



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



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

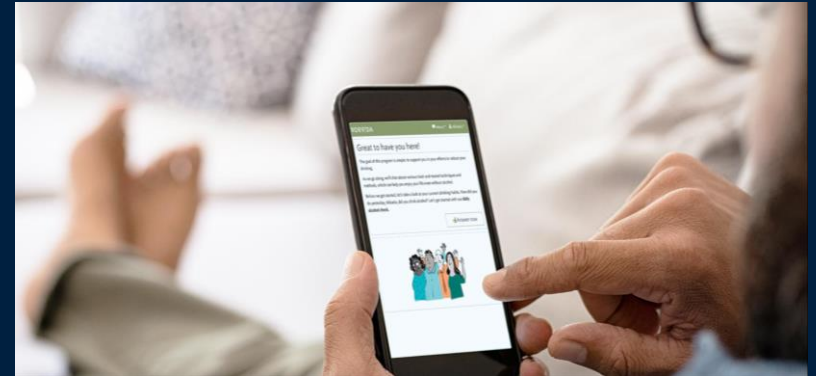
**Interim Report Q1 2020,  
April 28<sup>th</sup> 2020**

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# Overview

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# Resilient business driving continued growth in challenging times

## **Continued improvement in cash position – SEK 39 m in EBITDA and SEK 861 m in cash**

- Net revenues stable with positive impact from price, less returns and exchange rate and negative from anticipated volume decline in Q1
- Continued strong earnings contribution from US Pharma (Zubsolv® US) driving good Q1 EBITDA covering increased investment in R&D and digital therapeutics
- Cash position strengthened despite repurchase of bond and shares during Q1, leveraging weak SEK

## **Digital Therapies boosted by need to keep social distancing**

- New FDA policy enables an accelerated path to market for both OXD01 and vorvida®
- Investments in accelerated launch is being assessed for both products

## **R&D progress on track despite COVID-19**

- Pipeline progress and keep timelines despite some increased challenges due to COVID-19
- First human trial for OX125 planned to start in a few weeks and pivotal trial for OX124 in Q4 2020



# The profit contributions from Zubsolv® enables investments in building a broader and stronger Orexo

## Broaden

..the portfolio of commercial products to be promoted by our existing US organization in 2020

## Establish

..a new revenue generating business area within Digital Therapeutics (DTx) and launch first new product in 2020

## Maintain

.. Zubsolv® profit contribution in 2020 and ensure it is sustainable and growing over time

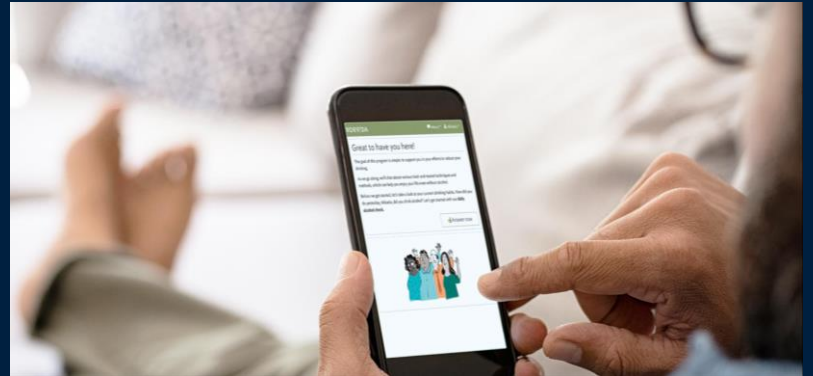
## Launch

..a new pharmaceutical product from Orexo's development pipeline within the next two years



# Growing the Zubsolv® franchise

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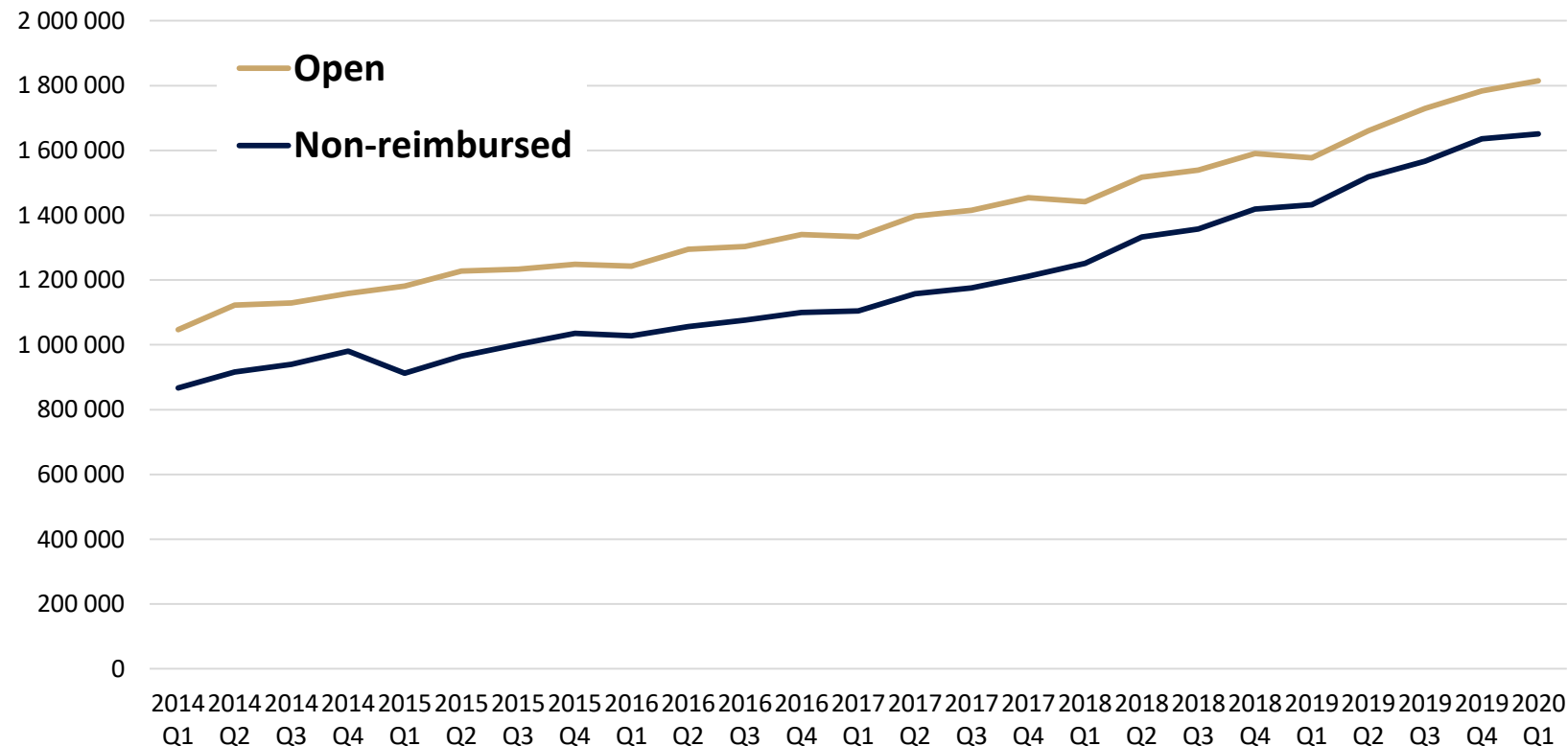


