

orexo

Zubsolv[®] continues its strong performance

Q2 2018 Interim Report, July 11, 2018

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

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Q2 2018 highlights

Financials:

YTD positive EBITDA

Strong net revenue growth and cash flow

- Total Q2 net revenue growth versus prior year of 25.5 percent mainly driven by increased Zubsolv® sales and milestone payment from Zubsolv Europe
- SEK 494.8 million in cash position further strengthening the financial foundation of the company
- EBITDA of SEK 50.6 and positive YTD even when excluding Zubsolv milestone payment from Europe, supported by 25 percent cost reduction per tablet in Q2 versus Q1
- Full-year profitability expected with continuous profit contributions in Q3 and Q4

Commercial Progress:

Market access wins maintain strong impact on Zubsolv growth

Zubsolv continued strong growth momentum from Q1

- Accelerating growth of the US buprenorphine/naloxone market showed continued strong growth of 12.3 percent in Q2 versus prior year (11.5 percent in Q1)
- Zubsolv grew 20.3 percent in prescriptions in Q2 versus prior year and 8.6 percent vs Q1
- Improved market access still 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 and YTD on a quarterly basis.
- Zubsolv launched in Europe in June in Sweden and Germany

R&D:

New project entering phase I

OX124 getting ready for phase I trial in Q4

- OX124 formulation work progressed very well and first human trial is expected in Q4
- Main target and objective of phase I is a differentiation to existing alternatives in the market for naloxone rescue medication with acute opioid overdose.

No final decision in the IP litigation on Zubsolv® 330' patent yet

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

- 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 was expected H1, 2018 after hearing October 4, 2017, in the Courts of Appeal
 - No new guidance on timelines
- 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

