



Develops improved pharmaceuticals and digital therapies addressing unmet needs within the growing space of substance use disorders and mental health



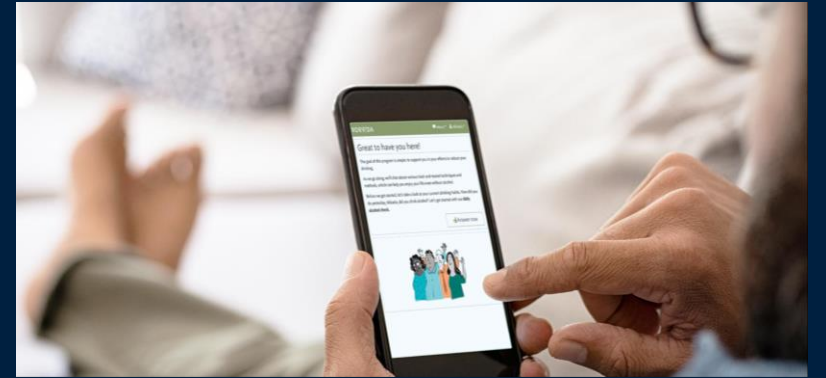
Interim Report Q2 2020, July 16th 2020

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

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Quarterly overview & strategic agenda



Investing in diversification to drive future growth

Continued strong financial performance by US Pharma

- Net revenues of SEK 179.1 m impacted negatively by Abstral® and some decline in ZUBSOLV® YoY
- Investments in R&D (OX124, OX125) and DTx result in a negative EBITDA of SEK -9 m
- Positive EBITDA and Net earnings when excluding DTx US launch expenses (SEK -35.5 m) and increased investments in R&D (SEK -19.1 m)
- Orexo US received subpoenas on July 14th to provide US Authorities with certain information with regards to ZUBSOLV® and other buprenorphine products. Orexo has no knowledge of the background to the requests

Launch of deprexis® and vorvida® initiated in the US

- Commercial activities for deprexis® and vorvida® initiated in July and broad launch planned for September 2020
- New FDA policy enables an accelerated path to market for OXD01 with launch expected Q4 more than one year ahead of plan
- DTx launch investments expected to increase expenses with ~ SEK 200 m compared to previous guidance

Pharma R&D continue to deliver according to plan

- First human trial for OX125 finalized with positive results from the exploratory PK-study in healthy volunteers showed extensive and rapid absorption of nalmefene across all three OX125 formulations
- OX124 with a significant focus on establishing commercial manufacturing in anticipation of pivotal trial late 2020
- Patent granted for novel nasal delivery platform establishing patent protection until 2039

The profit and cash contributions from ZUBSOLV® enables continued 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



Pipeline addressing large markets with significant patient needs and progresses according to plan

Development Projects										
		Exploratory	Preclinical	Phase			Registration	Approved and/or Launched		
				1	2	3		US	EU	RoW
Pharmaceuticals	OX124 -Naloxone Opioid Overdose	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
	OX125 -Nalmefene Opioid Overdose	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
	OX338 -Ketorolac Moderate to moderately severe pain	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
	OX382 -Buprenorphine Opioid Use Disorder/Pain	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
	OX-MPI -BI1029539 Microvascular Disease Partner: Gesynta Pharma	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
Digital Therapies		Technical Development					Registration	Approved and/or Launched		
								US	EU	RoW
	OXD01 -Opioid Use Disorder Partner: GAIA AG	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>

COVID-19 will create a tsunami of mental health issues and significantly increase the need for Orexo's products

Deaths from opioid overdose increase

The Washington Post
Democracy Dies in Darkness

Coronavirus Latest news U.S. map World map Reopening tracker Lives lost Your life at home Extraordinary people

Health

'Cries for help': Drug overdoses are soaring during the coronavirus pandemic

Suspected overdoses nationally jumped 18 percent in March, 29 percent in April and 42 percent in May, data from ambulance teams, hospitals and police shows.

Alcohol misuse increase

Drug and Alcohol Use Increase During COVID-19

Our recent survey shows more people are using drugs and alcohol to cope with stress, boredom and mental health issues.



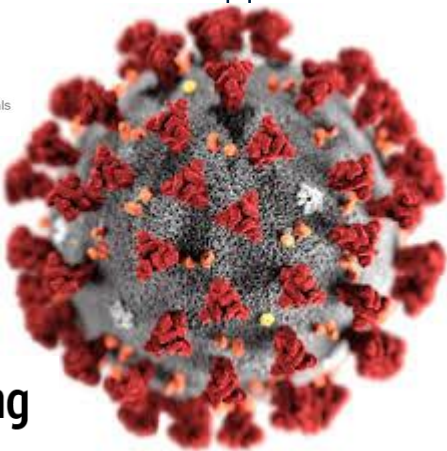
Opioid misuse increase

Alexander Caudarella: The pandemic is making the opioid crisis worse

Escalating numbers of overdoses and deaths are being reported in many parts of the country. In Toronto in both April and May, there were more suspected opioid deaths than any month since September 2017