# Market growth of 15% YTD vs prior year is the strongest growth rate since Zubsolv® launch

New market definitions applied

## Market Volume Sales

Quarterly NTRx



## Q1 YTD Growth

Total Market: +15%

## By Segment

+15%

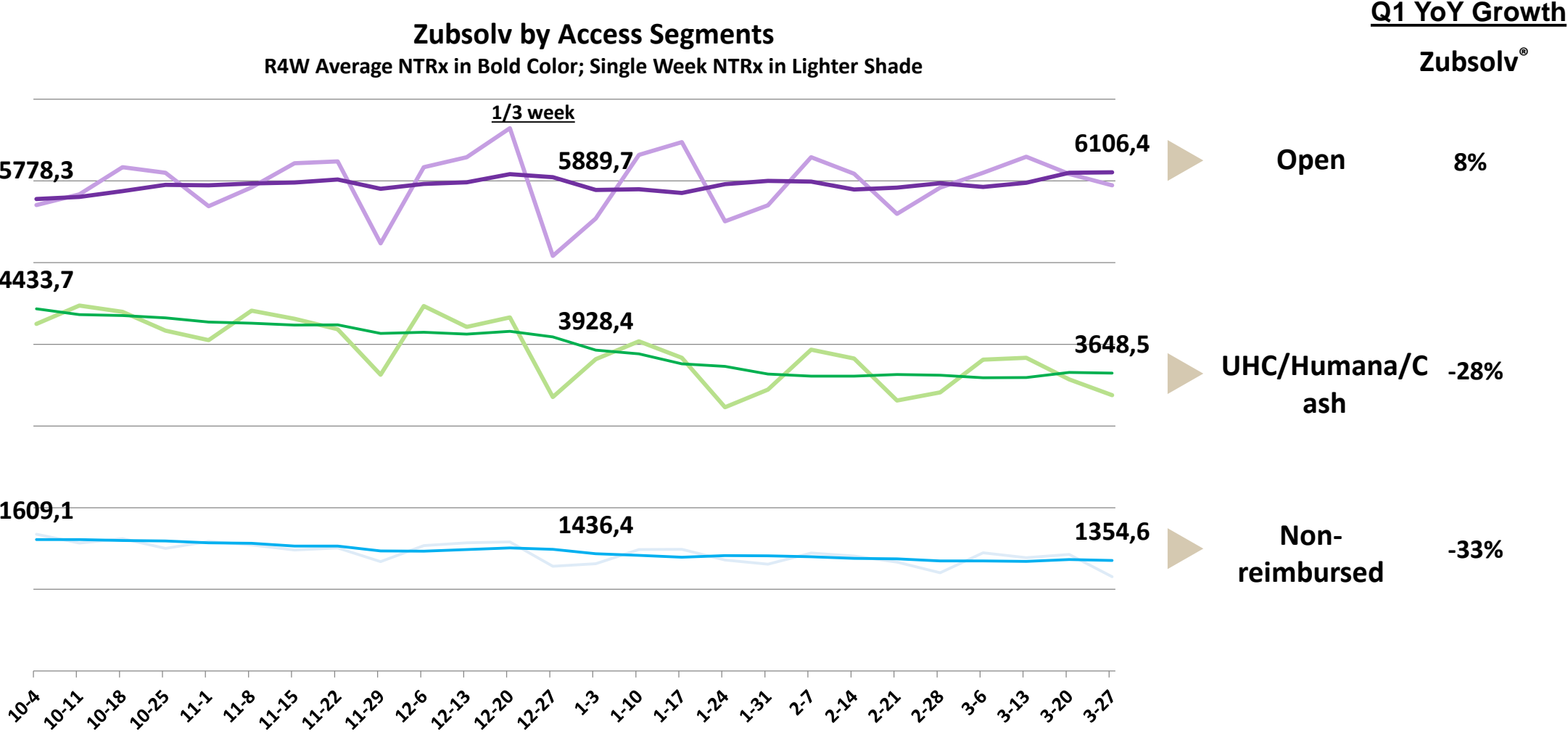
+15%

## Definitions

Payers / Market Access

- **“Open”**
  - Market segments where Zubsolv® is reimbursed either exclusively or non-exclusively
- **“Non-Reimbursed”**
  - Market segments where Zubsolv® is not reimbursed

# Open segment becomes an important growth driver, when the decline in UHC and Humana diminish in 2020



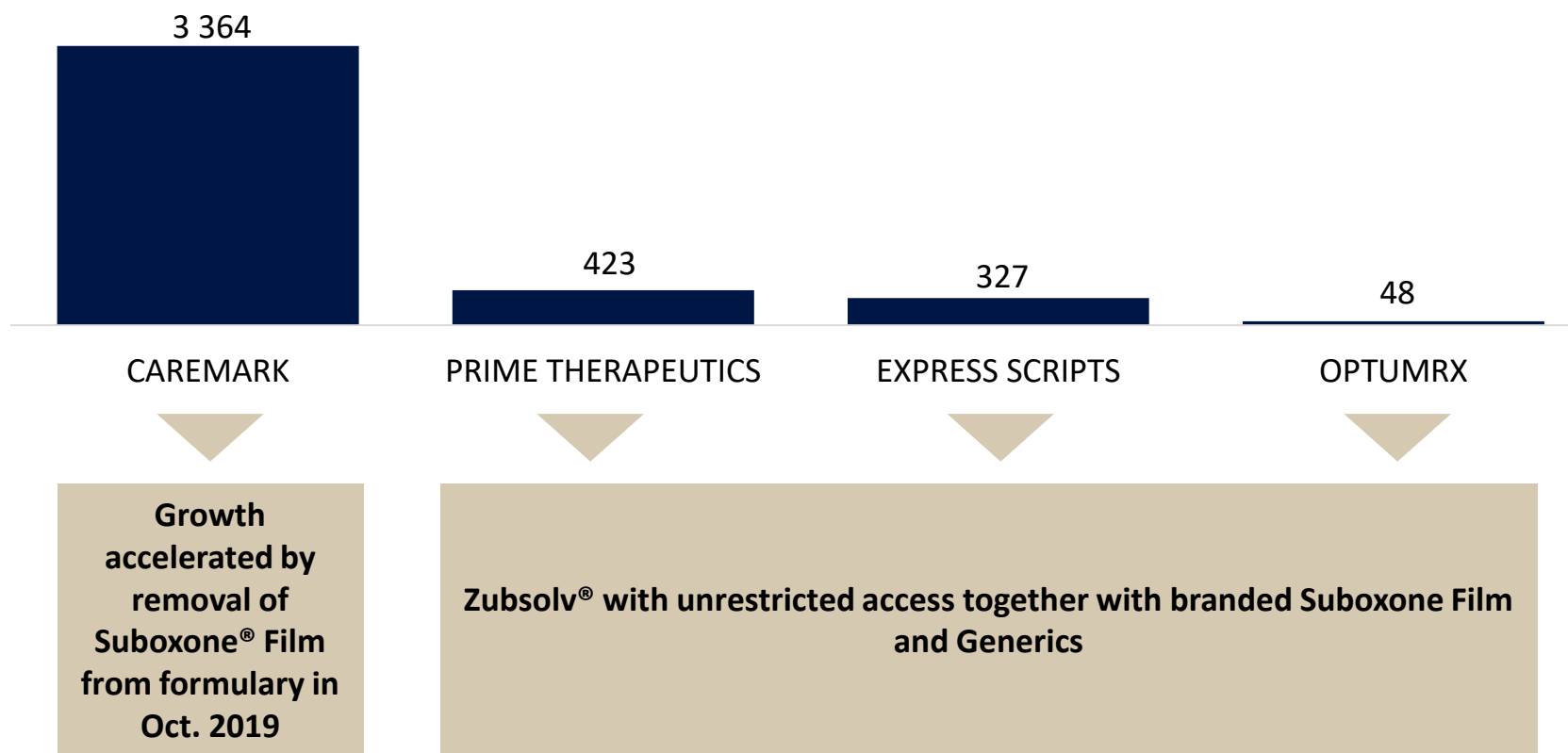
Source: IMS XPO  
NTRx = Total prescriptions adjusted to 30 tablet/film scripts  
Open: Market segments where Zubsolv® is reimbursed either exclusively or non-exclusively  
Non-Reimbursed: Market segments where Zubsolv® is not reimbursed