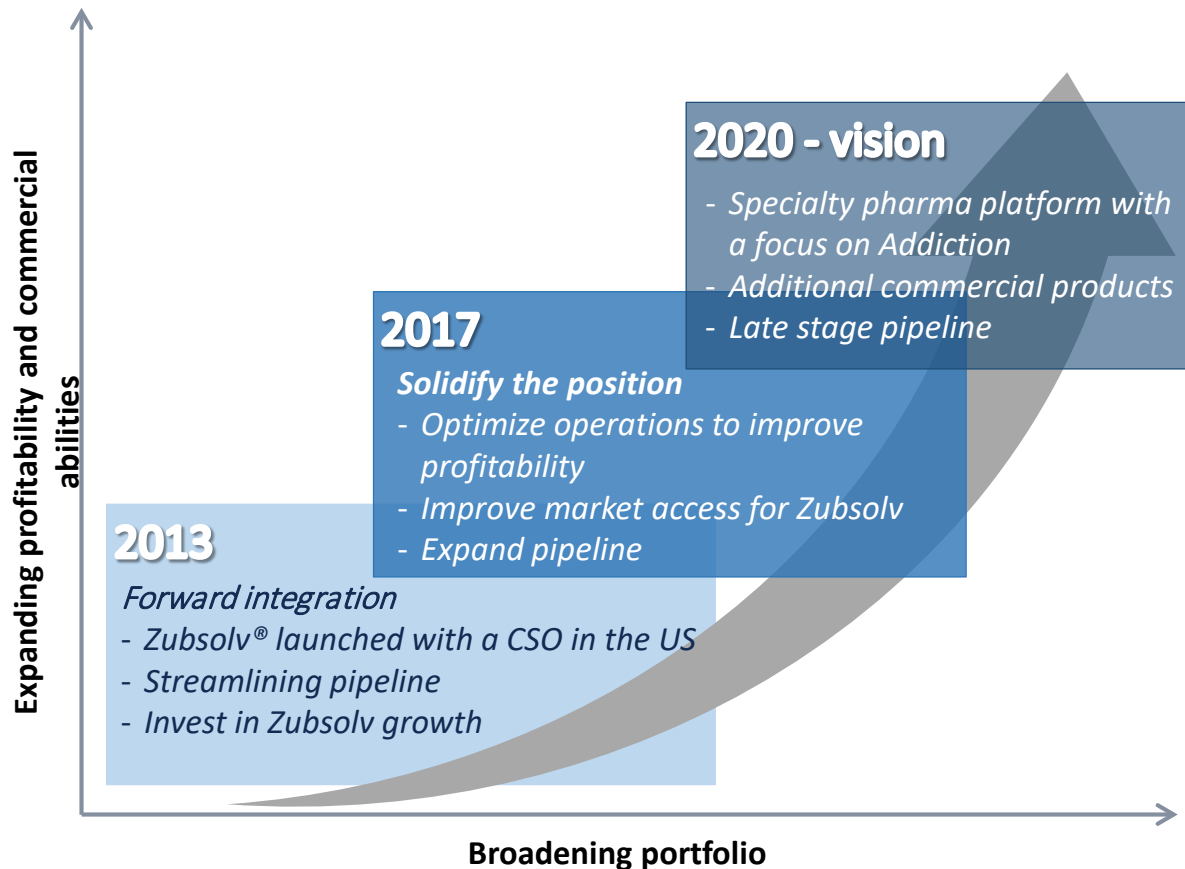
2.
Gx

Patent No	Expiration
8454996	2019

- Orexo has filed a litigation case against Actavis for infringement of '996 patent with their Suboxone® and Subutex® generics

Q2 performance strengthen the ability to reach the 2020 vision with a broader commercial scope and pipeline

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

OX124 in the Orexo pipeline is ready for an exploratory clinical trial phase I

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

Objective • Create a more convenient administration route for patients

Status • Exploring new formulation alternatives

OX124 *Opioid overdose rescue medication*

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

Status • **Phase I clinical trial planned for Q4, comparing with the leading treatment available 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

Status • Early formulation work ongoing

Orexo's pipeline updated with progress in Europe and OX124 moving into clinical phase I

Expanding early pipeline to fight addiction



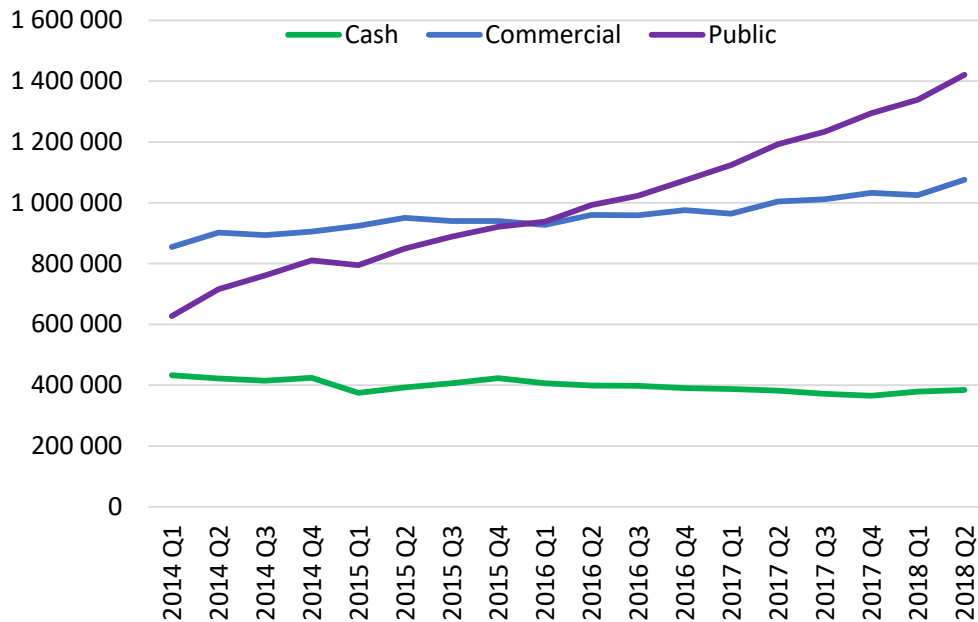
Update!

Update!

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

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

Strong growth in the public & commercial segments driving Q2 market growth (NTRx)



