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A profitable specialty pharmaceutical company – with the aim of becoming a leader within addiction

Interim Report Q4 2019, January 30th 2020

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

Overview
Q4 2019

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2019 – a record year further establishing a strong foundation for future growth

Financials: Continued strong financial performance

- Net revenues of SEK 238.1 m (227.1, Q418) up 4.8%, Zubsolv® growth of 7.5 % in USD (14.3% in SEK)
- EBITDA of SEK 85.8 m (42.8), ex Abstral® SEK 39.6 m (-9.6)
- US EBIT of USD 10.2 m (6.8) with a 51.6% EBIT margin (37%)
- US result explained by continued Zubsolv® growth in profitable "Open Formulary Business*", improved efficiency and prior period adjustments
- SEK 816.8 m in cash balance end of Q4
- Net earnings of SEK38.9 m impacted in Q4 by negative exchange rate adjustments and tax – Full Year of increase of 58.9% reaching all-time-high of SEK 219.1 m

R&D and Business development: expanding the new digital frontier in patient care

- New agreement signed with GAIA to commercialize vorvida®, a complementary Digital Therapy for alcohol use disorder with expected US launch in H2 2020
- OX338 - promising results from human PK study assessing novel ketorolac formulations for treatment of pain
- OX124 on track to start pivotal trial in H2 of 2020 and first human exploratory trial planned for OX125 in H1 of 2020
- Zubsolv® partnership ex US advancing with launch timing pending reimbursement decisions and national approval of the supply chain

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

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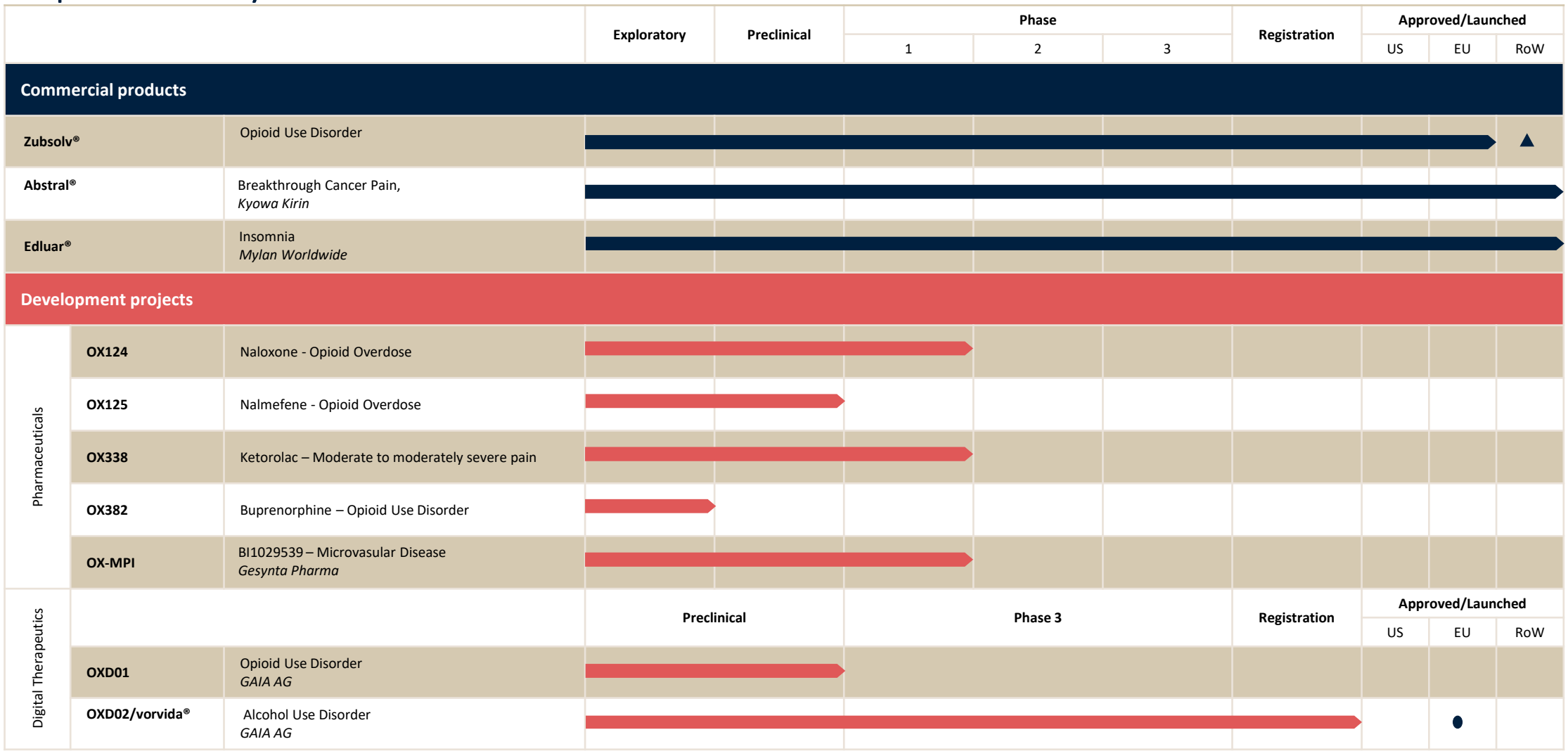
Three additional commercial stage products in the US expected by 2021