Depression increase

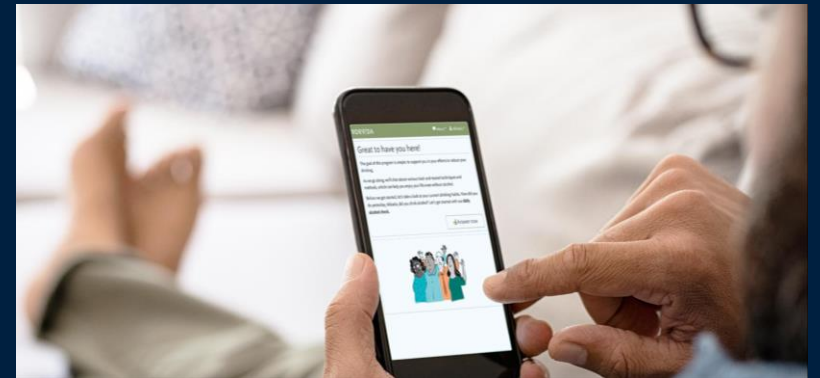


Building a broader commercial portfolio

VORV!DA®

deprexis®


zubsolv® sublingual
tablets
(buprenorphine and naloxone) ©



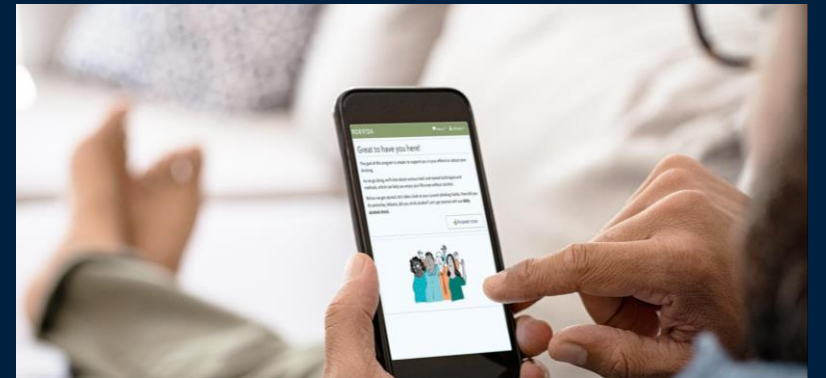
Commercial products addressing large markets with significant patient needs

Commercial Products										
		Exploratory	Preclinical	Phase			Registration	Approved and/or Launched		
				1	2	3		US	EU	RoW
Pharmaceuticals	ZUBSOLV® -Opioid Use Disorder									
	Abstral® -Breakthrough Cancer Pain Partner: Kyowa Kirin									
	Edluar® -Insomnia Partner: Mylan									
Digital Therapies	deprexis® -Depression Partner: GAIA AG									
	vorvida® -Alcohol misuse incl. Alcohol Use Disorder Partner: GAIA AG									

Building a broader
commercial portfolio

VORV!DA®

deprexis®



Launching two digital therapies, Orexo is well positioned to take a leading role addressing unmet needs within SUD and mental health issues

deprexis®

deprexis® is a fully automated digital therapy to help patients manage their symptoms of mild to severe depression and is one of the most researched such in the world



> 150-225

MUSD net sales potential in the US

vorvida®

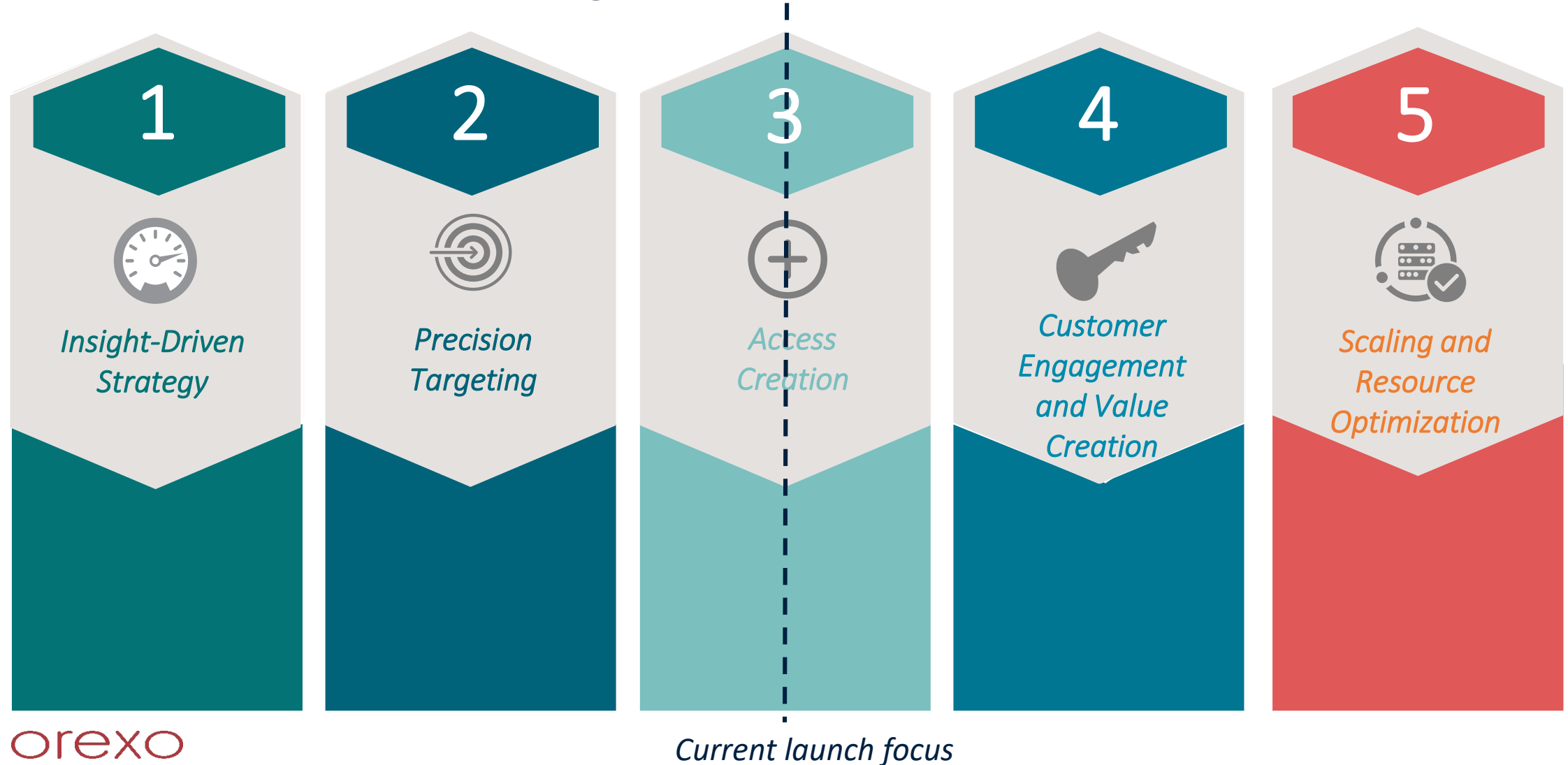
A fully automated digital therapy scientifically proven to reduce troublesome drinking patterns in adults suffering from alcohol misuse incl. alcohol use disorder (AUD)



