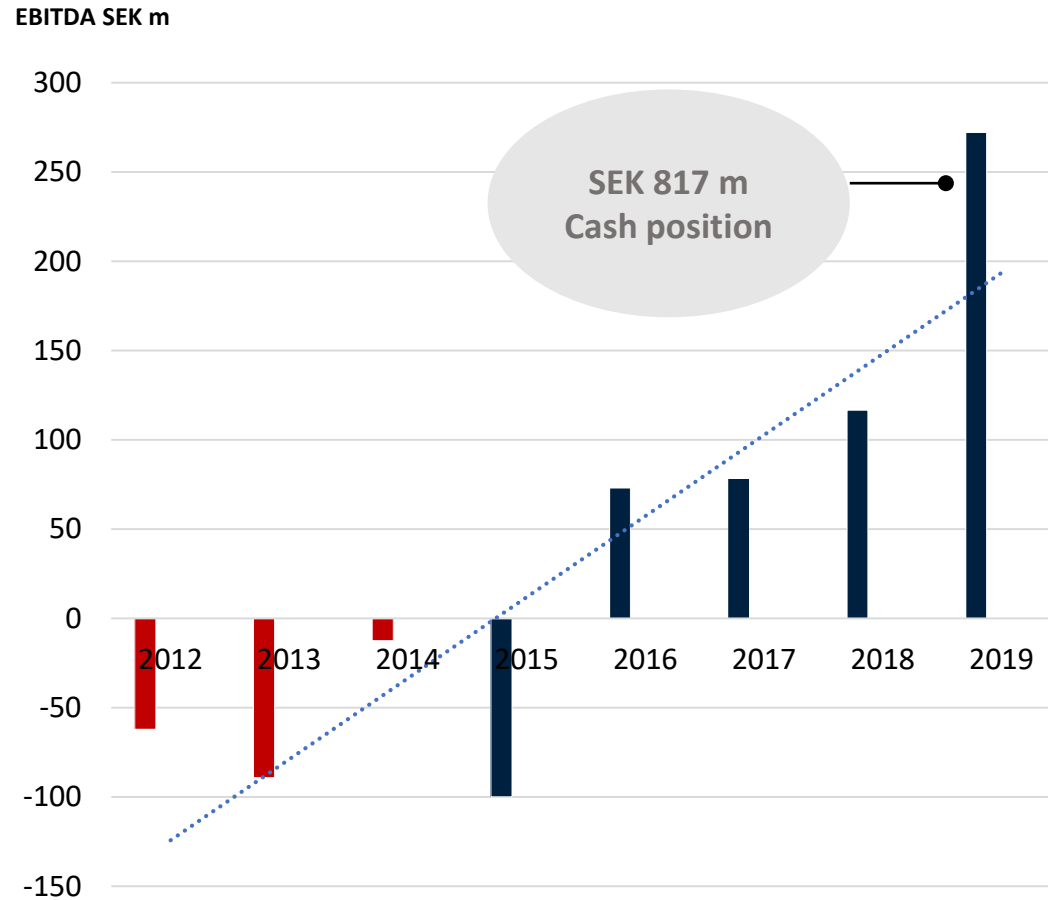
<sup>1</sup> As of January 31, 2020

# Strategic Agenda

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# 2012 – 2019 successful strategic focus on building a solid foundation



