



# INVESTOR & ANALYST PRESENTATION

*Autumn 2016*



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# H1 2016 highlights

## **Sales: All key products continue the solid momentum**

- Revenue increased by 5% to DKK 7.5 billion
- Key products grew 99% to DKK 2.9 billion - represents 39% of revenue

## **EBIT: Operational efficiencies well on track**

- EBIT increased from DKK (4.9) billion in H1 2015 to DKK 952 million this period
- EBIT-margin significantly improved to 12.7%

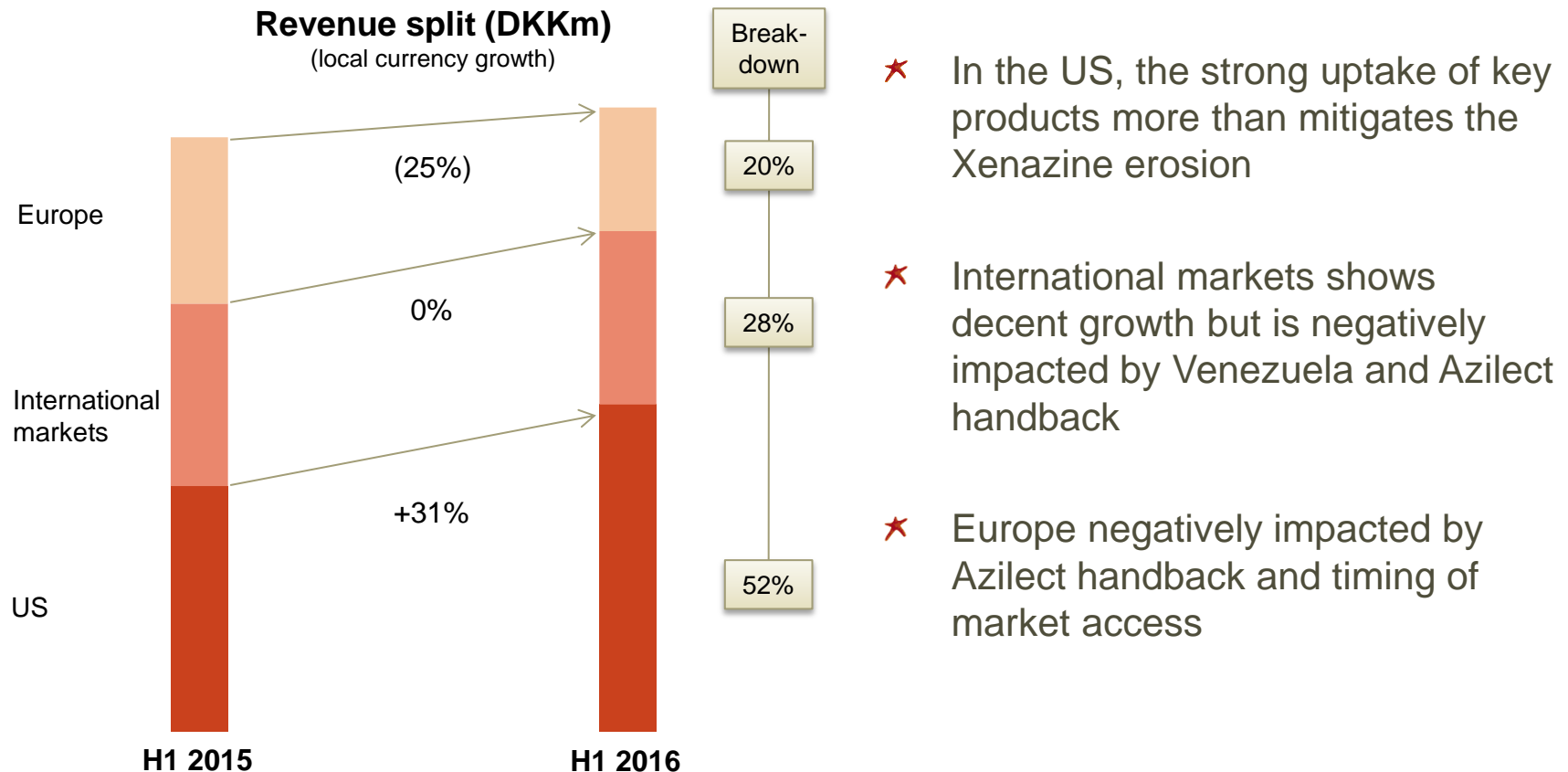
## **R&D: Continued progress in the second quarter**

- Fast-track designation for idalopirdine and patient recruitment finalised

## **2016: Financial guidance increased**

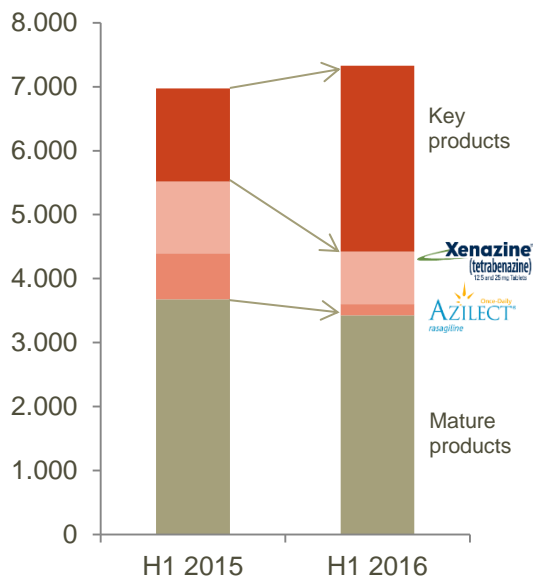
- Lundbeck now expects revenue of DKK 14.6-15.0 billion and EBIT of DKK 1.5-1.7 billion for 2016

# The US - the main driver of sales performance

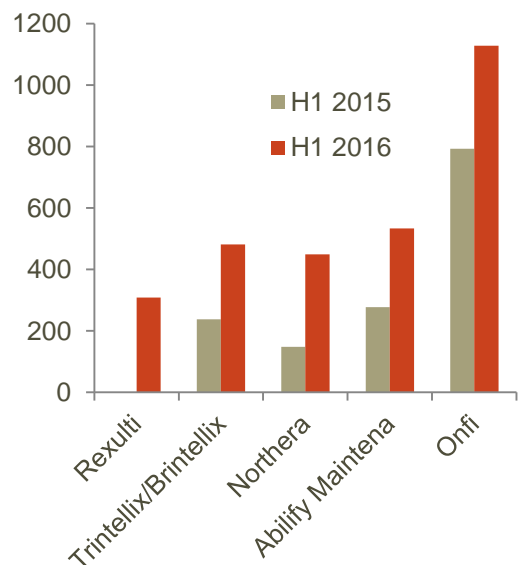


# Revenue growth contributors

## Revenue contributors



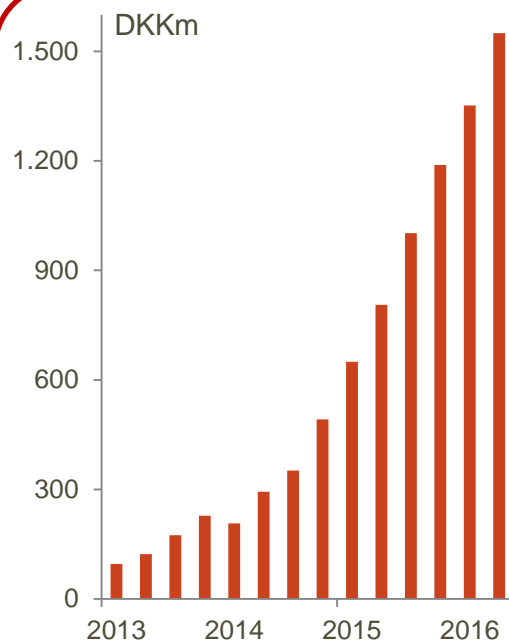
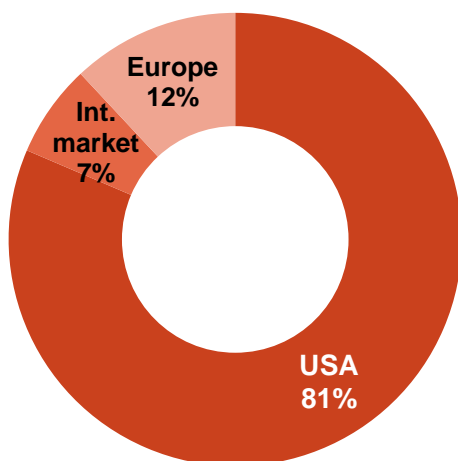
## Key products (DKKm)



- ★ Revenue grew 3% and 5% y/y in Q2 and H1 2016, respectively
- ★ Continued strong growth for all key products
- ★ Sales performance negatively impacted by Azilect handback and Xenazine erosion

# Key product sales of DKK 2,902 million – up 99% in H1 2016

Revenue split (H1)



- ★ Sales increased 92% in Q2 reaching DKK 1,550 million
- ★ Limited FX impact
- ★ Key products constitute 41% of revenue vs 22% in Q2 2015
- ★ Solid growth momentum set to continue

NEW  
**Abilify Maintena**  
400mg ONCE-MONTHLY

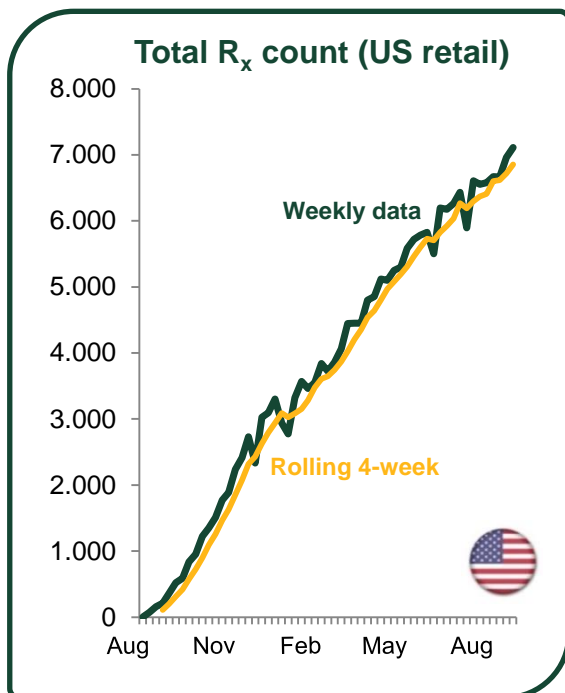
**Brintellix**  
vortioxetine

**Northera**  
(droxidopa) capsules  
100mg-200mg-300mg

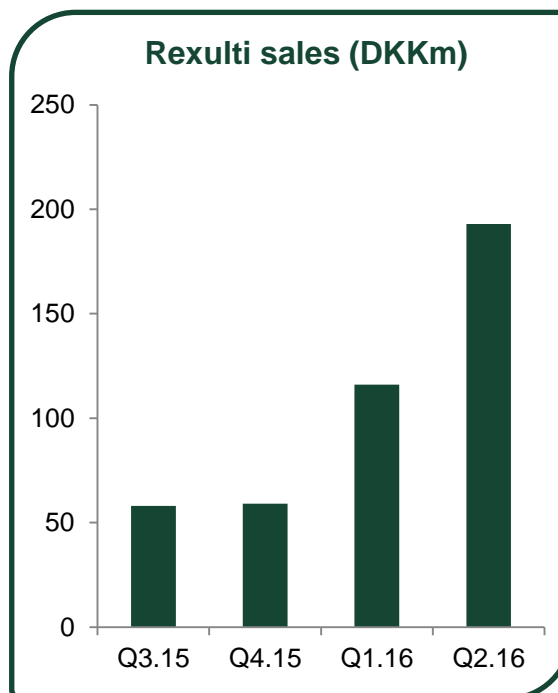
**Onfi.**  
(clobazam)  
5, 10, and 20 mg tablets