▲Zubsolv® has been approved in Australia
● vorvida® has been launched in Germany and Switzerland by GAIA

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

Expected launch of OX124 in 2021 in the US, 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 2nd 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 2nd doses
- **Pivotal trial of OX124 planned for H2 2020, with approval and launch expected 2021**

Committed to find new solutions to improve treatment of addiction

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

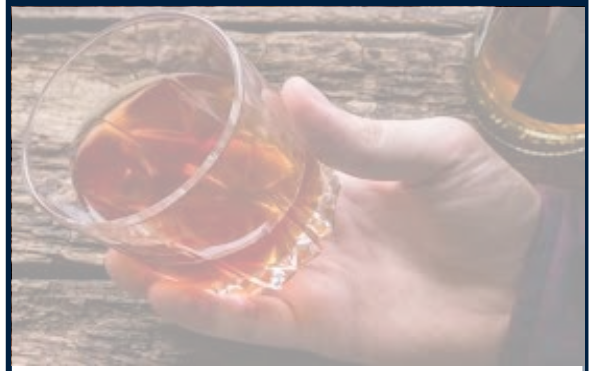
GAIA develops DTx with scientifically proven efficacy

- 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
- Expected US launch in 2021
- Orexo holds the global rights

OXD02 vorvida® (Alcohol Use Disorder, AUD)



- US license deal
- Synergistic asset
- FDA discussion initiated about regulatory route to market
- Launch in H2 2020

vorvida® target an unmet need in treatment of alcoholism

Background

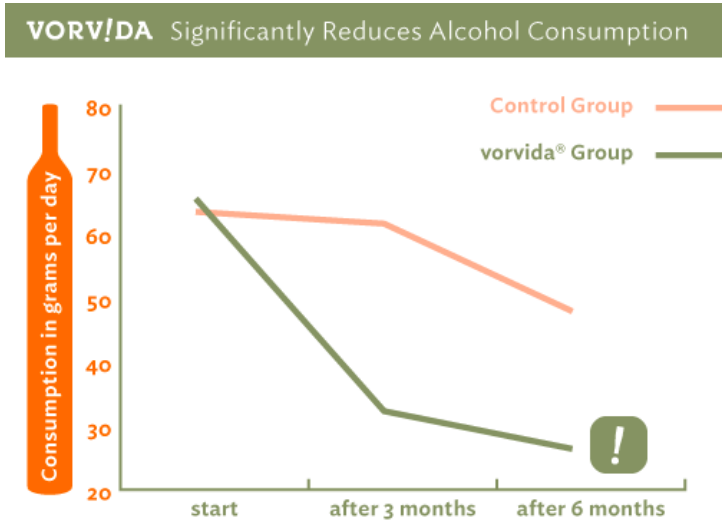
- There is a substantial unmet need and low treatment rate: Alcohol Use Disorder (AUD) Affected >14M Adults in 2017 in the US, of which <20% Received Treatment. ~60% of these attended Self-Help Group
- Alcoholism is highly stigmatized preventing patient from seeking treatment
- Abstinence is often the only goal, and current therapies require abstinence prior to initiating therapy but 85% of patients do not achieve long term abstinence
- Significant side effects of current pharmacotherapies
  - Mental : Nausea, dizziness, psychiatric disorders and depressive symptoms
  - Physical : Vomiting, abdominal pain, arthritis and joint fitness