120-200

MUSD net sales potential in the US

Our investment and go to market strategy is highly targeted and will scale as access is created in high need markets



To complement the significant evidence supporting our products, we are developing user experience driven program content

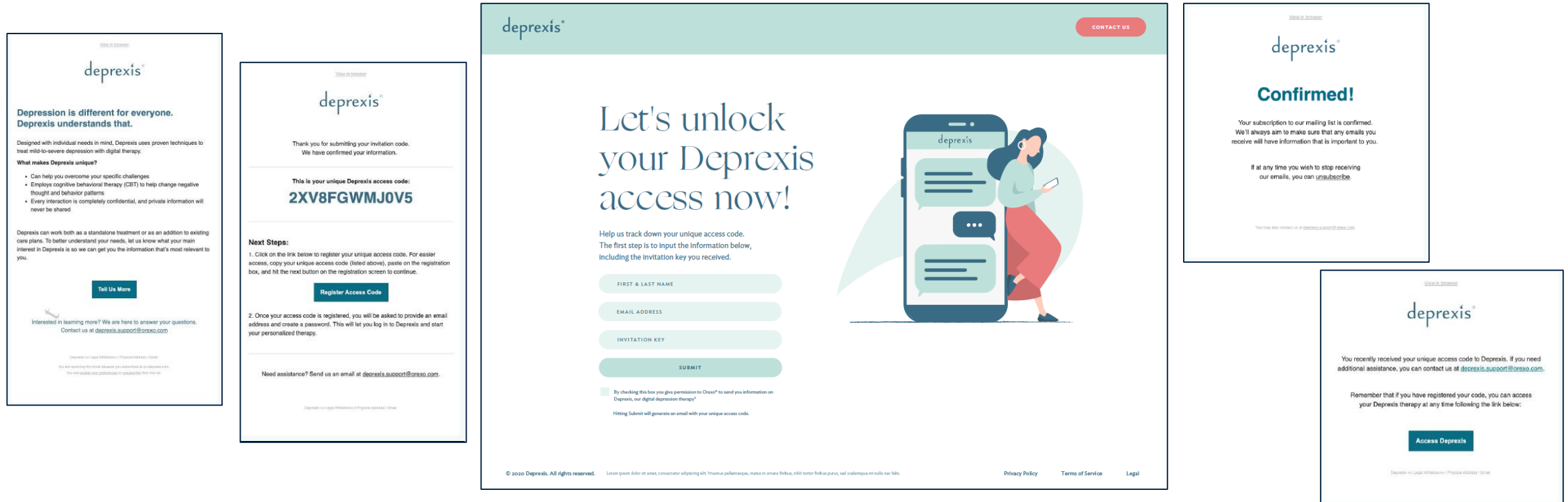
deprexis® “Day 1” site *meetdeprexis.com* live as of July 2nd, 2020



vorvida® communication materials coming Sept. 2020



Patients suffering from depression or alcohol misuse are vulnerable and Orexo prepare a range of services to ensure patient engagement and support



Patients services available from September include user friendly patient services spanning specialty hub services for insurance reimbursement, customer service, e-commerce storefronts, and on-going customer relationship management tools

Early customer feedback supports the market need and demonstrates a positive response to the products...

"I think that if it's something that can be used in addition to therapy with a live therapist, it's a good thing because it's another tool that people can use to get through the process of depression." – Patient

"I think this is better than live therapy, actually. People sometimes don't like to go in person or look at somebody and speak about their problems." – Caregiver

"The biggest advantage is that the product is available anytime, anywhere for individuals that can continue therapy outside of in-person sessions. I think that would be really helpful." – Therapist

"I think this is very relevant. I've been in meetings where there continues to be concern over excessive drinking by employees. It's certainly something we want to find solutions for." – Pharmacy Director

"Alcohol dependence is something we don't talk about. As an employee, being able to do something digitally and in the privacy of my own home seems like a great opportunity." – Employee Benefits Manager

"I have a lot of confidence in CBT, there are a lot of ways to tailor it for different populations and patients. It tends to be one of those gold standard treatments. I love it as a treatment." – Therapist

Establishing a pricing and payer model is critical for future success in digital therapy

Alternative Payer Models

Orexo sees several alternatives for future payer models and will not apply a traditional one-fits-all Rx model

Pharmaceutical Model

- Reimbursement similar to pharmaceuticals or other medical benefits by insurance companies and employers

Framework agreement models

- Agreements with specific insurance companies to cover all customers
- Agreement with institutional health care providers

Patient model

- Patients paying for the therapy out-of-pocket

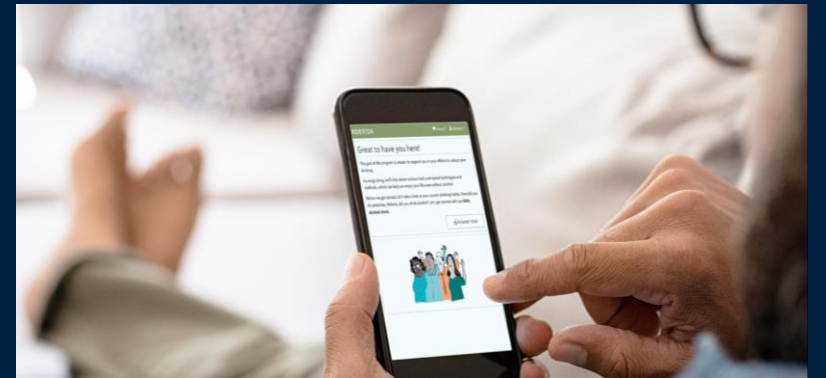
Current focus

Starting September

Payer models are evolving continuously, but no established standard has emerged

Building a broader commercial portfolio


zubsolv[®] sublingual
tablets
(buprenorphine and naloxone) 

