



# INVESTOR & ANALYST PRESENTATION

*Spring 2016*



# Company disclaimer

This presentation contains forward-looking statements that provide our expectations or forecasts of future events such as new product introductions, product approvals and financial performance.

Such forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations and it may cause any or all of our forward-looking statements here or in other publications to be wrong. Factors that may affect future results include interest rate and currency exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, government-mandated or market-driven price decreases for Lundbeck's products, introduction of competing products, Lundbeck's ability to successfully market both new and existing products, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws and related interpretation thereof, and unexpected growth in costs and expenses.

Lundbeck undertakes no duty to update forward-looking statements.

Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with products that are prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the products are currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.



# Q1 2016 highlights

## Restructuring programme well on track

- FTEs reduced to 5,070 compared to 5,859 at the end of Q1 2015
- Total costs down 9% improving EBIT margin from (0.9%) to 12.8%

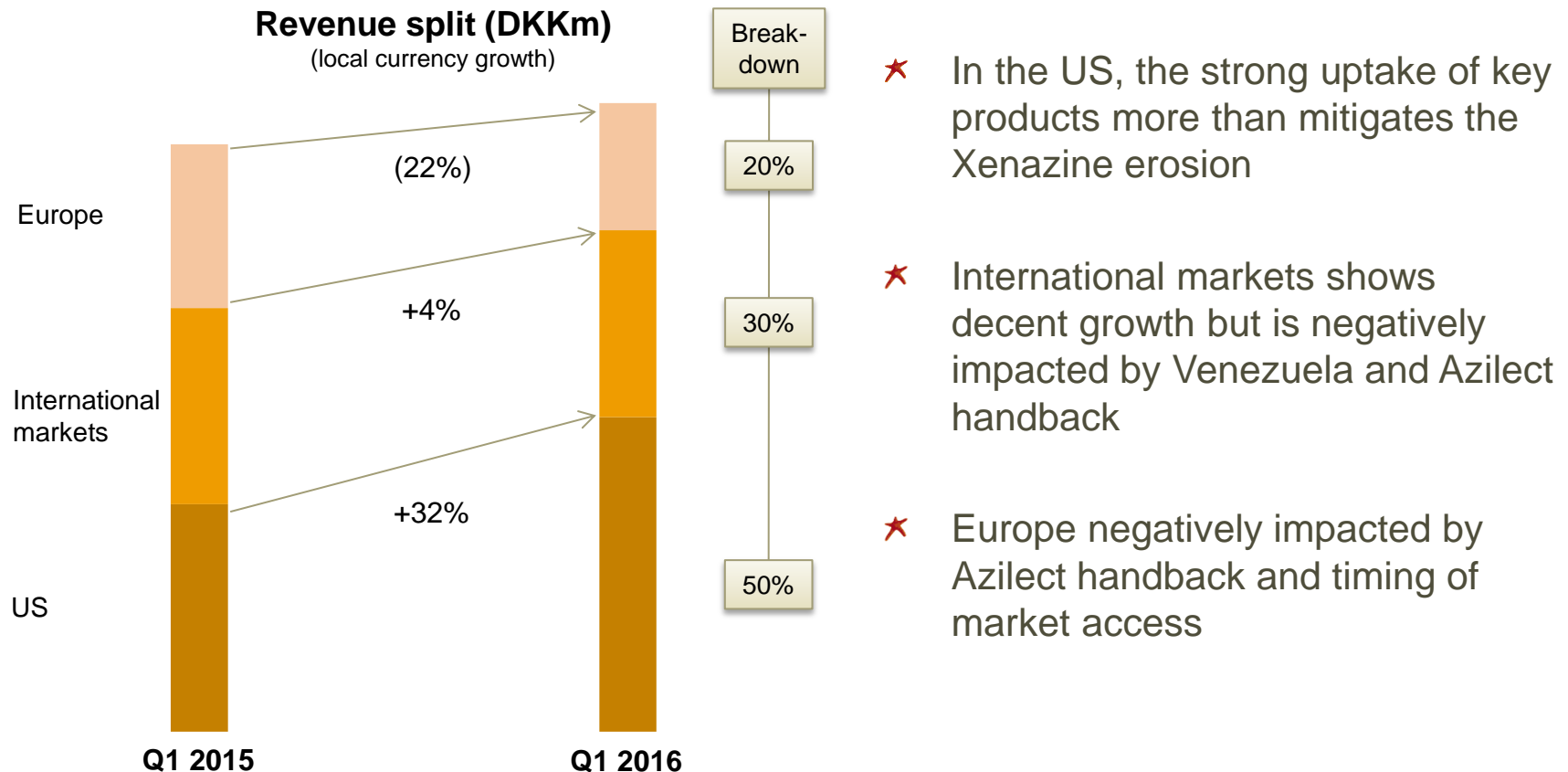
## All key products continue the solid momentum

- Key products grew 108% (103% in local currencies) to DKK 1,352m
- Represents 36% of total revenue in the quarter

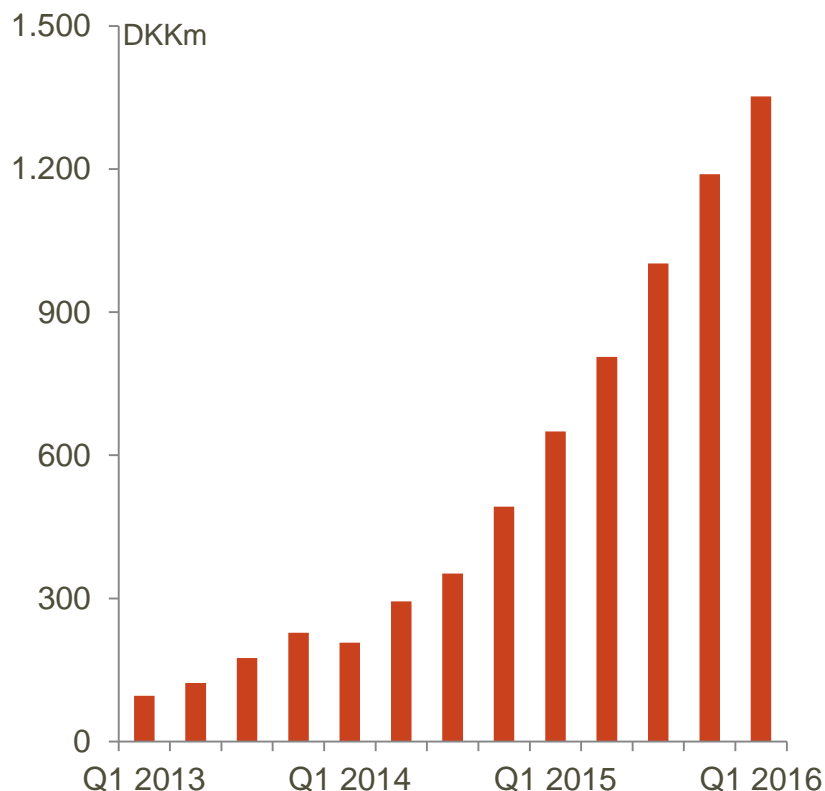
## 2016 guidance raised

- Lundbeck expects revenue of DKK 14.2-14.6 billion and EBIT of DKK 1.3-1.5 billion for 2016

# The US - a main driver of sales performance



# Key products\* continue solid growth momentum



- ★ Sales up 108% y/y in Q1 reaching DKK 1,352m
- ★ Limited FX impact
- ★ 36% of revenue vs 18% in Q1 2015

NEW  
Abilify Maintenance  
400mg ONCE-MONTHLY

Northera<sup>™</sup>  
(droxidopa) capsules  
100 mg-200 mg-300 mg

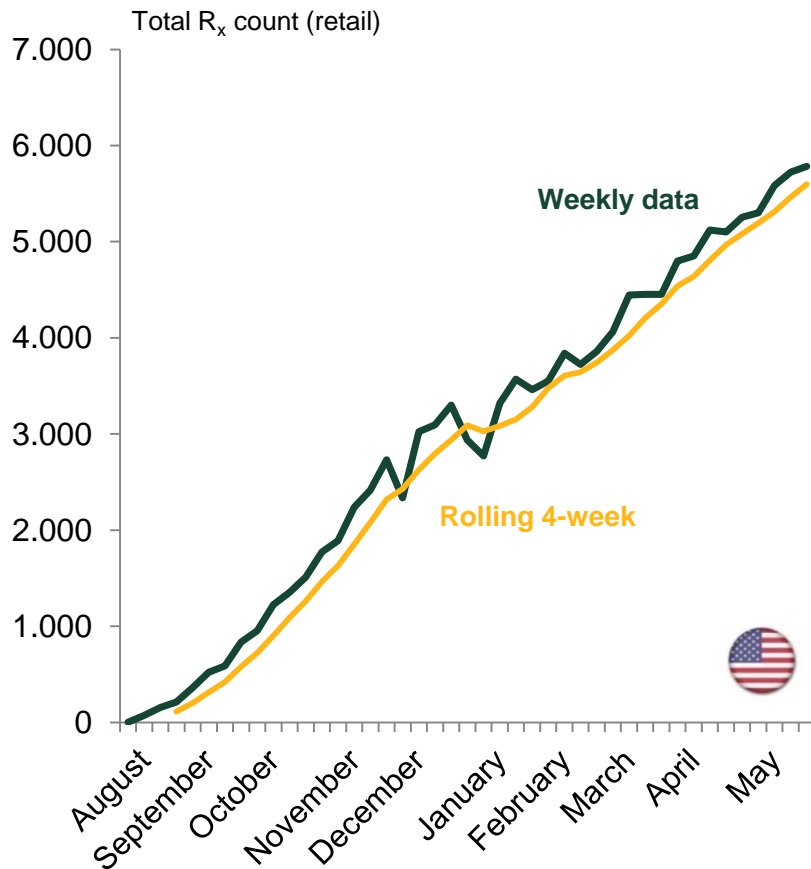
Brintellix  
vortioxetine

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

REXULTI<sup>™</sup>  
brexpiprazole  
tablets

\*Abilify Maintenance, Brintellix, Northera, Onfi, Rexulti included from August 2015