# Zubsolv® growth in open business explained by unrestricted access to all large national commercial PBMs

## Prescription incremental growth to major national PBMs

Zubsolv NTRx YoY Q1



**Total increase of  
4,162 NTRx YoY**

**Opportunity to continue to  
grow business and to  
translate successes to other  
payers as well**

**Additional removal of  
Suboxone® Film from  
formularies likely to drive  
additional growth**

**Growth in commercial  
formularies expected to  
increase after Q1 due to  
declining deductibles**

# Several possible triggers for Zubsolv® growth in 2020 and beyond



## **Continued improved market access**

- ...Orexo continues to aggressively pursue expanding market access in Medicare and Medicaid
- ...Largest branded competitor likely to lose reimbursement over time

## **Competition from “the preferred” authorized generic of Suboxone® Film will end**

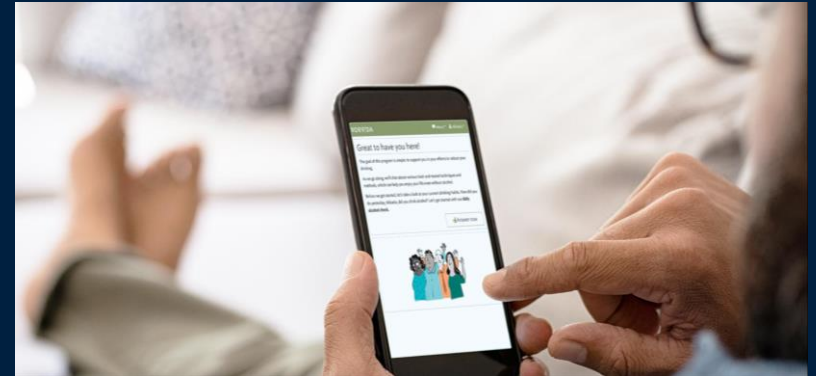
- ...Supply of authorized generic has ceased from the manufacturer (Indivior) and product will disappear when inventories are depleted
- ...Market share of authorized generic has dropped from >50% to 9% last week

## **Orexo will be the only pharmaceutical company promoting a Buprenorphine product to most prescribers**

- ...Sublocade® and other depot formulations primarily promoted to larger institutions
- ...Orexo has an expanding pipeline addressing the most urgent concerns in the industry

# A pipeline with significant future potential

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## 3 convincing development assets addressing critical unmet needs

### OX124 – opioid overdose

A powerful rescue medication, designed to reverse opioid overdoses, including those from synthetic opioids like fentanyl



**70-110**

MUSD net sales potential (US)

### OX125 – opioid overdose

A rescue medication to reverse opioid overdoses, developed for situations where very long-lasting effect is required



**40-60**

MUSD net sales potential (US)

### OX338 – non-opioid pain

A non-opioid pain killer with opioid-level efficacy for short-term pain (up to 5 days), but without the risk of addiction



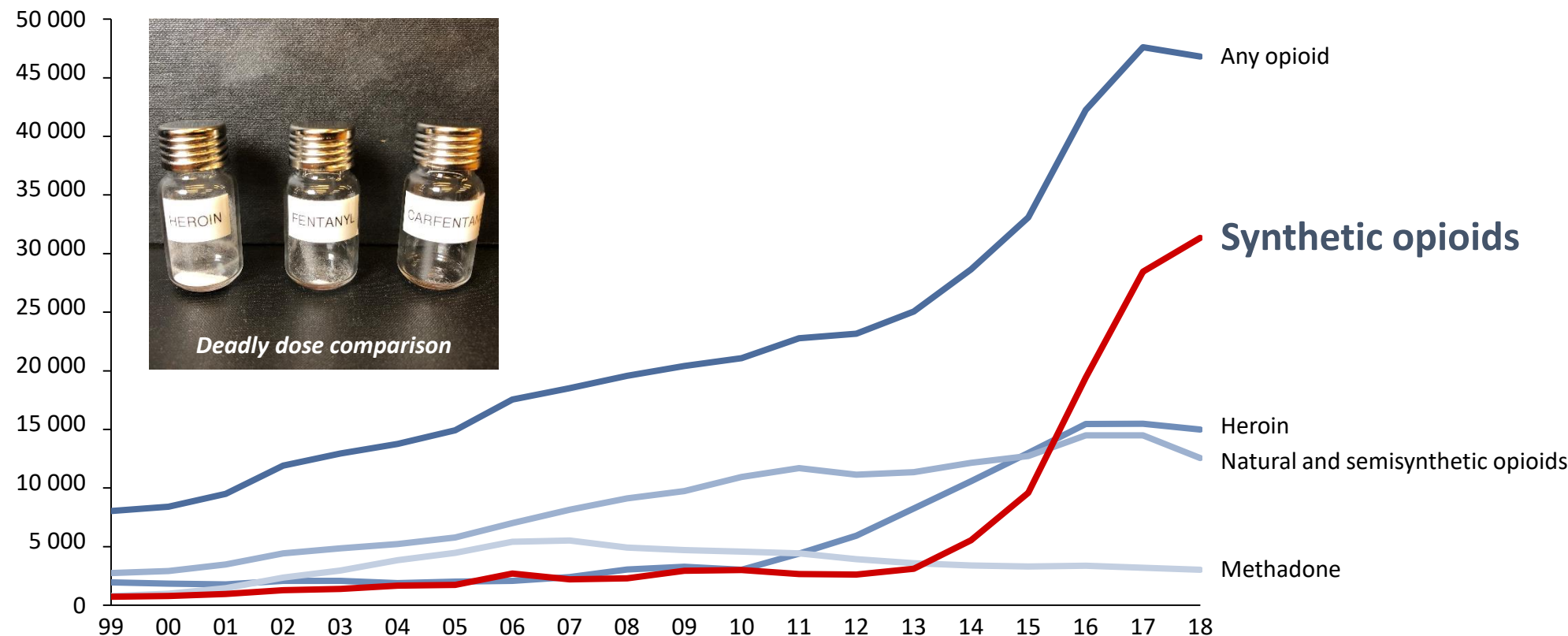
**>100**

MUSD net sales potential (US)