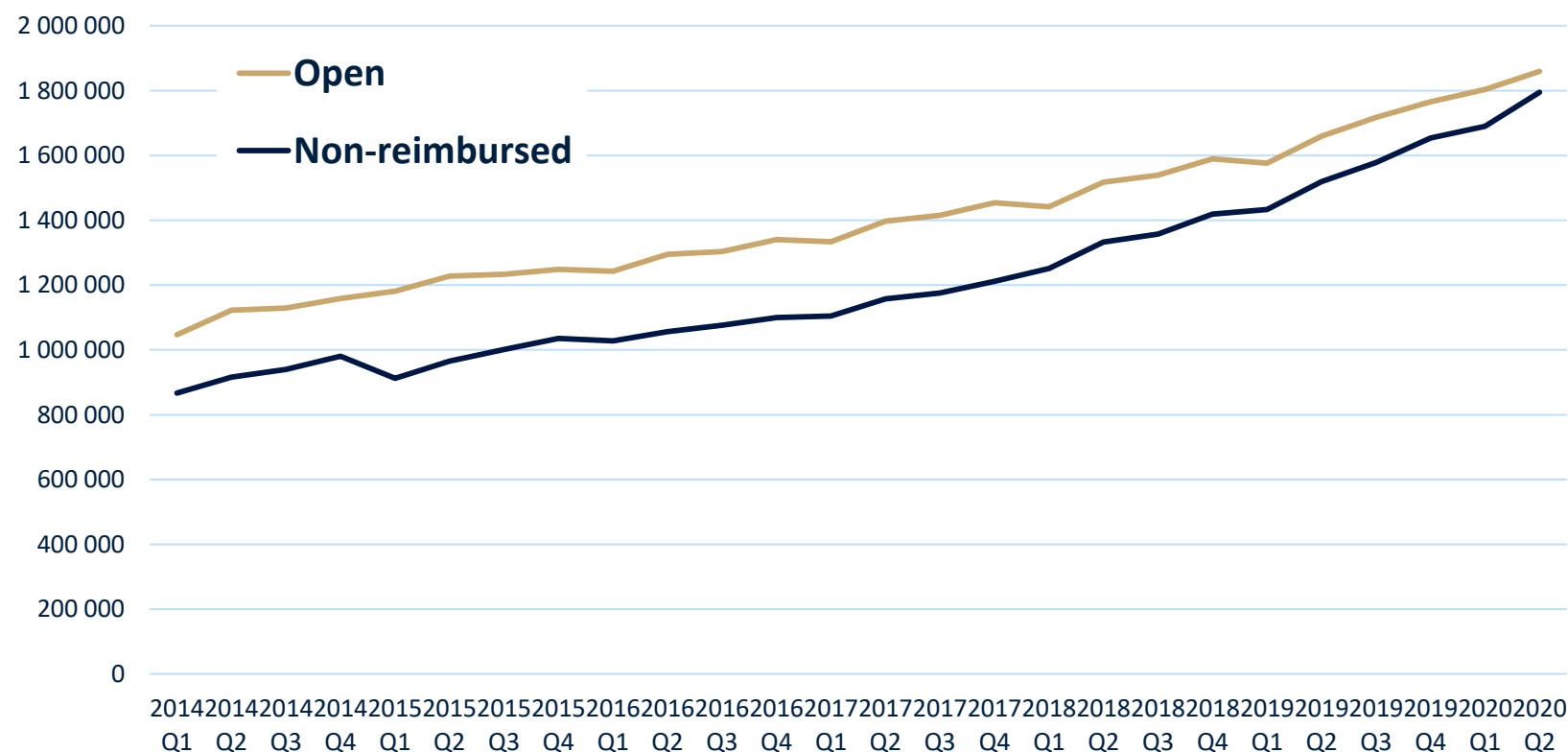


2020 market volume continues to have strongest growth rate since ZUBSOLV® launch

Market growth solely driven by the “Public Segment”

