



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



**Interim Report Q2 2019, July 11<sup>th</sup>**

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

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# Overview Q2 2019



## Q2 2019 – Zubsolv drive strong improvement in fundamentals

### Financials: Significant EBIT improvement

- US EBIT of 9.2 MUSD (6.4) with a 47.4% EBIT margin (35%)
- Continued Zubsolv® growth, with 16.4 percent (SEK) in Q2 vs Q2 18
- Strong growth of EBITDA with 19.4 percent from Q2 18 and 5X from Q1. EBITDA SEK 60,4 million (50.6) in Q2
- SEK 697 million in cash balance end of Q2 and positive cash flow of SEK 46.1 million

### R&D and Business development: First partner agreement ex US signed

- New agreement with Mundipharma Australia for the rights to Zubsolv in Australia and NZ
- Continued negotiations with potential partners in Europe for Zubsolv
- Active negotiations for additional products in the US
- OX124, OX125 progress according to plan, with main focus on establishing commercial manufacturing processes
- OX338 continues to progress towards the first clinical trial in H2 2019
- OX-MPI progress into phase I, by Gesynta AB

# Good progress with OX124, OX125 and OX338; preparing for next clinical development phase

			Exploratory	Preclinical	Phase			Registration	Approved/Launched		
					1	2	3		US	EU	RoW
Commercial products											
Zubsolv®		Opioid Dependence									
Abstral®		Breakthrough Cancer Pain, Kyowa Kirin ex- US, Sentynt US									
Edluar®		Insomnia Mylan Worldwide									
Development projects											
NEW FORMULATION TECHNOLOGIES	OX124	Naloxone - Opioid Overdose									
	OX125	Nalmefene - Opioid Overdose									
	OX338	Ketrorolac - Acute moderate to severe pain									
	OX382	Buprenorphine - Opioid Dependence/Pain									
OX-MPI		BI1029539 – Microvascular Disease									

# New partnering agreement with Mundipharma for Australia

## Opioid addiction in Australia

- Opioid addiction is a growing problem in Australia, increasing the need for treatment
  - 735,000 people used opioids for non-medical purposes in 2016-2017
  - 50,000 people received pharmacotherapy treatment for opioid dependence
  - 17,000 hospitalizations with a diagnosis of opioid dependence in 2016-2017
  - 1,045 opioid-induced deaths among Australians aged 15-64 years in 2016

## The deal with Mundipharma Pty.

- Mundipharma Pty. is already Marketing Authorization Holder for Zubsolv® in Australia
- Mundipharma Pty. will have commercialization rights for Australia and New Zealand
- Orexo will supply Zubsolv® under a Supply Agreement
- Pricing & Reimbursement dossier has been submitted, launch is anticipated in H1, 2020
- Orexo will earn royalties on future net sales