# Rexulti reached DKK 116 million in Q1 2016



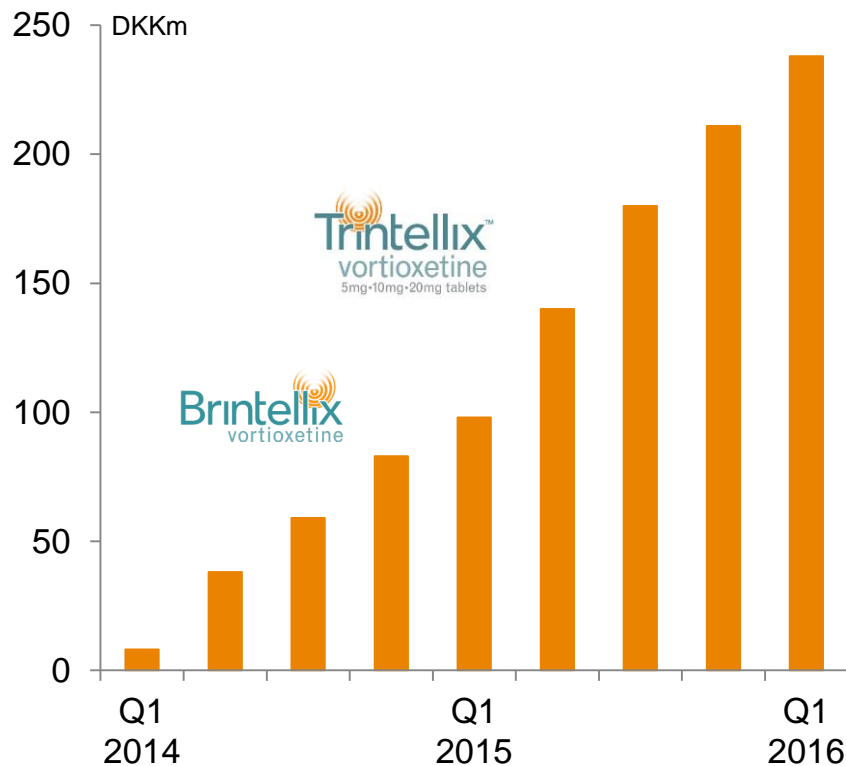
Source: Bloomberg (week ending 20/5 2016)

- ★ ~6.5% branded TR<sub>x</sub> market share and ~8% branded NR<sub>x</sub> market share
- ★ FDA accepts the sNDA filing for labeling update to include maintenance treatment
- ★ The PDUFA date is 23 Sept. 2016
- ★ Submitted in Canada and Australia



# Strong Brintellix growth continues

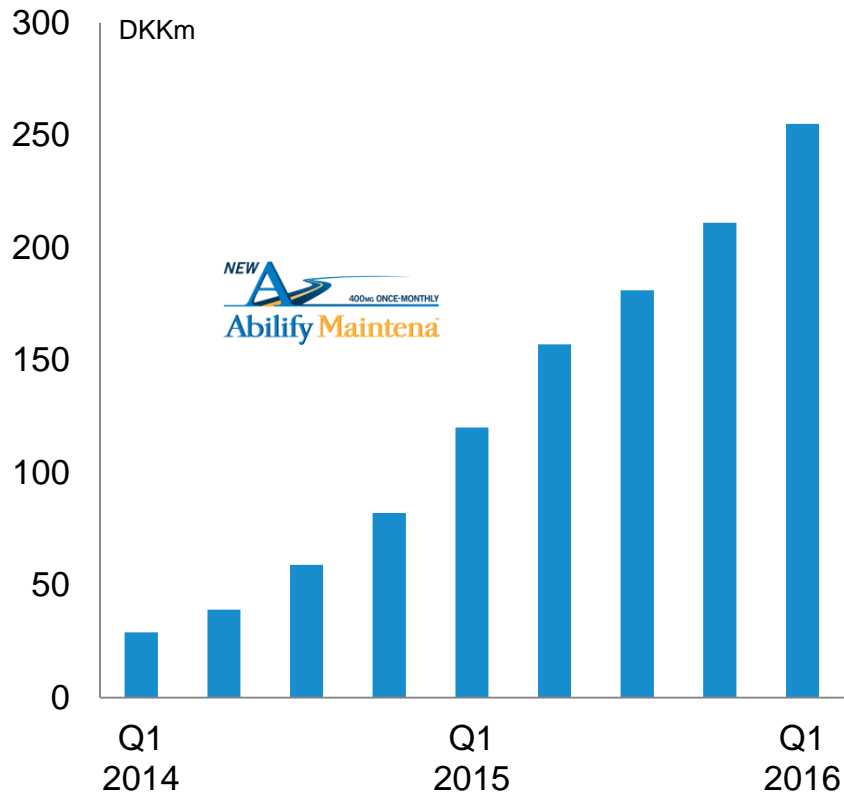
Brintellix total sales (DKKm)



- ★ Sales of DKK 238m – up 142% reported or 152% in local currencies
- ★ US represents close to 58% of sales
- ★ Value market share ranges from 1-8% in countries outside the US
- ★ Recently launched in Brazil, Italy and Spain

# Abilify Maintena continues its solid traction

Abilify Maintena total sales (DKK m)



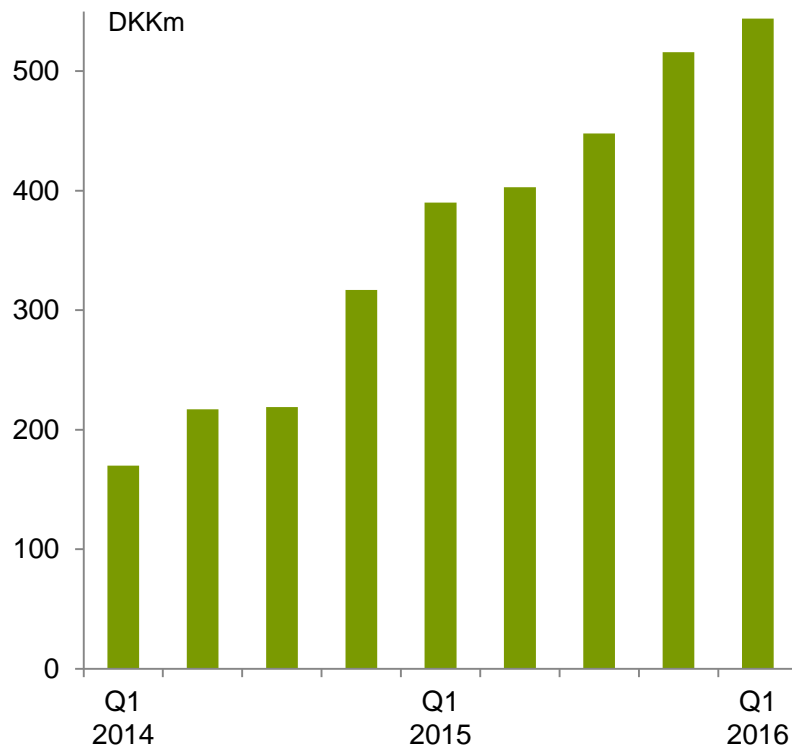
- ★ Sales of DKK 255m – up 113% or 110% in local currencies
- ★ US constitutes close to 41% of sales
- ★ 10-15% value market share in most markets
- ★ Continued solid growth momentum





# Onfi still favored by increased TR<sub>x</sub> volume

Onfi net sales (DKK<sub>m</sub>)

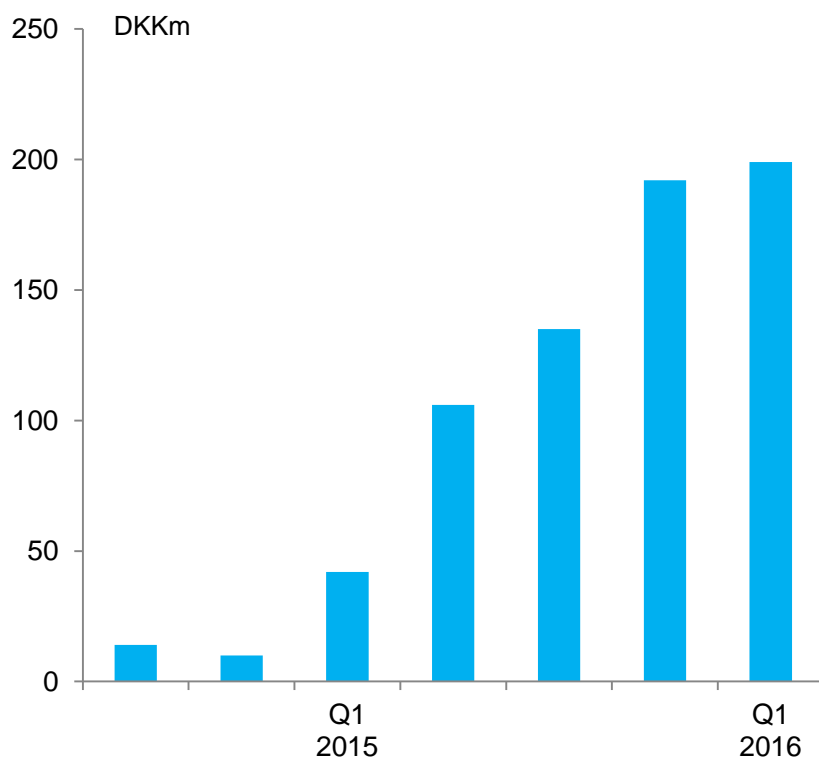


- ★ Sales of DKK 544m – up 39% or 33% in local currencies
- ★ Continued increased demand driven by increase in mg/R<sub>x</sub> and higher TR<sub>x</sub> volume
- ★ Launched in January 2012



# Northera further strengthens growth platform

Northera total sales (DKKm)



- ★ Sales of DKK 199m – up 371% or 346% in local currencies
- ★ Growth driven by favorable demand due to higher enrollees and conversion to standard R<sub>x</sub>
- ★ Launched in September 2014