Market Volume Sales

Quarterly NTRx



Q2'20 vs Q2'19 Growth

Total Market: +15%

By Segment

+12%

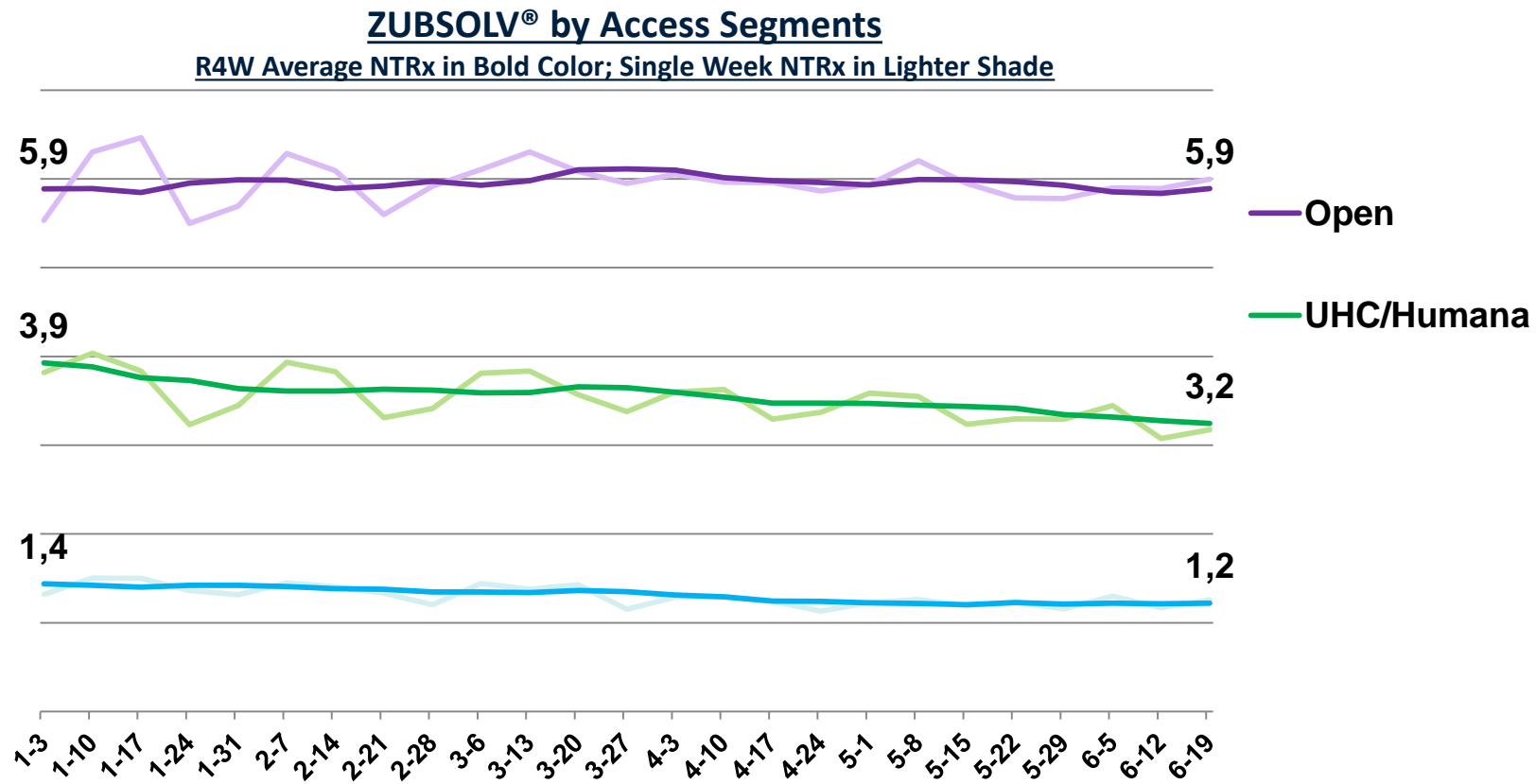
+18%

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

Despite COVID-19 lockdown, Open segment stable throughout 2020, UHC/Humana segment declining due to UHC, Non-Reimbursed segment slightly declining



ZUBSOLV® net sales up in Q2 vs Q1 despite a mild volume decline due to COVID-19 challenges during lockdown

... ZUBSOLV® grew net sales 5% though volume declined 4% QoQ

...Commercial segment showed a volume decline during Q2 due primarily to COVID related unemployment spike

...Main driver of market growth was Medicaid where ZUBSOLV® has limited access though ZUBSOLV® grew volume where it has “open” access in Medicaid

Several possible triggers for ZUBSOLV® growth in 2020 and beyond



Continued improvement in ZUBSOLV® market access

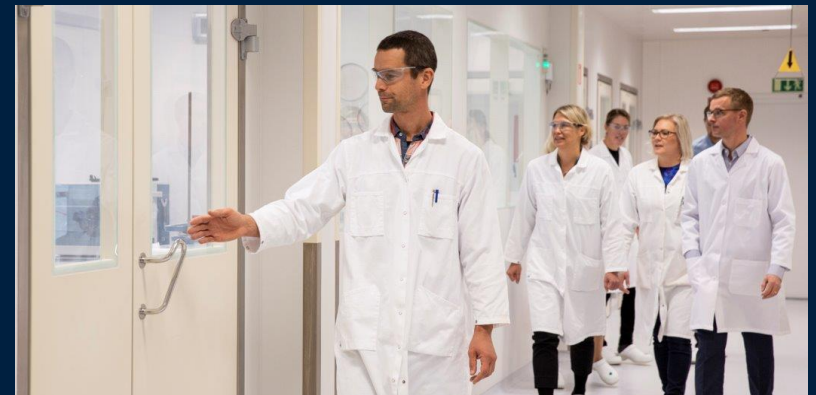
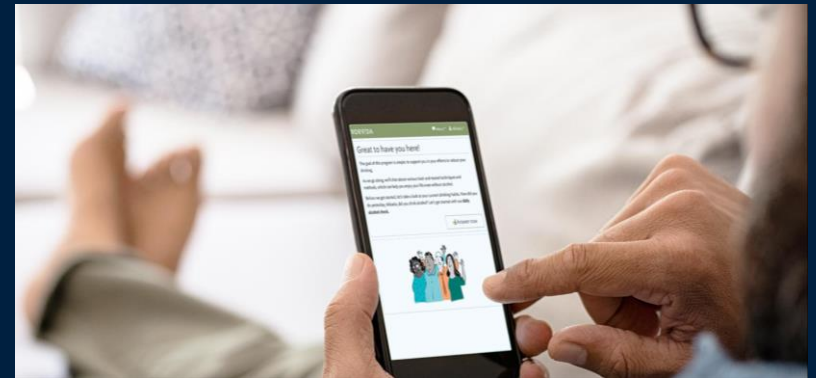
- ...Louisiana Medicaid added ZUBSOLV® to preferred formulary increasing “public access” from 35% to 37% (effective July 1)
- ...Orexo continues to pursue expanding market access in Medicare and Medicaid while maintaining 98% commercial market access leadership position
- ...Generic Film availability pressuring access status of largest branded competitor

Orexo Sales Force now back to office-based selling after 3 months

- ...Orexo stopped all office selling March 16th and the selling model was converted entirely to virtual setting (audio, video and e-mail) as necessitated by prescriber
- ... Currently entire team returning to office-based selling activities while continuing to use virtual selling as certain offices have entry restrictions based on policy & changing COVID environment

