

orexo

Zubsolv[®] US growth of 26 percent in local currency

Q1 2018 Interim Report, April 26, 2018

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

Legal Disclaimer

- This presentation, which is personal to the recipient, has been prepared and produced by Orexo AB (publ) (“Orexo”) solely for the benefit of investment analysis and may not be used for any purpose other than assessment of investments concerning Orexo. Unless otherwise stated, Orexo is the source for all data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form the basis of, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of Orexo
- The shares of Orexo have not been registered under the U.S. Securities Act of 1933, as amended (the “Securities Act”), and may not be offered or sold in the United States (as such term is defined in Regulation S under the Securities Act) except pursuant to an exemption from, or a transaction not subject to, the registration requirements of the Securities Act or unless registered under the Securities Act.
- The information in this presentation has not been independently verified. No representation or warranty, express or implied, is made as to, and no reliance should be placed on, the fairness, accuracy or completeness of the information or opinions contained herein. None of Orexo, any of its shareholders, or any of their respective subsidiary undertakings or affiliates or any of such person’s directors, officers or employees, advisers or other representatives, accepts any liability whatsoever (whether in negligence or otherwise) arising, directly or indirectly, from the use of this presentation or otherwise arising in connection therewith.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and Orexo expressly disclaim any obligation or undertaking to release any update of, or revisions to, any forward-looking statements in this presentation as a result of any change in our expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation is not a prospectus in accordance with the Swedish Financial Instruments Trading Act (Sw. lagen (1991:981) om handel med finansiella instrument) or any other Swedish laws or regulations. Neither the Swedish Financial Supervisory Authority (Sw. Finansinspektionen) nor any other Swedish regulatory body has examined, approved or registered this presentation.

Q1 2018 highlights

Financials:

Strong growth strengthened the net cash position

Strong net revenue growth and cash flow

- Net revenue growth from Zubsolv® of 26.2 percent in USD and total revenue growth of 9.7 percent for the company in SEK
- Cash flow from operating activities of SEK 106 million and cash position of SEK 437.5 million
- EBITDA of SEK -16.6 in line with guidance
- Profitability within reach with improved supply chain efficiency and excluding expenses related to new supply chain

Commercial Progress:

Market access wins key driver of Zubsolv growth in Q1 as expected

Zubsolv showed strong growth in Q1 in both volume and market share

- The US buprenorphine/naloxone market showed continued strong growth of 11.5 percent in Q1 versus prior year
- Zubsolv grew 11.9 percent in prescriptions in Q1 versus prior year
- Improved market access a significant driver of growth with the new preferred position with CVS Caremark and exclusive agreements with Envision and Humana
- Zubsolv is the only branded product to grow market share in Q1 with the market share improving to 5.7 percent from 5.1 percent in Q4, 2017
- Launch preparations for Europe on-track for launch during first half of 2018

R&D:

New projects added to the pipeline

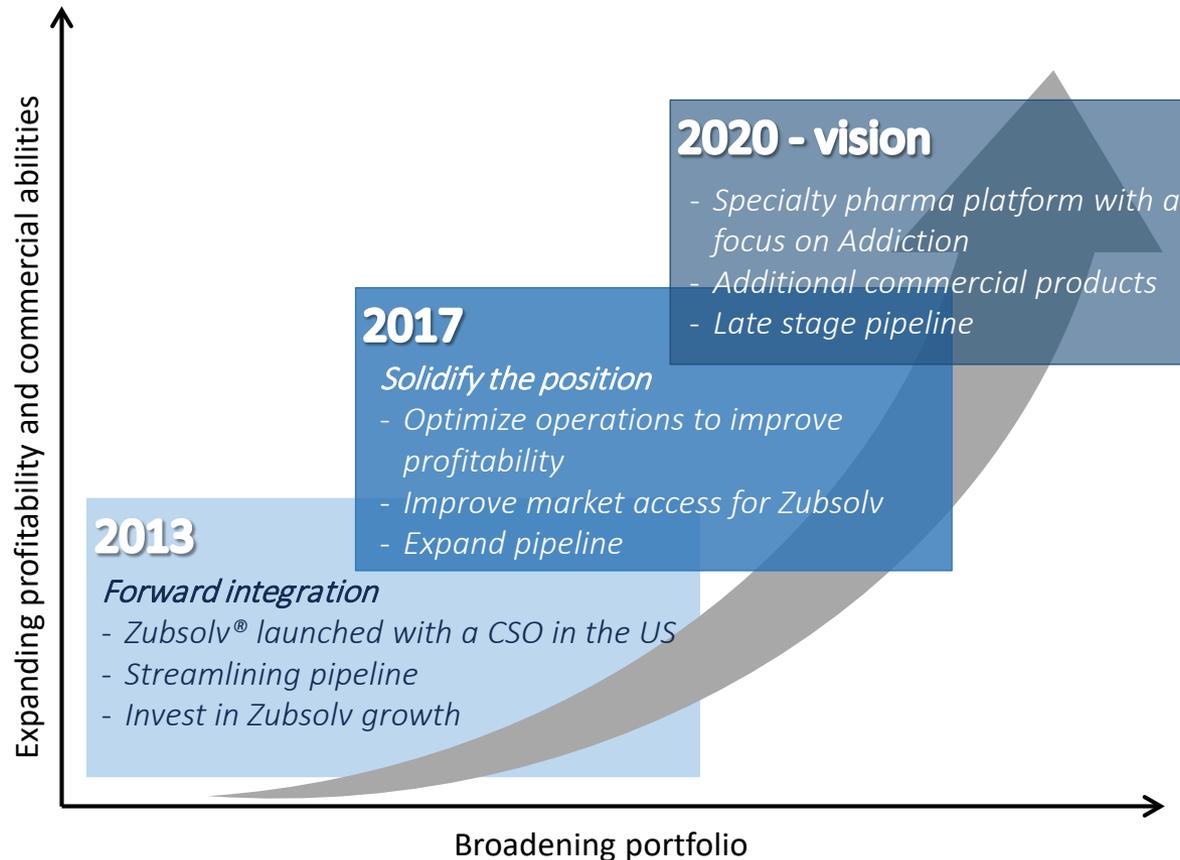
Two new pipeline projects announced

- OX124 for emergency treatment of opioid overdose and OX338 aiming at a new NSAID product to replace opioids in acute and emergency situations
- OX382 first results are ready and our formulation work will continue before progressing the project to the next phase
- OX51 Limited resources will be invested in the project in 2018, no partner as of today

The profitable business enables investments in the pipeline with an aim of becoming a leading addiction company

Orexo's evolution from a cash consuming R&D company to a profitable specialty pharmaco

Key drivers of growth



1 Maximise Zubsolv®'s potential in a globally fast growing market

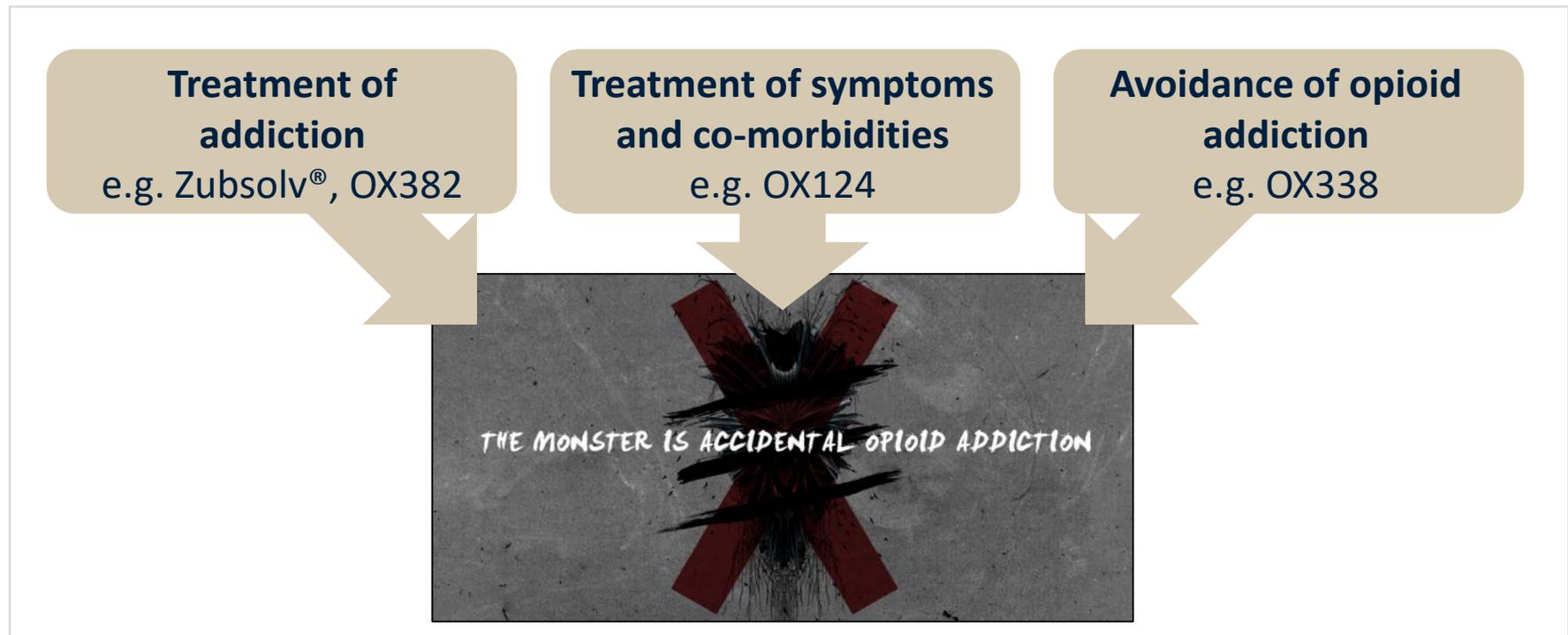
2 Drive profitability and cash flow growth with operational leverage achieved in manufacturing

3 Add commercial stage products in the US to leverage our commercial infrastructure

4 Progress the pipeline of internal development projects

R&D and BD teams are providing an answer to patients suffering from addiction

From prevention to treatment



Orexo has early stage projects and business development discussions in all categories

Pipeline projects now address the opioid epidemic from all angles

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

Objective • Create a more convenient administration route for patients

Status • Phase I clinical study concluded and preliminary results are indicating need for further formulation development

OX124 *Opioid overdose rescue medication*

Objective • Develop a differentiated emergency treatment of known or suspected opioid overdose

Status • Formulation developed with positive in-vitro data
• Now preparing for explorative phase I clinical study

OX338 *Sublingual formulation of undisclosed NSAID for Pain treatment*

Objective • Develop viable non-opioid treatment alternative for patients with moderate/severe pain