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



# Lundbeck invests to develop late-stage pipeline

## Key achievements:

### Rexulti

- ★ Submitted in Australia and Canada

### Brintellix/Trintellix

- ★ CRL received on the sNDA to include data on cognitive dysfunction in MDD

### Abilify Maintena

- ★ Study in bipolar maintenance reached primary endpoint

## Lundbeck sponsored or co-sponsored open clinical studies

| Project                      | No. of active studies and no. of patients to be recruited | Status       |
|------------------------------|---|--------------|
| Brintellix/Trintellix* - MDD | 3 (1,700 pts)   | Launched     |
| Brintellix/Trintellix - ADHD | 1 (225 pts)   | Phase II     |
| Abilify Maintena – bipolar I | 1 (755 pts)   | Phase III    |
| Selincro                     | 1 (400 pts)   | Launched     |
| Rexulti – adjunctive MDD     | 1 (2,363 pts)   | FDA approved |
| Rexulti – schizophrenia      | 3 (504 pts)   | FDA approved |
| Rexulti – Alzheimer's        | 2 (650 pts)   | Phase III    |
| Idalopirdine - Alzheimer's   | 4 (2,522 pts)   | Phase III    |
| Lu AF35700 - TRS             | 1 (964 pts)   | Phase III    |

*\*) Additionally Takeda has two studies ongoing including approx. 1,500 patients in Japan*

*Source: Clinicaltrials.gov. as per 4 May 2016*

# Our path to category leadership

## Current products

## Pipeline

### Depression



Research projects

### Schizophrenia



Lu AF35700

Research projects

### Alzheimer's



Rexulti

Idalopirdine

Lu AF20513

Research projects

### Parkinson's



Research projects

Early clinical projects

# Complete Response Letter for Brintellix/Trintellix sNDA

- ★ 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

**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 10 mg once daily

- ✓ Brintellix can be taken with or without food at any time of the day
- ✓ No dose adjustments are needed in patients with mild to moderate renal impairment or in patients with mild to moderate hepatic 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 a combination of oral contraceptives

**SIMPLE DOSING**

**EXCELLENT TOLERABILITY**  
Brintellix 10 mg once daily has a low risk of side effects typical of antidepressants.

**WEIGHT INCREASE**  
Brintellix is not associated with weight gain. In clinical studies, patients taking Brintellix gained less weight than those taking placebo.

**SEXUAL DYSFUNCTION AT PLACEBO LEVEL**  
Brintellix is not associated with sexual dysfunction. In clinical studies, patients taking Brintellix had sexual dysfunction rates similar to those taking placebo.

**SLEEP DISTURBANCE AT PLACEBO LEVEL**  
Brintellix is not associated with sleep disturbance. In clinical studies, patients taking Brintellix had sleep disturbance rates similar to those taking placebo.

**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 www.nice.org.uk for full details. © 2015 Lundbeck. All rights reserved.

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

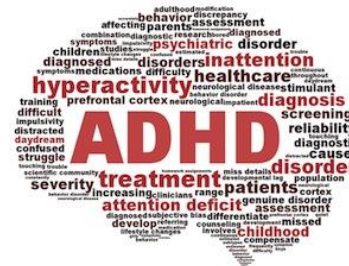
**Brintellix**  
vortioxetine

# Brintellix – PoC study in adult patients with ADHD

- ★ ~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
- ★ 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

# 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 has finalized recruiting
- ★ 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

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

# Rexulti for agitation/aggression in Alzheimer's

## The condition

- ★ Agitation/aggression is a core feature of Alzheimer's
- ★ >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
- ★ No drugs approved for this indication and it remains a high unmet need



## Clinical programme

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

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



Phase III data: H1 2018



# 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
- ★ 3/4 of the patients in the programme 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 clinical phase III program on idalopirdine

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

# Lu AF35700 in Treatment Resistant Schizophrenia (TRS)

- ★ Unique mode of action. In contrast to current treatment, antipsychotic effect at low  $D_2$  blockade
- ★ 5-HT<sub>6</sub> blockade may improve cognitive function
- ★ Combined  $D_1/D_2$  and 5-HT<sub>6</sub> profile gives good antipsychotic activity combined with a benign tolerability profile
- ★ Very long half-life leads to significantly reduced risk of relapse on per oral therapy
- ★ Four clinical studies have been conducted, three studies in healthy people and one in patients with schizophrenia\*)
- ★ Psychiatrists readily recognize the term '**Treatment Resistant Schizophrenia**'
- ★ They define TRS as an **inability to control symptoms** of schizophrenia after a full round of two to three antipsychotics

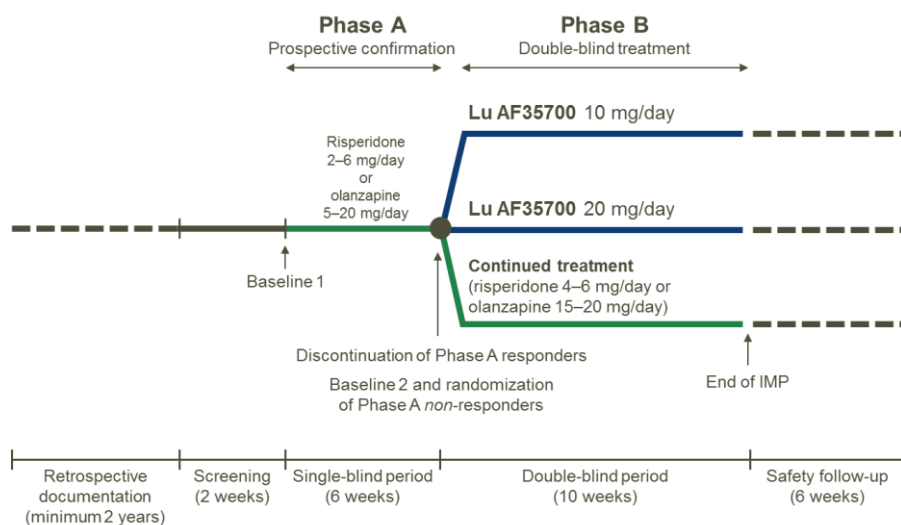


Majority of psychiatrists consider a third of their schizophrenia patients as treatment resistant



\*) Clinicaltrials.gov identifier: NCT02202226

# Lu AF35700 clinical phase III in Treatment Resistant Schizophrenia (TRS) commenced



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

# Strong R&D pipeline across focus areas

| Disease areas  | Phase I    | Phase II         | Phase III                                 | Registration |
|----------------|------------|------------------|---|--------------|
| Alzheimer's    | Lu AF20513 |                  | Idalopirdine<br>Brexiprazole              |              |
| Mood disorders |            | Brintellix, ADHD | Brexiprazole (EU)<br>Abilify Maintena, BP |              |
| Parkinson's    | Lu AE04621 |                  |   |              |
| Schizophrenia  |            |                  | Lu AF35700<br>Brexiprazole (EU)           |              |

# Q1 2016 financial performance

| DKK <b>m</b>   | Q1 2016 | Q1 2015 |
|----------------|---------|---------|
| Revenue        | 3,770   | 3,563   |
| EBITDA         | 824     | 308     |
| EBIT           | 483     | (32)    |
| Net financials | (123)   | -       |
| Tax            | 174     | 49      |
| Net profit     | 186     | (81)    |
| EPS            | 0.94    | (0.41)  |

★ Impact from LoE mitigated by growth in key products

★ Limited currency impact

★ EBIT margin increased from (0.9%) to 12.8%

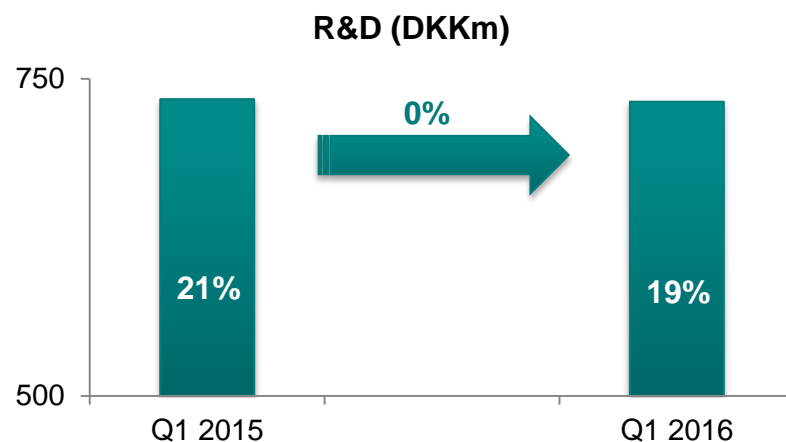
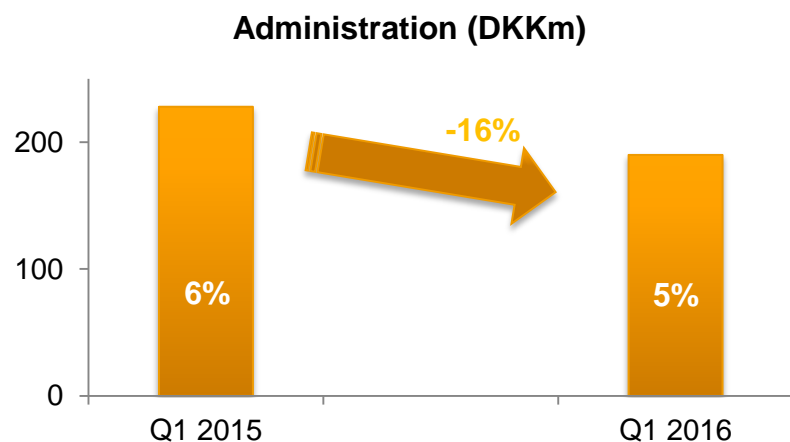
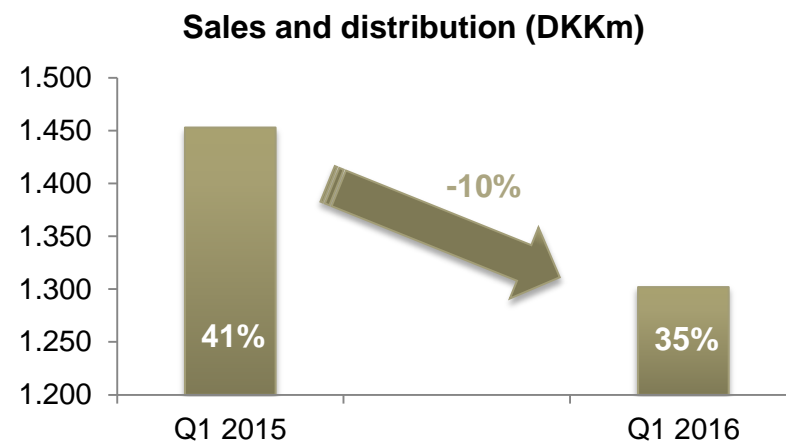
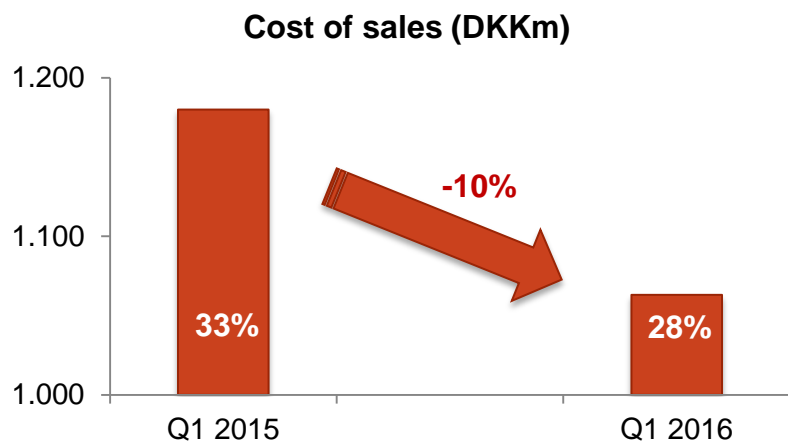
Continued margin improvements:

