



# INVESTOR & ANALYST PRESENTATION

*Q2 2014 - Summer 2014*



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## Q2 – New product launches on track

### Operations

Brintellix: More than 120,000 prescriptions in total since launch

Northera: To strengthen Lundbeck's US neurology franchise

Abilify Maintena/Selincro: Market access going according to plan

### R&D

Brexiprazole: Regulatory process initiated in the US

Desmoteplase: Effect in target population, however, desmoteplase did not meet the primary endpoint of the study (DIAS 3)

### Financials

Core revenue only slightly down in the quarter primarily as a result of strong New Product sales

Financial guidance maintained for 2014

**ON TRACK TO DELIVER LONG-TERM GROWTH**



# US neurology franchise up 33%\* - to be further strengthened by Northera

## Current neurology franchise:



★ Up 102%\* to DKK 217m



★ Up 14%\* to DKK 394m



★ Up 27%\* to DKK 176m

## Northera:

- ★ FDA approved in February 2014 for nOH\*\*
- ★ Expected launch during Autumn 2014
- ★ Significant unmet medical need
- ★ Growing market with aging US population
- ★ Projected annual sales potential of DKK >2bn



\* Local currency

\*\*nOH = neurogenic orthostatic hypotension

# Lundbeck's other platforms for long-term growth

New Products\* category up 41% in local currency to DKK 1bn in Q2 2014



- ★ Abilify Maintena continues to take share in the US
- ★ Market access progressing according to plan



- ★ Market share is volatile but develops as expected – end-June market share was 15%\*\*



- ★ Positive development in market access processes in major markets like UK, France and Spain
- ★ Recently launched in Spain, fully reimbursed



- ★ Treanda reached DKK 49m (+149% l.c.) in Canada

\*New Products include Xenazine, Sabril, Sycrest, Lexapro (Japan), Onfi, Treanda, Selincro, Abilify Maintena and Brintellix, \*\*Preliminary value market share for June 2014

# Good financial performance in the Q2 2014

★ <b>Core revenue</b> <ul style="list-style-type: none"><li>- Modest decline</li><li>- New Products up 32%</li><li>- US product portfolio up 37%</li></ul>	DKK 3.4bn
★ <b>Core EBIT</b> <ul style="list-style-type: none"><li>- Continued focus on operational and sourcing efficiencies through Project <i>Fit-for-the-Future</i></li></ul>	DKK 0.4bn
★ <b>Core EBIT margin</b> <ul style="list-style-type: none"><li>- Stable cost development – with significant launch investments</li></ul>	13%
★ <b>Operating cash flow</b>	DKK 0.5bn

# Guidance for 2014 maintained

- ★ **Unusual number** of variables
  - ★ E.g. FX headwind, launch uptake, generic erosion
- ★ Continued **elevated investments** in sales, promotion and R&D
- ★ Amortization will increase to DKK **~800 million**
- ★ **Major part** of earnings recognized in H1 2014

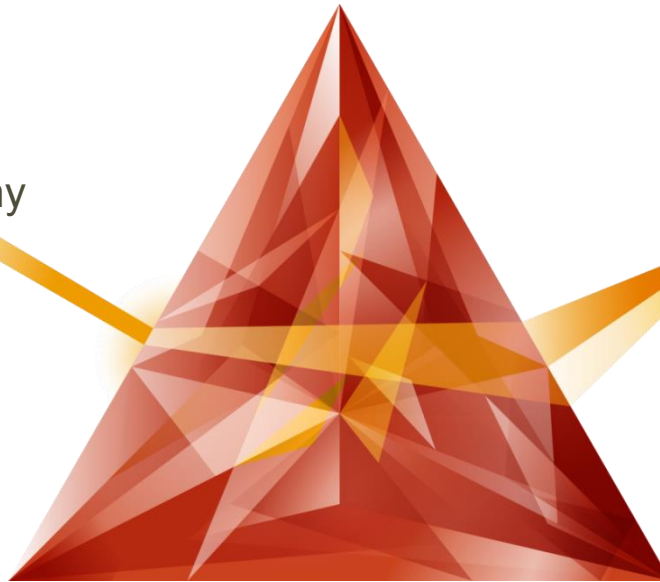
## Financial guidance 2014

DKK billion	2013 Actual	2014 Forecast
Revenue	15.3	~13.5
EBIT	1.6	0.0-0.5
Core EBIT	2.3	0.9-1.4

# Executing on Lundbeck's strategy

## The “Old” Lundbeck

- ★ “European” company
- ★ “One product” company



## The “New” Lundbeck

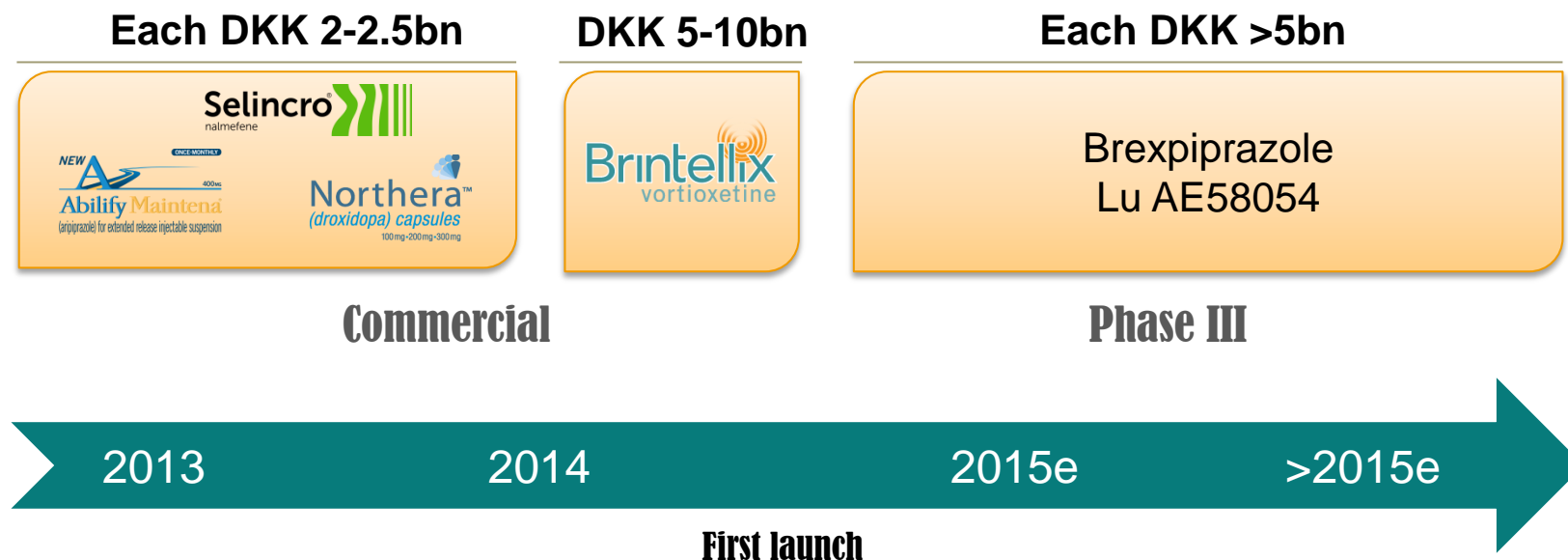
- ★ Global growth platform
- ★ Multiple product company
- ★ Executing on new product launches
- ★ Drive growth of diversified portfolio
- ★ Deliver on late stage pipeline



# Lundbeck invests for long-term growth... ...balances short-term results



# Lundbeck products have business transforming potential



# A new psychiatry portfolio of innovative therapies

## Abilify Maintena

- Market access progressing according to plan, with some early success
- Encouraging initial uptake

## Brintellix

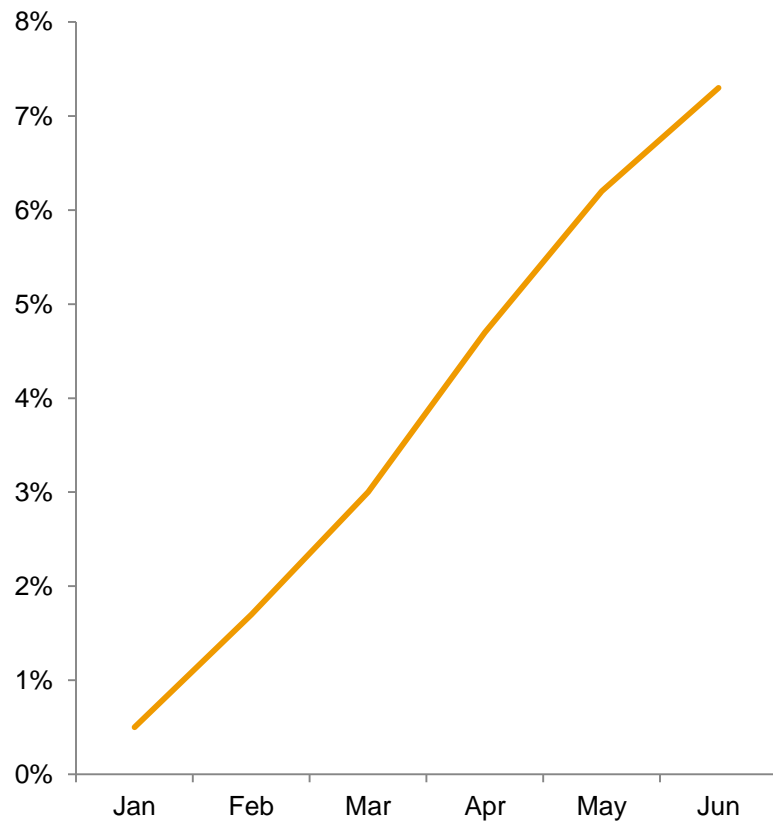
- Feedback from prescribers very positive
- Launches in International Markets and Europe during H2

## Brexpiprazole

- US regulatory process initiated
- Data to be presented later in 2014

# Brintellix launch encouraging in the US

Branded value share (monthly)



- ★ Solid market share gains
- ★ Several new studies presented
- ★ Brintellix revenue DKK 38m in Q2
- ★ Market access process in International Markets and Europe on track



Source: IMS Health

# Brintellix on track to deliver on expectations

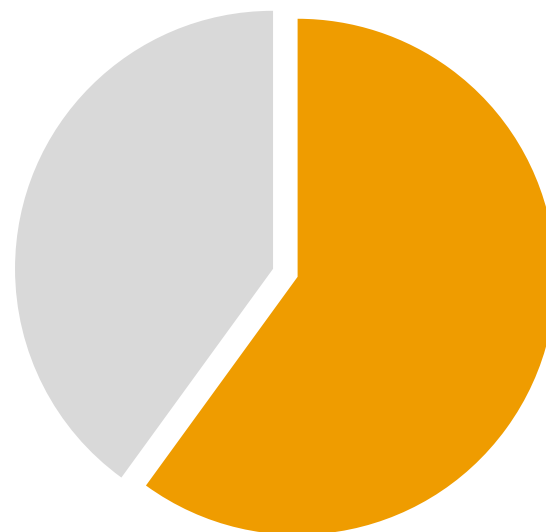
★ **>120,000** total Brintellix prescriptions achieved

★ **~50,000** Brintellix treated patients

★ **~20,000** total 'unique' Brintellix prescribers

★ Brintellix has the **highest number of new writers** among the branded agents

**Psychiatry accounted for majority of Brintellix cumulative TRx volume**



■ Psychiatry ■ Other

# R&D Update





# Lundbeck invests to develop late-stage pipeline

## Regulatory processes

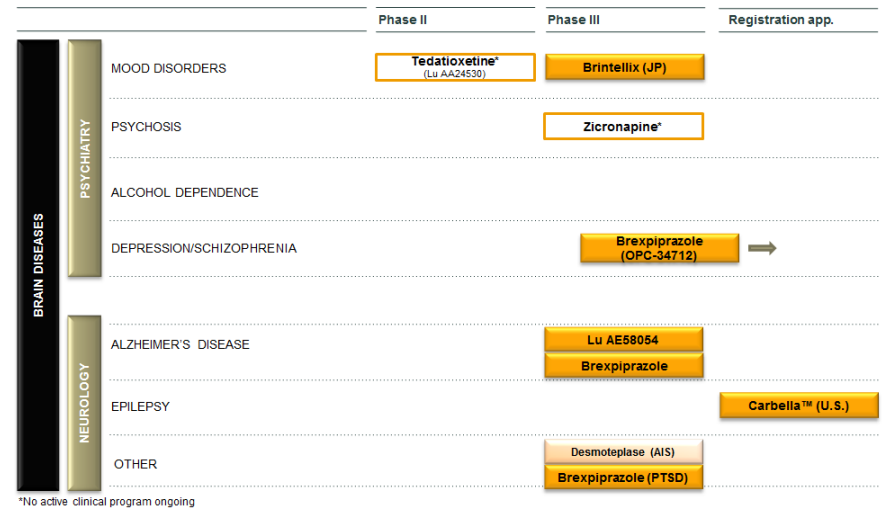
- ★ Brexpiprazole submitted for regulatory approval in the US in two indications

## Desmoteplase

- ★ DIAS 3 study did not meet the primary endpoint, but supportive findings in target population
- ★ Review of data ongoing

## Brexpiprazole

- ★ Significant data presentation at medical conferences later in 2014



# Unlocking depression



- ✓ **Advancing understanding and treatment of depression represents major commercial opportunity**
  - *High patient churn in one of the largest pharmaceutical markets*
- ✓ **Cognitive dysfunction in depression**
  - *Opportunity to raise awareness among patients, physicians and payers*
- ✓ **Unique pharmacology supports unique clinical profile**

# Despite progress and wide range of available therapies, no current therapy addresses all needs

## UNMET NEEDS IN DEPRESSION

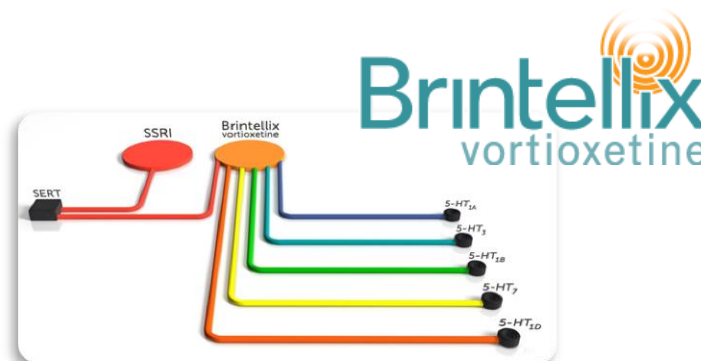
- Inadequate treatment response in many patients, despite treatment switches<sup>1</sup>
- Cognitive symptoms in depressed patients are not adequately treated with current antidepressants<sup>2-4</sup>
- Nausea, sexual dysfunction, insomnia and weight gain are common tolerability issues with e.g. SSRIs and SNRIs<sup>5-8</sup>



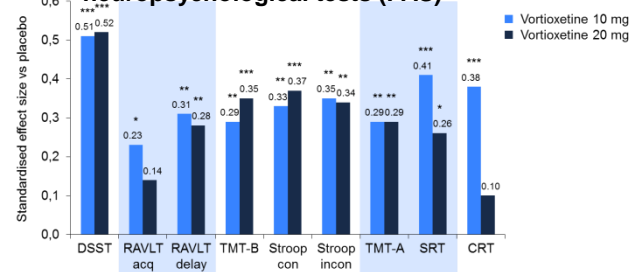
1. Rush AJ et al. 2006; 2. Uher R et al. 2012; 3. Wihall A et al. 2009; 4. Jaeger J et al. 2006; 5. Bull 2002; 6. Kelly 2008; 7. Cassano 2004; 8. Masand 2003

# Brintellix – approved with strong and meaningful label

- ★ Multimodal mode of action<sup>1-4</sup>
- ★ Broad antidepressant efficacy<sup>5-15</sup>, including:
  - ★ Patients with severe depression<sup>6</sup>
  - ★ Depressed patients with high levels of anxiety<sup>9</sup>
  - ★ The depressed elderly (≥65 years)<sup>12</sup>
  - ★ Depressed patients with an inadequate response to SSRI/SNRI (*REVIVE*)<sup>14</sup>
- ★ Efficacy in cognitive dysfunction of depression (*CONNECT* and *FOCUS*)<sup>12,13</sup>
- ★ Improves overall patient functioning and quality of life<sup>5,7,9,11,16</sup>
- ★ Well tolerated with low discontinuation rates<sup>5,17</sup>



Standardised effect size (Cohen's *d*) for the neuropsychological tests (FAS)<sup>18</sup>

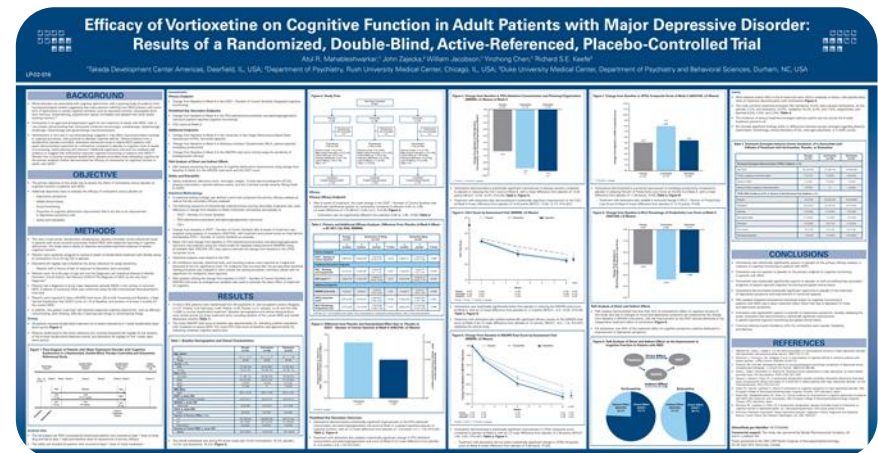


\*p<0.05; \*\*p<0.01; \*\*\*p<0.001 vs placebo;  
nominal p-values with no adjustment for multiplicity  
con/congruent; incon/incongruent

1. Bang-Anderson et al. J Med Chem 2011;54(9):3206–3221; 2. Mørk et al. J Pharmacol Exp Ther 2012;340(3):666–675; 3. Bétry et al. Int J Neuropsychopharmacol 2013;16(5):1115–1127; 4. Pehrson et al. Eur Neuropsychopharmacol 2013;23(2):133–145; 5. Vortioxetine EPAR; 6. Alvarez et al. Int J Neuropsychopharmacol 2012;15(5):589–600; 7. Baldwin et al. Eur Neuropsychopharmacol 2012;22(7):482–491; 8. Henigsberg et al. J Clin Psychiatry 2012;73(7):953–959; 9. Boulenger et al. Int Clin Psychopharmacol 2013;Epub ahead of print; 10. Mahabeshwarkar et al. Poster at APA 2013; 11. Jacobsen et al. Poster at APA 2013; 12. Katona et al. Int Clin Psychopharmacol 2012;27(4):215–223; 13. McIntyre et al. Poster at ACNP 2013; 14. Häggström et al. Poster at EPA 2013; 15. Boulenger et al. J Psychopharmacol 2012;26(11):1408–1416; 16. Florea et al. Poster at ISPOR 2013; 17. Vortioxetine SPC, 2013. 18. McIntyre; ACNP 2013 poster

