

orexo

2018 - A pivotal year for Orexo

Q4 2018 Interim Report, January 30, 2019

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

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2018 - A pivotal year for Orexo!

Financials:

- EBITDA of SEK 116.6 M growing 50% from 2017
- Positive Cash Flow of SEK 242 M from operations leading to a cash position of SEK 589.9 M
- Orexo US EBIT of SEK 198.3 M and EBIT Margin of 31.9%

Operations:

- Manufacturing efficiency program leading to 9% reduction in COGs per tablet in 2018
- Objective maintained to reach 35% reduction compared to 2017
- Upgrade initiated of Uppsala facilities to enable manufacturing of GMP

R&D Pipeline:

- Zubsolv rights outside the US regained from Mundipharma
- Three new projects announced, OX124, OX125, OX338
- OX124 show positive data in first clinical trial
- OX338 with positive in vivo data

People:

- Previously contract Field force in the US internalized
- Both Sweden and US employee engagement surveys show very positive feedback

Zubsolv's exclusivity in the US is secured until Sep. 2032

Q4 2018 highlights – Continued strong sales and pipeline development

Financials:

Significant growth in EBIT from Orexo US

Continued strong net revenue growth and profitability improvements

- Total Q4 net revenue SEK 227.1 M, a growth versus prior year of 18.9 percent mainly driven by increased Zubsolv® sales of USD 18.5 M an increase of 21.3 percent and 31.8% in SEK
- EBITDA of SEK 42.8 M and SEK 69.2 M excluding litigation costs.
- US EBIT of SEK 62 M up 11.5 percent from last quarter and 213% from Q4 2018
- Q4 with some additional non-recurrent legal costs, European manufacturing, market research and IR explaining deviation from guidance of approximately SEK 500 M in OPEX

Commercial

Progress:

Improved market access in a fast growing market

Continued strong development of Zubsolv compared to 2017

- The US buprenorphine/naloxone market showed an accelerated growth of 14.1% in Q4 versus prior year, up from 4.2% from Q3
- Zubsolv grew 22% in tablets in Q4 versus prior year, which makes Q4 the best quarter ever measured in prescriptions for Zubsolv
- Market access improve from January 1 in both commercial and public segments, with the most significant contributor being Ohio FFS Medicaid
- Zubsolv rights outside the US regained and work to identify new partners is making good progress

R&D:

First human trial for OX124 successful

Positive clinical trial on OX124

- OX124 first human trial successful
- OX338 with positive in-vivo data
- In-vivo testing of new formulation for OX382 initiated with expected results in Q1

Zubsolv's exclusivity in the US is secured until 2032

New patent litigation case requiring significant investments in Q1, 2019

Comprehensive patent protection in the Orange book until September 2032

Ongoing patent litigation against Actavis

1.

Zubsolv

The District Court of Delaware issued a final non-appealable judgement that Actavis infringe the Zubsolv patent US 8,940,330 and this case has been finalized.