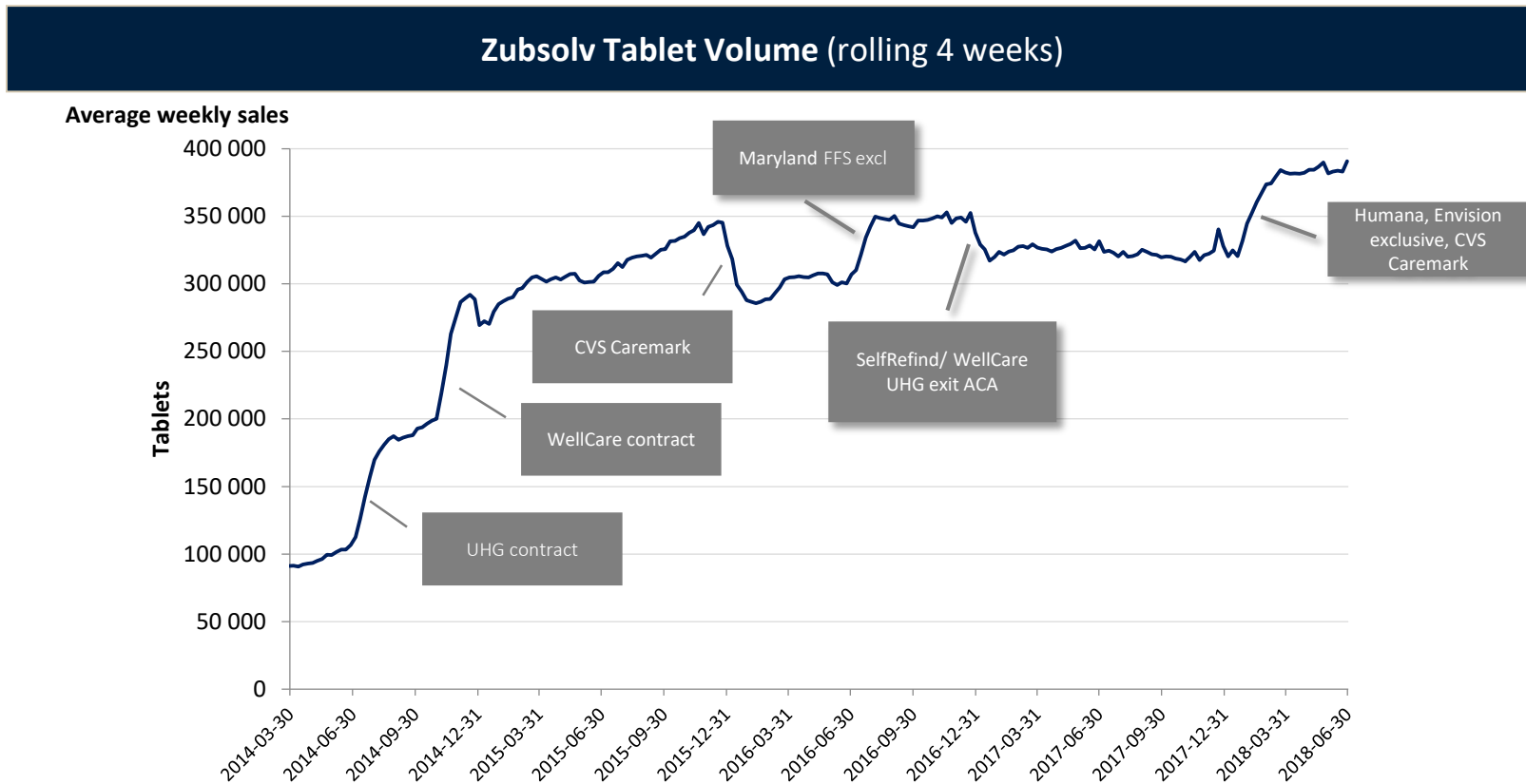
Overall market grew 12.3% in Q218 year over year, accelerating from earlier quarters.

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

Q2 with several all-time-high in tablets sold



Market share remained stable with 5.6% average in the quarter¹

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

Continued improvement in access to treatment behind strong market growth

Zubsolv® only brand to gain share due to growth in public and commercial

Zubsolv growth of 8.6% from Q1 2018 to Q2 2018 driven by public and commercial segments

- Public 13.5%¹
- Commercial 8.3%
- Cash (6.2%) – decline for all brands

Exclusive contracts lead overall growth with 11.4% Zubsolv growth over Q1

Commercial growth also driven by good performance in large competitive contracts e.g. CVS Caremark with 19% and ESI/Medco with 9% growth over Q1 in tablets prescribed

Zubsolv market share of 5.62% on Q2 compared to 5.52% in Q1²

¹ Public segment defined as FFS Medicaid, Managed Medicaid and Medicare Part D.