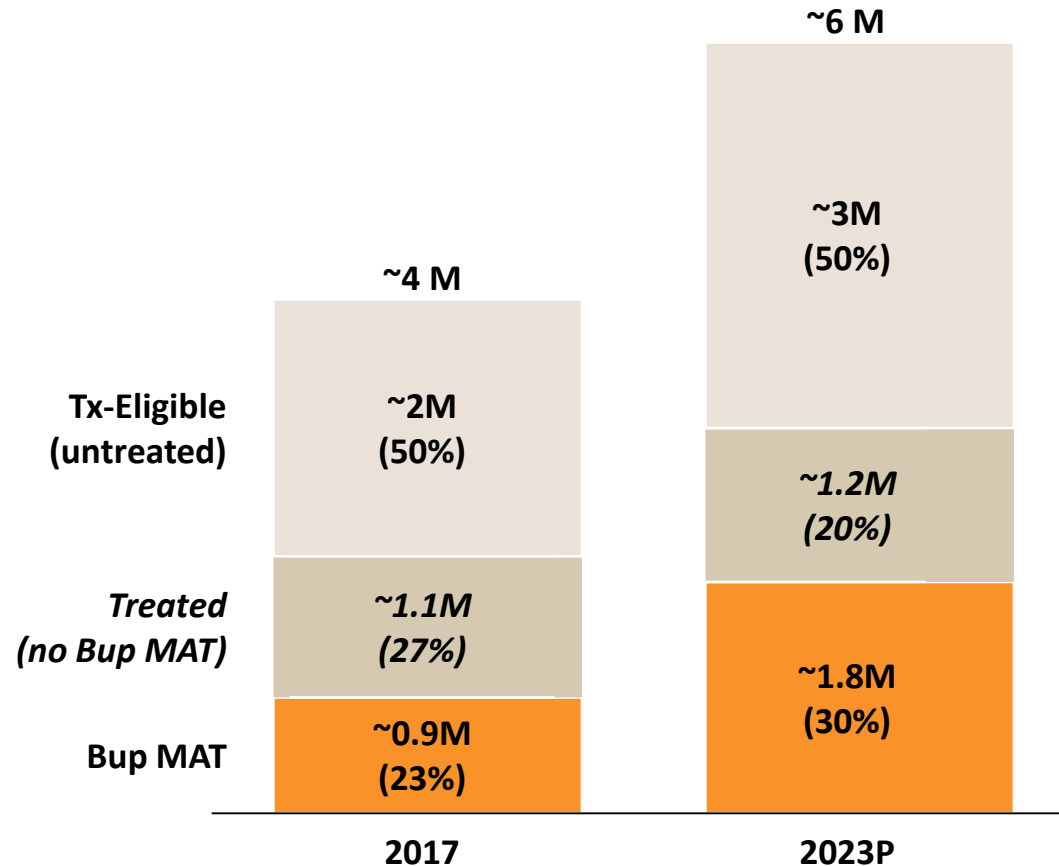


# Key Market & Sales

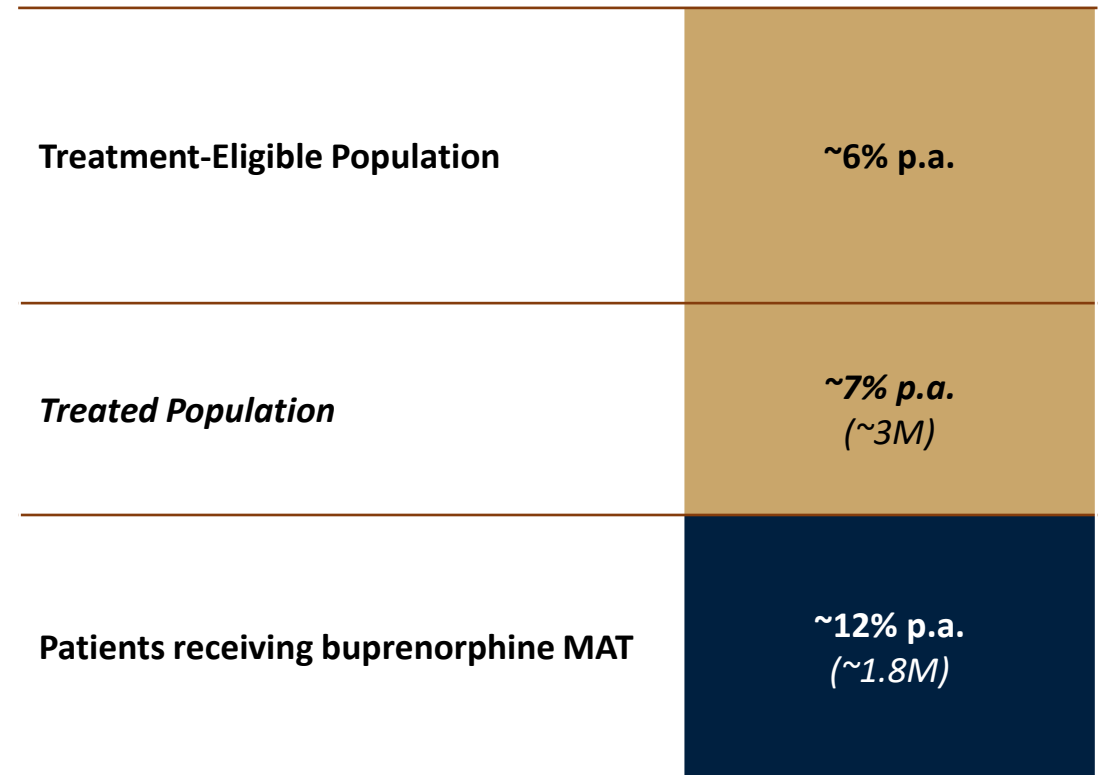


# US buprenorphine MAT population likely to double by 2023

2017 & 2023 US Treated Population



US Growth Rates

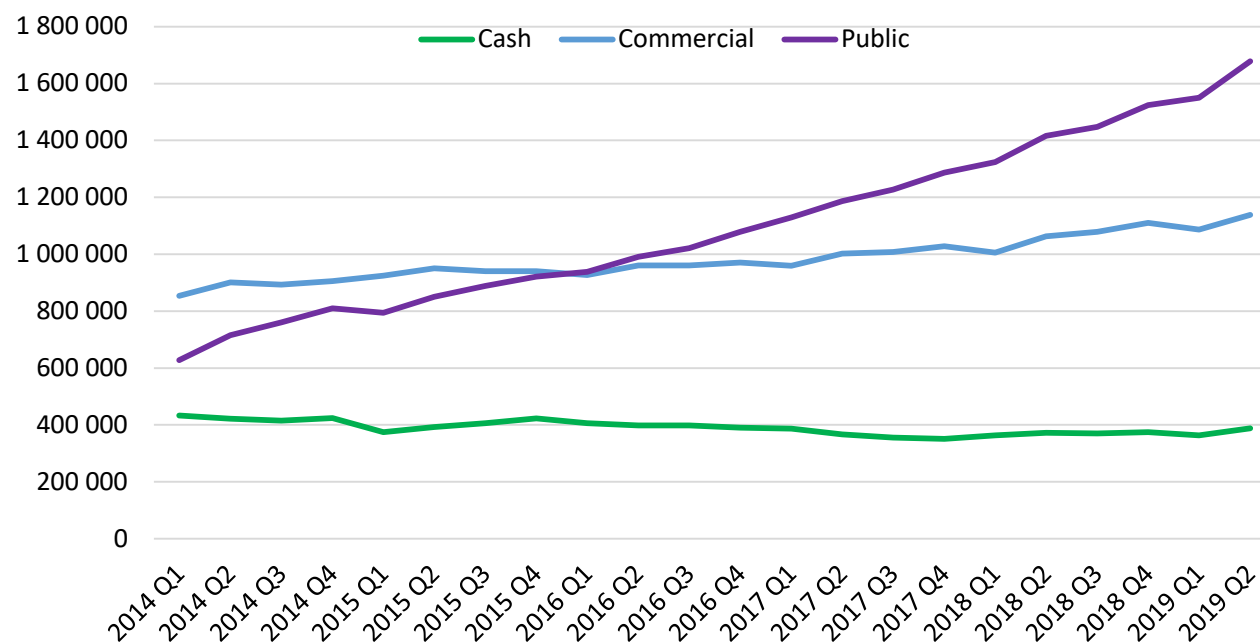


Sources: 1) SAMHSA NSDUH reports (2013, 2014, 2015, 2016); Clarion analysis

# YTD Year-over-year market growth at 13 percent

## New highs in Public and Commercial NTRx in Q2 and Zubsolv grows with the market (excluding WellCare)

Quarterly NTRx



Q2 YoY Growth	
Market	Zubsolv®
18%	-2%
(19% excl Wellcare)	
8%	7%
4%	-29%

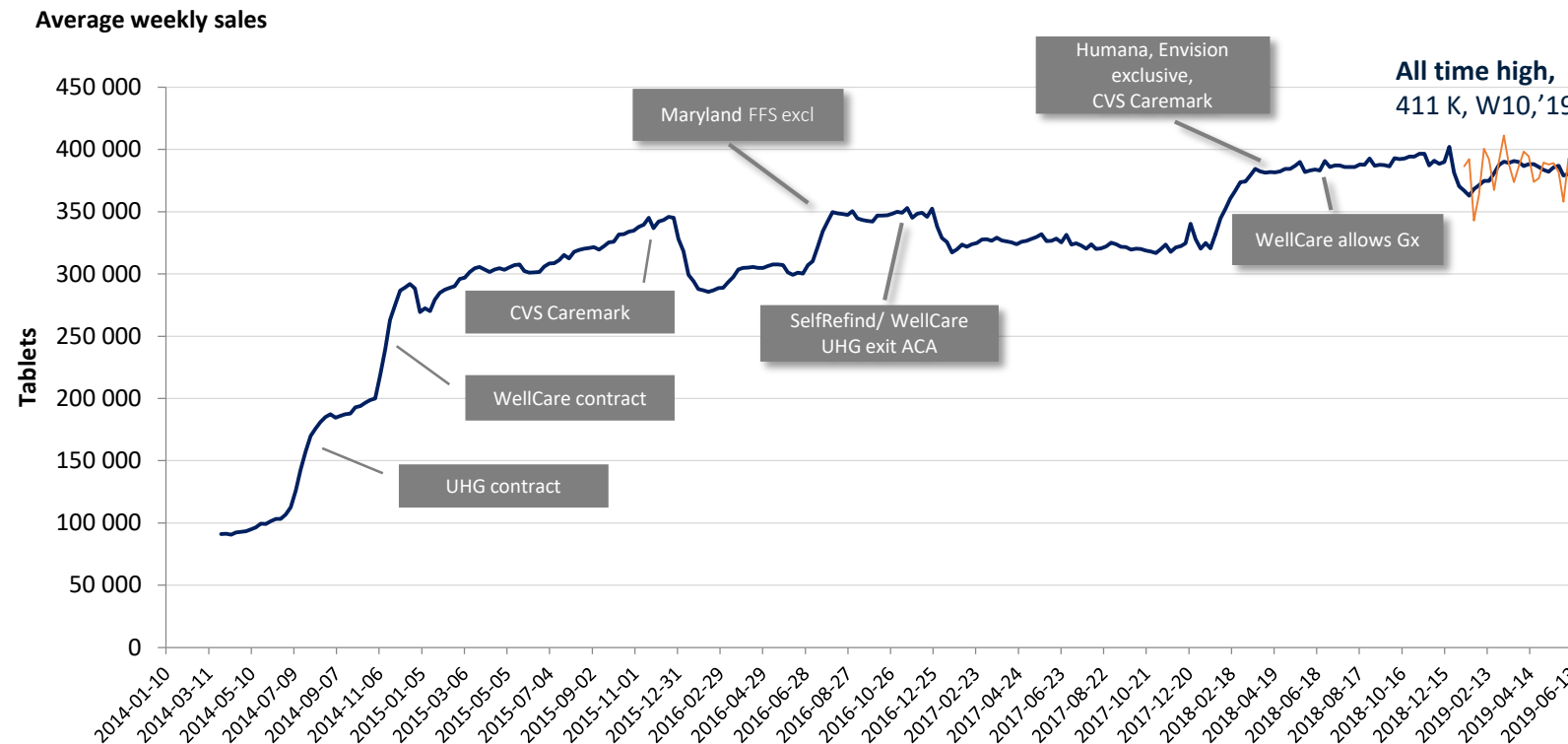
**Overall market grew 13% YoY in Q2 2019, on pace with YoY growth since Q1 2018**

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® volumes are close to all time high in week 10

