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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
- Brexpiprazole: 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

★ Core revenue
  - Modest decline
  - New Products up 32%
  - US product portfolio up 37%

★ Core EBIT
  - Continued focus on operational and sourcing efficiencies through Project *Fit-for-the-Future*

★ Core EBIT margin
  - Stable cost development – with significant launch investments

★ Operating cash flow

DKK 3.4bn

DKK 0.4bn

13%

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

<table>
<thead>
<tr>
<th>DKK billion</th>
<th>2013 Actual</th>
<th>2014 Forecast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>15.3</td>
<td>~13.5</td>
</tr>
<tr>
<td>EBIT</td>
<td>1.6</td>
<td>0.0-0.5</td>
</tr>
<tr>
<td>Core EBIT</td>
<td>2.3</td>
<td>0.9-1.4</td>
</tr>
</tbody>
</table>
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

Maximise the value of key Lundbeck brands

Execute on new product launches

Invest to develop the late-stage pipeline

Facilitate a culture of continuous improvement

Cost discipline – strategic resource allocation
Lundbeck products have business transforming potential

Each DKK 2-2.5bn

Selincro

Northera (droyxido) capsules

Commercial

Each DKK >5bn

Brexiprazole
Lu AE58054

DKK 5-10bn

Brintellix

vortioxetine

Phase III

2013 2014 2015e >2015e

First launch
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

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

Branded value share (monthly)

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

![Pie chart showing Psychiatry accounted for majority of Brintellix cumulative TRx volume](chart.png)
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

Brexipiprazole

- 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\(^1\)
- Cognitive symptoms in depressed patients are not adequately treated with current antidepressants\(^2-4\)
- Nausea, sexual dysfunction, insomnia and weight gain are common tolerability issues with e.g. SSRIs and SNRIs\(^5-8\)

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Brintellix – approved with strong and meaningful label

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

![Brintellix Diagram](image)

Standardised effect size (Cohen’s \(d\)) for the neuropsychological tests (FAS)\(^16\)

\(p<0.05\); \(p<0.01\); \(p<0.001\) vs placebo; nominal \(p\)-values with no adjustment for multiplicity (Bonferroni, Sidak adjustment)

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 ≥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

Digit Symbol Substitution Test (DSST), Rey Auditory Verbal Learning Test (RAVLT)
PDQ: Perceived Deficits Questionnaire. CPFQ: Cognitive & Physical Functioning Questionnaire.
UPSA: University of San Diego Performance-Based Skills Assessment
Brintellix improves cognitive dysfunction in acute MDD – a distinct profile in two active-referenced studies.
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)¹
- FOCUS (published in International Journal of Neuropsychopharmacology, May 2014)³
- CONNECT (presented at CINP2014)⁴
- TAK316 (presented at ECNP2013)²

Brintellix improves self-reported cognitive function as well as objective performance-based functioning (UPSA)

**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 ≥26 and a CGI-S score ≥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. Mahaleshwarkar, MD; Yinzhong Chen, PhD; Lambros Chrones, 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”

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

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

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¹ Brexpiprazole is a serotonin-dopamine activity modulator that combines 5-HT₁A receptor partial agonism and low-efficacy D₂L 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)\(^1\)
- Filing dossier includes 7 phase II and III studies
- First adjunct MDD data presented at EPA in March 2014\(^2\)
  - 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)**

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

➤ 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)

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

**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

- **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

= Lundbeck presence
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

**Latin America:**
- Emerging markets
- Strong commercial platform
- Saphris
- Cephalon brands
- Brintellix
- Abilify Maintena
- Brexpiprazole

**Europe:**
- Strong market position
- Sycrest
- Selincro
- Brintellix
- Abilify Maintena
- Brexpiprazole

**Asia:**
- Lexapro (Japan)
- Improved commercial platform in China
- Saphris
- Azilect
- Brintellix
Newer products

Northera®
(droxdopa) Capsules
500mg-200mg-300mg

Onfi®
(clobazam)®
3, 10 and 20 mg tablets

Xenazine®
(tetrahydroaminoacridine)
12.5 and 25 mg tablets

"TREANDA®
(bendamustine HCl)
for injection
Built for Action®

Sabril®
vigabatrin
500 mg tablets
500 mg powder for oral solution
Xenazine – only drug approved for Huntington’s chorea in the US