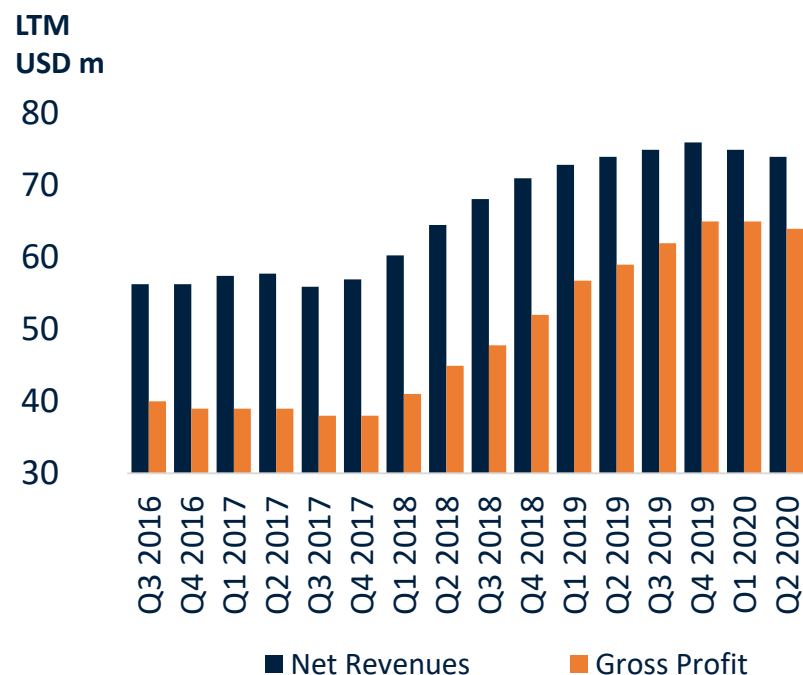
Financials

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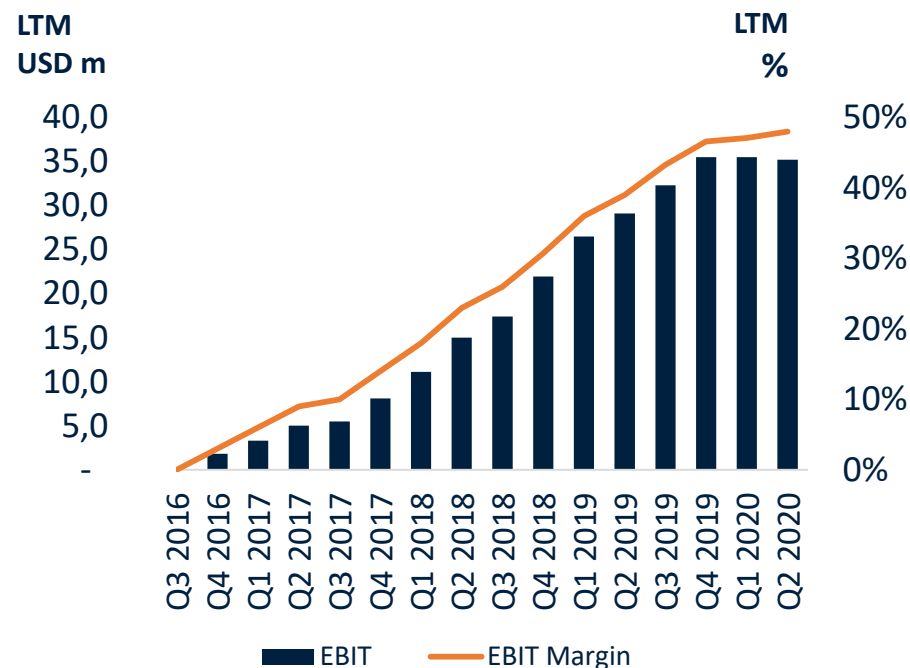


US Pharma Operating Margin (LTM) grew to 47.8%

Sales and gross profit



EBIT



- ZUBSOLV® US net sales declined slightly to USD 73.6 m from USD 74.1 m in Q219
- Strong growth in EBIT contribution to USD 35.2 m increasing from USD 29.1 m in Q219 driven by lower COGS and lower operating expenses
- US Pharma EBIT margin of 47.8% LTM in Q220 increasing from 39.3% in Q219, EBIT margin in Q2 2020 reached 51.5%
- 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.

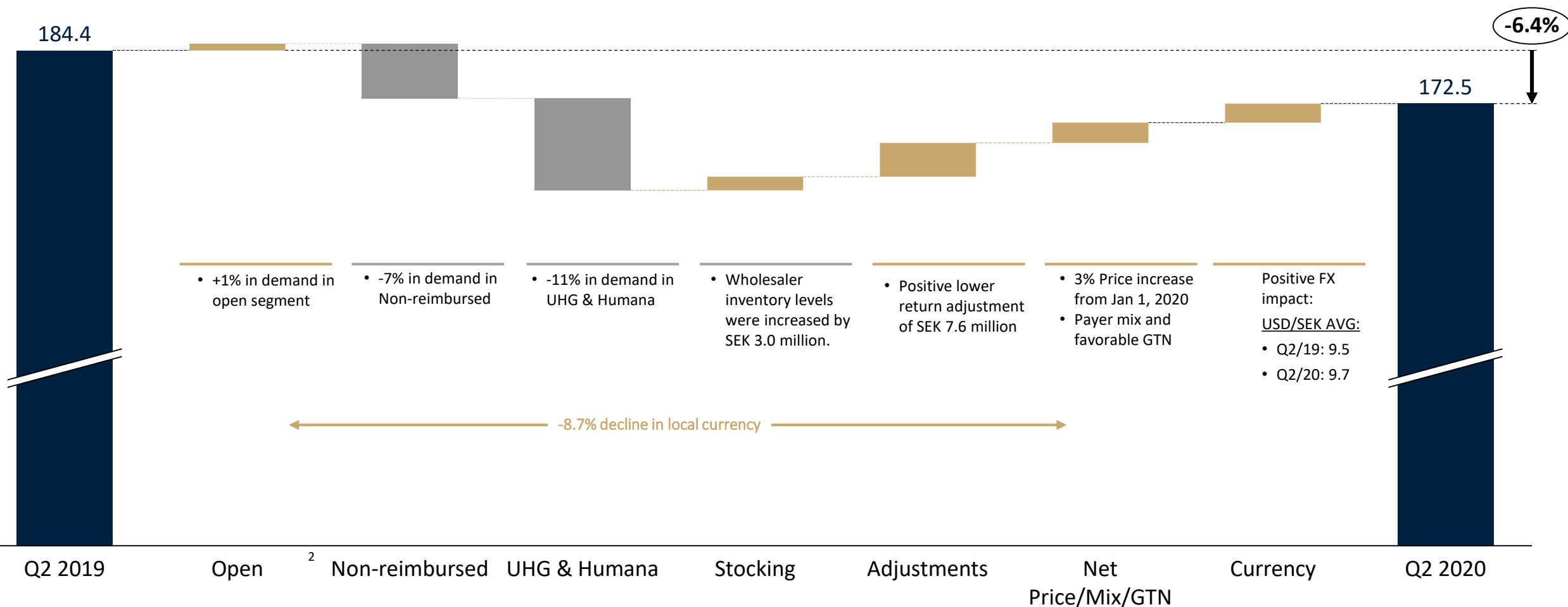
Note: COGS converted from SEK to USD using monthly average exchange rates for the period.

