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

Interim Report Q1 2019, May 2

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

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Overview

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Q1 2019 - continued strong performance in our US business, accelerated COGS savings and good progress in the pipeline

Financials: Significant EBIT improvement

- Strong Zubsolv® growth of 23.3% in Q1 driven by demand (6%), price increase (4%) and exchange rate (14%), 9.3% growth in local currency
- First time ever with positive EBIT and EBITDA in Q1
- EBITDA SEK 12.0 m (-16.6) in Q1
- EBITDA excluding IP litigation costs of SEK 60.8 m (-8.5) in Q1, SEK 263,7 m LTM (legal cost of SEK 118.5 m)
- US EBIT of SEK 71.9 m (25.3) and 44.5% EBIT margin (19.3%)

Projects and Pipeline: Good progress

- Zubsolv rights outside the US regained from Mundipharma, advanced negotiations with new partner(s)
- OX124 showed positive data in first clinical trial and next clinical trial expected latest 2020 for OX124 and OX125
- OX338 with positive in-vivo data and clinical trial planned for H2 2019
- OX382 in-vivo data does not support continuation into clinical phase I, new formulation options are being assessed

Operations: Accelerated COGS

- Accelerated manufacturing efficiency program leading to 43% reduction in COGS per tablet compared to 2017
- Objective updated to reach 35% reduction compared to 2017 on a full year basis 2019
- Uppsala facilities upgraded to enable manufacturing of GMP

Legal: Actavis case

- District Court found Actavis has not infringed the ‘996 patent with their Suboxone and Subutex Gx
- Orexo take first steps in appeal process with substantially reduced expenses
- No impact on Zubsolv patents and exclusivity is secured until 2032

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Pipeline Update

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

		Exploratory	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Approved/Launched US	Approved/Launched EU	Approved/Launched RoW
Commercial products										
Zubsolv®	Opioid Dependence									
Abstral®	Breakthrough Cancer Pain, *Kyowa Kirin ex- US, Sentynl 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									

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OX124 and OX125 – the projects at a glance

Significant unmet medical need

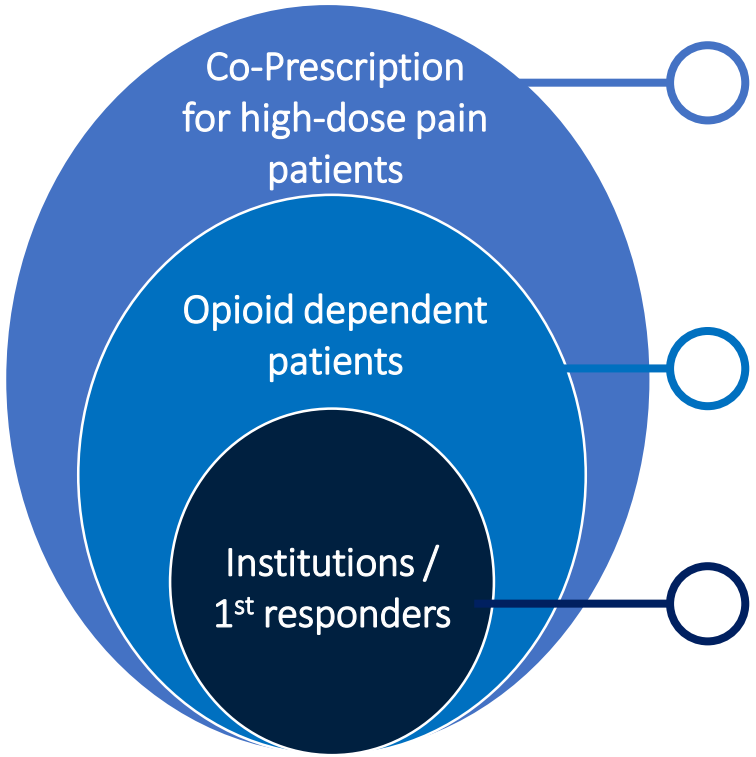
- 70,000 people died from a drug overdose in the US in 2017
- Synthetic opioids, such as fentanyl, are now the leading cause of death, which are more potent and stay in the body for a longer time than heroin
- Narcan® Nasal Spray, the leading naloxone rescue drug, is effective, but has shortcomings:
  - ~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

Large addressable market, with significant future upside

Market Segments



Description

- CDC guidelines for chronic pain opioid Rx encourage CO-Rx for high risk patients[3]
- CO-Rx legislation in place in Virginia and Vermont
- Vulnerable patient population requires broader naloxone access than is the case today
- Potent and needle free alternatives are critical given exposed situation and risk of contagion
- FDA is aiming to increase access to naloxone by making it OTC

Opportunity (Preliminary)

- 215 m Opioid Rx to ~58 m[1] adults
- ~26% of Rx ≥50 Morphine Milligram Equivalent[1]
- 4-5m of which 1.3 m receive ORT[2]
- ~1m emergency medical staff (EMT/Paramedics)
- ~0.8 m policemen
- ~0.3 m fire-fighters

Addressable market could potentially expand from today's ~USD 300-500 million to USD 1.5-2 billion

1 CDC 2017 "Annual Surveillance Report of Drug-Related Risks and Outcomes" indicate at least 1 opioid rx to 58m adults in year 2016
2 ORT = Opioid Replacement therapy; Est. 900,000 buprenorphine patients and 400,000 methadone patients
3 CDC March 2016: Clinicians should incorporate strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present

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OX124 - successful phase I confirms continued clinical development

OX124

- Strong data from human pharmacokinetic study, showing substantially higher plasma concentrations of naloxone than leading competitor in the US (Narcan®).
- Positive regulatory feedback where FDA generally accepted our product concept, bridging strategy and clinical development plan
- Pivotal pharmacokinetic study planned for 2020, estimated FDA submission in 2021

OX125

- Formulation development ongoing, estimated FDA submission in 2022 with first clinical trial expected latest 2020

Timelines may change depending on trial outcomes and development strategy

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OX338 is designed to avoid exposure to opioids for short-term pain (up to 5 days)

Opioid uses for short-term pain (examples)

Dental Procedures

Surgery / post-op

Trauma

Gynecology

Market insights

- Despite recent decline, **opioids are still widely used** in the US to treat short-term pain
- For many patients, their addiction journey started with their **first exposure to opioids** for pain treatment, e.g., after an accident
- There is a clear **need for non-opioid alternatives** to treat pain to avoid exposure to opioids and prevent addiction
- Wide-ranging **efforts to reduce opioid prescribing** will benefit non-opioid treatments