![Xenazine tablets](image)

**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 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
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)

**Two independent studies: Highly consistent efficacy**
Proportion of patients with ≥50% improvement in Dizziness Score

*) Neurogenic Orthostatic Hypotension; MSA=Multiple System Atrophy; PAF=Pure Autonomic Failure; PD=Parkinson’s Disease
Brintellix (vortioxetine, Lu AA21004)
As a result, the antidepressant market is characterized by significant patient “churn”

*First Psych Rx Intervention (Switch, Continuing, Add-on, Continuing Add).

Source: Lundbeck & Vanguard analysis

In contrast to many other markets, even a 3rd or 4th line antidepressant position is commercially attractive.
Taking depression treatment to the next level

REMISSON

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 antidepressants¹)

Note: Forward-looking and aspirational

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

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

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

---

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 ≥5% in any treatment group in the 8-Week treatment period (APTS)

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

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

### Number of subjects with sexual dysfunction at baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo</th>
<th>Brintellix 15mg</th>
<th>Brintellix 20mg</th>
<th>Duloxetine 60mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects without sexual dysfunction at baseline</td>
<td>-</td>
<td>-0.7%</td>
<td>-0.7%</td>
<td>17%</td>
</tr>
<tr>
<td>Δ from PBO</td>
<td>-</td>
<td>-8.7%</td>
<td>6.3%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Source: A.R. Mahabledshwarkar, 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\(^1\)

Percentage of patients with MDD experiencing work-related cognitive dysfunction\(^2\)

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
Subjective Patient-reported Symptoms

Objective Assessment of Functional Capacity in Basic Living Skills

“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?”

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

- **Tests Vortioxetine pos. effect**
  - Primary endpoint (composite score)
  - **DSST**
    - A measure of executive function, working memory, processing speed, and visuospatial attention
  - **RAVLT**
    - A measure of verbal learning and memory, including proactive inhibition, retention, encoding versus retrieval, and subjective organization

- **Domains impaired in MDD**
  - Executive function (verbal fluency, set-shifting, planning, response inhibition, working memory)
  - Speed of Processing
  - Attention
  - Memory

- **Tests used as tools for individual domains**
  - **STROOP**
    - A measure of mental (attentional) vitality and cognitive flexibility/response inhibition
  - **Trail Making B**
    - A measure of executive control and cognitive flexibility/set-shifting
  - **Trail Making A**
    - A measure of attention, visual searching, and mental processing speed
  - **Simple Reaction time task**
    - A measure of psychomotor function/speed of processing
  - **Choice Reaction time task**
    - A measure of visual attention and vigilance
Brintellix improved cognitive performance in depressed elderly patients¹

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---

DSST, Digit Symbol Substitution Test; RAVLT, Rey Auditory Verbal Learning Test;
Population groups of interest for achieving market access for Brintellix

Depressed patients with cognitive dysfunction symptoms

Switch patients due to lack of efficacy and/or tolerability

Previously treated with SSRI/SNRI, possibly augmentation therapy

Switch patients present cognitive symptoms more frequently and the number of previous depressive episodes is a predictor of future relapse
### “High dose” clinical programme using Brintellix in MDD

