



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



Interim Report Q3 2019, October 24th

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

Overview Q3 2019

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Q3 2019 – “The Rumors of My demise Have Been Greatly Exaggerated” – Mark Twain

Financials: All-Time-High financial performance

- Net revenues of SEK 231.2 m (216.6, Q318) up 6.7%, Zubsolv® growth of 3.0 % in USD (10.4% in SEK)
- EBITDA of SEK 114.1 m (39.8), ex Abstral® SEK 71.7 m (-8.9)
- US EBIT of USD 9.7 m (6.2) with a 51.1% EBIT margin (35%)
- US result explained by continued Zubsolv® growth in profitable “Open Business*”, improved efficiency and non-recurring adjustments
- SEK 812.9 m in cash balance end of Q3 after SEK 32.5 m amortization on the corporate bond

* Open Business segment includes all payers, excluding current & recently former exclusive payers

R&D and Business development: In-licensing of Digital Therapy and OX338 progress into phase I

- Agreement signed with GAIA to develop a complementary Digital Therapy for opioid use disorder with expected filing with FDA in 2021
- OX338 - first clinical trial initiated in October 2019 with results expected early 2020
- Business development activities intensified with the recruitment and establishment of business development position in the US

Development programs on track

The partnership with GAIA has extended Orexo's technology platform to also include Digital Therapies

			Exploratory	Preclinical	Phase			Registration	Approved/Launched		
					1	2	3		US	EU	RoW
Commercial products											
Zubsolv®		Opioid Dependence <i>Orexo US, Mundipharma Australia & NZ</i>									
Abstral®		Breakthrough Cancer Pain, <i>Kyowa Kirin ex US, Sentynl US</i>									
Edluar®		Insomnia <i>Mylan Worldwide</i>									
Development projects											
NEW FORMULATION TECHNOLOGIES	OX124	Naloxone - Opioid Overdose									
	OX125	Nalmefene - Opioid Overdose									
	OX338	Ketorolac - Acute moderate to severe pain									
	OX382	Buprenorphine - Opioid Dependence/Pain									
NCE	OX-MPI	BI1029539 – Microvascular Disease <i>Gesynta Pharma</i>									
DIGITAL THERAPIES				Preclinical	Phase			Registration	Approved/Launched		
					3				US	EU	RoW
	OXD01	Digital Therapy – Opioid Use Disorder									

Zubsolv® outside the US

Agreement in Australia

- Mundipharma Australia signed agreement to continue partnership for Australia and NZ
- Partnership in Australia has progressed well since original agreement was closed
- Launch expected during 2020



Some headwind in Europe

- Generic versions of Suboxone® tablets have been launched during 2019 in several markets, resulting in lower price and increased complexity in reimbursement processes
- Orexo is working with potential partners to obtain reimbursement in several markets, which will be decisive for a finalization of an agreement
- A new supply chain has to be established to enable European pack sizes and competitive prices. Some issues causing delays have emerged to obtain the required import licenses



OX338 – The project at a glance



Unmet medical need

- For many opioid dependent patients, their addiction started with the first exposure to opioids to treat short-term pain, e.g., after trauma, medical procedure or accident
- In face of the opioid epidemic, there is a desperate need to find non-opioid alternatives to effectively treat acute pain

OX338 concept

- Ketorolac is considered the most efficacious NSAID to treat pain for up to 5 days with proven morphine-like efficacy, but with no risk of addiction
- OX338 is an advanced sublingual formulation designed to be the best option for Ketorolac absorption
 - Gx oral tablets are available, but require the first dose to be given as an IV or IM injection
 - SPRIX Nasal Spray does not require an injection, but is inconvenient, caustic and expensive

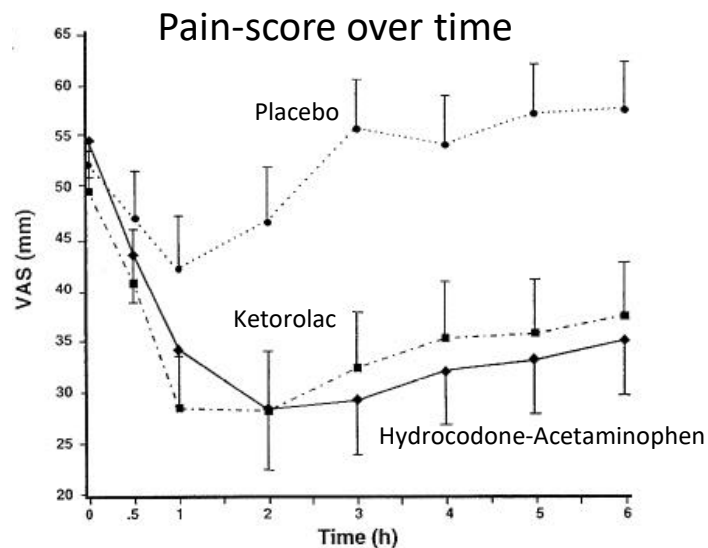
Studies have proven that Ketorolac has opioid level strength

“Ketorolac proved to be as effective as morphine in relieving pain and did so just as quickly.”

Jelinek. 2000. British Medical Journal

Table 4 Summary results for median rate of decrease in pain score per hour (95% confidence intervals)

	Ketorolac (n=75)	Morphine (n=73)	P value*
At rest	11.40 (9.41 to 12.77)	10.80 (10.20 to 13.54)	0.540
With activity	1.09 (1.05 to 2.02)	0.87 (0.84 to 1.06)	0.003



“In conclusion, there was no difference in the efficacy between oral ketorolac and hydrocodone-acetaminophen combination in controlling pain after outpatient arthroscopic surgery procedures.”