Launch Zubsolv® in the US



First actions taken to broaden the US commercial platform



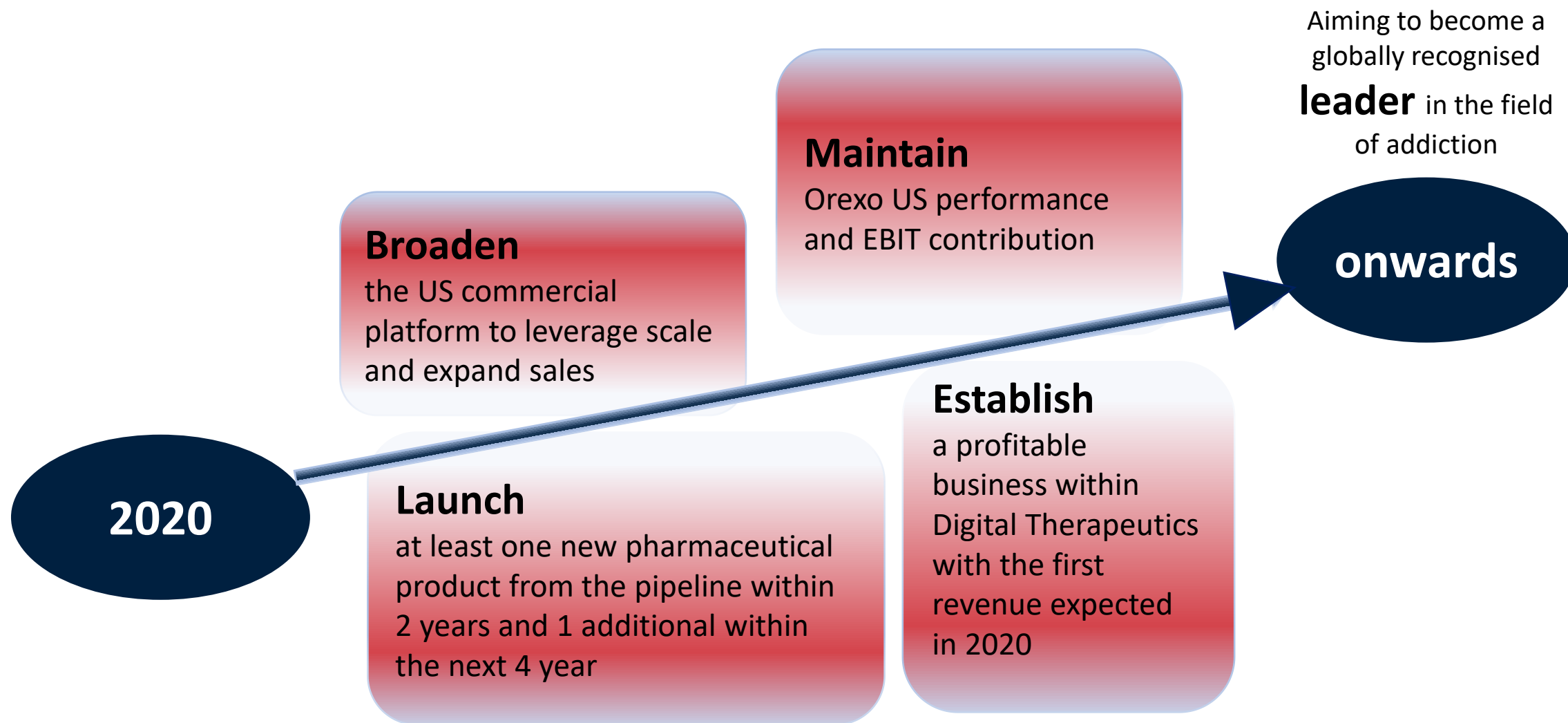
Secure profitability



Ensure a sustainable business model



## Taking Orexo to the next level – expand from areas of strength



# Pipeline addressing large markets with significant patient needs

			Exploratory	Preclinical	Phase			Registration	Approved/Launched		
					1	2	3		US	EU	RoW
Commercial products											
Zubsolv®		Opioid Use Disorder	<div><div></div></div> ▲								
Abstral®		Breakthrough Cancer Pain, <i>Kyowa Kirin</i>	<div><div></div></div>								
Edluar®		Insomnia <i>Mylan Worldwide</i>	<div><div></div></div>								
Development projects											
Pharmaceuticals	OX124	Naloxone - Opioid Overdose	<div><div></div></div>								
	OX125	Nalmefene - Opioid Overdose	<div><div></div></div>								
	OX338	Ketorolac – Moderate to moderately severe pain	<div><div></div></div>								
	OX382	Buprenorphine – Opioid Use Disorder	<div><div></div></div>								
	OX-MPI	BI1029539 – Microvascular Disease <i>Gesynta Pharma</i>	<div><div></div></div>								
Digital Therapies			Preclinical		Phase 3			Registration	Approved/Launched		
								US	EU	RoW	
	OXD01	Opioid Use Disorder <i>GAIA AG</i>	<div><div></div></div>								
	OXD02/vorvida®	Heavy alcohol use, incl. Alcohol Use Disorder <i>GAIA AG</i>	<div><div></div></div> ●								