<table>
<thead>
<tr>
<th>Clinicaltrials.gov identifier</th>
<th>Estimated enrolment</th>
<th>Study start</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01491035 (PIP)</td>
<td>48 (int.)</td>
<td>April 2012</td>
<td>Pharmacokinetics and tolerability of Brintellix (5-20mg) in child and adolescent patients with depressive or anxiety disorder</td>
</tr>
<tr>
<td>NCT01140906¹</td>
<td>600 (non-US)</td>
<td>May 2010</td>
<td>8 wks. Brintellix (15+20mg); duloxetine (60mg); Placebo</td>
</tr>
<tr>
<td>NCT01255787²</td>
<td>615 (Japan a.o.)</td>
<td>November 2010</td>
<td>8 wks. Brintellix (5+10+20mg); placebo</td>
</tr>
<tr>
<td>NCT01323478 #</td>
<td>300 (non-US)</td>
<td>April 2011</td>
<td>52 wks. extension. Brintellix (15+20mg)</td>
</tr>
<tr>
<td>NCT01163266*</td>
<td>450 (US)</td>
<td>July 2010</td>
<td>8 wks. Brintellix (10+20mg); placebo</td>
</tr>
<tr>
<td>NCT01153009*</td>
<td>600 (US)</td>
<td>June 2010</td>
<td>8 wks. Brintellix (15+20mg); duloxetine (60mg); placebo</td>
</tr>
<tr>
<td>NCT01179516*</td>
<td>450 (US)</td>
<td>August 2010</td>
<td>8 wks. Brintellix (10+15mg); placebo</td>
</tr>
<tr>
<td>NCT01152996</td>
<td>1,000 (US)</td>
<td>September 2010</td>
<td>52 wks. open label extension. Brintellix (15+20mg) – by invitation only</td>
</tr>
<tr>
<td>NCT01355081</td>
<td>360 (Japan)</td>
<td>May 2011</td>
<td>8 wks. Brintellix (5+10mg); placebo</td>
</tr>
<tr>
<td>NCT01395147</td>
<td>100 (Japan)</td>
<td>July 2011</td>
<td>52 wks. extension. Brintellix (5-20mg)</td>
</tr>
<tr>
<td>NCT01571453</td>
<td>410 (Asia)</td>
<td>May 2012</td>
<td>SOLUTION: 8 wks. Brintellix (10mg); venlafaxine XR 150mg</td>
</tr>
<tr>
<td>NCT01488071 (vs. agomelatine) @</td>
<td>500 (non-US)</td>
<td>January 2012</td>
<td>REVIVE: 8 wks. Brintellix (10-20mg); agomelatine (25-50mg)</td>
</tr>
<tr>
<td>NCT01364649 (sexual dysfunct.) ¤</td>
<td>440 (US+Canada)</td>
<td>June 2011</td>
<td>Brintellix (10-20mg); escitalopram (10-20mg). CSFQ</td>
</tr>
<tr>
<td>NCT01564862 (cognition) §</td>
<td>600 (US+int.)</td>
<td>April 2012</td>
<td>CONNECT: 8 wks. Brintellix (10-20mg); duloxetine (30-60mg); placebo</td>
</tr>
<tr>
<td>NCT01422213 (cognition) ¤</td>
<td>600 (US+int.)</td>
<td>December 2011</td>
<td>FOCUS: 8 wks. Brintellix (10+20mg); placebo</td>
</tr>
</tbody>
</table>

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

**Major depressive disorder**

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

**General anxiety disorder (all studies published)**

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

## Competitors’ clinical package for regulatory filing - 1

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

Source: Regulatory Intelligence Package – Depression (2009); Lundbeck; SPC’s & EPAR’s
<table>
<thead>
<tr>
<th>Product</th>
<th>Market</th>
<th>Indication</th>
<th>No. of short-term studies</th>
<th>No. of patients</th>
<th>No. of positive studies</th>
<th>No. of long-term studies</th>
<th>No. of patients</th>
<th>No. of positive studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilazodone (Viibryd) Forest</td>
<td>US</td>
<td>MDD</td>
<td>2</td>
<td>869</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mirtazapine (Remeron)</td>
<td>US</td>
<td>MDD</td>
<td>5</td>
<td>-</td>
<td>5</td>
<td>1</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>ScheringPlough/ Organon</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Aripiprazole (Abilify)</td>
<td>US</td>
<td>MDD (adjunctive therapy)</td>
<td>2</td>
<td>743</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BMS/Otsuka</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Olanzapine/ Paroxetine (Symbyax)</td>
<td>US</td>
<td>MDD</td>
<td>5</td>
<td>1,616</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion SR (Wellbutrin SR)</td>
<td>EU</td>
<td>MDD</td>
<td>8</td>
<td>-</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion IR (Wellbutrin IR)</td>
<td>EU</td>
<td>MDD</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bupropion XR (Wellbutrin XR)</td>
<td>EU</td>
<td>MDD</td>
<td>3</td>
<td>1,564</td>
<td>1</td>
<td>1</td>
<td>400</td>
<td>1</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>US</td>
<td>MDD</td>
<td>4</td>
<td>1,401</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Source: Regulatory Intelligence Package – Depression (2009); Lundbeck; SPC’s & EPAR’s
## Competitors’ clinical package for regulatory filing - 3