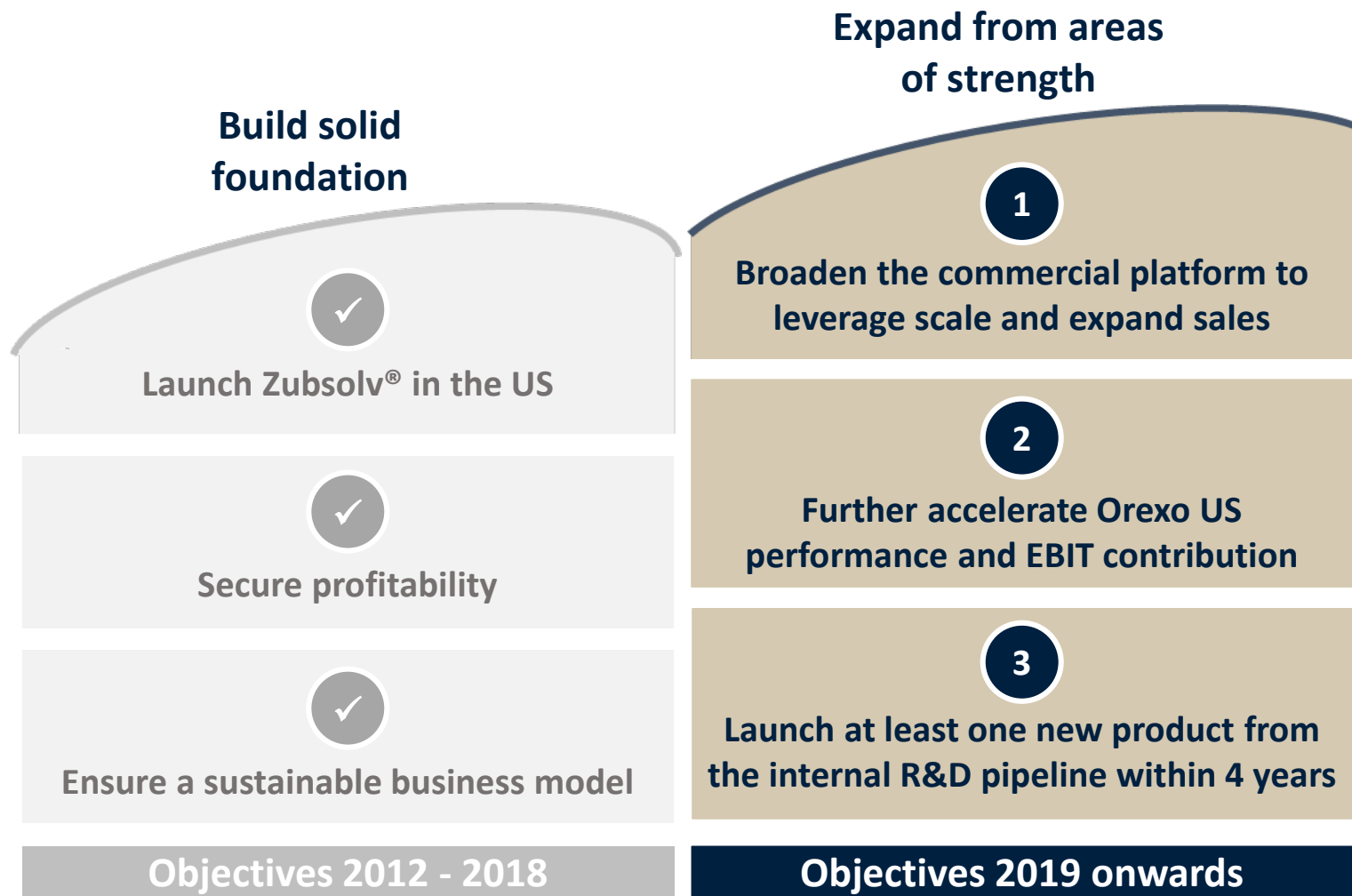
2.

Gx

Patent No	Expiration
8454996	2019

- Orexo has filed a litigation case against Actavis for infringement of '996 patent with their Suboxone® and Subutex® generics
- Significant investment expected in Q1, 2019, but expected to decline in Q2 and beyond
- Trial scheduled to start March 25-29, 2019 and the decision will come closely after

Our aim is to deliver growth by diversifying the commercial platform



OX124 in the Orexo pipeline has showed positive results from first human trial

OX382 1st Oral Swallowable Formulation of Buprenorphine for Opioid dependence and Pain

Objective