**REXULTI**  
brexpiprazole  
tablets

# Rexulti sales reached DKK 309 million in H1 2016



Source: Bloomberg (week ending 26/8 2016)



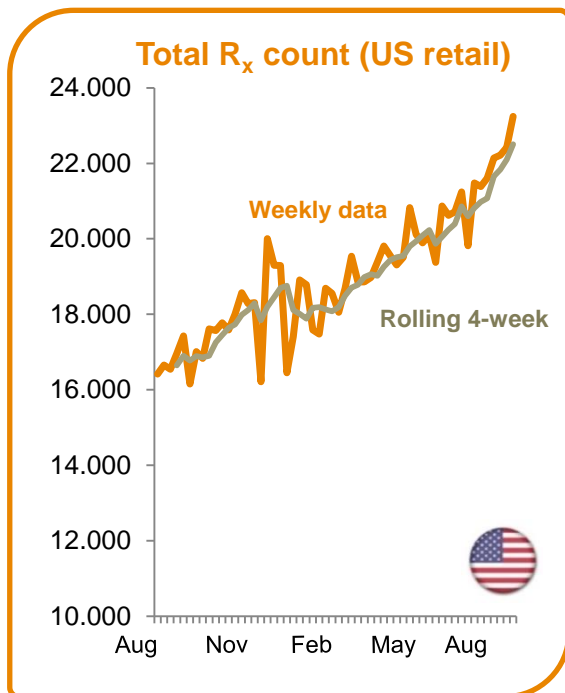
Lundbeck's share of revenue

- ★ Sales reached DKK 193 million in Q2
- ★ Strong sales for schizophrenia and major depressive disorder
- ★ Majority of R<sub>x</sub> prescribed for major depression
- ★ ~7.5% branded TR<sub>x</sub> market share and ~9% branded NR<sub>x</sub> market share

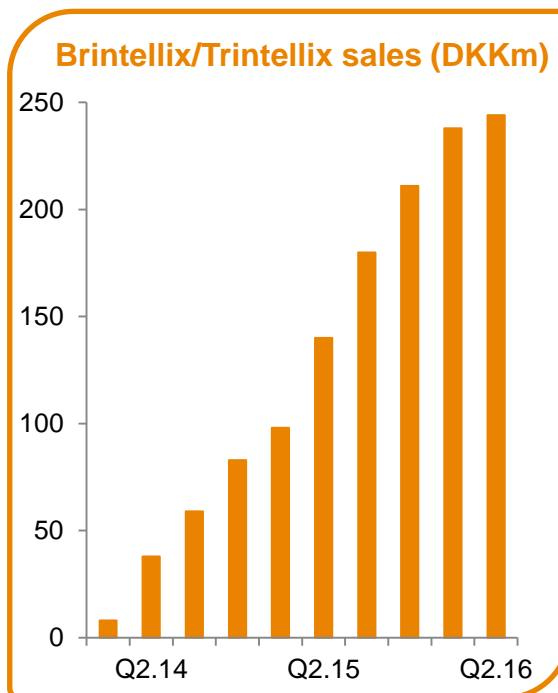




# Brintellix/Trintellix sales of DKK 482 million – up 103% in H1 2016



Source: Bloomberg (week ending 26/8 2016)



- ★ Sales reached DKK 244 million in Q2 – up 75%
- ★ Nation-wide DTC campaign commenced in the US
- ★ Value market share ranges from 1-8.5% in countries outside the US
- ★ As expected reimbursement was not granted in Germany

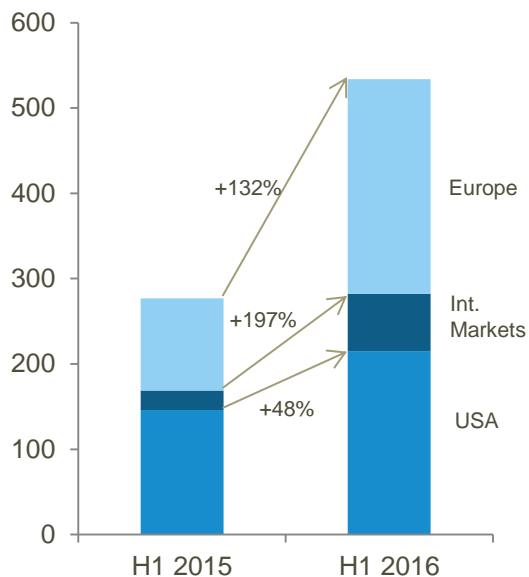
**Brintellix**  
vortioxetine

**Trintellix™**  
vortioxetine  
5mg•10mg•20mg tablets

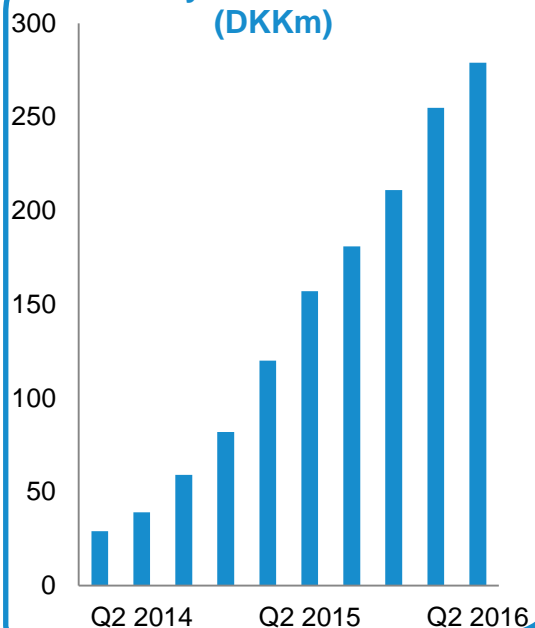


# Abilify Maintena sales of DKK 534 million – up 93% in H1 2016

Revenue contributors



Abilify Maintena sales (DKKm)



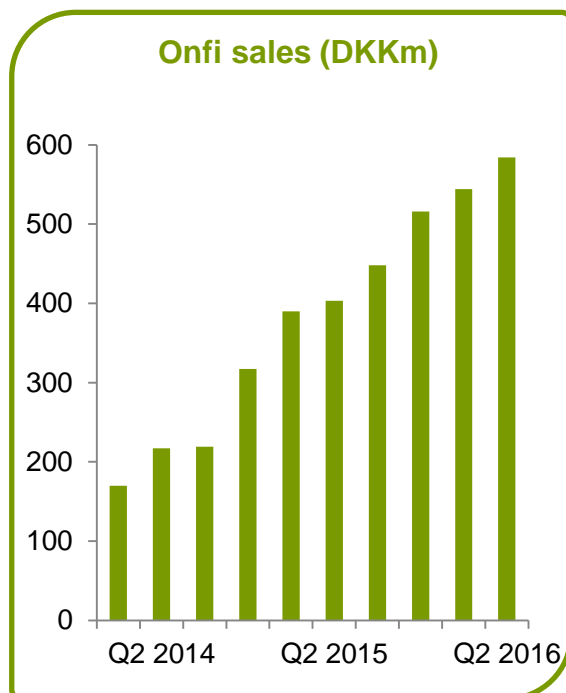
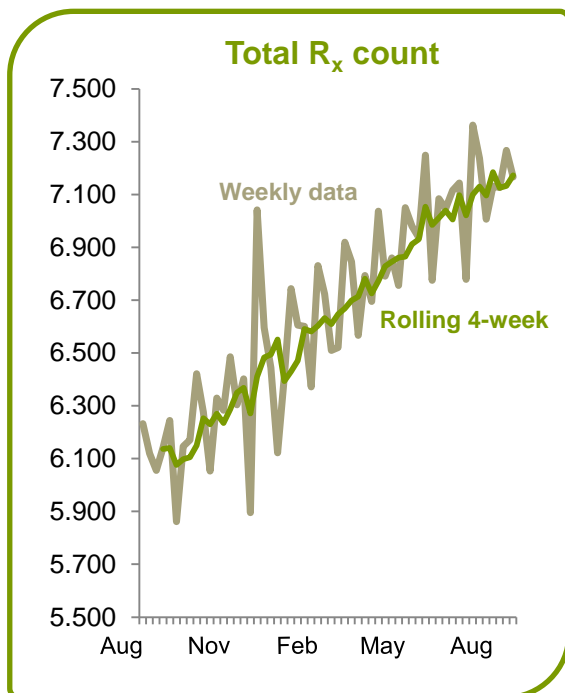
Lundbeck's share of revenue

- ★ Sales reached DKK 279 million in Q2 – up 78%
- ★ Sales grew as planned in the US and the EU (local currency basis)
- ★ Met primary endpoint in bipolar disorder phase III trial and plan to submit sNDA in H2 2016
- ★ 10-16% value market share (LAI retail) in most markets



LAI = Long-Acting Injectable anti-psychotics)

# Onfi sales of DKK 1,128 million – up 42% in H1 2016



- ★ Sales of DKK 584 million in Q2 – up 45%
- ★ Continued increased demand driven by increase in mg/R<sub>x</sub> and higher volume (TR<sub>x</sub>)

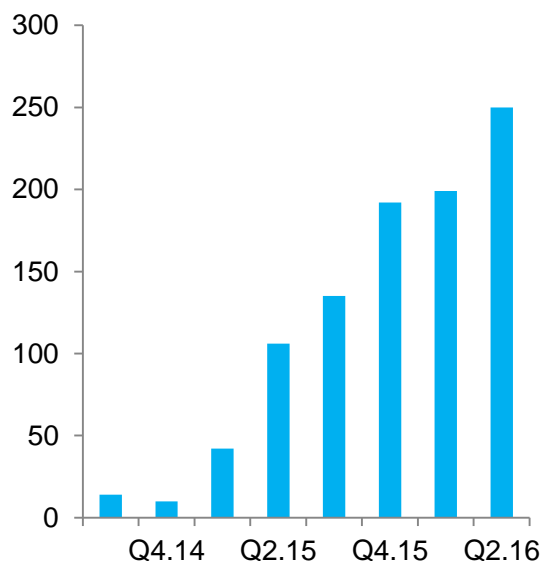


Source: Bloomberg (week ending 26/8 2016)

# Northera sales of DKK 449 million – up 203% in H1 2016

- ★ Launched in September 2014
- ★ Only chronic oral therapy treating root cause of symptomatic nOH<sup>1</sup>
- ★ Well documented safety and efficacy; marketed in Japan since 1989
- ★ Good synergies with exciting neurology franchise
- ★ 80,000-150,000 nOH patients in the US (MSA, PAF, PD only)<sup>2</sup>

Northera sales (DKKm)



- ★ Sales reached DKK 250 million in Q2 – up 136%
- ★ Growth primarily driven by increased milligram (mg) sold...
- ★ ...driven by longer treatment period and higher mg/patient

**Northera™**  
(droxidopa) Capsules  
100 mg • 200 mg • 300 mg



1) Neurogenic Orthostatic Hypotension; 2) MSA=Multiple System Atrophy; PAF=Pure Autonomic Failure; PD=Parkinson's Disease

# R&D highlights

## Key achievements:

### Idalopirdine

- ★ Fast-track designation by FDA
- ★ The three 24-week studies have finalised patient recruitment

### Abilify Maintena

- ★ Submission for bipolar disorder on track for H2 2016

### Rexulti

- ★ sNDA filed for labeling update to include maintenance treatment,...
- ★ ...and the PDUFA date is 23 September 2016