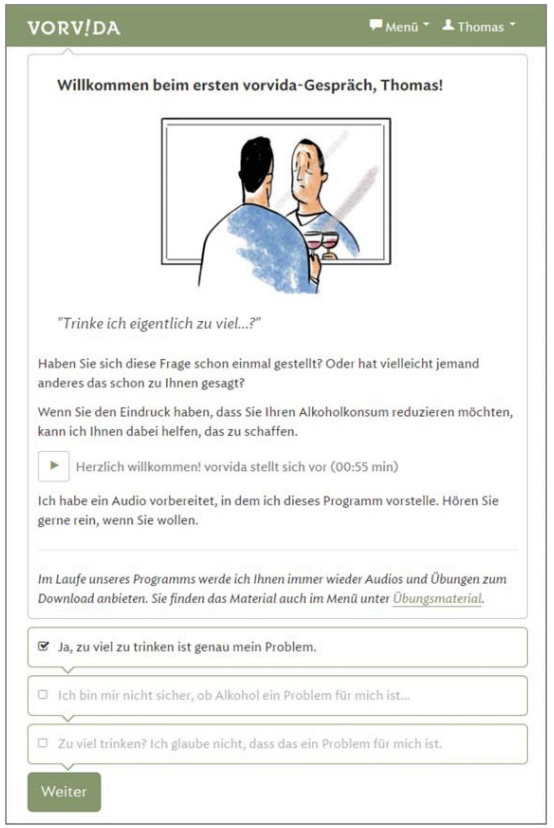
vorvida® overview

- vorvida® is a Fully Automated, AI-Powered 6 month digital therapy intervention for alcohol use disorder based on CBT
- Launched in Germany in 2019, supported e.g., by DAK (one of Germany's largest payors)
- Different behavior change techniques are employed:
  - Goal setting
  - Self-monitoring of symptoms with questionnaires
  - Cognitive and behavioral strategies for handling alcohol cues, craving and risk situations
  - Cognitive restructuring
  - Mindfulness-based methods
  - Mental imagery

vorvida® has strong clinical evidence supporting its efficacy

- Randomized controlled trial*:608 adults with problematic alcohol consumption randomized to vorvida or care as usual/waitlist.
  - 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
  - After 6 months: 63% remained in treatment in the vorvida-group and 73% in the waitlist control group.





Notes: * Funded by the German Federal Ministry of Education and Research. Patients were recruited online and offline.
Source: Zill et al. 2019. The effectiveness of an internet intervention aimed at reducing alcohol consumption in adults (Vorvida): Results of a randomized controlled trial. Deutsches Ärzteblatt

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Key Market & Sales

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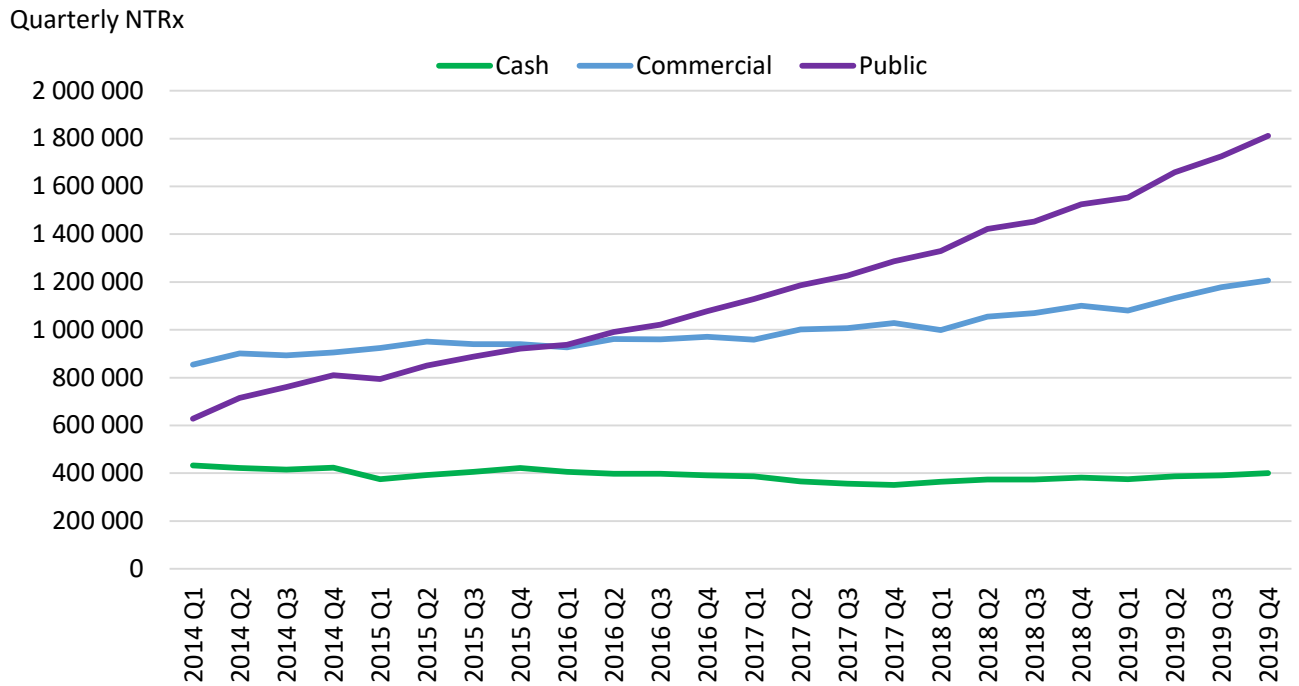
Full year market growth of 14% 2019 vs 2018 ahead of Orexo's forecast and strong Zubsolv® growth in open formularies