★ Effects from restructuring programme

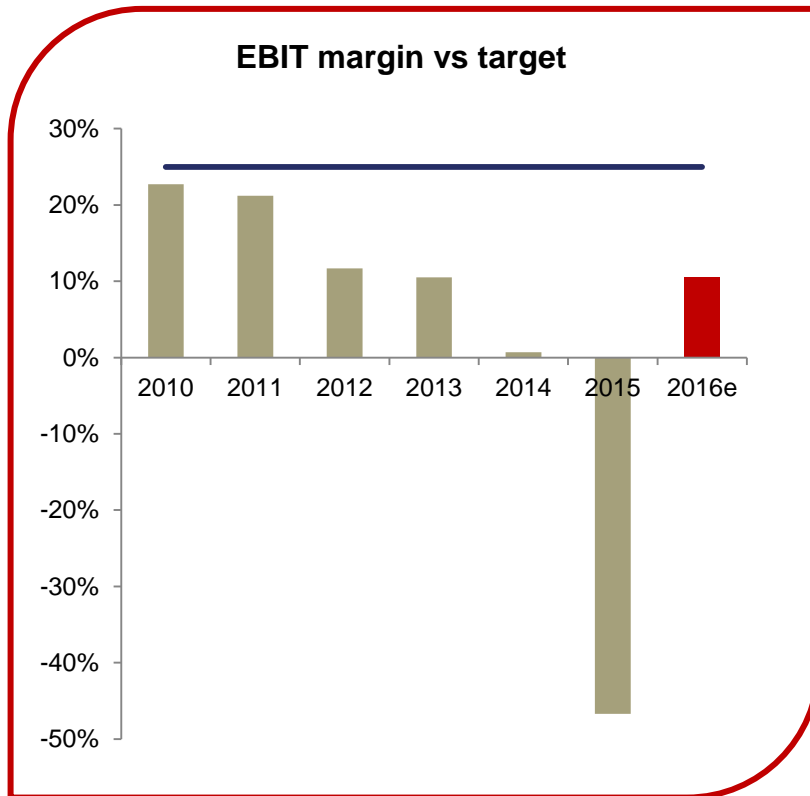
★ Growth in key products with higher margins

★ Erosion of low-margin products such as Azilect and Xenazine

# All cost ratios are down – driving the solid margin improvement



# Transformation of Lundbeck under way



- ★ 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



# Healthy operating cash flow

| DKK <b>m</b>              | <b>Q1<br/>2016</b> | <b>Q1<br/>2015</b> |
|---------------------------|--------------------|--------------------|
| Operating cash flow       | 357                | (382)              |
| Free cash flow            | 320                | (418)              |
| Net cash flow             | (28)               | (515)              |
| Cash                      | 1,383              | 3,160              |
| Net interest-bearing debt | (2,052)            | (86)               |
| Net debt/EBITDA           | 2.5x               | 0.3x               |

## Cash flow drivers:

- ★ Strong improvement in profitability
- ★ Improved working capital
- ★ Provisions reduced by spend on restructuring
- ★ Net interest-bearing debt expected at DKK 1.2-1.4 billion at year-end

# 2016 financial guidance raised

## Financial guidance 2016

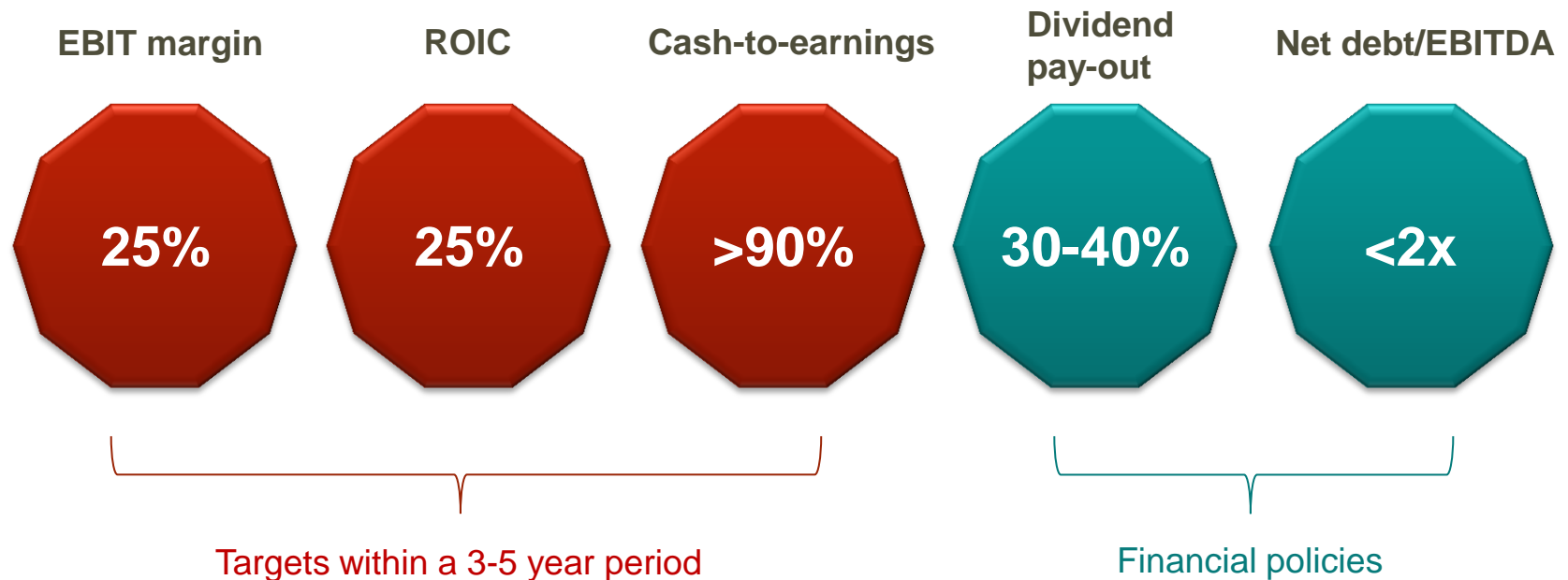
|               | Revised 2016 guidance* | Previous 2016 guidance |
|---------------|------------------------|------------------------|
| Revenue       | DKK 14.2-14.6bn        | DKK 13.8-14.2bn        |
| Reported EBIT | DKK 1.3-1.5bn          | DKK 1.0-1.2bn          |

\* Based on exchange rates as per ultimo April 2016

## Revenue and profit drivers

- ★ Accelerated growth in key products
- ★ Cost savings from restructuring initiatives
- ★ No new 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



**We strive for global leadership  
in psychiatry and neurology by  
improving the lives of patients**



# Our principles...



## **We are focused**

on innovating treatments for depression, schizophrenia, Parkinson's disease and Alzheimer's disease while creating value for all our stakeholders

## **We are passionate**

about helping patients and communities affected by psychiatric and neurological disorders

## **We are responsible**

and overcome challenges by demonstrating respect, open-mindedness and integrity

# 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

# Strategic objective: *We will grow our business with a strong focus on profitability*



**Cost base  
reduced by  
DKK 3bn\*  
in 2017**

**Improved profitability will enable us to:**

- ★ Continue investing in growth opportunities
- ★ Continue to develop potentially innovative products
- ★ Absorb fluctuations

## Restructuring program announced in August revisited

- ★ Reduce cost base by DKK 3 billion in 2017
- ★ One-off charges of DKK ~6.5 billion before tax in 2015
  - ★ Global workforce to be reduced by ~1,000 employees
  - ★ Reclassification of product rights to R&D costs (Q2.15)
  - ★ Provision for severance and restructuring: DKK ~1.1bn (Q3.15)
  - ★ Impairments and write-downs: DKK ~0.7bn (Q3.15)

### Progress:

- ★ ~80% of planned headcount reductions carried out
- ★ All workers consultations are finalized
- ★ Research activities at Paramus, NJ, closed
- ★ Non-core projects are being divested
- ★ Optimization of partnerships



\*) Based on cost plans prevailing before Q2 2015 announcement



# 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.

# The basis for achieving category leadership



# 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

# Lundbeck has a long history of conducting R&D programmes in all four therapeutic focus areas

## Examples of Lundbeck's R&D core

- MDD / SSRI accomplishments
- Monoaminergic / psychiatry
- Psychiatry novel target id. (CNVs)
- Established and novel CNS pharmacology models (e.g. new schizophrenia mouse)
- Kinase targets for neurological disorders
- Protein / antibody therapeutics to vaccines for neurological disorders (AD/PD)