White et al. 1997. Anesthesia & Analgesia

Oral and parenteral Ketorolac has been shown to provide opioid-level pain relief in several studies looking at strength and onset-time of effect

We are not only targeting the existing Ketorolac market, but seek to replace Rx Opioids

2 Rx Opioids Market

- **Market:** Multi-billion dollar market, slight decline due to efforts to curb opioid use
- **OX338 value proposition:** Non-opioid, non-addictive alternative for managing short term medium/severe pain (up to 5 days)

1 Ketorolac Market

- **Market:** > USD 100 m gross sales (excl. hospital)
- **OX338 value proposition:** Most attractive ketorolac formulation (no injection needed, less tolerability issues)



Digital Therapy has the potential to be the next “big thing” in healthcare



Digital Therapies have elements of traditional pharma products...

- GAIA has demonstrated that digital therapies can have similar value proposition as an NCE with well documented effect on treatment results
- DTx are increasingly being reimbursed like a (specialty) pharmaceutical
- To reach optimal effect the use needs to be explained to the patient like any treatment and require involvement of the physician
- Value for payers is well documented with HEOR data

... but the value proposition goes well beyond a standard “pill”

- Treatment is based on artificial intelligence and can thus be individualized and adapted to patients' treatment progress and specific needs
- Unprecedented possibilities for the HCP to get real-time feedback on patient progress
- Possibility to monitor patient progress, treatment utilization and obtain direct feedback on outcome

Orexo is excited about the opportunity to partner with GAIA, a world leader in developing DTx

GAIA is a global pioneer in digital therapeutics, successfully launching its first product in 2001

- GAIA has demonstrated digital therapies can have impressive improvement in treatment outcomes from supporting behavioral change and adherence to treatment – both critical for addiction treatment outcome
- GAIA's platform has proven effectiveness in numerous RCTs with over 10,000 patients
- GAIA has 12+ years R&D experience, 20+ CE & FDA compliant products
- GAIA's products use artificial intelligence and offer unique individualization of the treatment

Orexo has a solid foundation in OUD and is well positioned to lead a shift towards digital therapy

- Orexo has an effective commercial infrastructure, strong relationships with key stakeholders in this space and the necessary experience to launch a new product
- Orexo has built deep insights into the OUD market and understands that a traditional pharma approach alone will not suffice
- Orexo has small agile organization and ability to tailor and adapt the commercial approach to become a leader in digital therapy for addiction treatment
- Orexo has a long term commitment to addiction with Zubsolv's patent until 2032

Key Market & Sales

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”

We estimate that the total economic burden of the opioid crisis in the United States from 2015 through 2018 was at least \$631 billion”.

”

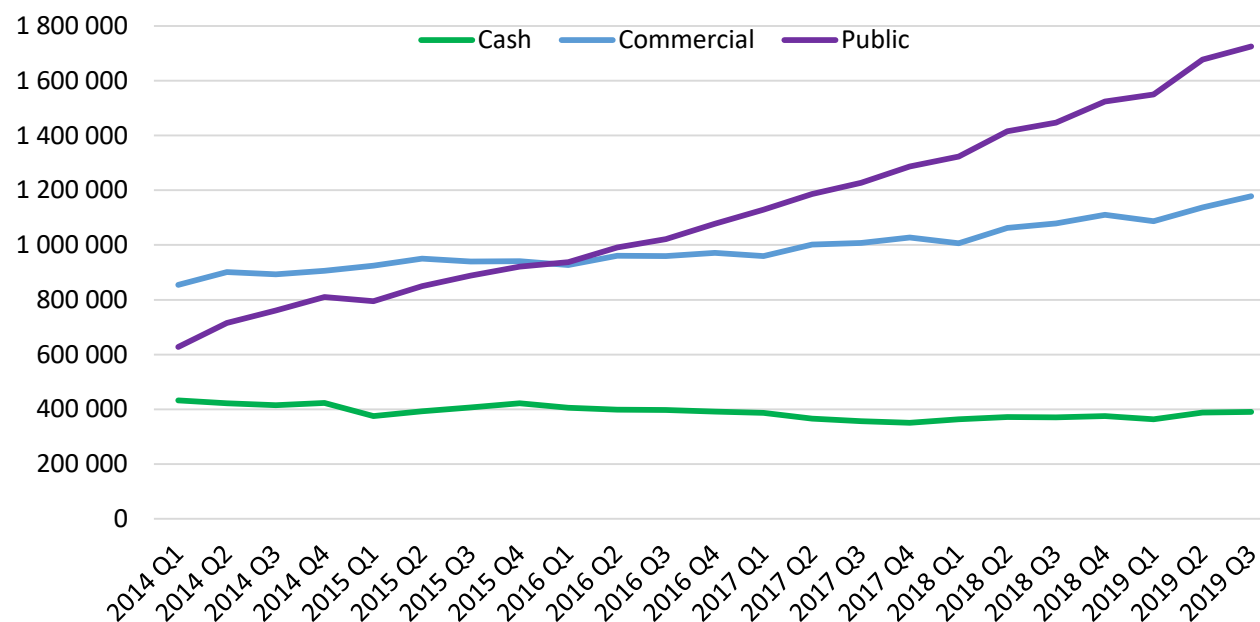
Opioid overdose deaths are now the single largest factor slowing the growth in U.S. life expectancy and have led to stagnation or decreases in life expectancy three years in a row for the first time since 1915–1918, when the country was facing World War I and the Spanish flu pandemic.”

