



# CITI'S 2014 GLOBAL HEALTHCARE CONFERENCE

*February 2014*



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# 2013 - A very successful year in every sense

## Operations

Significant growth in the U.S. and in International Markets

New Products up by 45% with additional launches to come

5 product approvals – 3 in Europe and 2 in the U.S.

Improved profitability in Europe after restructuring

Accelerated implementation of new efficiency measures

## Financials

Solid financial performance in 2013

Strong EBITDA in spite of major FX headwinds

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



# Lundbeck's other platforms for long-term growth



- ★ 2013 revenue: DKK 9.5m
- ★ Positive HTA decision expected in several major countries in 2014



- ★ U.S. launch in April 2013 - reinforced sales promotion started in October
- ★ European launch to commence in H1 2014



- ★ Onfi reached DKK 573m and grew by 132% (l.c.) in 2013



- ★ Lexapro Japan reached DKK ~250m and grew by 51% (l.c.) in 2013

New Product\* category up by 45% (51% in l.c.) to DKK 3.1bn in 2013

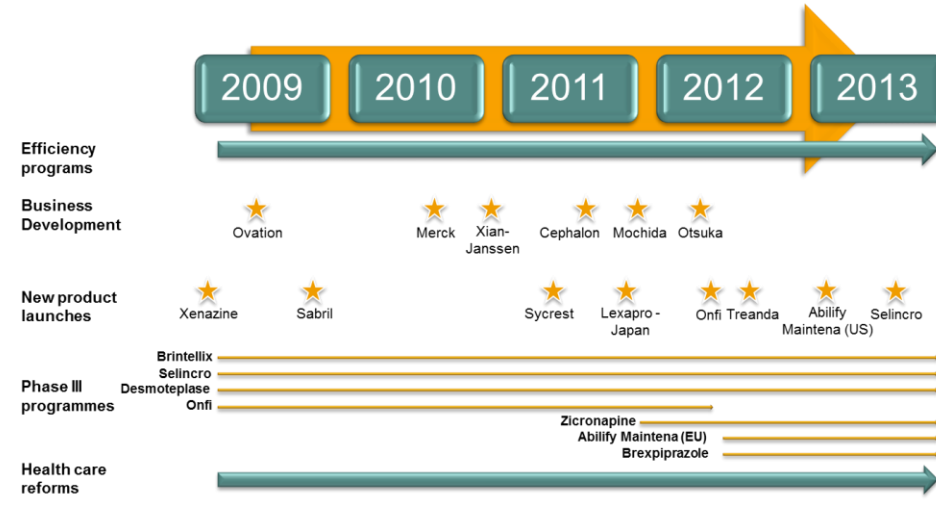
\*New Products include Xenazine, Sabril, Sycrest, Lexapro (Japan), Onfi, Treanda, Selincro, Abilify Maintena and Brintellix

# Executing on Lundbeck's strategy

From "One product" company...