### Brintellix/Trintellix

- ★ FDA regulatory dialogue ongoing

## Lundbeck's development pipeline

Disease areas	Phase I	Phase II	Phase III	Registration
Alzheimer's disease	Lu AF20513		Idalopirdine	
			Brexpiprazole	
Mood disorders		Brintellix, ADHD	Brexpiprazole (EU)	
			Abilify Maintena, BP	
Parkinson's disease	Lu AE04621			
Schizophrenia			Lu AF35700	
			Brexpiprazole (EU)	

# Our path to category leadership

## Current products

## Pipeline

### Depression

**Cipralex**  
escitalopram

**Brintellix**  
vortioxetine

**REXULTI**  
brexpiprazole  
tablets

Research projects

### Schizophrenia

**Saphris**®  
(asenapine)

**NEW**  
**Abilify** **Maintena**  
400mg ONCE-MONTHLY

**REXULTI**  
brexpiprazole  
tablets

Lu AF35700

Research projects

### Alzheimer's

20 mg Once-Daily  
**Ebixa**  
memantine

Rexulti

Idalopirdine

Lu AF20513

Research projects

### Parkinson's

Once-Daily  
**AZILECT**  
rasagiline

**Northera**  
(droxidopa) capsules  
100mg-200mg-300mg

Research projects

Early clinical projects

# Idalopirdine addresses medical need for additional improvements in cognitive function in Alzheimer's

## Differentiated profile

- ★ Additive/synergistic effect with donepezil
- ★ Blockade of the 5-HT<sub>6</sub> receptor improves cognition through several pathways: stimulation of acetylcholine and glutamate activity, while reducing GABA activity
- ★ Effect and benign tolerability profile established in phase II <sup>2)</sup>
- ★ Potentially first NCE to be approved for Alzheimer's since 2003

## Clinical phase III programme

- ★ >2,500 mild-to-moderate Alzheimer's patients
- ★ Patients in the programme have been recruited
- ★ Clinical study endpoints agreed with FDA and EMA
- ★ Receptor occupancy data supports once-daily dosing and dose-range <sup>1)</sup>



Phase III data: Q1 2017

1) Schmidt et al, A clinical positron emission tomography (PET) study investigating occupancy at the 5-HT<sub>6</sub> receptor after multiple oral doses of Lu AE58054 in healthy men. Poster at AAIC July 2014. 2) Wilkinson et al, Safety and efficacy of idalopirdine, a 5-HT<sub>6</sub> receptor antagonist, in patients with moderate Alzheimer's disease (LADDER): a randomised, double-blind, placebo-controlled phase 2 trial. Lancet Neurology 10/2014

# The idalopirdine *STARSHINE*, *STARBEAM* and *STARBRIGHT* studies are now fully recruited

## Baseline Data from the Ongoing *STARSHINE* Study

*(Poster #7842 presented at AAIC in  
Toronto, Canada; July 2016<sup>1</sup>)*



- ★ 933 patients began treatment
- ★ On average, patients were diagnosed with Alzheimer's 2.1 years prior to enrollment and treated with donepezil for 1.6 years
- ★ Patients had a mean ADAS-cog total score of 26 and an MMSE of 18 at baseline
- ★ Patients had a mean score of 56 on the ADCS-ADL scale<sup>2)</sup>
- ★ Headline conclusions on pivotal studies due in Q1 2017

1) Alireza Atri, MD, PhD, Neli Boneva, MD, PhD, Jeffrey L. Cummings, MD, ScD, Lutz Frölich, MD5, Pierre N. Tariot, MD and Kristian Windfeld, PhD: Idalopirdine, a 5-HT6 Antagonist in Phase III Development as Adjunctive Therapy to Cholinesterase Inhibitors in Patients with Mild-Moderate Alzheimer's Disease: Baseline Data from the Ongoing Starshine Study. 2) Alzheimer's Disease Consortium Study - Activities of Daily Living Inventory (ADCS-ADL)



# The clinical phase III programme on idalopirdine

		Design	Idalopirdine (mg/day)	Donepezil (mg/day)	Primary Endpoint Scale	No. of patients
NCT01955161 ( <i>STARSHINE</i> )	24 weeks	Randomized, DB, PBO, parallel- group, fixed-dose	30 and 60mg (QD)	10	ADAS-cog (#)	~930 (Study start: 10/2013)
NCT02006641 ( <i>STARBEAM</i> )	24 weeks	adjunctive treatment to donepezil	10 and 30mg (QD)	10	ADAS-cog (#)	~850 (Study start: 02/2014)
NCT02006654 ( <i>STARBRIGHT</i> )	24 weeks	AChEIs	60 (or 30mg) (QD)	-	ADAS-cog (#)	~720 (Study start: 03/2014)
NCT02079246* ( <i>STAR Extension</i> )	32 weeks	Adj. to donepezil	60 (or 30mg) (QD)	10	AEs Withdrawals	1,770 (Study start: 04/2014)
NCT01019421 (phase II)	24 weeks	Adj. to donepezil	90mg (TID)	10	ADAS-cog	278 (Study start: 12/2009)
NCT00810667 (phase II)	12 weeks	Adj. to risperidone	120mg (BID)	-	PANSS	124 (schizophrenia) (Study start: 11/2008) (Study comp.: 02/2010)

DB: double-blind; PBO: placebo-controlled

\*) Patients that conclude *STARSHINE* or *STARBEAM* can be included in a long-term open label study - NCT02079246. #) Both Activities of Daily Living Inventory (ADCS-ADL23) total score and Clinical Global Impression of Change (ADCS-CGIC) score included as secondary endpoints

# Abilify Maintena met primary endpoint in study for the maintenance treatment of bipolar I disorder

- ★ One of the most common causes of relapse in bipolar disorder is poor treatment adherence
- ★ ~50% of patients being partially adherent or non-adherent to their treatment regimens
- ★ Bipolar I disorder affects ~1% of the population in the US



## Clinical programme\*

- ★ ~730 patients in placebo-controlled phase III 52-week study
- ★ Primary efficacy endpoint of this trial is time to recurrence of any mood episode
- ★ An open-label safety study (ATLAS) is ongoing recruiting ~755 patients
- ★ Expected sNDA on track for H2 2016

\*) NCT01567527 (Start: Aug. 2012); NCT01710709 (Start: Nov. 2012)

# No drugs so far approved for agitation/aggression in Alzheimer's which remains a high unmet need

## The condition

- ★ >20% of individuals in a community setting and >50% of nursing home residents with dementia have agitation
- ★ >1.5 million dementia patients in the US with agitation/aggression
- ★ Agitation in Alzheimer's is associated with increased caregiver burden, decreased functioning and earlier nursing home placement

## The studies

<b>Study #1 (12 weeks)</b> (NCT01922258)	<b>Study #2 (12 weeks)</b> (NCT01862640)
~230 patients	~420 patients
0.5-2mg (flexible dose)	1mg and 2 mg
Study start: June 2013	Study start : July 2013

## Clinical programme

- ★ Target population: Institutionalized or non-institutionalized setting
- ★ Primary outcome: Change in the Cohen-Mansfield Agitation Inventory (CMAI) total score
- ★ Headline conclusions due in H1 2018



# Lu AF35700 in Treatment Resistant Schizophrenia (TRS)

## The condition

- ★ Psychiatrists readily recognize the term '**Treatment Resistant Schizophrenia**'
- ★ TRS is an **inability to control symptoms** of schizophrenia after a full round of two to three antipsychotics
- ★ Around 1/3 of schizophrenia patients is treatment resistant

## The molecule

- ★ Unique mode of action. In contrast to current treatment, antipsychotic effect at low D<sub>2</sub> blockade
- ★ Combined D<sub>1</sub>/D<sub>2</sub> and 5-HT<sub>6</sub> profile gives good activity combined with a benign tolerability profile
- ★ Very long half-life leads to significantly reduced risk of relapse

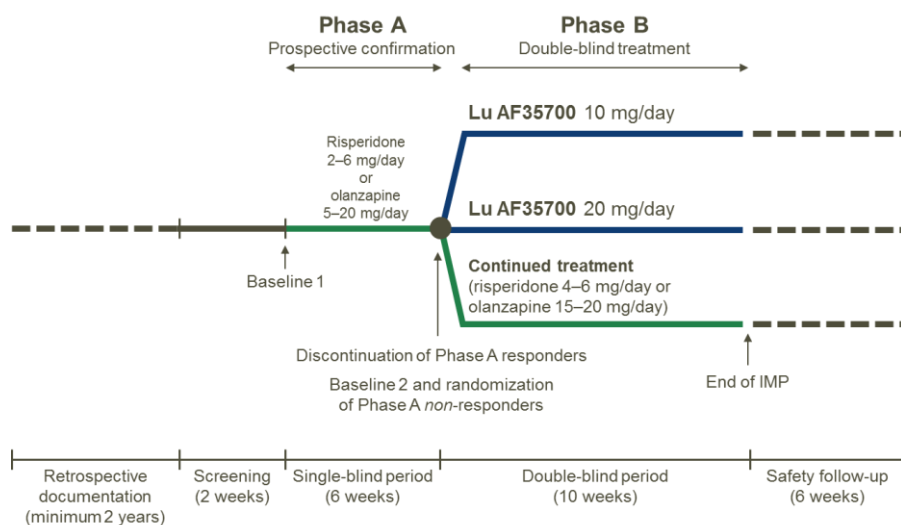
## Clinical programme

- ★ Four clinical studies have been conducted, three studies in healthy people and one in patients with schizophrenia\*)
- ★ The first study in the pivotal programme commenced in March 2016



\*) Clinicaltrials.gov identifier: NCT02202226

# Lu AF35700 study set-up in clinical phase III in Treatment Resistant Schizophrenia (TRS)



Clinicaltrials.gov ID: NCT02717195

- ★ Oral, once daily
- ★ Approximately 1,000 patients
- ★ Expected completion by 2018

## Primary endpoint

- ★ Change in PANSS total score

## Secondary endpoints

- ★ Clinical Global Impression Severity scale (CGI-S)
- ★ Personal and Social Performance (PSP) total score

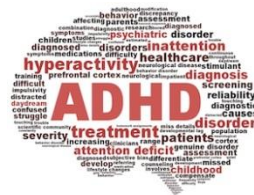
# Brintellix – PoC study in adult patients with ADHD

## The condition

- ★ ~4% of the US adult population, or ~8 million adults suffer from ADHD<sup>1)</sup>
- ★ Adults with ADHD may have:
  - ★ difficulty following directions, remembering information, concentrating, organizing tasks,...
  - ★ ...which can cause associated behavioural, emotional, social, vocational, and academic problems

## Brintellix in ADHD

- ★ Preclinical data supports the effects of Brintellix on attention and executive function
- ★ Clinical studies in MDD demonstrate positive effects on executive function and other domains of cognitive functions in patients with cognitive symptoms



## Study design<sup>2)</sup>

- ★ ~225 adult patients (18-55 years)
- ★ Two active arms (10+20mg) and placebo, 12 weeks
- ★ Primary endpoint: AISRS (Adult ADHD Investigator Symptom Rating Scale)
- ★ Study completion by end 2016

1) <http://www.webmd.com/add-adhd/guide/adhd-adults#2>. 2) NCT02327013



# Complete Response Letter for Brintellix/Trintellix sNDA received in March 2016

- ★ FDA recognizes the importance of cognitive dysfunction in MDD and views it as a legitimate target for drug development
- ★ We remain committed to Brintellix/Trintellix as a treatment option for patients with MDD
- ★ In February 2016, FDA Psychopharmacologic Drugs Advisory Committee (PDAC) voted 8 to 2 that Takeda and Lundbeck presented substantial evidence to support a claim of effectiveness for Brintellix in treating certain aspects of cognitive dysfunction in adults with MDD
- ★ Dialogue to address CRL is ongoing

**Depression does not only effect your mood: It may also effect your cognitive functioning**

**ATTENTION, CONCENTRATION**  
Do you...

- ✓ Lose track of conversations, TV programmes or reading?
- ✓ Find it difficult to do two things at once?
- ✓ Require many breaks while doing tasks?
- ✓ Struggle to talk on a cell phone while there is activity around you?