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

Source: Regulatory Intelligence Package – Depression (2009); Lundbeck; SPC’s & EPAR’s
Abilify Maintena (aripiprazole once monthly)
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**

- **ROW**
  - 2013 MAT = USD 0.4 B
  - (+2% vs. p.y.)

- **EU**
  - 2013 MAT = USD 1.1 B
  - (+5% vs. p.y.)

- **USA**
  - 2013 MAT = USD 1.4 B
  - (+13% vs. p.y.)

Source: IMS

* MAT=Moving annual total Q3 2013
Only 15 years ago, long-acting therapies were considered “standard of care” in several key markets.

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

LAI = long acting injectable

Source: IMS

* Moving annual total Q3 2013
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.
## Clinical programme with Abilify Maintena

<table>
<thead>
<tr>
<th>Clinicaltrials.gov identifier</th>
<th>Estimated enrolment</th>
<th>Study start</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01509053 (ARRIVE-EU)</td>
<td>30</td>
<td>Dec. 2011</td>
<td>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</td>
</tr>
<tr>
<td>NCT01909466 (phase I)</td>
<td>141</td>
<td>Jul. 2013</td>
<td>An Open-label, Multiple Dose, Safety and Tolerability Study of Aripiprazole IM Depot Administered in the Deltoid Muscle in Adult Subjects With Schizophrenia</td>
</tr>
<tr>
<td>NCT01552772 (phase I)</td>
<td>60</td>
<td>Jan 2012</td>
<td>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</td>
</tr>
<tr>
<td>NCT01663532 (phase III)</td>
<td>310 (US)</td>
<td>Oct 2012</td>
<td>Acute treatment of schizophrenia 12 wks. Abilify Maintena; placebo, endpoint: PANSS score</td>
</tr>
<tr>
<td>NCT01567527 (phase III)</td>
<td>600 (global)</td>
<td>Aug 2012</td>
<td>Maintenance treatment of bipolar I disorder 52 wks. Abilify Maintena; placebo, endpoint: relapse</td>
</tr>
<tr>
<td>NCT00705783 (phase III)*</td>
<td>1,025 (global)</td>
<td>Jul 2008</td>
<td>Study 246: Maintenance treatment in schizophrenia (ASPIRE) 52 wks. Abilify Maintena; placebo, endpoint: relapse</td>
</tr>
<tr>
<td>NCT00706654 (phase III)***</td>
<td>1,148 (global)</td>
<td>Sep 2008</td>
<td>Study 247: Maintenance treatment in schizophrenia (ASPIRE) 38 wks. Abilify Maintena; Abilify oral, endpoint: relapse</td>
</tr>
<tr>
<td>NCT01432444 (phase III)****</td>
<td>500 (US)</td>
<td>Sep 2011</td>
<td>Study 283: Hospitalization rates of schizophrenic patients treated with oral antipsychotics vs. Abilify Maintena (ARRIVE US)</td>
</tr>
<tr>
<td>NCT01795547 (phase III) #</td>
<td>286 (US)</td>
<td>Feb 2013</td>
<td>QUALIFY: Maintenance treatment in Schizophrenia 28 wks, randomised, open-label study, Abilify Maintena vs. paliperidone palmitate</td>
</tr>
</tbody>
</table>

Selincro (nalmefene)
Less than 10% of alcohol dependent patients receive treatment

14,600,000 Europeans are alcohol dependent

92% are not treated

Alcohol abuse and dependence have the widest treatment gap among all mental disorders

- Schizophrenia: 82%
- Bipolar disorder: 60%
- Major depression: 55%
- Panic disorder: 53%
- Generalised anxiety disorder: 38%
- Alcohol abuse/dependence: 8%