Despite WellCare (November 2018) and Humana (March 2019) adding Gx to their formulary list

## Zubsolv Tablet Volume (rolling 4 week average)

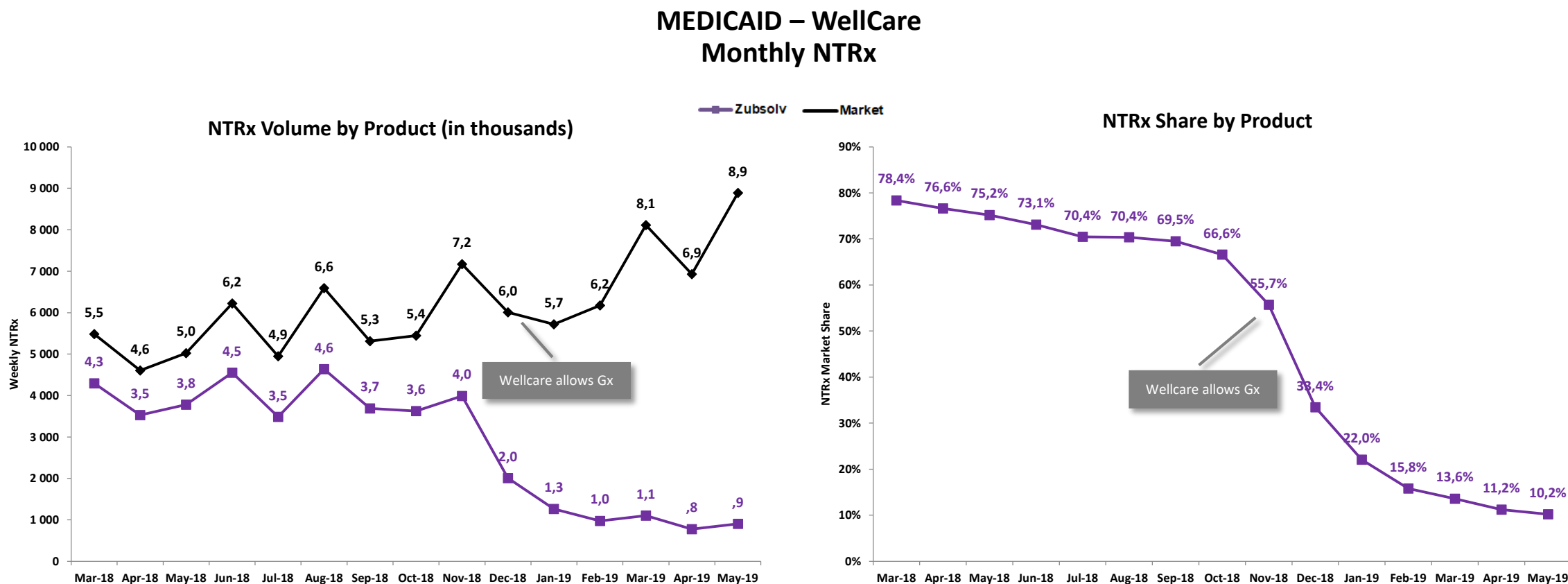


### Zubsolv® volume growth continues, despite WellCare loss

- Growth of 3 percent vs Q1 and 1 percent vs Q2 18
- WellCare change from exclusivity has a negative effect of ~6% on overall volume growth vs Q2 18 and WellCare volume continues to decline in 2019, but positive impact on EBIT
- Caremark and ESI both grew double digit vs Q2 18
- Zubsolv has in 2019 gained access to previously closed public plans and grown 66% within these new accounts Q2 19 vs Q1 19