# CONNECT: Now clinical data in cognitive dysfunction from four Brintellix studies in patients with MDD

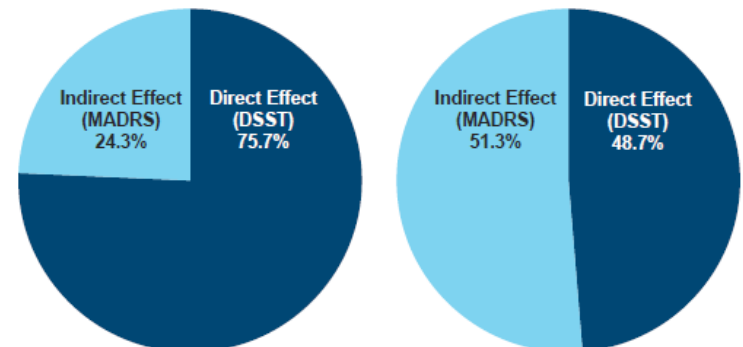
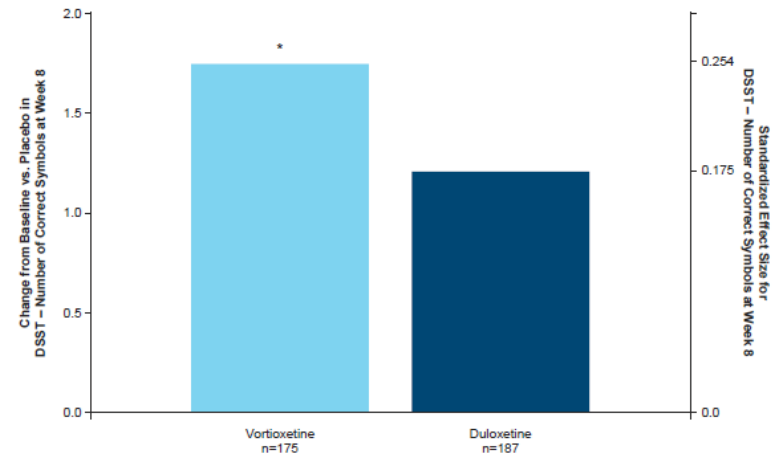
- ★ 602 patients enrolled
- ★ Mainly Europe and USA
- ★ 3 arms: 10/20 mg Brintellix, 60 mg duloxetine or placebo
- ★ MADRS total score  $\geq 26$ , a DSST score of  $< 70$ , and duration of at least 3 months for the current episode
- ★ In addition, the patient must have self-reported subjective cognitive dysfunction



Atul R. Mahableshwarkar; John Zajecka; William Jacobson; Yinzhong Chen; Richard S.E. Keefe: "Efficacy of Vortioxetine on Cognitive Function in Adult Patients with Major Depressive Disorder: Results of a Randomized, Double-Blind, Active-Referenced, Placebo-Controlled Trial": Poster presented at the 29th CINP World Congress of Neuropsychopharmacology, 22–26 June 2014, Vancouver, Canada. (NCT01564862)

# CONNECT: Brintellix “*stat-sig*” superior to placebo on the primary and on both key secondary endpoints

- ★ Primary endpoint (DSST at Week 8):
  - ★ Brintellix was significantly superior to placebo
  - ★ Duloxetine was not significantly different from placebo
- ★ Additional functional endpoints:
  - ★ UPSA\*: Brintellix, but not duloxetine, significantly superior to placebo
- ★ A pre-specified path-analysis indicated Brintellix’s impact on cognitive performance and functional capacity was primarily a direct treatment effect



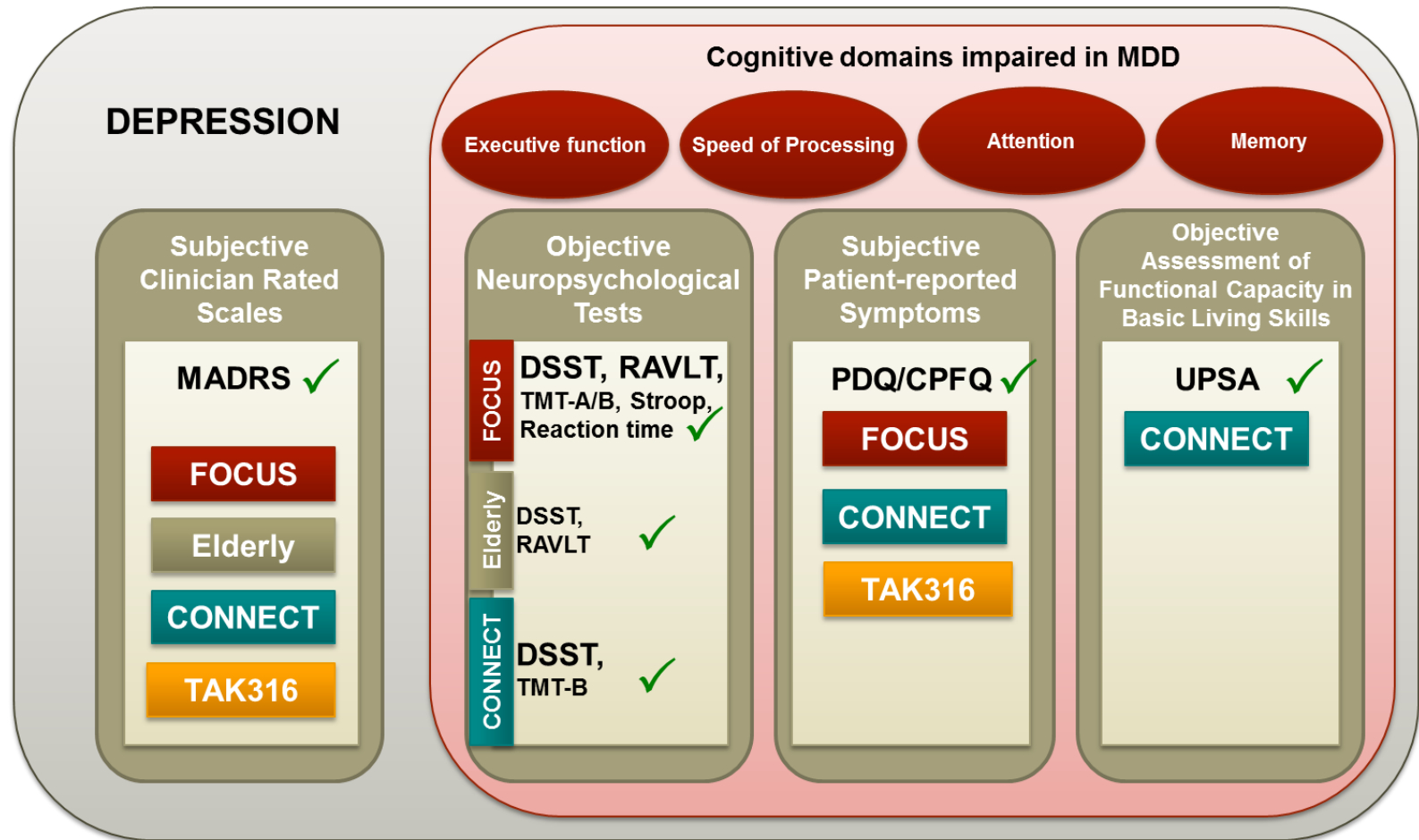
\*) UPSA: University of San Diego Performance-Based Skills Assessment

Source: Atul R. Mahableshwarkar; John Zajecka; William Jacobson; Yinzhong Chen; Richard S.E. Keefe: "Efficacy of Vortioxetine on Cognitive Function in Adult Patients with Major Depressive Disorder: Results of a Randomized, Double-Blind, Active-Referenced, Placebo-Controlled Trial"

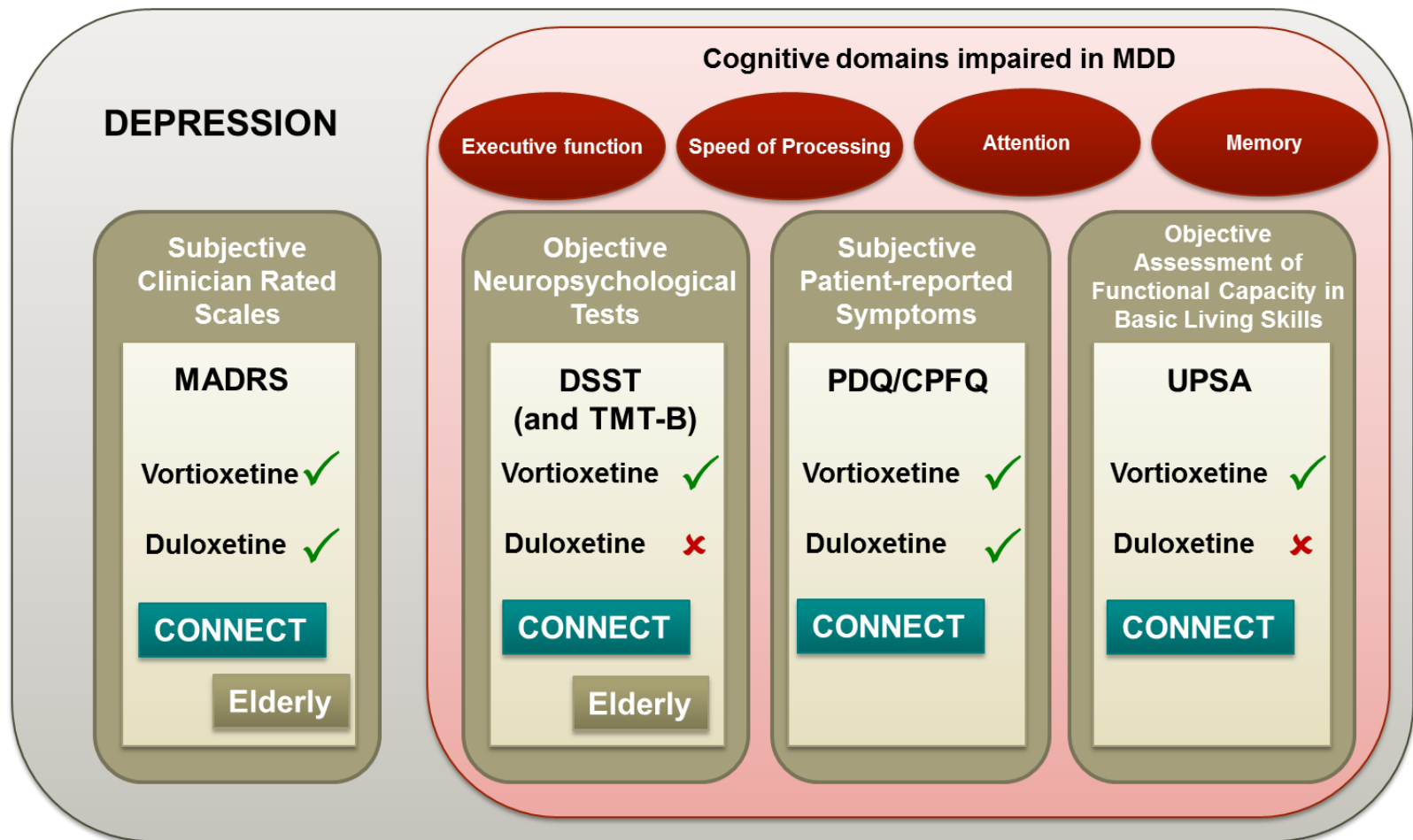


# Brintellix improves cognitive dysfunction in acute MDD

## – superior to placebo



# Brintellix improves cognitive dysfunction in acute MDD – a distinct profile in two active-referenced studies



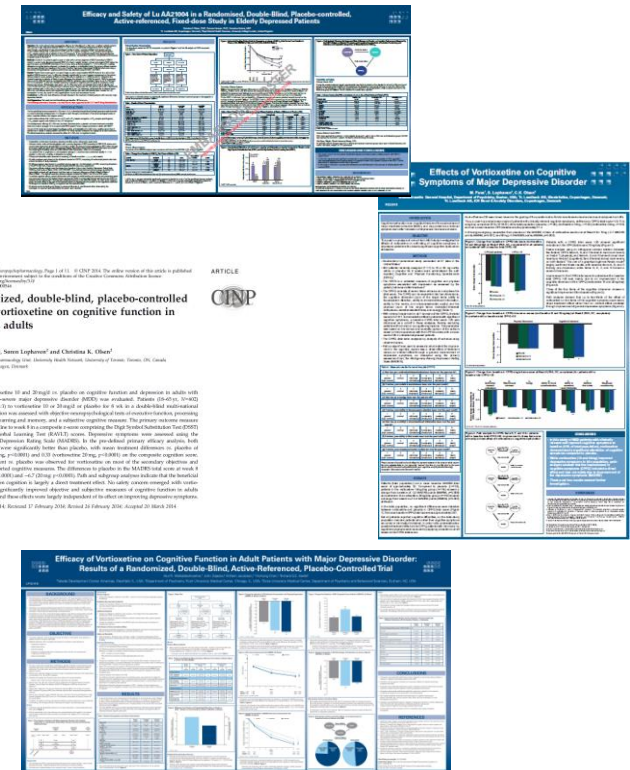
Significant vs placebo



NOT significant vs placebo

# Clinical data support Brintellix for cognitive dysfunction in major depression

- ★ Four clinical studies support a role for Brintellix in cognitive function associated with major depression
- ★ Study in elderly MDD patients (published in International Clinical Psychopharmacology, May 2012)<sup>1)</sup>
- ★ *FOCUS* (published in International Journal of Neuropsychopharmacology, May 2014)<sup>3)</sup>
- ★ *CONNECT* (presented at CINP2014)<sup>4)</sup>
- ★ *TAK316* (presented at ECNP2013)<sup>2)</sup>
- ★ Brintellix improves self-reported cognitive function as well as objective performance-based functioning (UPSA)



1) NCT00811252. 2) M. Fava, S. Lophaven, C.K. Olsen: "Effects of Vortioxetine on Cognitive Symptoms of Major Depressive Disorder"; NCT01163266. 3) NCT01422213. 4) NCT01564862.

# SOLUTION: Brintellix at least as efficacious as venlafaxine on the primary efficacy endpoint

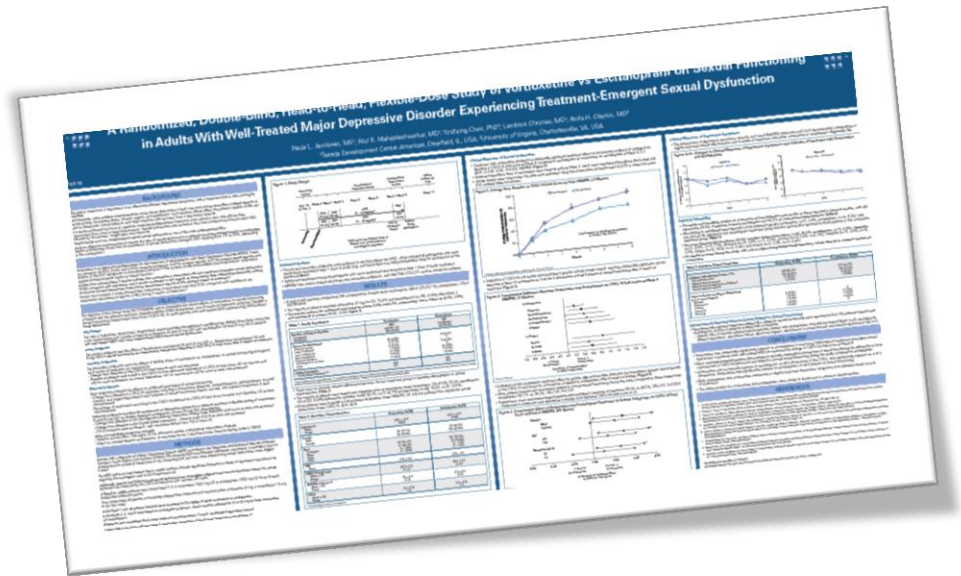
- ★ 424 patients (FAS) enrolled
- ★ China, South Korea, Taiwan, Thailand
- ★ 10 mg Brintellix or 150 mg venlafaxine (1:1)
- ★ MADRS total score  $\geq 26$  and a CGI-S score  $\geq 4$



Gang Wang, Mette Gislum, Gleb Filippov: "Randomised, Double-Blind Study of Vortioxetine versus Venlafaxine in Adults with Major Depressive Disorder". Data presented at the Congress of the International College of Neuropsychopharmacology (CINP); poster session (P-42-33 Depression C)

# TAK-318/CSFQ: Brintellix statistically significantly superior to escitalopram in improving SSRI-induced TESD

- ★ 447 patients enrolled
- ★ USA and Canada
- ★ 10 or 20 mg Brintellix or escitalopram (1:1)
- ★ Patients with well treated MDD who were experiencing SSRI-induced sexual dysfunction



CSFQ: Changes in Sexual Functioning Questionnaire  
TESD: Treatment-Emergent Sexual Dysfunction

Paula L. Jacobsen, MS; Atul R. Mahabeshwarkar, MD; Yinzhong Chen, PhD; Lambros Chrunos, MD; Anita H. Clayton, MD: "A Randomized, Double-Blind, Head-to-Head, Flexible-Dose Study of Vortioxetine vs Escitalopram on Sexual Functioning in Adults With Well-Treated Major Depressive Disorder Experiencing Treatment-Emergent Sexual Dysfunction". Presented at the 29th CINP World Congress of Neuropsychopharmacology 22–26 June 2014, Vancouver, Canada. (NCT01364649)

# Brexpiprazole to report additional headline results from phase III clinical program in H2

## ★ Major Depression

- Significant patient “churn” in search for response, remission and recovery
- Late but growing use of atypicals due to safety and tolerability concerns

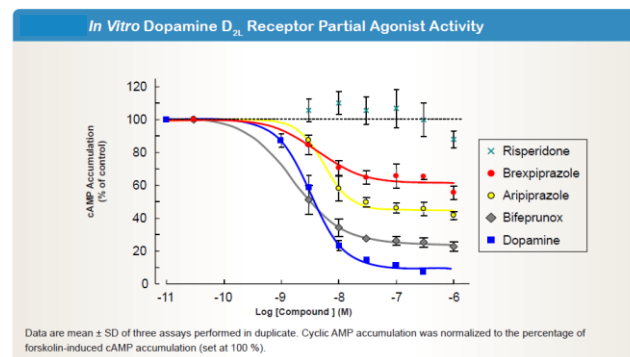
## ★ Schizophrenia

- Increased disease understanding: normalizing hyper- and hypo-dopaminergic states; finding the “sweet spot”

Additional development programs for agitation in Alzheimer’s disease, post-traumatic stress disorder (PTSD)

## Brexpiprazole

- ★ Potentially best-in-class tolerability
- ★ Opportunity to capture space between “activation” (aripiprazole) and “sedation” (quetiapine)
- ★ Unique and distinct pharmacology;<sup>1)</sup> potentially optimal dopamine modulator with strong serotonergic effect

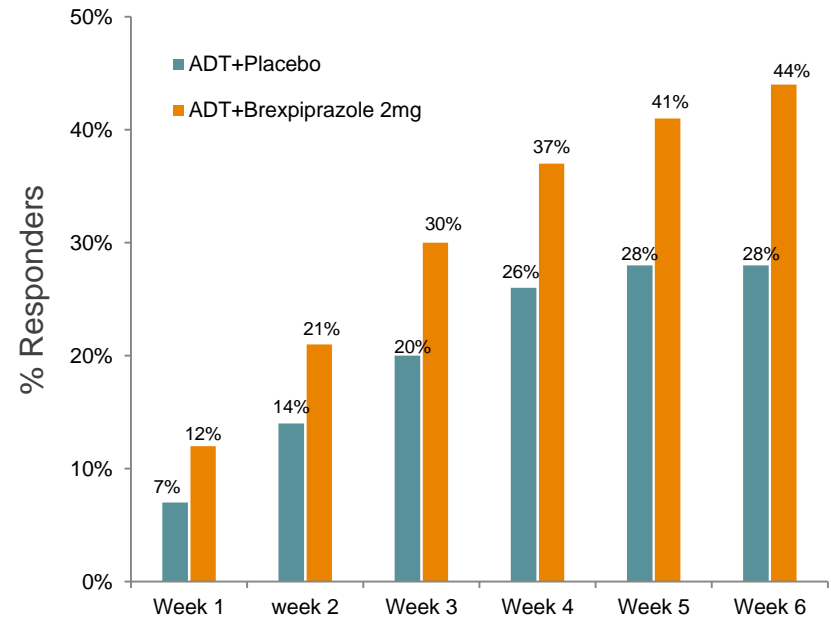


1) Brexpiprazole is a serotonin-dopamine activity modulator that combines 5-HT<sub>1A</sub> receptor partial agonism and low-efficacy D<sub>2L</sub> receptor partial agonism with antagonist activity on a variety of 5-HT and α-adrenaline receptors