**2009**

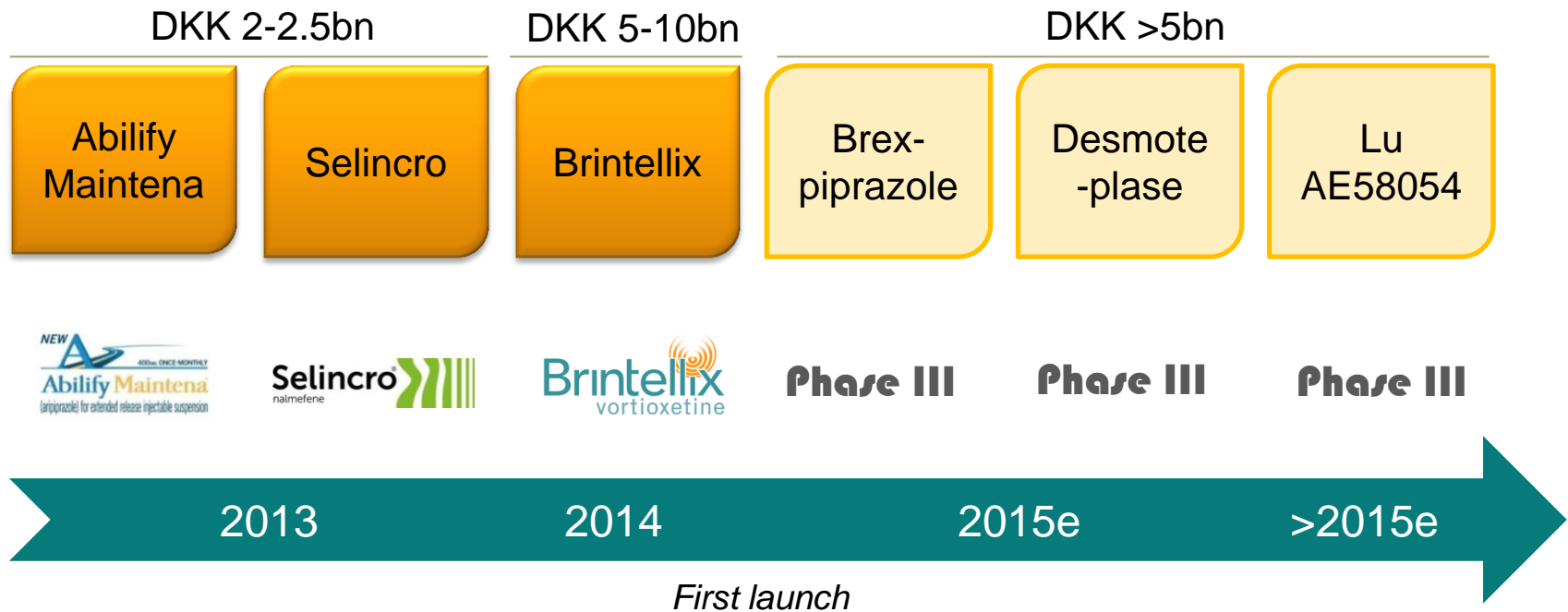
The journey started in 2009



...To the "New Lundbeck"

**2014+**

# Lundbeck products have business transforming potential



# Lundbeck invests to develop the late-stage pipeline

## Initiation of clinical studies

- ★ Lu AE58054 phase III program initiated in October 2013
- ★ Several additional studies on brexpiprazole initiated during 2013

## Planned data disclosures in 2014

- ★ Additional Brintellix and brexpiprazole data at various conferences<sup>1)</sup>

## Potential phase III readouts (internal)

- ★ Desmoteplase (DIAS-3)
- ★ Brexpiprazole (1 adjunct MDD and 2 schizophrenia studies)
- ★ Brintellix (*CONNECT*)

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

	Phase II	Phase III	Registration app.
PSYCHIATRY	MOOD DISORDERS	Tedatioxetine* (Lu AA24530)	Brintellix (CA) (vortioxetine)
	PSYCHOSIS	Zicronapine*	
	ALCOHOL DEPENDENCE		
	DEPRESSION/SCHIZOPHRENIA	Brexpiprazole (OPC-34712)	
NEUROLOGY	ALZHEIMER'S DISEASE	Lu AE58054	
	EPILEPSY	IV carbamazepine →	
	OTHER	Desmoteplase (stroke)	

1) EPA (March), APA (May), NCDEU (June), CINP (June), ECNP (October), ACNP (December) etc.