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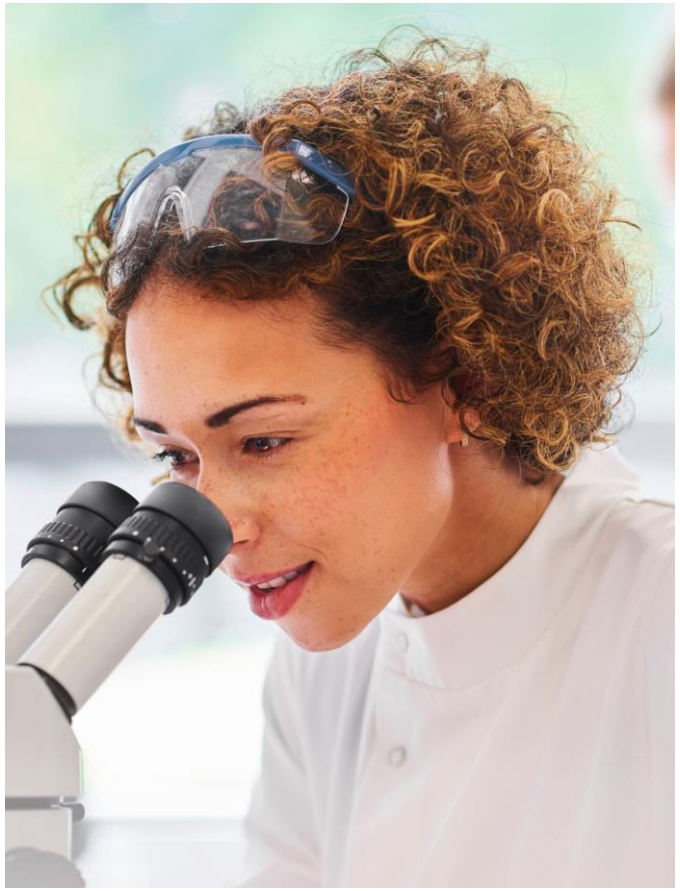
OX338 – clinical phase I study planned for H2 2019

- Formulation work and a Proof-of-Concept (PoC) in-vivo study successfully completed
- First human pharmacokinetic study planned for H2 2019
- Pivotal pharmacokinetic study and potential efficacy studies to be initiated following positive human clinical study
- Estimated FDA submission in 2021/2022



Timelines may change depending on trial outcomes and development strategy

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OX-MPI progressing towards clinical trials, while OX382 requires further development work

OX382 *1st Oral Swallowable Formulation of Buprenorphine for Opioid dependence and/or 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 does not support continuation into clinical phase with the current formulation, continued work to assess other formulation options**

OX-MPI (GS248) *Microvascular Diseases (partnered project – Gesynta Pharma AB)*

Status	• OX-MPI is progressing according to plan and first clinical study is expected later this year (2019) • Gesynta Pharma AB has announced that EUR 6 m was secured in a financing round led by Industrifonden enabling continued development of OX-MPI

Key Market & Sales

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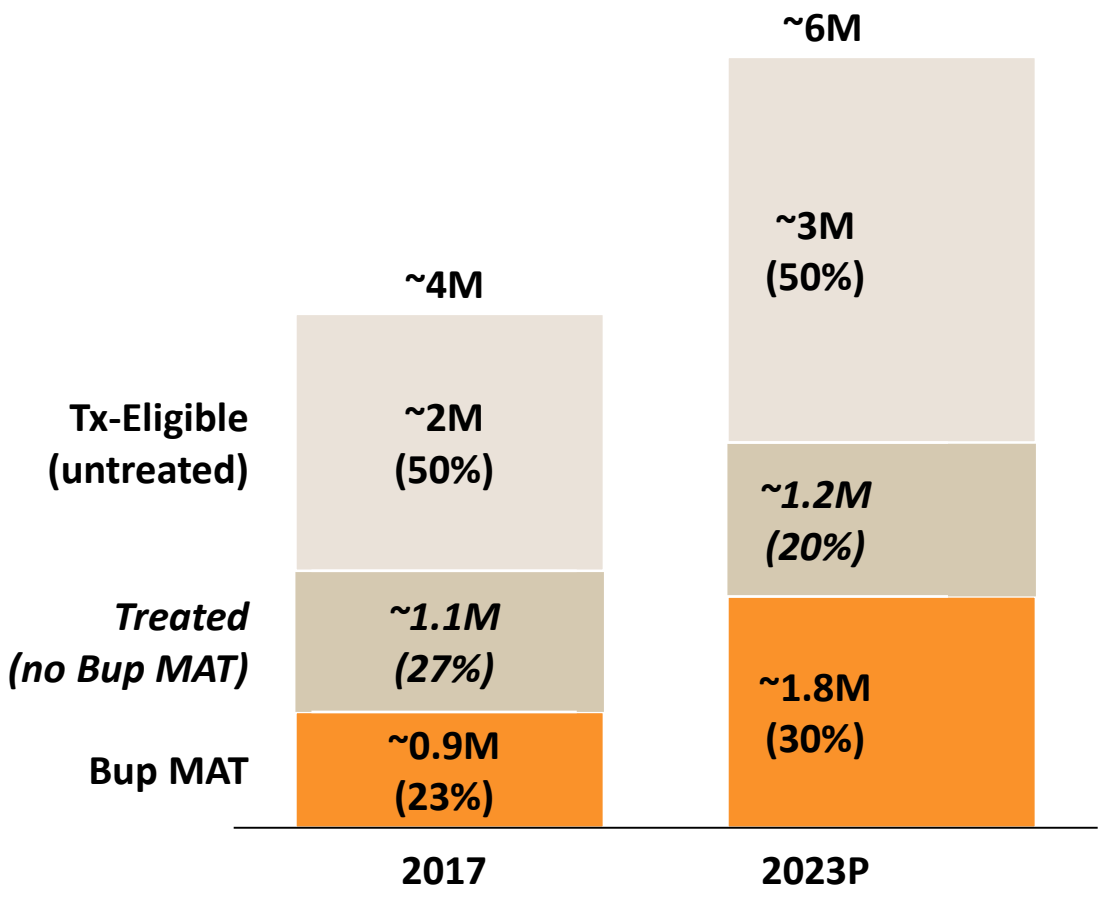
US buprenorphine MAT population likely to double by 2023