# Committed to find new solutions to improve treatment of addiction

Recently closed two deals with GAIA AG, a world leader within digital therapeutics (DTx)

## GAIA develops DTx with scientifically proven efficacy

- GAIA has demonstrated digital therapies can have impressive improvement in treatment outcomes from supporting behavioral change and adherence to treatment
- GAIA's platform has proven efficacy in numerous RCTs with over 10,000 patients
- GAIA has 12+ years R&D experience, 20+ CE & FDA compliant products
- GAIA's products use artificial intelligence and offer unique individualization of the treatment

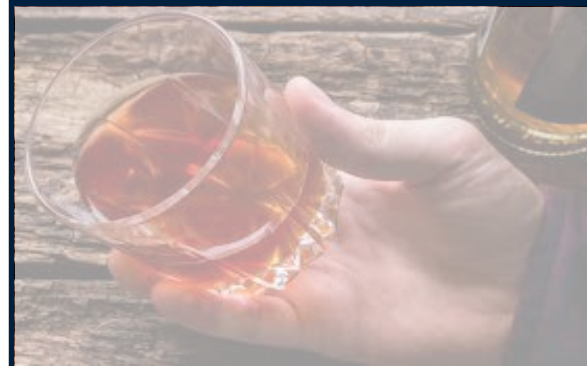


## OXD01 (Opioid Use Disorder, OUD)



- Complementary product
- Significant synergies across the entire value chain
- Orexo holds the global rights
- **Expected US launch in 2021**

## OXD02 vorvida® (Heavy alcohol use, incl. AUD)



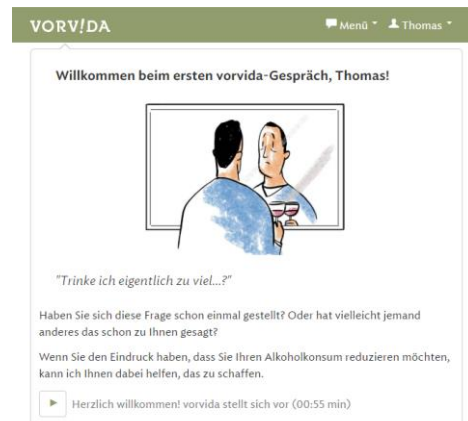
- US license deal
- Synergistic asset
- FDA application submitted March 5, expects to hear from FDA within 60 days
- **Launch in H2 2020**



# GAIA has shown strong clinical evidence for vorvida®

## The product - vorvida®

- vorvida® is a 6-month digital therapy intervention for heavy alcohol use based on cognitive behavioral therapy (CBT)
- Fully Automated, AI-Powered Digital Therapy, accessible across all devices
- Launched in Germany in 2019, supported e.g., by DAK (one of Germany's largest payors)



## Clinical evidence

- Randomized controlled trial funded by the German Federal Ministry of Education and Research: 608 adults with problematic alcohol consumption randomized to vorvida® or care as usual/waitlist. Patients were recruited online and offline.
  - Mean reduction in alcohol consumption of 104g per week compared to control condition (169g vs 65g after 6 months)
  - >10 fewer binge drinking days per month compared to control condition (5.3 vs 16.5 after 6 months)
  - >30% of study participants in the intervention group reduced their drinking behavior from high to low risk (vs. 7% in the control group) after 6 months

# OX124/OX125 – Overdose rescue medications targeting a USD 300 m market with strong growth

## Unmet medical need

- 70,200 people died from a drug overdose in the US in 2017
- Synthetic opioids, such as fentanyl, are now the leading cause of death, which are more potent and stay in the body for a longer time than heroin
- Narcan® Nasal Spray, the leading naloxone rescue drug, is effective, but has shortcomings:
  - ~34% of overdose patients require more than one dose of Narcan
  - Half life of 2 hours (vs. 8-10 for fentanyl) bears risk of 2<sup>nd</sup> overdoses