Status • Early formulation work ongoing

Orexo's core pipeline progress according to plan

Expanding early pipeline to fight addiction



OX-51 removed from the pipeline to reflect decision limit investments in 2018

The opioid crisis is a “national crisis” gaining significant attention

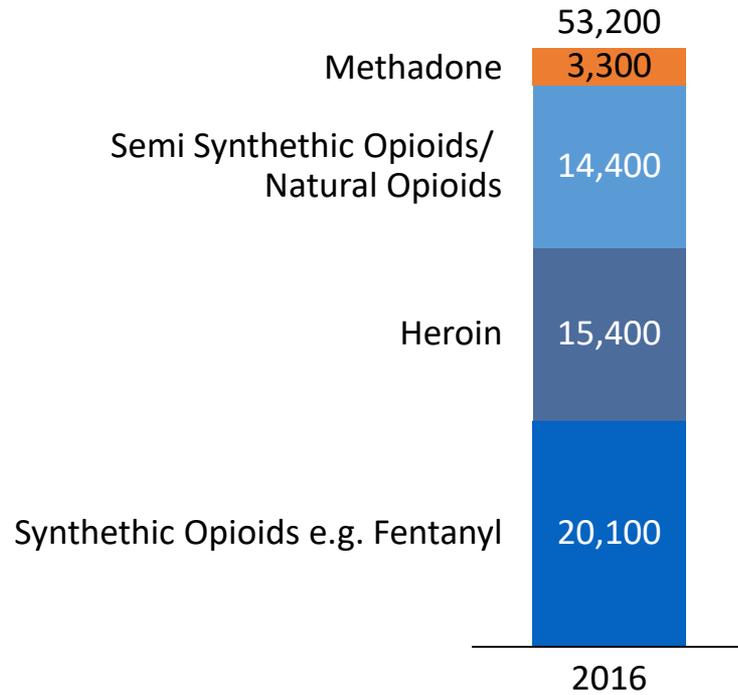
An entire special edition of TIME Magazine was recently devoted to the #opioidcrisis

The image displays a promotional graphic for a special edition of TIME Magazine. On the left is the magazine cover, featuring a black and white photograph of a person's hands holding a syringe. The cover text includes "SPECIAL REPORT", "MARCH 5, 2019", "TIME", "THE OPIOID DIARIES", and "Photographs by JAMES NACHTWEY". To the right of the cover is a large red rectangular area with the text "OUR NATIONAL CRISIS" in large, bold, black letters. Below this, it says "FROM THE EDITORS OF TIME" and includes social media icons for Facebook, Twitter, and Email. At the bottom of the graphic are three smaller panels with text: "OPIOIDS REACH EVERY PART OF SOCIETY: BLUE COLLAR, WHITE COLLAR, EVERYBODY. IT'S NONSTOP. IT'S EVERY DAY. AND IT DOESN'T SEEM LIKE IT'S GETTING ANY BETTER." attributed to "WALTER BENDER, A DEPUTY SHERIFF IN MONTGOMERY COUNTY, OHIO"; "'THIS COULD KILL ME, BUT I'M GOING TO DO IT ANYWAY.'"; and "'SHE'S GOING TO BE BORN ADDICTED'".

The opioid crisis is likely to continue escalating in the US

Large and growing need for treatment options

Alarming number of opioid related overdoses leading to >50,000 deaths in the US



Negative trend continues according to CDC surveillance data (Increases in opioid overdoses July 2016 – September 2017)

Overall: +30% in 52 areas in 45 states



The Midwestern region: +70%

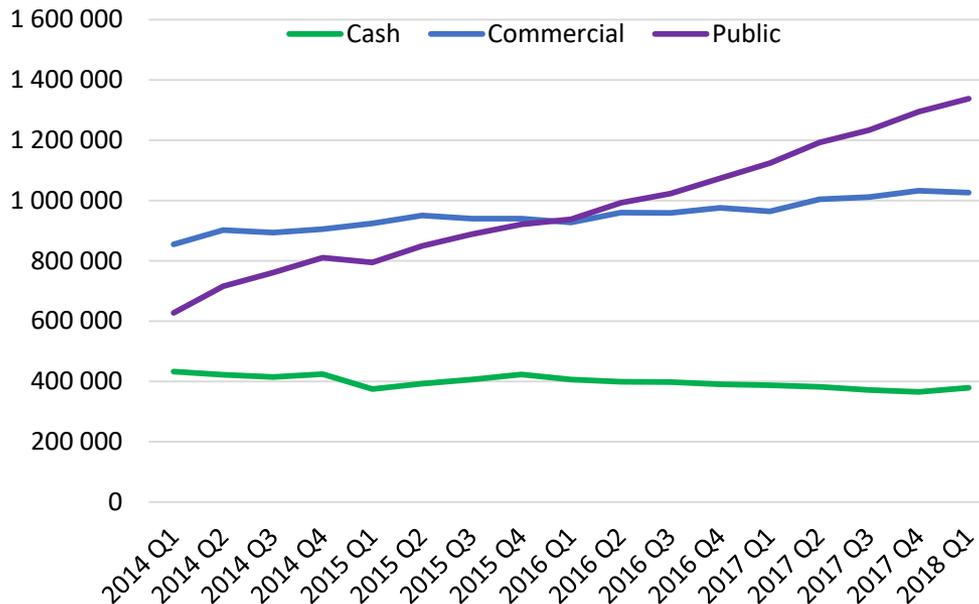
Large cities: +54% in 16 states



Source: Centers for disease control and prevention

Zubsolv® US market continues to show strong growth, driven by the public segment

Continued strong growth in the public segment in Q1 driving overall market growth (NTRx)



Overall market grew 11.5% in Q1 2018 year over year, accelerating from earlier quarters

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

US Bup/Nal market dynamics explained by market access changes and growth in Public segment