2017 & 2023 US Treated Population



US Growth Rates

Treatment-Eligible Population	**~6% p.a.**
Treated Population	***~7% p.a.*** *(~3M)*
Patients receiving buprenorphine MAT	**~12% p.a.** *(~1.8M)*

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

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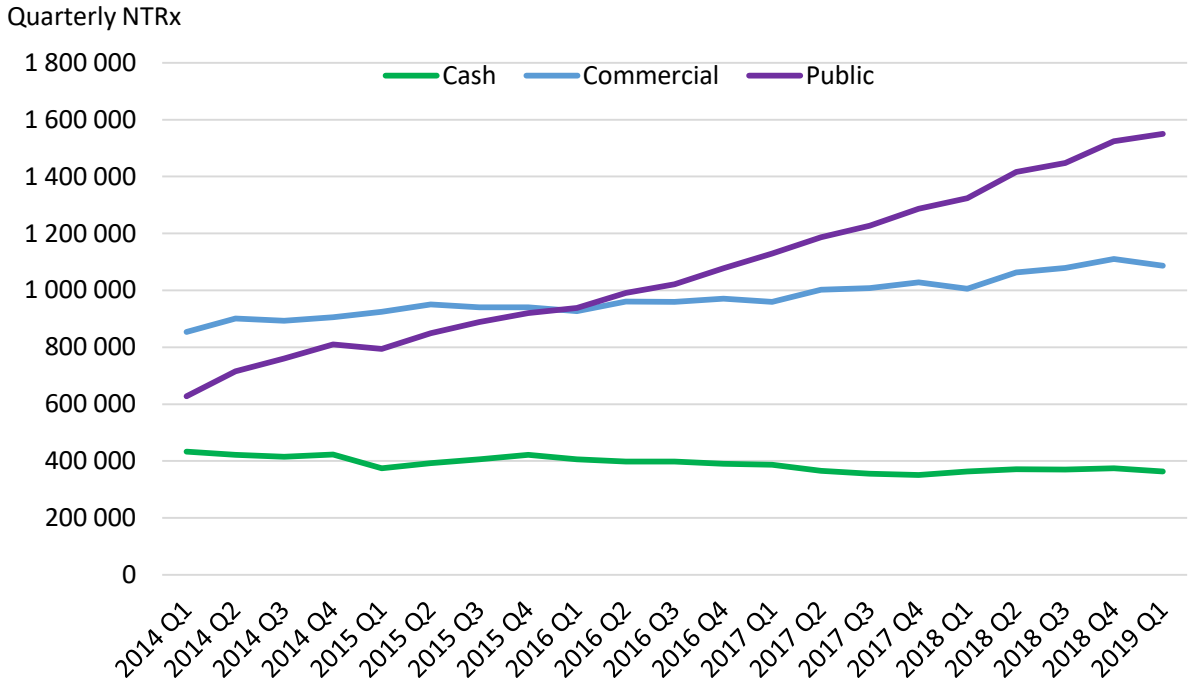
Q1 year-over-year market growth accelerating in 2019

New highs in Public NTRx in Q1, but Commercial and Cash segment show slight decline in Q1 2019 over Q4 2018



Overall market grew 13% YoY in Q1 2019, up from 11% YoY in 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

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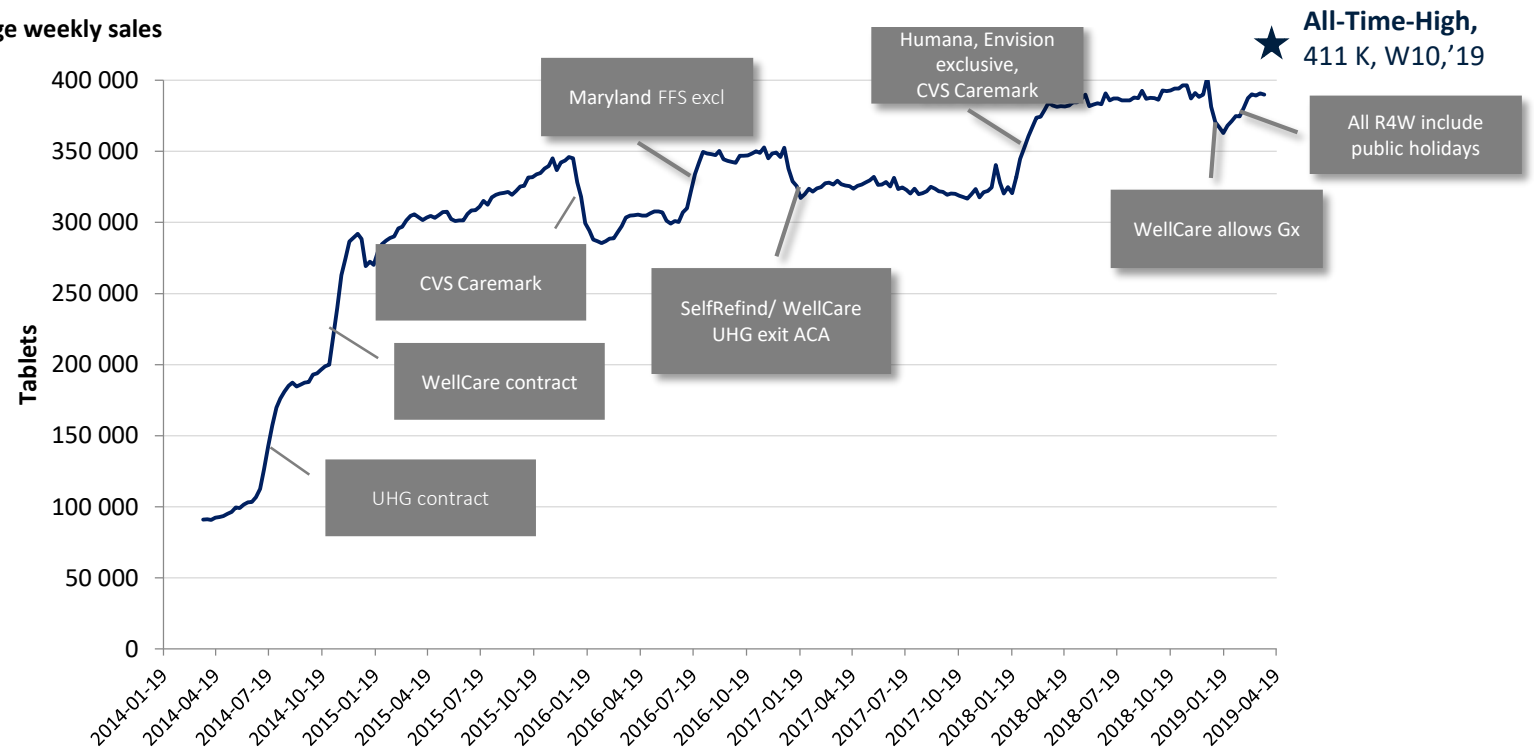
Zubsolv® volumes reached All-Time-High in week 10 2019