## Lundbeck's capabilities

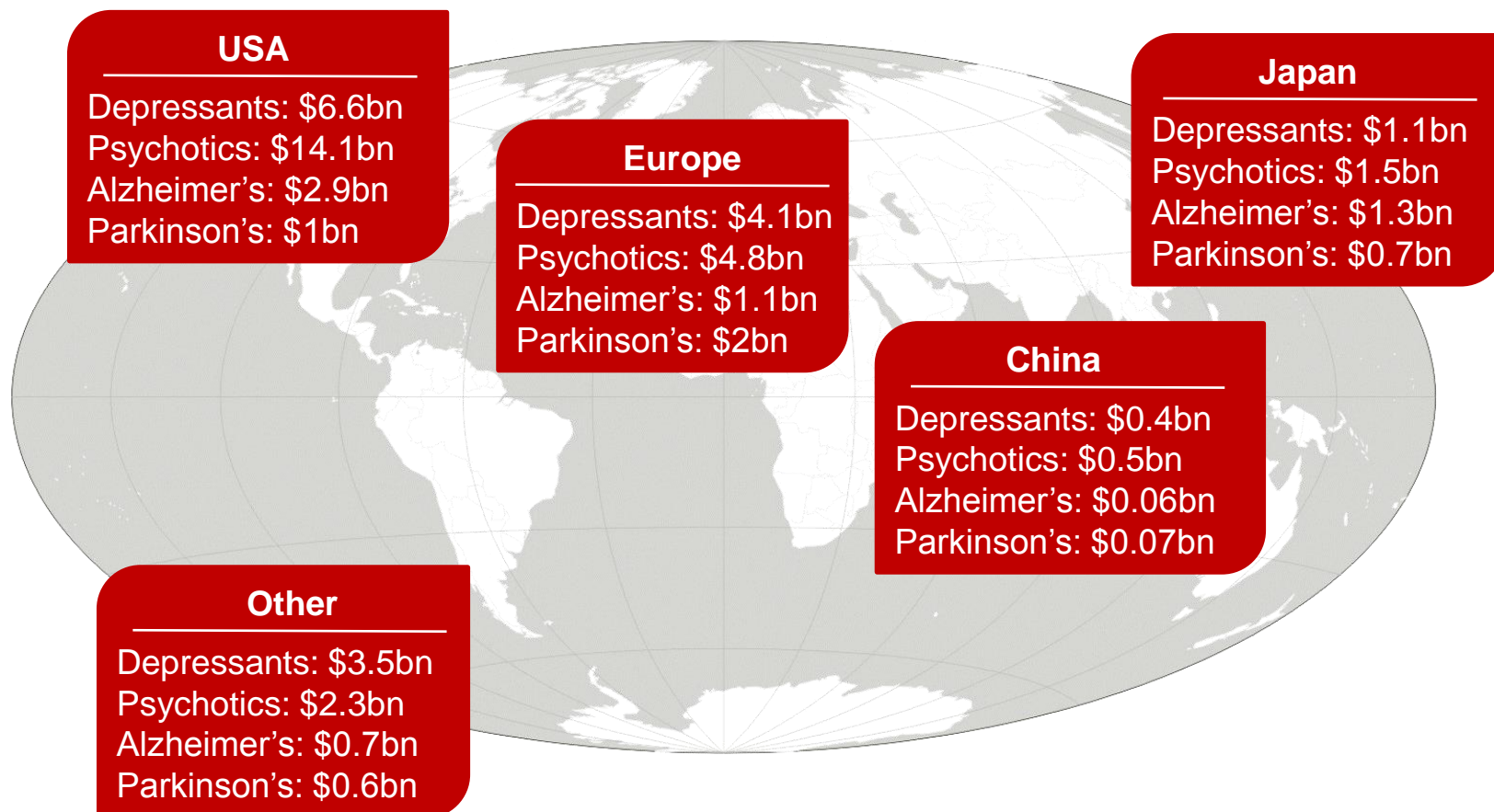
Integrated translational capabilities from biological targets to disease manifestation within CNS

## Selected external research collaborations



**Core capabilities enhanced by strategic collaborations –  
Lundbeck has ~50 early-stage partnerships**

# Market sizes of our four core therapeutic areas



Source: IMS Health Analytics Link 2015 (Audited sales)

# 2014 - CNS market overview

|                               | Market size (2014) |              |               | # of patients*                 | Unmet medical needs   | Market leaders (2014)   |                                |
|-------------------------------|--------------------|--------------|---------------|--------------------------------|---|---|--------------------------------|
|                               | Value (USDbn)      | Value Growth | Volume Growth |                                |   | 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<br>2. Rivastigmine<br>3. Donepezil<br>4. Galantamine             | 50%<br>22%<br>21%<br>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<br>2. Escitalopram<br>3. Venlafaxine<br>4. Bupropion            | 25%<br>11%<br>8%<br>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<br>2. Pramipexole<br>3. Rasagiline<br>4. Stalevo<br>5. Ropinirole | 20%<br>16%<br>15%<br>10%<br>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<br>2. Quetiapine<br>3. Risperidone<br>4. Olanzapine           | 40%<br>14%<br>9%<br>9%         |

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

# Supply operations



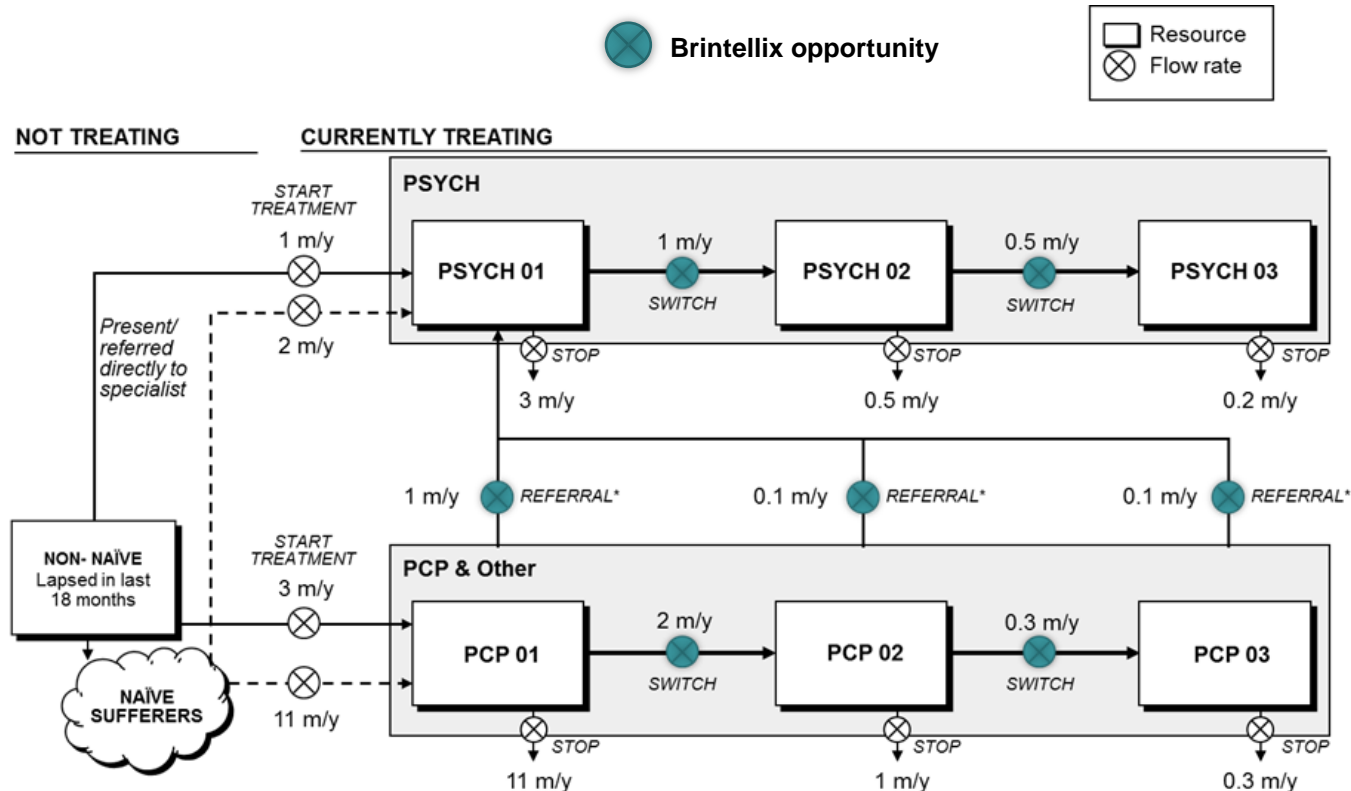
# Brintellix (vortioxetine, Lu AA21004)