# Taking depression treatment to the next level



**REMISSION**

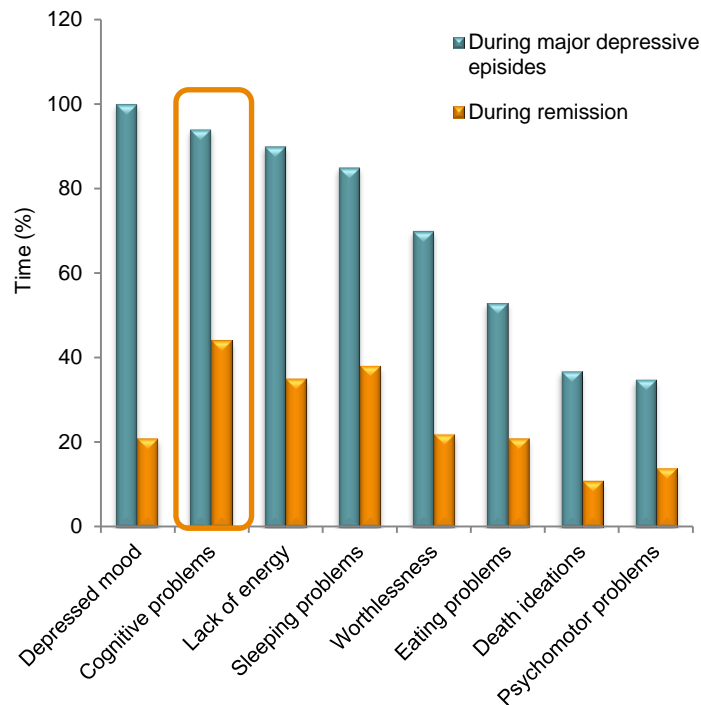
**REDUCED  
side effects**

**TREATMENT  
beyond  
core  
symptoms**

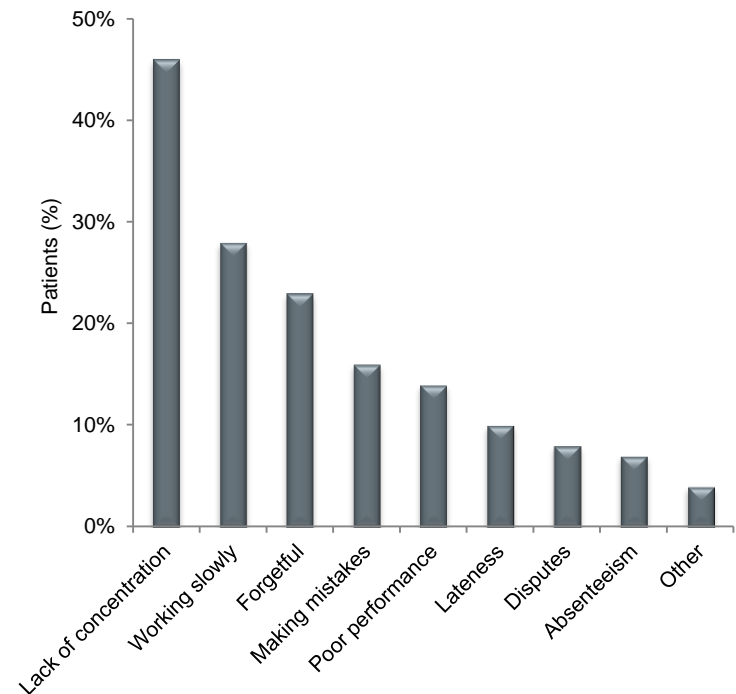


# Cognitive symptoms of depression are frequent and affect work productivity

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



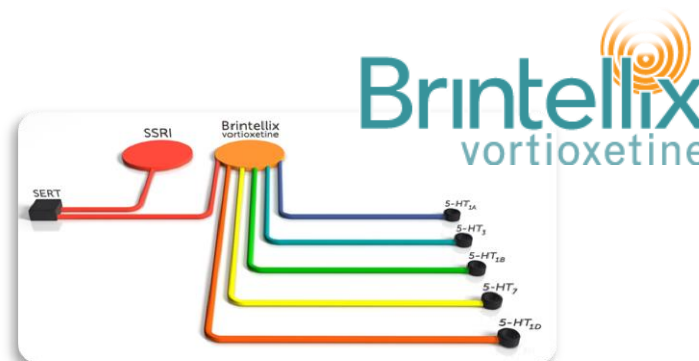
- ★ Percentage of patients with MDD experiencing work-related cognitive dysfunction<sup>2)</sup>



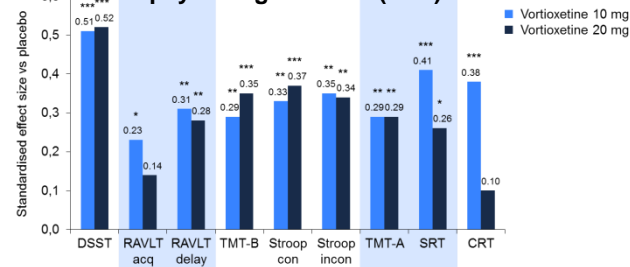
1. Conradi HJ et al. Psychol Med 2011;41:1165-1174;  
2. Adelphi Neurosis DSP VIII, 2009