1. Bahn et al. Alcohol consumption, alcohol dependence, and attributable burden of disease. Centre for Addiction and Mental Health, Toronto, ON
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

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

Relative risk of reducing 5 drinks per day
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%

**SELINCRO**

For the reduction of alcohol consumption

**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**: 12 bottles of wine per week
- **After 1 month**: 6 bottles (40% reduction)
- **After 6 months**: 4 bottles (60% reduction)
- **After 12 months**: 3 bottles (67% reduction)

Equivalent to 10 bottles of wine per week.
Appendix

★ Lundbeck overview
★ Commercial operations
★ **Pipeline**
★ Financials
★ The CNS market
★ The Lundbeck share
Lundbeck invests to grow – a solid late-stage development portfolio

<table>
<thead>
<tr>
<th><strong>MOOD DISORDERS</strong></th>
<th><strong>Phase II</strong></th>
<th><strong>Phase III</strong></th>
<th><strong>Registration app.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Tedaloxetine*</td>
<td>Brintellix (JP)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Lu AA24530)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>PSYCHOSIS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Zicronapine*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ALCOHOL DEPENDENCE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Brexpiprazole (OPC-34712)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>DEPRESSION/SCHIZOPHRENIA</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Brexpiprazole</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ALZHEIMER’S DISEASE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lu AE58054</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>NEUROLOGY</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EPILEPSY</strong></td>
</tr>
<tr>
<td>---------------</td>
</tr>
<tr>
<td>Carbella™ (US)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>OTHER</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Desmoteplase (AIS)</td>
</tr>
</tbody>
</table>

| Brexpiprazole (PTSD) |

*No active clinical program ongoing*
Otsuka collaborations (brexipiprazole 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

<table>
<thead>
<tr>
<th></th>
<th>Abilify Maintena</th>
<th>Brexpiprazole</th>
<th>Lu AE58054</th>
<th>Selincro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development milestones/upfront</td>
<td>USD 200m</td>
<td>USD 600m³</td>
<td>USD 150m</td>
<td>EUR 105m*</td>
</tr>
<tr>
<td>Approval milestones</td>
<td>USD 275m¹</td>
<td>USD 300m²</td>
<td>USD 300m</td>
<td>undisclosed</td>
</tr>
<tr>
<td>Sales milestones</td>
<td>Up to USD 425m depending on sales development</td>
<td>Up to USD 375m depending</td>
<td>undisclosed</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Abilify Maintena</th>
<th>Brexpiprazole</th>
<th>Lu AE58054</th>
<th>Selincro</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>20%</td>
<td>45%</td>
<td>55%</td>
<td>-</td>
</tr>
<tr>
<td>EU-5, Nordic and Canada</td>
<td>50%</td>
<td>50%</td>
<td>50%</td>
<td>-</td>
</tr>
<tr>
<td>Other Lundbeck territories</td>
<td>65%**</td>
<td>65%**</td>
<td>~50%***</td>
<td>undisclosed</td>
</tr>
</tbody>
</table>

* 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

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

Development status

- Schizophrenia: Six studies recruiting
- MDD adjunctive therapy: Six studies recruiting
- Agitation in Alzheimer’s: Two studies recruiting
- PTSD: One study recruiting
The development plan for brexpiprazole

Comprehensive phase III program
- 15 ongoing studies
- 6,000+ patients
Clinical programme with brexpiprazole - adjunctive therapy in major depression