# Brexpiprazole submitted for regulatory approval process in US for schizophrenia and adjunct MDD

- ★ Brexpiprazole is a novel serotonin-dopamine activity modulator (SDAM)<sup>1)</sup>
- ★ Filing dossier includes 7 phase II and III studies
- ★ First adjunct MDD data presented at EPA in March 2014<sup>2)</sup>
  - ★ Statistical significant outcome on both primary and secondary endpoints
  - ★ Well-tolerated
  - ★ More than 90% of patient participants completed the trial



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

2) M.E. Thase et al: "Efficacy and safety of adjunctive brexpiprazole (OPC-34712) in major depressive disorder (MDD): A phase III, randomized, placebo-controlled study"; EPA 2014 (abstract)

## Expected main events in 2014

- ★ Launch Brintellix in the US ✓
- ★ Brexpiprazole data on first MDD study out of two at EPA in March ✓
- ★ Start the launch of Abilify Maintena in Europe ✓
- ★ Clinical data presentations at medical conferences for Brintellix ✓
- ★ Desmoteplase: Headline conclusions from DIAS-3 ✓
- ★ Brexpiprazole: FDA submission ✓
- ★ Brexpiprazole: FDA acceptance of file
- ★ Northera: Launch in the US
- ★ Selincro: HTA assessment in selected major European markets
- ★ Brintellix: Launch in Europe and International Markets
- ★ Brexpiprazole: Clinical data presentations



## ON TRACK TO DELIVER LONG-TERM GROWTH

- New Products continue the solid momentum
- Additional products to be launched
- US psychiatry infrastructure established
- Expansion in International Markets

# Appendix

- ★ **Lundbeck overview**
- ★ Commercial operations
- ★ Pipeline
- ★ Financials
- ★ The CNS market
- ★ The Lundbeck share

# Our vision, mission and values



## OUR VISION

...is to become a world leader in psychiatry and neurology



## OUR MISSION

...is to improve the quality of life of people suffering from psychiatric and neurological disorders



## OUR VALUES

**Imaginative** – Dare to be different  
**Passionate** – Never give up  
**Responsible** – Do the right thing

# Lundbeck is involved in indications costly to society and with high unmet medical needs

## DALY\* ranking (non communicable conditions)

Rank	Disease
1	Cancer diseases
<b>2</b>	<b>Unipolar depressive disorder and anxiety</b>
3	Ischaemic heart disease
<b>4</b>	<b>Cerebrovascular disease</b>
5	Chronic obstructive pulmonary disease
6	Refractive errors
7	Hearing loss, adult onset
8	Congenital anomalies
<b>9</b>	<b>Alcohol use disorders</b>
10	Diabetes mellitus
11	Cataracts
<b>12</b>	<b>Schizophrenia</b>
.....	.....
<b>15</b>	<b>Bipolar disorder</b>
.....	.....
<b>17</b>	<b>Alzheimer and other dementias</b>
...	...
<b>23</b>	<b>Epilepsy</b>
...	...
<b>40</b>	<b>Parkinson's disease</b>

\*) Disability adjusted life years, Source: Lundbeck based on Global Burden of Disease 2004, WHO

- ★ Lundbeck's focus areas rank high in terms of burden to society
- ★ These conditions are often of a serious nature and devastating for patients and family...
- ★ ... and are characterised by high unmet needs
- ★ CNS disorders are difficult to treat because of...
  - ★ the complexity of the brain
  - ★ high level of adverse effects
  - ★ the blood/brain barrier (BBB)

# CNS comprises many disease areas and diseases

## Psychiatry



### Multiple sub-classifications

#### Mood Disorders

- MDD
- TRD
- Seasonal Affective Dis.
- Melancholic Depression
- Stress-related

#### Anxiety Disorders

- GAD
- Panic Disorder
- Social Anxiety
- OCD
- PTSD

#### Psychotic Disorders

- Schizophrenia
- Bipolar disorder
- Schizoaffective disorder
- Delusional disorders

#### Personality Dis.

- Paranoid PD
- Borderline PD
- Schizoid PD
- Schizotypal PD
- others

#### Addiction

- Alcohol Dependence
- Nicotine addiction
- Drug addiction
- Compulsive shopping
- Pathological gambling

#### Development Dis.

- Autism
- ADHD
- Asperger's
- Fragile-X
- Down's Syndrome

#### Eating Disorders

- Anorexia nervosa
- Bulimia nervosa
- Binge eating disorder

 = Lundbeck presence

## Neurology



### Multiple sub-classifications

#### Movement Disorders

- Parkinson's Disease
- Huntington's Disease
- Friedreich's Ataxia
- Restless legs syndrome
- Tourette's syndrome

#### Dementias

- Alzheimer's Disease
- Vascular Dementia
- Frontotemporal Dementia
- Dementia with Lewy bodies
- Creutzfeldt-Jakob disease

#### Cerebrovascular

- Ischaemic Stroke
- Haemorrhagic Stroke
- Subarachnoid haemorrhage

#### Demyelinating Dis.

- Multiple sclerosis
- Optic neuritis
- Guillain-Barré
- Charcot-Marie-Tooth

#### Sleep disorders

- Primary insomnia
- Narcolepsy
- Sleep apnoea

#### Traumatic Injuries

- Traumatic brain injury
- Spinal cord injury

#### Pain

- Acute pain
- Migraine
- Other headaches
- Diabetic polyneuropathy
- Post-herpetic neuralgia

#### Epilepsies

- Simple partial seizures
- Complex partial seizures
- Infantile spasms
- Lennox-Gastaut
- Temporal lobe epilepsy



# Business development activities strengthen product offerings

- ★ Licensing partner of choice in CNS
- ★ Strong history and experience with all forms of licensing
- ★ Use of partnerships to ensure critical mass and innovation
- ★ Business development remains a priority



# Appendix

- ★ Lundbeck overview
- ★ **Commercial operations**
- ★ Pipeline
- ★ Financials
- ★ The CNS market
- ★ The Lundbeck share

# Improving product and geographical diversification

## North America:

- + New platform for growth
- + Northera, Onfi, Sabril and Xenazine
- + Brintellix
- + Saphris (Canada)
- + Treanda (Canada)
- + Abilify Maintena
- + Brexpiprazole

## Europe:

- + Strong market position
- + Sycrest
- + Selincro
- + Brintellix
- + Abilify Maintena
- + Brexpiprazole


## Latin America:

- + Emerging markets
- + Strong commercial platform
- + Saphris
- + Cephalon brands
- + Brintellix
- + Abilify Maintena
- + Brexpiprazole

## Asia:

- + Lexapro (Japan)
- + Improved commercial platform in China
- + Saphris
- + Azilect
- + Brintellix

## 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

 **TREANDA**<sup>®</sup>  
(bendamustine HCl)  
for Injection  
**Built for Action**<sup>®</sup>

 **Xenazine**<sup>®</sup>  
(tetrabenazine)  
12.5 and 25 mg Tablets

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

# Xenazine – only drug approved for Huntington's chorea in the US



**Xenazine®**  
(tetrabenazine)  
12.5 and 25 mg Tablets

## Chorea associated with Huntington's disease (HD)

- ★ ~ 20,000 people in the US suffer from HD
  - ★ Chorea, the most common symptom of HD (~90%), is characterized by involuntary movements.
- ★ Life expectancy is 15-20 years after onset and death often caused by pneumonia or choking
- ★ Depression is a common co-morbid condition of the disease.

- ★ Selectively inhibiting vesicular monoamine transporter enzyme (VMAT)-2, thereby depleting pre-synaptic dopamine
- ★ Approved for chorea associated with Huntington's disease
- ★ Addresses high unmet medical needs and has shown strong efficacy
- ★ Peak-sale estimate: DKK >1.5bn
- ★ Data exclusivity to expire in 2015 (orphan drug)

# Sabril – addressing high unmet needs



## Sabril

- ★ Unique method of action as a selective and irreversible inhibitor of GABA-transaminase
- ★ Peak-sale estimate: DKK ~1bn
- ★ Data exclusivity to expire in the US in 2014 (rCPS) and 2016 (IS – orphan drug status)



## 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%

## 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

# Onfi launch exceeds expectations

- ★ Onfi close to DKK 600m in 2013
- ★ Launched in in the US January 2012
- ★ Peak-sale estimate: DKK 1-1.5bn
- ★ Orphan drug status (2019)

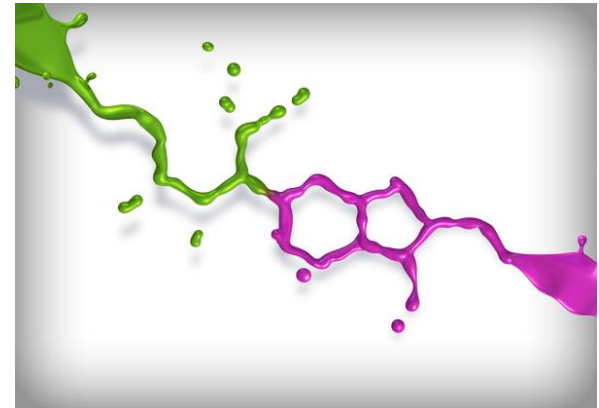


- ★ Onfi approved for adjunctive treatment of seizures related to Lennox-Gastaut Syndrome (LGS)
- ★ LGS is one of the most severe forms of epilepsy and there is a clear need for new treatment options
- ★ Only 10% experience full seizure remission with current therapies
- ★ Most patients experience ongoing cognitive impairment and refractory epilepsy
  - ★ Before age 11, the mortality rate is 4-7%
- ★ Around 25,000-75,000 patients



# Launch of Treanda substantially improves the growth outlook in International markets

- ★ Treanda launched in Canada indicated for two types of cancer (09/2012)
  - ★ Chronic lymphocytic leukaemia (CLL)
  - ★ Indolent non-Hodgkin's lymphoma (iNHL)
- ★ Lundbeck has Canadian rights to Treanda
- ★ 2013 revenue of DKK 129m
- ★ Peak sale estimate: DKK ~0.5bn



[www.treanda.com](http://www.treanda.com)

 **TREANDA**<sup>®</sup>  
(bendamustine HCl)  
for Injection  
**Built for Action**<sup>®</sup>

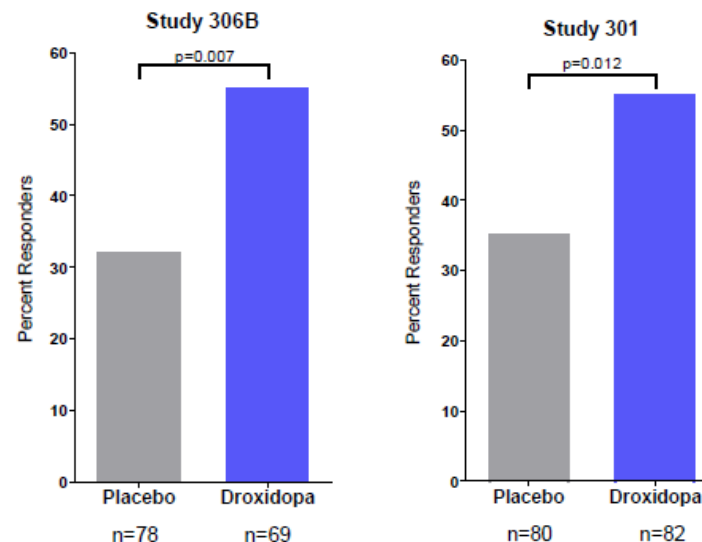
# Preparing for launch of Northera in US

- ★ Only chronic oral therapy treating root cause of symptomatic nOH\*
- ★ Well documented safety and efficacy; marketed in Japan since 1989
- ★ Good synergies with exciting neurology franchise
- ★ Differentiated product label
- ★ 80,000-150,000 nOH patients in the US (MSA, PAF, PD\* only)

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

## Two independent studies: Highly consistent efficacy

Proportion of patients with  $\geq 50\%$  improvement in Dizziness Score



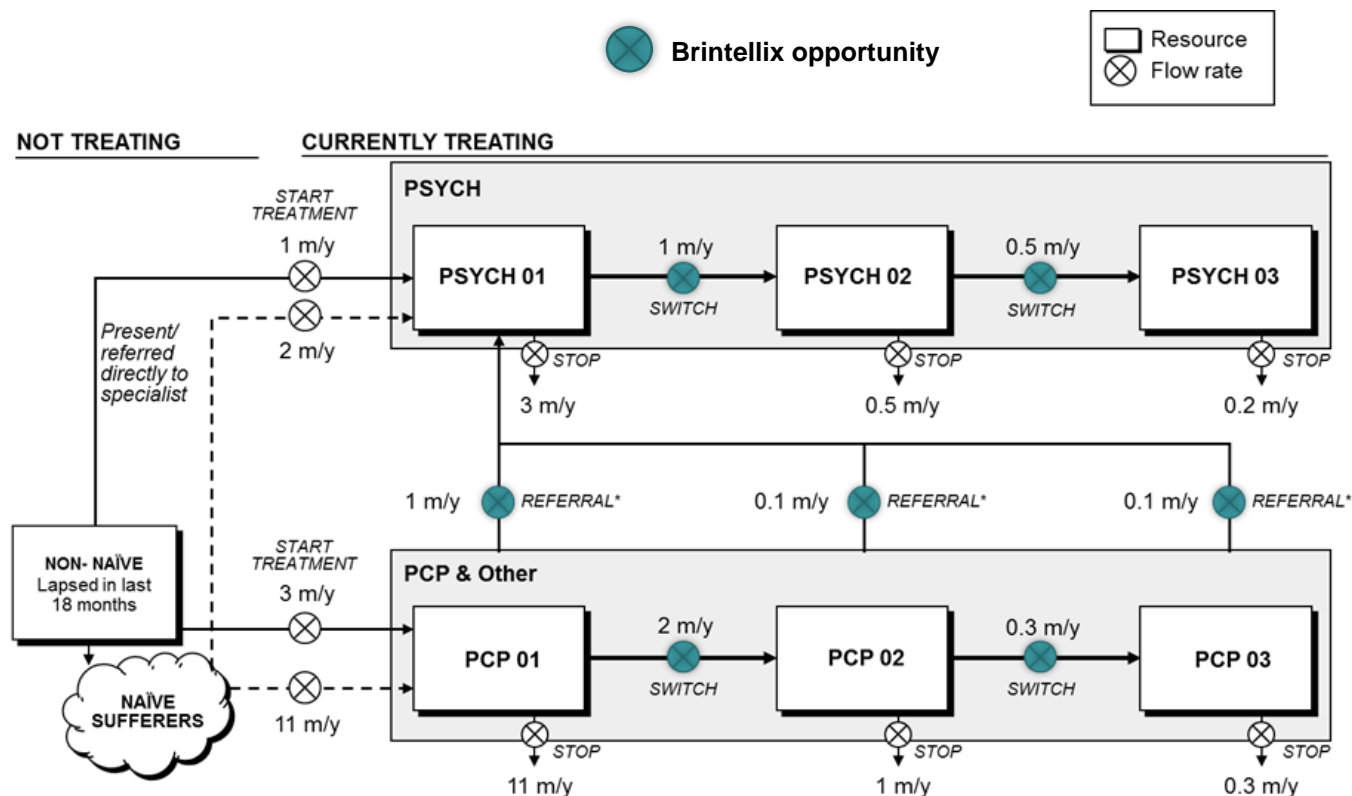
**Northera™**  
(droxidopa) Capsules  
100 mg • 200 mg • 300 mg

# Brintellix (vortioxetine, Lu AA21004)



# As a result, the antidepressant market is characterized by significant patient “churn”

## Patient flow in US antidepressant market



In contrast to many other markets, even a 3<sup>rd</sup> or 4<sup>th</sup> line antidepressant position is commercially attractive

\*First Psych Rx Intervention (Switch, Continuing, Add-on, Continuing Add).  
Source: Lundbeck & Vanguard analysis

# Taking depression treatment to the next level



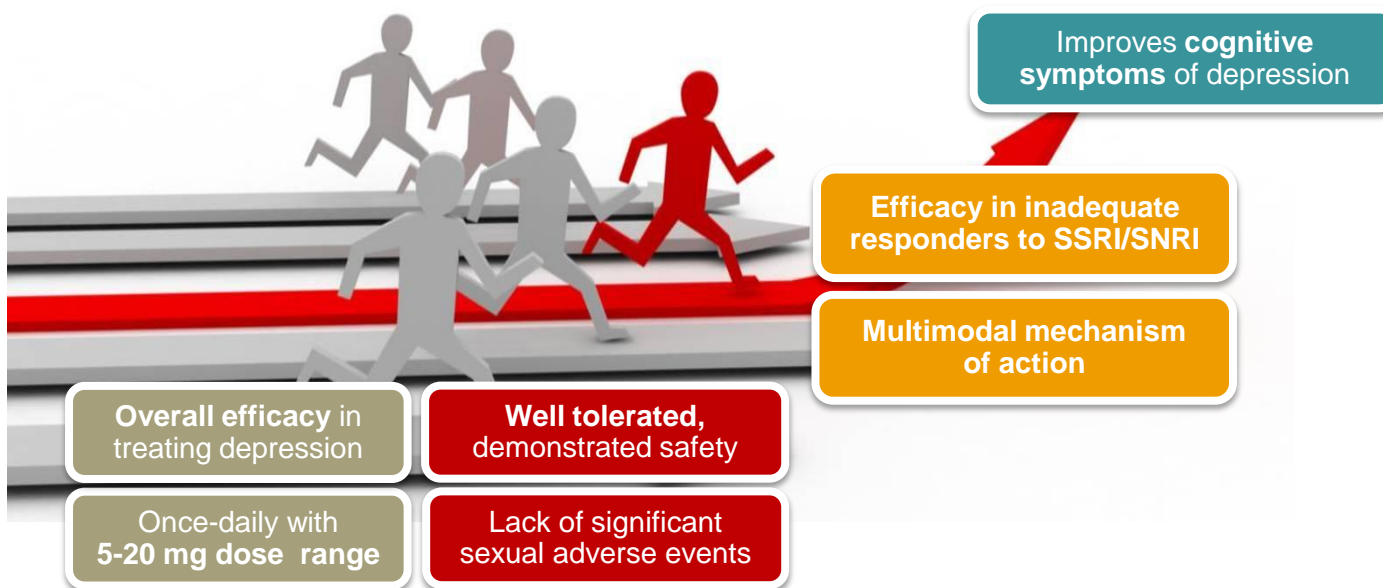
**REMISSION**

**REDUCED  
side effects**

**TREATMENT  
beyond  
core  
symptoms**

# Brintellix: What do we have?

*Effective antidepressant with differentiation in MoA, tolerability and cognition*



Comprehensive data package with >7,500 individuals in studies

70% phase III success rate vs. 48% US average for antidepressants<sup>1)</sup>

Note: Forward-looking and aspirational

1) Proportion of Failed Trials of Antidepressants in the FDA Data Sets (total). Khan A et al. J Clin Psychopharmacology 2002; 22:40-45