- Create a more convenient administration route for patients and stable delivery of buprenorphine for us in addiction treatment and pain

Status

- **In vivo test results expected in Q1**

OX124 and OX125 Opioid overdose rescue medication

Objective

- Develop a differentiated emergency treatment of known or suspected opioid overdose

Status

- **Phase I clinical trial completed with positive outcome for OX124, showing substantially higher plasma concentrations of naloxone than leading competitor in the US**

OX338 Sublingual formulation of undisclosed NSAID for Pain treatment

Objective

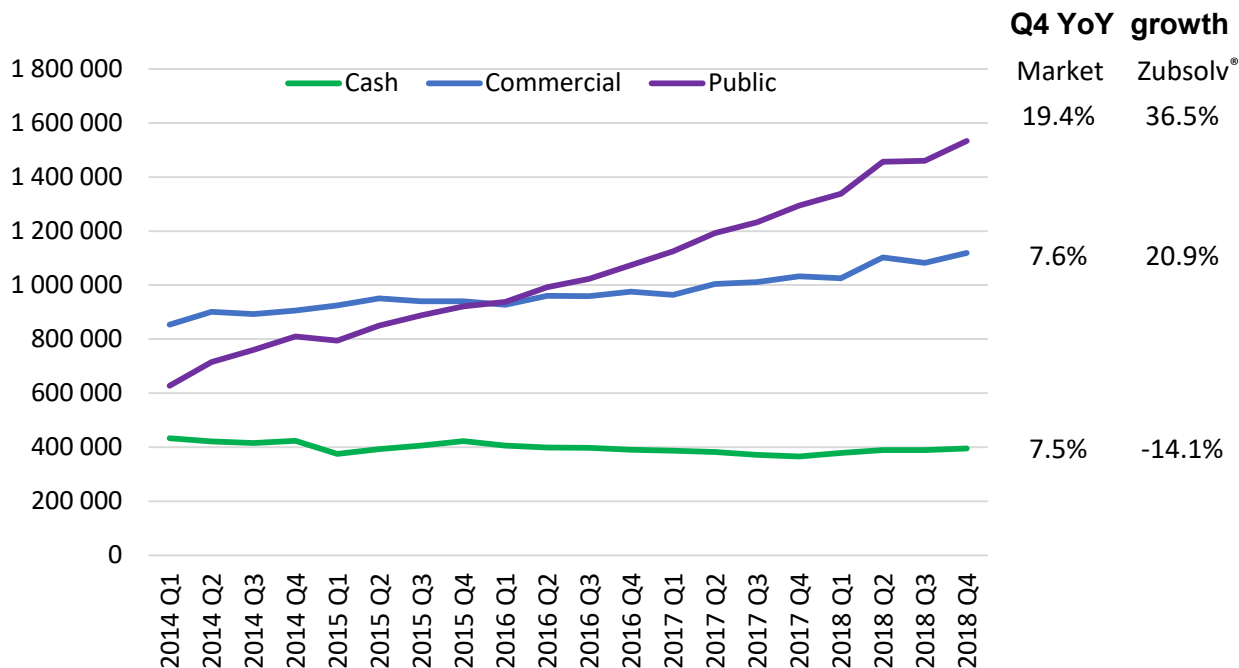
- Develop viable non-opioid treatment alternative for patients with moderate/severe pain with equal effect to morphine