² Market share defined as average markets share for the quarter

Source: IMS weekly prescription data and Orexo analysis and projections

New competitors with mixed impact on the market dynamics

Depot formulation with minimal traction according to IMS

- Complex distribution
- Patient resistance

Two generics of the market leader approved

- One launched in a few hours before receiving a temporary restraining order
- ~4% market share recorded the following week
- One Gx likely to have limited impact on Zubsolv as the market already includes several Gx in a tablet formulation
- New opportunities for Zubsolv expected from market dynamics if the new Gx Film is launched

Net Revenues – 25% increase vs Q2 2017

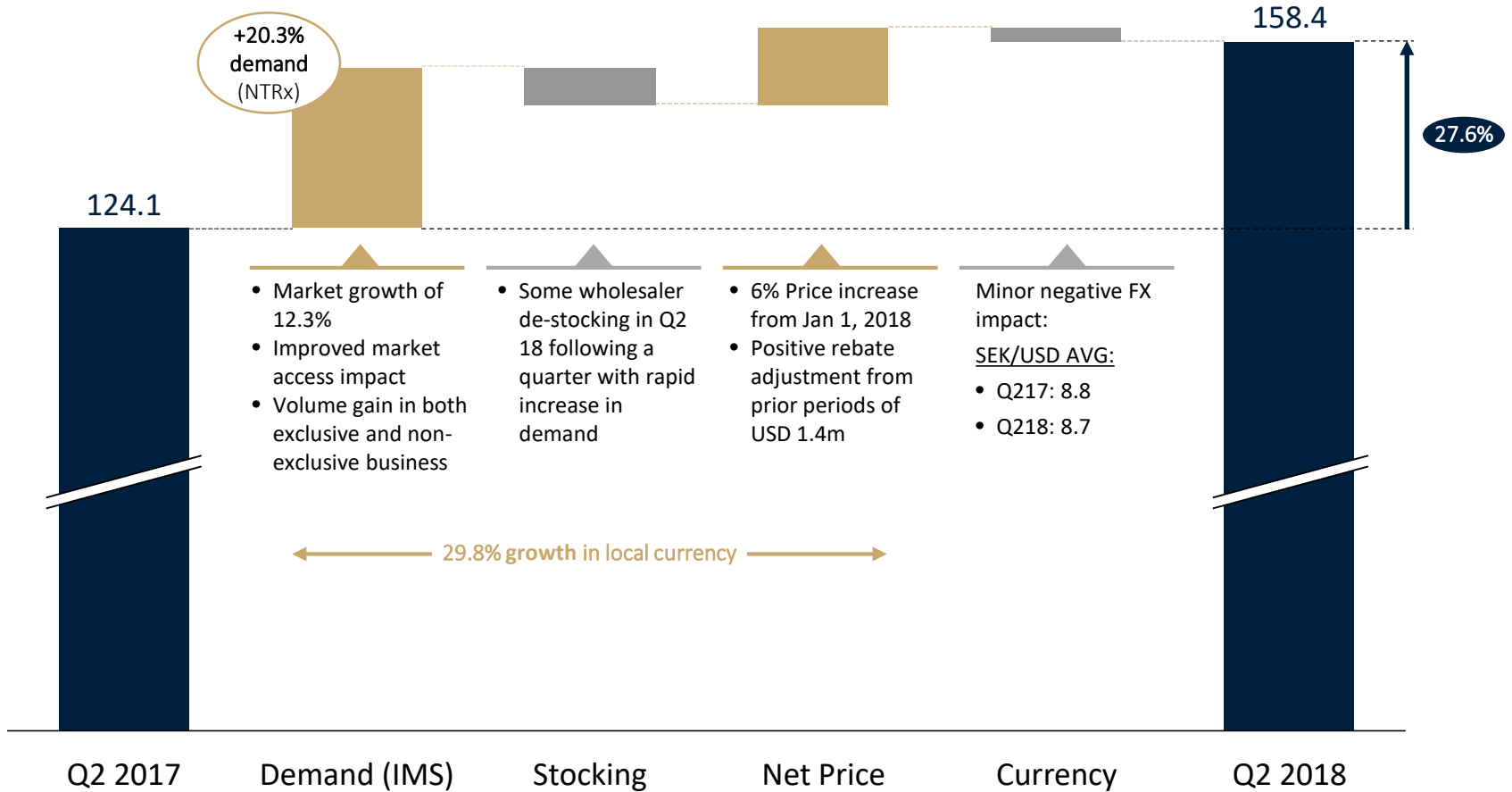
January – June 2018

MSEK	Q2 2018	Q2 2017	H1 2018	H1 2017	12 mth July 2017 – June 2018
Zubsolv® US	158.4	124.1	289.5	238.2	537.1
Zubsolv® – Rest of the world	30.8	-	30.8	-	36.4
Zubsolv® – total	189.2	124.1	320.3	238.2	573.5
Abstral® royalties	11.9	9.8	17.7	18.4	112.5
Milestone payment Abstral		-		-	-
Abstral® – total	11.9	9.8	17.7	18.4	112.5
Edluar® royalties	-1.4	3.4	1.4	8.0	10.7
OX-CLI		21.8		21.8	-
TOTAL	199.7	159.1	339.4	286.4	696.7