**EXECUTIVE FUNCTIONING/ INDECISIVENESS**  
Do you...

- ✓ Have difficulty planning tasks or reaching goals?
- ✓ Have difficulty in predicting obstacles in a situation?
- ✓ Find it difficult to motivate yourself to start or complete tasks?
- ✓ Struggle to make decisions or plans?

**MEMORY**  
Do you...

- ✓ Forget details after hearing them?
- ✓ Struggle to remember?
- ✓ Ask people to repeat what they said?
- ✓ Struggle to do familiar tasks?

**SPEED OF PROCESSING**  
Do you...

- ✓ Have to take things slowly and complete each step very carefully?
- ✓ Panic if you have to rush familiar tasks?
- ✓ Feel that your speech is slower?
- ✓ Feel that your responses are slower?

**Brintellix**  
A New Way of Thinking about Antidepressants

Patients can start feeling on Brintellix 15 mg once daily

- ✓ Brintellix has been shown to be effective in treating depression in patients with moderate to severe depression.
- ✓ No dose adjustments are needed in patients with mild to moderate renal impairment.
- ✓ Brintellix can be stopped without the need for gradual dose reduction.
- ✓ Brintellix has a low potential for drug-drug interactions and can be used with many common drugs, including antidepressants.

**SIMPLE DOSING**

**EXCELLENT TOLERABILITY**  
Brintellix 15 mg once daily has been shown to be well tolerated in clinical studies.

**NO WEIGHT GAIN**  
Brintellix has been shown to be effective in treating depression in patients with moderate to severe depression.

**SEXUAL DYSFUNCTION AT PLACEBO LEVEL**  
Brintellix has been shown to be effective in treating depression in patients with moderate to severe depression.

**SLEEP DISTURBANCE AT PLACEBO LEVEL**  
Brintellix has been shown to be effective in treating depression in patients with moderate to severe depression.

**NEW Brintellix**  
vortioxetine

**Brintellix:**  
Taking care of more than mood

**RECOMMENDED BY NICE\***

\*NICE (National Institute for Health and Care Excellence) has recommended Brintellix as a first-line treatment for major depressive disorder in adults. See the full NICE guideline at: [www.nice.org.uk/guidance/TA297](http://www.nice.org.uk/guidance/TA297)

**Trintellix™**  
vortioxetine  
5mg-10mg-20mg tablets

**Brintellix**  
vortioxetine



# The solid operational performance continues

DKK <b>m</b>	Q2 2016	Q2 2015	Variance	
			DKK	Local currencies
Revenue	3,751	3,629	3%	5%
Key products	1,550	806	92%	96%
EBIT	469	(4,833)		
EBIT margin	12.5%	(133.2%)		
Tax	244	(994)		
EPS	1.18	(19.84)		

★ Limited currency impact

★ Impact from loss of Azilect in Europe and generics mitigated by growth in key products

★ EBIT positively impacted by effects from restructuring

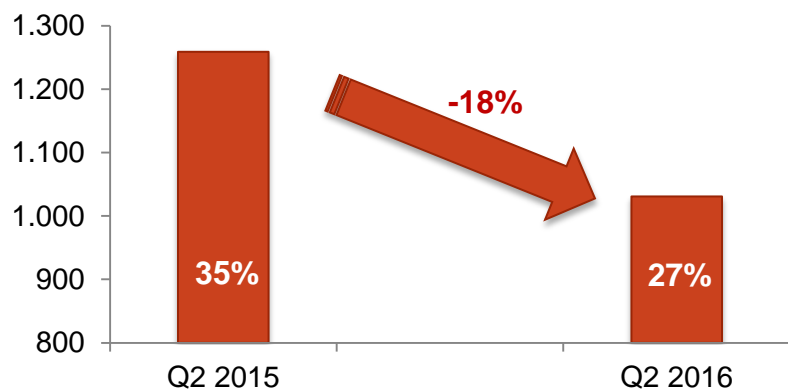
DKK <b>m</b>	H1 2016	H1 2015	Variance	
			DKK	Local currencies
Revenue	7,521	7,192	5%	5%
Key products	2,902	1,456	99%	99%
EBIT	952	(4,865)		
EBIT margin	12.7%	(67.6%)		
Tax	418	(945)		
EPS	2.12	(20.26)		

★ Core EBIT improved from DKK 135 million to DKK 726 million (Q2)...

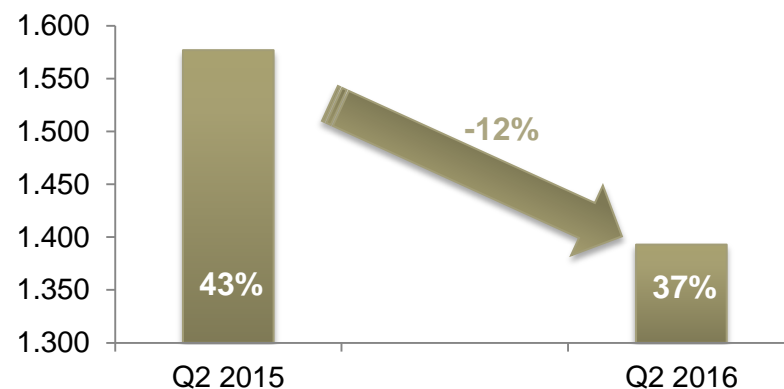
★ ...Core EBIT-margin improved from 3.7% to 19.3%

# Continued focus on cost

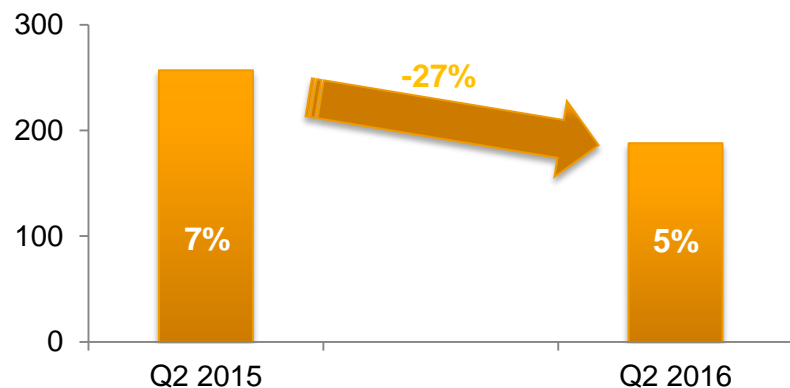
## Cost of sales (DKKm)



## Sales and distribution (DKKm)

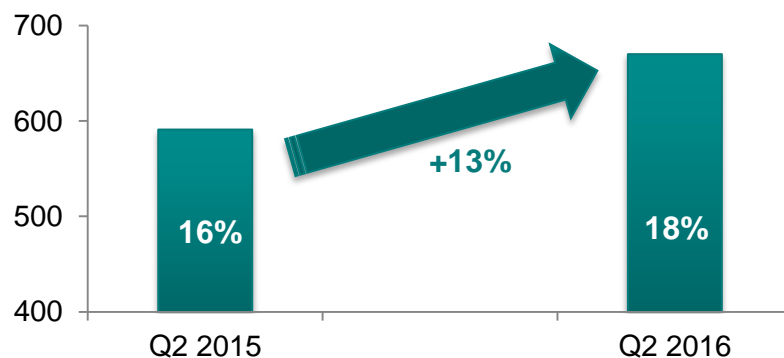


## Administration (DKKm)



## R&D (DKKm)

(Q2 2015 adjusted for impairment charges)



# Solid improvement in Lundbeck's cash flow

DKK <b>m</b>	Q2 2016	Q2 2015
Operating cash flow	435	(1,384)
Free cash flow	376	(1,384)
Net cash flow	50	(1,363)
Cash	1,436	1,787
Net interest-bearing debt	(1,778)	(1,461)
Net debt/EBITDA	2.2x	6.3x

DKK <b>m</b>	H1 2016	H1 2015
Operating cash flow	792	(1,766)
Free cash flow	696	(1,802)
Net cash flow	22	(1,878)
Cash	1,436	1,787
Net interest-bearing debt	(1,778)	(1,461)
Net debt/EBITDA	1.1x	2.7x

## Cash flow drivers:

- ★ Strong improvement in profitability
- ★ Improved working capital
- ★ Provisions reduced by spend on restructuring
- ★ Net interest-bearing debt expected to be around DKK 1 billion at year-end

# 2016 financial guidance increased

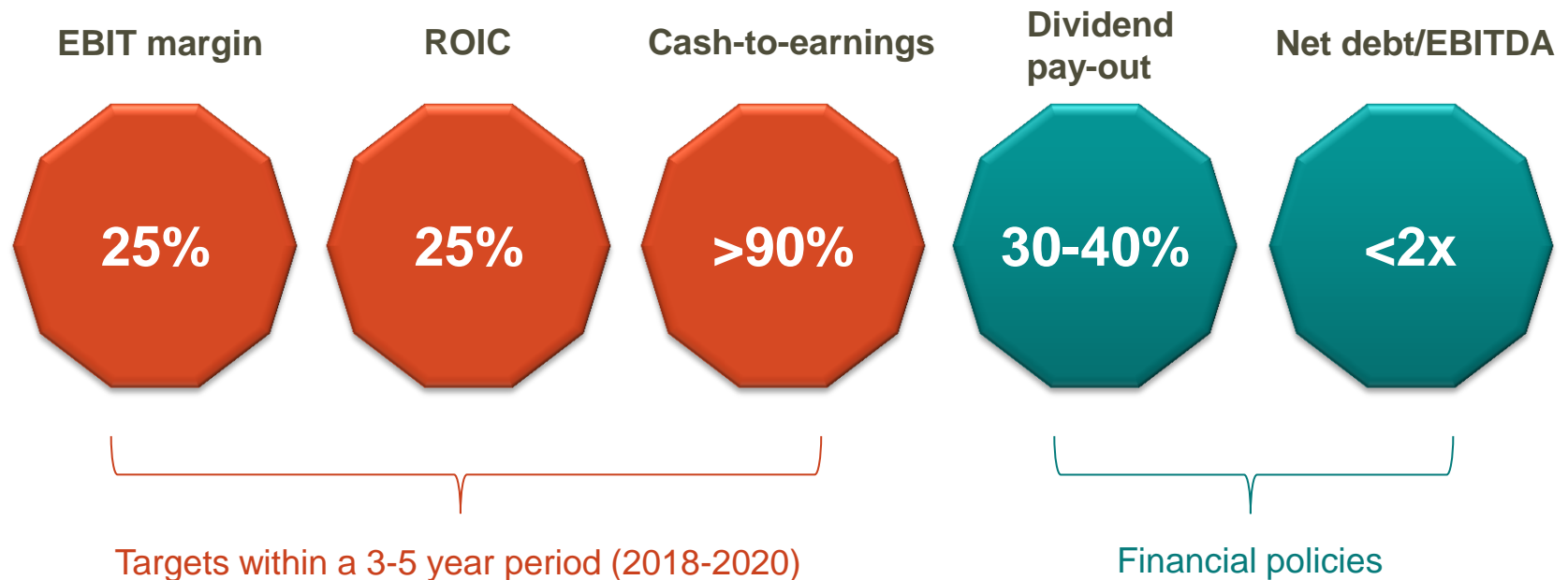
## Financial guidance 2016

	Revised 2016 guidance	Previous 2016 guidance
Revenue	DKK 14.6-15.0bn	DKK 14.2-14.6bn
Reported EBIT	DKK 1.5-1.7bn	DKK 1.3-1.5bn

## Revenue and profit drivers

- ★ Continued growth in key products
- ★ Cost savings from restructuring initiatives
- ★ No acquisitions, milestones or up-front payments included in our 2016 targets

# Long-term financial targets



ROIC: EBIT after tax as a percentage of average invested capital.

