# Orexo

## First profitable year in the history of Orexo AB

Annual General Meeting April 6 2017

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

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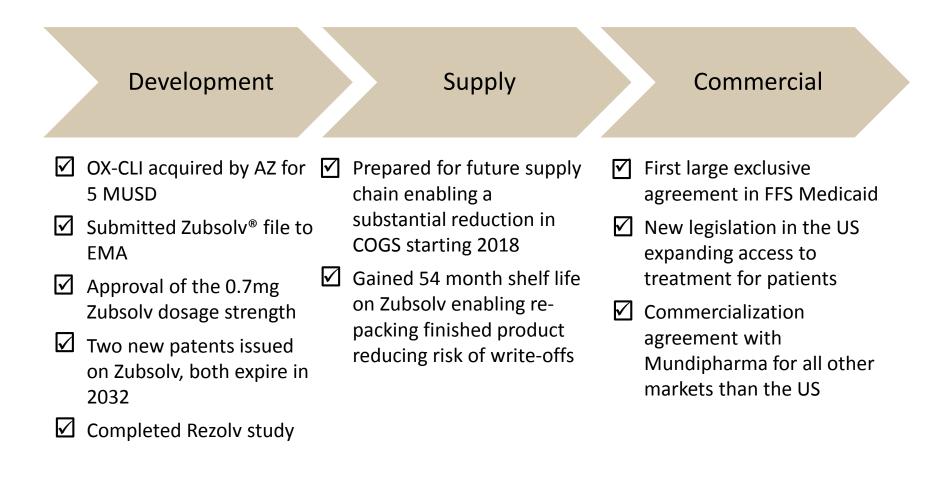
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# Orexo has completed a transformation of the company the last five years





# Apart from full-year profitability in 2016 several important milestones were reached



## The litigation process against Actavis with an unexpected outcome in the district court

Validity and infringement of Zubsolv <sup>®</sup> patents	Infringement by Actavis with their generic versions of Suboxone <sup>®</sup> and Subutex <sup>®</sup>				
<ul> <li>First decision by the district court in November 2016         <ul> <li>Zubsolv patent 8,454,996 patent found valid and infringed</li> </ul> </li> </ul>	<ul> <li>Orexo alleges that Actavis's generic versions of Suboxone and Subutex tablets infringe Orexo's US patent '996</li> </ul>				
- Actavis has not cross-appealed decision on ´996 patent and Zubsolv exclusivity secure until at least Sep/2019	<ul> <li>Orexo is seeking compensation for damages caused by Actavis's infringement</li> </ul>				
<ul> <li>Zubsolv '330 patent found invalid, decision has been appealed to federal circuit</li> <li>Decision on appeal would traditionally come in</li> </ul>	<ul> <li>Actavis has been successful with their launch with accumulated gross sales<sup>1</sup> since launch of Suboxone and Subutex Gx exceeding MUSD 500</li> </ul>				
<ul> <li>12 months</li> <li>Two new patents issued in 2016 expiring in 2032 and subject to separate litigations</li> </ul>	Suboxone Gx Manufacturer NTRx (in thousands) Volume (IMS) 80000 60000				
<ul> <li>Expenses for the appeal and new patent litigation processes expected to be lower than first process</li> </ul>	00005 Feb 2013 Apr 2013 Apr 2013 Apr 2013 Apr 2013 Apr 2013 Apr 2014 Apr 2014 Jun 2014 Apr 2013 Apr 2014 Apr 2014 Jun 2014 Apr 2014 Apr 2013 Apr 2015 Apr 2015 Apr 2015 Apr 2015 Apr 2015 Apr 2015 Dec 2015 Apr 2016 Apr 2015 Dec 2015				
<sup>1</sup> Damage calculations likely to be based on net sales, Orexo has no insight into the actual net sa	les of AMNEAL PHARM ACTAVIS				

WEST WARD

<sup>1</sup>Damage calculations likely to be based on net sales, Orexo has no insight into the actual net sales of Actavis generic versions of Suboxone and Subutex.