- Net revenues for the period April -June 2018 grew by 25.5% versus prior year driven by higher Zubsolv US revenue Zubsolv Ex-US milestone of SEK 30.8 million partially offset by absence of OX-CLI milestone of SEK 21.8 million and by lower Edluar royalties
- Zubsolv US revenues grew by 27.6% in Q2 2018 versus Q2 2017 to SEK 158.4 million
 - Positive drivers: Market growth of 12.3%, positive net price impact, including USD 1.4M adjustment of rebate accruals relating to prior periods
 - Negative drivers: Some wholesaler de-stocking following a quarter with rapid increase in demand. Minor negative FX impact.
- Zubsolv - Rest of the World milestone of SEK 30.8 million was earned during Q2 2018 triggered by EU launch.

Zubsolv[®] US growth factors – Q2 2018 vs Q2 2017

SEK Million



Orexo analysis using IMS demand data plus institutional sales

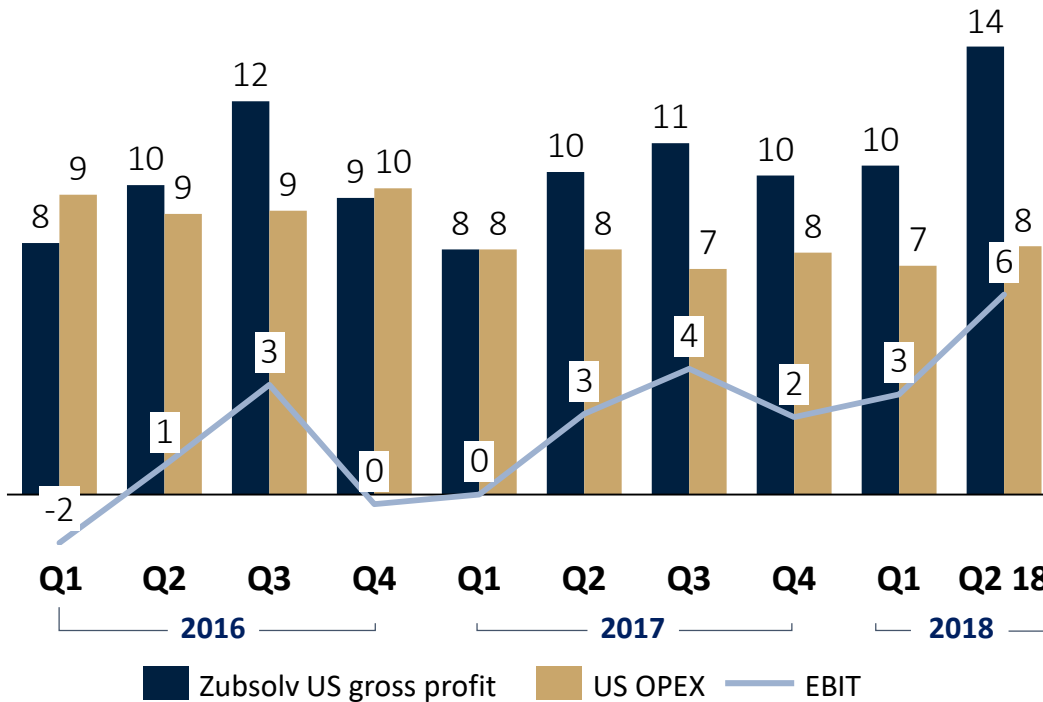
P&L in Summary, April – June 2018 and January – June 2018