# The antidepressant market is characterized by significant patient “churn”

*Patient flow in US antidepressant market*

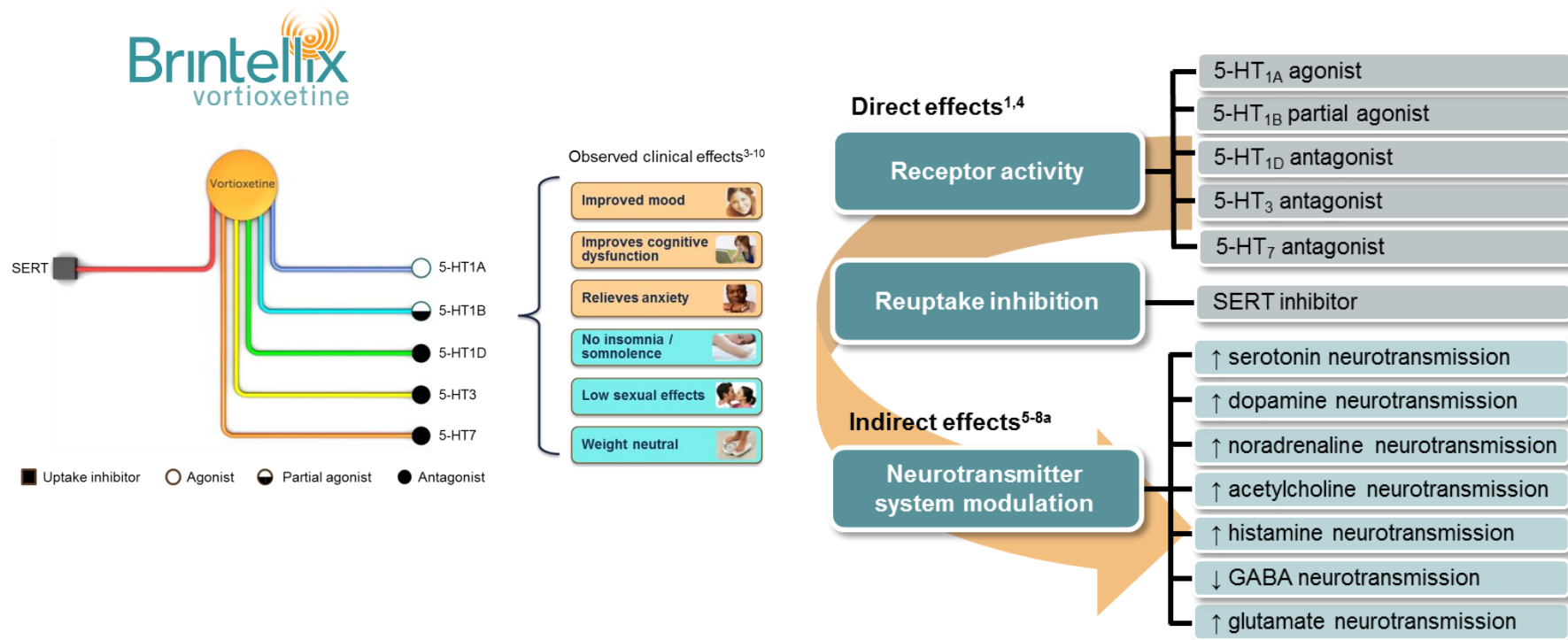


**Brintellix**  
vortioxetine

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

# 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

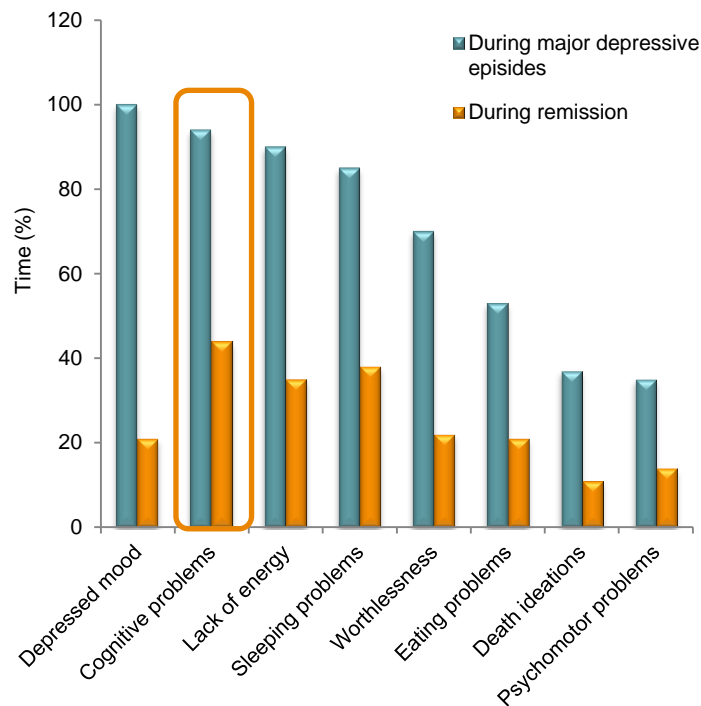
# With Brintellix our vision is to advance the treatment of depression so that patients not only feel but think and do better



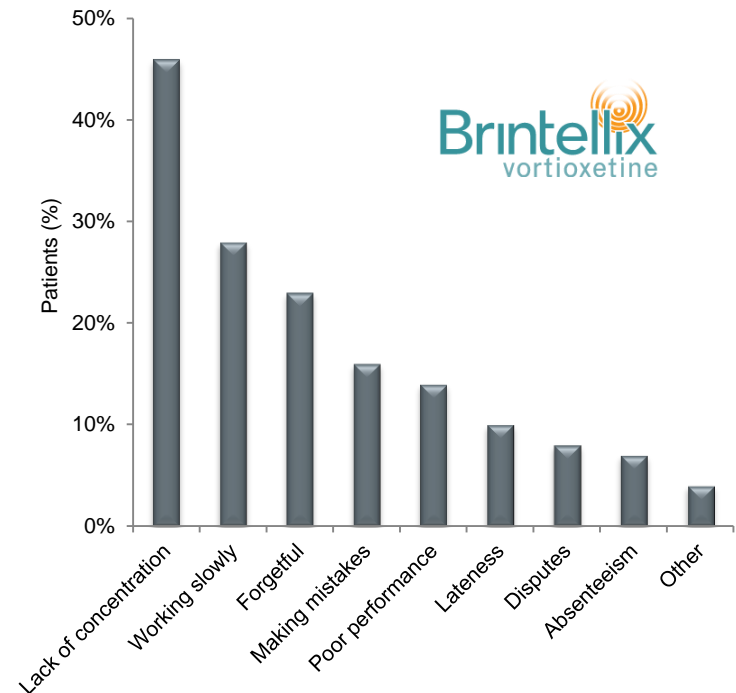
- ★ Efficacy in cognitive symptoms of depression
  - 3 studies with objective measures
  - European SmPC update to include clinical data on cognitive dysfunction in patients with depression
- ★ Superior efficacy in patients with inadequate response to SSRIs / SNRIs vs. agomelatine
- ★ Superior sexual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

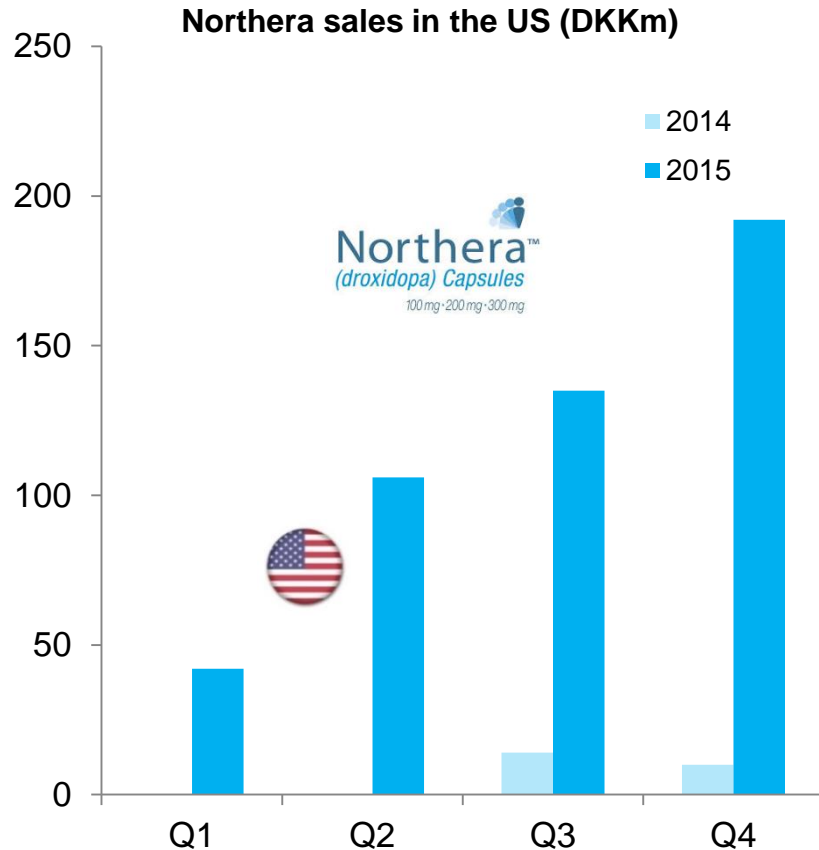
## Newer products

  
**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

# Northera launched in the US end-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
- ★ Differentiated product label
- ★ 80,000-150,000 nOH patients in the US (MSA, PAF, PD only)<sup>2</sup>

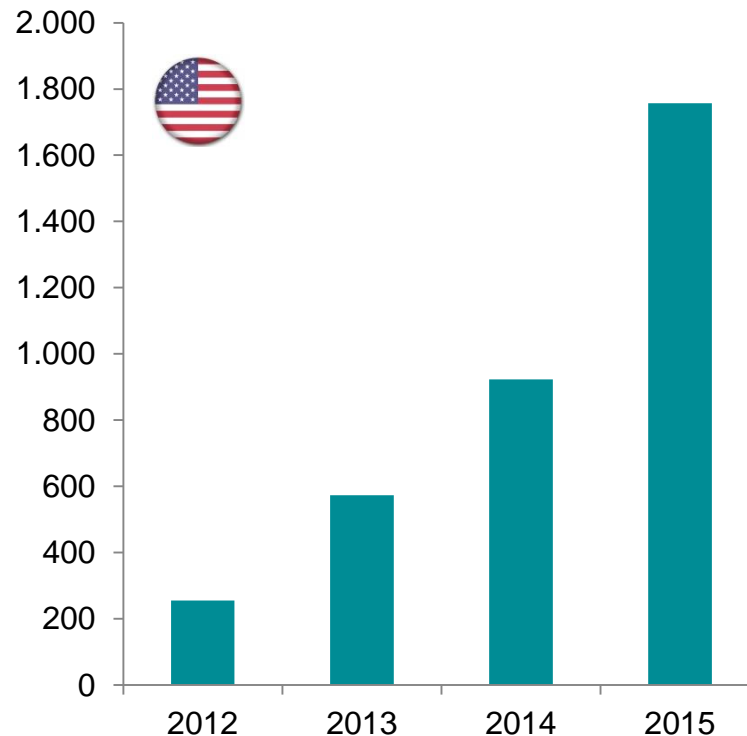
1) Neurogenic Orthostatic Hypotension; 2) MSA=Multiple System Atrophy; PAF=Pure Autonomic Failure; PD=Parkinson's Disease

# Onfi continues to exceed expectations

- ★ Launched in the US in January 2012
- ★ 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
- ★ Most patients experience ongoing cognitive impairment and refractory epilepsy
- ★ Orphan drug status



Onfi sales in the US (DKKm)