Despite WellCare adding Gx to their formulary list in November 2018

Zubsolv Tablet Volume (rolling 4 week average)



Note: Weekly prescription data is based on extrapolation and is associated with uncertainties and may differ between sources
Source: Orexo analysis, IMS weekly data

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** • Approval **March** • Launch	***Limited uptake thus far***			
Braeburn's Brixadi® (Depot)	**January** • Complete Response Letter (CRL)			**December** • Tentative FDA approval restricts launch until Q4 2020	**2019** • Possible launch of weekly depot (later in 2019)
Gx Suboxone® Film		**June** • Approval of Dr. Reddy Gx • Launch and injunction by Indivior on the same day	***Dr. Reddy's launch captured ~8% of total film market share before injunction***	**November** • Preliminary injunction overturned by the Federal Court in favor of Dr. Reddy	**Q1** • Launch of Gx, by Dr. Reddy, Alvogen, Mylan and Sandoz (Indivior), as the Federal Court decision regarding Dr. Reddy was sustained

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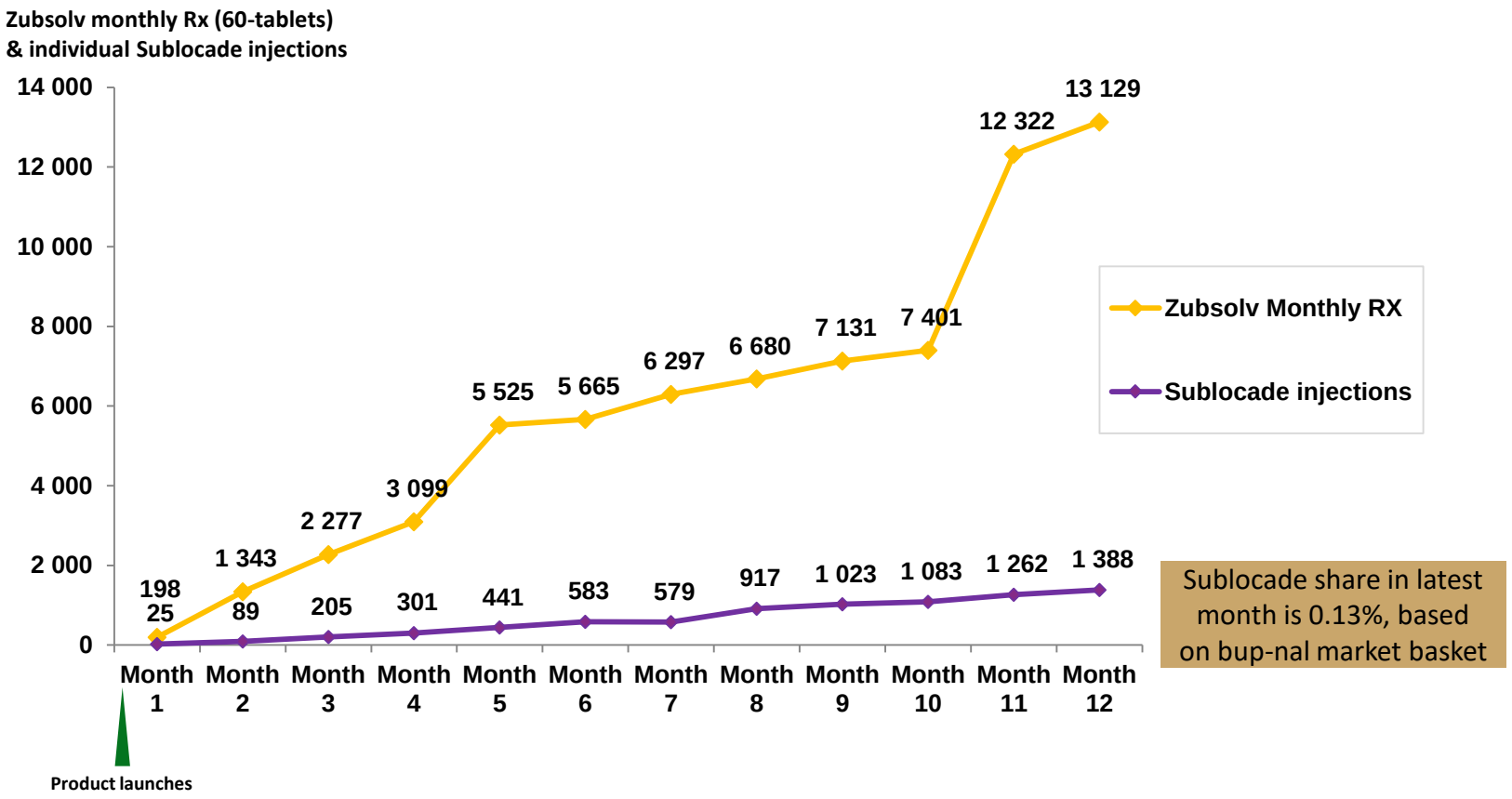
Sublocade's launch trajectory significantly behind expectation