Accelerating market growth

Q1 traditionally a “weak” quarter, but 2018 started with a 2.7% growth

Main growth drivers is expansion of access to treatment

>5,500 (3,800) PAs and nurses practitioners waived to prescribe

>4,000 (3,700) physicians waived to expand to 275 patients

Growth remains predominately from the Public segment ¹

Public segment maintained significant growth with 19% (21.6%), but even commercial is picking up with 6.5% (5.4%) year over year

Zubsolv[®] only branded product to gain market share in Q1 2018

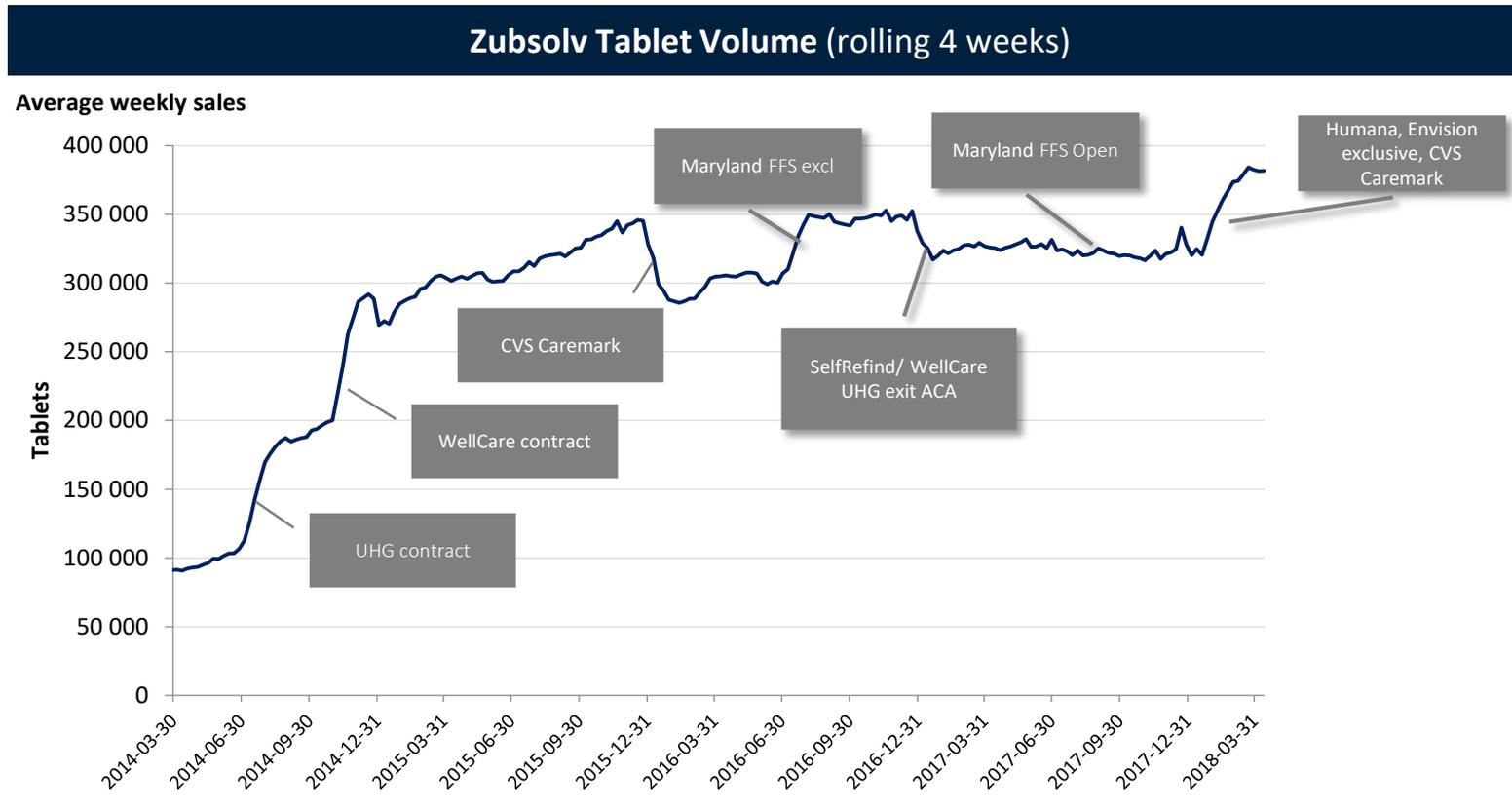
Zubsolv[®] growth of 12.4% from Q4 2017 to Q1 2018

- Public 23.2%
- Commercial 8.9%
- Cash 1.2%

Zubsolv volume growth mainly in public segment while commercial is the main value driver due to lower rebate and higher share of Zubsolv overall business (54%)

¹ Public segment defined as FFS Medicaid, Managed Medicaid and Medicare Part D.
Source: IMS weekly prescription data and Orexo analysis and projections

Strong re-bounce in Zubsolv[®] tablet volume in 2018...