# 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 (*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>**



<sup>\*</sup>*p*<0.05; <sup>\*\*</sup>*p*<0.01; <sup>\*\*\*</sup>*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

# Brintellix meets many unmet needs in the marketplace

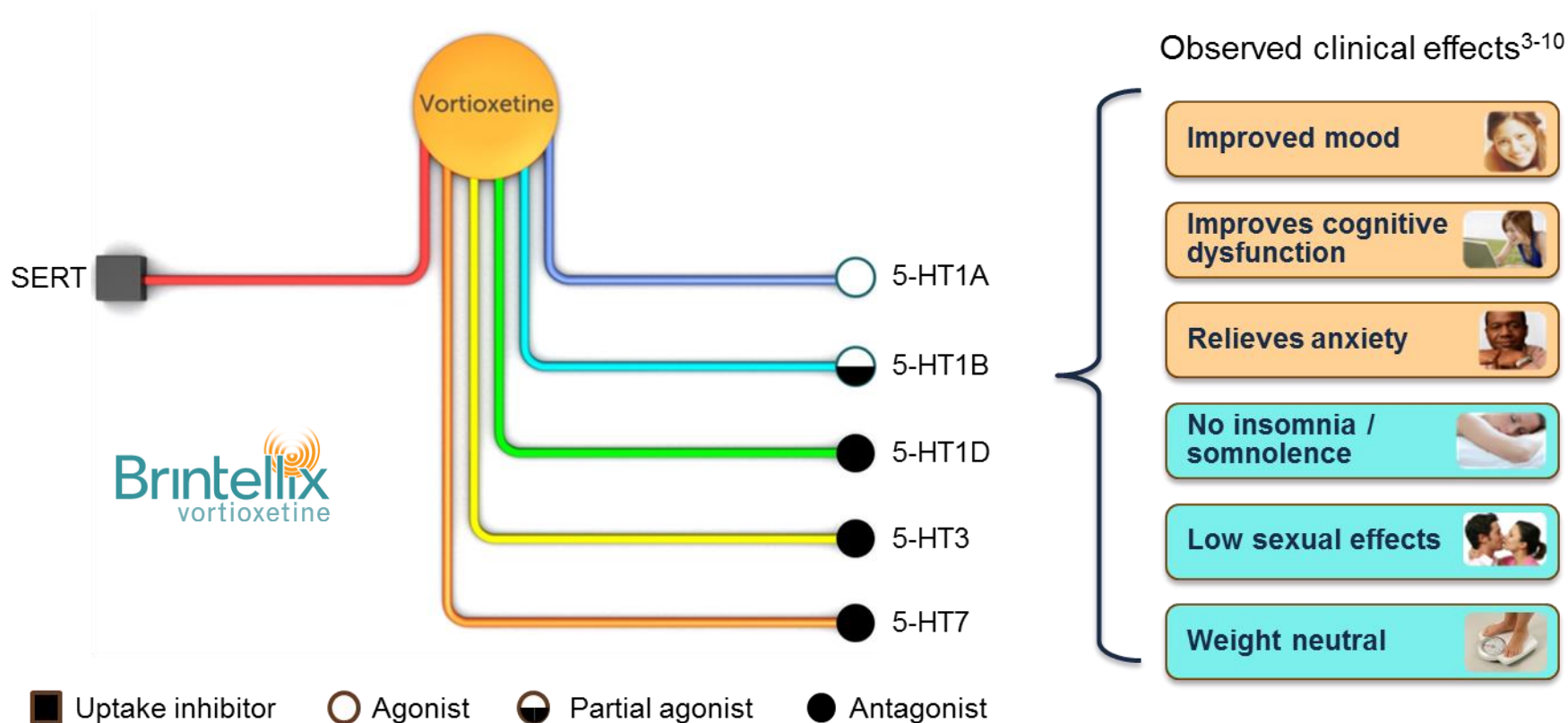
- ★ Launched in the U.S. (01/2014) with competitive salesforce
- ★ Strong and differentiated label
- ★ Early experience program
- ★ First year goal is to secure formulary positions at parity to other brands
- ★ Approved in Europe (12/2013) – market access ongoing
- ★ Read-out from *CONNECT* study upcoming