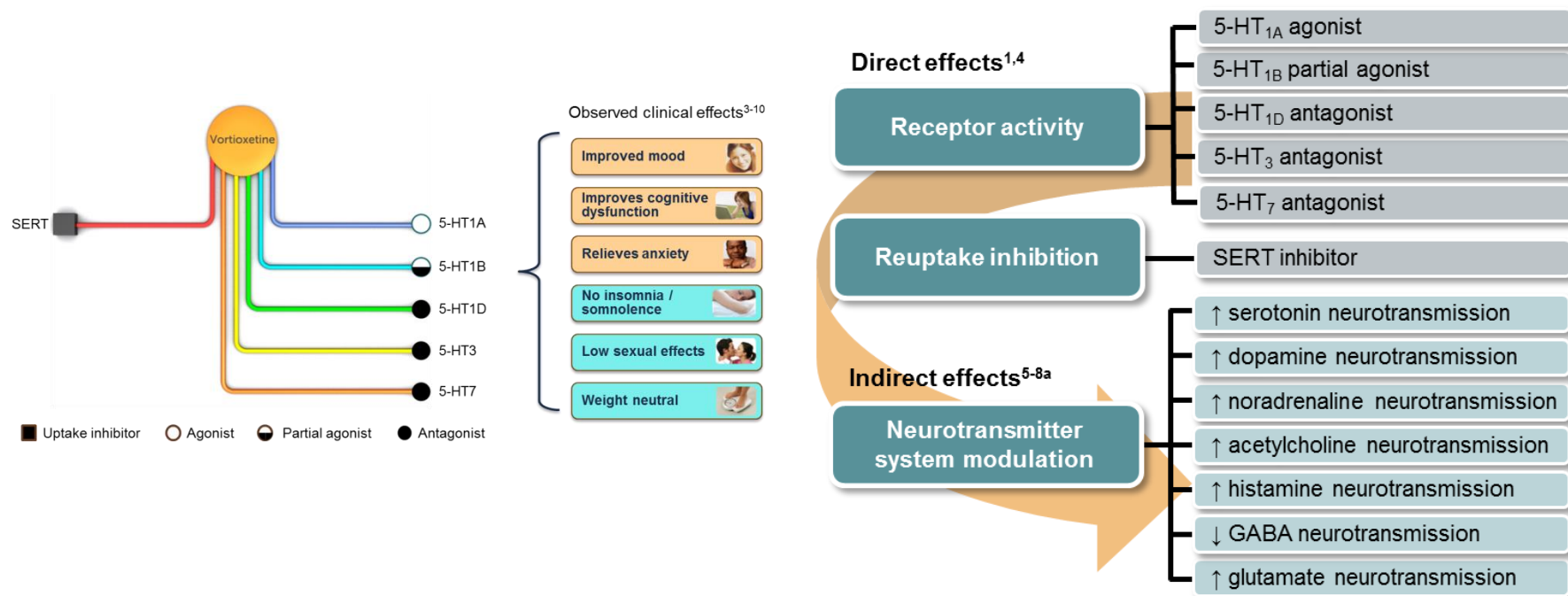
# Brintellix approved with a highly differentiated label



- ★ 6/9 **positive** studies support efficacy, including one elderly study
- ★ Maintenance of effect in a **relapse prevention** study
- ★ 5-20 mg, **dose response**, increase dose as tolerated for all patients
- ★ 9/12 studies **positive**, supporting efficacy, including one elderly study
- ★ Maintenance of effect in a **relapse prevention** study
- ★ **Superiority** to agomelatine
- ★ 5-20 mg, **dose response**, caution on >10mg in elderly
- ★ Effect on a **broad range** of symptoms



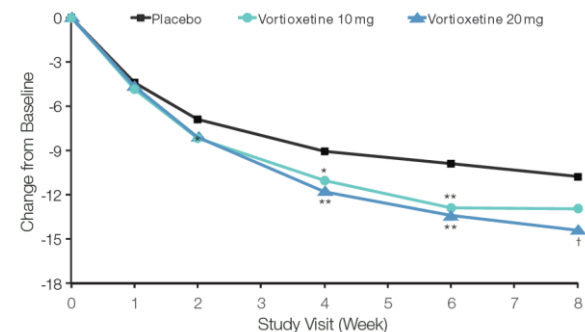
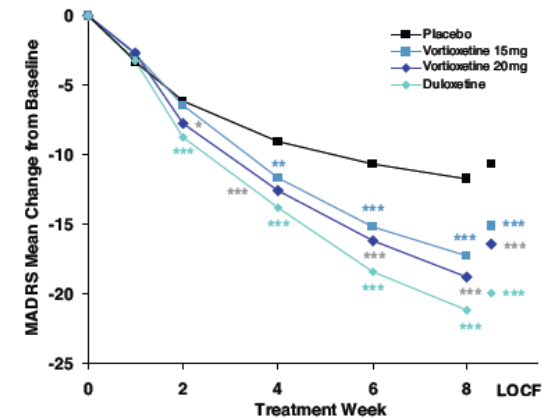
# Brintellix has a distinct pharmacological profile



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

# Brintellix is a new multimodal anti-depressant with robust and broad efficacy

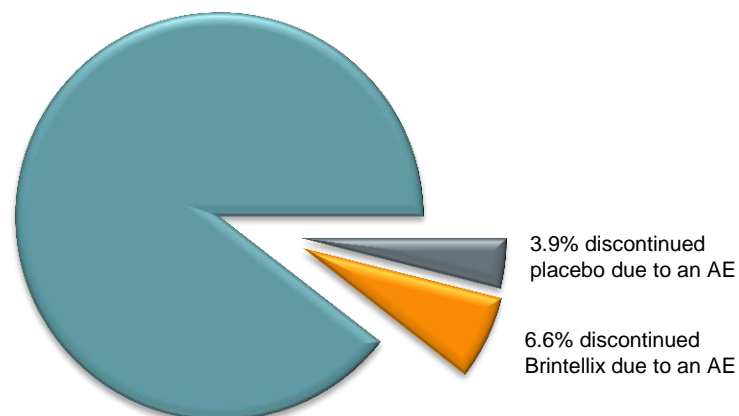
- ★ Efficacious in the treatment of depression in adults, elderly and when used as maintenance treatment to prevent relapse
- ★ Is efficacious in the treatment of depressive symptoms in patients with an inadequate response to SSRI/SNRI
- ★ It leads to improvement in the overall depressive syndrome, including the items of the MADRS, response and remission rates and global clinical impression as measured by the CGI-I
- ★ Improves cognitive function in depressed patients, assessed as performance on the neuropsychological tests DSST and RAVLT
- ★ Improves health-related quality-of-life outcomes (SF-36 MCS), overall health rating (EQ-5D) and overall functioning (SDS)



# Brintellix was well tolerated across the large clinical trial program

The tolerability profile of Brintellix was established in a robust program of clinical trials involving >7,500 patients<sup>1</sup>

- In clinical trials the **most common** adverse event was nausea<sup>2</sup>
- Adverse events were usually **mild or moderate** and occurred within the first two weeks of treatment<sup>2</sup>
- The events were usually **transient** and did not generally lead to cessation of therapy<sup>2</sup>
- **Neutral** on liver and renal assessments, body weight, ECG, and vital signs
- **No QTc-prolongation** in thorough QT study with healthy individuals



**Brintellix**  
vortioxetine

1. H. Lundbeck A/S MAA  
2. Vortioxetine, Summary of Product Characteristics

# Brintellix has a favorable tolerability and safety profile



- ★ In clinical studies, the incidence of nausea was low, and nausea was generally mild to moderate and transient
- ★ Placebo-level insomnia
- ★ Low incidence of sexual dysfunction
- ★ Placebo-level effects on blood pressure, heart rate and renal and hepatic assessments
- ★ Brintellix treatment can be stopped abruptly without discontinuation symptoms

**Adverse Events (AEs) with an Incidence of  $\geq 5\%$  in any treatment group in the 8-Week treatment period (APTS)**

Preferred term	Placebo	Brintellix 15mg	Brintellix 20mg	Duloxetine 60mg
Pts w. TEAEs	50.6%	57.0%	66.2%	65.3%
Nausea	10.1%	26.5%	31.8%	30.6%
Headache	7.6%	10.6%	12.6%	10.9%
Diarrhoea	3.8%	4.0%	7.3%	6.1%
Dry mouth	3.2%	3.3%	6.0%	9.5%
Dizziness	6.4%	4.6%	5.3%	10.2%
Fatigue	2.5%	4.0%	3.3%	5.4%
Hyperhidrosis	3.8%	3.3%	0.0%	7.5%

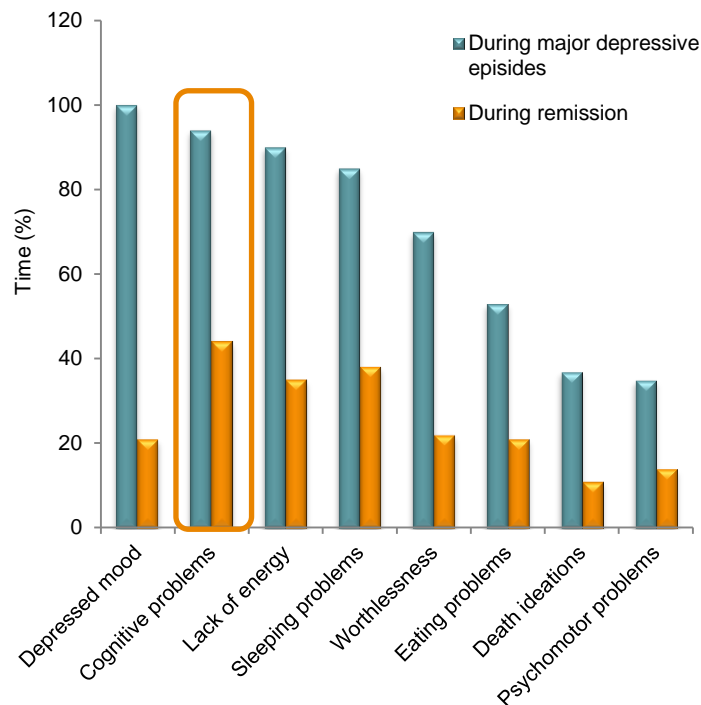
Source: J.P.Boulenger, APA2013 (Poster NR3-055)

Variable	Placebo	Brintellix 15mg	Brintellix 20mg	Duloxetine 60mg
Number of subjects without sexual dysfunction at baseline				
$\Delta$ from PBO	-	-0.7%	-0.7%	17%
Number of subjects with sexual dysfunction at baseline				
$\Delta$ from PBO	-	-8.7%	6.3%	1.5%

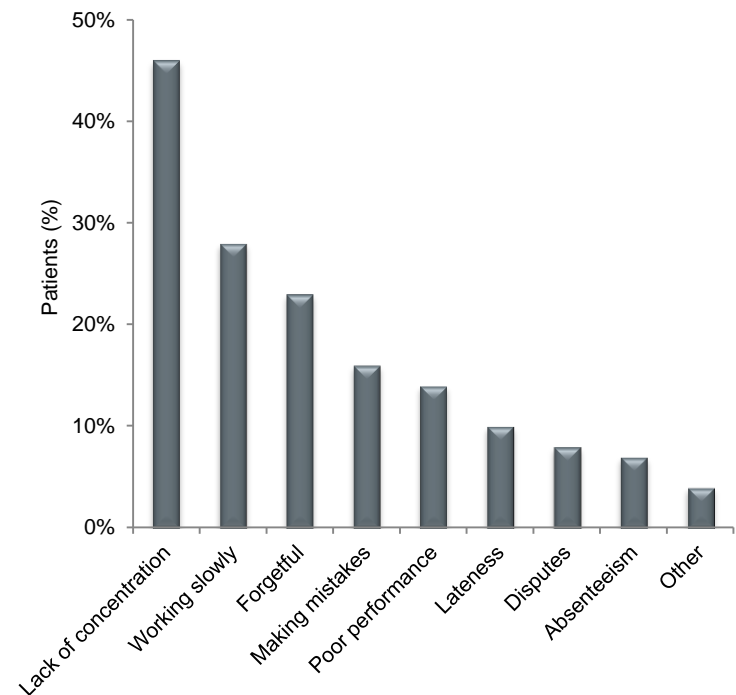
Source: A.R. Mahableshwarkar, APA2013 (Poster NR9-01)

# 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

# Assessing effect on cognitive dysfunction of depression and functional capacity by objective and subjective measurements

## Cognitive domains impaired in MDD

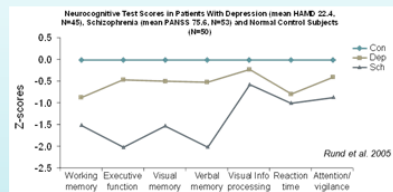
### Executive function

### Speed of Processing

### Attention

### Memory

#### Objective Neuropsychological Tests



#### Digit Symbol Substitution Test (DSST)

1	2	3	4	5	6	7	8	9
—	⊥	□	⊏	⊐	○	△	X	=
2	3	4	5	6	7	8	9	

#### Subjective Patient-reported Symptoms

*"I didn't realize the traffic light turned red until it was too late"*

*"I can't figure out what I need from the supermarket right now to make dinner tonight?"*



During the past 4 weeks, how often did you...	(0) Never	(1) Rarely	(2) Sometimes	(3) Often	(4) Almost always
1 lose your train of thought when speaking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 have difficulty remembering the names of people, even ones you have met several times?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 forget what you came into the room for?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 have trouble getting things organized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Perceived Deficit Questionnaire (PDQ) - 20-items assessing self-perceived cognitive difficulties within 4 dimensions

#### Objective Assessment of Functional Capacity in Basic Living Skills

##### 1 Financial skills

- Counting money and making bills
- Paying bills



##### 2 Communication

- Telephone use
- Medical appointment



##### 3 Household chores

- Preparing shopping list

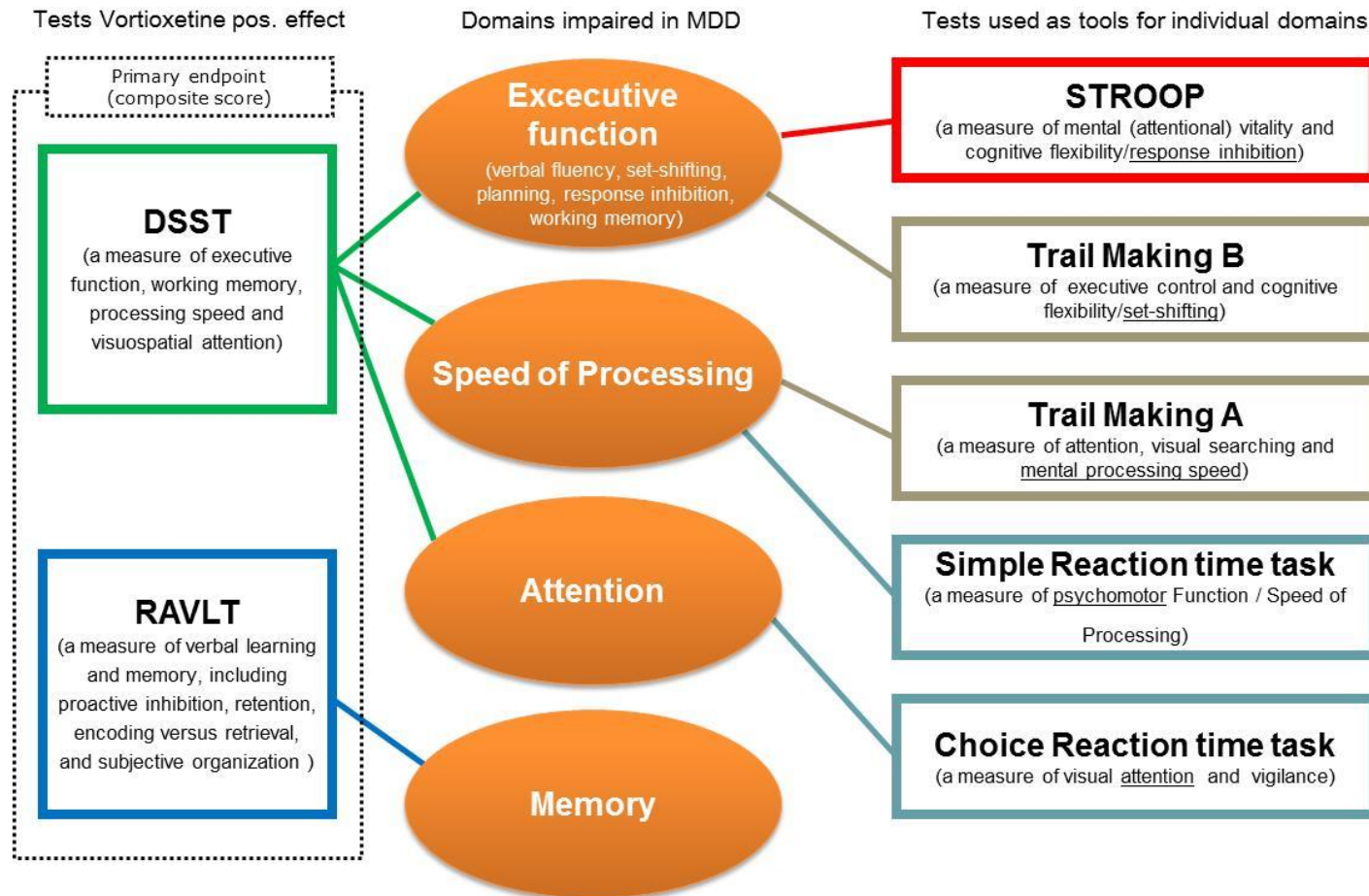
##### 4 Transportation

- Public bus system

##### 5 Planning recreational activities

- Preparing for a trip to a waterpark

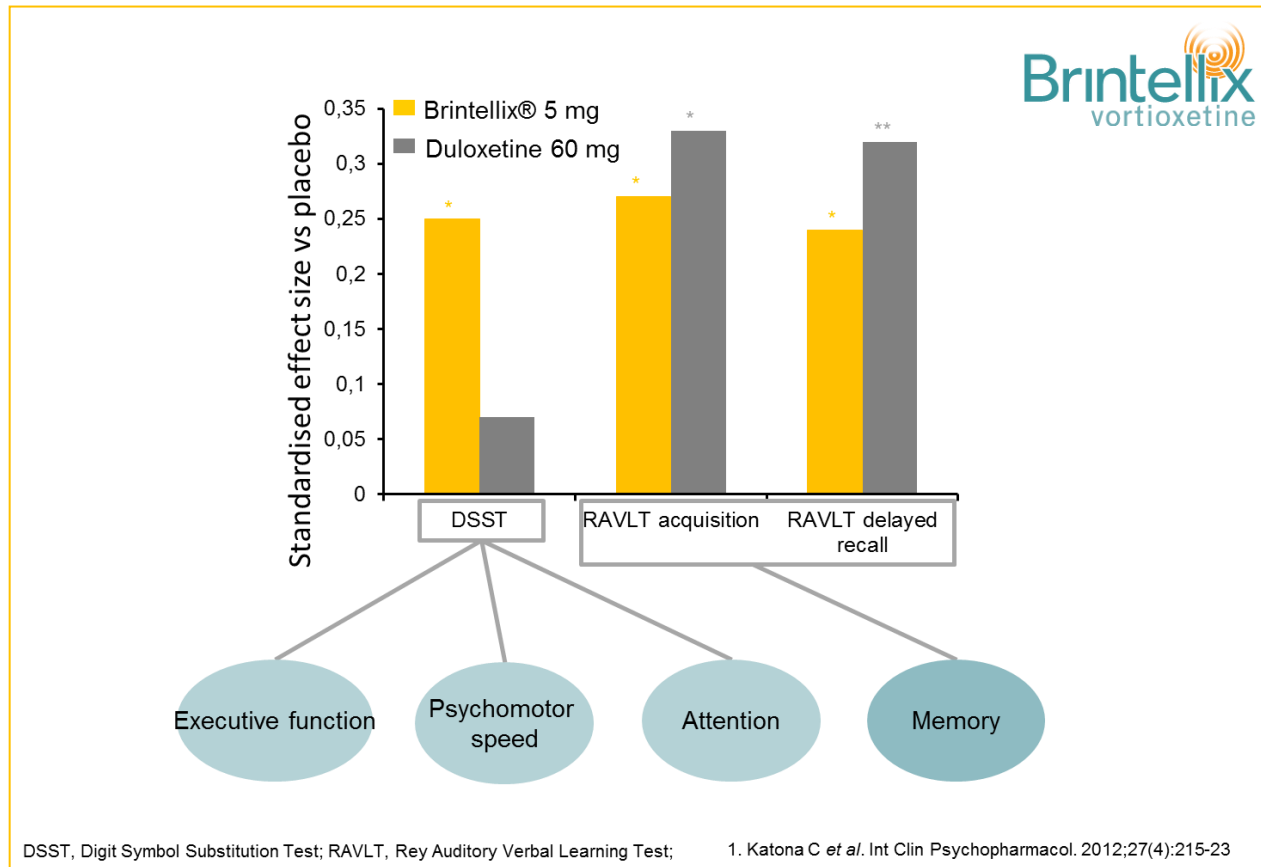
# Test Selection Strategy to evaluate cognitive performance