While overall deaths from opioid overdoses showed a slight decline in 2018, deaths from synthetic opioids continue to rise

Deaths from opioid overdose  
By type of opioid, United States



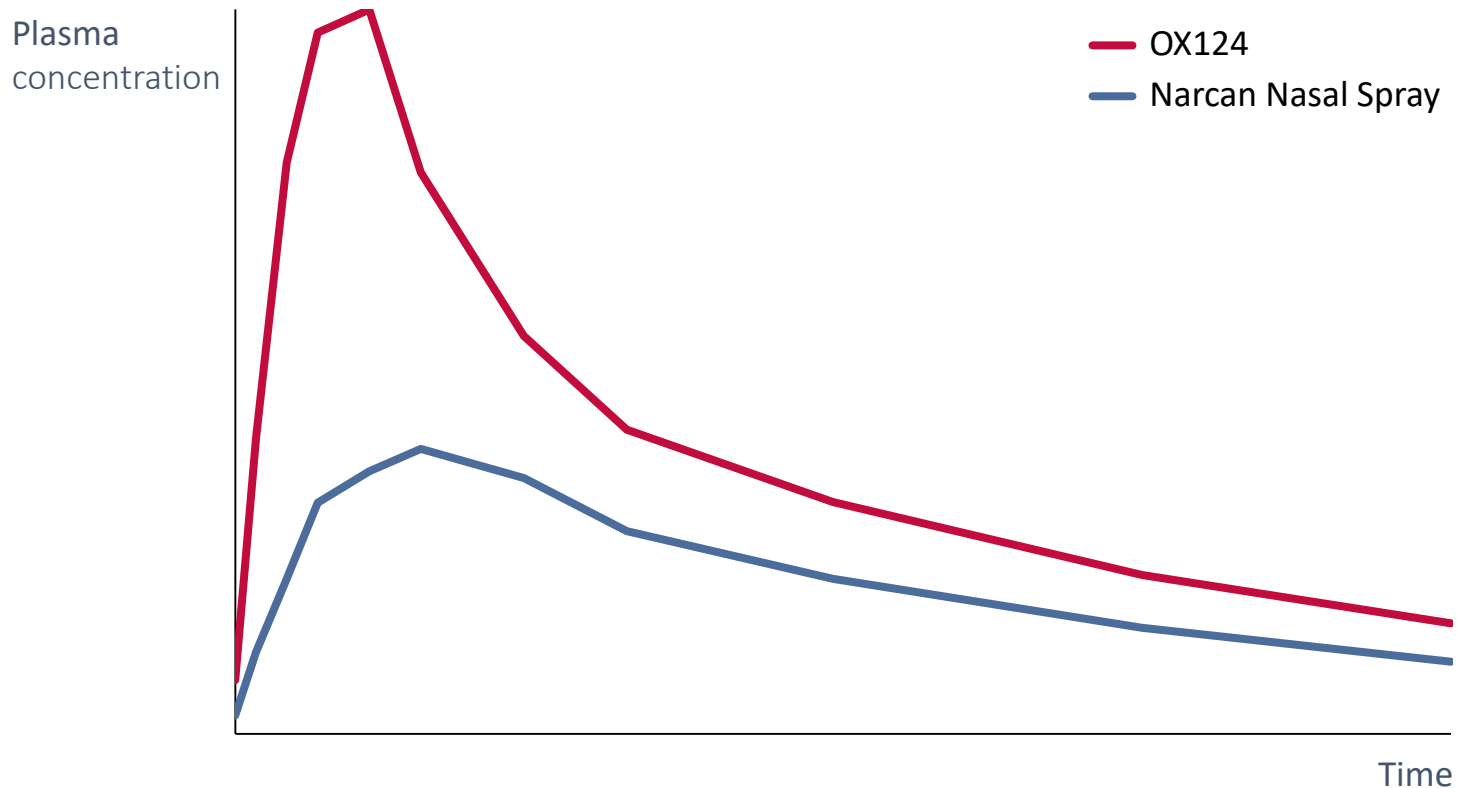


# We have shown better PK profile than Narcan® Nasal Spray

Faster, stronger and longer-acting vs Narcan® Nasal Spray

Expected patient benefit

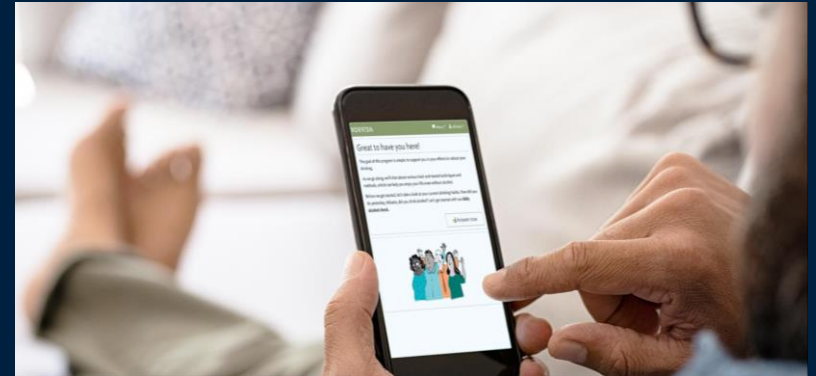
Results from exploratory PK study in healthy volunteers, 2019



- Rescue more patients with the first dose (~34% of overdose patients require more than one dose of Narcan)
- Avoid "second overdoses" thanks to longer duration (Fentanyl has a half life of 8-10 hours vs. 2 hours for naloxone)

# DTx – new frontiers in patient care

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# The COVID-19 global situation has significantly raised awareness and demand for digital therapies, particularly in certain conditions such as substance abuse

March 2020

Hospitals stress at unprecedented levels

Patients are flooding to virtual clinics and online medical councils

Companies are boosting their digital strategy on the back of the coronavirus

Digital and delivery services thrive on the coronavirus outbreak

## Patienter strömmar till nätläkarna efter corona

Av JOHANNES KARLSSON | onsdag 11 mars 2020 kl. 20:19 | [johannes.karlsson@di.se](mailto:johannes.karlsson@di.se) | [@Karlsson\\_J](https://twitter.com/Karlsson_J)



## As Italy's Hospitals Overwhelmed by Coronavirus, Top Health Official Says 'Worst Is Yet Come' for US

"We will see more cases and things will get worse than they are right now."