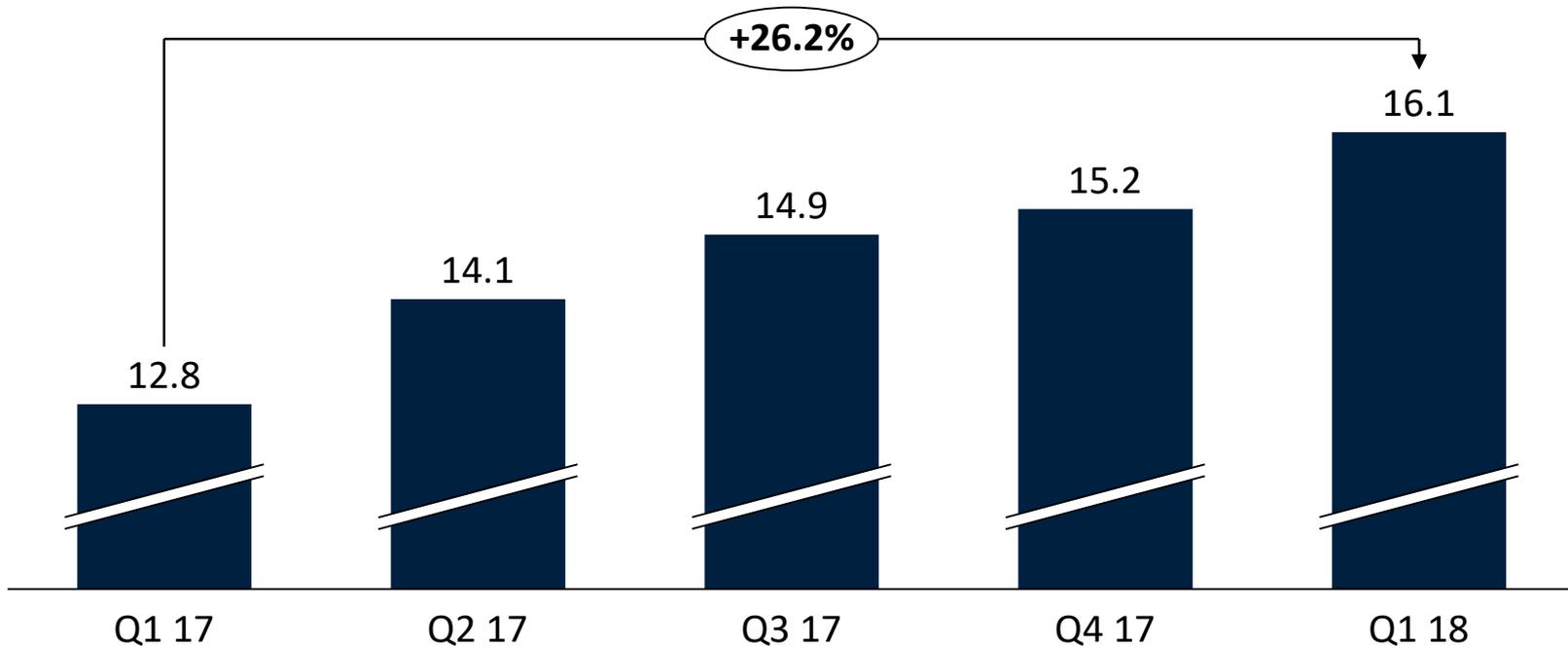


Market share reached 5.7% in Q1 jumping from ~5.1% in Q4¹

¹ Market share in terms of Orexo share of the total market quantity of tablets, film and patch of Bup/Nal
 Note: Weekly prescription data is based on extrapolation and is associated with uncertainties and may differ between sources
 Source: Orexo analysis, IMS weekly data

... leading to a 26 percent net revenue growth of Zubsolv[®] in the US

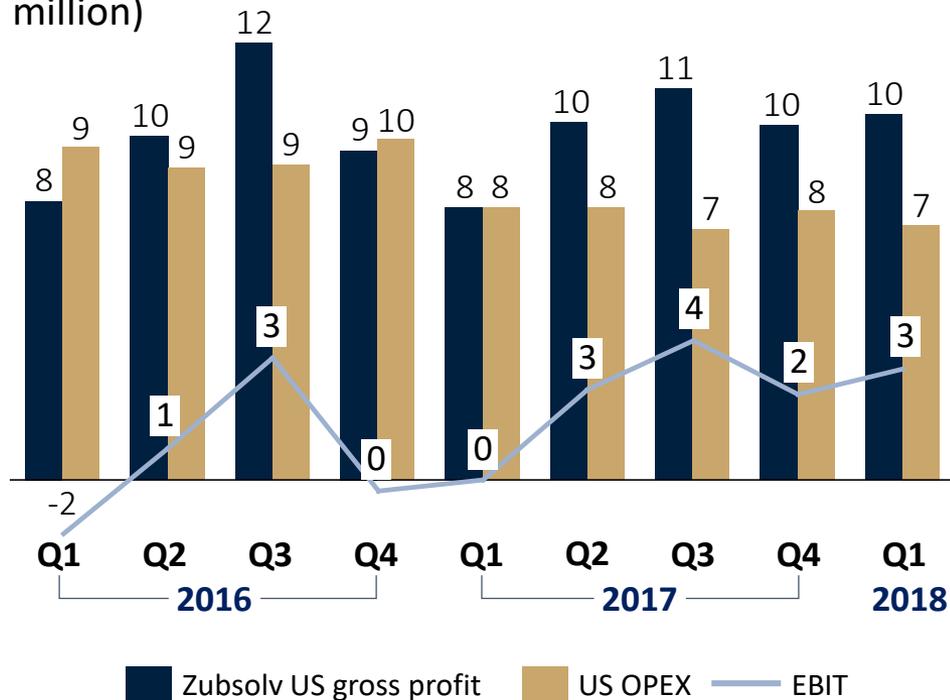
Zubsolv US Net Revenue Development (MUSD)



Improved market access position combined with strong sales force pull through driving performance

EBIT contribution from US operations increased more than 3X from 2016 to 2017

Operating costs and profit contribution (USD million)