MSEK	Q2 2018	Q2 2017	H1 2018	H1 2017	LTM July 2017 – June 2018
Net revenues	199.7	159.1	339.4	286.4	696.7
Cost of goods sold	-37.6	-35.8	-86.0	-82.0	-168.4
Gross Profit	162.1	123.3	253.4	204.4	528.3
Selling expenses	-48.6	-49.7	-92.0	-97.9	-184.6
Administrative expenses	-34.0	-22.4	-61.2	-48.8	-108.4
Research & development expenses	-37.0	-39.1	-82.4	-69.4	-147.2
Other operating income & expenses	2.9	-2.3	5.7	-1.9	6.4
Operating Costs	-116.7	-113.5	-229.9	-218.0	-433.8
EBIT	45.4	9.8	23.5	-13.6	94.5
Net financial items	4.0	-5.1	1.0	-11.7	-15.0
EBT	49.4	4.7	24.5	-25.2	79.5
Tax	0.7	-1.6	-0.4	-6.4	-0.5
Net profit/loss	50.1	3.1	24.1	-31.4	79.0
EBITDA	50.6	15.0	33.8	-3.2	115.2

- Gross Profit for the quarter 32% higher vs prior year driven by higher gross profit for Zubsolv® US of SEK 32.5 million and by earned Zubsolv - Rest of the World milestone of SEK 30.8 million partially offset by absence of OX-CLI milestone of SEK 21.8 million and by lower partner revenue of SEK 2.6 million driven by lower Edluar® royalties.
- COGS shows first signs of positive impact from the Manufacturing Efficiency Program. Average COGS/tablet in Q2 2018 17% lower than average for 2017.
- Operating Costs slightly above prior year mainly driven by higher Administrative due to higher legal expenses.
- 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 revaluation of USD deposits.
- Tax positively impacted by revaluation of deferred tax asset in parent company.

EBIT contribution from US operations already at FY 2017 level

Operating costs and profit contribution (USD million)



Comments

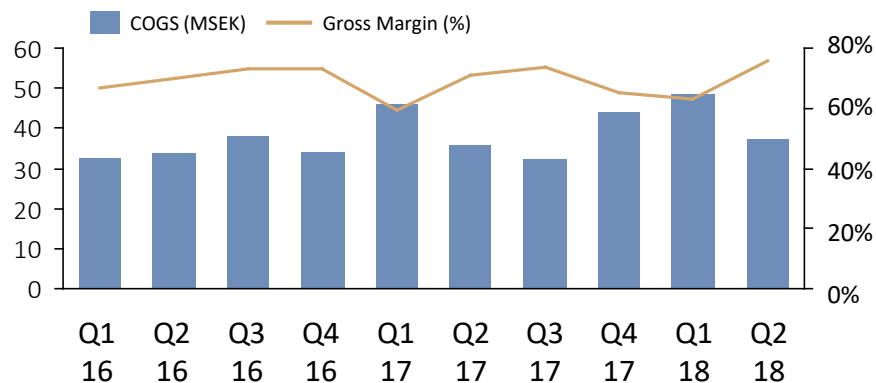
- Profit contribution from the US commercial operations has increased from USD 2.5 M to USD 8.8 M 2016 to 2017. First HY 2018 already at USD 9 M.
- Highly flexible infrastructure enables fast adoption to market dynamics and optimization of the operations to growth opportunities and threats
- Significant 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:

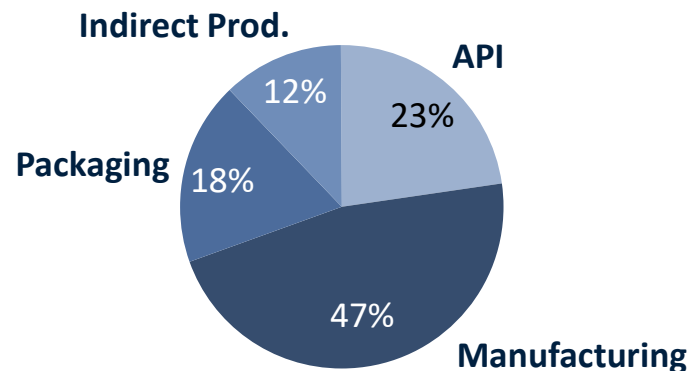
- Gross profit is calculated as Zubsolv® US net revenue (USD) minus group Cost of Goods Sold (COGS)
- COGS is translated to USD using average SEK/USD exchange rate for the relevant quarter and includes indirect product costs covering certain overhead directly related to the manufacturing processes (e.g. 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

Zubsolv[®] Cost of Goods Sold (COGS). Savings slightly ahead of plan!