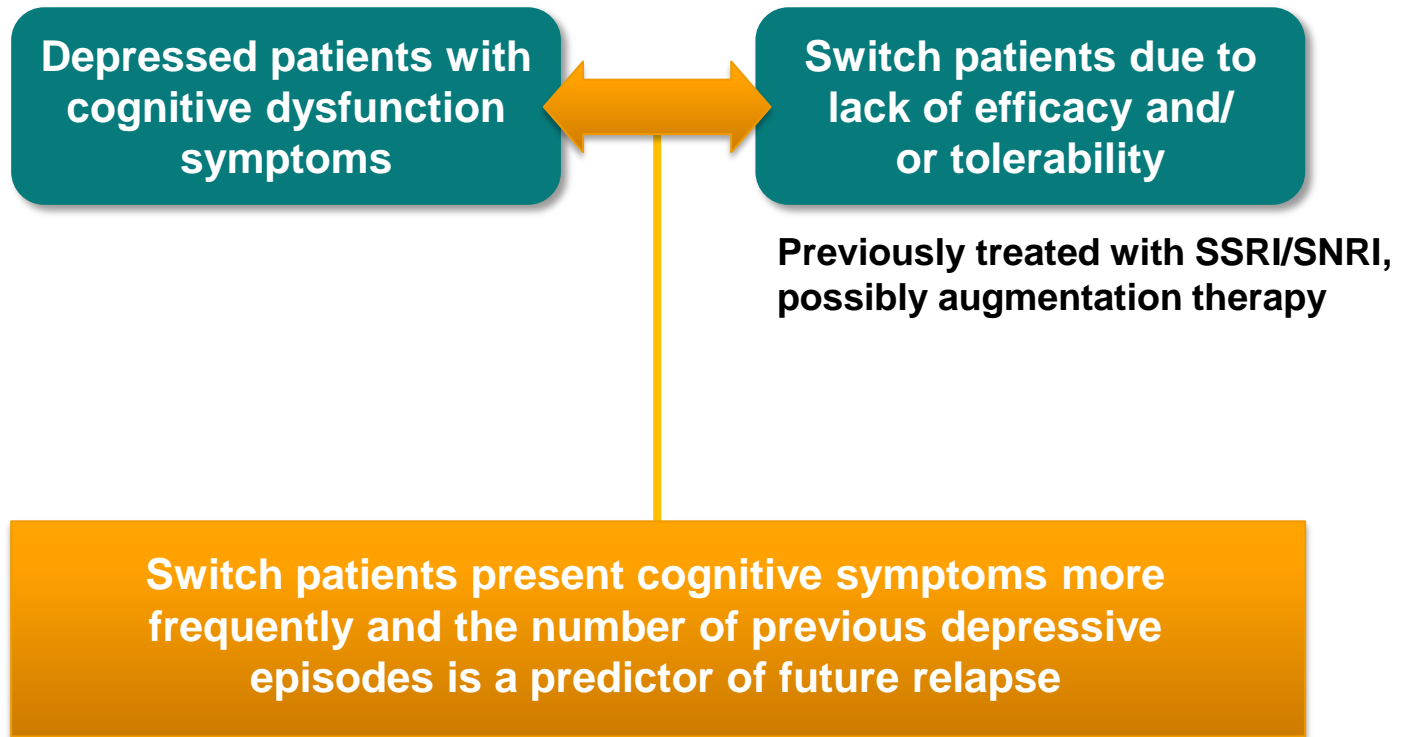
13



# Brintellix improved cognitive performance in depressed elderly patients<sup>1</sup>



# Population groups of interest for achieving market access for Brintellix



# “High dose” clinical programme using Brintellix in MDD

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Intervention
NCT01491035 (PIP)	48 (int.)	April 2012	Pharmacokinetics and tolerability of Brintellix (5-20mg) in child and adolescent patients with depressive or anxiety disorder
<b>NCT01140906<sup>1)</sup></b>	<b>600 (non-US)</b>	<b>May 2010</b>	<b>8 wks. Brintellix (15+20mg); duloxetine (60mg); Placebo</b>
<b>NCT01255787<sup>2)</sup></b>	<b>615 (Japan a.o.)</b>	<b>November 2010</b>	<b>8 wks. Brintellix (5+10+20mg); placebo</b>
<b>NCT01323478 #</b>	<b>300 (non-US)</b>	<b>April 2011</b>	<b>52 wks. extension. Brintellix (15+20mg)</b>
<b>NCT01163266*</b>	<b>450 (US)</b>	<b>July 2010</b>	<b>8 wks. Brintellix (10+20mg); placebo</b>
<b>NCT01153009*</b>	<b>600 (US)</b>	<b>June 2010</b>	<b>8 wks. Brintellix (15+20mg); duloxetine (60mg); placebo</b>
<b>NCT01179516*</b>	<b>450 (US)</b>	<b>August 2010</b>	<b>8 wks. Brintellix (10+15mg); placebo</b>
NCT01152996	1,000 (US)	September 2010	52 wks. open label extension. Brintellix (15+20mg) –by invitation only
NCT01355081	360 (Japan)	May 2011	8 wks. Brintellix (5+10mg); placebo
NCT01395147	100 (Japan)	July 2011	52 wks. extension. Brintellix (5-20mg)
<b>NCT01571453</b>	<b>410 (Asia)</b>	<b>May 2012</b>	<b><i>SOLUTION</i>: 8 wks. Brintellix (10mg); venlafaxine XR 150mg</b>
<b>NCT01488071 (vs. agomelatine) @</b>	<b>500 (non-US)</b>	<b>January 2012</b>	<b><i>REVIVE</i>: 8 wks. Brintellix (10-20mg); agomelatine (25-50mg)</b>
<b>NCT01364649 (sexual dysfunct.) ☐</b>	<b>440 (US+Canada)</b>	<b>June 2011</b>	<b>Brintellix (10-20mg); escitalopram (10-20mg). CSFQ</b>
<b>NCT01564862 (cognition) §</b>	<b>600 (US+int.)</b>	<b>April 2012</b>	<b><i>CONNECT</i>: 8 wks. Brintellix (10-20mg); duloxetine (30-60mg); placebo</b>
<b>NCT01422213 (cognition) ☐</b>	<b>600 (US+int.)</b>	<b>December 2011</b>	<b><i>FOCUS</i>: 8 wks. Brintellix (10+20mg); placebo</b>

1) Boulenger, International Clinical Psychopharmacology; Oct. 2013. 2) Data published in EPAR and at clinicaltrials.gov. \*) Data presented at APA 2013 in May. @) Data presented at EPA 2013 in April 2013. #) Data presented at ECNP Oct. 2013. ☐) ACNP December 2013; ☐) Poster at ASCP, May 2014. § CINP2014

# “Low dose” clinical programme using Brintellix in MDD and GAD

## Major depressive disorder

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Intervention
NCT00635219 <sup>2,5</sup>	766 (non-US)	April 2009	8 wks. Brintellix (2.5+5+10mg); duloxetine (60mg); placebo
NCT00735709 <sup>2</sup>	560 (non-US)	August 2008	8 wks. Brintellix (1+5+10mg); placebo
NCT00672620 <sup>10)</sup>	611 (US)	April 2008	8 wks. Brintellix (2.5+5 mg), duloxetine (60mg); placebo
NCT00672958 <sup>2</sup>	600 (US)	April 2008	6 wks. Brintellix (5mg); placebo
NCT00694304 (safety)	536 (non-US)	May 2008	52 wks. Brintellix (2.5-10mg flexible dose)
NCT00596817 (relapse) <sup>2</sup>	400 (non-US)	December 2007	<76 wks. Brintellix (5+10mg); placebo
NCT00707980 <sup>3</sup>	836 (non-US)	June 2008	<52 wks. Brintellix (2.5+5+10mg)
NCT00811252 (elderly) <sup>3,6</sup>	453 (US)	January 2009	8 wks. Brintellix (5mg); duloxetine (60mg); placebo
NCT00761306 (safety)	74 (non-US)	June 2007	52 wks. Brintellix (5+10mg)
NCT00839423 (phase II) <sup>1,7</sup>	429 (non-US)	August 2006	8 wks. Brintellix (5+10mg); venlafaxine XL (225mg); placebo

## General anxiety disorder (all studies published)

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Intervention
NCT00730691 <sup>8)</sup>	781 (US)	June 2008	8 wks. Brintellix (2.5+5+10mg); duloxetine (60mg); placebo
NCT00731120 <sup>9)</sup>	457 (US)	June 2008	#309: 8 wks. Brintellix (2.5mg+10mg); placebo
NCT00734071 <sup>4</sup>	309 (US)	June 2008	8 wks. Brintellix (5mg); placebo
NCT00744627 <sup>4</sup>	301 (Non-US)	September 2008	8 wks. Brintellix (5mg); placebo
NCT00788034 (relapse prev.) <sup>3,6</sup>	459 (Non-US)	October 2008	8 wks. Brintellix (5mg+10mg); placebo

1) APA 2009, 2) APA 2011, 3) APA 2012, 4) ACNP 2011, 5) European Neuropsychopharmacology (2011), 6) Int. Clinical Psychopharmacology (2011), 7) Int. Journal of Neuropsychopharmacology (2011). 8) Mahableshwarkar; International Journal of Clinical Practice, Jan 2014. 9) Mahableshwarkar; *Hum Psychopharmacol Clin Exp.* 2014;29(1):64-72. 10) Mahableshwarkar; *Curr Med Res Opin.* 2013;29(3):217-226

# Competitors' clinical package for regulatory filing - 1

Product	Market	Indication	No. of short-term studies	No. of patients	No. of positive studies	No. of long-term studies	No. of patients	No. of positive studies
Duloxetine (Cymbalta) Eli Lilly/ Boehringer Ingelheim	EU	MDD	6	1,978	4	1	278	1
		GAD	4	1,908	4	1	429	1
	US	MDD	6	1,586	3	1	278	1
		GAD	3	1,163	3	-	-	-
Desvenlafaxine (Pristiq) Wyeth/Pfizer	US (same data submitted to EMA but was decided to be withdrawn)	MDD	9	3,272	4 (2 other studies nominally negative but positive on alternative analyses)	1 (but FDA decided not to review this study due to higher dose-range than proposed dosage regimen)	-	-
Agomelatine (Valdoxan) Servier	EU	MDD	12	4,678	3	2 (one of the two studies was filed in the second submission but not in the first)	706	1 (only the study included in the second submission was positive)
Quetiapine XR (Seroquel XR) AstraZeneca	US	MDD (monotherapy) (only filed not approved)	5	2,454	4 (only positive on primary endpoint)	1	1,876	1
		MDD (adjunctive therapy)	2	939	2 (only positive in primary endpoints)	-	-	-
		GAD	4	2,658	4	1	432	1

Source: Regulatory Intelligence Package – Depression (2009); Lundbeck ; SPC's & EPAR's

# Competitors' clinical package for regulatory filing - 2

Product	Market	Indication	No. of short-term studies	No. of patients	No. of positive studies	No. of long-term studies	No. of patients	No. of positive studies
Vilazodone (Viibryd) Forest	US	MDD	2	869	2	-	-	-
Mirtazapine (Remeron) ScheringPlough/ Organon	US	MDD	5	-	5	1	-	1
Aripiprazole (Abilify) BMS/Otsuka	US	MDD (adjunctive therapy)	2	743	2	-	-	-
Olanzapine/ Paroxetine (Symbyax) Eli Lilly	US	MDD	5	1,616	1	-	-	-
Bupropion SR (Wellbutrin SR) GlaxoSmithKline	EU	MDD	8	-	2	-	-	-
Bupropion IR (Wellbutrin IR) GlaxoSmithKline	EU	MDD	7	-	-	-	-	-
Bupropion XR (Wellbutrin XR) GlaxoSmithKline	EU	MDD	3	1,564	1	1	400	1
	US	MDD	4	1,401	1	-	-	-

Source: Regulatory Intelligence Package – Depression (2009); Lundbeck ; SPC's & EPAR's

# Competitors' clinical package for regulatory filing - 3

Product	Market	Indication	No. of short-term studies	No. of patients	No. of positive studies	No. of long-term studies	No. of patients	No. of positive studies
Sertraline (Zoloft) Pfizer	US	MDD	2	-	2	1	295	1
		PTSD	4	757	2	2	252 (in one of the studies – total number unknown)	2
		PD	4	686	3	1	183	1
		OCD	3	-	3	1	224	1
		OCD in children & adolescents	1	187	Study showed positive results but was found inadequate due to design for adults	-	-	-
		SAD	2	-	2	1	-	1
Levomilnacipran Forest	US	MDD (not yet approved)	3	>1,600	3	-	-	-

Source: Regulatory Intelligence Package – Depression (2009); Lundbeck ; SPC's & EPAR's

## Abilify Maintena (aripiprazole once monthly)





# A paradigm shift in the making

*CNS Spectrums* (2014), 19, 3–5. © Cambridge University Press 2014  
doi:10.1017/S1092852913001016



## BRAINSTORMS—Clinical Neuroscience Update

### Long-acting injectable antipsychotics: shall the last be first?

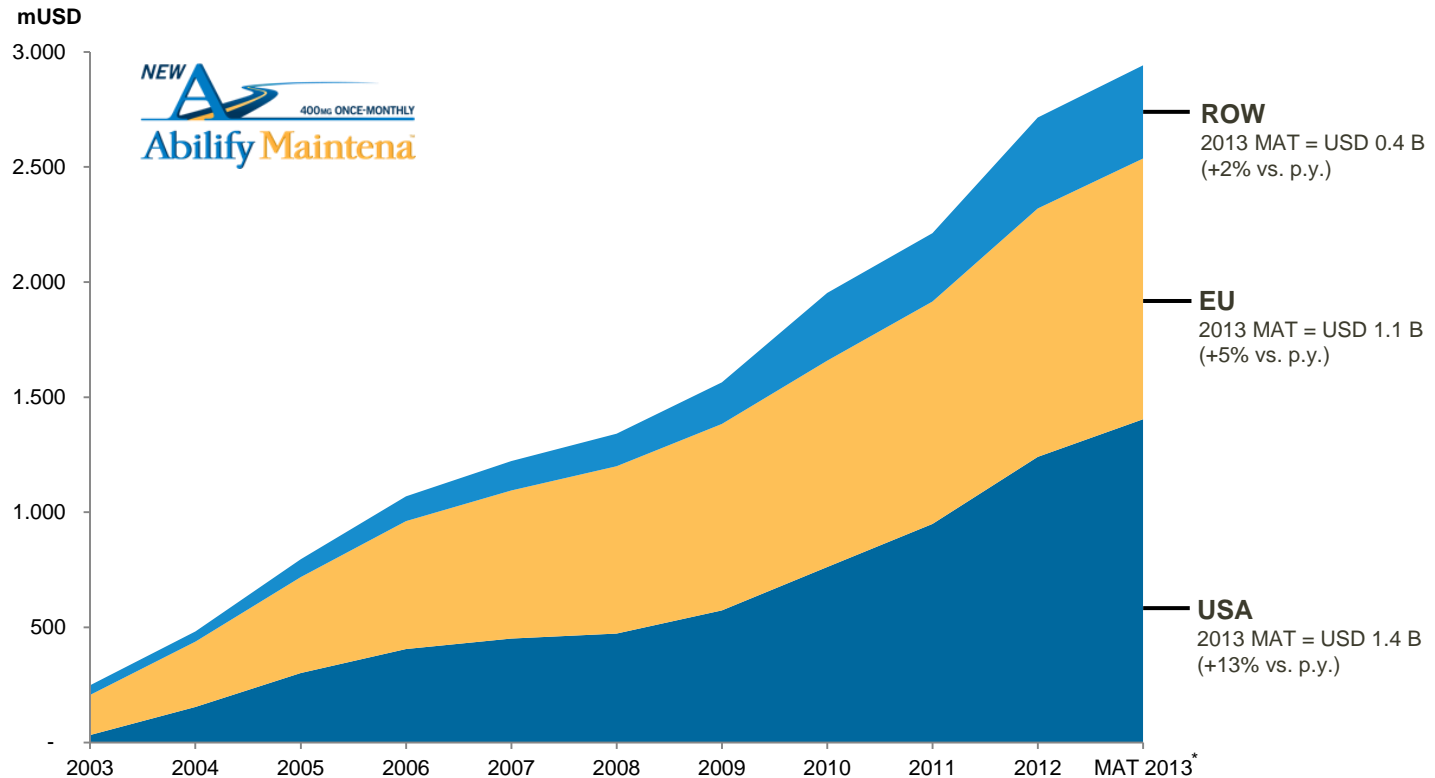
*Stephen M. Stahl*

ISSUE:

A paradigm shift is afoot in which the “last shall be first,” namely, use of long-acting injectable (LAI) antipsychotics, rather than being reserved for use only at the last stages of schizophrenia, may be shifting to first-line treatment of early episodes of this illness.