## OX124 and OX125 concept

- Unique and improved nasal formulations of naloxone (OX124) and nalmefene (OX125) to specifically address the challenges arising from the fentanyl crisis
  - Ability to reverse effect of most powerful synthetic opioids
  - Longer duration than currently approved formulations to reduce need for 2<sup>nd</sup> doses
- **Pivotal trial of OX124 planned for H2 2020, with approval and launch expected 2021**

# OX338 – Promising results from human PK study assessing novel ketorolac formulations for treatment of pain

## Unmet medical need

- For many opioid dependent patients, their addiction started with the first exposure to opioids to treat short-term pain, e.g., after trauma, medical procedure or accident
- In face of the opioid epidemic, there is a desperate need to find non-opioid alternatives to effectively treat acute pain

## OX338 concept

- Ketorolac is considered the most efficacious NSAID to treat pain for up to 5 days with proven morphine-like efficacy, but with no risk of addiction
- OX338 is designed to be the best option for Ketorolac absorption
- OX338 formulations demonstrated improved bioavailability and tolerability compared to the commercially available reference product.
- One of the formulations demonstrated more rapid absorption, which may be beneficial when immediate pain relief is needed
- Further formulation work is required to ensure optimal product properties
- **Assuming further successful development registration with FDA is planned 2022/2023**

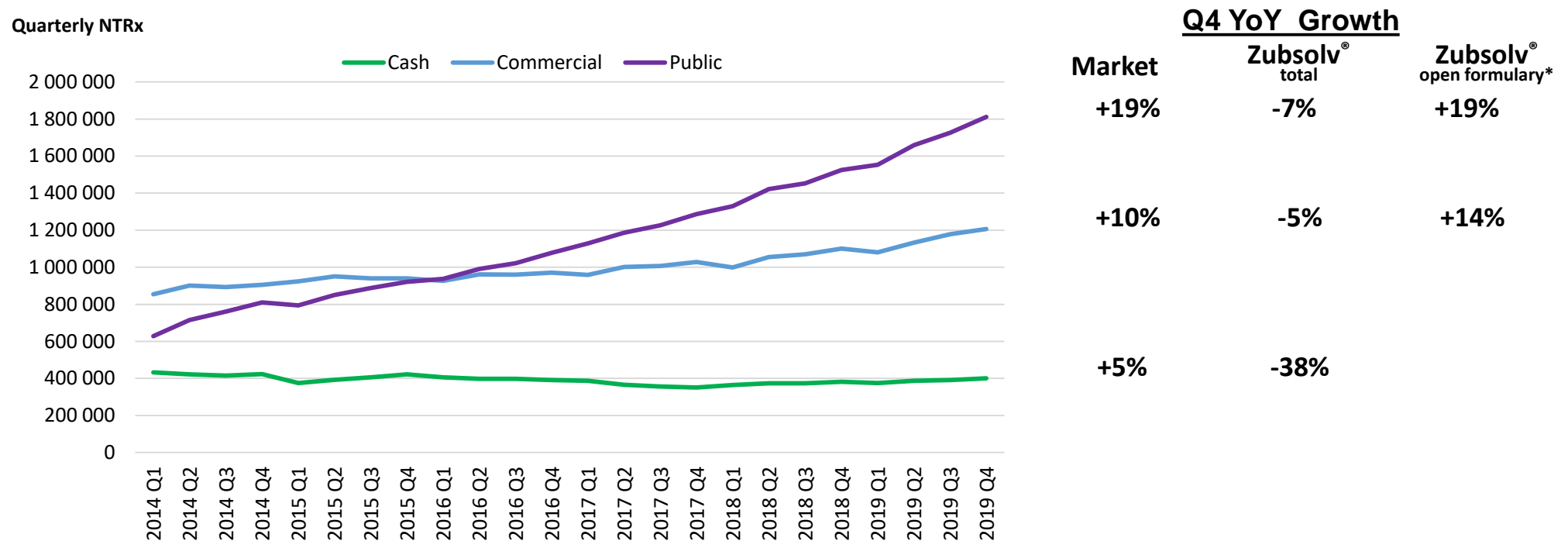
# Key Market & Sales

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# Full year market growth of 14% 2019 vs 2018 ahead of Orexo's forecast and strong Zubsolv® growth in open formularies