Lower ZUBSOLV® net revenues and ceased Abstral royalties in the EU and the US

SEK m	Q2 2020	Q2 2019	H1 2020	H1 2019	Jan - Dec 2019
ZUBSOLV® US	172.5	184.4	336.4	346.1	719.2
US Pharma - Total	172.5	184.4	336.4	346.1	719.2
Abstral® royalties	3.5	13.1	12.2	24.0	112.6
Edluar® royalties	3.1	2.4	5.5	4.2	11.6
ZUBSOLV® – ex US	-	-	0.1	-	0.1
OX-MPI	-	1.3	-	1.3	1.4
HQ & Pipeline – Total	6.6	16.8	17.8	29.4	125.6
TOTAL	179.1	201.2	354.2	375.5	844.8

- Net revenues for Q220 declined 11.0% due to lower ZUBSOLV® US revenues and due to absence of Abstral EU and US royalties, ZUBSOLV® US revenues declined 6.4% in Q220 vs Q219 to SEK 172.5 m
- Abstral Q220 decline explained by expired agreement for EU royalties and by discontinued sales since October 31 2019 in the US following loss of patent protection
- 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® US net revenues growth by key drivers, Q2 2020 vs Q2 2019



Financial performance per business segment

US Pharma SEK m	Q2 2020	Q2 2019	H1 2020	H1 2019	Jan - Dec 2019
Net revenues	172.5	184.4	336.4	346.1	719.2
Cost of goods sold (COGS)	-19.3	-31.3	-39.3	-56.6	-105.6
Gross Profit	153.2	153.1	297.1	289.5	613.6
Operating expenses	-64.4	-69.3	-132.6	-137.5	-266.5
EBIT	88.8	83.8	164.5	152.0	347.1

- **US Pharma** Reduced cost of goods and OPEX drive EBIT growth, despite lower revenue

Digital Therapeutics SEK m	Q2 2020	Q2 2019	H1 2020	H1 2019	Jan - Dec 2019
Net revenues	-	-	-	-	-
Cost of goods sold (COGS)	-0.6	-	-0.6	-	-
Gross Profit	-0.6	-	-0.6	-	-
Operating expenses	-34.9	-	-47.0	-	-0.9
EBIT	-35.5	-	-47.6	-	-0.9

- **Digital Therapeutics** Negative EBIT solely explained by investments in launch preparations of deprexis® and vorvida®.

HQ & Pipeline SEK m	Q2 2020	Q2 2019	H1 2020	H1 2019	Jan - Dec 2019
Net revenues	6.6	16.8	17.8	29.4	125.6
Cost of goods sold (COGS)	-	-	-	-	-
Gross Profit	6.6	16.8	17.8	29.4	125.6
Operating expenses	-73.2	-47.8	-114.0	-127.5	-240.6
EBIT	-66.6	-31.0	-96.2	-98.1	-115.0

- **HQ and Pipeline** Investments in R&D and reduced royalties from Abstral explains increase in negative EBIT contribution.

Increased investments in DTx and Pipeline

SEK m	Q2 2020	Q2 2019	H1 2020	H1 2019	Jan - Dec 2019
Net revenues	179.1	201.2	354.2	375.5	844.8
Cost of goods sold (COGS)	-19.9	-31.3	-39.9	-56.6	-105.6
Gross Profit	159.2	169.9	314.3	318.9	739.2
Selling expenses	-70.0	-49.0	-124.4	-96.3	-191.9
Administrative expenses	-32.7	-24.5	-56.5	-94.6	-139.6
Research & development expenses	-62.6	-43.5	-115.6	-81.2	-181.3
Other operating income & expenses	-7.1	-0.1	2.9	6.9	4.8
Operating Costs	-172.5	-117.1	-293.6	-265.1	-508.0
EBIT	-13.3	52.8	20.7	53.8	231.2
Net financial items	-22.2	5.7	21.8	10.5	-3.3
EBT	-35.5	58.5	42.5	64.3	227.9
Tax	3.0	-3.9	7.6	4.3	-8.8
Net profit/loss	-32.5	54.6	50.1	68.6	219.1
EBITDA	-9.0	60.4	30.1	72.3	272.1

Q220 comments:

- **COGS** for the quarter 36.4% lower vs prior year driven by manufacturing efficiency program and higher production volumes
- **Operating Costs** above prior year due to:
 - Selling expenses increased explained by costs related to preparations to launch vorvida® in the US, in Q2 2020
 - Administrative expenses higher, explained by higher costs for the long-term incentive programs following positive share price development and fair value adjustment vs prior quarter.
 - R&D expenses higher due to development projects
 - Other operating income contributed negatively due to exchange-rate losses derived from revaluations of parent company balance sheet items in foreign currency, predominantly in USD
- **Net Financial items** had negative impact mainly explained by negative unrealized exchange-rate impact of SEK 18.2 m derived from the parent company's foreign currency bank accounts mainly in USD and by costs for corporate bonds of SEK 3.5 m.

Strong financial position after investment in DTx and buyback of corporate bond loan

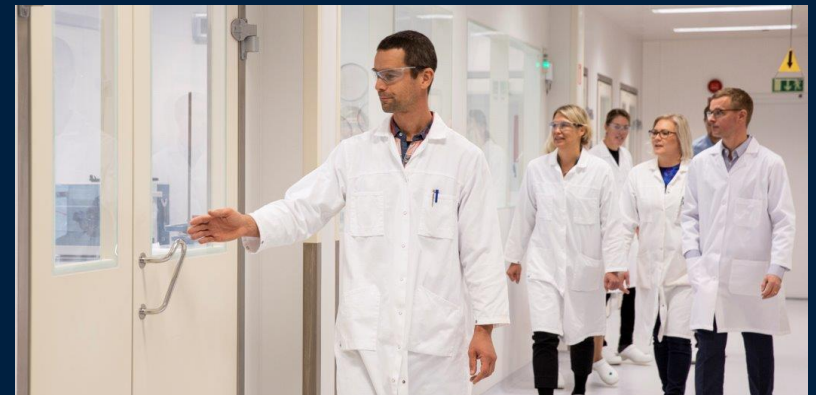
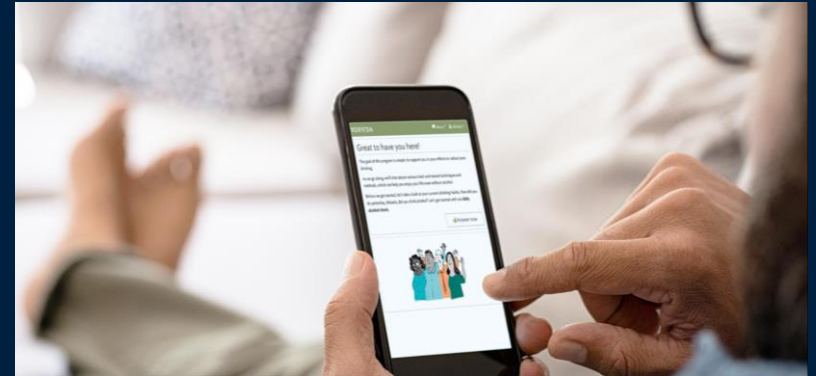
Cash position of SEK 677.2 m and a positive net cash position of SEK 453.4 m