Source: Society of Actuaries, Economic Impact of Non-Medical Opioid Use in the United States

YTD Year-over-year market growth at 14 percent

New market highs in Public and Commercial NTRx in Q3 and Zubsolv grows 16 percent in open business

Quarterly NTRx



Market	Q3 YoY Growth	
	Zubsolv [®] total	Zubsolv [®] open*
+19%	-5%	+17%
+11%	+1%	+16%
+4%	-33%	

Overall market grew >14 percent YoY in Q3 2019

Note: Quarterly NTRx levels =Total prescriptions adjusted to 30 tablet/film scripts

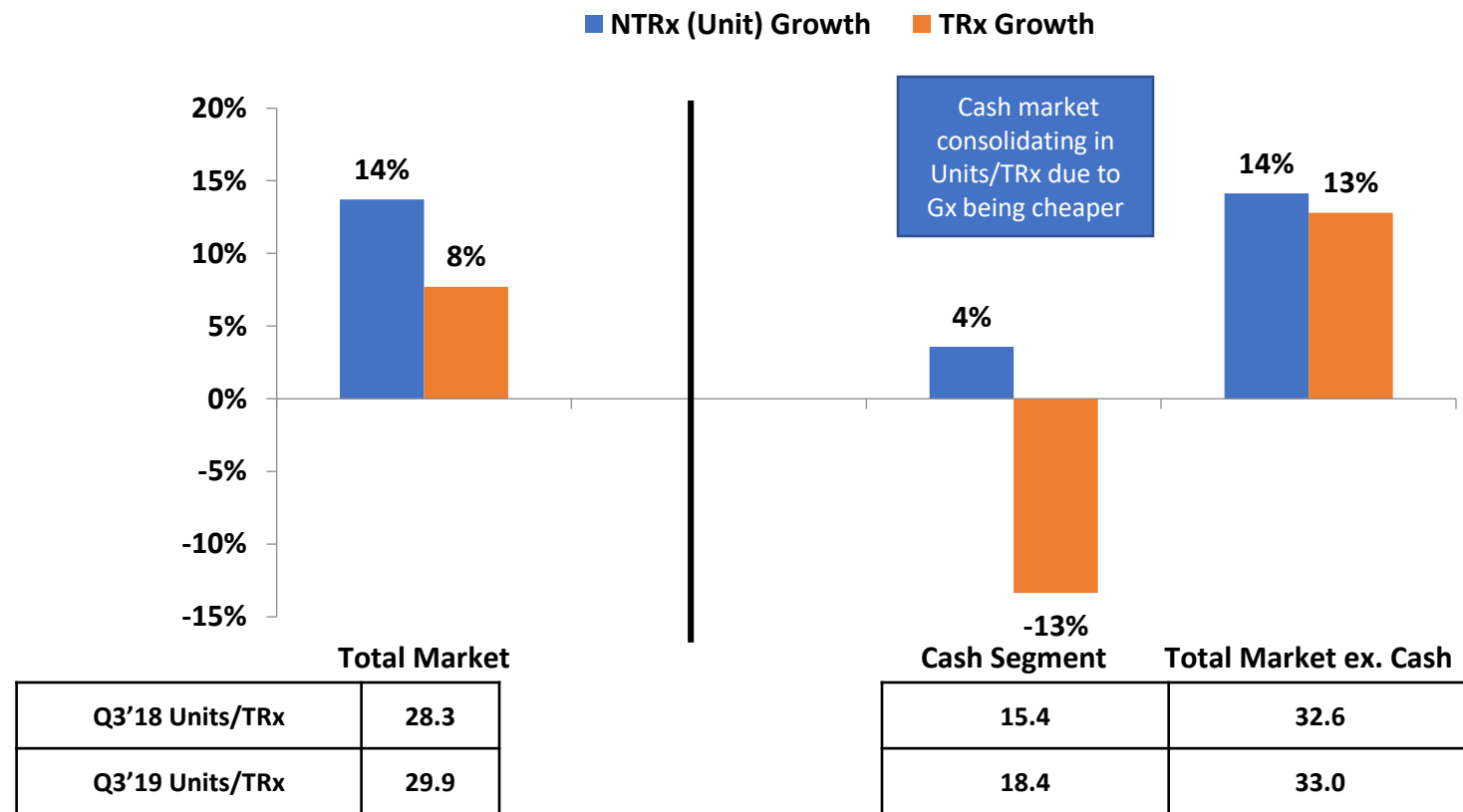
Note: Historical quarters restated due to IMS recategorization

*Open Business segment includes all payers, excluding current & recently former exclusive payers

Source: Orexo analysis, IMS data

Market TRx growth behind NTRx growth because Cash segment is declining in TRxs while still growing its total NTRx volume