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



Q4 YoY Growth

	Market	Zubsolv® total	Zubsolv® open formulary*
	+19%	-7%	+19%
	+10%	-5%	+14%
	+5%	-38%	

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

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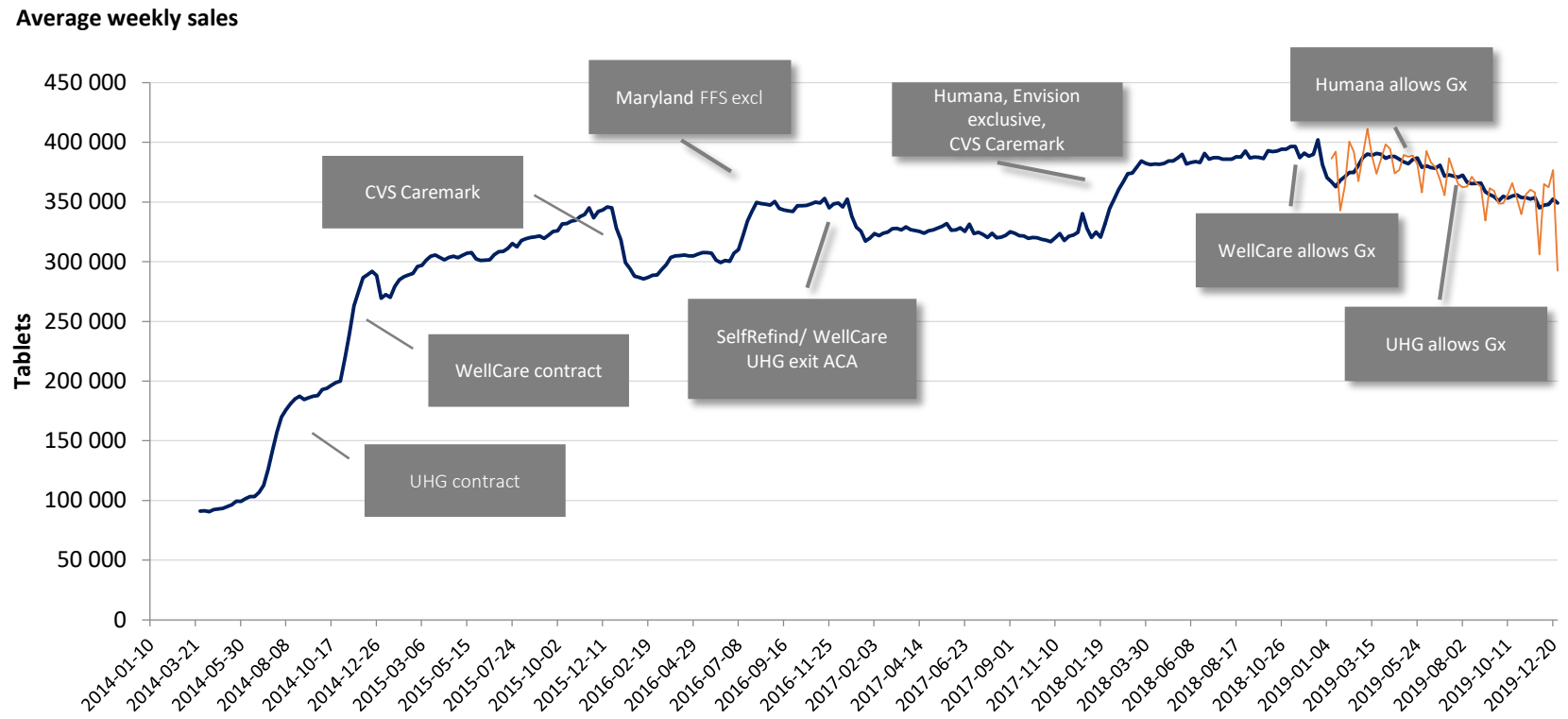
Zubsolv® volumes declined due to loss of three exclusive formulary positions and the genericization of the cash segment