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

# Wellcare - Zubsolv® volume stabilizing since start of the year despite formulary restrictions<sup>1</sup>

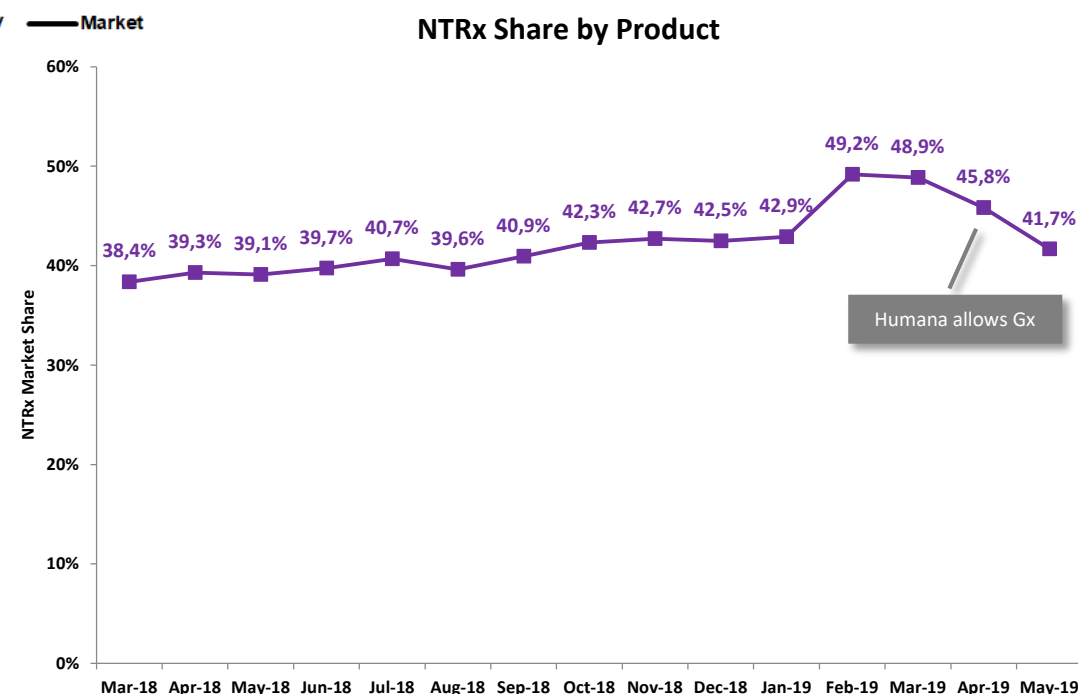
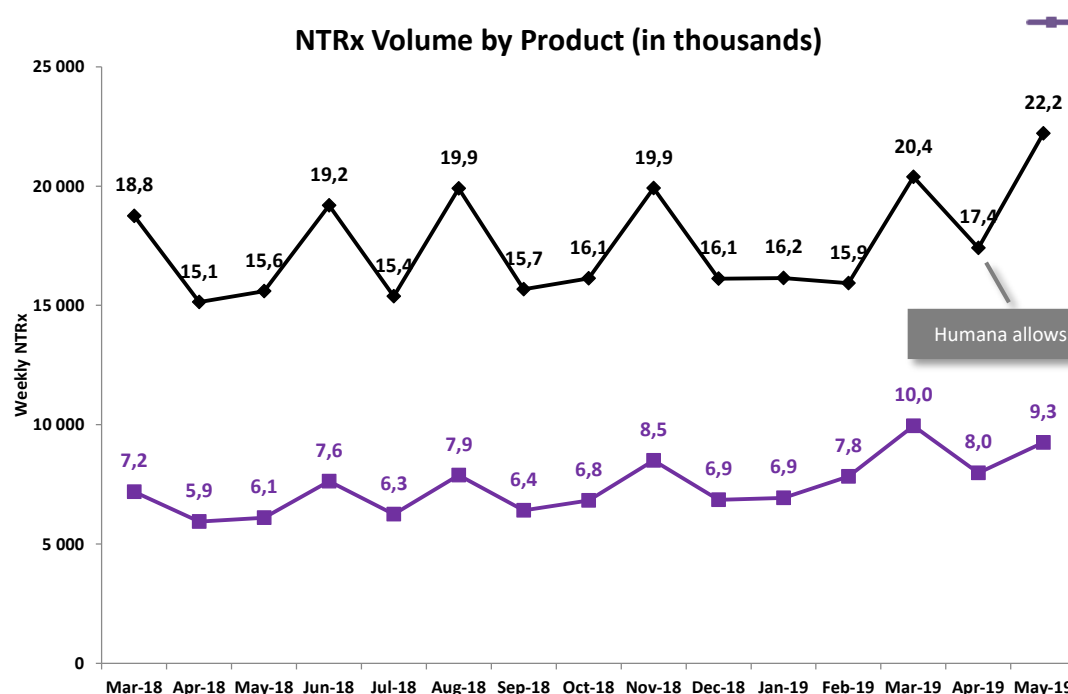


WellCare volumes increased when opening up for Gx film and tablets, reversing positive from Zubsolv exclusivity in reducing diversion

# Zubsolv maintaining high volumes post formulary change possibly explained by no formulary restrictions<sup>1</sup> and patient preference

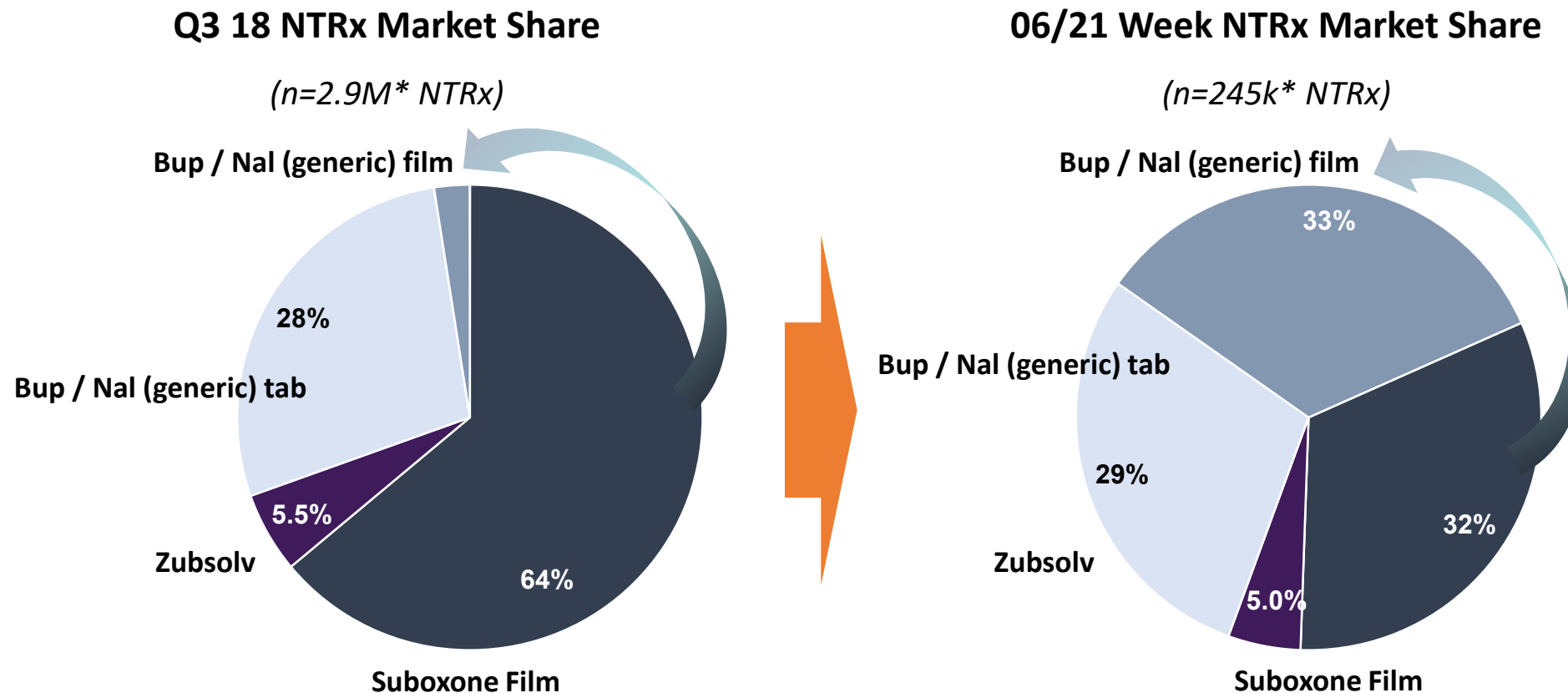
## HUMANA (COMMERCIAL and MEDICARE D)