Comments

- Profit contribution from the US commercial operations has increased from 2.5 MUSD to 8.8 MUSD 2016 to 2017.
- Highly flexible infrastructure enables fast adoption to market dynamics and optimization of the operations to growth opportunities and threats
- Significant potential to improve operational leverage on the two main cost items
 - Improvement of COGS and supply chain efficiency
 - Leverage of infrastructure with additional commercial products

Notes:

- Gross profit is calculated as Zubsolv US net revenue (USD) minus group Cost of Goods Sold (COGS)
- COGS is translated to USD using average SEK/USD exchange rate for the relevant quarter and includes indirect product costs covering certain overhead directly related to the manufacturing processes (e.g. planning and management of manufacturing and quality)
- US OPEX (operating expenses) includes all expenses directly incurred by the US subsidiary (Orexo US Inc)
- OPEX and COGS does not include other more indirect overhead from the site in Sweden

Strong Q1 in the US paves the way for a good 2018

The 96 percent unrestricted market access in commercial from January 1st has been an important value and net revenue growth driver

- CVS Caremark sales with an increase of 83 percent from December to March in total volume
- Commercial volumes expected to improve due to traditionally stronger Q2-Q3 explained by US reimbursement structure

New exclusive agreement with Humana in Medicare Part D a main volume growth driver in the public segment, despite a late start

- Strong growth contribution in February and March in Humana, but marginal impact in January due to prior authorization process
- Humana Med D volumes in March in line with expectations and additional growth potential exist within the account from further market share capture
- Ohio FFS Medicaid has delayed final decision to internalize control of all Medicaid pharmacy benefit until 2019

Market access is core to the commercial strategy, but with improved market access the Orexo field force have proven their ability to win market share in a levelled playing field!

Zubsolv® main growth driver of net revenues with 15 percent (26 percent in local currency)

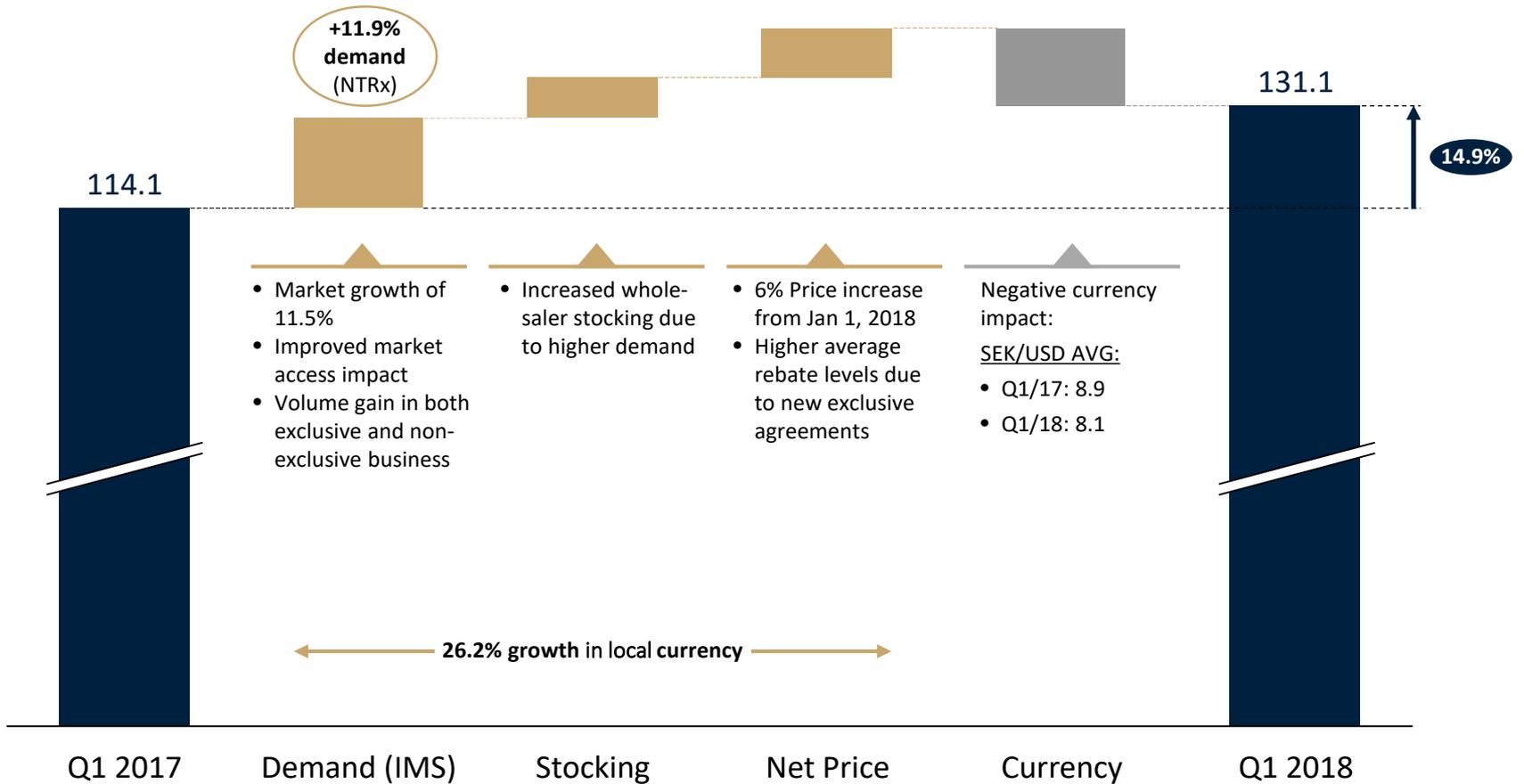
Total Net Revenues January – March 2018 and 12 MTH April 2017 – March 2018, SEK million