**Brintellix**  
vortioxetine

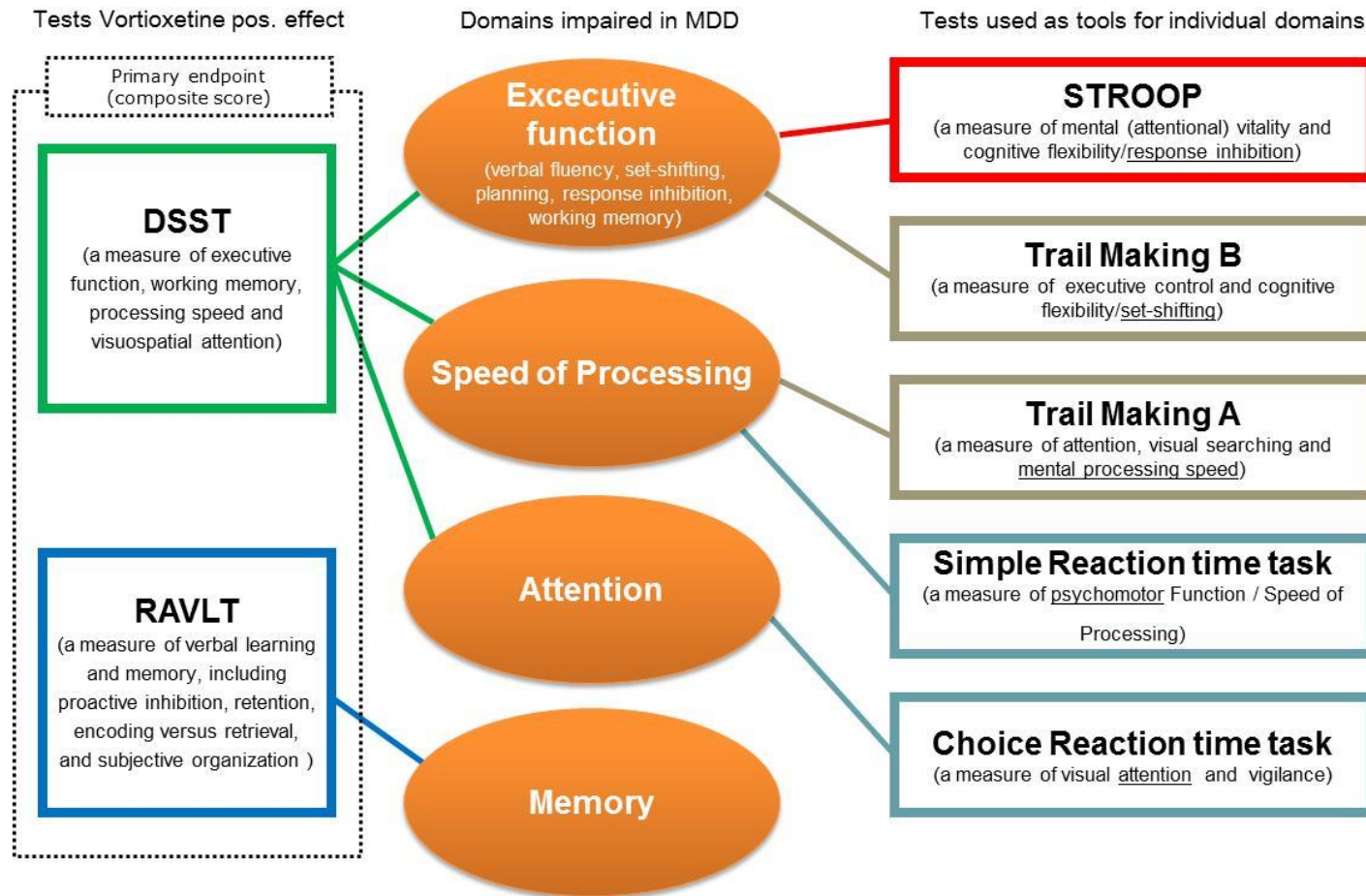


# Brintellix has a distinct pharmacological profile



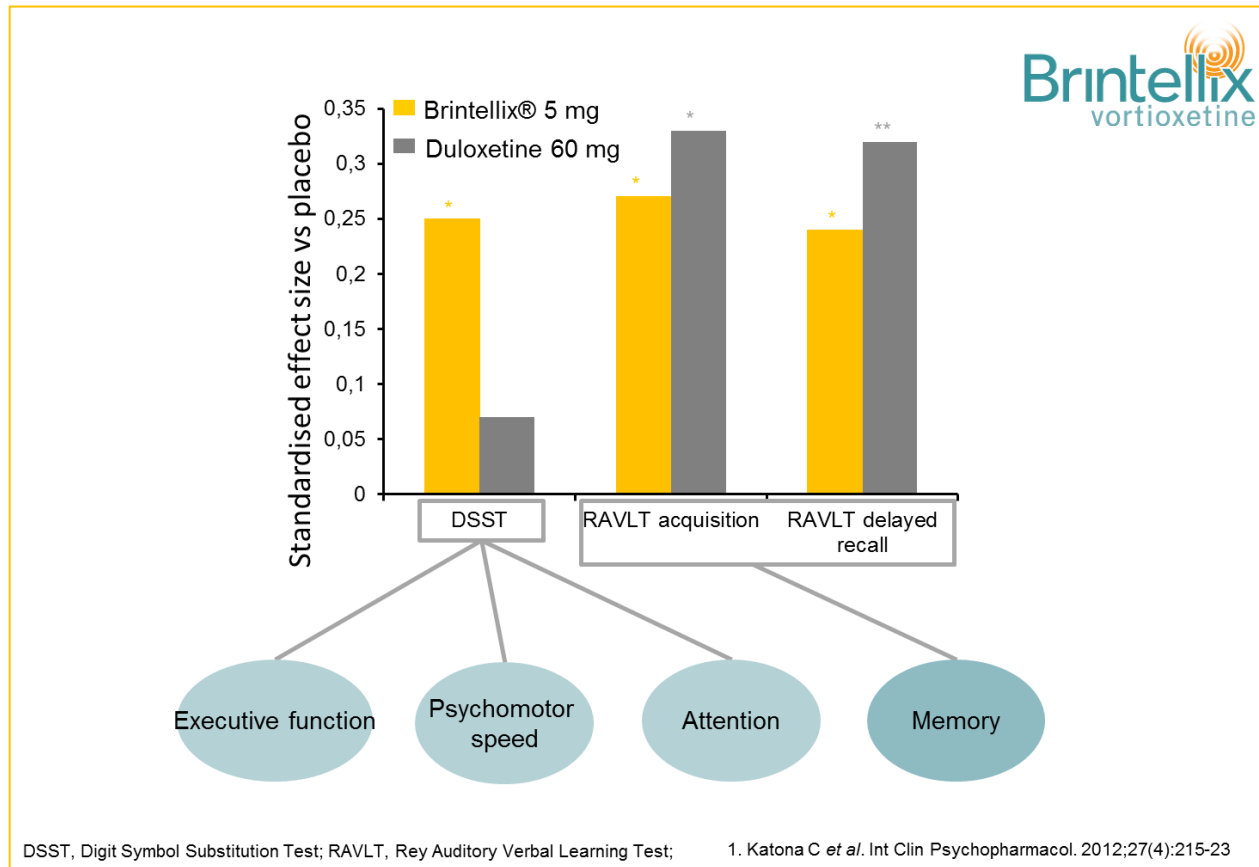
1. Bang-Anderson 2011; 2. Mørk 2012; 3. H. Lundbeck A/S 4. Alvarez 2012;  
5. Katona 2012; 6. Baldwin 2012; 7. Heningsberg 2012; 8. Boulenger 2012; 9. Vortioxetine SPC; 10. Bidzan 2012