### Monthly NTRx



Humana volumes increased when opening up for Gx film and tablets, impacting Zubsolv share negatively despite maintained volumes

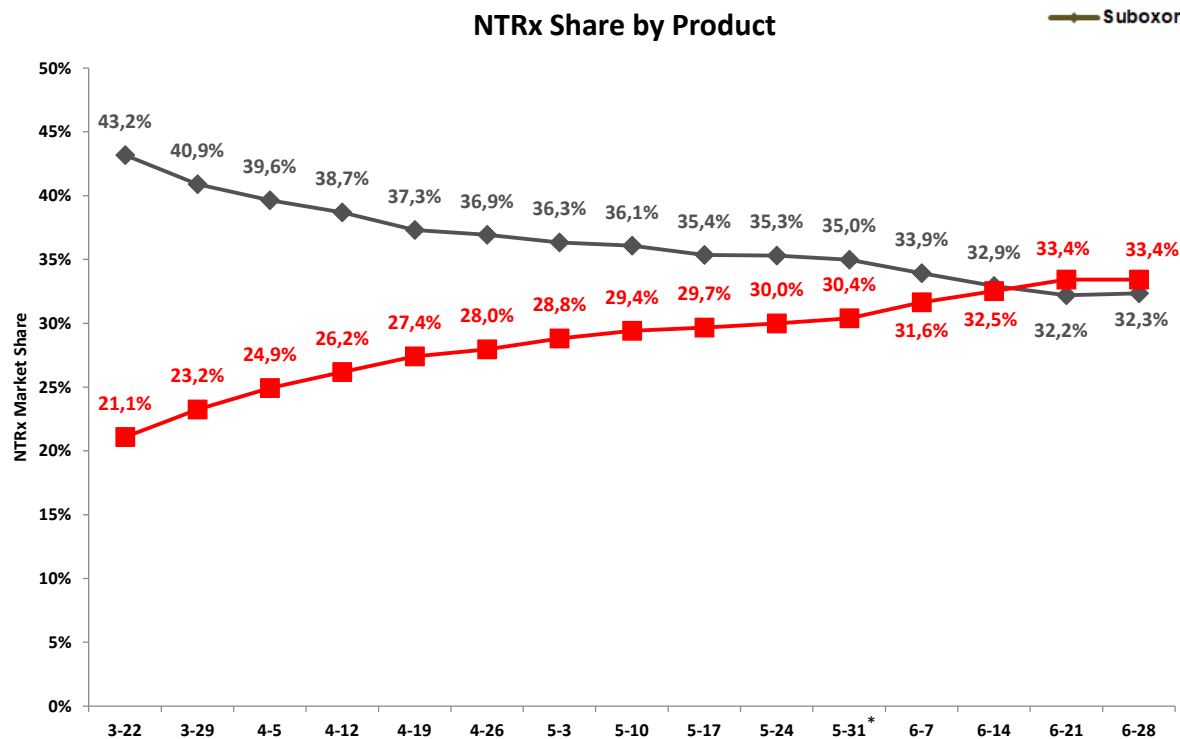
Generics are now the majority of the market, primarily due to decline in branded Suboxone® Film



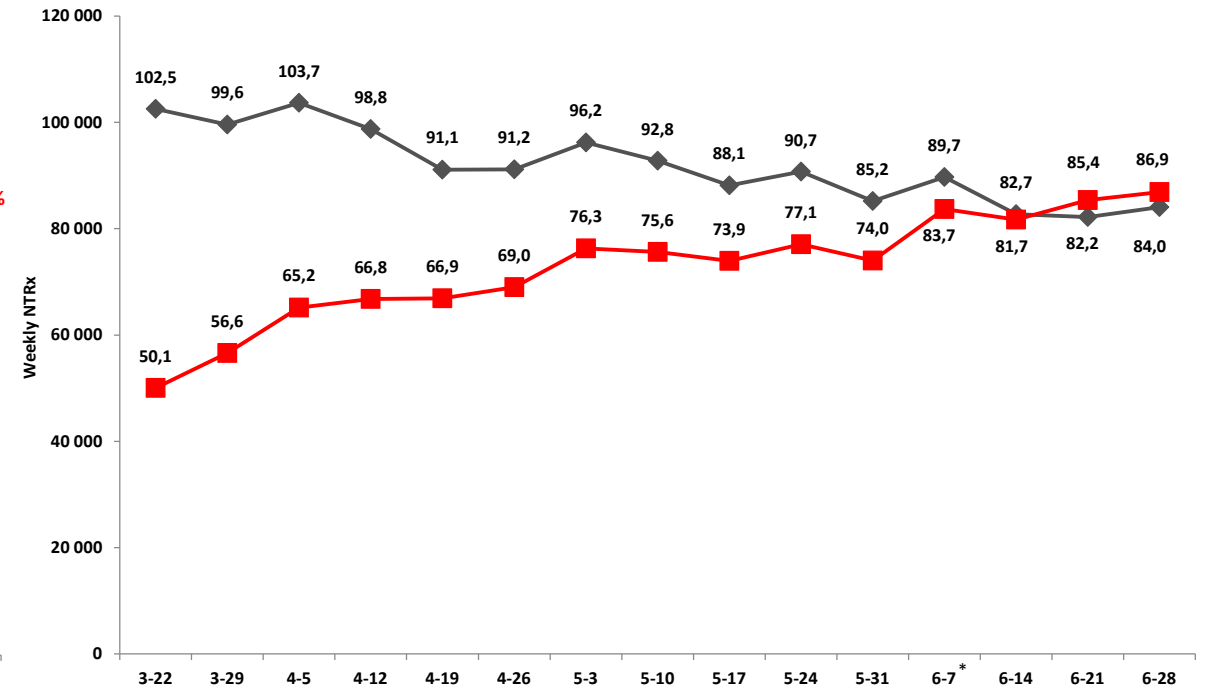
Zubsolv® share decline due to volume reduction at WellCare and Humana, and highest market growth in lower access Public segment