Sublocade® vs. Zubsolv® prescribing based on months from respective launches



Sublocade share in latest month is 0.13%, based on bup-nal market basket

Source: IMS XPO for Zubsolv, IMS NPA for Sublocade

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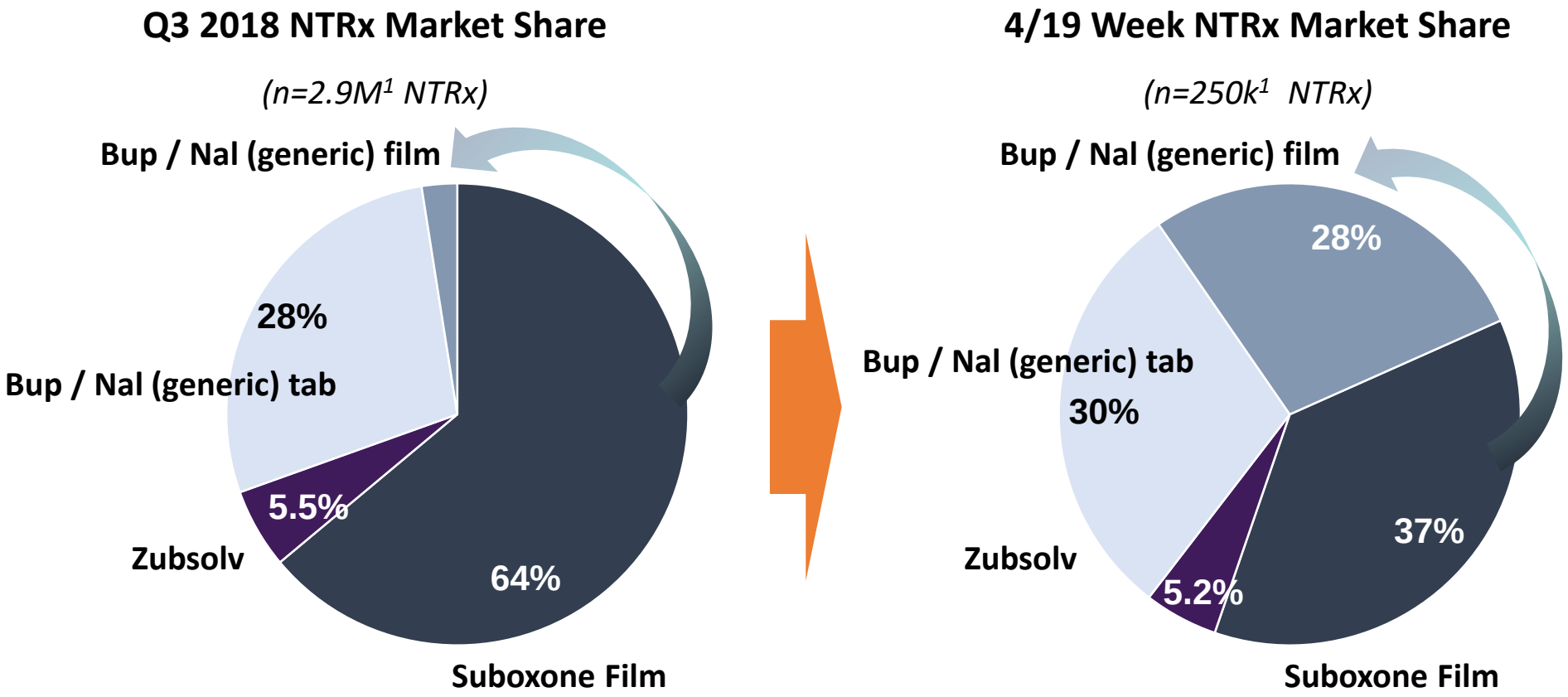
Generic Film launch to date has primarily impacted branded Suboxone® Film

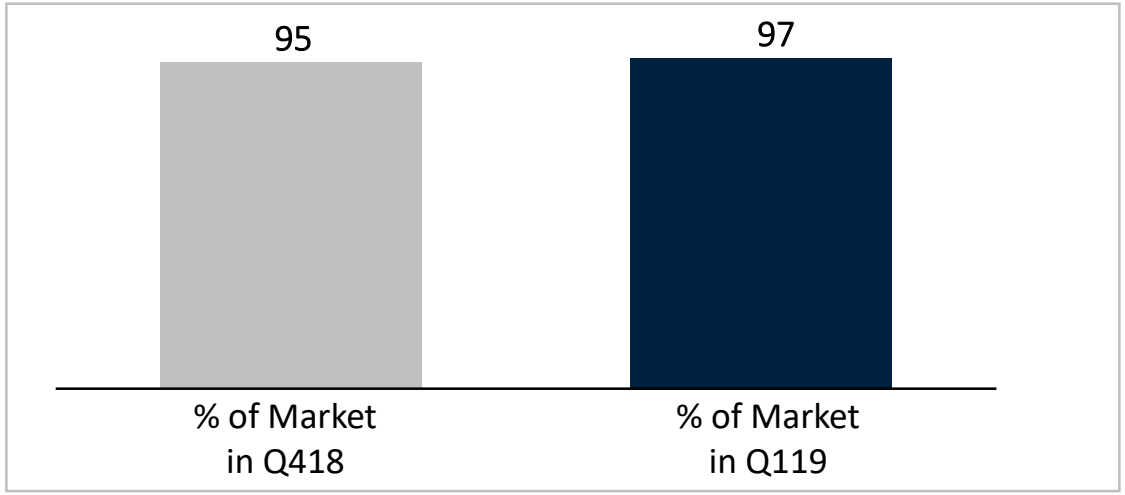


Zubsolv® share decline due to volume reduction at Wellcare, and highest market growth in Public segment

[1] Does not include Bunavail or Sublocade (combined share 0.4%)
Sources: IMS XPO

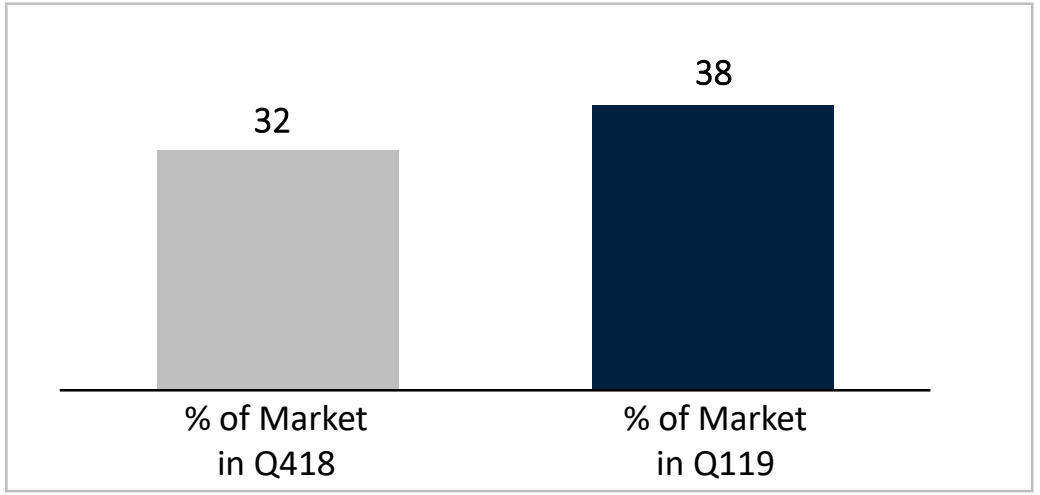
Zubsolv® continues to have best in class commercial market access, with improvements in public market