**New market highs in Public and Commercial NTRx in Q4, Zubsolv grew 17 percent YoY in open formulary business ex cash**



**Zubsolv outgrew the market in the open formulary segment**

Note: Quarterly NTRx levels = Total prescriptions adjusted to 30 tablet/film scripts

Note: Historical quarters restated due to IMS recategorization

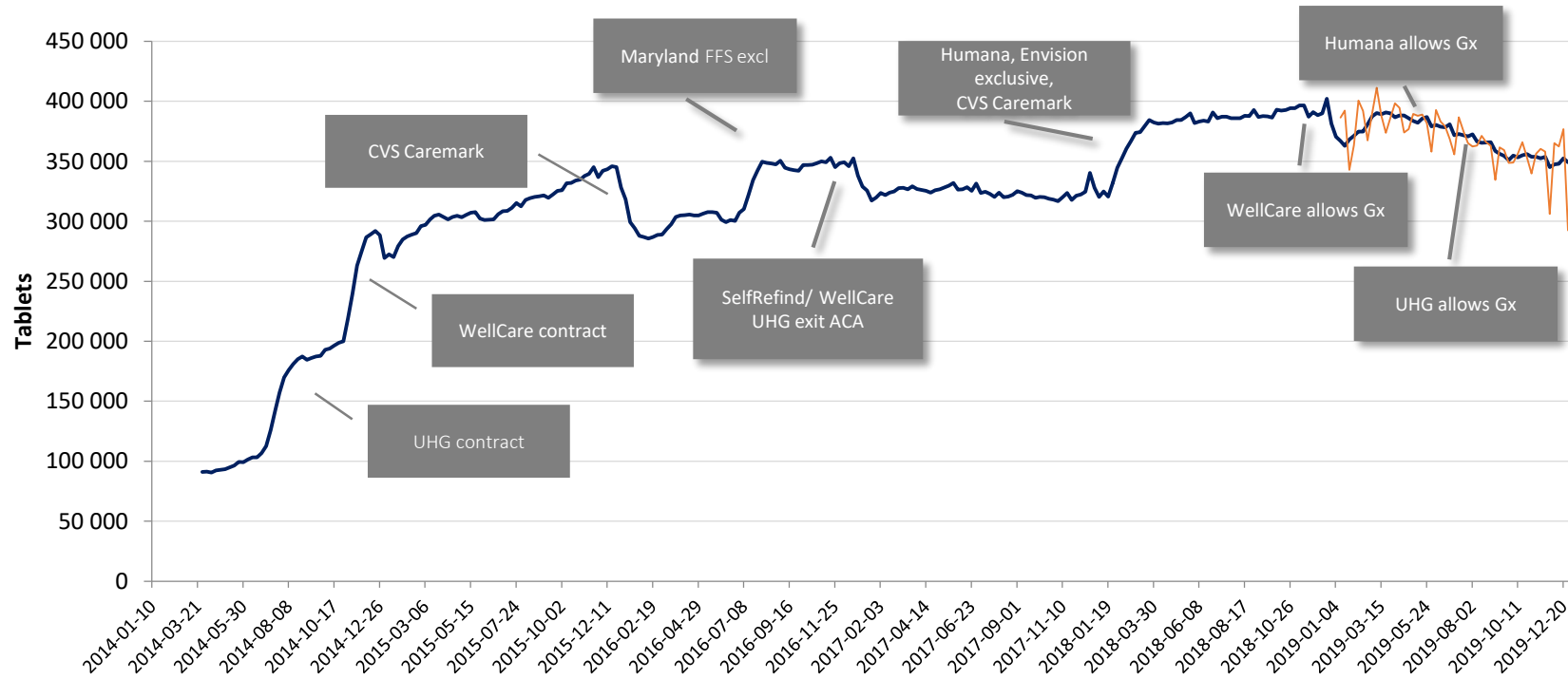
\* Open Formulary Business segment includes all payers, excluding current & recently former exclusive payers