Status

- **In vivo test completed with positive results, supporting advancing the project into clinical studies**

Accelerating market growth during Q4 2018

Q4 with new highs in Commercial and Public NTRx

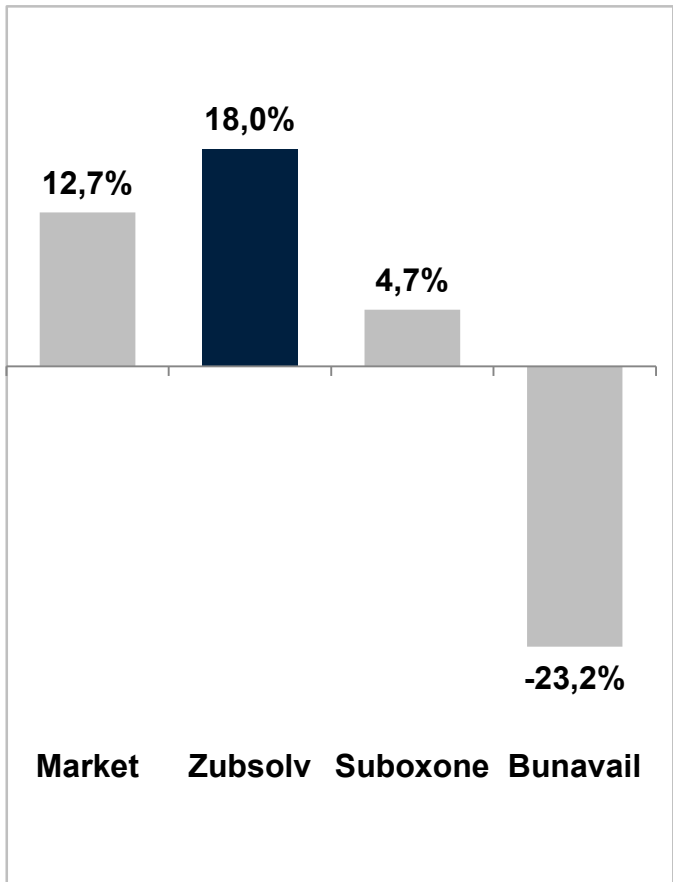


Overall market grew 14.1% in Q4'18 year over year and 4.2 percent from Q3 2018

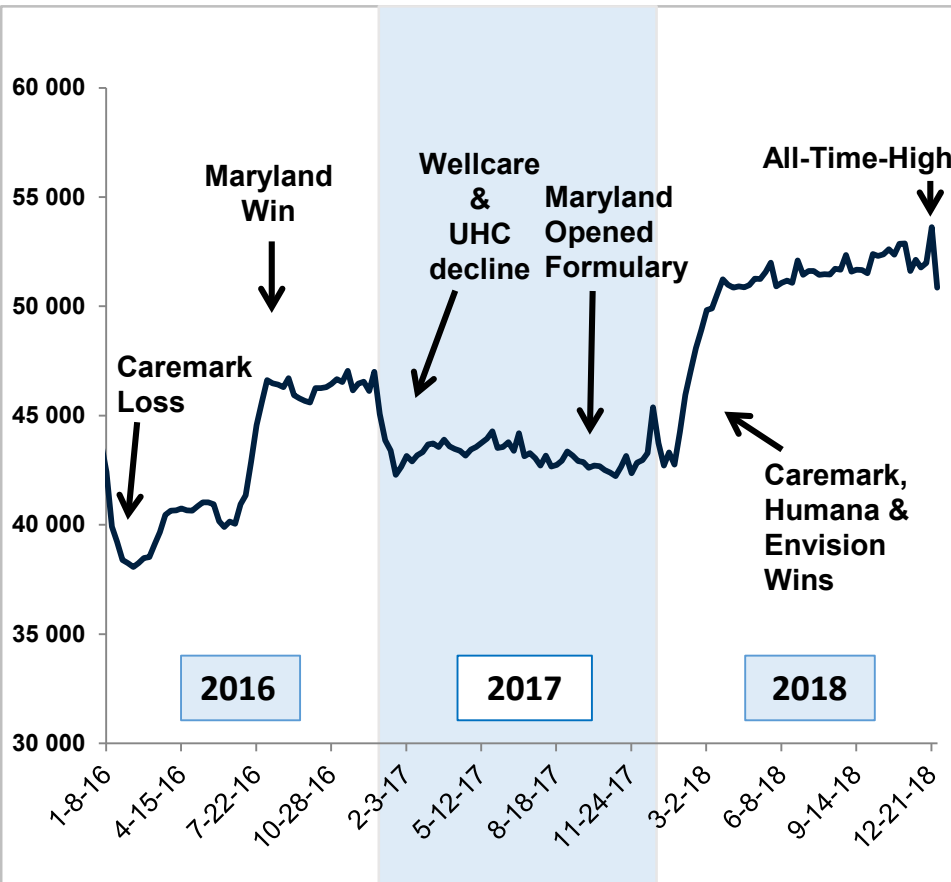
Note: Quarterly NTRx levels = Total prescriptions adjusted to 30 tablet/film scripts
 Note: Historical quarters restated due to IMS recategorization of Commercial Rx to Cash Rx
 Source: Orexo analysis, IMS data

Zubsolv[®] volume growth is outpaced the market and branded competitors in 2018

2018 vs 2017 Branded Growth %



Zubsolv R4W NTRx Volume (~patients)



Source: IMS NPA

Recent competitive news expected to create dynamic shift in otherwise stable market

Products	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Indivior's Sublocade (Depot)	January <ul style="list-style-type: none"> Approval 	March <ul style="list-style-type: none"> Launch 	<i>Launch phase ongoing with limited uptake thus far</i>		
Braeburn's CAM2038 (Depot)	January <ul style="list-style-type: none"> Complete Response Letter (CRL) 			December <ul style="list-style-type: none"> FDA approval, but cannot launch before end of 2021 	2019 <ul style="list-style-type: none"> Possible launch of weekly depot
Gx Suboxone Film		June <ul style="list-style-type: none"> Approval of Dr. Reddy Gx Launch and injunction by Indivior on the same day 		November <ul style="list-style-type: none"> Preliminary injunction overturned by the Federal Court in favor of Dr. Reddy 	Q1 <ul style="list-style-type: none"> January approval of Alvogen Gx Launch of Gx expected if Federal Court decision is sustained

Dr. Reddy's launch captured ~8% of total film market share before injunction

Zubsolv[®] is well positioned to capture share in this competitive market

New competitors face significant challenges

Depot formulations associated with complexities

Long and cumbersome prescription journey

- Specialty pharmacy dispensing requires over 30 touch-points in a paper-driven manually administered process
- Long duration: 16-22 days to dispensing¹
- Success rate: 35% of initial prescription

Weak initial patient & physician experience

- Pre-treatment anxiety; injection site pain
- Overall frustration with process, cost and time from prescription to injection
- Initial experience has shown no improvement in treatment retention

Generic(s) not always preferred

Certain payers would lose financial incentives

- High list price of Gx keeps Zubsolv competitive
- Loss of Administration fee and direct rebates for some payers

Physician loss of office support

- Ease of initiation via patient support programs
- Education / supportive resources