Q3 YoY 2019 Market Growth

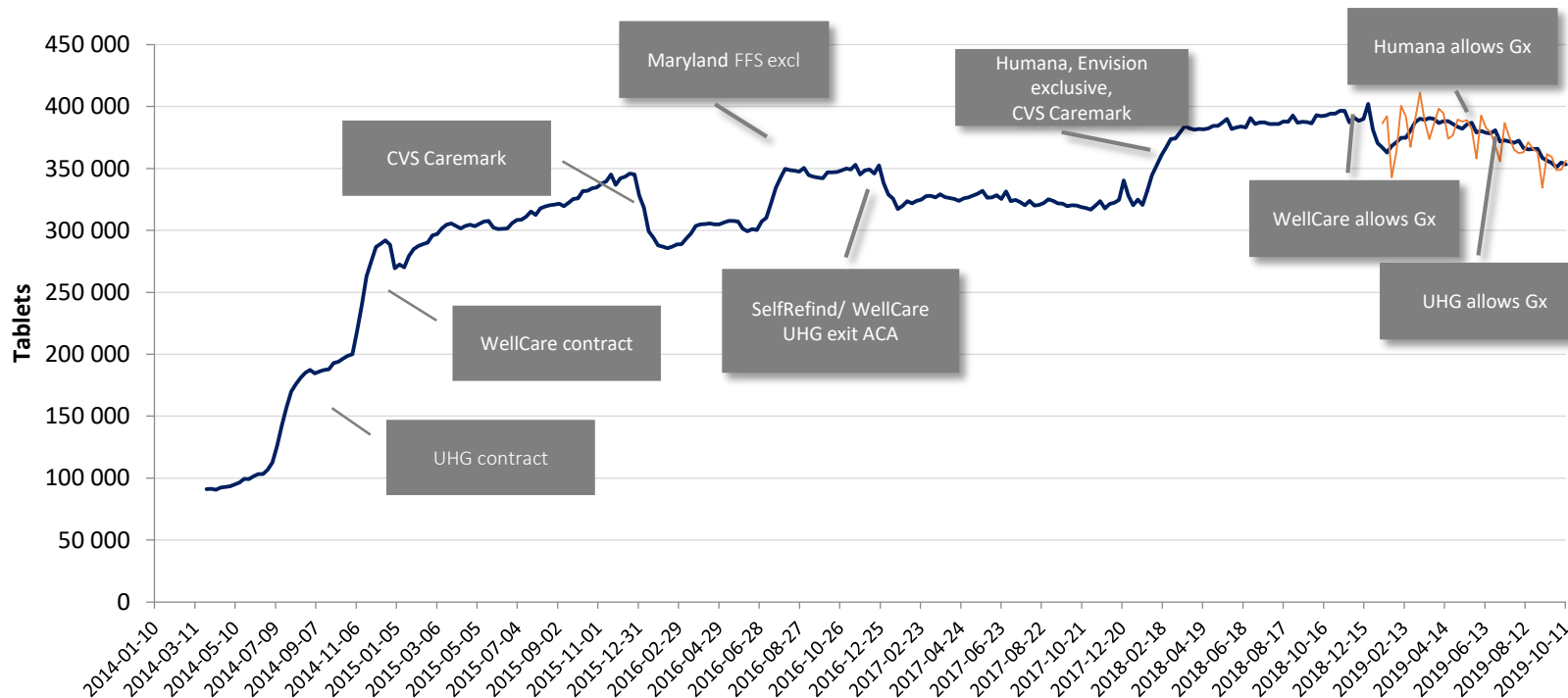


Source: IMS XPO

Zubsolv[®] volume declined due to formulary changes and Cash segment

Zubsolv Tablet Volume (rolling 4 week average)

Average weekly sales

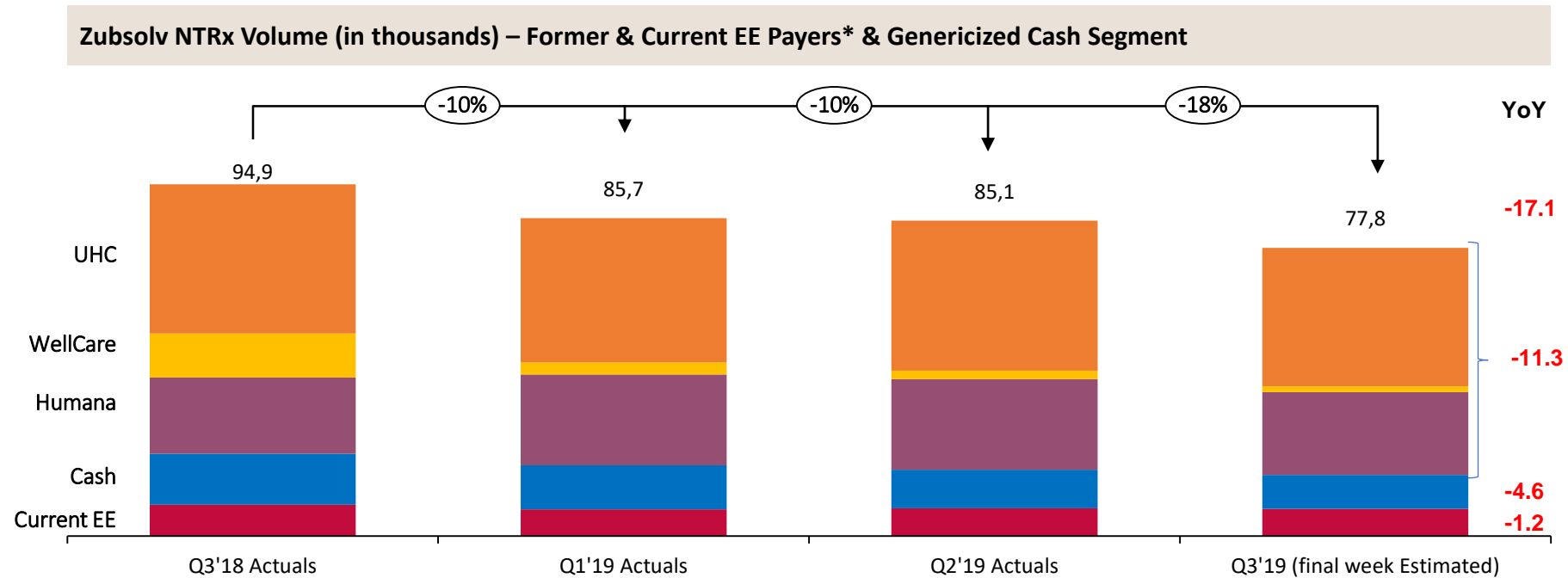


Zubsolv volume decline due to loss of exclusive contracts

- Volume declined 4% since Q318 and 5% from Q219
- WellCare, Humana and UHG change from exclusivity and declining cash segment has a negative effect of ~18% on overall volume growth vs Q318 and 9% since Q2 19
- Decline from loss of three exclusive contracts continue but at a slowing pace
- “Open business*” grew 16 percent from Q318 and no change since Q219

*Open Business segment includes all payers, excluding current & recently former exclusive payers
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