<table>
<thead>
<tr>
<th>Clinicaltrials.gov identifier</th>
<th>Estimated enrolment</th>
<th>Study start</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01727726 (phase III)</td>
<td>1,785 (global)</td>
<td>Dec 2012</td>
<td>DELPHINUS TRIAL (Study 282): Adjunctive therapy in MDD - flexible-dose. Brexpiprazole+ADT; placebo+ADT; seroquel+ADT. endpoint: MADRS score</td>
</tr>
<tr>
<td>NCT01360866 (phase III)</td>
<td>1,209 (global)</td>
<td>Oct 2011</td>
<td>ORION: Adjunctive therapy in MDD. 0.5-3 mg brexpiprazole+ADT. endpoint: adverse events</td>
</tr>
<tr>
<td>NCT01360645 (phase III) ²)</td>
<td>925 (global)</td>
<td>Jul 2011 (completed)</td>
<td>PYXIS (Study 228): Adjunctive therapy in MDD. 2mg brexpiprazole+ADT; placebo+ADT, endpoint: MADRS score</td>
</tr>
<tr>
<td>NCT01360632 (phase III)</td>
<td>1,650 (global)</td>
<td>Jun 2011 (completed)</td>
<td>POLARIS (Study 227): Adjunctive therapy in MDD. 1+3mg brexpiprazole+ADT; placebo+ADT, endpoint: MADRS score</td>
</tr>
<tr>
<td>NCT02196506 (phase III)</td>
<td>900 (global)</td>
<td>July 2014</td>
<td>Study 214: 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</td>
</tr>
<tr>
<td>NCT01838681 (phase III)</td>
<td>1,462 (EU)</td>
<td>May 2013</td>
<td>ARGO: 1-3mg. Inadequate responders in MDD; Up to 36 wks</td>
</tr>
<tr>
<td>NCT01944969 (phase III)</td>
<td>1,184 (US)</td>
<td>October 2013</td>
<td>Open-label, Long-term Extension Study to Evaluate the Safety and Tolerability of Brexpiprazole as Adjunctive Treatment in Patients With Major Depressive Disorder</td>
</tr>
<tr>
<td>NCT01942785 (phase III)</td>
<td>50 (US)</td>
<td>October 2013</td>
<td>To explore the anti-impulsive and anti-aggressive properties of brexpiprazole in a naturalistic setting of depressed patients with irritability</td>
</tr>
<tr>
<td>NCT02013622 (phase III)</td>
<td>50 (US)</td>
<td>November 2013</td>
<td>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.</td>
</tr>
<tr>
<td>NCT02012218 (phase III)</td>
<td>80 (US)</td>
<td>November 2013</td>
<td>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.</td>
</tr>
<tr>
<td>NCT01837797 (phase III)</td>
<td>1,334 (elderly, US)</td>
<td>April 2013</td>
<td>1-3mg. Up to 20wks</td>
</tr>
<tr>
<td>NCT01942733 (phase III)</td>
<td>50 (US)</td>
<td>September 2013</td>
<td>Exploratory Study of Brexpiprazole (&lt;3mg) as Adjunctive Treatment of Sleep Disturbances in Patients With Major Depressive Disorder</td>
</tr>
<tr>
<td>NCT01447576 (phase II)</td>
<td>1,038 (US)</td>
<td>Sep 2009 (completed)</td>
<td>Adjunctive therapy in MDD. 1-3mg brexpiprazole+ADT, endpoint: adverse events</td>
</tr>
<tr>
<td>NCT00797966 (phase II) ¹)</td>
<td>850 (US)</td>
<td>May 2009 (compl.)</td>
<td>Adjunctive therapy in MDD. 1-4mg brexpiprazole+ADT; placebo+ADT, endpoint: depression rating scale</td>
</tr>
<tr>
<td>NCT01052077 (phase II)</td>
<td>773 (US)</td>
<td>Mar 2010 (completed)</td>
<td>Adjunctive therapy in MDD (STEP-D222). 1-3mg brexpiprazole+ADT; placebo+ADT, endpoint: depression rating scale</td>
</tr>
</tbody>
</table>

*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”

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

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

“Other indications”

<table>
<thead>
<tr>
<th>Clinicaltrials.gov identifier</th>
<th>Estimated Enrolment</th>
<th>Study start</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCT01074294 (phase II)</td>
<td>675 (US)</td>
<td>Mar 2010</td>
<td>Complementary treatment in ADHD. 0.25+1mg brexpiprazole+ST; placebo+ST, endpoint: efficacy/safety</td>
</tr>
<tr>
<td>NCT01862640</td>
<td>560 (global)</td>
<td>May 2013</td>
<td>Agitation Associated With Dementia of the Alzheimer’s Type, 2-week, placebo, 3 Fixed Doses of Brexpiprazole (0.5mg, 1mg and 2mg)</td>
</tr>
<tr>
<td>NCT01922258</td>
<td>230 (global)</td>
<td>Sep 2013</td>
<td>Agitation Associated With Dementia of the Alzheimer’s Type, 12-week, placebo, 0.5-2mg</td>
</tr>
<tr>
<td>NCT01987960</td>
<td>592 (US)</td>
<td>Dec 2013</td>
<td>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</td>
</tr>
</tbody>
</table>
Lundbeck has significant presence in psychiatric disorders in years to come