TEVA PHARMACEUTICA

## Top strategic priorities

Maximize Zubsolv's potential

**Grow Zubsolv®** sales

Launch Zubsolv in new markets together with Mundipharma

Improve profit contribution

Expand the commercial portfolio with revenue generating products

Additional commercial products in the US

Out-licence products for other geographies than the US Expand the pipeline

Developing products for the oral tract and in particular sublingual products

The products shall address patients unmet needs and create a paradigm shift

Seek collaborations with partners where values could be added

## Commercial products and development pipeline

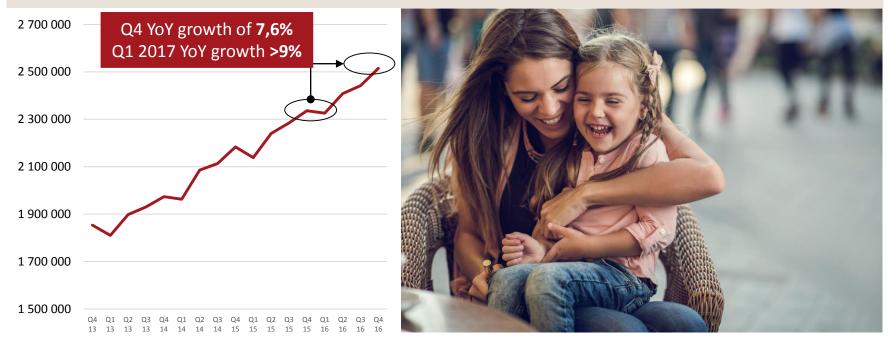
We are now developing next generation drug delivery technologies

PRODUCT	EXPLORATORY	PRECLINICAL	PHASE I	PHASE II	PHASE III	REGISTRATION	LAUNCHED	
Zubsolv® US	Opioid Depe	ndence						
Abstral®	Breakthroug Partnered wit	<b>h Cancer Pain</b> th Kyowa Kirin a	and Sentynl The	erapeutics				KYOWA KIRIN SENTYNL
Edluar®	<b>Insomnia</b> Partnered wit	h Mylan						III Mylan
Zubsolv® Europe	<b>Opioid Depe</b> Partnered wit	<b>ndence</b> :h Mundipharm	a					mundipharma
OX51	Acute Pain E	pisodes						Discussions ongoing
OX-CLI	<b>Asthma</b> Partnered with	n AstraZeneca						AstraZeneca
OX-MPI	Inflammation	'n						Discussions ongoing
New Formulation	Novel Oral							
Technologies	2 <sup>nd</sup> Gen. Sublingual							
	Commercia	l Products	Partner Projects	Developm	ent Projects			

# Our key market has continued growth trend, while waiting for new inflection point

New legislative changes expected to increase growth rate

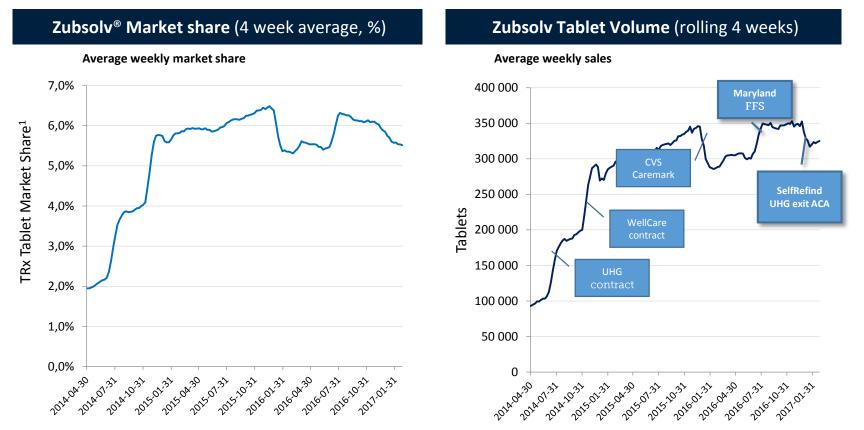
### **Quarterly NTRx levels continue to increase**



#### Growth in 2016 and 2017 driven by Medicaid expansion

Note: Quarterly NTRx levels = Total *prescriptions* adjusted to 30 tablet/film scripts *Source: Orexo analysis, IMS data* 

# Slow down in Q4 primarily caused by changes in Maryland, WellCare and United Health Group



#### Market share negatively impacted by growth in Medicaid favouring generics

<sup>1</sup> Market share in terms of Orexo share of the total market quantity of tablets, film and patch of Bup/Nal Note: Weekly script data is based on extrapolation and is associated with uncertainties in the launch phase of new pharmaceuticals

Source: Orexo analysis, IMS weekly data

## Two isolated events caused a drop in Zubsolv<sup>®</sup> sales

Growth continued positive when excluding these events

### • Approximately 1,250 NTRx<sup>1</sup> in weekly volumes lost due to two isolated events

- SelfRefind, a provider group in Kentucky left WellCare from December 1
- United Health Group (UHG) exited most health exchanges under Affordable Care Act
- Orexo market share within UHG remain stable above 75%, and in WellCare with a slight decline from ~90% to 85%, both with a lower volume
- Orexo has recovered around 450 weekly NTRx<sup>1</sup> from growth in other accounts
  - UHG patients and WellCare patients maintaining Zubsolv with new insurance company
  - Increased market share in the commercial segment in non-exclusive accounts
  - Zubsolv win disproportionate market share from market growth in areas where Zubsolv is reimbursed
- Current volumes of Zubsolv more than 10% above the volumes YTD last year (IMS weekly prescription data)