## Coronavirus' biggest winners: From Netflix to fitness bike maker Peloton

The COVID-19 virus has battered global markets and threatens to worsen the global economic slowdown. But not everyone is losing money even as the fast-spreading epidemic wipes out trillions from global markets.

## Stay home, stay connected

Shares in teleconferencing startup Zoom Video have soared nearly 50% since February as investors bet on a rise in remote workplaces amid fears of the coronavirus spreading further. The company has already added more active users this year — 2.22 million — than it did in all of 2019, Bernstein Research analysts said.

April 2020

US outbreak surges, surpassing all other countries in confirmed cases and deaths

Strict lock down mandates implemented across all US states

Isolation consequences appearing as jobless claims skyrocket

Burden in psychiatric conditions intensifies

Emergency policy guidance issued to try to address demand

*Contains Nonbinding Recommendations*

## Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

## Guidance for Industry and Food and Drug Administration Staff

April 2020

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S2-14-26  
Baltimore, Maryland 21244-1850



*CMCS Informational Bulletin*

DATE: April 2, 2020

FROM: Calder Lynch, Deputy Administrator and Director

SUBJECT: Rural Health Care and Medicaid Telehealth Flexibilities, and Guidance Regarding Section 1009 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271), entitled Medicaid Substance Use Disorder Treatment via Telehealth

The Orexo digital therapy portfolio is well positioned to directly help patients in serious need while also contributing to revenue growth

**vorvida®**

A fully automated digital therapy scientifically proven to reduce trouble-some drinking patterns in adults with AUD



**120-200**

MUSD net sales potential in the US

**OXD01**

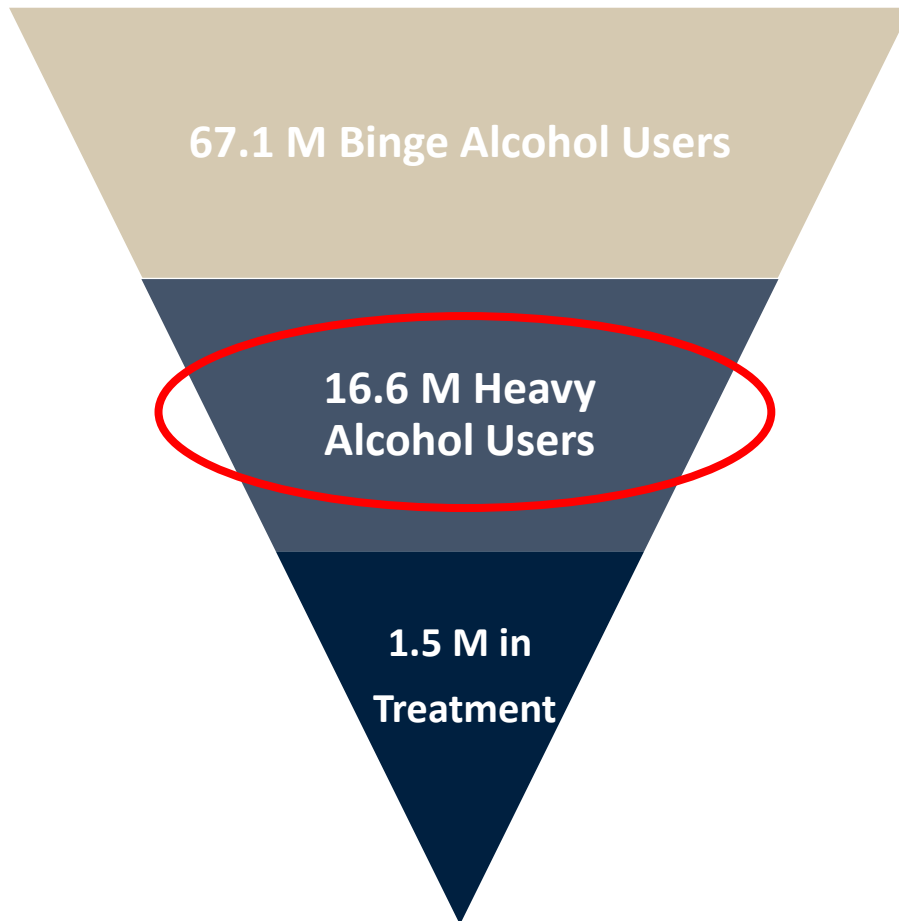
“Digitizing” counselling at scale to offer with Zubsolv®, a full medication assisted therapy (MAT) solution for so many opioid use disorder (OUD) patients in need.



**150-225**

MUSD net sales potential in the US

Vorvida® is positioned to help 16.6 million people with heavy problematic drinking, COVID-19 is expected to grow this already sizeable base



- Roughly **95 percent** of Americans struggling with alcoholism do not feel they need treatment for their condition
- In 2014, 431,000 women and 1.1 million men received treatment for an alcohol use disorder
- Lack of treatment is a result of **stigmatization, limited understanding of one's own dependence**, and a lack of effective and private treatment options
- Consequently, there is a significant gap in the market and thus, an opportunity for Orexo

*Binge Drinking:*

**Men:** Drinking five or more drinks on the same occasion on at least 1 day in the past 30 days

**Women:** Drinking four or more drinks on the same occasion on at least 1 day in the past 30 days

**Heavy alcohol use** is defined as binge drinking on 5 or more days in the past 30 days



# Managing OUD recovery in isolation will demand new approaches with deep category expertise, an ideal position for Orexo and OXD01

## **Compulsory Part of Pharmacological Therapy**

- All Buprenorphine/Naloxone (Bup/Nal) come with label instructing it "should be used as part of a complete treatment plan that includes counseling and psychosocial support"
- Limited access to psychosocial support is an issue for many patients and physicians

## **Well defined market**

- Bup/Nal market is well defined and highly concentrated

## **Opioid Epidemic**

- Opioid crisis creates a significant support for new innovative treatment alternatives, COVID-19 accelerates this crisis and introduces challenges to traditional methods

## **Orexo has a strong position**

- Orexo is well established in the Bup/Nal market and the only company with a field force reaching into the smaller clinics with highly limited access to psychosocial support

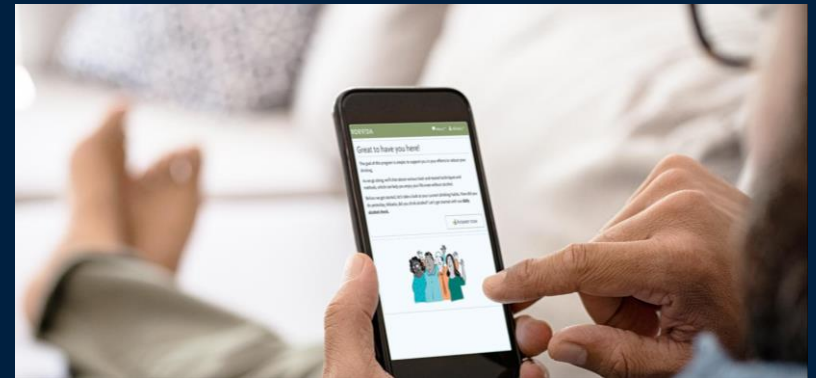
## **Potential spill-over effects**

- OXD01 offers significant stand-alone potential, but is likely to have positive spill-over effects on Zubsolv®