Cash-to-earnings: Free cash flow as a percentage of net profits

PATIENTS  
**FOCUSED**  
PASSIONATE  
RESPONSIBLE  
INNOVATION  
LEADERSHIP  
PROFITABILITY ORGANIZATION

DEPRESSION  
ALZHEIMER'S  
SCHIZOPHRENIA  
PARKINSON'S  
GLOBAL

# Our strategic objectives...



## **Four disease areas**

We will strive for leadership in the treatment of depression, schizophrenia, Parkinson's disease and Alzheimer's disease

## **Innovation**

We will develop innovative treatments that address unmet patient needs

## **Globalization**

We will expand and optimize our global organization

## **Profitability**

We will grow our business with a strong focus on profitability

## **Organization**

We will be a specialized company with strong cross-functional collaboration



# Focus - focus - focus



Depression



Psychotic disorders<sup>1)</sup>



Parkinson's disease



Alzheimer's disease

- ★ Increased therapeutic focus within CNS
  - ★ Organic development and global brands
  - ★ Country specific optimization in Europe
  - ★ Expand in regions of growth
- 
- ★ Profitability, cash generation and cash reallocation

1) While the Artist Louis Wain was developing a psychotic disorder, his perceptions of reality changed, at first subtly, and then more severely

# Our chosen therapeutic categories all have large potentials

## High unmet medical needs



<50% has satisfactory treatment outcome

## Large market segments



- Antipsychotics: USD 23.9bn
- Depression: USD 15.8bn
- Alzheimer's: USD 6.1bn
- Parkinson's: USD 4.4bn

## Substantial growth opportunities

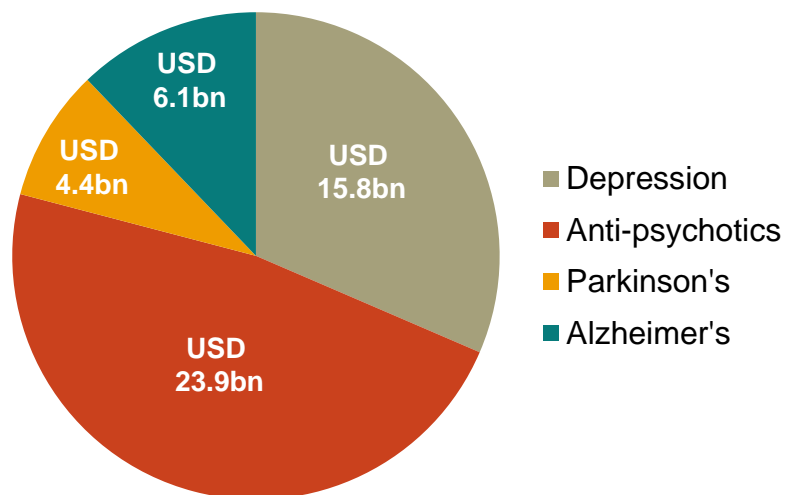


Lundbeck's revenue represents ~5% value share

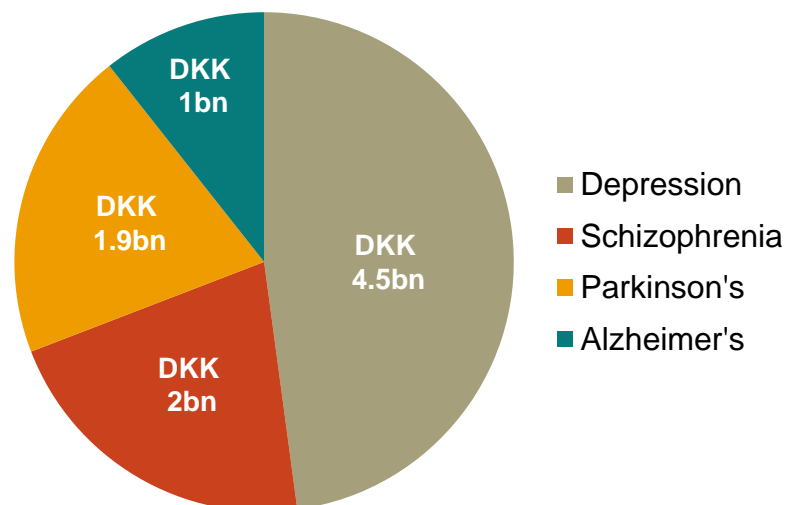
1) In 2014, IMS Health Analytics Link 2015.

# Distribution of sales in the four key strategic areas

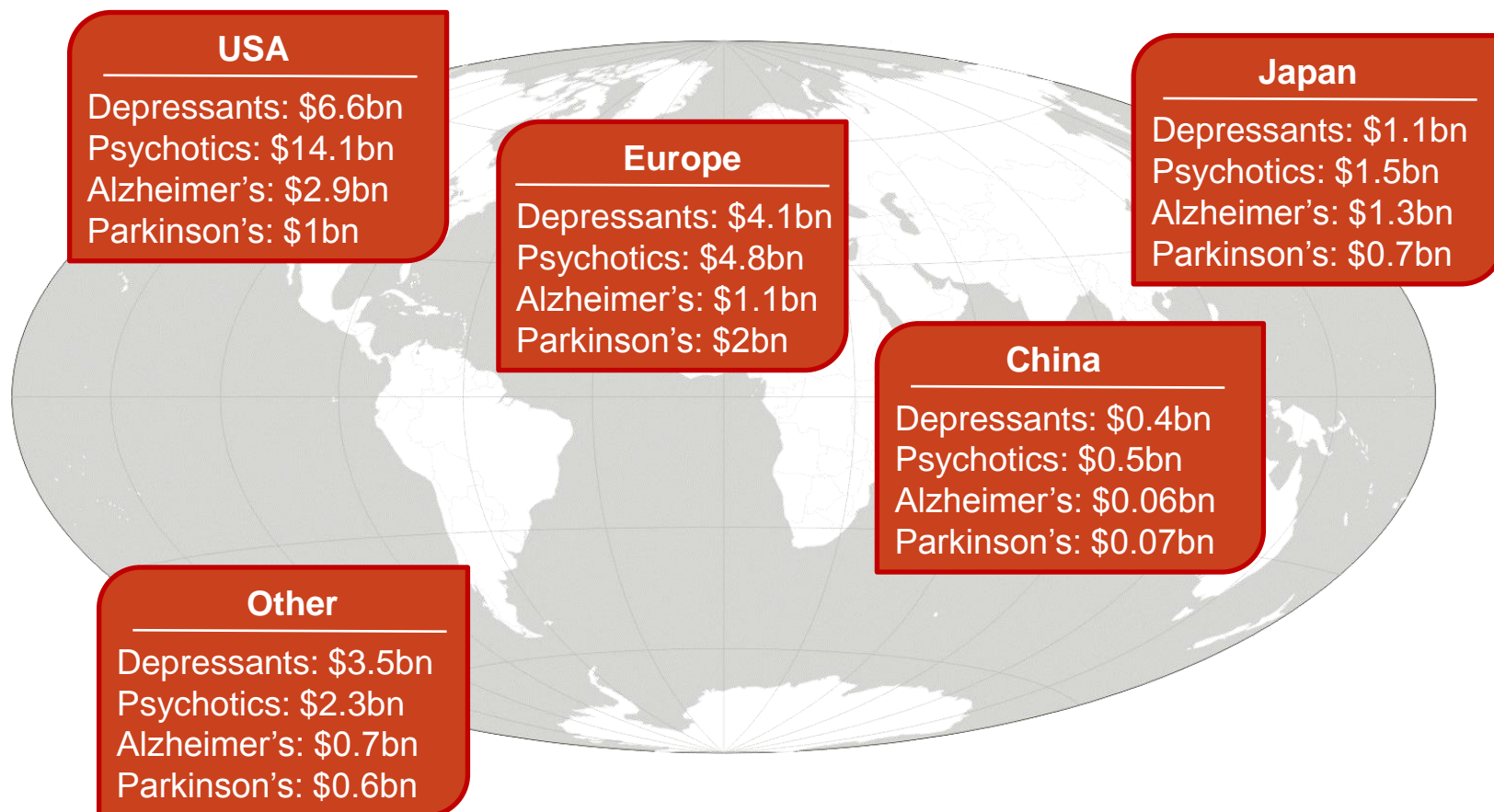
Distribution of WW sales according to IMS Health (2014)



Indicative distribution of Lundbeck's 2015 revenue



# Market sizes of our four core therapeutic areas



Source: IMS Health Analytics Link 2015 (Audited sales)

# 2014 - CNS market overview

	Market size (2014)				Unmet medical needs	Market leaders (2014)	
	Value (USDbn)	Value Growth	Volume Growth	# of patients*		Compound	Share value
<b>Total pharma</b>	927	+6%	+2%	-	-	-	-
<b>Total CNS</b>	134	+4%	+2%	-	-	-	-
<b>Anti-Alzheimer's (N7D)</b>	6.1	-4%	+2%	>7 million <sup>2</sup>	<ul style="list-style-type: none"> <li>• Disease modifying treatment</li> <li>• Disease slowing agents</li> <li>• Improved symptomatic treatments</li> <li>• Longer lasting symptomatic treatments</li> </ul>	1. Memantine 2. Rivastigmine 3. Donepezil 4. Galantamine	50% 22% 21% 7%
<b>Anti-depressants (N6A)</b>	15.8	-13%	+4%	~40 million <sup>2</sup>	<ul style="list-style-type: none"> <li>• Drugs with higher remission rates</li> <li>• Increased onset of action</li> <li>• Current therapies are relatively well-tolerated but still room for improvement especially on sexual side effects</li> </ul>	1. Duloxetine 2. Escitalopram 3. Venlafaxine 4. Bupropion	25% 11% 8% 8%
<b>Anti-Parkinson's (N4A)</b>	4.4	+2%	+1%	>3 million <sup>2</sup>	<ul style="list-style-type: none"> <li>• Therapies that provide neuroprotection and/or neurorestoration</li> <li>• An optimal trial design for demonstrating neuroprotection and/or neurorestoration</li> <li>• Control of levodopa-induced motor response complications</li> </ul>	1. Levodopa 2. Pramipexole 3. Rasagiline 4. Stalevo 5. Ropinirole	20% 16% 15% 10% 9%
<b>Anti-psychotics (N5A)</b>	23.9	+9%	+3%	Approx 1% of global population	<ul style="list-style-type: none"> <li>• Improved treatment of cognitive dysfunction</li> <li>• Improved treatment of negative symptoms</li> <li>• Improved treatment of co-morbid depression and anxiety</li> <li>• Early stage, definitive diagnostics</li> </ul>	1. Aripiprazole 2. Quetiapine 3. Risperidone 4. Olanzapine	40% 14% 9% 9%