# Abilify Maintena is launched into a high-growth market close to USD 3bn in global value

## Global market for antipsychotic long-acting injectables



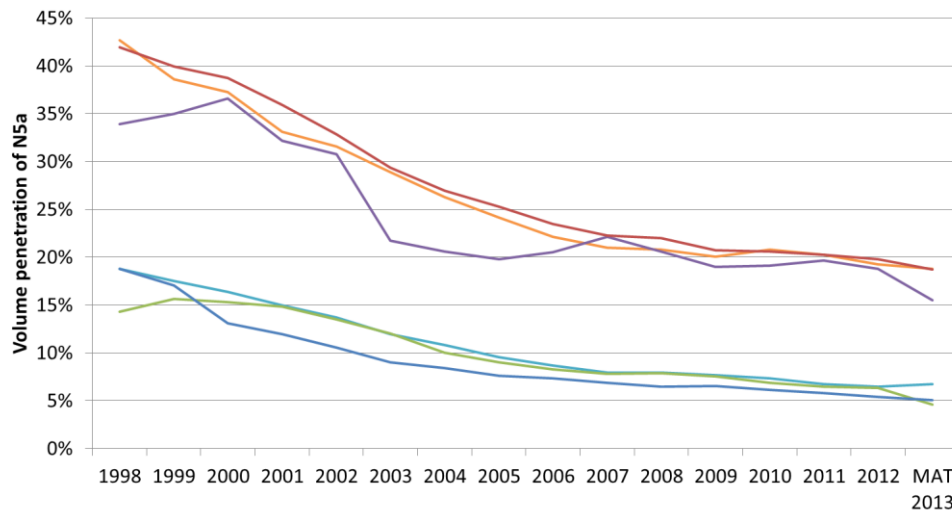
Source: IMS

\* MAT=Moving annual total Q3 2013

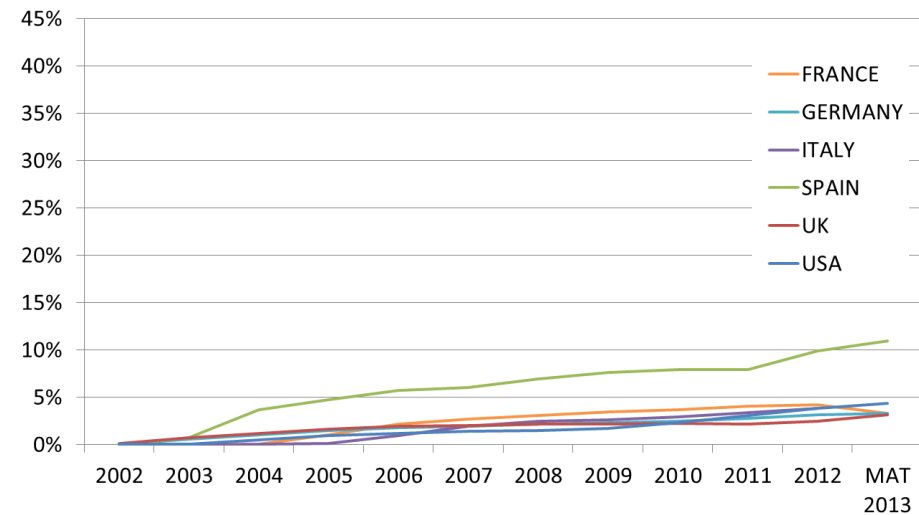
# Only 15 years ago, long-acting therapies were considered “standard of care” in several key markets



Typical depot penetration



Atypical depot penetration



LAI = long acting injectable  
Source: IMS

\* Moving annual total Q3 2013

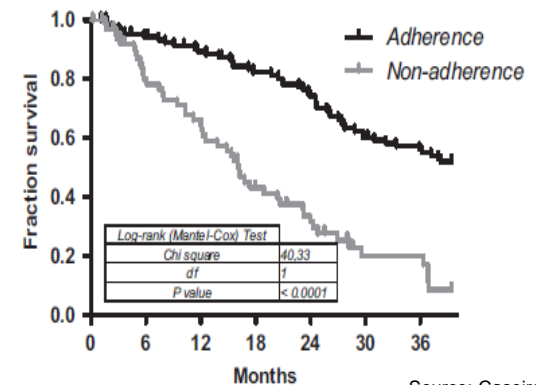
**With only limited product options the atypical LAI market remains underdeveloped**

# Worsening of symptoms in schizophrenia is driven by relapses

- ★ **Approximately half of patients** experience relapses and a worsening of their symptoms
- ★ This fluctuating course of the disease is devastating for a person with schizophrenia and the people around them
- ★ With each relapse, it becomes **less likely** that people with schizophrenia will return to the level of **functioning** and the life they had before their relapse

Therefore, one of the key long-term therapy goals is to **prevent relapses**

Time to relapse in adherent and non-adherent patients



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

# Clinical programme with Abilify Maintena

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Indication
NCT01959035	100	Oct. 2013	Interventional, Open-label, Flexible-dose Extension Study of Aripiprazole Once-monthly in Patients With Schizophrenia who completed NCT01795547
NCT01509053 (ARRIVE-EU)	30	Dec. 2011	Open-label Study to Assess Hospitalization Rates in Adult Schizophrenic Patients Treated With Oral Antipsychotics for 6 Months and IM Depot Aripiprazole for 6 Months, Respectively, in a Naturalistic Community Setting, Europe, Canada and Asia
NCT01909466 (phase I)	141	Jul. 2013	An Open-label, Multiple Dose, Safety and Tolerability Study of Aripiprazole IM Depot Administered in the Deltoid Muscle in Adult Subjects With Schizophrenia
<b>NCT01552772 (phase I) ▣</b>	<b>60</b>	<b>Jan 2012</b>	<b>Open-label, safety and tolerability trial of aripiprazole IM Depot treatment initiation in adult subjects with schizophrenia stabilized on atypical oral antipsychotics other than aripiprazole</b>
NCT01663532 (phase III)	310 (US)	Oct 2012	Acute treatment of schizophrenia 12 wks. Abilify Maintena; placebo, endpoint: PANSS score
NCT01567527 (phase III)	600 (global)	Aug 2012	Maintenance treatment of bipolar I disorder 52 wks. Abilify Maintena; placebo, endpoint: relapse
<b>NCT00705783 (phase III)*</b>	<b>1,025 (global)</b>	<b>Jul 2008</b>	<b>Study 246: Maintenance treatment in schizophrenia (ASPIRE) 52 wks. Abilify Maintena; placebo, endpoint: relapse</b>
<b>NCT00731549 (phase III)**</b>	<b>1,224 (global)</b>	<b>Dec 2008</b>	<b>Study 248: Maintenance treatment in schizophrenia (ASPIRE) 52 wks. Abilify Maintena, endpoint: stability in treatment; 52 wks.</b>
<b>NCT00706654 (phase III)***</b>	<b>1,148 (global)</b>	<b>Sep 2008</b>	<b>Study 247: Maintenance treatment in schizophrenia (ASPIRE) 38 wks. Abilify Maintena; Abilify oral, endpoint: relapse</b>
<b>NCT01432444 (phase III)****</b>	<b>500 (US)</b>	<b>Sep 2011</b>	<b>Study 283: Hospitalization rates of schizophrenic patients treated with oral antipsychotics vs. Abilify Maintena (ARRIVE US)</b>
<b>NCT01795547 (phase III) #</b>	<b>286 (US)</b>	<b>Feb 2013</b>	<b>QUALIFY: Maintenance treatment in Schizophrenia 28 wks, randomised, open-label study, Abilify Maintena vs. paliperidone palmitate</b>

Clin Med Res Opin. 2013 29(10):1241-51. \* J Clin Psychiatry, 2012; 73(5):617-624 and Int Clin Psychopharmacol, 2013; 28(4):171-6. \*\* Poster at APA 2014. \*\*\* Br J Psychiatry, 2014, Poster at ACNP2012, ECNP 2013 and EPA 2014. \*\*\*\* J Med Econ, 2013; 16(7):917-925, Poster at APA2013 and SIRS2014. # Interim data presented at NCDEU 2013

# Selincro (nalmefene)



# Less than 10% of alcohol dependent patients receive treatment

14,600,000

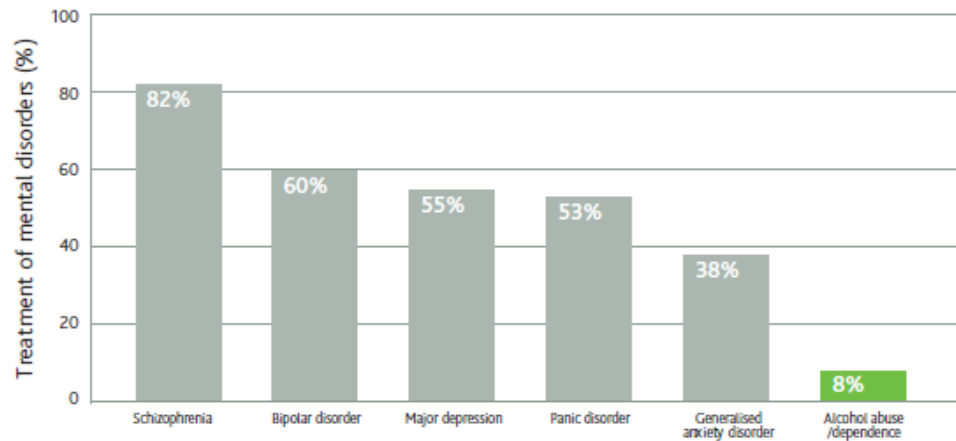
EUROPEANS ARE  
ALCOHOL DEPENDENT<sup>2</sup>



92%

ARE NOT TREATED<sup>3,4</sup>

Alcohol abuse and dependence have the widest treatment gap among all mental disorders<sup>4</sup>



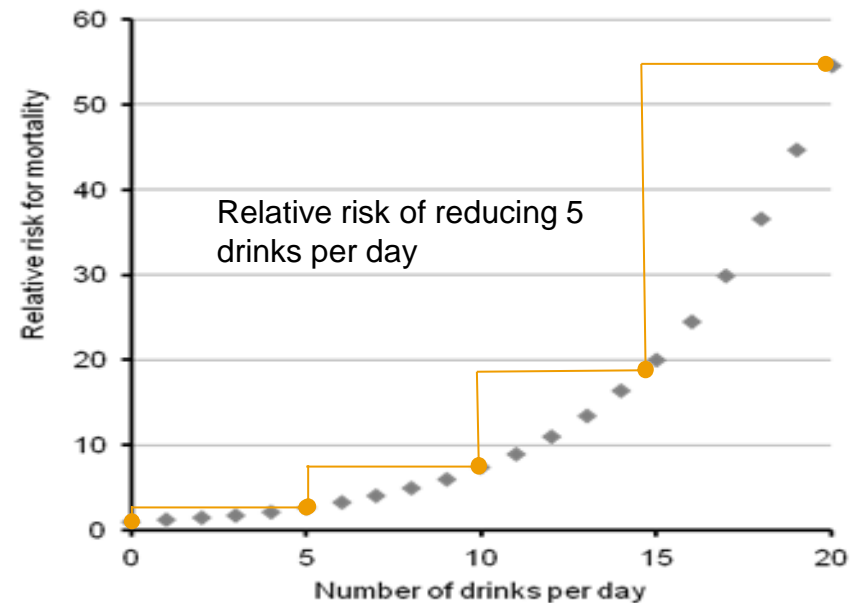
1. Rehm et al. Alcohol consumption, alcohol dependence, and attributable burden of disease. Centre for Addiction and Mental Health, Toronto, ON
2. Wittchen et al. Eur Neuropsychopharmacol 2011; 21(9):655–679
3. Alonso et al. Acta Psychiatr. Scand. 2004; 109: 47–54
4. Kohn et al. Bull World Health Organ 2004;82:858–866

# Reducing harm by reducing high alcohol consumption

- ★ Alcohol is a causal factor in more than 60 diseases
- ★ From 10 to 4.5 drinks per day after 6 months
- ★ From 6 to 3 heavy drinking days per week
- ★ Launched in selected European countries from mid-2013

**Selincro**  
nalmefene

**Typical risk curve for alcohol (e.g., liver cirrhosis mortality)**





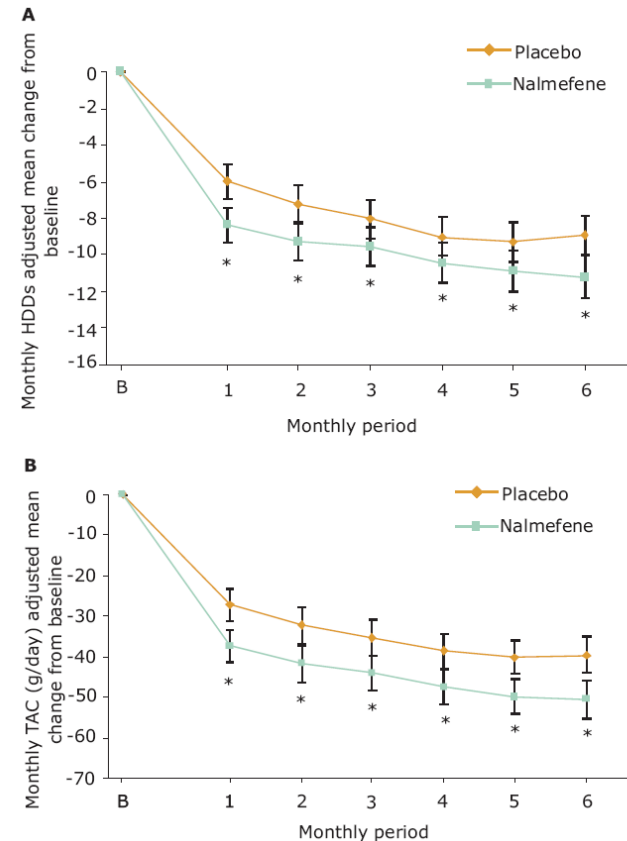
# Selincro is the first treatment approved for the reduction of alcohol consumption

- ★ EU approval in February 2013
- ★ Selincro breaks the cycle of continuous drinking and reduced alcohol consumption by 57%



## THE SELINCRO PATIENT

- Alcohol dependent
- High drinking risk level\*\*
- No physical withdrawal symptoms/  
no need for immediate detoxification



# In clinical trials, Selincro demonstrated a significant reduction in alcohol consumption



Baseline



Equivalent to 10 bottles of wine per week

**Selincro**  
nalmefene

After 1 month



6 bottles

**40%**  
reduction

**Selincro**  
nalmefene

After 6 months



4 bottles

**60%**  
reduction

**Selincro**  
nalmefene

After 12 months



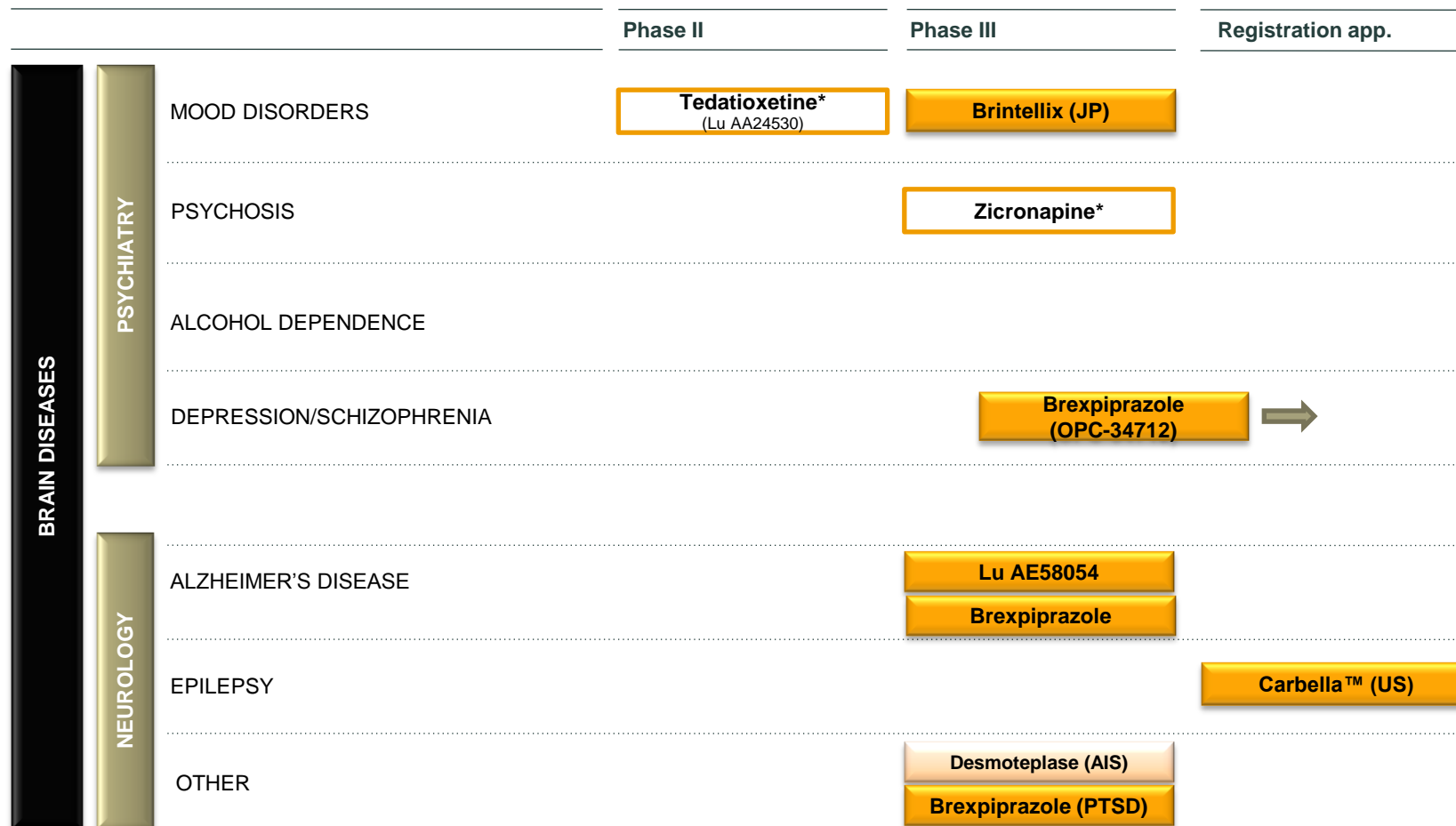
3 bottles

**67%**  
reduction

# Appendix

- ★ Lundbeck overview
- ★ Commercial operations
- ★ **Pipeline**
- ★ Financials
- ★ The CNS market
- ★ The Lundbeck share

# Lundbeck invests to grow – a solid late-stage development portfolio



\*No active clinical program ongoing

# Otsuka collaborations (brexpiprazole and Lu AE58054)



# Financial terms and territory structure of the Otsuka alliance

- ★ Co-development and co-commercialization agreements with Otsuka in November 2011
- ★ Potential peak sales (for the alliance):
  - ★ USD >1bn for Abilify Maintena
  - ★ USD >2.5bn for brexpiprazole
  - ★ USD >1bn for Lu AE58054
- ★ Patent expiration: Abilify Maintena (2024), brexpiprazole (>2025), Lu AE58054 (>2030)
- ★ Selincro in Japan added to the alliance in October 2013

## Milestones payments

Payment to:



	Abilify Maintena	Brexpiprazole	Lu AE58054	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	Brexpiprazole	Lu AE58054	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



# Brexpiprazole – a new treatment for a range of psychiatric disorders

## Brexpiprazole phase III in adjunct MDD (PYXIS)\*

- ★ Statistically significant improvements in mean MADRS total score were observed for subjects receiving adjunctive brexpiprazole 2 mg/day compared with placebo ( $p=0.0001$ )
- ★ On all secondary endpoints brexpiprazole showed a statistically significant advantage over placebo
- ★ Brexpiprazole was considered well-tolerated and completion rate was high

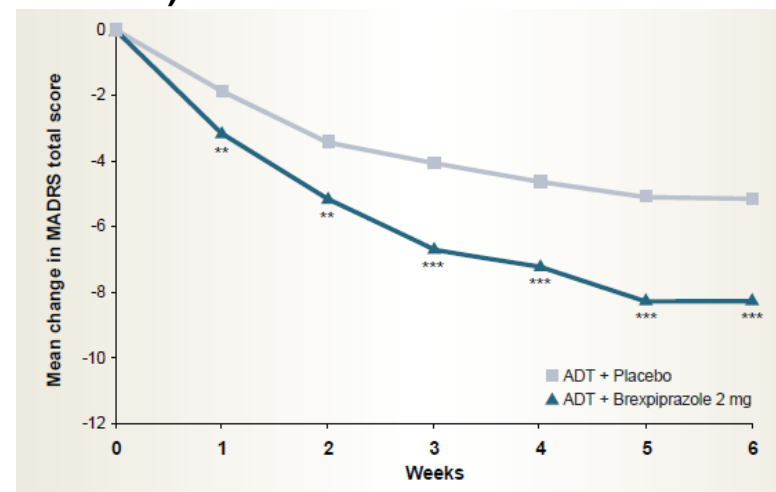
## Development status

- ★ **Schizophrenia:** Six studies recruiting
- ★ **MDD adjunctive therapy:** Six studies recruiting
- ★ **Agitation in Alzheimer's:** Two studies recruiting
- ★ **PTSD:** One study recruiting