Gross margin



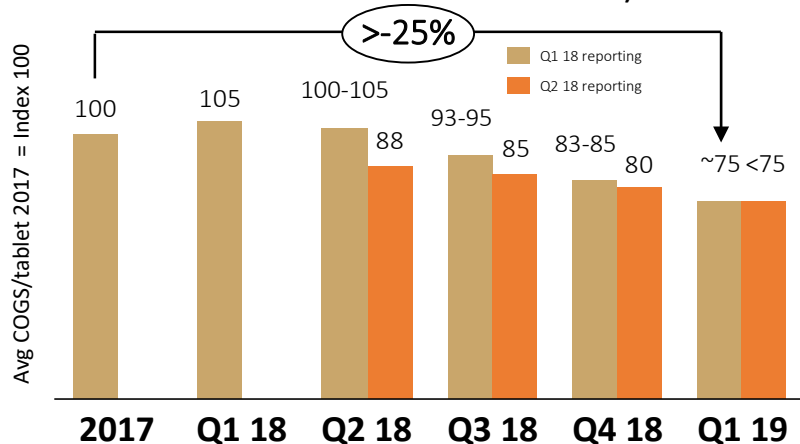
COGS composition (illustrative example, 5.7mg, 2017)



Expected COGS improvements

(Directional, assuming other parameters unchanged)

Normalized trend – i.e. without unusual COGS variances)



Description

- Zubsolv gross margin has varied between 63% and 76% 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 the Manufacturing costs (47% of total COGS in the illustrative example above). 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 at least 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.

Solid financial position

Financial Position, January – June 2018

Cash flow MSEK	Q2 2018	Q2 2017	H1 2018	H1 2017	LTM July 2017 – June 2018
Cash flow from operating activities	39.0	49.0	144.9	76.9	146.6
Investment activities	-1.7	-0.5	-1.7	-0.8	-1.6
Financing activities	0.5	-	0.9	-59.0	-85.4
Cash flow (excl exchange rate differences)	37.8	48.5	144.1	17.2	59.6
Liquid funds	498.4	294.3	494.8	294.3	327.9

- Positive cash flow from operating activities for the period May – June 2018
 - SEK 39.0 million positive contribution from operating activities driven by positive operating earnings and by increased provisions relating to US payer rebates. Changes in working capital had a negative impact due to increased receivables partially off-set by increased payables and lower inventories. EUR 3 M Zubsolv® Europe milestone will be paid to Orexo in July 2018 and was recognized as a receivable in June 2018.
- Strong cash position at the end of Q2 with SEK 498.4 million

Financial outlook 2018

Good progress in all areas in line or ahead of guidance

Performance YTD is in line with guidance provided previously

- EBTIDA negative in Q1 and positive in Q2
- Milestone slightly above 2017 realized with SEK 30.8 M (SEK 21.8 M from OX-CLI)

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

- Positive EBITDA expected in Q3 and Q4

With the improved market access situation for Zubsolv US, Orexo expects to gain volume and market share during 2018

- 14.9 percent growth YTD compared to 2017 and market share 0.6 percentage point above 2018 exit

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

- First effects visible in Q2 with a 25% reduction in COGs per tablet compared to Q1

Full year OPEX is expected to be approximately SEK 500 million. The increase compared to H1 2018 is driven by:

- Increased spend in pipeline with OX-124 entering clinical phase I in Q4
- Legal expenses related to litigation against Actavis on their Suboxone and Subutex generics
- Only a limited amount has been included for the Actavis litigation for Zubsolv, assuming a positive outcome.
- Nearly 9% appreciation of USD vs SEK since original guidance. Updated guidance assumes July FX rates.

Forward looking statements, see Legal Disclaimer on page 1

2018 continues to evolve according to plan with strong financial performance laying the foundation for growth

- **Core business at the heart of the biggest health problem in the US**
- **Strong financial performance and position** with SEK 498.4 M in cash and strong trajectory towards record year in profitability (EBITDA)
- **A pipeline of interesting internal projects** progressing well with OX124 entering exploratory clinical phase I
- **Market access for Zubsolv® significantly improved** and continue to drive growth with 11.4 percent growth in exclusive contracts in Q2
- **Launch of Zubsolv® in Europe**, in Germany and Sweden
- **Business development** efforts continue to identify opportunities to add commercial products to the US operations
- A **decision** on the Zubsolv **US patent litigation** against Actavis was expected first half 2018 and should come shortly



Q&A

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