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 implemented during Q1
- Humana has added Gx Film in a preferred position, ending the exclusive coverage of Zubsolv

Source: IMS weekly prescription data and Orexo analysis

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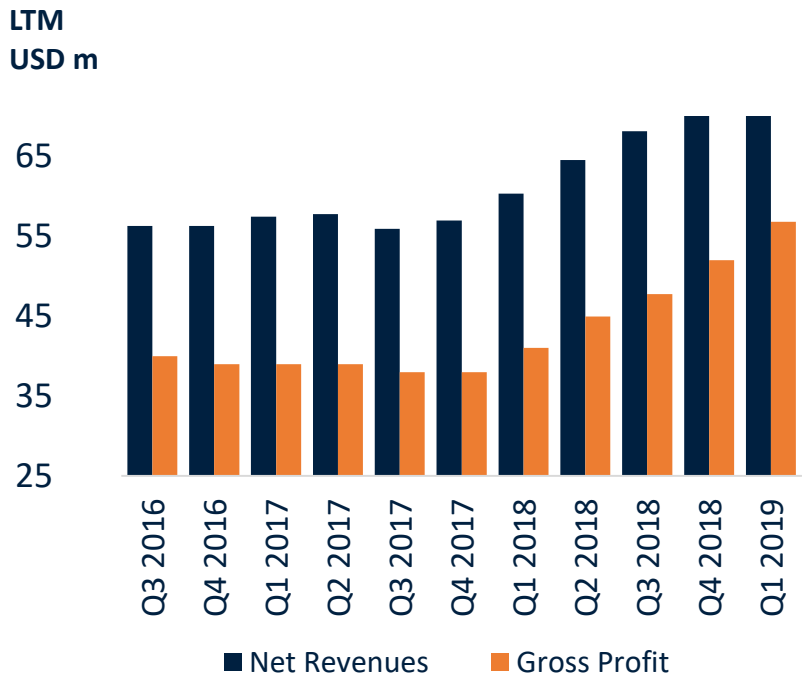
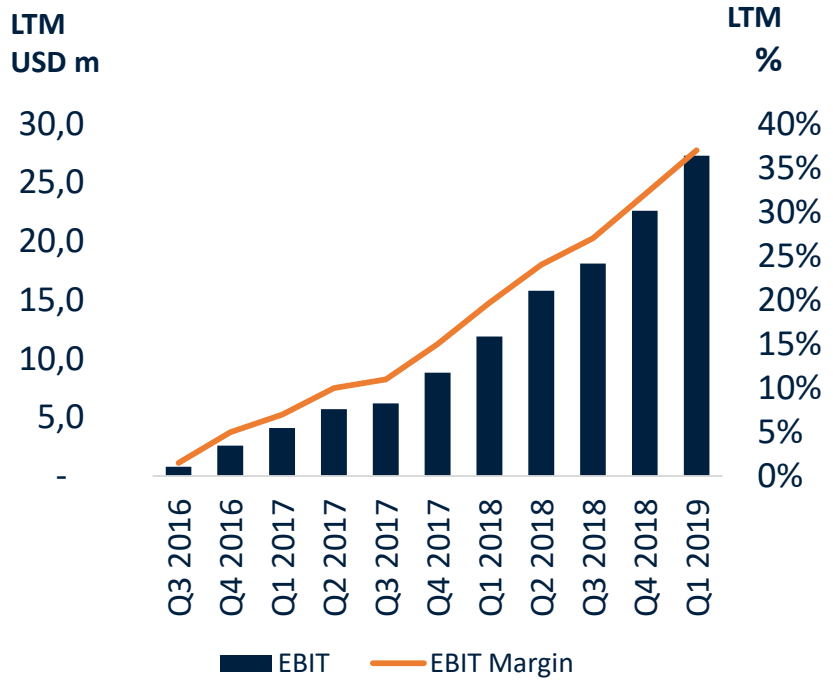
Orexo US has improved EBIT (LTM) with 130 percent from Q1 2018

Sales and Gross Profit (Orexo US)



Operating Profit (Orexo US)



39% growth in Gross Profit LTM (YoY)	COGS/tablet reduced with 43% vs 2017	EBIT margin Q119 of 44.5% vs 19.3% Q118	144% EBIT growth in Q119 (YoY)

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

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

Strong underlying Zubsolv® business creating foundation for growth

- Demand growth of 6% Q1 2019 vs Q1 2018 and price increase of 4% in January 2019
- Strong growth in EBIT contribution to SEK 71,9 m increasing from SEK 25.3 m in Q1 2018
- US EBIT margin of 44.5% increasing from 19.3% in Q1 2018

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

Market Access:

- Continued improvement despite increased generic competition, Zubsolv continue to outpace the market in plans with equal market access as competitors e.g. ESI, CVS.
- Some loss of market share in plans opening up for Gx competition, however EBIT impact often positive due to less rebates e.g. WellCare

Sales and Marketing:

- Strong focus on the consistency offered by Zubsolv being the only promoted sublingual product without generic substitution

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Financials

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Zubsolv® - main growth driver of net revenues with 23.3 percent (9.3 percent in local currency)

January – March 2019 and 12 MTH April 2018 – March 2019

SEK m	Q1 2019	Q1 2018	Jan – Dec 2018	12 MTH Apr 2018 – Mar 2019	12 MTH Apr 2017 – Mar 2018
Zubsolv US	161.7	131.1	621.5	652.1	502.8
Zubsolv – Rest of the world	-	-	36.2	36.2	5.6
Zubsolv® – total	**161.7**	**131.1**	**657.7**	**688.3**	**508.4**
Abstral® royalties	10.9	5.8	118.8	123.9	110.3
Edluar® royalties	1.7	2.8	6.6	5.5	15.5
OX-CLI	-	-	-	-	21.8
TOTAL	**174.3**	**139.7**	**783.1**	**817.7**	**656.0**