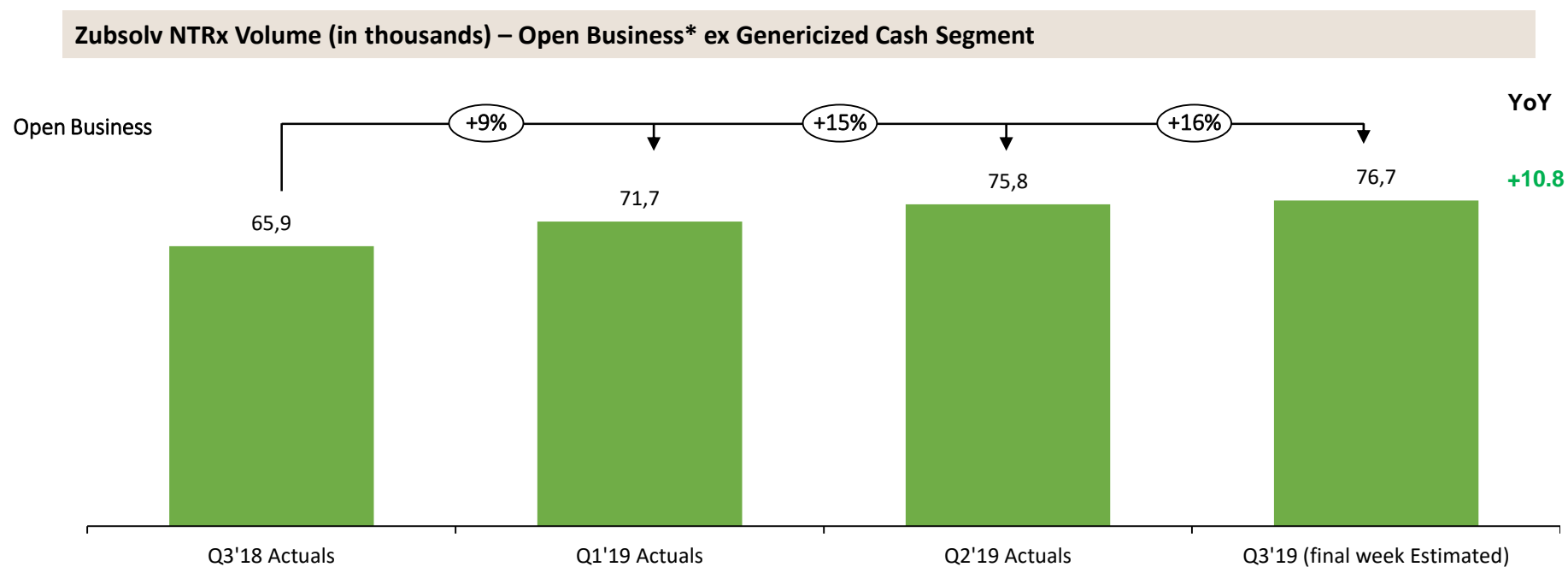
Zubsolv® declining volumes are due to former exclusive agreements and the genericized Cash segment



Source: IMS XPO
Historical data updated to actuals in place of prior reported estimates

*Former EE payers in chart, Current EE payers include Envision Commercial, IHA Commercial & Medicaid, Highmark Medicare D, (IHA Medicare D also included here although formerly EE)

Zubsolv[®] volume is growing in Competitive Payer Segment (Open Business)



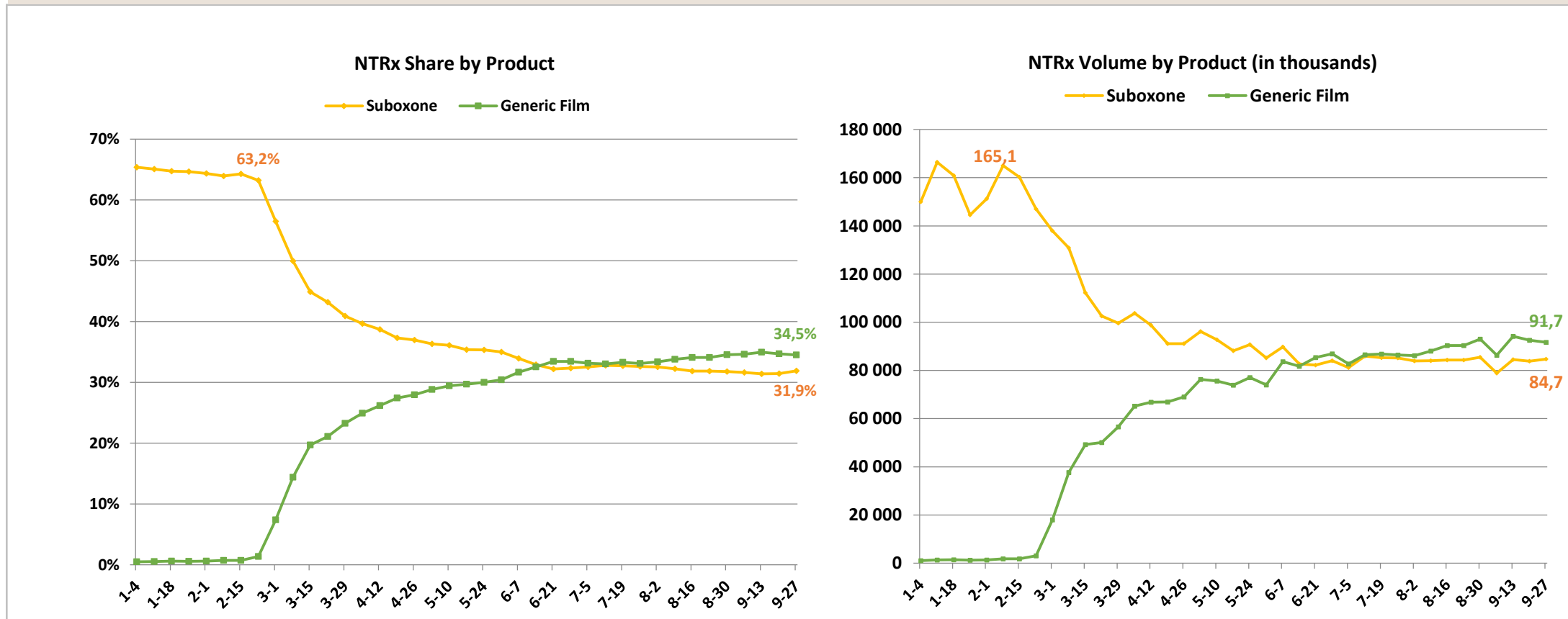
Source: IMS XPO
Historical data updated to actuals in place of prior reported estimates