Zubsolv Tablet Volume (rolling 4 week average)



*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

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

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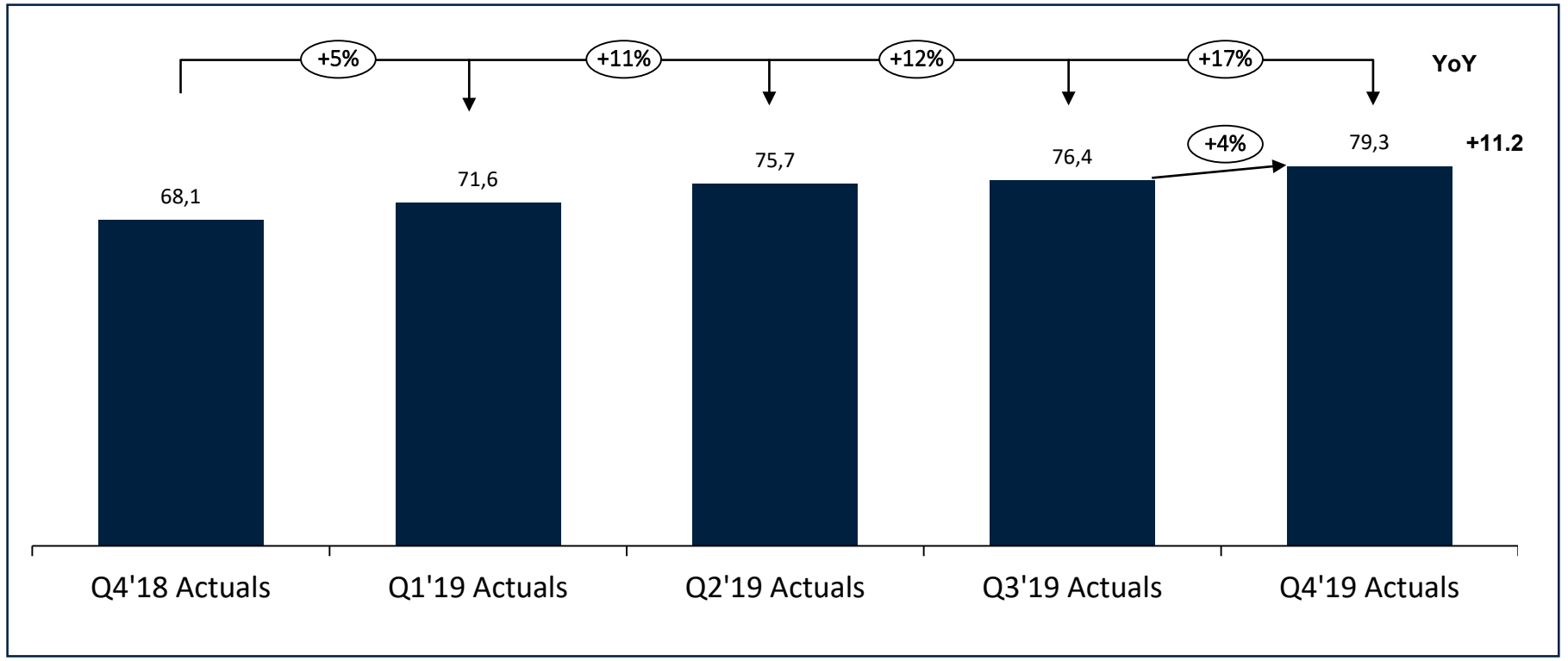
Zubsolv® volume continue to show strong performance in growing and profitable Open Formulary Business

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

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Market access slightly improved in the profitable commercial segment in 2020

Continued excellent market access in profitable commercial segment

- 98% of patients with commercial health insurance have unrestricted access to Zubsolv from January 1, 2020
- Zubsolv® outgrew the market in “open formularies” in commercial with 4 percentage points
- Caremark is the main growth driver with 34% growth over Q3 2019
- Open formularies (including public segment) continue with strong growth (17% over Q4 2018 and 4% over Q3 2019) partly compensating for loss in previously exclusive contracts and cash segment
- Overall volume decline compensated by payer mix and price resulting in growing USD net sales

Market growth expected to continue

- Number of waivered health care professionals continue to increase which will drive continued market growth, although Q1 is traditionally a “weaker” quarter and is likely to show less growth quarter over quarter
- The authorized generic of Suboxone film continues to be the dominant generic player and the announced removal of the authorized generic has not yet been implemented
- A removal of the authorized generic is likely to have effect on the market dynamics in favor of Zubsolv

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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