**Logic for  
investing in  
OXD01**

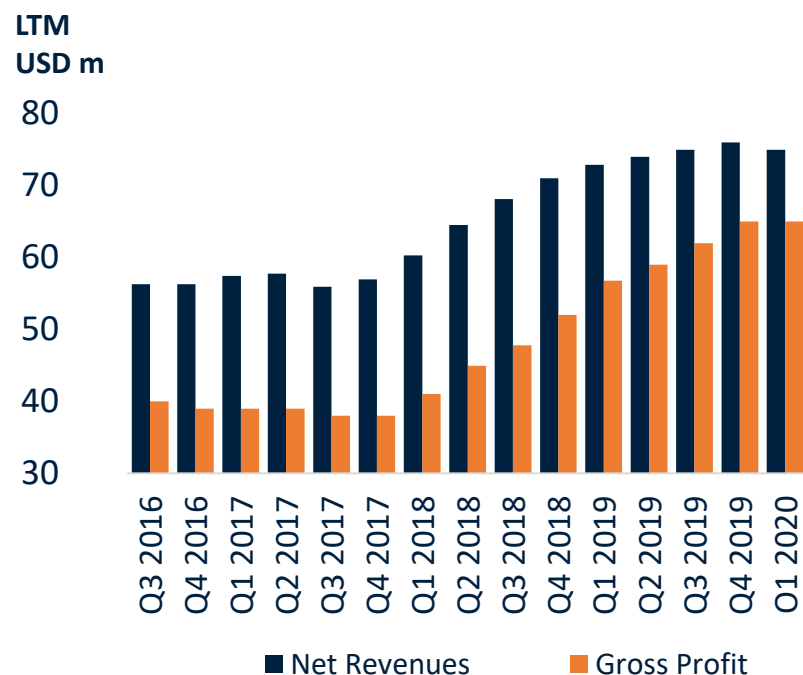
# Financials

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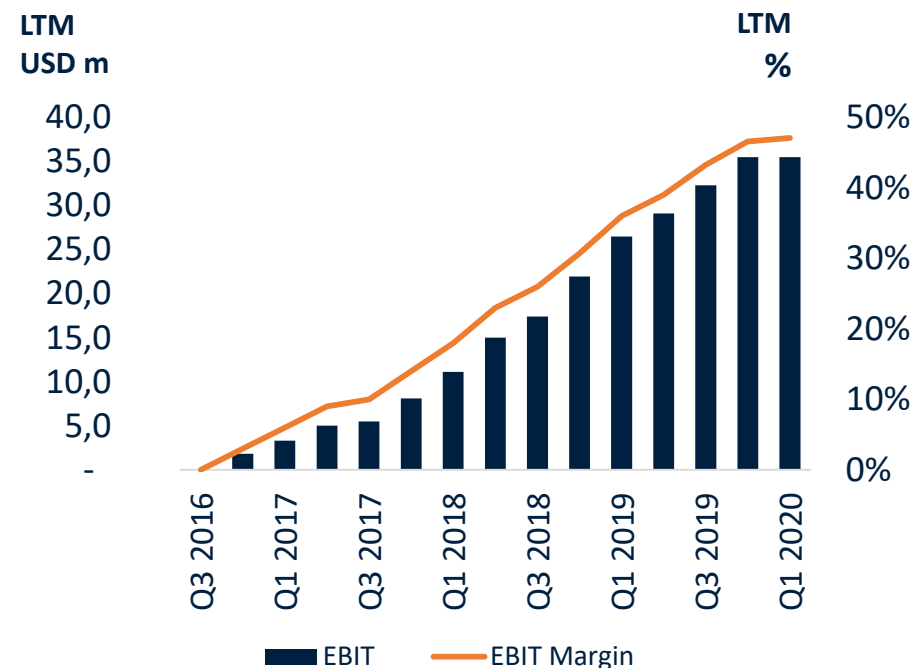


# US Pharma Operating Margin (LTM) grew to 47.1%

## Sales and gross profit



## EBIT



- Zubsolv US net sales grew to USD 75.3 m from USD 72.9 m LTM in Q119
- Strong growth in EBIT contribution to USD 35.5 m increasing from USD 26.5 m in Q119 driven by higher net revenues and by lower COGS
- US Pharma EBIT margin of 47.1% LTM in Q120 increasing from 36.4% in Q119, EBIT margin in Q1 2020 reached 44.2%
- Full year US Pharma EBIT margin of 45-50% is expected in 2020 and a short term flattening of the net sales due to volume decline in previously exclusive contracts. Price increase of 3% from January 2020.

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

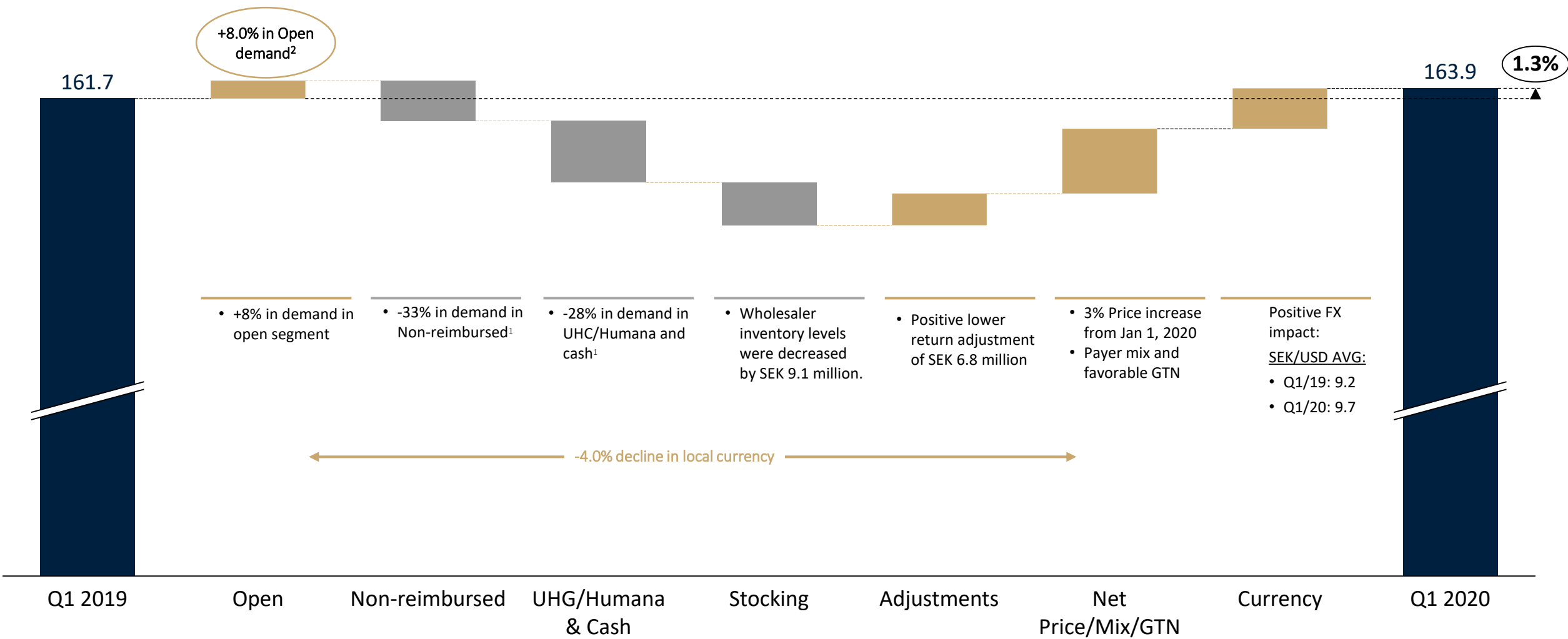
# Zubsolv® main growth driver of net revenues with 1.3 percent