# Sabril – launched in Q3 2009 and addresses high unmet needs

## Infantile spasms (IS):

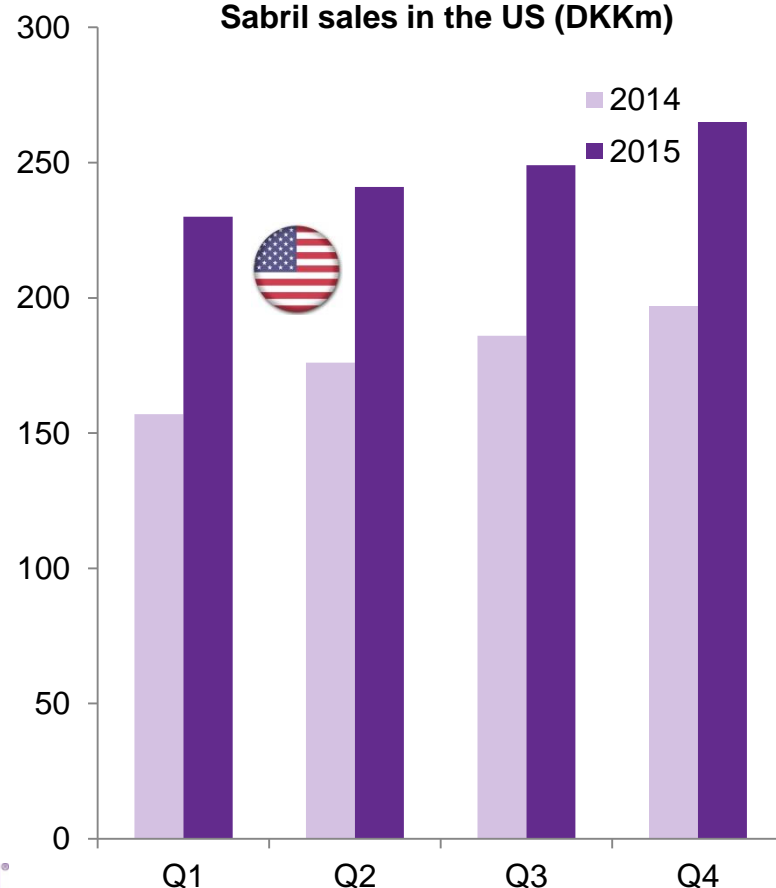
- ★ ~2,500 patients/year in the US with IS
- ★ Serious disease with substantial unmet medical need
  - ★ 70-90% suffers from mental retardation, mortality of around 5%

## 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



Sabril sales in the US (DKKm)

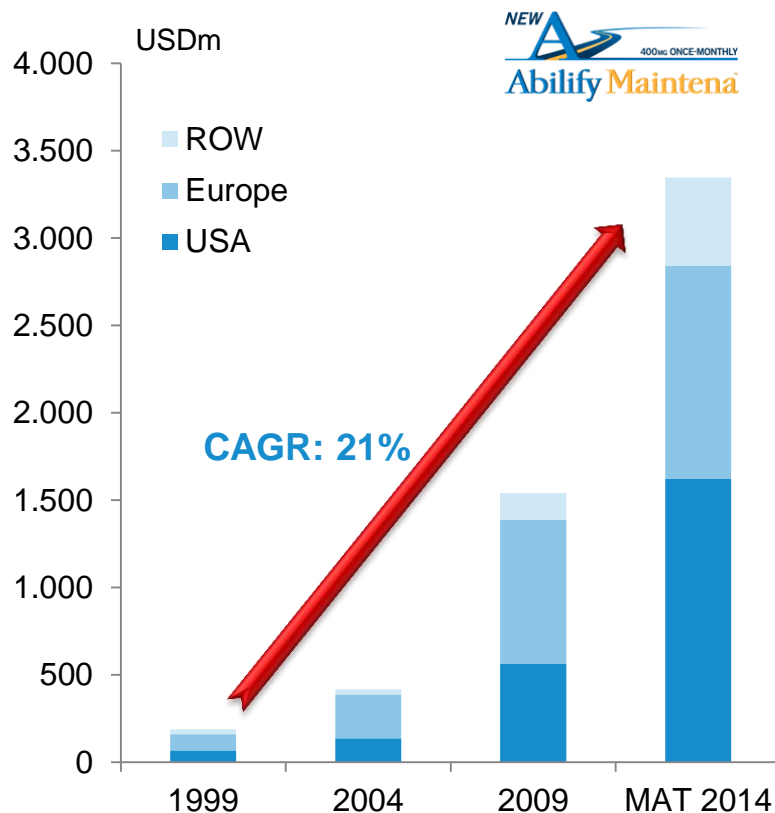




## Abilify Maintena (aripiprazole once monthly)



# Global market for long-acting injectable antipsychotics shows fast growth and exceeds USD 3bn



\*) LAI = Long-acting injectable antipsychotics

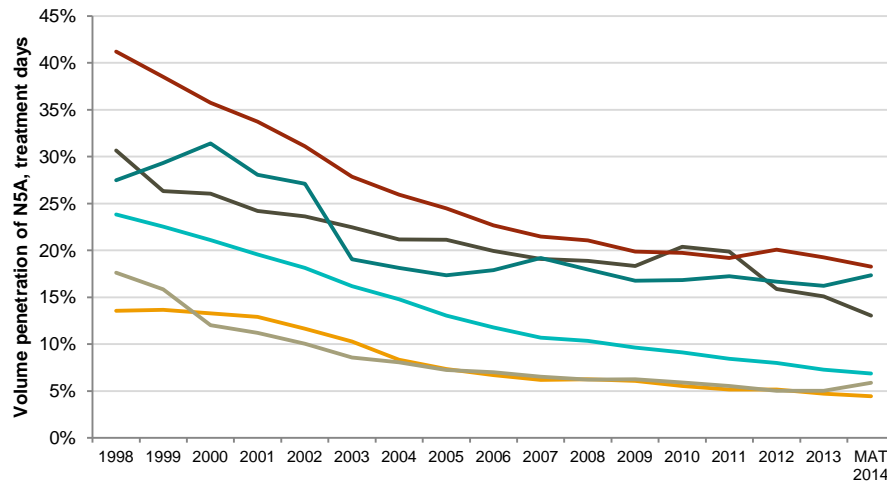
- ★ Substantial amount of outcome data and increased confidence in LAIs\*
- ★ More entrants with common message
- ★ Increased focus on total cost to society
- ★ Gradually reduced noise from promotion of oral atypical antipsychotics



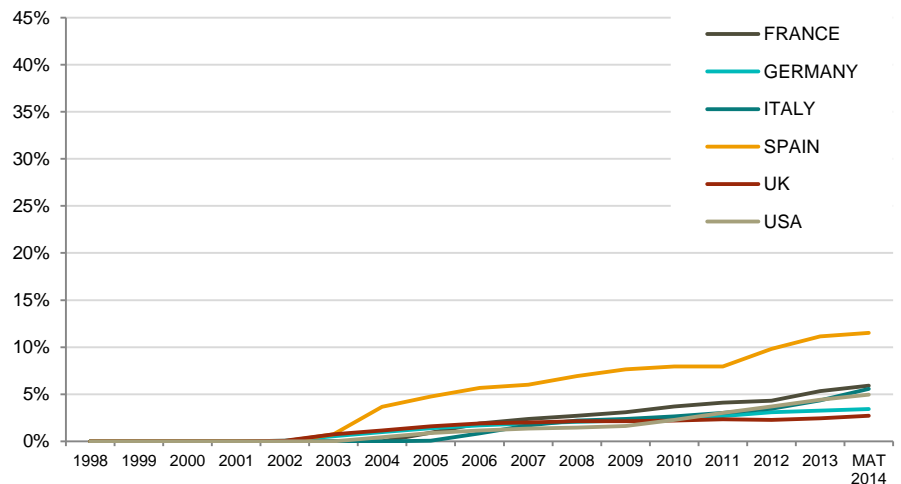
# Only ~15 years ago, long-acting therapies were considered “standard of care” in several key markets



Typical depot penetration



Atypical depot penetration



LAI = long acting injectable  
Source: IMS

MAT=Moving annual total Q3 2014

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

# 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 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

# Rexulti launched – a major milestone for patients and physicians in the US

- ★ Rexulti launched early August 2015
- ★ Approved dose-range provides flexibility
- ★ Programmes in place to support broad patient access in the US
- ★ There are approximately 15m adults in the US with MDD and 2.4m adults with schizophrenia who still struggle to find effective, well-tolerated treatments

## Indication statement

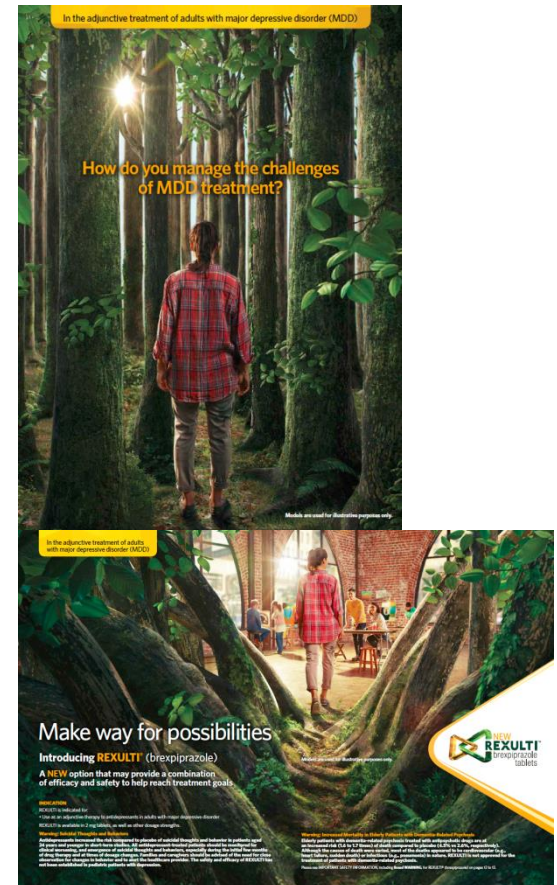
Rexulti is an atypical antipsychotic indicated for:

- Use as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD)
- Treatment of schizophrenia
- Tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg



# 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



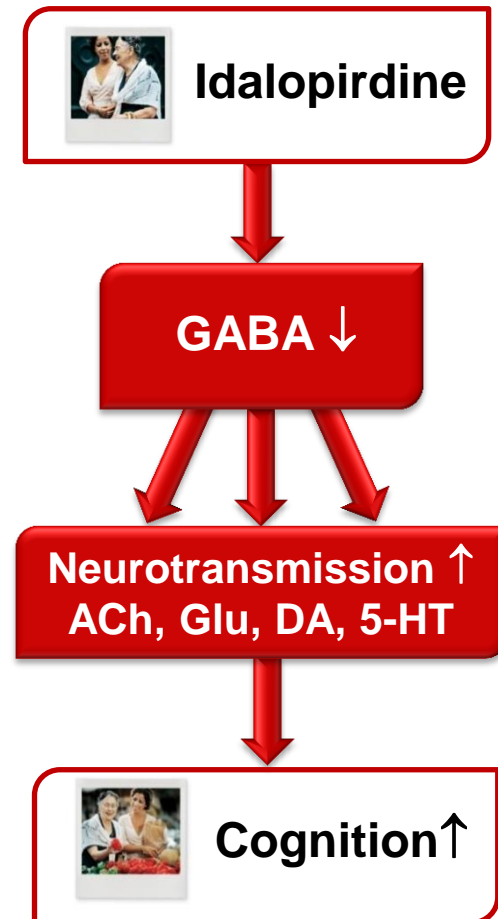
# Through its favourable benefit/risk profile adjunctive Rexulti offers improved value in schizophrenia

- ★ 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?