Source: Orexo analysis, IMS data

# Zubsolv® volumes declined due to loss of three exclusive formulary positions and the genericization of the cash segment

## Zubsolv Tablet Volume (rolling 4 week average)

Average weekly sales



\*Open Formulary Business segment includes all payers, excluding current & recently former exclusive payers, and the Cash segment  
Note: Weekly prescription data is based on extrapolation and is associated with uncertainties and may differ between sources  
Source: Orexo analysis, IMS NPA weekly data

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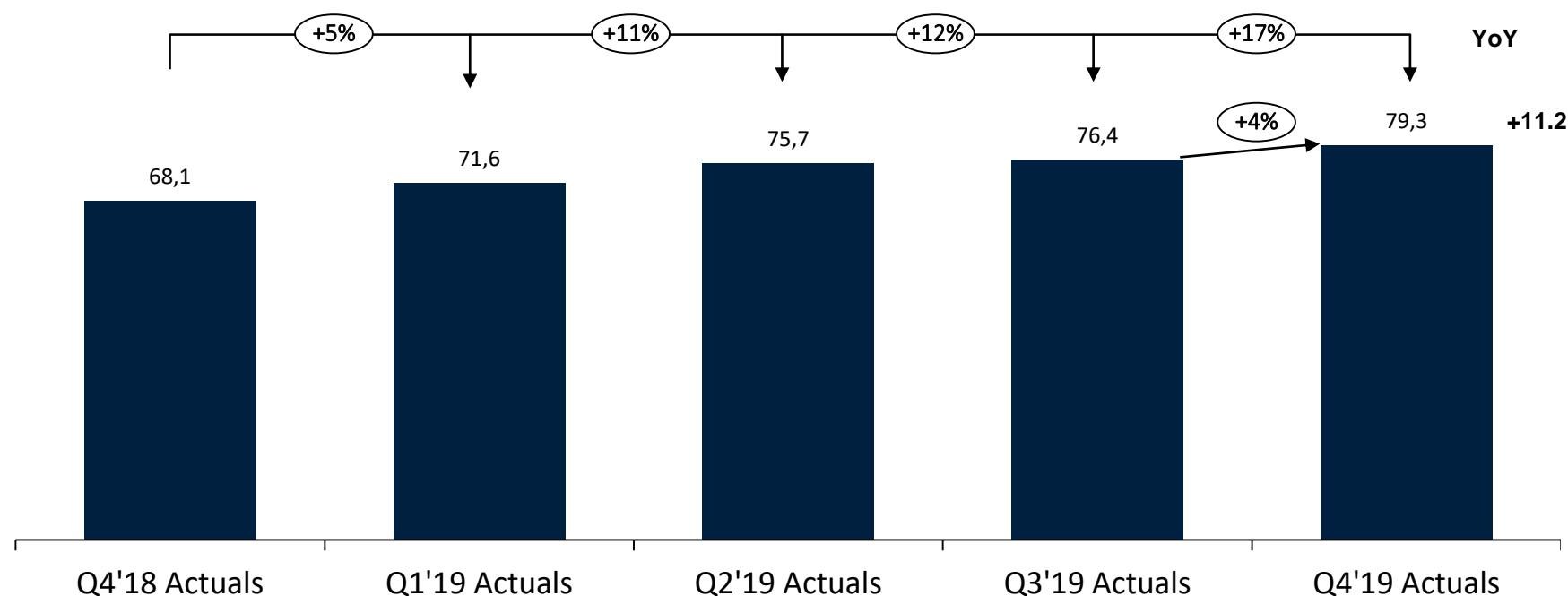
### Zubsolv® volume declined due to loss of three exclusive formulary positions