# Test Selection Strategy to evaluate cognitive performance



13

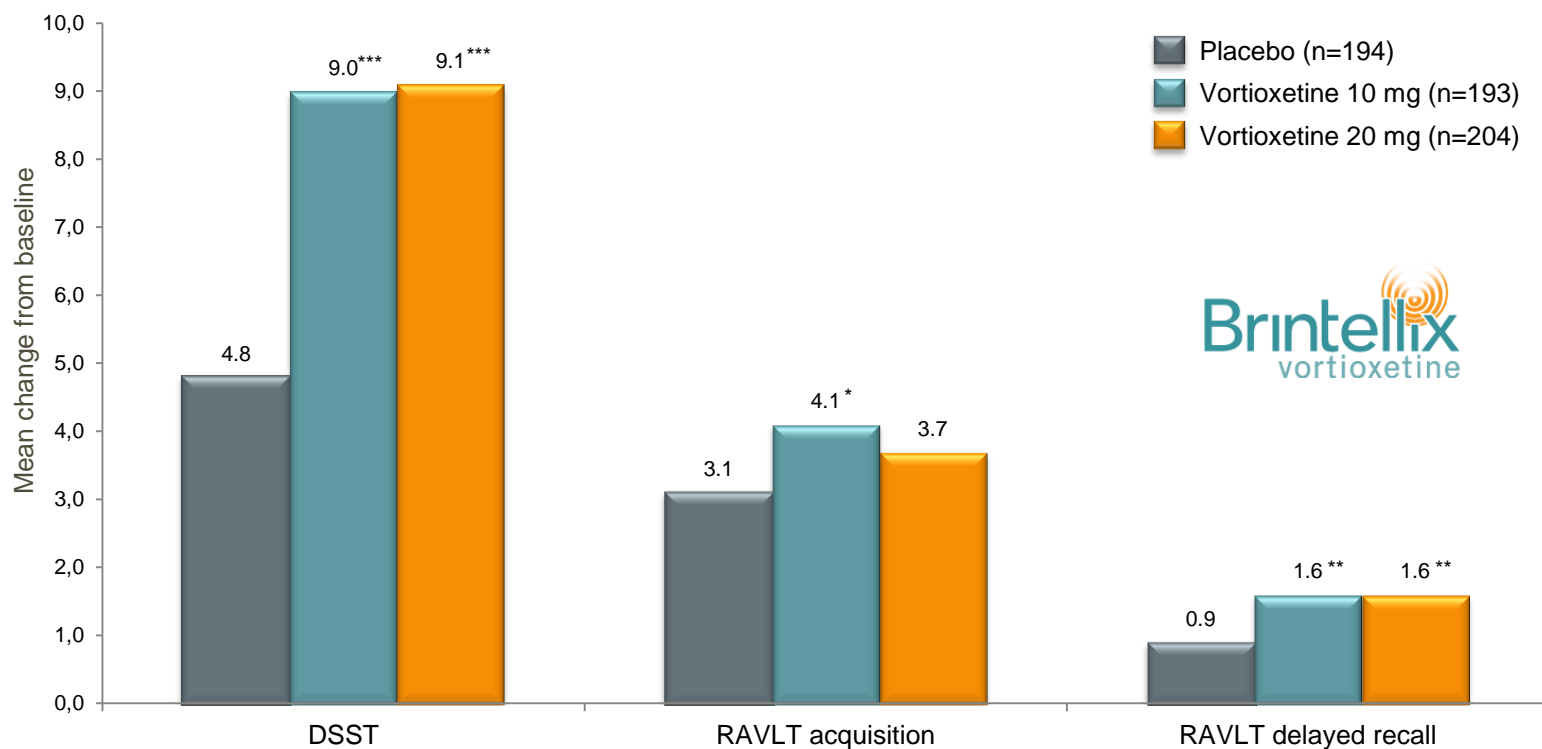
# Brintellix improved cognitive performance in depressed elderly patients<sup>1</sup>





# FOCUS - Brintellix 10 mg and 20 mg are significantly superior to placebo, according to key cognitive scores

Mean change from baseline to week 8 (FAS, MMRM)



\*p<0.05, \*\*p<0.01; p<0.001 vs placebo; nominal p-values (with no adjustments for multiplicity) for RAVLT scores

McIntyre et al. Poster presented at ACNP 2013

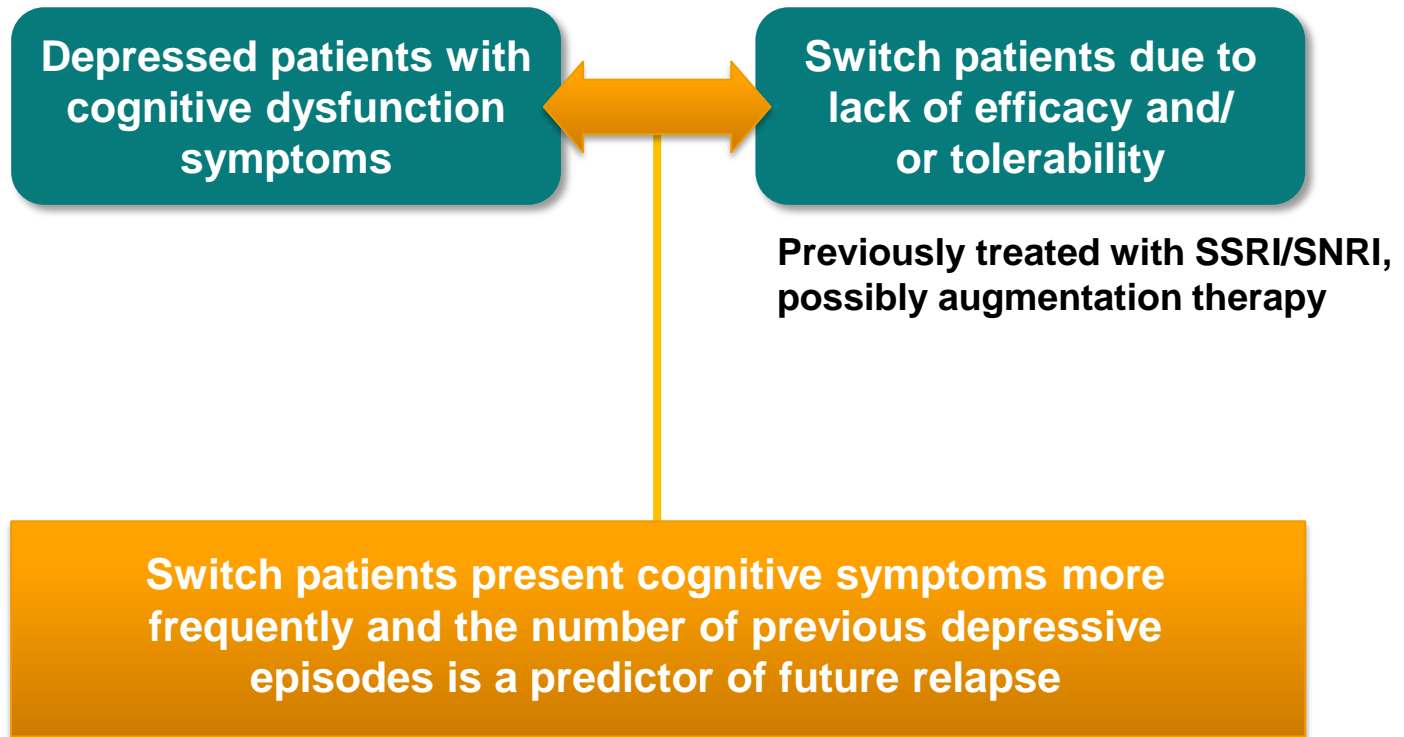
# Data support Brintellix for cognitive dysfunction in major depression