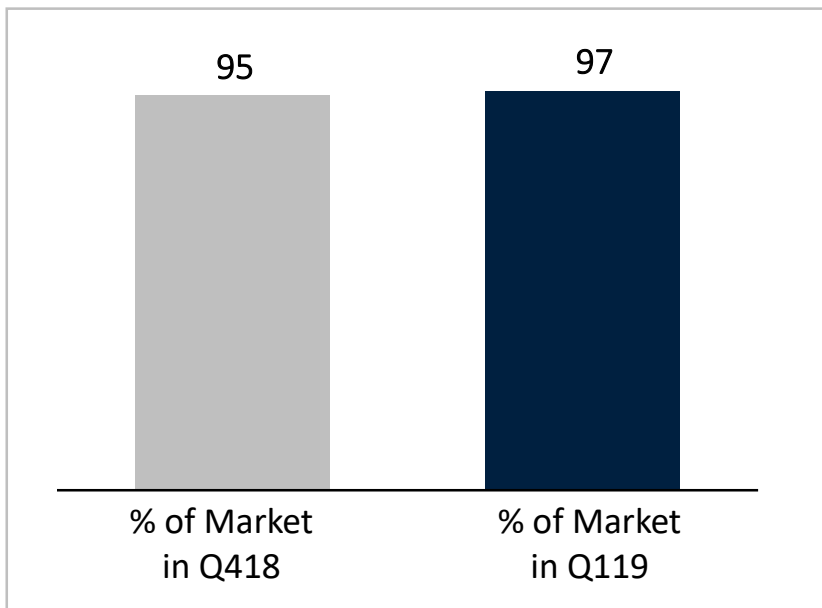
Possible patient issues

- No co-pay support
- Product quality

¹ Requirements: HCP education, Accuracy of application, HUB capacity, Payer coverage, Specialty pharmacy coordination between patient and HCP office
 Source: Indivior H1 '18 Financial Results Presentation. July 25, 2018; Indivior Q3 '18 Financial Results. Nov 1, 2018.

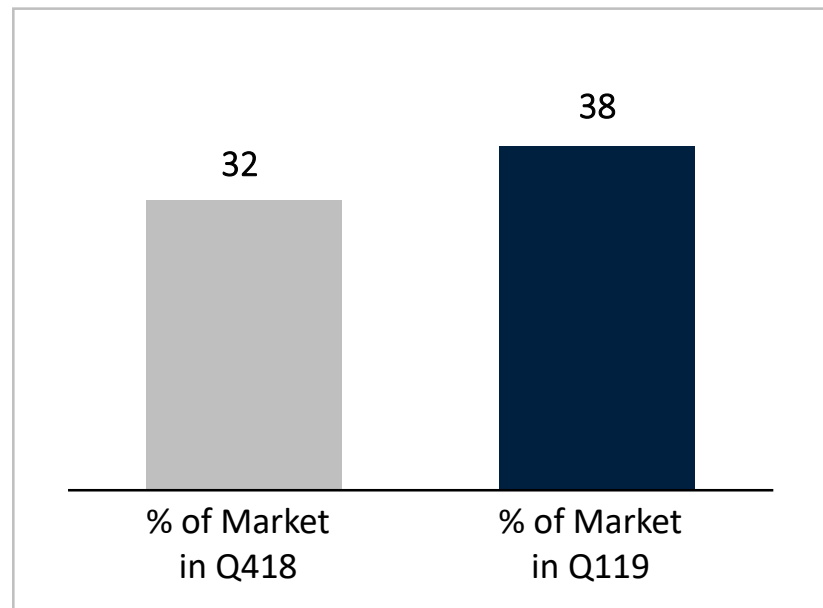
Zubsolv[®] strengthen best in class commercial market access and good improvements in public segment

Coverage in commercial plans



- All agreements from Q4 2018 confirmed
- New agreement with Blue Cross North Carolina

Coverage in public plans

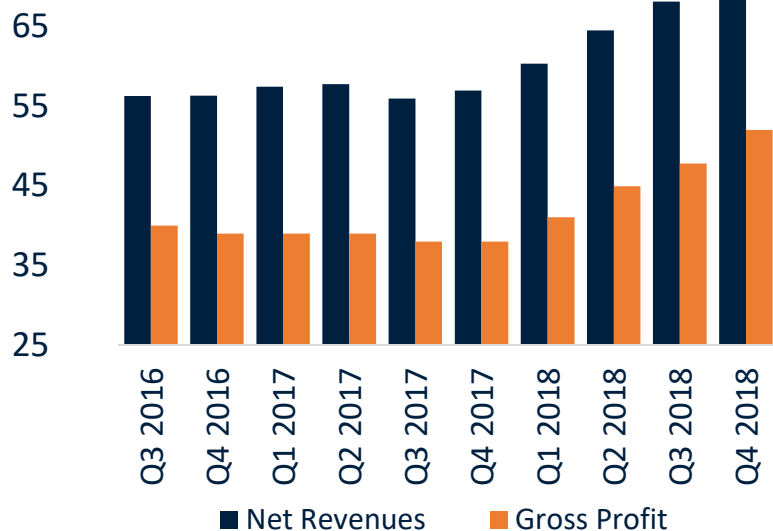


- New agreement with Ohio and Alabama FFS Medicaid from Jan 1, 2019
- New agreement with Texas, Florida and Washington DC FFS Medicaid to be implemented during Q1
- WellCare has included Gx in a preferred position, ending the exclusive coverage of Zubsolv