<table>
<thead>
<tr>
<th>Compound</th>
<th>Status</th>
<th>Mood disorders</th>
<th>Anxiety disorders</th>
<th>Developmental disorders</th>
<th>Psychotic disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cipralex</td>
<td>Launched</td>
<td>Fully responsive depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brintellix</td>
<td>Launched (US) Approved (EU)</td>
<td>Incomplete responsive depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tedatiosctxetine</td>
<td>Phase II*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brexpiprazole</td>
<td>Filed (US) Phase III</td>
<td>non / inadequate responsive depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sycrest/Saphris</td>
<td>Launched</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abilify Maintena</td>
<td>Launched</td>
<td>Maintenance treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zicronapine</td>
<td>Phase III*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lu AF11167 (PDE¹)</td>
<td>Phase I**</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*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_6 receptors)
- Blocking this particular kind of serotonin receptors (5-HT_6 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

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

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 >2x ULN in 13 patients
  - LFT abnormalities asymptomatic
  - Return towards baseline values in all cases

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

ALAT=alanine aminotransferase; ASAT=aspartate aminotransferase; LFT=liver function test; ULN=upper limit of normal
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-Aβ 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 2nd biggest cause of mortality globally.  

---

### Potential desmoteplase advantages over rt-PA

<table>
<thead>
<tr>
<th>Advantage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extended treatment window</td>
</tr>
<tr>
<td>Lower risk of bleeding</td>
</tr>
<tr>
<td>No neurotoxicity - survival of brain tissue</td>
</tr>
<tr>
<td>No disruption of BBB* integrity</td>
</tr>
<tr>
<td>Ease of administration (single bolus, i.v. injection)</td>
</tr>
<tr>
<td>Longer half-life - positive impact on re-occlusion rate</td>
</tr>
</tbody>
</table>

---

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)

<table>
<thead>
<tr>
<th>DKKm</th>
<th>H1 2014</th>
<th>H1 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBIT</td>
<td>843</td>
<td>1,020</td>
</tr>
<tr>
<td>- Amortization</td>
<td>325</td>
<td>296</td>
</tr>
<tr>
<td>- Non-recurring items</td>
<td>0</td>
<td>171</td>
</tr>
<tr>
<td>Core EBIT</td>
<td>1,168</td>
<td>1,487</td>
</tr>
</tbody>
</table>

Materiality level for each none-core item is DKK >100m
### Revenue performance in Q2 2014

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

*New Products: Xenazine, Sabril, Sycrest, Lexapro (Japan), Onfi, Treanda, Selincro, Abilify Maintena and Brintellix*
## Geographic distribution of revenue – Q2 2014

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

<table>
<thead>
<tr>
<th>DKKm</th>
<th>Q2 2014</th>
<th>Q2 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cash flows from operating activities</td>
<td>459</td>
<td>1,346</td>
</tr>
<tr>
<td>Cash flows from investing activities</td>
<td>(3,024)</td>
<td>(711)</td>
</tr>
<tr>
<td><strong>Cash flows from operating and investing activities</strong></td>
<td>(2,565)</td>
<td>635</td>
</tr>
<tr>
<td>Cash flows from financing activities</td>
<td>(571)</td>
<td>2</td>
</tr>
<tr>
<td><strong>Change in cash</strong></td>
<td>(3,136)</td>
<td>637</td>
</tr>
<tr>
<td>Cash</td>
<td>1,424</td>
<td>3,485</td>
</tr>
<tr>
<td>Securities</td>
<td>18</td>
<td>1,041</td>
</tr>
<tr>
<td>Interest-bearing debt</td>
<td>(2,158)</td>
<td>(1,891)</td>
</tr>
<tr>
<td><strong>Interest-bearing net cash and cash equivalents, end of period</strong></td>
<td>(716)</td>
<td>2,635</td>
</tr>
</tbody>
</table>
## Balance sheet and dividend