- ★ Robust pre-clinical research indicates differentiated profile for Brintellix on measures of cognitive functioning
- ★ Data from two clinical studies support a role for Brintellix in cognitive function associated with major depression
- ★ Further studies ongoing

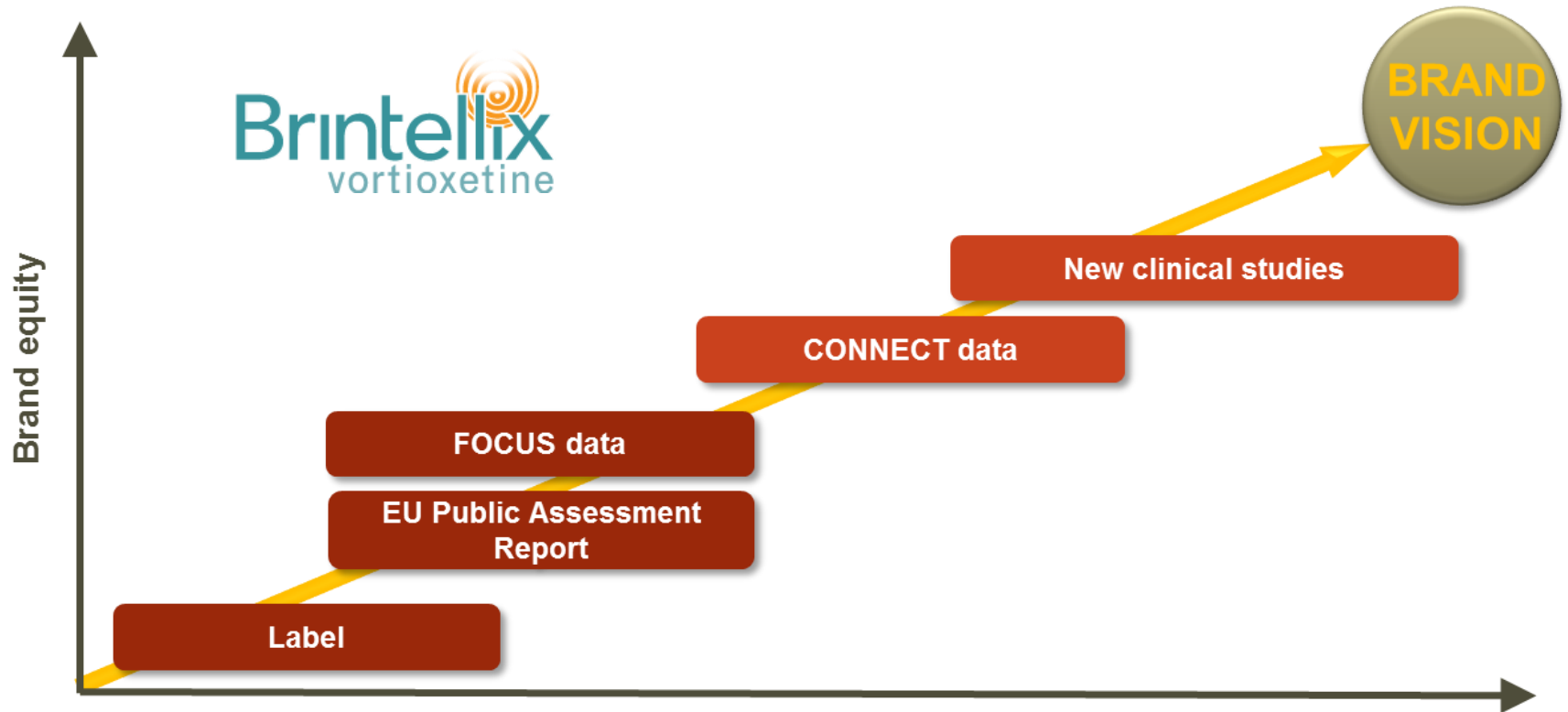


**Brintellix**  
vortioxetine

# Population groups of interest for achieving market access for Brintellix



# With new clinical data we will build and strengthen the Brintellix brand over time



# Brexpiprazole represents a substantial promise and rationale

## Major depression

- ★ Favourable tolerability profile vs. other anti-psychotics
- ★ Synergistic effect with SSRIs/SNRIs
- ★ Positive outcome<sup>1)</sup> from first out of two studies (EPA) – read-out from second trial in mid-2014