*Open Business segment includes all payers, excluding current & recently former exclusive payers

Suboxone® Film demonstrating strong resilience vs generic film

Indivior/Sandoz authorized generic has ~50% market share of generic film market

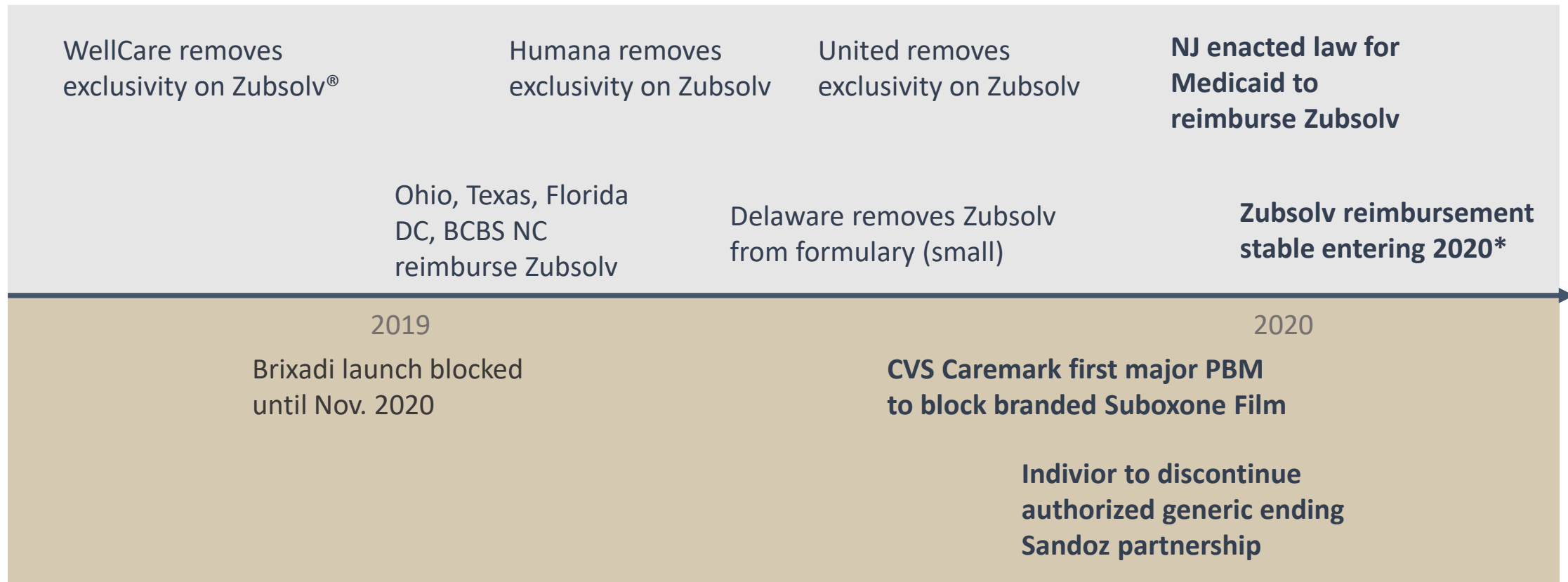
Buprenorphine-naloxone film product' market share & volume



Source: IMS NPA

Note: Generic Film injunction lifted WE 02/22/19

The entry of generic film caused the loss of exclusive contracts, but recent market dynamic will offer opportunities



* As per October 24th 2019

Current legal battles around damages will lead to improved access to treatment, but much remains unclear

Settlements will drive billions of USD to improve treatment...

- States and seek substantial damages to be paid as a compensation for the costs of the opioid epidemic
- Settlements has been reached with individual counties, but no “global” agreement has been reached
- States and counties clearly express the damages should be invested into improved treatments
- Current trend to open up for more patient choice can partly be attributed to states desire to increase investments in treatment and expectations of damage payments

...and some pharmaceutical companies offer “free” product in the settlement

- Teva recently announced settlement with two counties in Ohio
- Teva also confirmed a global settlement framework has been agreed to in principle with the attorneys general from four states, but based on public reporting, our understanding is that no global settlement agreement has been finalized
- Teva and Purdue have indicated it would donate buprenorphine and naloxone products
- Significant questions remain



Topline challenging quarter, but underlying trends positive and significant changes in market dynamics expected



Increased focus on patient choice drive expansion of Zubsolv® market access

- Legislation in Texas, Washington, NJ and potentially even NY to remove prior authorization on all MAT products
- Ohio has removed prior authorization of all MAT product
- Discussions ongoing in several additional states to open up for reimbursement of all products

Risks outlined in Q2 and previous reports have materialized, but also first upsides have emerged and more are expected

- Zubsolv has lost exclusivity with WellCare (2018, Nov), Humana (2019, April) and United Health Group (July 2019)
- Volume loss in WellCare and Humana is offset by lower rebates
- Zubsolv performs well in profitable “open business” segment, showing ability to compete without exclusive contracts against generics
- Branded Suboxone® Film remains the a hurdle, but recent CVS Caremark decision to remove reimbursement of branded Suboxone Film and the stop of authorized generics will open for new opportunities