## Mechanism of action

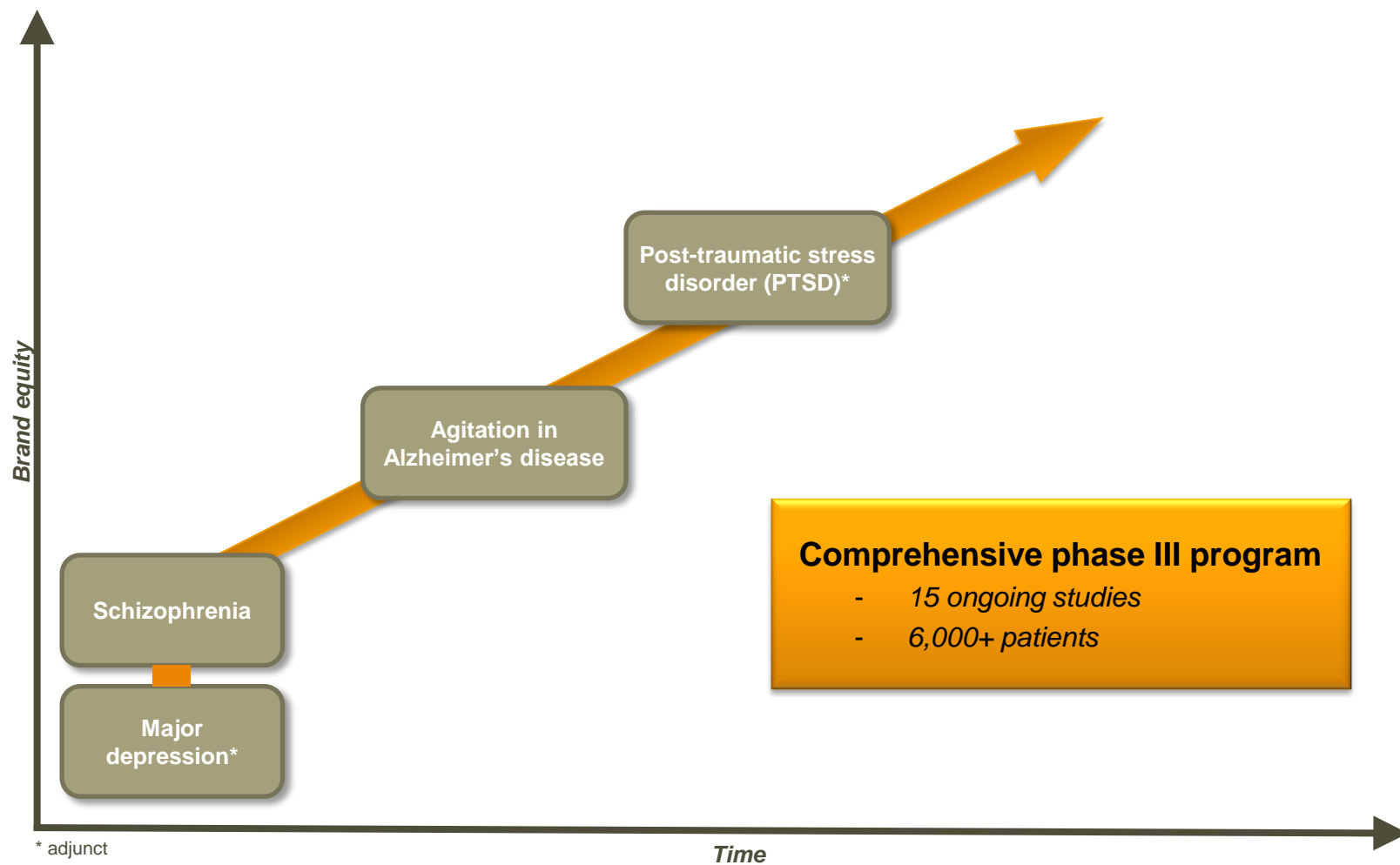
- ★ Novel  $D_2/D_3$  receptor partial agonist
- ★  $5-HT_{1A}$  partial agonist
- ★  $5-HT_{2A}$  antagonist

## Mean change in MADRS total score from baseline\*)



\*) M.E. Thase et al: "Efficacy and safety of adjunctive brexpiprazole (OPC-34712) in major depressive disorder (MDD): A phase III, randomized, placebo-controlled study". Poster at EPA March 2014

# The development plan for brexpiprazole





# Clinical programme with brexpiprazole - adjunctive therapy in major depression

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Indication
NCT01727726 (phase III)	1,785 (global)	Dec 2012	<i>DELPHINUS TRIAL (Study 282)</i> : Adjunctive therapy in MDD - flexible-dose. Brexpiprazole+ADT; placebo+ADT; seroquel+ADT, endpoint: MADRS score
NCT01360866 (phase III)	1,209 (global)	Oct 2011	<i>ORION</i> : Adjunctive therapy in MDD. 0.5-3 mg brexpiprazole+ADT, endpoint: adverse events
<b>NCT01360645 (phase III) <sup>2)</sup></b>	<b>925 (global)</b>	<b>Jul 2011 (completed)</b>	<b><i>PYXIS (Study 228)</i>: Adjunctive therapy in MDD. 2mg brexpiprazole+ADT; placebo+ADT, endpoint: MADRS score</b>
NCT01360632 (phase III)	1,650 (global)	Jun 2011 (completed)	<i>POLARIS (Study 227)</i> : Adjunctive therapy in MDD. 1+3mg brexpiprazole+ADT; placebo+ADT, endpoint: MADRS score
NCT02196506 (phase III)	900 (global)	July 2014	<i>Study 214</i> : Tolerability, safety, and efficacy of brexpiprazole (2.0 mg/day) as adjunctive therapy in adult subjects with a diagnosis of MDD with and without anxious distress
NCT01838681 (phase III)	1,462 (EU)	May 2013	<i>ARGO</i> : 1-3mg. Inadequate responders in MDD; Up to 36 wks
NCT01944969 (phase III)	1,184 (US)	October 2013	Open-label, Long-term Extension Study to Evaluate the Safety and Tolerability of Brexpiprazole as Adjunctive Treatment in Patients With Major Depressive Disorder
NCT01942785 (phase III)	50 (US)	October 2013	To explore the anti-impulsive and anti-aggressive properties of brexpiprazole in a naturalistic setting of depressed patients with irritability
NCT02013622 (phase III)	50 (US)	November 2013	Efficacy and safety of flexibly dosed adjunctive brexpiprazole treatment in subjects with major depressive disorder and anxiety symptoms, who are experiencing an inadequate selective serotonin reuptake inhibitor (SSRI)/serotonin norepinephrine reuptake inhibitor (SNRI) response.
NCT02012218 (phase III)	80 (US)	November 2013	Exploratory trial are to evaluate the efficacy, safety, and subjects' subjective satisfaction when switching to adjunctive brexpiprazole in subjects with MDD who have responded inadequately to preceding adjunctive drug therapy.
NCT01837797 (phase III)	1,334 (elderly, US)	April 2013	1-3mg. Up to 20wks
NCT01942733 (phase III)	50 (US)	September 2013	Exploratory Study of Brexpiprazole (<3mg) as Adjunctive Treatment of Sleep Disturbances in Patients With Major Depressive Disorder
NCT01447576 (phase II)	1,038 (US)	Sep 2009 (completed)	Adjunctive therapy in MDD. 1-3mg brexpiprazole+ADT, endpoint: adverse events
<b>NCT00797966 (phase II) <sup>1)</sup></b>	<b>850 (US)</b>	<b>May 2009 (compl.)</b>	<b>Adjunctive therapy in MDD. 1-4mg brexpiprazole+ADT; placebo+ADT, endpoint: depression rating scale</b>
NCT01052077 (phase II)	773 (US)	Mar 2010 (completed)	Adjunctive therapy in MDD (STEP-D222). 1-3mg brexpiprazole+ADT; placebo+ADT, endpoint: depression rating scale

\*ST=stimulant therapy, ADT=FDA approved antidepressant treatment, 1) Published at APA 2011. 2) Data presented at EPA, March 2014 and APA May 2014.

# Clinical programme with brexpiprazole – schizophrenia plus “other indications”

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Indication
NCT01810380 (phase III)	465 (US)	March 2013	<i>LIGHTHOUSE</i> : To determine the efficacy and safety of brexpiprazole for the treatment of adults experiencing an acute episode of schizophrenia. Active ref: Seroquel
NCT01810783 (phase III)	140 (US)	May 2013	<4mg Safety and tolerability in schizophrenia. PANSS is secondary end-point. Up to 52 wks
NCT01668797 (phase III)	420 (US)	Oct 2012	<i>EQUATOR</i> : Maintenance treatment of schizophrenia. 1-4mg brexpiprazole; placebo, endpoint: relapse
NCT01397786 (phase III)	1,000 (global)	Sep 2011	<i>ZENITH</i> : Maintenance treatment of schizophrenia. 1-2mg, 1-4mg brexpiprazole, Endpoint: adverse events
NCT01393613 (phase III)	660 (global)	Jul 2011 (completed)	<i>BEACON (Study 230)</i> : Acute schizophrenia. brexpiprazole (low/medium/high dose), placebo, end point: PANSS score
NCT01396421 (phase III)	630 (global)	Jul 2011 (completed)	<i>VECTOR (Study 231)</i> : Acute schizophrenia. brexpiprazole (low/medium/high dose), placebo, end point: PANSS score
NCT02054702 (phase III)	81	February 2014	The purpose of this study is to explore changes in efficacy, cognitive functioning, and safety of flexibly-dosed brexpiprazole monotherapy in subjects with acute schizophrenia. <20mg aripiprazole or <4mg brexpiprazole
NCT02013622	46	November 2013	Early episode schizophrenia
NCT01456897 (phase III)	Na. (Japan)	Oct 2011	Long-term trial in schizophrenia.
<b>NCT00905307 (phase II) <sup>1)</sup></b>	<b>450 (US)</b>	<b>Jul 2009 (completed)</b>	<b>Acute schizophrenia. 4 diff. doses (0.25-6mg) of brexpiprazole (STEP 203); aripiprazole; placebo, dose establishing study</b>
NCT01451164 (phase II/III)	N/A (Japan)	Oct 2011	Dose-finding trial in patients with schizophrenia. brexpiprazole (low/medium/high dose), placebo, end point: PANSS score

1) Published at 24th Annual US Psychiatric and Mental Health Congress, 7-11 November 2011, Las Vegas, NV, USA

## “Other indications”

Clinicaltrials.gov identifier	Estimated Enrolment	Study start	Indication
NCT01074294 (phase II)	675 (US)	Mar 2010	Complementary treatment in ADHD. 0.25+1mg brexpiprazole+ST; placebo+ST, endpoint: efficacy/safety
NCT01862640	560 (global)	May 2013	Agitation Associated With Dementia of the Alzheimer's Type, 2-week, placebo, 3 Fixed Doses of Brexpiprazole (0.5mg, 1mg and 2mg)
NCT01922258	230 (global)	Sep 2013	Agitation Associated With Dementia of the Alzheimer's Type, 12-week, placebo, 0.5-2mg
NCT01987960	592 (US)	Dec 2013	Brexpiprazole as Adjunctive Treatment to Paroxetine or Sertraline in Adult Patients Suffering From Post-traumatic Stress Disorder (PTSD), 28 wks, placebo, up to 3mg/day

# Lundbeck has significant presence in psychiatric disorders in years to come

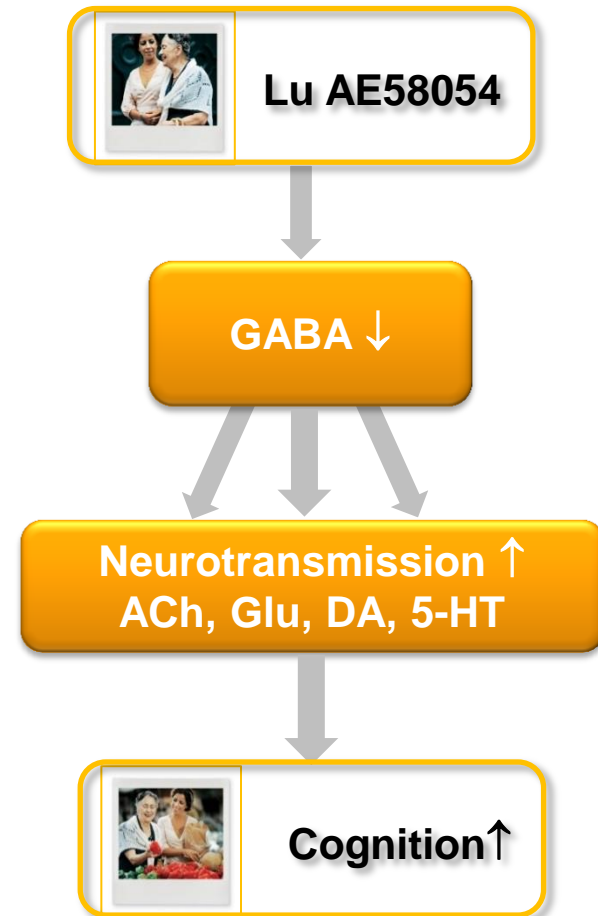
Compound	Status	Mood disorders	Anxiety disorders	Developmental disorders	Psychotic disorders
Cipralex	Launched	Fully responsive depression			
Brintellix	Launched (US) Approved (EU)	Incomplete responsive dep.			
Tedatioxetine	Phase II*				
Brexpiprazole	Filed (US) Phase III	non / inadequate responsive dep.			
Sycrest/Saphris	Launched				
Abilify Maintena	Launched				Maintenance treatment
Zicronapine	Phase III*				
Lu AF11167 (PDE <sup>1)</sup> )	Phase I**				

\*No active clinical programme ongoing

1) Phosphodiesterase enzyme \*\*March 2011

# Why could Lu AE58054 be a new valuable treatment in Alzheimer's?

- ★ Lu AE58054 has a different mode of action compared to existing symptomatic treatments (blockade of 5-HT<sub>6</sub> receptors)
- ★ Blocking this particular kind of serotonin receptors (5-HT<sub>6</sub> receptors) has beneficial effects on several neurotransmitter systems in the brain
- ★ Lu AE58054 has demonstrated beneficial effects on cognition in animal models
- ★ Lu AE58054 has demonstrated beneficial effects on cognition in AD patients on stable donepezil treatment



# The planned clinical phase III program on Lu AE58054

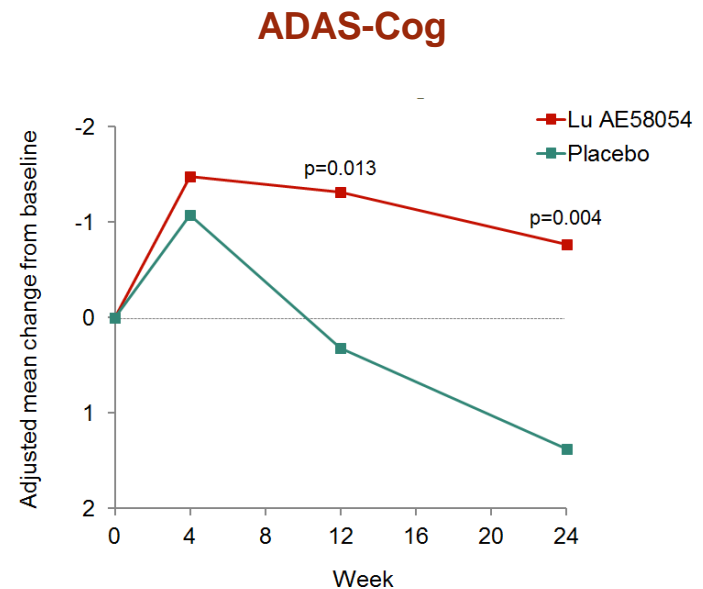
Study	Treatment Duration	Design	Lu AE58054 (mg/day)	Donepezil (mg/day)	Primary Endpoint Scale	No. of patients
<b>Currently planned phase III studies</b>						
NCT01955161 ( <i>STARSHINE</i> )	24 weeks	Randomized, DB, PBO, parallel-group, fixed-dose adjunctive treatment to donepezil	30 and 60	10	ADAS-cog	~930
NCT02006641 ( <i>STARBEAM</i> )	24 weeks		10 and 30	10	ADAS-cog	~850
Study 3	24 weeks		60	10	ADAS-cog	~550
NCT02006654 ( <i>STARBRIGHT</i> )	24 weeks	AChEIs	60 (or 30mg)	-	ADAS-cog	~750
NCT02079246 * ( <i>STAR</i> Extension)	32 weeks	Adj. to donepezil	60 (or 30mg)	10		1,770
NCT01019421 (phase II)	24 weeks	Adj. to donepezil	90	10	ADAS-cog	278
DB: double-blind; PBO: placebo-controlled						

\* Patients that conclude *STARSHINE* or *STARBEAM* can be included in a long-term open label study - NCT02079246

# Lu AE58054 phase II clinical results presented at AAIC in Boston

- ★ Statistically significant effect on cognitive performance with Lu AE58054 as adjunctive treatment to donepezil in patients with moderate AD (MMSE 12–19)
- ★ Trends toward improvement in measures of function (ADL) and global impression (CGIC)
- ★ Lu AE58054 appeared well tolerated in the study
- ★ ALAT or ASAT values  $>2\times$  ULN in 13 patients
  - ★ LFT abnormalities asymptomatic
  - ★ Return towards baseline values in all cases

ALAT=alanine aminotransferase; ASAT=aspartate aminotransferase; LFT=liver function test; ULN=upper limit of normal



Wilkinson J., et al. "A clinical Phase II study of Lu AE58054 added to stable donepezil treatment in patients with moderate Alzheimer's disease."