Strong US sales reached USD 71 million with an EBIT margin of 32 percent

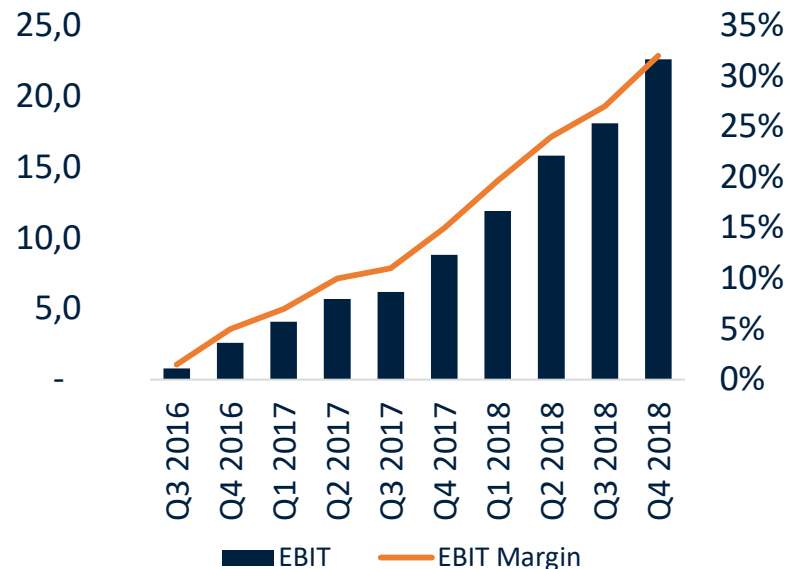
Sales and gross profit

LTM
MUSD



Operating Profit

LTM
MUSD



- **Actively working to further improve our margins:**
 - Limited additional investments needed in OPEX as top line grows i.e. operational leverage together with decreased COGs will improve EBIT Margin

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

Orexo US is well positioned to further accelerate performance and to expand its commercial platform



Strong underlying Zubsolv® business creating foundation for growth

- Sales growth of 18% 2018
- Strong growth in EBIT contribution of 2.5 times 2017 and margin more than doubled to 32%

Operational agility to respond to changing market dynamics which can also be translated to new commercial assets (e.g.)

- **Market Access:** Continued improvement despite anticipation of increased generic competition
- **Sales and Marketing:** Entire organization internalized and limited additional investments expected in current market
- **Supply Chain:** COGs is reaching a very competitive level and will continue to improve in 2019
- **Medical and Government Affairs:** Orexo pipeline addressing significant health issues open new doors and collaboration opportunities

Net Revenues

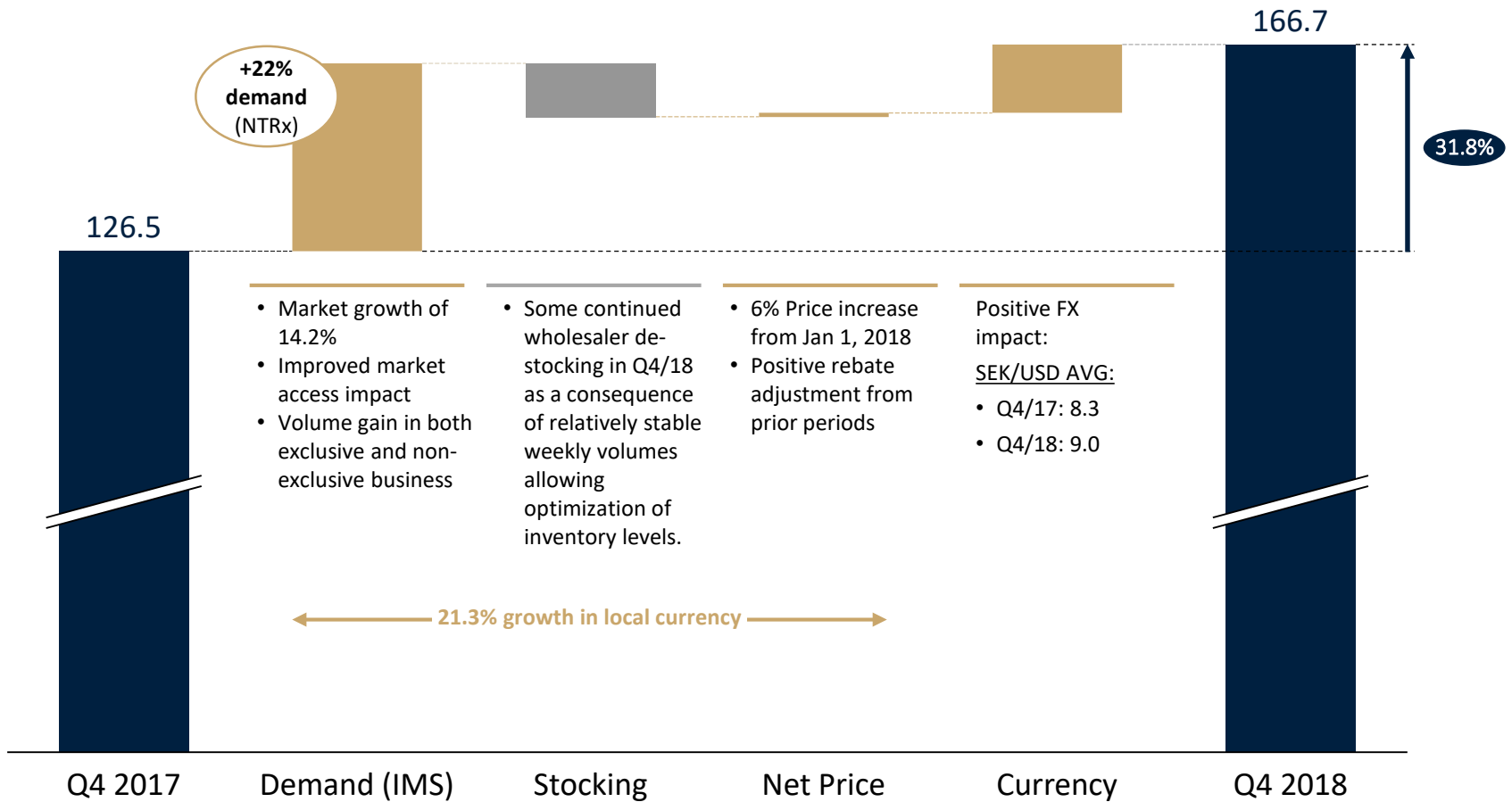
October – December 2018 and January – December 2018