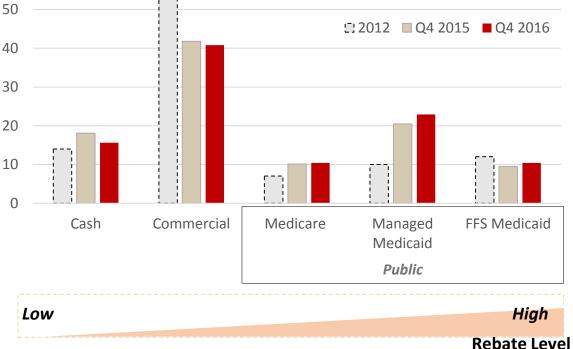
<sup>1</sup>NTRx=Prescription normalized to 30 tablets

Note: Calculations based on average sales in Q4 prior to changes in WellCare (Dec) and UHG(Jan1) and comparing with weekly average YTD 2017, week ending Feb 17th, 2017



# Managed Medicaid driving growth while Commercial remains the most important segment

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#### Comments

Managed Medicaid growth likely positively influenced by the Affordable Care Act

Rebate agreements with Managed Medicaid and FFS Medicaid based on best price in commercial plus an substantial additional rebate

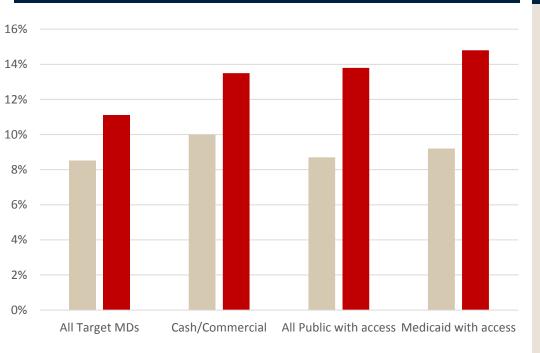
Zubsolv<sup>®</sup> rebate level highly influenced by payer mix - increased share from public will increase overall gross to net rebates

All products increased price 5-6% partly compensating for the increased overall rebates

# Zubsolv<sup>®</sup> starting to show positive share capture of the physicians increasing to 275 patients

Market access and sales force key to gain share

Zubsolv share capture of C275 growth



Base share

Growth share

#### Comments

Orexo sales force covers 60% of C275 physician prescribing volumes in Q4

78% of the 2,600 C275 physicians by year-end within geographic reach with existing field force

Of the growth in the Public segment 51% is from health plans with unrestricted access to Zubsolv

Note: Include physicians covered by Orexo sales force, all commercial and cash growth, <u>exclude changes in Maryland and SelfRefind</u>. Public and Medicaid with access are all growth within health plans with unrestricted access for Zubsolv and covered by Orexo sales force. "Base share" is defined as Zubsolv average share 4 weeks before C275 was implemented mid-august and "Growth share" is Zubsolv share of growth with C275 physicians in December 2016.



## Zubsolv<sup>®</sup> well positioned to improve share in 2017 despite loss around year-end

#### Expanded treatment of opioid dependence will bring new growth opportunities

- Fast growth in physicians certified to treat 275 patients
- Strong indications of a continued political interest in expanding access to treatment even after transition of power in US Federal Government
- Expanded buprenorphine prescribing rights to Nurse Practioners and Physician Assistants
- Zubsolv has taken disproportionate market share of the first growth driven by expansion to C275, especially among current targets

#### Market access will improve in 2017 compared to 2016

- New contract with CIGNA from October 15 and two larger regional plans from Jan 1<sup>st</sup> are adding Zubsolv to preferred list
- First large contract in Medicare Part D adding Zubsolv to preferred list from January 1, 2017
- Additional improvements in smaller regional plans in all segments

## 2017 set up to be an eventful year!

Development

Supply

### Commercial

- Announcement of new OX-xx project, following successful proof of principle in H2
- Approval of Zubsolv<sup>®</sup>
   in Europe anticipated
   in Q4
- Complete establishment of global supply chain and confirmation on future COGs reduction
- Addition of commercial product to US organization
- Increased market share during the year and disproportionate share capture of C275 growth
- Zubsolv revenue growth in 2017 in the US
- Decision from the appeal of the first decision in the litigation against Actavis late Q4 or early 2018

#### Forward looking statement:

This report includes forward-looking statements. Actual results may differ from those stated. Internal and external factors may affect Orexo's results.





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