# Generic Film has become the market leader as of WE 06/21/19

NTRx Share by Product



NTRx Volume by Product (in thousands)



Branded film decline steadily, but slow pace show resilience and demonstrate value of patient preferences

# General trend towards opening up reimbursement for more alternatives



## **Broader reimbursement of more treatment alternatives on initiative to address the opioid crisis and reduce administrative burden**

- With generics becoming the market leader and lowering prices more insurance companies tend to reduce complexity and offering more choice
- Legal initiatives ongoing in several states to make it mandatory to offer more products to patients e.g. NY and NJ

## **New trend offers both opportunities and some increased risk for Zubsolv®**

- Exclusivity challenged by some insurance companies e.g. Maryland (2017), WellCare (2018), Humana (2019) and potentially United Health Group (TBD)
- Removal of exclusivity in Maryland, WellCare and Humana followed by reduced rebates and increased profitability
- Zubsolv has proven competitive when the playing field is leveled e.g. Humana move to open access, market share gains in both competitive commercial and public insurance plans
- Branded Suboxone® Film remains the main hurdle for broader access and most fierce competitor for patient preference. When Suboxone Film volumes decline new opportunities to improve Zubsolv market access are likely to emerge

# Financials



# Zubsolv® main growth driver of net revenues with 16.4 percent (6.7 percent in local currency)

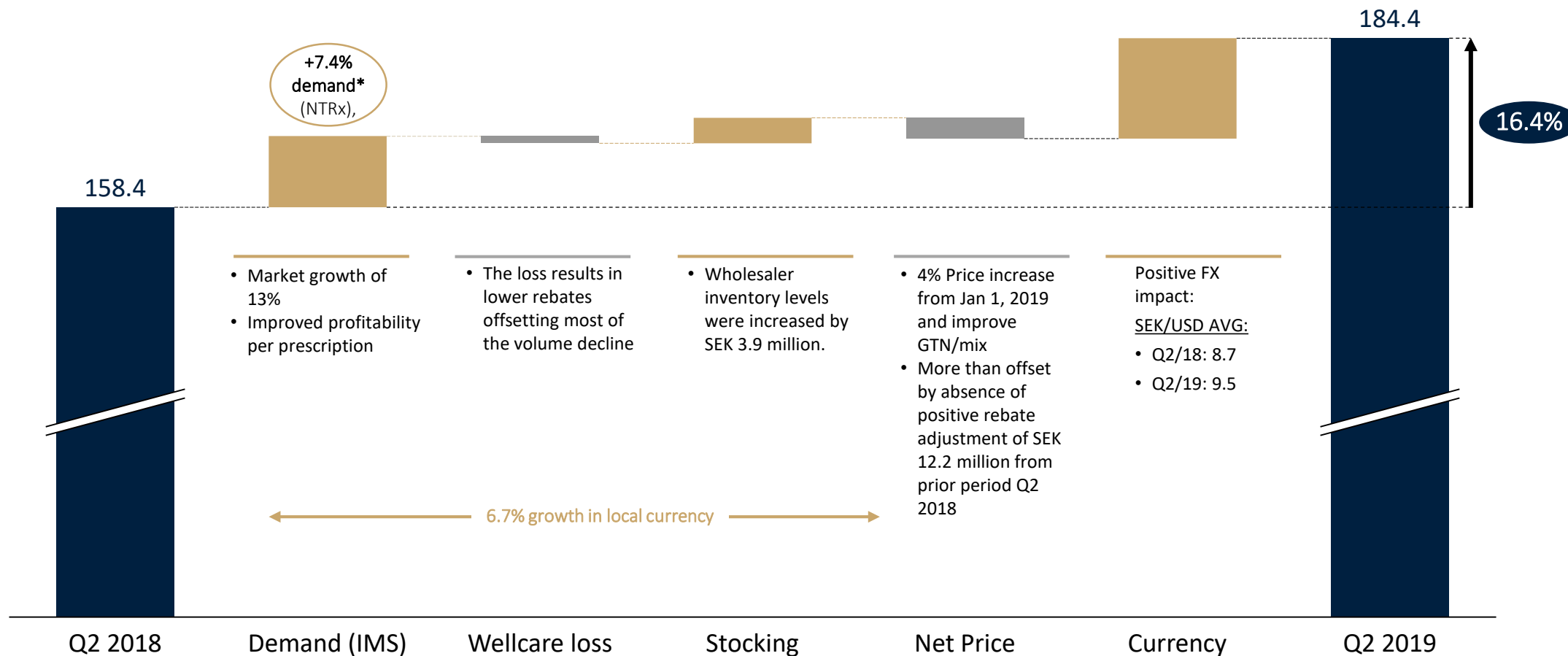
January – June 2019 and 12 MTH July 2018 – June 2019, SEK million

MSEK	Q2 2019	Q2 2018	H1 2019	H1 2018	12 mth July 2018 – June 2019
Zubsolv US	184.4	158.4	346.1	289.5	678.2
Zubsolv – Rest of the world	-	30.8	-	30.8	5.4
<b>Zubsolv® – total</b>	<b>184.4</b>	<b>189.2</b>	<b>346.1</b>	<b>320.3</b>	<b>683.6</b>
Abstral® royalties	13.1	11.9	24.0	17.7	125.1
Edluar® royalties	2.4	-1.4	4.2	1.4	9.4
OX-MPI	1.3	-	1.3	-	1.3
<b>TOTAL</b>	<b>201.2</b>	<b>199.7</b>	<b>375.5</b>	<b>339.4</b>	<b>819.3</b>

- Net revenues for the Q2 2019 grew by 19.1%, driven by higher Zubsolv US Revenue, when excluding the one time Q2 2018 Zubsolv – Rest of the world milestone.
- Zubsolv US revenues strong growth driver with 16.4% in Q2 2019 versus Q2 2018 to SEK 184.4 million.
- Abstral Q1 2019 growth primarily driven by positive true-up adjustments made to prior period estimates.