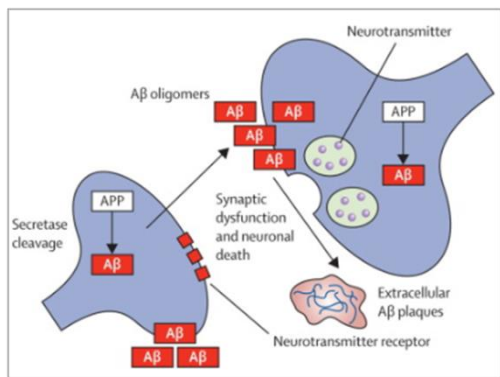
- ★ Through blockade of 5-HT<sub>6</sub> receptors idalopirdine has a **different mode of action** compared to existing symptomatic treatments
- ★ Blocking this particular kind of serotonin receptors (**5-HT<sub>6</sub> receptors**) has beneficial effects on several neurotransmitter systems in the brain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

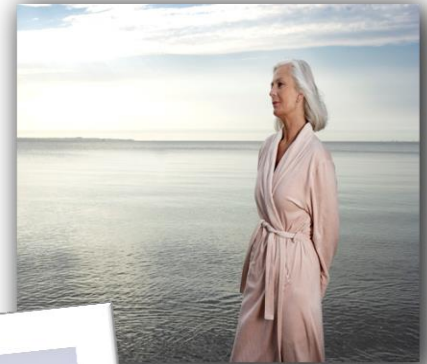
## Not wanted from study

- ★ 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

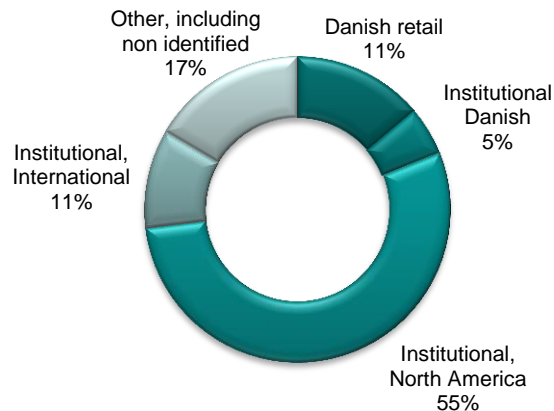
# Broad-based Alzheimer's pipeline

- ★ **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



# 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 (2014):
  - ★ **Lundbeck** (70%): DKK 16.9bn
  - ★ **ALK-Abello** (42%/69%): DKK 2.7bn
  - ★ **Falck** (57%): DKK 5.1bn
  - ★ **LundbeckFond Invest**: DKK 13.7bn
  - ★ **Ventures & Emerge**: DKK 1.5bn

# Sponsored ADR program

- ★ 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:

|                |                          |
|----------------|--------------------------|
| Ticker Symbol  | HLUYY                    |
| CUSIP          | 40422M206                |
| Ratio          | 1 ADR : 1 ordinary share |
| 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)

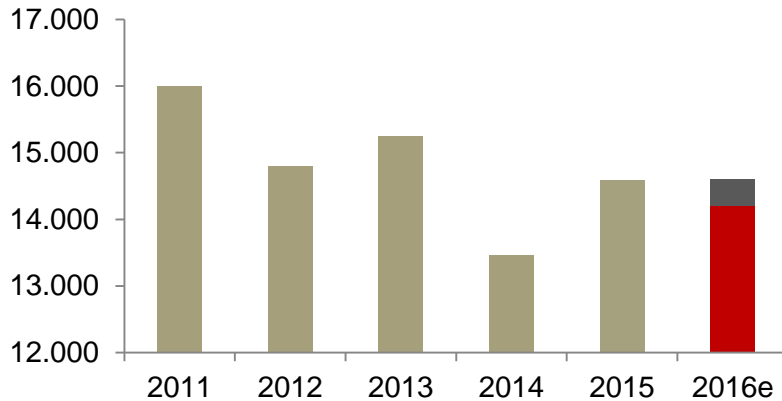






# Transformation of Lundbeck on the way

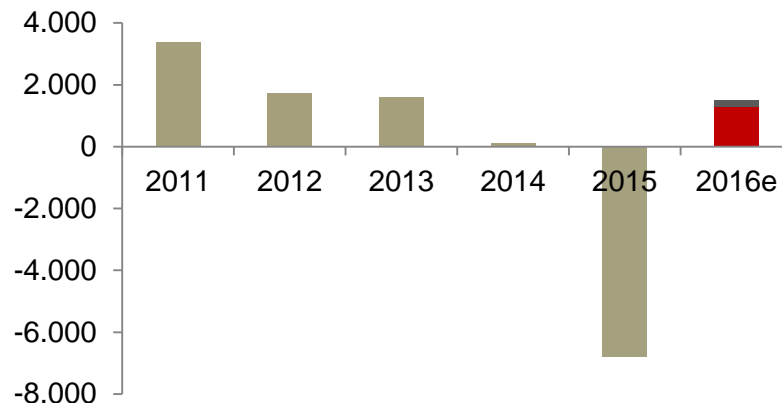
Revenue (DKKbn)



## Revenue drivers in Q1 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

# Q1 2016 - Geographic distribution of revenue - 1

| DKKm                          | FY 2015 | Q1 2016 | Q1 2015 | Growth | Growth in local currencies |
|-------------------------------|---------|---------|---------|--------|----------------------------|
| <b>EUROPE:</b>                |         |         |         |        |                            |
| Abilify Maintena              | 281     | 119     | 45      | 168%   | 169%                       |
| Brintellix                    | 105     | 45      | 7       | 582%   | 673%                       |
| Cipralex                      | 893     | 198     | 245     | (19%)  | (18%)                      |
| Other pharmaceuticals         | 2,617   | 385     | 664     | (42%)  | (43%)                      |
| Total revenue                 | 3,896   | 747     | 961     | (22%)  | (22%)                      |
| <b>INTERNATIONAL MARKETS:</b> |         |         |         |        |                            |
| Abilify Maintena              | 64      | 31      | 7       | 328%   | 354%                       |
| Azilect                       | 175     | 29      | 48      | (40%)  | (37%)                      |
| Brintellix                    | 121     | 55      | 17      | 216%   | 264%                       |
| Cipralex/Lexapro              | 1,698   | 552     | 567     | (3%)   | 12%                        |
| Ebixa                         | 576     | 145     | 181     | (20%)  | (18%)                      |
| Other pharmaceuticals         | 1,193   | 284     | 331     | (14%)  | (12%)                      |
| Total revenue                 | 3,827   | 1,096   | 1,151   | (5%)   | 4%                         |

## Q1 2016 - Geographic distribution of revenue - 2

| DKKm                  | FY 2015 | Q1 2016 | Q1 2015 | Growth | Growth in local currency |
|-----------------------|---------|---------|---------|--------|--------------------------|
| <b>USA:</b>           |         |         |         |        |                          |
| Abilify Maintena      | 324     | 105     | 68      | 54%    | 46%                      |
| Brintellix/Trintellix | 403     | 138     | 74      | 86%    | 80%                      |
| Northera              | 475     | 199     | 42      | 371%   | 346%                     |
| Onfi                  | 1,757   | 544     | 390     | 39%    | 33%                      |
| Rexulti               | 117     | 116     | -       | -      | -                        |
| Sabril                | 985     | 287     | 230     | 25%    | 18%                      |
| Xenazine              | 2,182   | 440     | 501     | (12%)  | (16%)                    |
| Other pharmaceuticals | 110     | 17      | 30      | (42%)  | (48%)                    |
| Total revenue         | 6,353   | 1,846   | 1,335   | 38%    | 32%                      |

# Q1 2016 - Cash generation

| DKKm  | Q1 2016        | Q1 2015      | FY 2015        |
|---|----------------|--------------|----------------|
| Cash flows from operating activities  | 357            | (382)        | 197            |
| Cash flows from investing activities  | (37)           | (36)         | (2,842)        |
| <b>Cash flows from operating and investing activities</b>                         | <b>320</b>     | <b>(418)</b> | <b>(2,645)</b> |
| Cash flows from financing activities  | (348)          | (97)         | 501            |
| <b>Net cash flow for the period</b>   | <b>(28)</b>    | <b>(515)</b> | <b>(2,144)</b> |
| Cash and bank balances, end of period   | 1,383          | 3,160        | 1,504          |
| Securities  | 17             | 18           | 17             |
| Interest-bearing debt   | (3,452)        | (3,264)      | (3,770)        |
| <b>Interest-bearing debt, cash, bank balances and securities, net end of year</b> | <b>(2,052)</b> | <b>(86)</b>  | <b>(2,249)</b> |

# Q1 2016 - Balance sheet

| DKKm  | 31.03.16       | 31.12.15       |
|---|----------------|----------------|
| Intangible assets   | 9,234          | 9,794          |
| Other non-current assets  | 3,689          | 3,871          |
| Current assets  | 7,691          | 7,660          |
| <b>Assets</b>   | <b>20,614</b>  | <b>21,325</b>  |
| Equity  | 8,733          | 8,785          |
| Non-current liabilities   | 4,407          | 4,792          |
| Current liabilities   | 7,474          | 7,748          |
| <b>Equity &amp; liabilities</b>   | <b>20,614</b>  | <b>21,325</b>  |
| Cash and bank balances  | 1,383          | 1,504          |
| Securities  | 17             | 17             |
| Interest-bearing debt   | (3,452)        | (3,770)        |
| <b>Interest-bearing debt, cash, bank balances and securities, net end of year</b> | <b>(2,052)</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)

## Contact information

### **Palle Holm Olesen**

VP; Head of Investor Relations

Tel: +45 36 43 24 26

[palo@lundbeck.com](mailto:palo@lundbeck.com) or [polesen3@bloomberg.net](mailto:polesen3@bloomberg.net)

Thank you!

Lundbeck