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Financials

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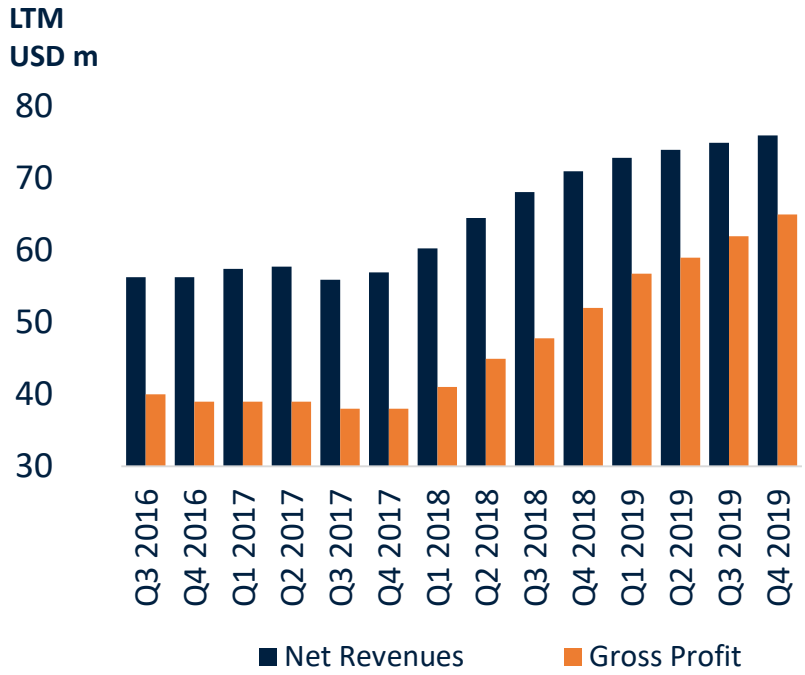
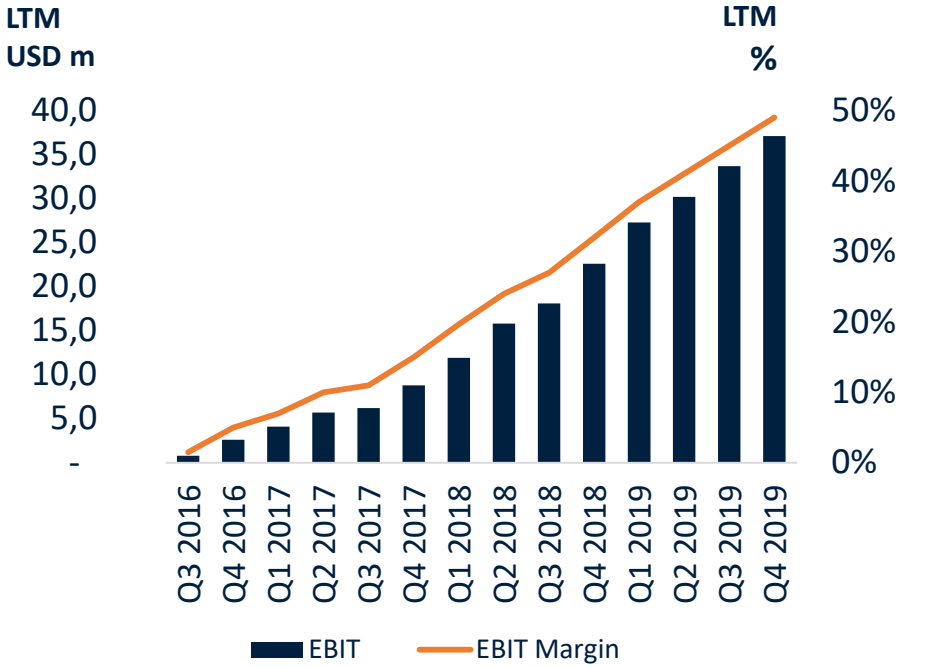
EBIT growth of 64% in USD and EBIT Margin (LTM) reaching 50% Orexo US

Net sales and gross profit



Operating Profit



- Net Sales grew to USD 76.0 m from USD 71.4 m in Q418
- Strong growth in EBIT contribution to USD 37.1 m increasing 64.4% from USD 22.6 m in Q418 driven by higher net revenues and lower COGS
- US EBIT margin of 48.8% LTM in Q419 increasing from 31.6% in Q418, EBIT margin in Q4 2019 reached 51.6%
- Full year 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