# Zubsolv® growth primarily driven by increased demand and boosted by stronger USD

Zubsolv US growth factors, Q219 vs Q218

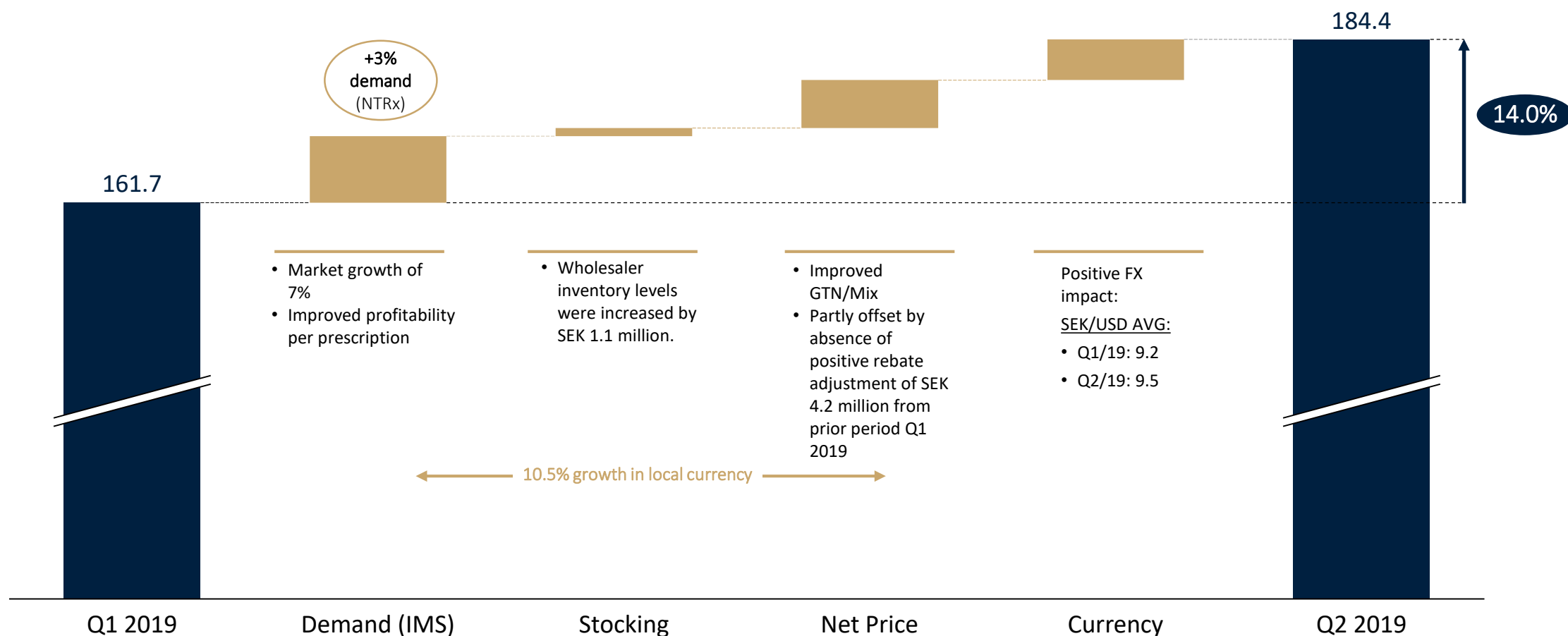


1) Orexo analysis using IMS demand data plus institutional sales

\* Excluding Wellcare loss and 4 price increase

# Zubsolv® growth primarily driven by increased demand and by improved GTN /Mix supported by stronger USD

## Zubsolv US growth factors, Q219 vs Q119



# Q2 EBITDA of SEK 60.4 million (50.6)

P&L in Summary, January – June 2019 and 12 MTH July 2018 – June 2019, SEK million

MSEK	Q2 2019	Q2 2018	H1 2019	H1 2018	12 mth July 2018 – June 2019
Net revenues	201.2	199.7	375.5	339.4	819.2
Cost of goods sold	-31.3	-37.6	-56.6	-86.0	-142.4
<b>Gross Profit</b>	<b>169.9</b>	<b>162.1</b>	<b>318.9</b>	<b>253.4</b>	<b>676.8</b>
Selling expenses	-49.0	-48.6	-96.3	-92.0	-195.8
Administrative expenses	-24.5	-34.0	-94.6	-61.2	-200.1
Research & development expenses	-43.5	-37.0	-81.2	-82.4	-165.6
Other operating income & expenses	-0.1	2.9	6.9	5.7	10.7
<b>Operating Costs</b>	<b>-117.1</b>	<b>-116.7</b>	<b>-265.1</b>	<b>-229.9</b>	<b>-550.8</b>
<b>EBIT</b>	<b>52.8</b>	<b>45.4</b>	<b>53.8</b>	<b>23.5</b>	<b>126.0</b>
Net financial items	5.7	4.0	10.5	1.0	6.0
<b>EBT</b>	<b>58.5</b>	<b>49.4</b>	<b>64.3</b>	<b>24.5</b>	<b>132.0</b>
Tax	-3.9	0.7	4.3	-0.4	50.4
<b>Net profit/loss</b>	<b>54.6</b>	<b>50.1</b>	<b>68.6</b>	<b>24.1</b>	<b>182.4</b>
<b>EBITDA</b>	<b>60.4</b>	<b>50.6</b>	<b>72.3</b>	<b>33.7</b>	<b>155.0</b>

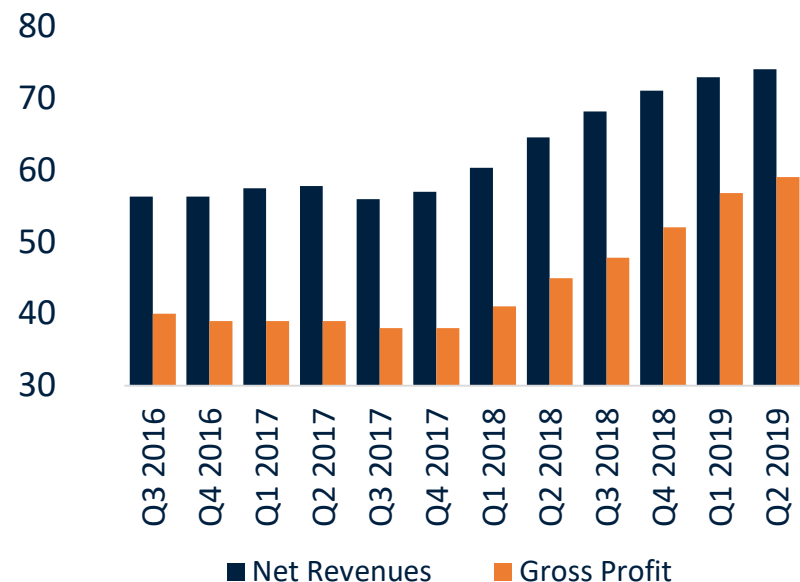
## Q2 2019 comments:

- **Gross Profit** for the quarter 29% higher vs prior year when excluding the Q2 2018 Zubsolv – Rest of the world milestone in Q2 2018. This is driven by lower COGS per tablet and by Zubsolv US growth.
- COGS reach index<sup>1</sup> 62 H1 and 67 Q2
- **Operating Costs** slightly above prior year due to more investment in our pipeline offset by lower IP litigation costs
- Administrative expenses lower due to legal expenses related to IP litigations amounting to SEK 3.1 million (17.0).
- R&D expenses above due to higher activity level in the pipeline.
- **Tax** negatively impact by a SEK 2.4 million adjustment to deferred tax assets related to temporary differences.