Abstract presented at the Alzheimer's Association International Conference; 13-18 July 2013; Boston, MA

# Our Alzheimer's R&D pipeline is unique

- ★ **Lu AE58054** demonstrated positive phase II results as add-on to donepezil in moderate AD
  - ★ Phase III commenced in October 2013
- ★ **Brexpiprazole** 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 to commence in Q4 2014



# Other pipeline projects



# DIAS 3 study did not meet the primary endpoint, but supportive findings

- ★ The first of two phase III clinical studies (DIAS 3) in patients with acute ischaemic stroke **did not meet the primary endpoint**
- ★ Patients fulfilling all protocol requirements (per protocol population) **desmoteplase showed an effect** relative to placebo
- ★ AIS\* is the **leading cause** of serious, long-term disability in the US....
  - ★ ...and the 2<sup>nd</sup> biggest cause of mortality globally<sup>1)</sup>

---

## Potential desmoteplase advantages over rt-PA

Extended treatment window

Lower risk of bleeding

No neurotoxicity - survival of brain tissue

No disruption of BBB\* integrity

Ease of administration  
(single bolus, i.v. injection)

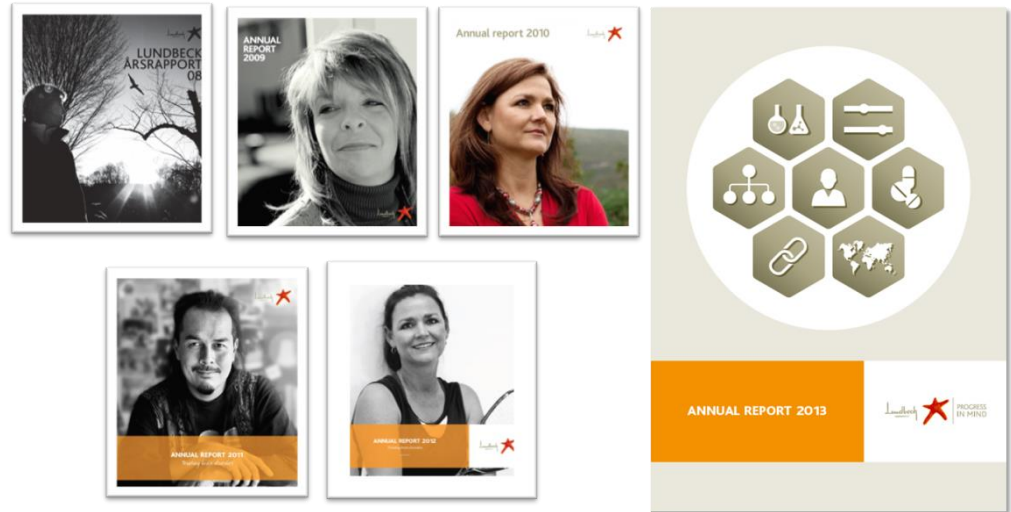
Longer half-life - positive impact on re-occlusion rate

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1) US Centers for Disease Control and Prevention and WHO. BBB: Blood-Brain Barrier

# Appendix

- ★ Lundbeck overview
- ★ Commercial operations
- ★ Pipeline
- ★ **Financials**
- ★ The CNS market
- ★ The Lundbeck share



# Core earnings in Lundbeck

- ★ Amortization and impairments of assets
- ★ Major restructuring cost
- ★ Legal fees and settlements
- ★ Acquisitions and integration activities
- ★ Non-recurring items (divestments, milestones)

DKKm	H1 2014	H1 2013
EBIT	843	1,020
- Amortization	325	296
- Non-recurring items	0	171
Core EBIT	1,168	1,487

Materiality level for each none-core item is DKK >100m

# Revenue performance in Q2 2014

DKK <b>m</b>	Q2 2014	Q2 2013	<i>Index</i>	FY 2013	FY 2012	<i>Index</i>
Cipralex	1,316	1,511	87	5,933	5,827	102
Azilect	371	339	109	1,392	1,224	114
Xenazine	402	372	108	1,420	1,197	119
Onfi	217	114	190	573	255	225
Sabril	176	147	120	530	376	141
Brintellix	38	0	-	0	0	-
Other pharmaceuticals	779	961	81	3,926	5,297	74
Other revenue	149	92	161	1,484	626	237
<b>Total revenue</b>	<b>3,448</b>	<b>3,536</b>	<b>98</b>	<b>15,258</b>	<b>14,802</b>	<b>103</b>
<i>New Products*</i>	<i>1,014</i>	<i>769</i>	<i>132</i>	<i>3,096</i>	<i>2,141</i>	<i>145</i>

\*New Products: Xenazine, Sabril, Sycrest, Lexapro (Japan), Onfi, Treanda, Selincro, Abilify Maintena and Brintellix

# Geographic distribution of revenue – Q2 2014

DKK <b>m</b>	Q2 2014	Q2 2013	Growth	Growth in local currency
<b>Europe:</b>				
Cipralex	698	847	(18%)	(17%)
Azilect	336	314	7%	7%
Ebixa	144	446	(68%)	(68%)
Other pharmaceuticals	207	210	(1%)	(1%)
<b>Total revenue</b>	<b>1,385</b>	<b>1,817</b>	<b>(24%)</b>	<b>(24%)</b>
<b>US:</b>				
Xenazine	394	363	9%	14%
Onfi	217	114	90%	102%
Sabril	176	147	20%	27%
Brintellix	38	-	-	-
Other pharmaceuticals	57	21	177%	178%
<b>Total revenue</b>	<b>882</b>	<b>645</b>	<b>37%</b>	<b>44%</b>
<b>International Markets:</b>				
Cipralex	618	664	(7%)	0%
Ebixa	125	113	10%	11%
Treanda	49	22	119%	149%
Azilect	35	25	41%	32%
Other pharmaceuticals	205	158	30%	43%
<b>Total revenue</b>	<b>1,032</b>	<b>982</b>	<b>5%</b>	<b>12%</b>

# Cash generation - Q2 2014

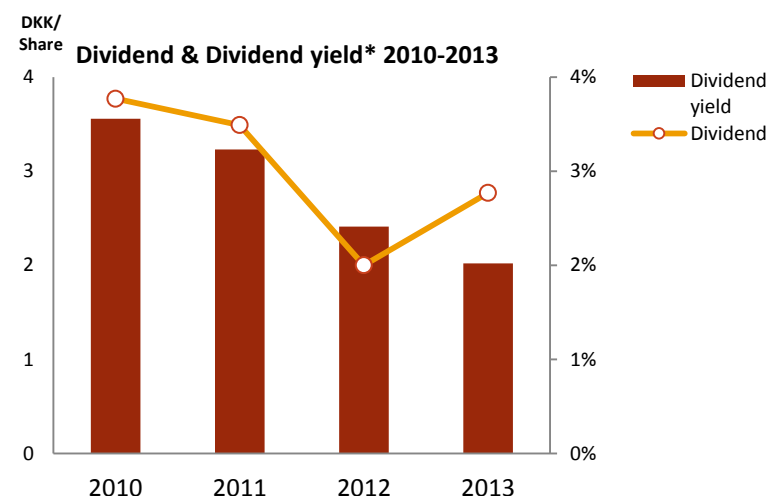
DKK <b>m</b>	Q2 2014	Q2 2013
Cash flows from operating activities	459	1,346
Cash flows from investing activities	(3,024)	(711)
<b>Cash flows from operating and investing activities</b>	<b>(2,565)</b>	<b>635</b>
Cash flows from financing activities	(571)	2
<b>Change in cash</b>	<b>(3,136)</b>	<b>637</b>
Cash	1,424	3,485
Securities	18	1,041
Interest-bearing debt	(2,158)	(1,891)
<b>Interest-bearing net cash and cash equivalents, end of period</b>	<b>(716)</b>	<b>2,635</b>

# Balance sheet and dividend

## Balance sheet

DKKm	30.06.14	30.06.13
Intangible assets	12,535	9,117
Other non-current assets	3,450	3,754
Current assets	6,969	10,510
<b>Assets</b>	<b>22,954</b>	<b>23,381</b>
Equity	13,406	13,391
Non-current liabilities	3,754	3,342
Current liabilities	5,794	6,648
<b>Equity &amp; liabilities</b>	<b>22,954</b>	<b>23,381</b>
Cash	1,424	3,485
Securities	18	1,041
Interest-bearing debt	(2,158)	(1,891)
<b>Interest-bearing net cash and cash equivalents</b>	<b>(716)</b>	<b>2,635</b>

## Dividend



\*Dividend yield = dividend per share/share price, year-end

- ★ Dividend of DKK 2.77 per share for 2013, corresponding to a payout ratio of 64%
- ★ A total of DKK 544 million and a yield of 2%\*\*
- ★ For 2014-2015 the pay-out ratio is expected to be 25-35%

\*\*Based on the share price of DKK 137.00

# Revenue, yearly figures

	Revenue, DKKm					Growth, Y/Y, %			
	2013	2012	2011	2010	2009	2013	2012	2011	2010
Total revenue	15,258	14,802	16,007	14,765	13,747	3%	(8%)	8%	7%
Cipralext	5,933	5,827	5,957	5,808	5,320	2%	(2%)	3%	9%
Ebixa	2,096	2,803	2,751	2,403	2,162	(25%)	2%	14%	11%
Azilect	1,392	1,224	1,187	1,028	769	14%	3%	15%	34%
Xenazine	1,420	1,197	852	610	298	19%	40%	40%	105%
Sabril	530	376	309	179	-	41%	22%	73%	-
Onfi	573	255	-	-	-	125%	-	-	-
Other pharmaceuticals*	1,830	2,494	4,562	4,479	4,920	(27%)	(45%)	2%	(9%)
Other revenue	1,484	626	389	258	278	137%	61%	51%	(7%)

\*including Lexapro US



# Costs, yearly figures

	DKKm					Growth, Y/Y, %			
	2013	2012	2011	2010	2009	2013	2012	2011	2010
Revenue	15,258	14,802	16,007	14,765	13,747	3%	(8%)	8%	7%
Cost of sales	4,038 <sup>1)</sup>	3,720	3,553	3,371	2,982	9%	5%	5%	13%
Sales and distribution costs	4,200	4,836 <sup>3)</sup>	4,132	3,539	3,281	(13%)	17%	17%	8%
Administrative exp.	2,549 <sup>2)</sup>	1,601	1,608	1,453	1,430	59%	0%	11%	2%
R&D	2,872	2,919	3,319	3,045	3,196	(2%)	(12%)	9%	(5%)
EBIT	1,599	1,726	3,395	3,357	2,858	(7%)	(49%)	1%	17%
<i>Cost of sales</i>	<i>26%</i>	<i>25%</i>	<i>22%</i>	<i>22%</i>	<i>21%</i>				
<i>Sales and distribution costs</i>	<i>28%</i>	<i>32%</i>	<i>26%</i>	<i>24%</i>	<i>24%</i>				
<i>Administrative exp.</i>	<i>17%</i>	<i>11%</i>	<i>10%</i>	<i>10%</i>	<i>11%</i>				
<i>R&amp;D</i>	<i>19%</i>	<i>20%</i>	<i>21%</i>	<i>21%</i>	<i>23%</i>				
<i>EBIT-margin</i>	<i>10%</i>	<i>12%</i>	<i>21%</i>	<i>23%</i>	<i>21%</i>				

Included are 1) DKKm 210 write-down of Sycrest 2) EU fine of DKKm 700 and restructuring charge of DKKm 200 3) Restructuring charge (RECO) of DKKm 530

# Appendix

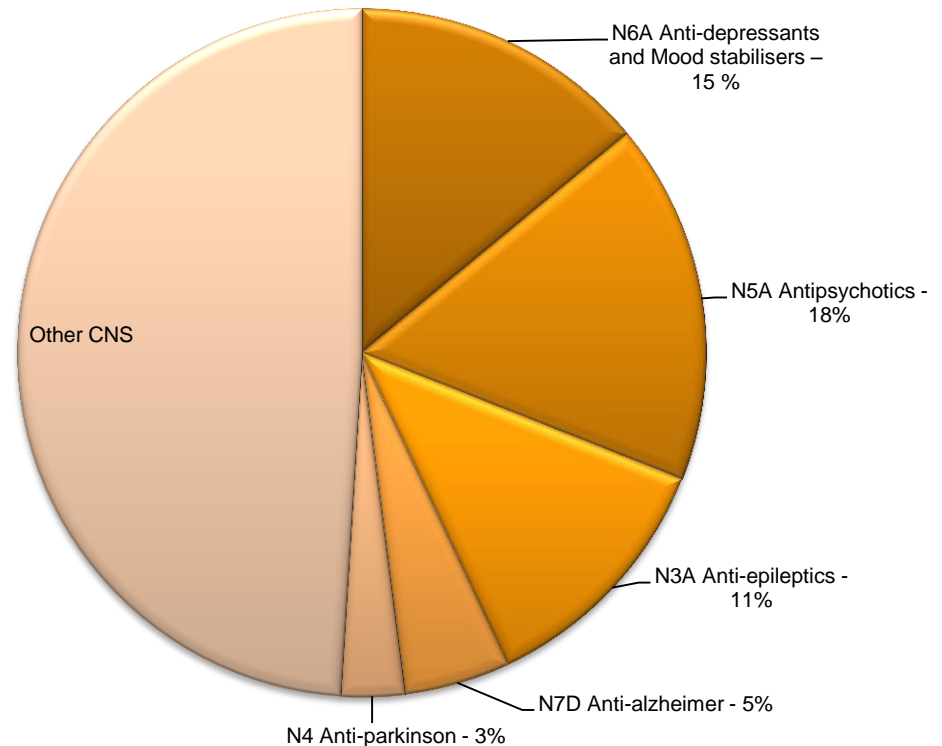
- ★ Lundbeck overview
- ★ Commercial operations
- ★ Pipeline
- ★ Financials
- ★ **The CNS market**
- ★ The Lundbeck share

# The CNS market 2013 – USD 129 billion (+1% y/y)

## The largest pharmaceutical category

### Lundbeck's current focus areas (Share of total CNS market and growth)

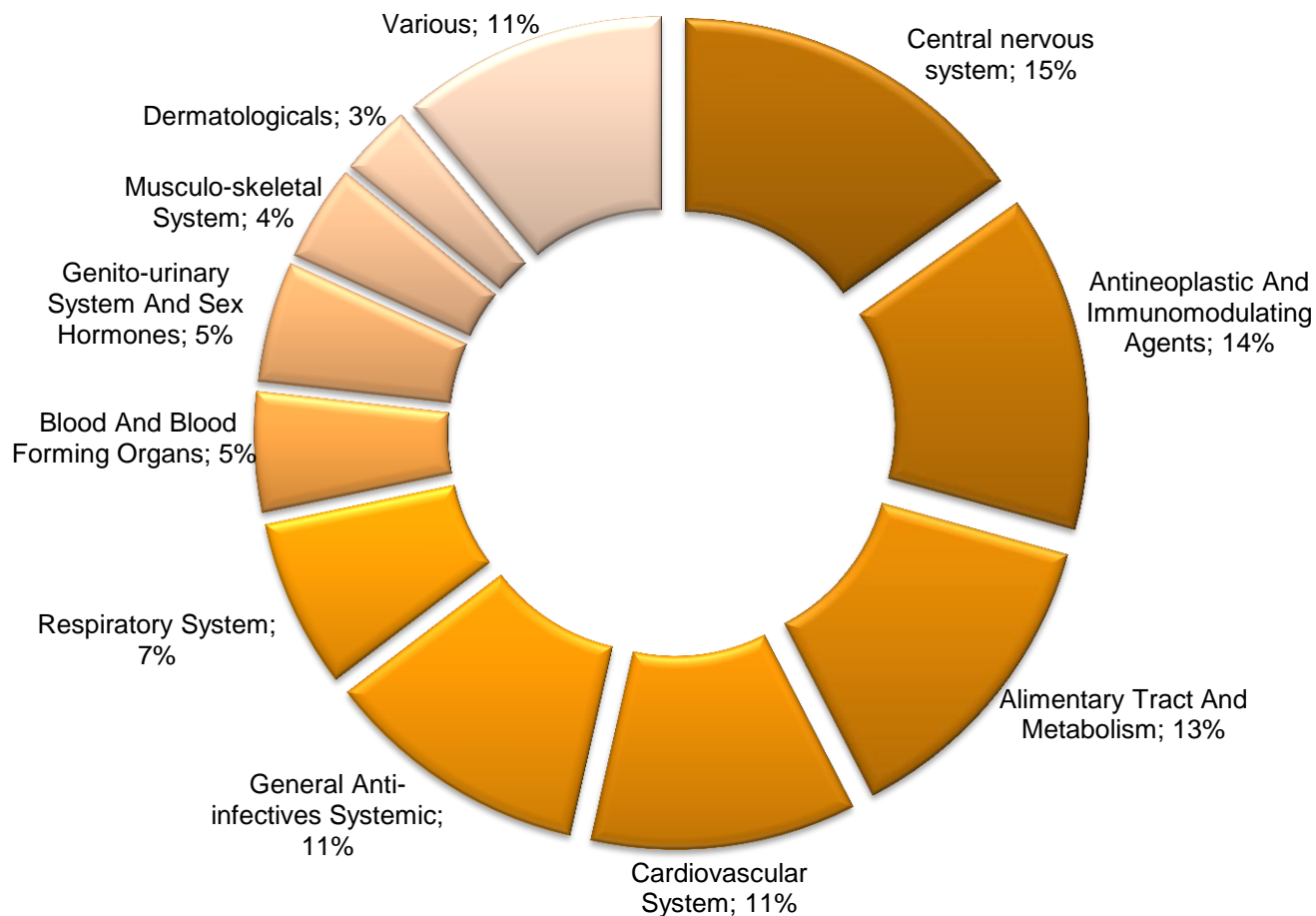
- ★ The CNS market represents 15% of the total pharmaceutical market
- ★ Lundbeck is also present within Huntington's disease with Xenazine...
- ★ ... and has one compound in clinical development in ischaemic stroke



Source: IMS Health Analytics Link 2014 (Audited sales), Growth, 12 months to Q4 2013/2012, \$(%)

# Worldwide pharmaceutical market 2013

## USD 870 billion (+2%)



Source: IMS Health Analytics Link 2014 (Audited sales), Growth, 12 months to Q4 2013/2012, \$(%)

# CNS market overview (2013)

	Market size (2013)		Volume Growth	# of patients*	Unmet medical needs	Market leaders (2013)	
	Value (USDbn)	Value Growth				Compound	Share (value)
<b>Total pharma</b>	870	+2%	+4%	-	-	-	-
<b>Total CNS</b>	129	+1%	+4%	-	-	-	-
<b>Alcohol therapy (N7E)</b>	0.34	+15%	+1%	5% of men and 1.4% of women in Europe	<ul style="list-style-type: none"> <li>• Greater resources – number of treatment facilities and trained physicians is inadequate</li> <li>• The integration of alcohol treatment into primary care</li> <li>• Improved effectiveness</li> <li>• Improved compliance</li> </ul>	1.Vivitrol 2.Campral 3.Antabuse	\$82m \$52m \$13m
<b>Anti-Alzheimer's (N7D)</b>	6.4	-3%	+5%	>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.Donepezil 3.Rivastigmine 4.Galantamine	46% 27% 21% 7%
<b>Anti-depressants (N6A)</b>	18.2	-2%	+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.Paroxetine	37% 11% 7% 7%
<b>Anti-Parkinson's (N4A)</b>	4.3	+2%	+5%	>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	22% 18% 15% 10% 9%
<b>Anti-psychotics (N5A)</b>	21.3	-6%	+4%	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	37% 16% 11% 10%

Source: IMS Health Analytics Link 2014 (Audited sales), Growth,12 months to Q4 2013/2012,\$(%)

# CNS market size – overview (2013)

	Total market		USA		Europe		Int. Markets	
	Value (USDbn)	Growth	Share	Growth	Share	Growth	Share	Growth
Total pharma	870	2%	38%	4%	26%	5%	36%	-2%
Total CNS	129	1%	47%	2%	25%	2%	27%	-2%
Alcohol	0.3	15%	34%	24%	27%	1%	39%	19%
Anti-Alzheimer's	6.4	-3%	42%	9%	23%	-16%	36%	-6%
Antidepressants	18.2	-2%	49%	-4%	23%	5%	28%	-5%
Anti-epileptics	15.8	9%	44%	18%	29%	6%	27%	1%
Anti-Parkinson's	4.3	2%	22%	6%	47%	5%	31%	-5%
Anti-psychotics	21.3	-6%	56%	-7%	23%	-2%	21%	-6%
Fibrinolytics (incl. stroke)	1.2	12%	55%	19%	22%	3%	24%	5%

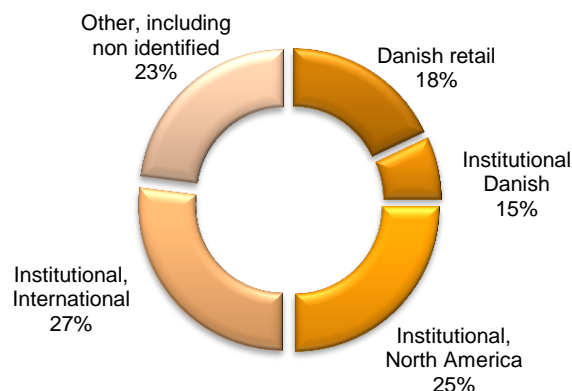
Source: IMS Health Analytics Link 2014 (Audited sales), Growth, 12 months to Q4 2013/2012, \$(%)

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# The Lundbeck share

## Composition of free float ownership (end 2013)



- ★ Free float in the Lundbeck share is 30%
  - ★ The Lundbeck Foundation holds 70% of the total share capital
- ★ Free float (approximately 60m shares) is traded approx. once over annually

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LUNDBECKFONDEN

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- ★ The Lundbeck Foundation is a commercial foundation established in 1954 by Grete Lundbeck, widow of the founder of H. Lundbeck A/S
- ★ The main objective of the Lundbeck Foundation 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



# Sponsored ADR programme

- ★ In May 2012 Lundbeck established a sponsored Level I ADR program in the US. The ADRs trade on the premier tier of Over-The-Counter (“OTC”) market in the US. Details are as follows:

<b>Ticker Symbol</b>	<b>HLUYY</b>
CUSIP	40422M206
Ratio	1 ADR : 1 Ordinary Shares
ADR depositary	Deutsche Bank



Deutsche Bank

- ★ Please contact Deutsche Bank’s dedicated ADR broker desks:

New York Tel: +1 212 250 9100

London Tel: +44 20 7547 6500

Email: [adr@db.com](mailto:adr@db.com)

# 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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