Cash flow SEK m	Q2 2020	Q2 2019	H1 2020	H1 2019	Jan - Dec 2019
Cash flow from operating activities	-7.2	46.1	40.9	97.1	287.0
Investment activities	-106.0	-0.8	-109.9	-0.8	-22.4
Financing activities	-33.9	-3.8	-102.7	-14.5	-53.7
Cash flow (excl exchange rate differences)	-147.1	41.6	-171.7	81.7	210.8
Liquid funds	677.2	697.0	677.2	697.0	816.8
Net cash position	453.4	375.7	453.4	375.7	527.2

- Negative cash flow from operating activities for the period Q220
 - SEK 7.2 m negative contribution from operating activities.
 - Investment activities had a negative impact of SEK 106.0 m primarily due to payment of a non-refundable milestone to GAIA AG for deprexis®
 - Financing activities had a negative impact of SEK 33.9 m due to share buyback of SEK 2.9 m, due to buyback of corporate bond loan of SEK 26.1 m and due to negative IFRS 16 impact of SEK 4.9 m
 - SEK 37.1 m negative impact on cash position due to weaker USD in June 2020
- Strong cash position at the end of Q220 with SEK 677.2 m

Outlook

orexo



To enable accelerated launch of all three digital therapies investments will increase and OPEX guidance for FY 2020 will be impacted by approx. SEK 200 m

- Previous OPEX guidance excluded launch expenses for vorvida®, all expenses for deprexis® and launch of OXD01 ahead of original plan in 2022
- New guidance includes all expenses related to the build up of the DTx venture and the commercialization incl.
 - Creating a "digital therapy engine" to offer a range of services and ensure patients engagement, e.g. building up a specialty service hub insurance reimbursement, customer service platform, e-commerce storefront
 - Launch preparations for three products to develop marketing material, OXD01 branding, customer insight generation, field force preparation etc
 - Launch of three products during 2020 including non-personal promotion, field force activities
- The increased investment will impact all remaining quarters including Q2
- Investments will be monitored closely and adjusted pending our success in securing reimbursement during 2020
- Except for depreciation, the guidance does not include capitalized investments, such as milestone payments to GAIA AG and some limited infrastructure investments

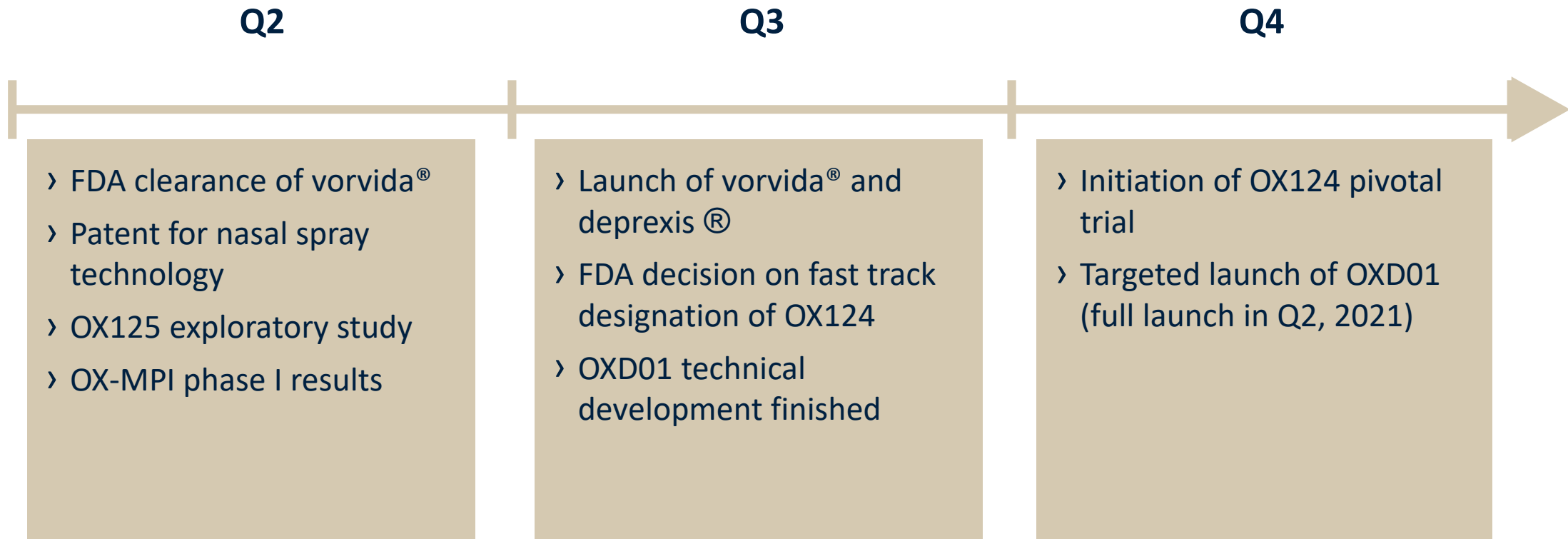
Financial outlook 2020

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, establishment of DTx business and accelerated DTx US launch OPEX will reach a level of SEK 750-800 m
- › 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 OPEX, EBITDA will decrease
- › US Pharma EBIT 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



Thank You

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