MSEK	Q1 2018	Q1 2017	12 MTH Apr 2017 – Mar 2018	12 MTH Apr 2016 – Mar 2017
Zubsolv US	131.1	114.1	502.8	497.5
Zubsolv – Rest of the world	-	-	5.6	65.9
Zubsolv® – total	131.1	114.1	508.4	563.4
Abstral® royalties	5.8	8.7	110.3	100.9
Milestone payment Abstral	-	-	-	2.2
Abstral® – total	5.8	8.7	110.3	103.1
Edluar® royalties	2.8	4.6	15.5	15.8
OX-CLI	-	-	21.8	-
TOTAL	139.7	127.4	656.0	682.3

- Total net revenues for Q1 2018 increased by 9.7% versus prior year driven by Zubsolv US sales.
- Zubsolv US revenue grew by 14.9% versus prior year; 26.2% in local currency .
- Abstral® royalty amounted to SEK 5.8 million in Q1 2018 vs SEK 8.7 million in Q1 2017. The decline is explained by true-up adjustments made to prior period estimates.
- Edluar® royalty amounted to SEK 2.8 million in Q1 2018 vs SEK 4.6 million in Q1 2017 and was impacted by correction to prior periods reported by our partner Mylan.

Strong demand main growth factor in Q1 2018 vs Q1 2017

Zubsolv® growth drivers, SEK million



1) Orexo analysis using IMS demand data plus institutional sales

P&L in Summary

January – March 2018 and 12 MTH April 2017 – March 2018

MSEK	Q1 2018	Q1 2017	12 MTH Apr 2017 – Mar 2018	12 MTH Apr 2016 – Mar 2017
Net revenues	139.7	127.4	656.0	682.3
Cost of goods sold	-48.4	-46.2	-166.6	-163.3
Gross Profit	91.3	81.2	489.4	519.0
Selling expenses	-43.3	-48.3	-185.5	-228.1
Administrative expenses	-27.2	-26.3	-97.0	-152.8
Research & development expenses	-45.3	-30.3	-149.2	-117.6
Other operating income & expenses	2.7	0.5	1.1	34.2
Operating Costs	-113.1	-104.4	-430.6	-464.3
EBIT	-21.8	-23.2	58.8	54.7
Net financial items	-3.0	-6.6	-24.1	-16.3
EBT	-24.8	-29.8	34.7	38.4
Tax	-1.1	-4.8	-2.8	-9.4
Net profit/loss	-25.9	-34.6	31.9	28.9
EBITDA	-16.6	-18.1	79.7	74.4

- Gross Profit for the quarter higher by 12.4% vs prior year driven by SEK 14.8 million higher Zubsolv® US gross profit partially offset by lower Abstral and Edluar contributions.
- COGS negatively impacted by higher Zubsolv sales including tablets with higher cost partially offset by positive impact from production variance. Q1 2017 was negatively impacted by de-blistering of tablets.
- Operating Costs above prior year mainly due to investment in pipeline and new sourcing (R&D).
- Other operating inc/exp primarily relates to exchange rate gains/losses from revaluation of operating receivables and payables in foreign currency and income/expenses from activities other than normal business.
- Net financial items positively impacted by unrealized gains on USD cash position held by Orexo AB and by lower cost for bond loan.
- Tax for the quarter was lower than prior year mainly explained by a true-up adjustment included in Q1 2017.

Solid financial position

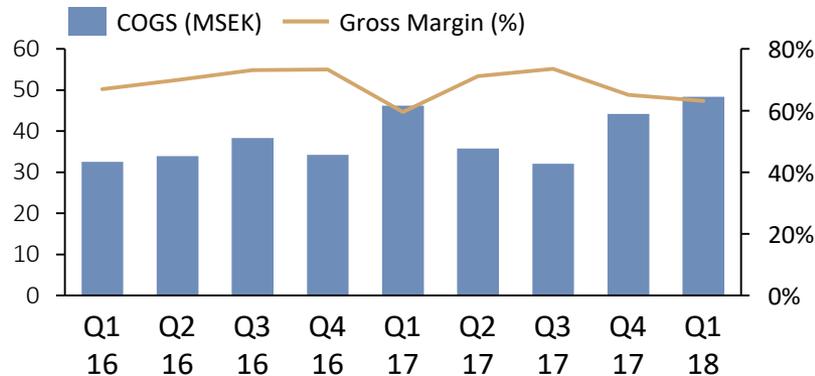
January – March 2018 and 12 MTH April 2017 – March 2018

Cash flow MSEK	Q1 2018	Q1 2017	12 MTH Apr 2017 – Mar 2018	12 MTH Apr 2016 – Mar 2017
Cash flow from operating activities	106.0	28.2	244.4	150.9
Investment activities	-	-0.3	-1.3	5.3
Financing activities	0.4	-59.0	-26.1	-149.6
Cash flow (excl exchange rate differences)	106.3	-31.1	197.0	6.6
Liquid funds	437.5	250.6	437.5	250.6