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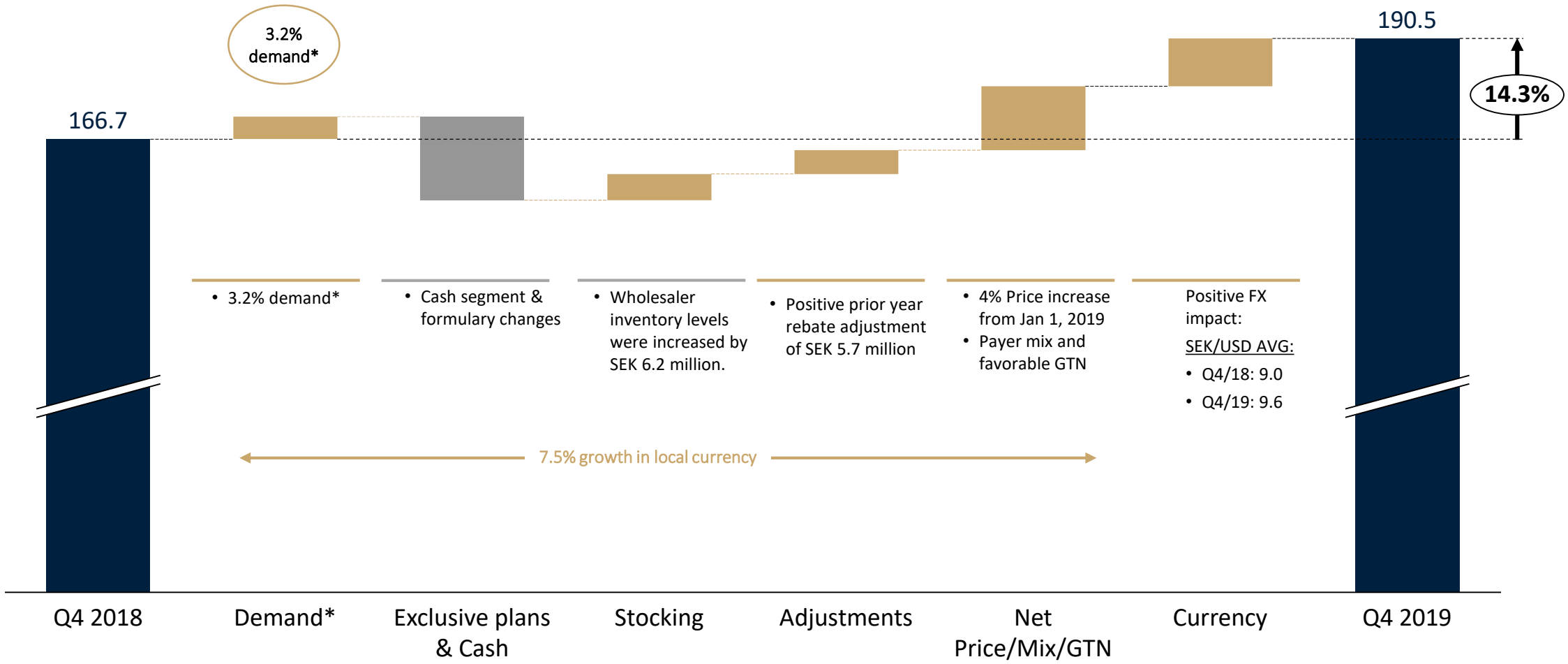
Zubsolv® main growth driver of net revenues with 14.3 percent

Corresponding to a 7.5 percent growth in local currency

SEK m	Q4 2019	Q4 2018	Jan - Dec 2019	Jan - Dec 2018
Zubsolv® US	190.5	166.7	719.2	621.5
Zubsolv – ex US	0.0	5.2	0.1	36.2
Zubsolv – total	**190.5**	**171.9**	**719.3**	**657.8**
Abstral® royalties	46.2	52.4	112.6	118.8
Edluar® royalties	1.3	2.9	11.6	6.6
OX-MPI	0.0	-	1.4	-
TOTAL	**238.1**	**227.1**	**844.8**	**783.1**

- Total net revenues for Q419 grew 4.8% driven by higher Zubsolv US revenues
- Zubsolv US revenues grew 14.3% in Q419 vs Q418 to SEK 190.5 m
- Abstral Q419 decline explained by lower volumes in Europe and 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 ~85 MSEK in 2020

Demand growth of 3.2% excluding loss in exclusive contracts and cash segment



1Orexo analysis using IMS demand data plus institutional sales
* Excluding cash segment and formulary changes (Wellcare, UHC and Humana)

Continued strong financial performance in Q419

EBITDA reached SEK 78.7 m (42.8, Q418) and ex Abstral® SEK 39.6 m (-9.6)