## Schizophrenia

- ★ Broad efficacy profile
- ★ Favourable tolerability profile vs. other anti-psychotics
- ★ Read-out from two phase III studies in mid-2014

## Agitation in Alzheimer's disease

- ★ Two phase III studies with ~800 patients ( $\leq 2\text{mg}$ )
- ★ Read-out from phase III possible in 2017

## Post-traumatic stress disorder

- ★ A phase III study with ~600 patients ( $\leq 3\text{mg}$ )
- ★ Read-out from phase III possible in 2015

1) 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 2004 (abstract)

# 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	Approved in the US and EU	Incomplete responsive dep.			
Tedatioxetine	Phase II*				
Brexpiprazole	Phase III	non / inadequate responsive dep.			
Sycrest/Saphris	Launched				
Abilify Maintena	Launched (US) Filed (EU)				Maintenance treatment
Zicronapine	Phase III*				
Lu AF11167 (PDE <sup>1)</sup> )	Phase I**				

\*No active clinical programme ongoing

1) Phosphodiesterase enzyme \*\*March 2011



# Desmoteplase to report first headline conclusions from phase III clinical program in Q2

- ★ Desmoteplase represents a **potential break-through** therapy
- ★ In pooled analysis of patients with occlusion (TIMI 0-1) desmoteplase showed **significant effect** versus placebo<sup>1)</sup>
- ★ Stroke is the **leading cause** of serious, long-term disability in the U.S....
  - ★ ...and the 2<sup>nd</sup> biggest cause of mortality globally<sup>2)</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

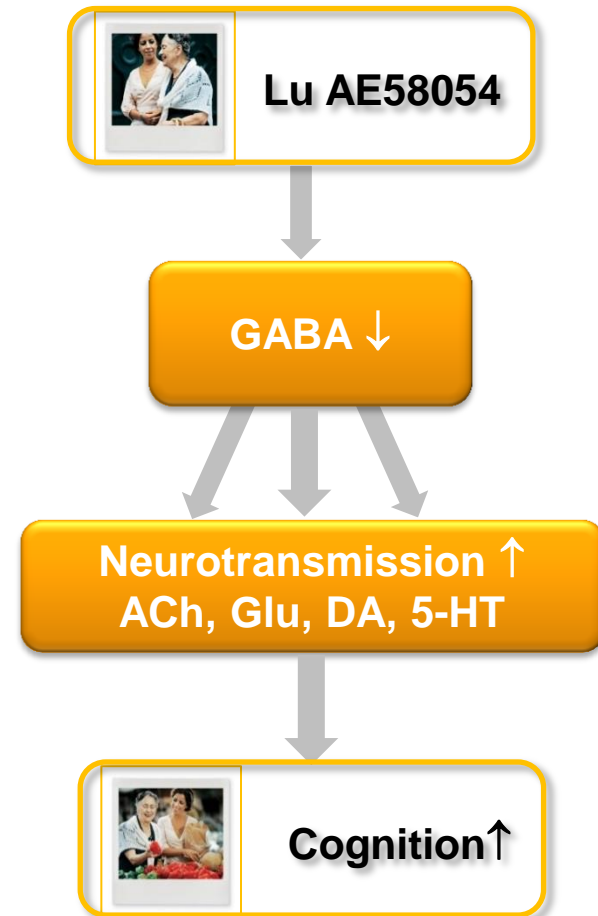
Ease of administration  
(single bolus, i.v. injection)

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

1) Fiebach et al. Stroke 2012; 43:1561-1566. 2) U.S. Centers for Disease Control and Prevention and WHO.

# 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

## – data read-out possible in 2016

Study	Treatment Duration	Design	Lu AE58054 (mg/day)	Donepezil (mg/day)	Primary Endpoint Scale	No. of patients
<b>Current phase III program</b>						
NCT01955161	24 weeks	Randomized, DB, PBO, parallel-group, fixed-dose adjunctive treatment to donepezil	30 and 60	10	ADAS-cog	~930
NCT02006641	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
NCT01019421 (phase II)	24 weeks	Adj. to donepezil	90	10	ADAS-cog	278
DB: double-blind; PBO: placebo-controlled						

# 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
  - ★ Phase I to commence in 2014



# 2014 will be an investment year

## 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 ~675m** from DKK 592m in 2013
- ★ **Major part** of earnings will be recognised in H1 2014

## Financial guidance 2014

DKK	Reported 2013	2014 Guidance
Revenue	15,258m	~13.5bn
EBIT	1,599m	0.5-1.0bn

# Expected main events in 2014

## H1 2014

- Launch Brintellix in the U.S. ✓
- Start the launch of Brintellix in Europe
- Start the launch of Abilify Maintena in Europe
- Desmoteplase (DIAS 3) headline conclusions
- Brexpiprazole data on first MDD study out of two at EPA in March
- *CONNECT* headline conclusions on Brintellix
- Brexpiprazole study read-out from three additional phase III studies (mid-year)

## H2 2014

- HTA assessment on Selincro in selected major European markets
- Brexpiprazole FDA submission (pending data)
- Phase I start on Lu AF20513 in Alzheimer's





## ON TRACK TO DELIVER LONG-TERM GROWTH

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