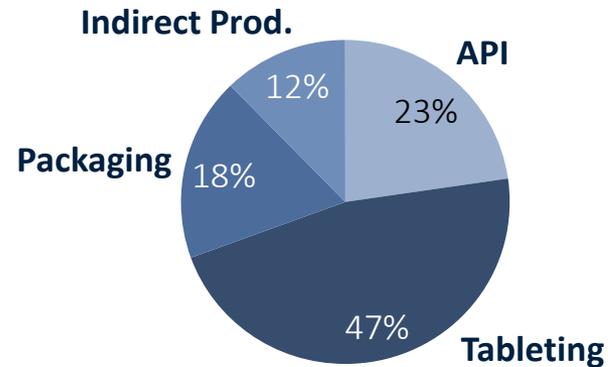
- Strong positive cash flow from operating activities for the period January – March 2018
 - SEK 106.0 million positive contribution from operating activities driven by increased provisions for US payer rebates, decreased inventories and decreased receivables
- Strong cash position SEK 437.5 million
- The cash position enables Orexo to pursue its strategy to progress the development pipeline and continue business development activities aiming to add commercial stage product to the US operations

Zubsolv[®] Cost of Goods Sold (COGS) deep dive

Gross margin

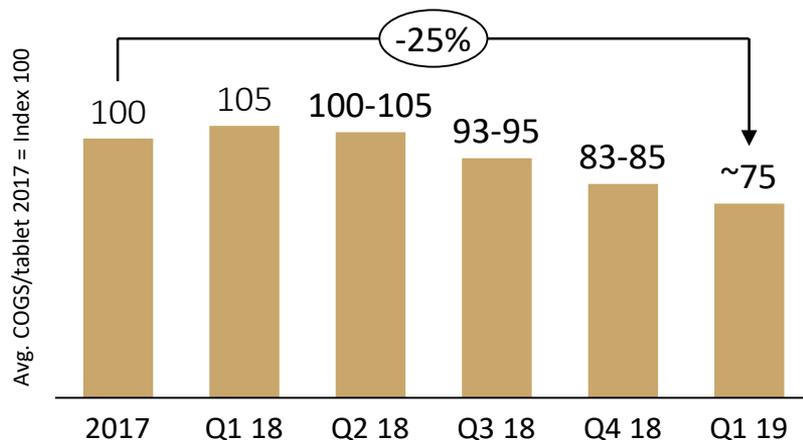


COGS composition (illustrative example, 5.7mg, 2017)



Expected COGS improvements

(Directional, assuming other parameters unchanged)



Description

- Zubsolv gross margin has varied between 63% and 73% and is impacted by many factors like price, currency, G-t-N ratios, COGS per tablet, SEK/USD exchange rate.
- Manufacturing efficiency program (MEP) is addressing all parts of the COGS. Short to medium term the key drivers will be moving from small scale to large scale manufacturing and sourcing initiatives.
- Indirect Production Cost (IPC) are fixed overhead costs allocated to manufactured tablets. In periods without any manufacturing the IPC will go directly to COGS in the P&L.
- The MEP project will generate around 25% saving on total COGS level compared with average 2017 levels. Assuming all other parameters are unchanged.
- Additional initiatives will be pursued to lower the COGS level even further beyond Q1 2019.

Financial outlook 2018

No changes from Full Year Report 2017

For 2018 Orexo expects to continue to deliver positive EBITDA on a full year basis, primarily driven by Zubsolv® US revenue growth and continued focus on cost control. The impact from new Zubsolv US market access agreements will ramp up during the year and a negative EBITDA is expected for Q1 2018.

With the improved market access situation for Zubsolv US, Orexo expects to gain volume and market share during 2018. Total milestone payment level in 2018 is expected to be slightly above the 2017 level.

Manufacturing efficiency programs aimed to reduce COGS is expected to have affect from second half year 2018.

Full year OPEX is expected to be approximately SEK 500 million. The increase over 2017 is driven by expansion of US commercial footprint and progression of development projects. Only a limited amount has been included for the Actavis litigation for Zubsolv, assuming a positive outcome.

The outlook is based on current exchange rates (January 2018).

Forward looking statements, see Legal Disclaimer on page 1

NB: The outlook is based on January 2017 exchange rates.

Still awaiting the final outcome of the patent litigation with regards to one of three patents expiring in 2032

Two ongoing patent litigations against Actavis

Comprehensive patent protection in Orange book until September 2032

Ongoing patent litigation against Actavis

1. Zubsolv®

Patent No	Expiration
8454996	2019
8658198	2027
8470361	2030
8940330	2032
9259421	2032
9439900	2032

2. Gx

Patent No	Expiration
8454996	2019

- US district court have affirmed validity and infringement of '996 patent
- US district court found '330 patent invalid and decision is appealed to the federal circuit
 - Decision expected H1, 2018
- Orexo has filed litigation cases against Actavis for infringement of '421 and '900 patents
 - On hold until final decision in '330 process
- Ex US patents not affected by US litigation
- Orexo has filed a litigation case against Actavis for infringement of '996 patent with their Suboxone® and Subutex® generics

Strong platform and exciting opportunities for 2018

- **Core business at the heart of the biggest health problem in the US**
- **Strong financial performance and position** with full year positive EBIT in 2017, secured long term financing and a 437.5 MSEK in cash
- **A pipeline of interesting internal projects** that will progress further during 2018
- **Market access for Zubsolv® significantly improved** in 2018 driving the 26.2% net revenue growth (USD)
- **Launch of Zubsolv® in Europe expected Q2** following approval and first supply of products to Mundipharma
- **Business development** efforts to add commercial products to the US operations continues
- **A decision on the Zubsolv US patent litigation** against Actavis **expected during first half of 2018**



Q&A

For more information please visit www.Orexo.com. You can also follow Orexo at Twitter @orexoabpubl, LinkedIn and YouTube

IR Contact: Lena Wange, IR & Communications Manager
ir@orexo.com