MSEK	Q4 2018	Q4 2017	Jan – Dec 2018	Jan - Dec 2017
Zubsolv US	166.7	126.5	621.5	485.8
Zubsolv – Rest of the world	5.2	5.6	36.2	5.6
Zubsolv® – total	171.9	132.1	657.8	491.4
Abstral® royalties	52.4	55.4	118.8	113.2
Edluar® royalties	2.9	3.6	6.6	17.3
OX-CLI	-	-	-	21.8
TOTAL	227.1	191.0	783.1	643.7

- Net revenues for the Q4 2018 grew by 18.9% versus prior year driven by higher Zubsolv US revenue partly offset by lower revenues from partners.
- Zubsolv US revenues strong growth driver with 31.8% in Q4 2018 versus Q4 2017 to SEK 166.7 million.
- Final shipment of Zubsolv delivered to Mundipharma which has decided for strategic reasons to exit the partnership as of April 13, 2019.
- Slight Abstral Q4 2018 decline predominantly explained by less demand in individual European markets.
- Some recovery of Edluar sales after manufacturing problems in H1 have been resolved.

Zubsolv[®] US growth factors – Q4 2018 vs Q4 2017

SEK Million



1) Orexo analysis using IMS demand data plus institutional sales

P&L in Summary, October – December 2018 and January – December 2018

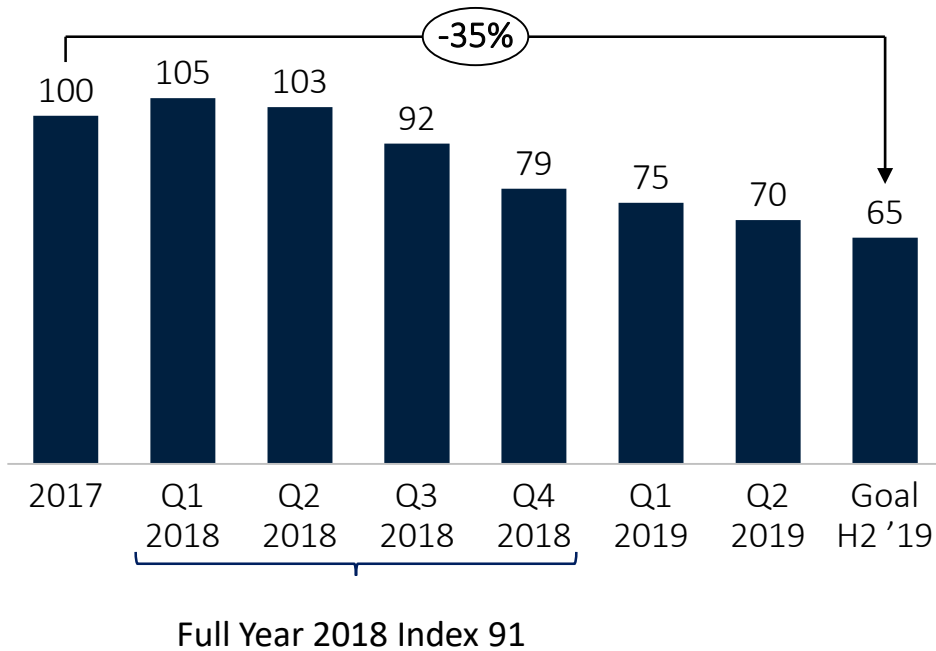
MSEK	Q4 2018	Q4 2017	Jan – Dec 2018	Jan - Dec 2017
Net revenues	227.1	191.0	783.1	643.7
Cost of goods sold	-43.4	-50.3	-171.8	-164.4
Gross Profit	183.7	140.7	611.4	479.3
Selling expenses	-48.0	-49.2	-191.4	-190.5
Administrative expenses	-54.7	-26.3	-166.7	-96.1
Research & development expenses	-47.0	-35.8	-166.8	-134.2
Other operating income & expenses	3.6	0.7	9.3	-1.1
Operating Costs	-146.1	-110.6	-515.6	-421.9
EBIT	37.6	30.1	95.8	57.4
Net financial items	-0.3	-4.7	-3.6	-27.7
EBT	37.3	25.4	92.2	29.7
Tax	14.3	1.3	45.7	-6.5
Net profit/loss	51.6	26.7	137.9	23.2
EBITDA	42.8	35.3	116.6	78.2