- Net revenues for the Q1 2019 grew by 24.8% versus prior year driven by higher Zubsolv US revenue
- Zubsolv US revenues strong growth driver with 23.3% in Q1 2019 versus Q1 2018 to SEK 161.7 m
- Abstral® Q1 2019 growth primarily driven by positive true-up adjustments made to prior period estimates

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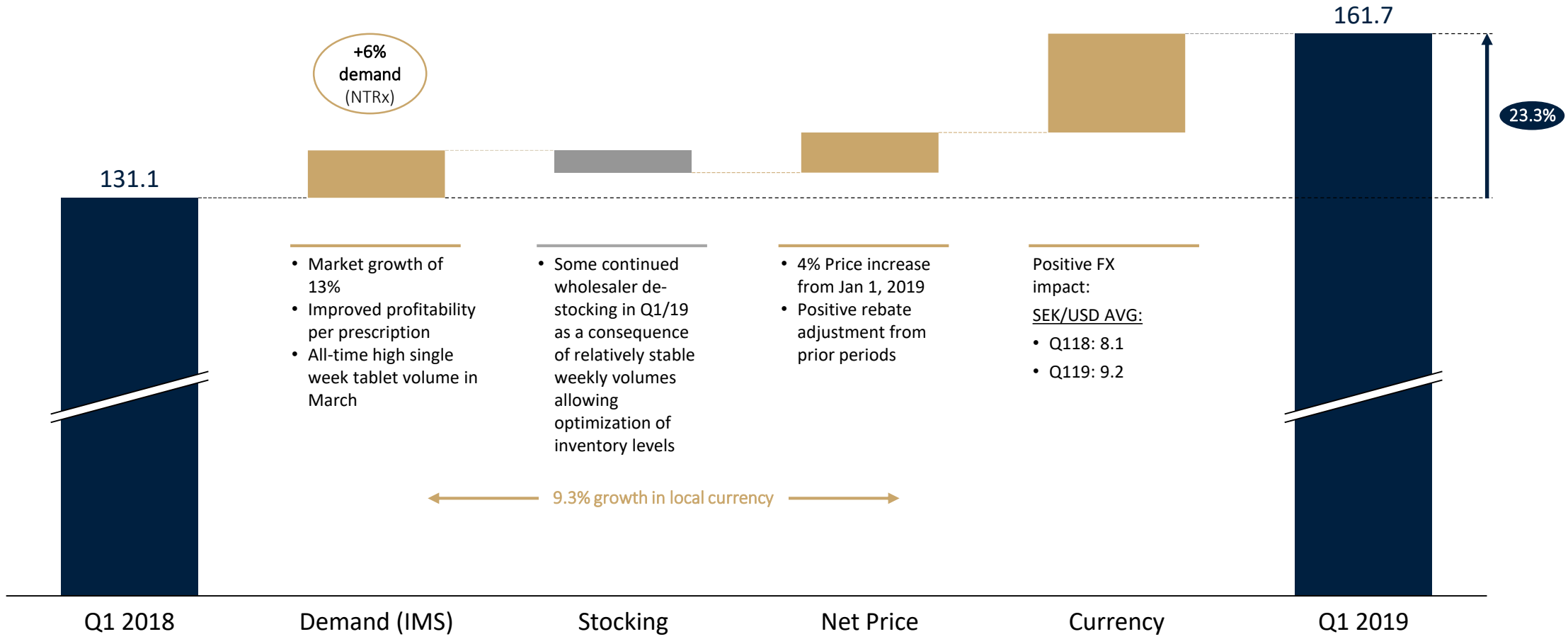
Zubsolv® growth primarily driven by increased demand and boosted by stronger USD

Zubsolv US growth factors, Q119 vs Q118



Q1 - EBITDA excl. IP litigation costs of SEK 60.8 m (-8.5)

P&L in Summary, January – March 2019 and 12 MTH April 2018 – March 2019

MSEK	Q1 2019	Q1 2018	Jan – Dec 2018	12 MTH Apr 2018 – Mar 2019	12 MTH Apr 2017 – Mar 2018
Net revenues	174.3	139.7	783.1	817.7	656.0
Cost of goods sold	-25.3	-48.4	-171.8	-148.7	-166.6
Gross Profit	**149.0**	**91.3**	**611.4**	**669.1**	**489.4**
Selling expenses	-47.2	-43.3	-191.4	-195.4	-185.5
Administrative expenses	-70.1	-27.2	-166.7	-209.5	-97.0
Research & development expenses	-37.6	-45.3	-166.8	-159.1	-149.2
Other operating income & expenses	7.0	2.7	9.3	13.6	1.1
Operating Costs	**-147.9**	**-113.1**	**-515.6**	**-550.4**	**-430.6**
EBIT	**1.1**	**-21.8**	**95.8**	**118.7**	**58.8**
Net financial items	4.8	-3.0	-3.6	4.3	-24.1
EBT	**5.9**	**-24.8**	**92.2**	**122.9**	**34.7**
Tax	8.2	-1.1	45.7	55.0	-2.8
Net profit/loss	**14.1**	**-25.9**	**137.9**	**177.9**	**31.9**
EBITDA	**12.0**	**-16.6**	**116.6**	**145.2**	**79.7**

Q1 2019 comments:

- **Gross Profit** for the quarter 63% higher vs prior year driven by 49 % lower COGS per tablet and by 23% Zubsolv® US growth
- **Operating Costs** above prior year due to IP litigation costs
- Administrative expenses higher due to legal expenses related to IP litigations amounting to SEK 48.8 m (8.2)
- R&D expenses lower due to the manufacturing efficiency program of which major part was finalized during 2018
- **Tax** positively impacted by a SEK 9.3 m adjustment to deferred tax assets related to temporary differences