Corresponding to a -4.0 percent growth in local currency

SEK m	Q1 2020	Q1 2019	Jan - Dec 2019
Zubsolv® US	163.9	161.7	719.2
<b>US Pharma - Total</b>	<b>163.9</b>	<b>161.7</b>	<b>719.2</b>
Abstral® royalties	8.6	10.9	112.6
Edluar® royalties	2.4	1.7	11.6
Zubsolv – ex US	0.1	-	0.1
OX-MPI	-	-	1.4
<b>HQ &amp; Pipeline - Total</b>	<b>11.1</b>	<b>12.6</b>	<b>125.6</b>
<b>TOTAL</b>	<b>175.0</b>	<b>174.3</b>	<b>844.8</b>

- Net revenues for Q120 grew 0.4% driven by favorable exchange rate and higher Zubsolv US revenues in SEK
- Zubsolv US revenues grew 1.3% in Q120 vs Q119 to SEK 163.9 m
- Abstral Q120 decline explained by lower positive adjustments from Q419 vs Q417
- Orexo will not receive Abstral royalties from Europe and US in 2020, resulting in a negative impact on revenue of SEK ~85 m in 2020

# Zubsolv® Net Sales grow 1.3% YOY despite losses in Exclusive Plans<sup>1</sup>



<sup>1</sup> Orexo analysis using IMS demand data plus institutional sales  
<sup>2</sup> Excluding Cash segment and formulary changes (Wellcare, UHC and Humana)



# Continued strong financial performance in Q120 despite COVID-19

Net profit reached SEK 82.6 m (14.1, Q119)

SEK m	Q1 2020	Q1 2019	Jan - Dec 2019
Net revenues	175.0	174.3	844.8
Cost of goods sold (COGS)	-20.0	-25.3	-105.6
<b>Gross Profit</b>	<b>155.0</b>	<b>149.0</b>	<b>739.2</b>
Selling expenses	-54.6	-47.2	-191.9
Administrative expenses	-23.7	-70.1	-139.6
Research & development expenses	-52.9	-37.6	-181.3
Other operating income & expenses	10.1	7.0	4.8
<b>Operating Costs</b>	<b>-121.1</b>	<b>-147.9</b>	<b>-508.0</b>
<b>EBIT</b>	<b>34.0</b>	<b>1.1</b>	<b>231.2</b>
Net financial items	44.0	4.8	-3.3
<b>EBT</b>	<b>78.0</b>	<b>5.9</b>	<b>227.9</b>
Tax	4.6	8.2	-8.8
<b>Net profit/loss</b>	<b>82.6</b>	<b>14.1</b>	<b>219.1</b>
<b>EBITDA</b>	<b>39.1</b>	<b>12.0</b>	<b>272.1</b>

## Q120 comments:

- **Gross Profit** for the quarter 4% higher vs prior year. This is mainly driven by higher Zubsolv US revenues in SEK and lower COGS per tablet
- **Operating Costs** below prior year due to:
  - Selling expenses increased explained by costs related to preparations to launch vorvida® in the US, in Q2 2020
  - Administrative expenses lower, due to less spending SEK 0.1 m (48.8) on IP litigation since the win in the appeal process securing Zubsolv's US patents until 2032
  - R&D expenses higher due to development projects
  - Other operating income contributed positively due to exchange-rate gains derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD
- **Net Financial items** had positive impact explained by realized exchange-rate gain of SEK 29.0 m from converting funds from USD to SEK and by positive unrealized exchange rate impact of SEK 12.3 m derived from the parent company's foreign currency bank accounts mainly in USD. Earned interest contributed with SEK 1.6 m and the buyback of corporate bonds had a positive impact of SEK 1.1 m

# To improve transparency Orexo will present financial performance per business segment in the quarterly report

US Pharma SEK m	Q1 2020	Q1 2019	Jan - Dec 2019
Net revenues	163.9	161.7	719.2
Cost of goods sold (COGS)	-20.0	-25.3	-105.6
<b>Gross Profit</b>	<b>143.9</b>	<b>136.4</b>	<b>613.6</b>
<b>Operating Costs</b>	<b>-68.1</b>	<b>-68.2</b>	<b>-266.5</b>
<b>EBIT</b>	<b>75.9</b>	<b>68.2</b>	<b>347.1</b>



- **US Pharma** consist of Orexo US commercial operations in the US and cost allocated to promote pharmaceutical products, currently Zubsolv®

Digital Therapeutics SEK m	Q1 2020	Q1 2019	Jan - Dec 2019
Net revenues	-	-	-
Cost of goods sold (COGS)	-	-	-
<b>Gross Profit</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Operating Costs</b>	<b>-12.1</b>	<b>-</b>	<b>-0.9</b>
<b>EBIT</b>	<b>-12.1</b>	<b>-</b>	<b>-0.9</b>



- **Digital Therapeutics** consist of Orexo development and commercialization of digital therapies across the world. Digital therapeutics will have a cost allocation from the resources shared with other parts of the organization e.g. sales force resources shared with US Pharma

HQ & Pipeline SEK m	Q1 2020	Q1 2019	Jan - Dec 2019
Net revenues	11.1	12.6	125.6
Cost of goods sold (COGS)	-	-	-
<b>Gross Profit</b>	<b>11.1</b>	<b>12.6</b>	<b>125.6</b>
<b>Operating Costs</b>	<b>-41.0</b>	<b>-79.7</b>	<b>-240.6</b>
<b>EBIT</b>	<b>-29.9</b>	<b>-67.1</b>	<b>-115.0</b>



- **HQ and Pipeline** consist of Orexo head quarter, pharmaceutical development and royalty income from ex US pharma products.