Source: IMS Health Analytics Link 2015 (Audited sales), Growth, USD % y/y

# Supply operations

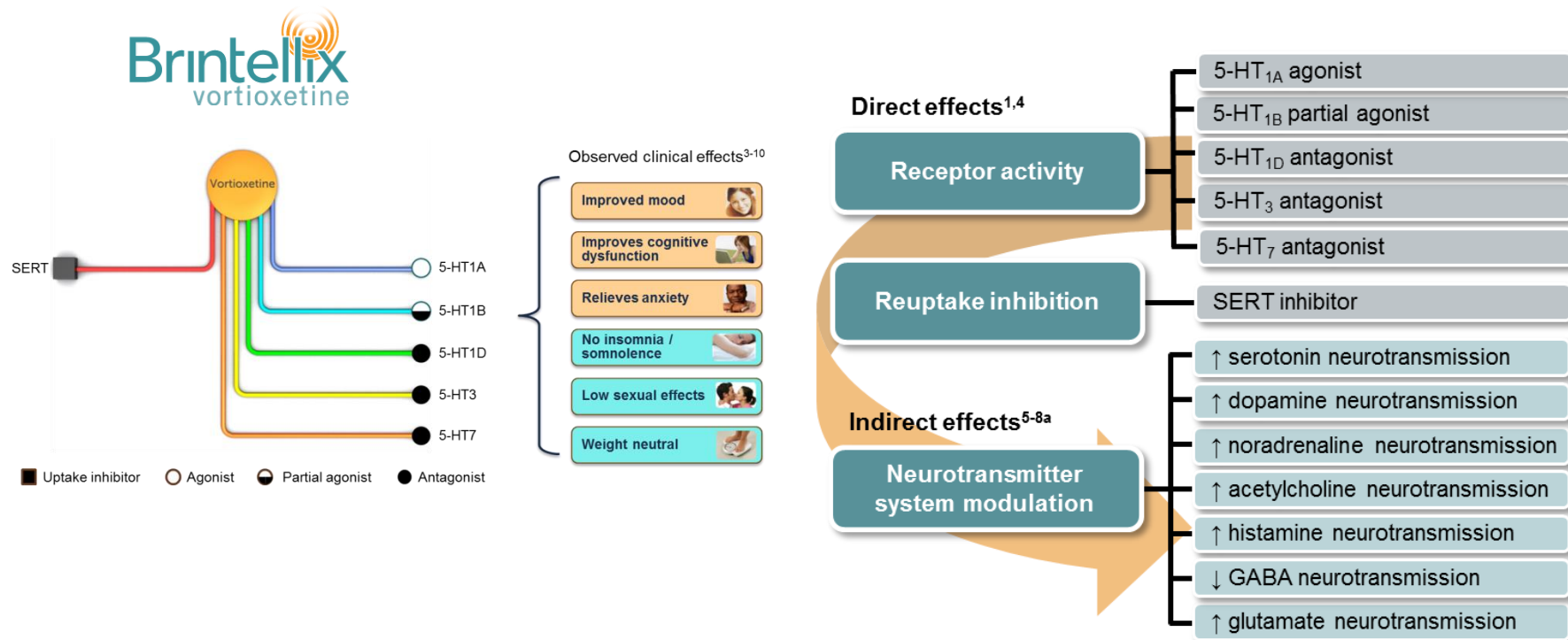


# Brintellix (vortioxetine, Lu AA21004)





# Brintellix has a distinct pharmacological profile



1. Bang-Anderson 2011; 2. Mørk 2012; 3. H. Lundbeck A/S 4. Alvarez 2012;  
5. Katona 2012; 6. Baldwin 2012; 7. Heningsberg 2012; 8. Boulenger 2012; 9. Vortioxetine SPC; 10. Bidzan 2012

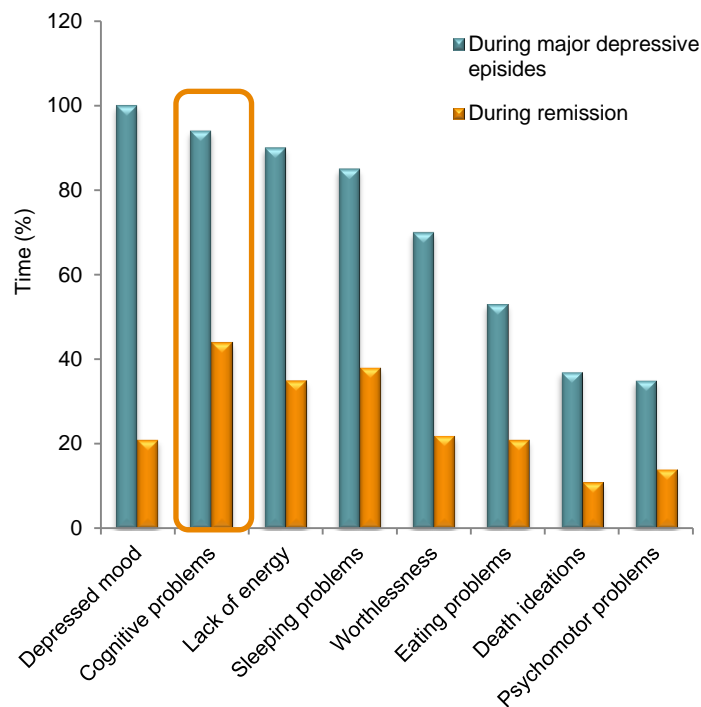
# With Brintellix our vision is to advance the treatment of depression so that patients not only feel but think and do better



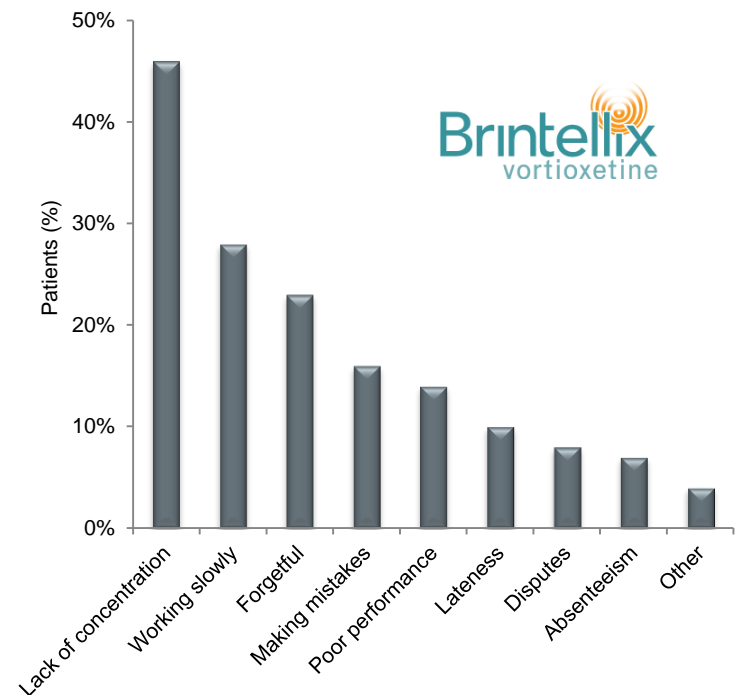
- ★ Efficacy in cognitive symptoms of depression
  - 3 studies with objective measures
  - European SmPC update to include clinical data on cognitive dysfunction in patients with depression
- ★ Superior efficacy in patients with inadequate response to SSRIs / SNRIs vs. agomelatine
- ★ Superior sexual dysfunction data vs. escitalopram
- ★ Unique pharmacology supports unique clinical profile

# Cognitive symptoms of depression are frequent and affect work productivity

- ★ Cognitive symptoms (difficulty concentrating, planning, decision making and forgetfulness) are very prevalent and have a direct impact at the workplace<sup>1)</sup>




- ★ Percentage of patients with MDD experiencing work-related cognitive dysfunction<sup>2)</sup>



1. Conradi HJ et al. Psychol Med 2011;41:1165-1174;

2. Adelphi Neurosis DSP VIII, 2009

## Newer products

  
**Northera**<sup>™</sup>  
(droxidopa) Capsules  
100 mg • 200 mg • 300 mg

  
**Onfi**<sup>™</sup>  
(clobazam)<sup>®</sup>  
5, 10, and 20 mg Tablets

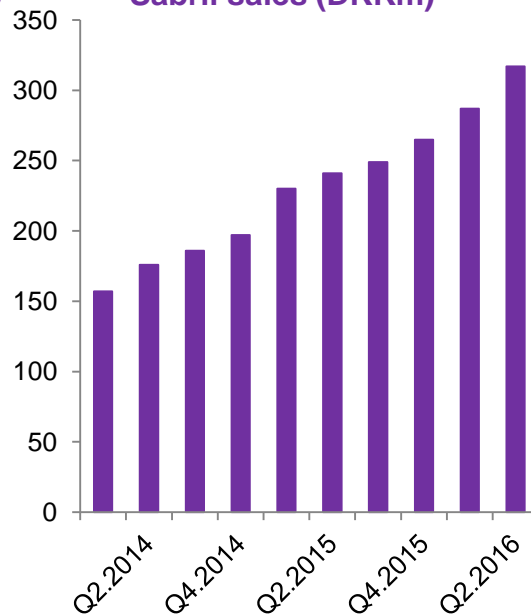
 **Sabril**<sup>®</sup>  
vigabatrin  
500 mg tablet  
500 mg powder for oral solution

# Sabril – launched in Q3 2009 and reached DKK 604 million - up 28% in H1 2016

## Refractory complex partial seizures (rCPS):

- ★ ~1 million patients in the US suffer from CPS
  - ★ 30-36% of patients are refractory
- ★ Poorly controlled by current therapies
- ★ Uncontrolled seizures has ~40x higher risk of inflicting mortality

## Sabril sales (DKKm)



## Infantile spasms (IS):

- ★ ~2,500 patients/year in the US with IS
- ★ Serious disease with substantial unmet medical need
  - ★ 70-90% suffers from mental retardation, mortality of around 5%

**Sabril**<sup>®</sup>  
vigabatrin  
500 mg tablet  
500 mg powder for oral solution

# Otsuka collaborations (Rexulti and idalopirdine)



# Financial terms and territory structure of the Otsuka alliance

- ★ Co-development and co-commercialization agreements with Otsuka in November 2011
- ★ Idalopirdine added to the alliance in March 2013
- ★ Selincro for Japan added to the alliance in October 2013

## Milestone payments

Payment to:



	Abilify Maintena	Rexulti	Idalopirdine	Selincro
Development milestones/upfront	USD 200m	USD 600m <sup>3)</sup>	USD 150m	EUR 105m*
Approval milestones	USD 275m <sup>1)</sup>	USD 300m <sup>2)</sup>	USD 300m	Un-disclosed
Sales milestones	Up to USD 425m depending on sales development		Up to USD 375m depending	Un-disclosed

1) USD 100m upon US approval, USD 75m upon EU approval in schizophrenia, and USD 50m US and EU for a second indication. 2) USD 100m (US) and USD 50m (EU) for each of the two first indications  
 3) Development milestones of up to USD 600m after which shared development costs between parties