Financials

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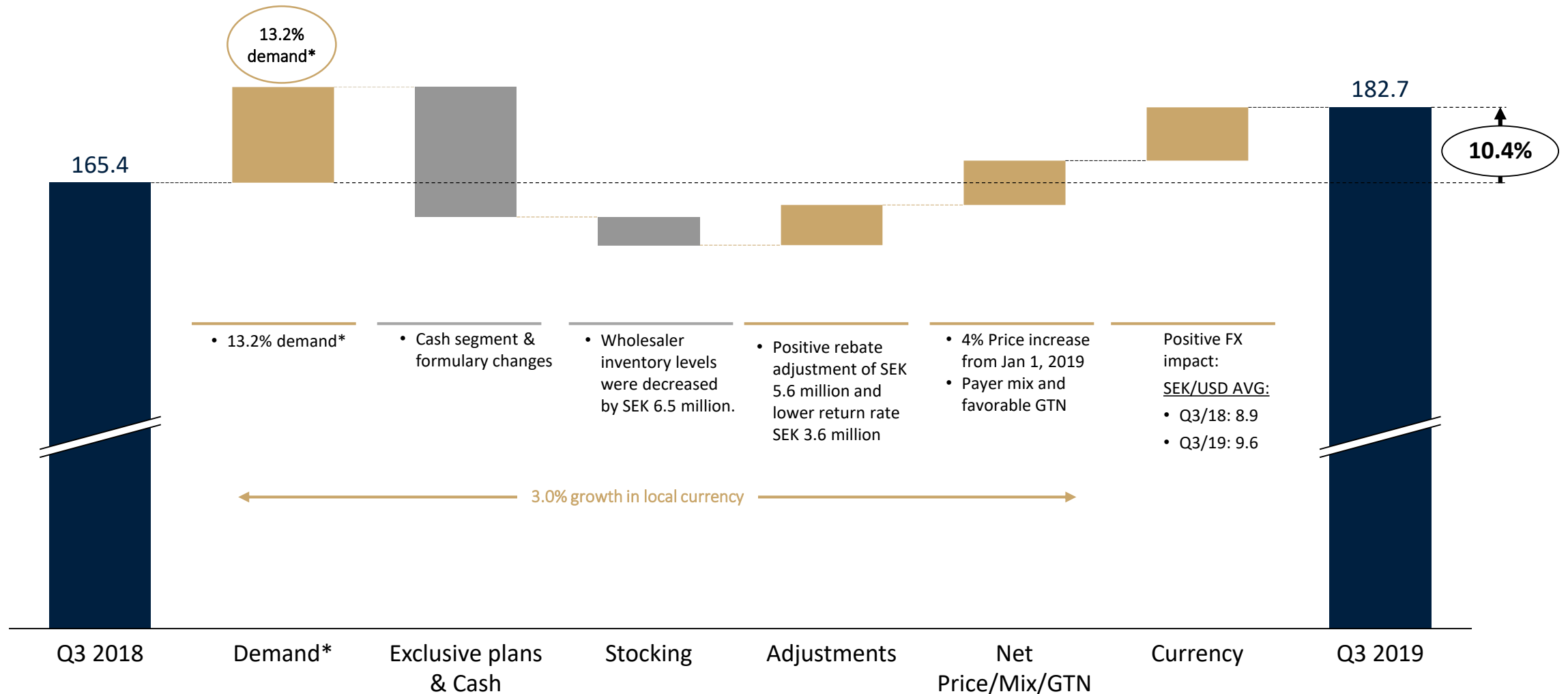
Zubsolv® main growth driver of net revenues with 10.4 percent

Corresponding to a 3 percent growth in local currency

SEK m	Q3 2019	Q3 2018	Jan - Sep 2019	Jan - Sep 2018	12 mth Oct 2018 - Sep 2019
Zubsolv® US	182.7	165.4	528.7	454.9	695.4
Zubsolv – ex US	-	0.2	0.1	31.0	5.3
Zubsolv – total	182.7	165.6	528.8	485.9	700.7
Abstral® royalties	42.4	48.7	66.3	66.4	118.7
Edluar® royalties	6.1	2.3	10.2	3.7	13.1
OX-MPI	0.1	-	1.4	-	1.4
TOTAL	231.2	216.6	606.7	556.0	833.9

- Net revenues for Q319 grew 6.7% primarily driven by higher Zubsolv US revenues
- Zubsolv US revenues grew 3.0% in Q319 vs Q318 to SEK 182.7 m
- Abstral Q319 decline explained by lower volumes in Europe and in the US
- Edluar sales are building up since the supply issues in the US market in 2018 were solved

Strong demand growth of 13.2% excluding loss in exclusive contracts and cash segment



All-Time-High financial performance in Q319

EBITDA reached SEK 114 m (39.8, Q318) and ex Abstral® SEK 71.7 m (-8.9)