# Strong financial position enabling Orexo to pursue its growth strategy

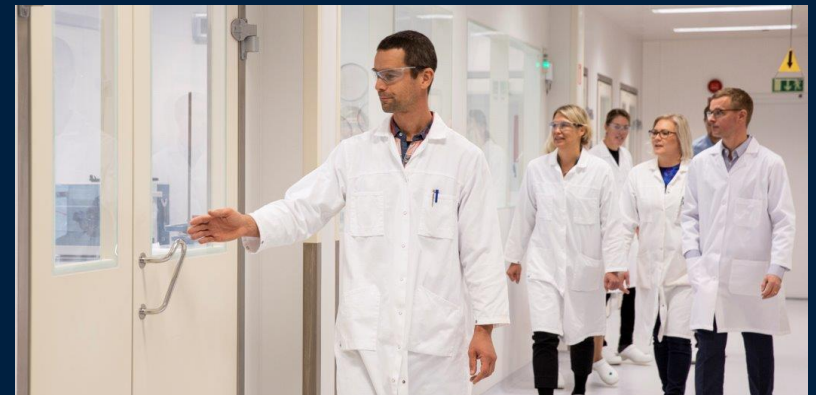
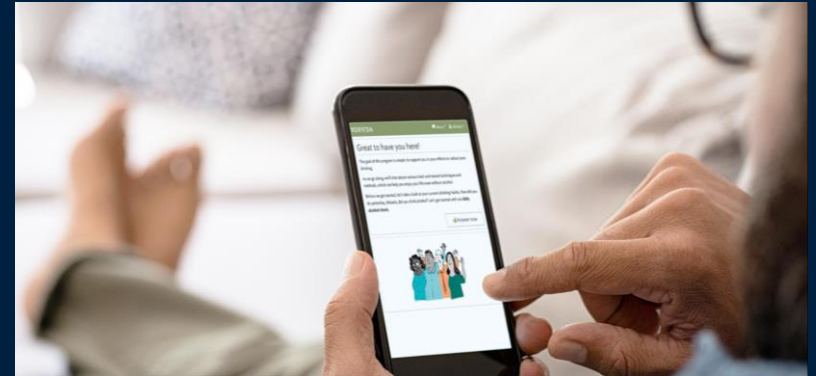
Cash position of SEK 861.4 m and a positive net cash position of SEK 611.9 m

Cash flow SEK m	Q1 2020	Q1 2019	Jan - Dec 2019
Cash flow from operating activities	48.1	50.9	287.0
Investment activities	-3.9	-0.1	-22.4
Financing activities	-68.8	-10.7	-53.7
Cash flow (excl exchange rate differences)	-24.6	40.2	210.8
<b>Liquid funds</b>	<b>861.4</b>	<b>647.4</b>	<b>816.8</b>

- Positive cash flow from operating activities for the period Q120
  - SEK 48.1 m positive contribution from operating activities.
  - Financing activities had a negative impact of SEK -68.8 m mainly due to share buyback of 464 035 shares for SEK 24.4 m, due to buyback of Bond loan in total of SEK 40,5 m and due to IFRS 16 impact of SEK 3,9 m
  - SEK 44.7 m positive impact on cash position due to stronger USD in March of 2020
- Strong cash position at the end of Q120 with SEK 861.4 m
  - Exchange rate gain of SEK 69.2 m of which SEK 29.0 M is realized

# Outlook

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# Limited impact from the COVID-19 disease currently<sup>1</sup>





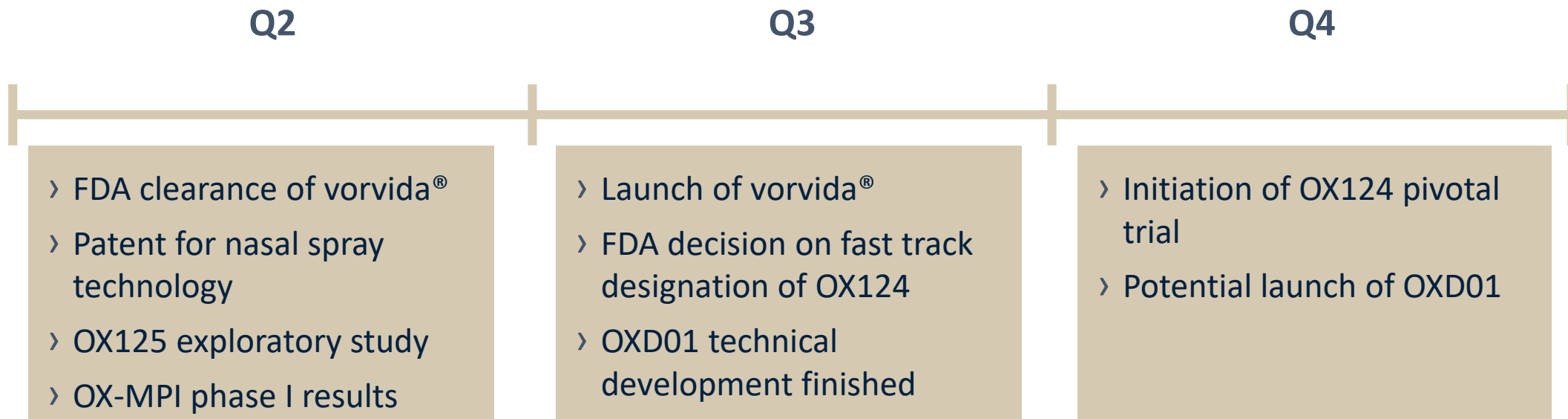
# Financial outlook 2020

Increased uncertainty due to COVID-19 and exchange rate fluctuations

- › The buprenorphine/naloxone market will continue to show a double-digit growth
- › Zubsolv® net sales are expected to be in line with 2019. The open businesses will grow, whilst the previously highly rebated exclusive segments, including cash, will decrease.
- › Due to increased R&D investments OPEX will reach a level of SEK 550-600 m, excluding potential investments in an accelerated launch of digital therapies
- › Due to a decrease in Abstral® royalties of approx. SEK 85 m, as an effect of expiration of IP protection in the US and the EU, and increased investments in R&D, EBITDA will decrease
- › US Pharma margin will be in the range of 45-50 percent

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

## 2020 a year with a steady news flow expected



# Strong value drivers for long-term growth

## Investment thesis

### 1. Addressing large markets with significant patient needs

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

### 2. Strong financial position and profitability

Fueled by the sales of the lead product Zubsolv® which will continue to be an important cash and profitability contributor

### 3. Leverage the US commercial platform

Strategic focus on product portfolio expansion, through M&A and business development, to leverage the US commercial infrastructure

### 4. Expanding pipeline

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

### 5. Entering DTx, the new megatrend in life science

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!

IR Contact: Lena Wange, IR & Communications Manager, [ir@orexo.com](mailto:ir@orexo.com). For more information please visit [www.orexo.com](http://www.orexo.com).

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