## Lundbeck's share of revenue and costs

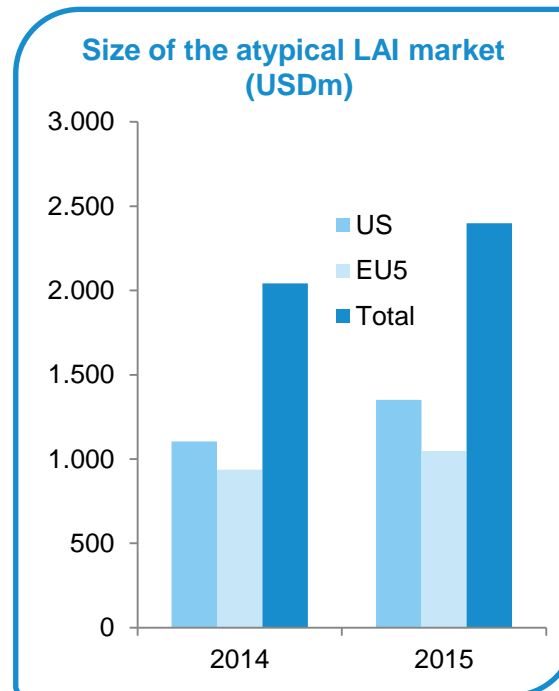
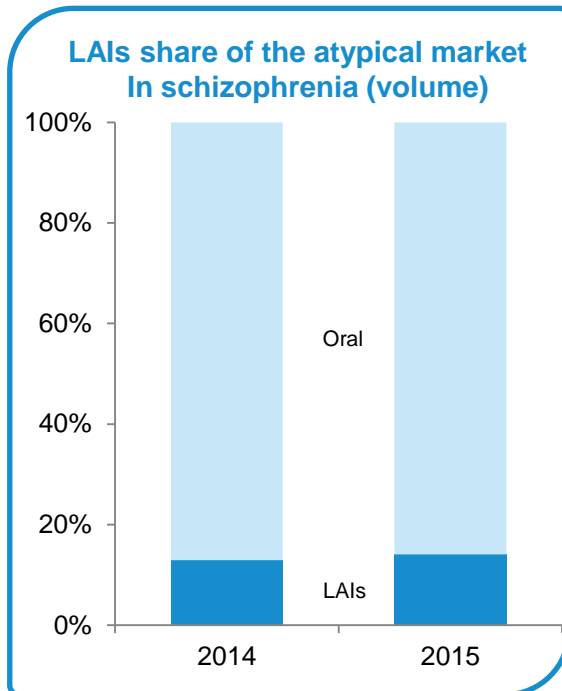
	Abilify Maintena	Rexulti	Idalopirdine	Selincro
USA	20%	45%	55%	-
EU-5, Nordic and Canada	50%	50%	50%	-
Other Lundbeck territories	65%**	65%**	~50%***	Un-disclosed

\* Includes sales milestones

\*\* All regions except Asia, Turkey and Egypt

\*\*\* All regions except Thailand and Vietnam

# The long-acting injectables (atypicals) in schizophrenia – 2015 vs. 2014



- ★ Sales of atypicals in schizophrenia was USD 5.9bn in 2015,...
- ★ ...of which the LAIs constituted USD 2.4bn
- ★ In volume 18.5% and 9.6% have been converted in EU and the US respectively
- ★ The LAI market grew 13% and 17% y/y in volume and value, respectively
- ★ Abilify Maintena's share increased from 6.7% to 15.6%

Source: Decision Ressource (data is US and EU5)  
LAI = Long-Acting Injectable anti-psychotics)





# The balance of Rexulti - a real opportunity to differentiate from existing treatments



**Mechanism of action:** Novel D<sub>2</sub>/D<sub>3</sub> receptor partial agonist; 5-HT<sub>1A</sub> partial agonist; 5-HT<sub>2A</sub> antagonist

## ACTIVATING SIDE EFFECTS:

- ★ Hyper-dopaminergic state
- ★ Akathisia, agitation, anxiety, insomnia
- ★ Aripiprazole – 25% akathisia<sup>1)</sup>

## SEDATING SIDE EFFECTS:

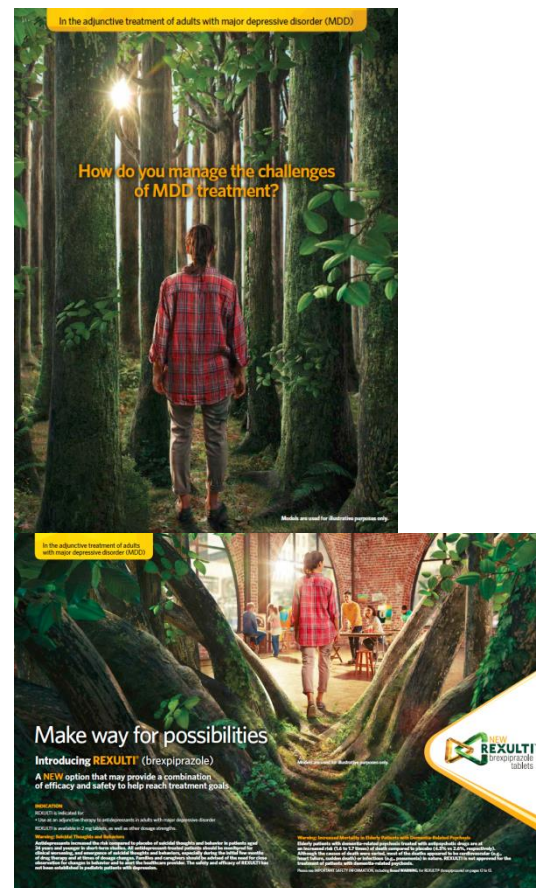
- ★ Hypo-dopaminergic state
- ★ Sedation, somnolence, fatigue, lethargy
- ★ Quetiapine fumarate – 37% somnolence<sup>2)</sup>

In the US, two antipsychotics are approved for adjunctive therapy in MDD

1) Abilify prescribing information. 2) Seroquel XR prescribing information

# Through its favourable benefit/risk profile Rexulti offers improved value in depression and schizophrenia

- ★ Rexulti is a **rationally designed** serotonin-dopamine activity modulator (SDAM) <sup>1)</sup>
- ★ Rexulti **significantly improves** symptoms of depression and schizophrenia
- ★ Rexulti has low levels of side effects that can impair patients' **functioning**
- ★ Rexulti has an excellent and **predictable** tolerability and safety profile



1) Kenji Maeda et al: "In Vitro Pharmacological Profile of Brexpiprazole, a Novel Serotonin-Dopamine Activity Modulator (APA 2014 Poster)

# Through its favourable benefit/risk profile adjunctive Rexulti offers improved value in depression

- ★ Early optimization of treatment is critical in case of inadequate response to treatment
- ★ Adjunctive Rexulti significantly improves symptoms of depression
- ★ Currently available antipsychotics are associated with tolerability concerns
- ★ Rexulti has low levels of side effects that can impair patients' functioning



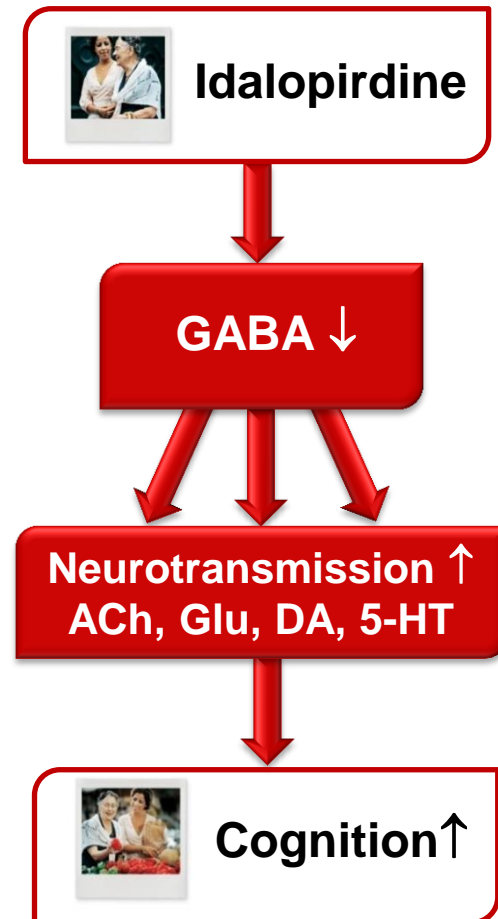
# Through its favourable benefit/risk profile adjunctive Rexulti offers improved value in schizophrenia

- ★ Second-generation antipsychotics have tolerability and safety issues
- ★ Rexulti has efficacy in positive, negative and other functionally-impairing symptoms
- ★ Symptom control without tolerability issues is required to maintain meaningful social interaction
- ★ Rexulti has an excellent and predictable tolerability profile



# Why could idalopirdine be a valuable new treatment in Alzheimer's?

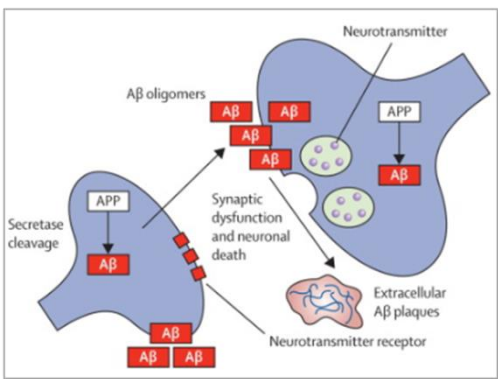
- ★ Through blockade of 5-HT<sub>6</sub> receptors idalopirdine has a **different mode of action** compared to existing symptomatic treatments
- ★ Blocking this particular kind of serotonin receptors (**5-HT<sub>6</sub> receptors**) has beneficial effects on several neurotransmitter systems in the brain
- ★ Idalopirdine has demonstrated beneficial effects on **cognition** in animal models
- ★ Idalopirdine has demonstrated beneficial effects on cognition in **AD patients** on stable donepezil treatment



# Lu AF20513 – Anti-A $\beta$ active vaccine concept; getting beyond symptomatic treatment

## Phase I study<sup>1)</sup>

- ★ 35 patients from centres in Europe
- ★ Expected completion: mid-2017
- ★ Patients with mild AD (MMSE 19-26)
- ★ Four injections of Lu AF20513
- ★ Purpose:
  - ★ Evaluate safety and tolerability
  - ★ Measure A $\beta$ -specific antibody titer



## Wanted from study

- ★ Safe and tolerable:
  - ★ Low level of ARIA-E and ARIA-H<sup>2)</sup>
  - ★ No meningo-encephalitis
  - ★ High antibody responder rate
  - ★ Fast antibody response (< 6 months)
  - ★ High affinity A $\beta$  specific antibodies (for CNS clearance)

## Not wanted from study

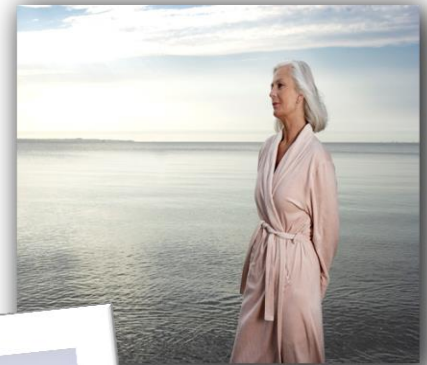
- ★ A $\beta$  specific T-cells
- ★ High IgM over IgG ratio
- ★ Very low responder rate

- 1) NCT02388152
- 2) Amyloid Related Imaging Abnormalities (ARIA): ARIA-E refers to the MR signal alterations thought to represent vasogenic edema (VE) and related extravasated fluid phenomena. ARIA-H refers to the MR signal alterations attributable to microhemorrhages (mH) and hemosiderosis



# Broad-based Alzheimer's pipeline

- ★ **Idalopirdine** demonstrated positive phase II results as add-on to donepezil in moderate Alzheimer's
  - ★ Phase III commenced in October 2013
- ★ **Rexulti** in patients with agitation associated with dementia of the Alzheimer's type
  - ★ Phase III commenced in July 2013
- ★ **Lu AF20513** to be the next generation active vaccination with potential to modify disease progression
  - ★ An active anti-A $\beta$  vaccine candidate
  - ★ Phase I commenced in Q1 2015