Q4 2018 comments:

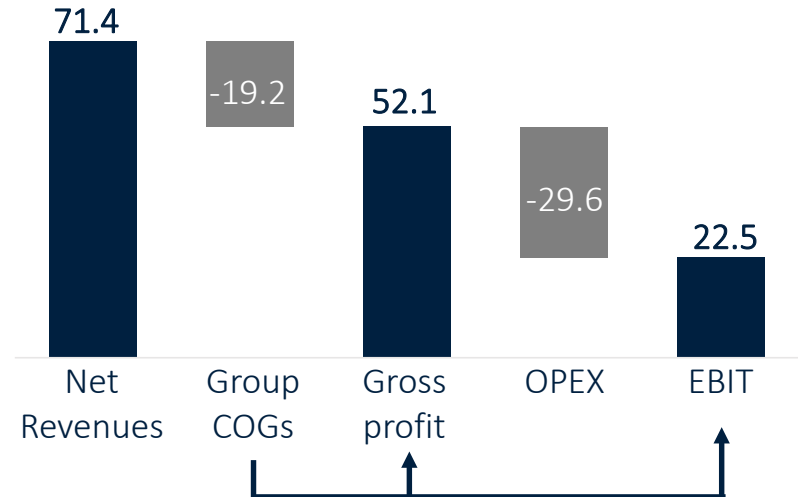
- **Gross Profit** for the quarter 31% higher vs prior year driven by Zubsolv US growth and lower COGs per tablet.
- **Operating Costs** significantly above prior year
- Administrative expenses due to legal expenses related to IP litigations amounting to SEK 26.4 million (7.8)
- R&D expenses due to higher activity level including the human PK study for OX124, the manufacturing efficiency program and restructure of European supply chain due to Mundipharma situation.
- **Tax** positively impact by revaluation of deferred tax asset in the parent company driven by an updated assessment and by an increased profitability.

New COGs will further enhance profitability and competitiveness

Expected COGS improvement (Index)



Orexo US profit contribution (FY 2018 MUSD)



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

Solid financial position

Financial Position, January – December 2018

Cash flow MSEK	Q4 2018	Q4 2017	Jan – Dec 2018	Jan - Dec 2017
Cash flow from operating activities	71.7	-23.0	242.0	146.6
Investment activities	-3.9	-0.8	-6.2	-1.6
Financing activities	-	-26.4	-	-85.4
Cash flow (excl exchange rate differences)	67.8	-50.2	235.8	59.6
Liquid funds	589.8	327.9	589.8	327.9

- Positive cash flow from operating activities for the period Q4 2018
 - SEK 71.7 million positive contribution from operating activities driven by positive operating earnings and by changes in working capital due to decreased receivables, increased payables and lower inventories. This was partly offset by interest paid and by income taxes paid in the US.
- Strong cash position at the end of Q4 2018 with SEK 589.8 million

Financial outlook 2018

Good progress in all areas in line or ahead of guidance

- 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 years
- Overall volume of Zubsolv® sales in the US in 2019 will increase, despite increased competition from a potential launch of Suboxone Film generics. However we do expect that a launch of corresponding generics will increase market risk and uncertainty but will also offer opportunities.
- 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
- 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.
- 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.
- The first new partnerships for Zubsolv outside the US is expected to be initiated in 2019
- The outlook is based on current exchange rates (January 2019)

Forward looking statements, see Legal Disclaimer on page 1

Looking forward to 2019 with confidence

- **IP secured for Zubsolv® until 2032** and legal activities will decline significantly after Q1
- **Financial performance and position continue to improve** led by strong performance in Orexo US with SEK 198.3 M in EBIT 2018 resulting in SEK 589.8 M in EBIT
- **R&D efforts start to materialize** with OX124 passing proof of concept in successful phase I trial and positive in-vivo data on OX338
- **Market access for Zubsolv in the US continue to improve** best in class commercial access now reaching 97% of the market and Public access taking a leap to 38% of the market
- **Zubsolv rights regained outside the US**, several partner discussions on-going and Orexo prepare to take a more active role managing multiple partnerships
- **Business development** efforts continue with some concrete opportunities



Thank You

Q&A

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