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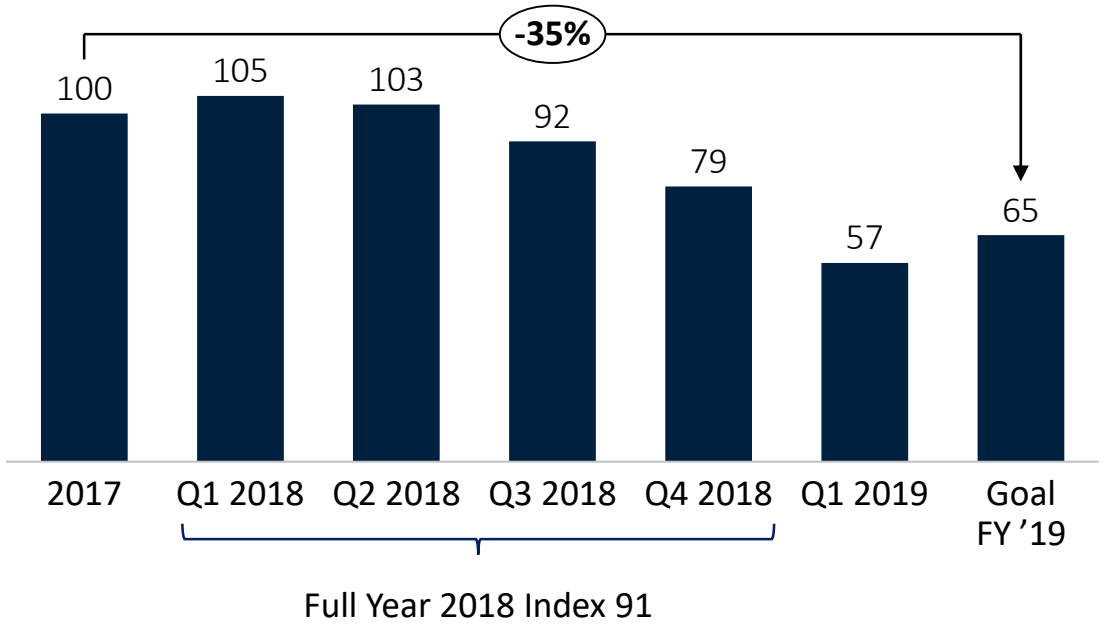
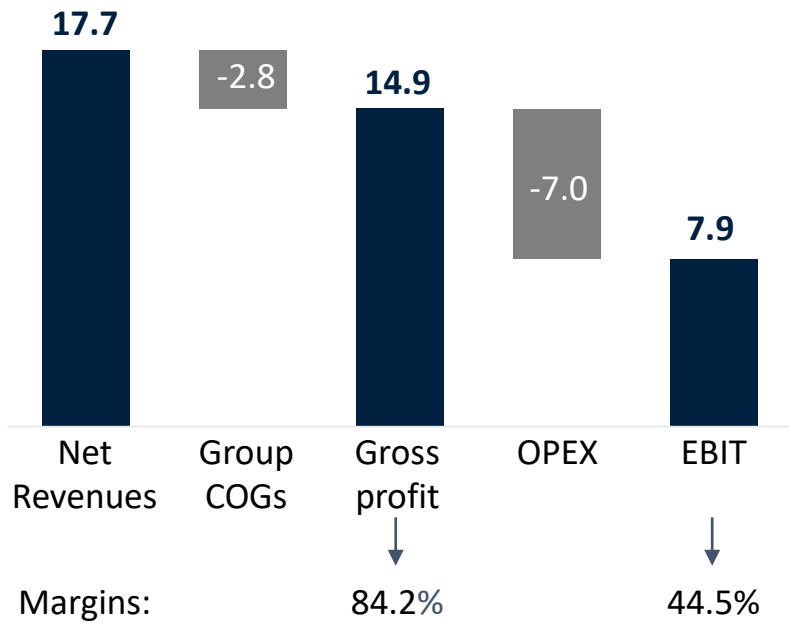
Accelerated COGS reduction will further enhance profitability and competitiveness in 2019

Expected COGS improvement (Index)



Orexo US profit contribution (Q1 2019 MUSD)



Group COGS will have variations each quarter due to allocation of indirect manufacturing costs and volumes manufactured

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

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Strong financial position

Financial Position, January – March 2019 and 12 MTH April 2018 – March 2019

Cash flow MSEK	Q1 2019	Q1 2018	Jan – Dec 2018	12 MTH Apr 2018 – Mar 2019	12 MTH Apr 2017 – Mar 2018
Cash flow from operating activities	50.9	106.3	242.0	186.9	224.4
Investment activities	-0.1	-	-6.2	-6.3	-1.3
Financing activities	-10.7	-	0.0	-11.0	-26.1
Cash flow (excl exchange rate differences)	40.2	106.3	235.8	169.6	197.0
Liquid funds	**647.4**	**437.5**	**589.8**	**647.4**	**437.5**

- Positive cash flow from operating activities for the period Q1 2019
  - SEK 50.9 m positive contribution from operating activities driven by increased provisions relating to US payer rebates and by changes in working capital due to decreased receivables and lower inventories partly offset by decreased current liabilities. This was partly offset by repayment of loans of SEK -10.7 m.
- Strong cash position at the end of Q1 2019 with SEK 647.4 m

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Record-breaking performance in 2018 further improved in Q1 2019

Group Net Revenues (LTM) **SEK 818 m** *USD ~89 m, 80% from Zubsolv®*	Growth (LTM) **25%** *(Zubsolv US 30%)*
Group EBITDA (LTM) **SEK 145 m** *USD ~16 m*	Growth **81%**
US EBIT (LTM) **SEK 245 m** *USD 27 m*	Growth **148%** *USD 129%*
Cash position **SEK 647 m** *USD ~70 m*	Net Cash position **SEK 326 m** *USD ~35 m*

Note: USD based on average exchange rate from Q1, 2019 SEK/USD 9.2

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Outlook

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Strong value drivers for long-term growth

Future value drivers	**1. Growing key market** 13% growth in Q1 2019 in a market adressing one of the largest health crises ever in America and a growing global concern	**2. Strong financial position and profitability** USD 35 m in cash and EBIT contribution from the US improving with 130% (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

Q1 2019 – Updated 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 volume of Zubsolv® sales in the US in 2019 will increase, despite increased competition from Suboxone® Film generic formulation. However we do expect that a launch of corresponding generic formulations will increase market risk and uncertainty but will also offer opportunities
- Previous target of achieving 35 percent reduction in the average Cost of Goods Sold (COGS) compared to 2017 in H2 2019 has been updated. **New target** is a full year effect of 35 percent reduction in COGS 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 m.
- The first new partnerships for Zubsolv outside the US is expected to be initiated in 2019

The outlook is based on current exchange rates (March 2019)

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Thank You

Q&A

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