# Orexo US has improved EBIT (LTM, USD) with 91 percent from Q2 2018

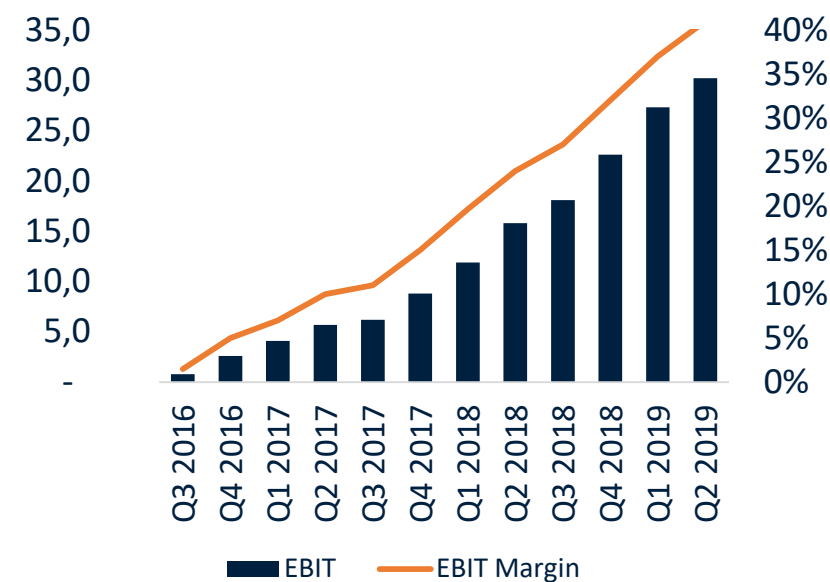
## Sales and gross profit

LTM MUSD



## Operating Profit

LTM MUSD



- Net Sales driven by demand growth of 7,4% Q2 2019 excluding Wellcare loss and price increase and improved GTN/mix
- Strong growth in EBIT contribution to USD 9.2 million increasing from USD 6.4 million in Q2 2018 driven by sales increase and COGS
- US EBIT margin of 47.4% in Q2 2019 increasing from 35.0% in Q2 2018

Note: COGS converted from SEK to USD using monthly average exchange rates for the period; LTM is "Last Twelve Months"

# Strong financial position

Financial Position, January – June 2019 and 12 MTH July 2018 – June 2019, SEK million

Cash flow MSEK	Q2 2019	Q2 2018	H1 2019	H1 2018	12 mth July 2018 – June 2019
Cash flow from operating activities	46.1	39.0	97.1	144.9	193.3
Investment activities	-0.8	-1.7	-0.8	-1.7	-5.3
Financing activities	-3.8	0.5	-14.5	0.9	-14.6
Cash flow (excl exchange rate differences)	41.6	37.8	81.7	144.1	173.4
<b>Liquid funds</b>	<b>697.0</b>	<b>494.8</b>	<b>697.0</b>	<b>494.8</b>	<b>697.0</b>

- Positive cash flow from operating activities for the period Q2 2019
  - SEK 46.1 million positive contribution from operating activities driven by operating earnings and by increased provisions relating to US payer rebates partly offset by negative changes in working capital due to increased receivables partly offset by decreased inventories and by increased current liabilities. Repayment of loans contributed negatively with SEK -3.8 million due to reduced leasing liability recognized according to IFRS 16.
- Strong cash position at the end of Q2 2019 with SEK 697.0 million
- Orexo will leverage the strong cash position to repay 10 percent of the corporate bond in August to limit interest costs and reduce SEK/USD exposure

## Record-breaking performance in 2018 further improved in Q2 2019

Group Net Revenues LTM <b>SEK 819 m (697)</b> <i>USD ~86 m, 82.8% from Zubsolv</i>	Growth <b>18%</b> <i>(Zubsolv 26%)</i>
Group EBITDA LTM <b>SEK 155 m (115)</b> <i>USD ~13 m</i>	Growth <b>35%</b>
US EBIT LTM <b>SEK 277 m (132)</b> <i>USD ~29 m</i>	Growth <b>109%</b> <i>USD 109%</i>
Cash position Q2 2019 <b>SEK 697 m (495)</b> <i>USD ~73 m</i>	Net Cash position Q2 2019 <b>SEK 376 m</b> <i>USD ~40 m</i>

Note: USD based on average exchange rate from Q2, 2019 SEK/USD 9.5; Comparator is LTM Q2 2018; LTM is "Last Twelve Months"

# Outlook



# Strong value drivers for long-term growth

## Future value drivers

### 1. Growing key market

13% growth in YTD 2019 in a market addressing one of the largest health crises ever in America and a growing global concern

### 2. Strong financial position and profitability

USD 73 m in cash and EBIT contribution from the US improving with 109% (LTM). Continuous improving gross margins will drive further profit growth.

### 3. Strong track record of developing products

Orexo has developed four Products with worldwide approval.

### 4. M&A and business development

Add commercial stage products in the US to leverage the commercial infrastructure and expand sales.

### 5. Expanding pipeline

Growing pipeline including several interesting projects to embrace all aspects of opioid addiction.

## Q2 – Financial outlook 2019

COGs reduction, reaching 35 percent reduction on full year basis

- For 2019 Orexo expects to improve the positive EBITDA on a full year basis
- Orexo believes that the overall Zubsolv sales in the US in 2019 will increase, despite increased competition from generic Film. However we do expect that the 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 2019 compared to 2017 (~30 percent compared to 2018)
- Full year OPEX is expected to stay at the same level as 2018 with approximately SEK 500 million
- ✓ The first new partnerships for Zubsolv outside the US is expected to be initiated in 2019

*The outlook is based on current exchange rates (June 2019)*

# Thank You

# Q&A

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