SEK m	Q4 2019	Q4 2018	Jan - Dec 2019	Jan - Dec 2018
Net revenues	238.1	227.1	844.8	783.1
Cost of goods sold (COGS)	-23.0	-43.4	-105.6	-171.8
Gross Profit	**215.0**	**183.7**	**739.2**	**611.4**
Selling expenses	-50.6	-48.0	-191.9	-191.4
Administrative expenses	-26.9	-54.7	-139.6	-166.7
Research & development expenses	-58.6	-47.0	-181.3	-166.8
Other operating income & expenses	-7.4	3.6	4.8	9.3
Operating Costs	**-143.5**	**-146.1**	**-508.0**	**-515.6**
EBIT	**71.5**	**37.6**	**231.2**	**95.8**
Net financial items	-22.5	-0.3	-3.3	-3.6
EBT	**49.0**	**37.3**	**227.9**	**92.2**
Tax	-10.1	14.3	-8.8	45.7
Net profit/loss	**38.9**	**51.6**	**219.1**	**137.9**
EBITDA	**85.8**	**42.8**	**272.1**	**116.6**

Q419 comments:

- **Gross Profit** for the quarter 17% higher vs prior year. This is driven by 49% lower COGS per tablet vs the average in 2017, limited improvement of COGS expected in 2020
- **Operating Costs** below prior year due to:
  - Selling expenses moderately higher explained by timing of activities
  - Administrative expenses lower, due to less spending of SEK 0.6 m (26.4) 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.
  - OPEX expected to increase in 2020 to 550-600 MSEK due to increased investment in R&D incl. DTx, legal expenses expected to remain low

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Strong financial position enabling Orexo to pursue its growth strategy

Cash position of SEK 816.8 m and a positive net cash position of SEK 527.2 m

Cash flow SEK m	Q4 2019	Q4 2018	Jan - Dec 2019	Jan - Dec 2018
Cash flow from operating activities	60.2	71.7	290.9	242.0
Investment activities	-11.0	-3.9	-26.3	-6.2
Financing activities	-4.3	0.0	-53.7	0.0
Cash flow (excl exchange rate differences)	44.8	67.8	210.8	235.8
Liquid funds	**816.8**	**589.8**	**816.8**	**589.8**

- Positive cash flow from operating activities for the period Q419
  - SEK 60.2 million positive contribution from operating activities.
  - Investment activities had a negative impact of SEK -11.0 m mainly due to payment of a non-refundable initial milestone of SEK 15.8 m
  - 40.9 MSEK negative impact on cash position due to weakening USD in December of 2019
- Strong cash position at the end of Q419 with SEK 816.8 million

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Outlook

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Orexo in an exciting position to drive long-term growth

Zubsolv expected to return to strong growth over time

- Strong underlying growth of opioid addiction market expected to continue
- Positive trend in open formularies for Zubsolv expected to have full effect on top-line growth from Q2 as negative impact from loss of exclusive formulary position with three payers is expected diminish
- Several possible triggers of accelerated growth opportunities for Zubsolv

Pipeline assets approach commercialization

- OX124 expected to be launched in 2021 with positive outcome of last clinical trial planned for H2 2020
- Planned launch of vorvida® in H2 2020
- Zubsolv ex US likely to launch when reimbursement processes are finalized and supply chain established

Strong financial position enables investments in growth

- Cash position of SEK 816 m, strong EBIT contribution from Zubsolv US, enables investments in business development, M&A and accelerated R&D

Good outcome of 2019 financial outlook

- For 2019 Orexo expects to improve the positive EBITDA on a full year basis and on a quarterly basis the development will follow the same pattern as previous year - **Outcome: +133 percent**
- Orexo believes the overall net sales of Zubsolv® in the US will increase in local currency, despite increased competition from Suboxone® Film generics - **Outcome: +8 percent**
- The manufacturing efficiency program aimed to reduce the average Cost of Goods Sold (COGS) per tablet by 35 percent in H2, 2019 compared to 2017- **Outcome: +40 percent**
- Full year OPEX is expected to stay at the same level as 2018 with approximately SEK 500 million. The final outcome is dependent on the cost of the IP litigation against Actavis for their generic versions of Suboxone and Subutex® and possible appeals after the court hearing in the District Court in March - **Outcome: SEK 508 million**
- Additional investments may be needed if development programs reach clinical stage faster than anticipated. Orexo expects to advance at least one additional development program to phase I trial during 2019. -**Outcome: OX338 advanced in phase 1 trial**
- The first new partnerships for Zubsolv outside the US is expected to be initiated in 2019 - **Outcome: Initiated partnership with Mundipharma Pty. for Australia and New Zeeland**

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

Thank You
Q&A

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