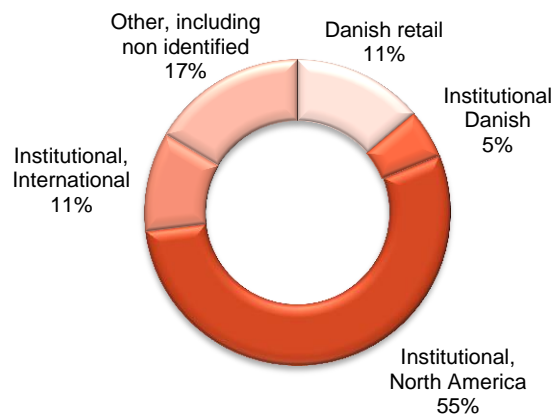
# Finance & other





# Ownership and the Lundbeck Foundation

## Composition of free float ownership (end 2015)



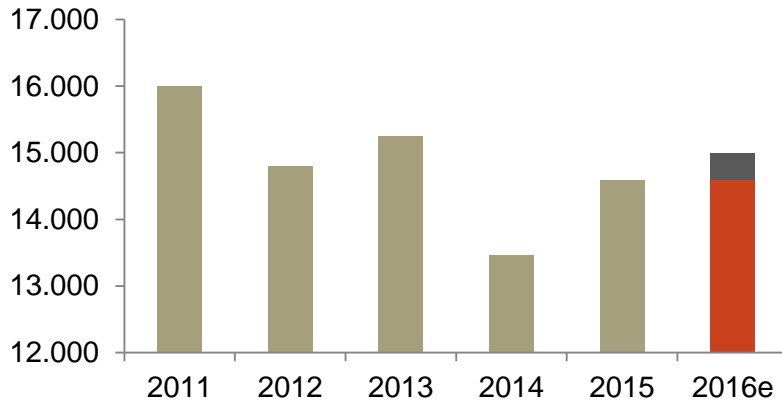
- ★ Free float is 30%
- ★ Free float of approximately 60m shares is traded approximately once over annually

## LUNDBECKFONDEN

- ★ Commercial foundation established in 1954 by Grete Lundbeck, widow of the founder
- ★ The main objective is to
  - ★ Maintain and expand the activities of the Lundbeck Group
  - ★ Provide financial support for research of the highest quality in biomedical and natural sciences
- ★ Ownership and value (2015):
  - ★ **Lundbeck** (70%): DKK 32,333m
  - ★ **ALK-Abello** (42%/69%): DKK 3,574m
  - ★ **Falck** (57%): DKK 3,422m
  - ★ **LundbeckFond Invest**: DKK 13,937m
  - ★ **Ventures & Emerge**: DKK 2,173m

# Transformation of Lundbeck on the way

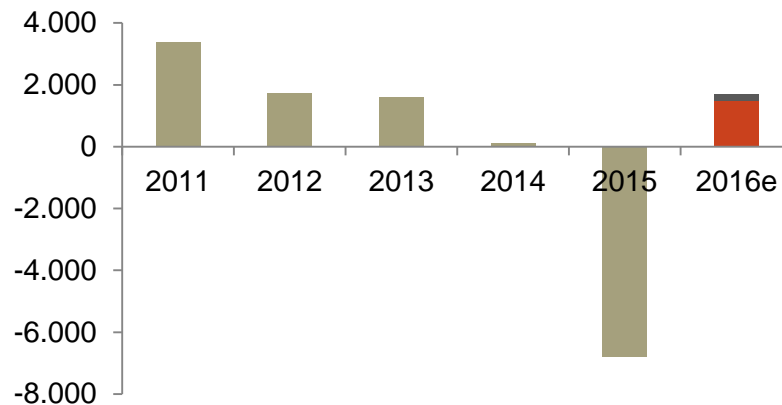
Revenue (DKKbn)



## Revenue drivers in H1 2016

- ★ Strong positive momentum for key products
- ★ Strong growth in US franchise
- ★ Negative impact from generic erosion

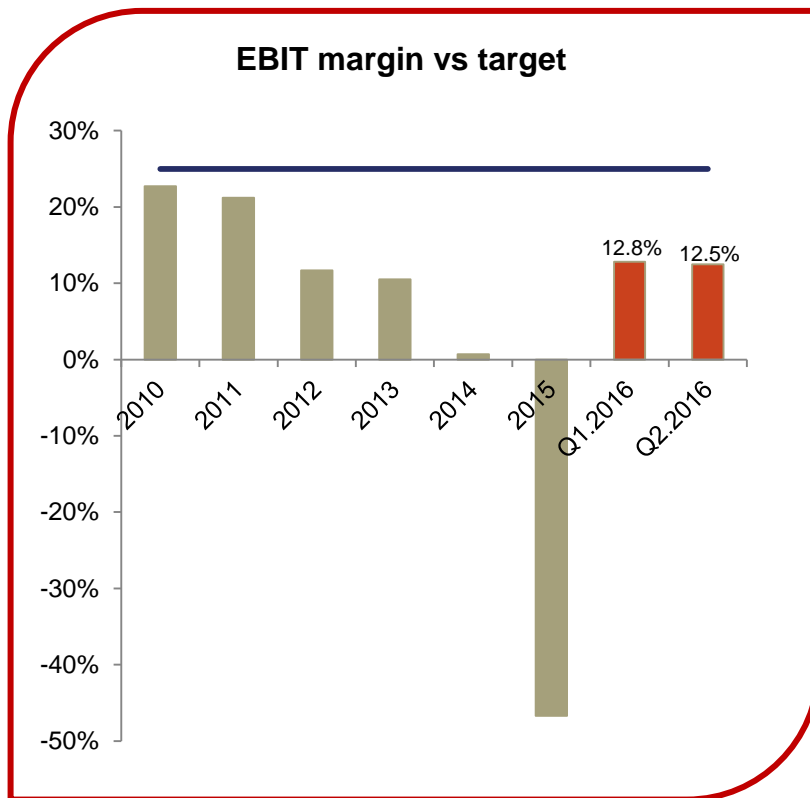
EBIT (DKKbn)



## Operating profit (EBIT)

- ★ Restructuring programme impacts with DKK 7bn in 2015
- ★ Substantial investments in launch programme and late-stage pipeline
- ★ Benefits from restructuring programme already visible

# Lundbeck's EBIT margin vs. long-term target



- ★ Strong improvement in EBIT margin
- ★ Margin benefits are coming faster than expected
- ★ Strong margin improvement sustainable

## Continued margin improvements:

- ★ Effects from restructuring programme
- ★ Growth in key products with higher margins
- ★ Erosion of low-margin products such as Azilect and Xenazine

# Q2 2016 - Geographic distribution of revenue - 1

DKKm	FY 2015	Q2 2016	Q2 2015	Growth	Growth in local currency
<b>USA:</b>					
Abilify Maintena	324	110	78	43%	47%
Brintellix/Trintellix	403	124	94	32%	34%
Northera	475	250	106	136%	143%
Onfi	1,757	584	403	45%	46%
Rexulti	117	193	-	-	-
Sabril	985	317	241	31%	36%
Xenazine	2,182	375	612	(39%)	(38%)
Other pharmaceuticals	110	41	13	205%	221%
Total revenue	6,353	1,994	1,547	29%	30%

## Q2 2016 - Geographic distribution of revenue - 2

DKKm	FY 2015	Q2 2016	Q2 2015	Growth	Growth in local currencies
<b>EUROPE:</b>					
Abilify Maintena	281	133	63	107%	109%
Brintellix	105	50	17	189%	181%
Cipralex	893	181	239	(24%)	(24%)
Other pharmaceuticals	2,617	342	672	(49%)	(48%)
Total revenue	3,896	706	991	(29%)	(28%)
<b>INTERNATIONAL MARKETS:</b>					
Abilify Maintena	64	36	16	134%	148%
Azilect	175	28	39	(28%)	(22%)
Brintellix	121	70	29	149%	179%
Cipralex/Lexapro	1,698	402	432	(7%)	(15%)
Ebixa	576	120	141	(16%)	(7%)
Other pharmaceuticals	1,193	281	333	(16%)	(9%)
Total revenue	3,827	937	990	(5%)	(4%)

## Q2 2016 - Cash generation

DKKm	Q2 2016	Q2 2015	FY 2015
Cash flows from operating activities	435	(1,384)	197
Cash flows from investing activities	(59)	-	(2,842)
<b>Cash flows from operating and investing activities</b>	<b>376</b>	<b>(1,384)</b>	<b>(2,645)</b>
Cash flows from financing activities	(326)	21	501
<b>Net cash flow for the period</b>	<b>50</b>	<b>(1,363)</b>	<b>(2,144)</b>
Cash and bank balances, end of period	1,436	1,787	1,504
Securities	17	18	17
Interest-bearing debt	(3,231)	(3,266)	(3,770)
<b>Interest-bearing debt, cash, bank balances and securities, net end of year</b>	<b>(1,778)</b>	<b>(1,461)</b>	<b>(2,249)</b>

## Q2 2016 - Balance sheet

DKKm	30.06.16	31.12.15
Intangible assets	9,127	9,794
Other non-current assets	3,884	3,871
Current assets	7,289	7,660
<b>Assets</b>	<b>20,300</b>	<b>21,325</b>
Equity	8,862	8,785
Non-current liabilities	4,195	4,792
Current liabilities	7,243	7,748
<b>Equity &amp; liabilities</b>	<b>20,300</b>	<b>21,325</b>
Cash and bank balances	1,436	1,504
Securities	17	17
Interest-bearing debt	(3,231)	(3,770)
<b>Interest-bearing debt, cash, bank balances and securities, net end of year</b>	<b>(1,778)</b>	<b>(2,249)</b>

# Costs - yearly figures

DKKm	Growth, Y/Y, %				
	2015	2014	2013	2015	2014
Revenue	<b>14,594</b>	13,468	15,258	8%	(12%)
Cost of sales	<b>5,395</b>	4,160	4,038 <sup>3)</sup>	30%	3%
Sales and distribution costs	<b>6,706</b>	5,164	4,530	30%	14%
Administrative expenses	<b>1,160</b>	1,134	2,140 <sup>4)</sup>	2%	(47%)
R&D	<b>8,149</b>	2,911 <sup>2)</sup>	2,951	180%	(1%)
Total costs	<b>21,410<sup>1)</sup></b>	13,369	13,659	60%	(2%)
EBIT	<b>(6,816)</b>	99	1,599	-	(94%)
Core EBIT	<b>847</b>	1,228	2,282	(31%)	(46%)
<i>Cost of sales</i>	<b>37%</b>	31%	26%		
<i>Sales and distribution costs</i>	<b>46%</b>	38%	31%		
<i>Administrative expenses</i>	<b>8%</b>	8%	14%		
<i>R&amp;D</i>	<b>56%</b>	22%	19%		
<i>EBIT-margin</i>	<b>(47%)</b>	1%	10%		

Included are 1) Restructuring costs of DKK 7bn. 2) writedown of desmoteplase of DKK 309m; 3) writedown of Sycrest of DKK 210m; 4) EU fine of DKK 700m and restructuring charge of DKK 200m



# For more information please contact Investor Relations

## Share information

Lundbeck's shares are listed on the stock exchange in Copenhagen under the symbol "LUN".

Lundbeck has a sponsored Level 1 ADR programme listed in the US (OTC) under the symbol "HLUYY".

For additional company information, please visit Lundbeck at: [www.lundbeck.com](http://www.lundbeck.com)

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Thank you!

Lundbeck