- Volume declined 9 percent since Q4 18 and 3 percent from Q3 19
- Loss of exclusive contracts with WellCare, Humana and UHG and declining cash segment have a negative effect of 26 percent on overall volume growth vs Q4 18 and 10 percent since Q3 19
- The impact of the formulary changes slowed down during Q4 19
  - Humana reversed its decline trend and grew in December
  - UHG Group stabilized for a number of weeks in December



# Zubsolv® volume continue to show strong performance in growing and profitable Open Formulary Business

## Zubsolv NTRx Volume (in thousands) – Open Formulary Business\* ex Genericized Cash Segment



Source: IMS XPO

Historical data updated to actuals in place of prior reported estimates or restated due to IMS re-categorization

\*Open Formulary Business segment includes all payers, excluding current and recently lost exclusive contracts

# Several potential drivers of Zubsolv® growth in 2020 and beyond

## Market dynamics

- Market growth has been beyond expectation and recently expansion of C275 can lead to continued acceleration
- Commercial segment traditionally weak in Q1, but growth has accelerated H2 2019 which can compensate for seasonal variation
- Loss of three exclusive formulary positions for Zubsolv expected to negatively impact sales in Q1 as patients “reset” their high deductibles
  - Positive trend in December and loyalty to Zubsolv may reduce negative impact
- If Zubsolv maintains growth of 17% in open formularies, this will be a strong growth driver in Q1 and beyond

## Changed competitive landscape

- The market leading generic, the authorized generic (AGx) of Suboxone® Film, has been announced to be withdrawn from the market
- Patients clearly favors the original product and a withdrawal of the AGx is likely to positively impact sales of branded alternatives
  - Zubsolv only branded alternative with several insurance companies and PBMs e.g. CVS Caremark, Humana, UHG
  - Market access of the branded Suboxone Film likely to decline over time
- Zubsolv grew 34% in Q4 over Q3 in CVS Caremark after branded Suboxone® Film was blocked, additional insurance companies and PBMs may follow, which is a major upside for Zubsolv

# Financials

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## 2019 delivered the strongest financial results ever

Group net revenues <b>SEK 845 m</b> <i>85% from Zubsolv®</i>	Growth <b>8%</b> <i>(Zubsolv® 16%)</i>
Group EBITDA <b>SEK 272 m</b>	Growth <b>133%</b>
US EBIT <b>SEK 351 m</b>	Growth <b>77%</b>
Cash position <b>SEK 817 m</b>	Positive net cash position <b>SEK 527 m</b>

# Outlook

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# Financial outlook 2020

- The buprenorphine/naloxone market will continue to show a double-digit growth
- Net sales of Zubsolv® in the US are expected to be in line with 2019. The open formulary businesses will grow, while the previously highly rebated exclusive segments and cash will decrease
- EBIT margin from Zubsolv US will be in the range of 45-50 percent
- vorvida® for alcohol use disorder will be launched in the US H2 2020
- Due to increased R&D investments, OPEX will reach a level of SEK 550-600 million
- Due to a decrease in the Abstral royalty of approximately SEK 85 million, as an effect of expiration of IP protection in the US and the EU, and increased investments in R&D, EBITDA will decrease

*The outlook is based on exchange rates in December 2019*



# Strong value drivers for long-term growth

<b>Investment thesis</b>	<b>1. Addressing large markets with significant patient needs</b>  Focusing on becoming a leader within the large and growing space of addiction, alongside addressing the opioid epidemic, one of the largest health crises ever in America and a growing global concern	<b>2. Strong financial position and profitability</b>  Fueled by the sales of the lead product Zubsolv® which will continue to be an important cash and profitability contributor
<b>3. Leverage the US commercial platform</b>  Strategic focus on product portfolio expansion, through M&A and business development, to leverage the US commercial infrastructure	<b>4. Expanding pipeline</b>  Continues to build on the strong track record of developing products with worldwide approval by expanding the pipeline with multiple assets based on innovative drug delivery technologies and digital therapeutics addressing unmet medical need in addiction	<b>5. Entering DTx, the new mega-trend in life science</b>  Digital therapeutics (DTx) will become an integral part of the healthcare landscape and addiction is one of the therapeutic areas where it is most needed

# Thank You!



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