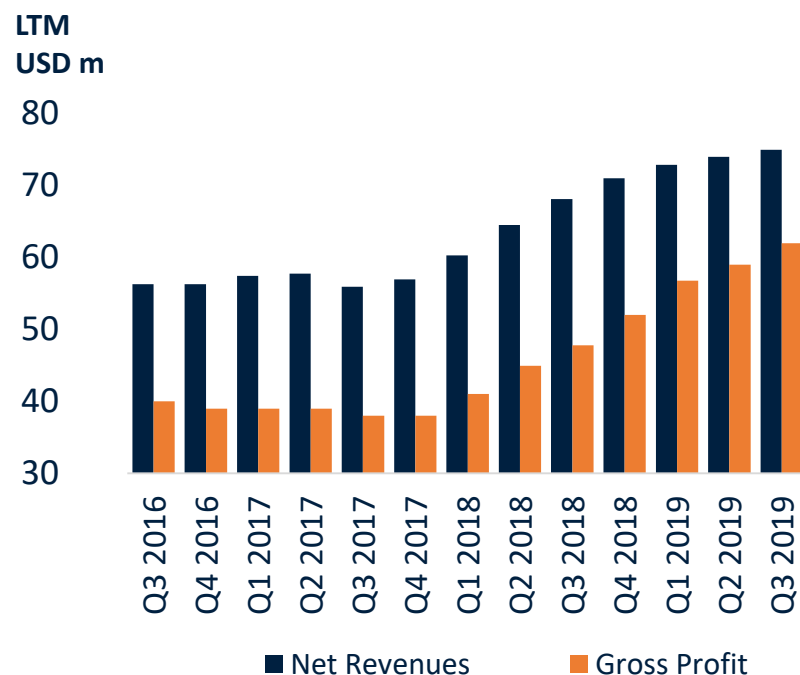
SEK m	Q3 2019	Q3 2018	Jan - Sep 2019	Jan - Sep 2018	12 mth Oct 2018 - Sep 2019
Net revenues	231.2	216.6	606.7	556.0	833.9
Cost of goods sold (COGS)	-25.9	-42.4	-82.5	-128.4	-125.9
Gross Profit	205.3	174.2	524.2	427.6	707.9
Selling expenses	-45.0	-51.5	-141.3	-143.4	-189.3
Administrative expenses	-18.1	-50.8	-112.7	-112.0	-167.4
Research & development expenses	-41.6	-37.5	-122.7	-119.8	-169.7
Other operating income & expenses	5.3	0.2	12.3	5.8	15.9
Operating Costs	-99.4	-139.6	-364.5	-369.4	-510.7
EBIT	105.9	34.6	159.7	58.2	197.4
Net financial items	8.7	-4.2	19.2	-3.2	18.9
EBT	114.6	30.4	178.9	55.0	216.3
Tax	-3.0	31.8	1.3	31.4	15.6
Net profit/loss	111.7	62.2	180.3	86.4	231.9
EBITDA	114.1	39.8	186.3	73.7	229.3

Q319 comments:

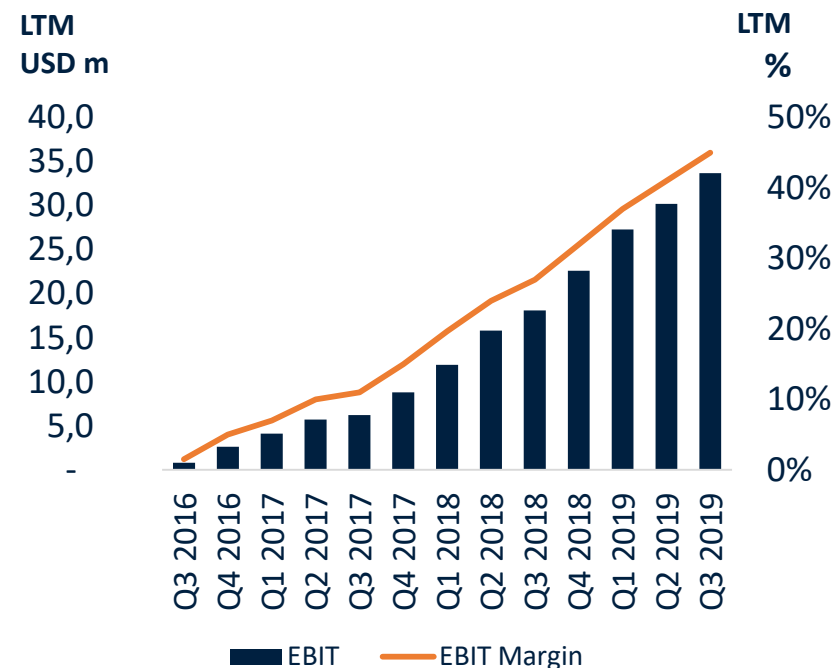
- **Gross Profit** for the quarter 23% higher vs prior year. This is driven by lower 37% lower COGS per tablet vs the average in 2017
- **Operating Costs** below prior year due to:
 - Selling expenses lower as a result of organizational efficiencies
 - Administrative expenses lower, SEK -3.0 m (31.2) due to no spending on IP litigation since the win in the appeal process securing Zubsolv's US patents until 2032.
 - R&D expenses higher due to the manufacturing of OX338 tablets for the coming clinical study.

Orexo US Operating Margin (LTM) grew to 45.2%

Sales and gross profit



Operating Profit



- Net Sales grew to USD 74.6 m from USD 68.1 m in Q318
- Strong growth in EBIT contribution to USD 33.7 m increasing from USD 18.1 m in Q318 driven by organizational efficiencies and by lower COGS
- US EBIT margin of 45.2% LTM in Q319 increasing from 26.6% in Q318, EBIT margin in Q3 reached 51.1%

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

Strong financial position enabling Orexo to pursue its growth strategy

Cash position of SEK 812.9 m and a positive net cash position of SEK 523.7 m

Cash flow SEK m	Q3 2019	Q3 2018	Jan - Sep 2019	Jan - Sep 2018	12 mth Oct 2018 - Sep 2019
Cash flow from operating activities	135.7	24.5	230.7	170.4	302.5
Investment activities	-14.5	-0.5	-15.3	-2.2	-19.2
Financing activities	-36.9	-0.1	-49.4	0.0	-49.4
Cash flow (excl exchange rate differences)	84.3	23.9	166.0	168.2	233.8
Liquid funds	812.9	516.6	812.9	516.6	812.9

- Positive cash flow from operating activities for the period Q319
 - SEK 135.7 million positive contribution from operating activities.
 - Financial activities had a negative impact of SEK -36.9 million due to prepayment of 10 percent of the corporate bond
- Strong cash position at the end of Q319 with SEK 812.9 million

Outlook

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Strong value drivers for long-term growth

Future value drivers

1. Growing key market

14 percent growth YTD in 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

Fueled by the US commercial organization which is an important cash and profitability contributor on a Group level

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

Q319 – Updated financial outlook 2019

- For 2019 Orexo expects to improve the positive EBITDA on a full year basis
- Orexo believes the overall net sales of Zubsolv® in the US will increase in local currency, despite increased competition from Suboxone® Film generics.
- 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 outlook is based on current exchange rates (September 2019)

Thank You

Q&A

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