### Balance sheet

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

### Dividend

#### Dividend & Dividend yield* 2010-2013

- **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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total revenue</strong></td>
<td>15,258</td>
<td>14,802</td>
<td>16,007</td>
<td>14,765</td>
<td>13,747</td>
<td>3%</td>
<td>(8%)</td>
<td>8%</td>
<td>7%</td>
</tr>
<tr>
<td><strong>Cipralex</strong></td>
<td>5,933</td>
<td>5,827</td>
<td>5,957</td>
<td>5,808</td>
<td>5,320</td>
<td>2%</td>
<td>(2%)</td>
<td>3%</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Ebixa</strong></td>
<td>2,096</td>
<td>2,803</td>
<td>2,751</td>
<td>2,403</td>
<td>2,162</td>
<td>(25%)</td>
<td>2%</td>
<td>14%</td>
<td>11%</td>
</tr>
<tr>
<td><strong>Azilect</strong></td>
<td>1,392</td>
<td>1,224</td>
<td>1,187</td>
<td>1,028</td>
<td>769</td>
<td>14%</td>
<td>3%</td>
<td>15%</td>
<td>34%</td>
</tr>
<tr>
<td><strong>Xenazine</strong></td>
<td>1,420</td>
<td>1,197</td>
<td>852</td>
<td>610</td>
<td>298</td>
<td>19%</td>
<td>40%</td>
<td>40%</td>
<td>105%</td>
</tr>
<tr>
<td><strong>Sabril</strong></td>
<td>530</td>
<td>376</td>
<td>309</td>
<td>179</td>
<td>-</td>
<td>41%</td>
<td>22%</td>
<td>73%</td>
<td>-</td>
</tr>
<tr>
<td><strong>Onfi</strong></td>
<td>573</td>
<td>255</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>125%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*<em>pharmaceuticals</em></td>
<td>1,830</td>
<td>2,494</td>
<td>4,562</td>
<td>4,479</td>
<td>4,920</td>
<td>(27%)</td>
<td>(45%)</td>
<td>2%</td>
<td>(9%)</td>
</tr>
<tr>
<td><strong>Other revenue</strong></td>
<td>1,484</td>
<td>626</td>
<td>389</td>
<td>258</td>
<td>278</td>
<td>137%</td>
<td>61%</td>
<td>51%</td>
<td>(7%)</td>
</tr>
</tbody>
</table>

*including Lexapro US
## Costs, yearly figures

<table>
<thead>
<tr>
<th></th>
<th>DKKm</th>
<th></th>
<th></th>
<th></th>
<th>Growth, Y/Y, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>15,258</td>
<td>14,802</td>
<td>16,007</td>
<td>14,765</td>
<td>13,747</td>
</tr>
<tr>
<td>Cost of sales</td>
<td>4,038(^1)</td>
<td>3,720</td>
<td>3,553</td>
<td>3,371</td>
<td>2,982</td>
</tr>
<tr>
<td>Sales and distribution costs</td>
<td>4,200</td>
<td>4,836(^3)</td>
<td>4,132</td>
<td>3,539</td>
<td>3,281</td>
</tr>
<tr>
<td>Administrative exp.</td>
<td>2,549(^2)</td>
<td>1,601</td>
<td>1,608</td>
<td>1,453</td>
<td>1,430</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>2,872</td>
<td>2,919</td>
<td>3,319</td>
<td>3,045</td>
<td>3,196</td>
</tr>
<tr>
<td>EBIT</td>
<td>1,599</td>
<td>1,726</td>
<td>3,395</td>
<td>3,357</td>
<td>2,858</td>
</tr>
</tbody>
</table>

### Cost of sales
- 26% 25% 22% 22% 21%

### Sales and distribution costs
- 28% 32% 26% 24% 24%

### Administrative exp.
- 17% 11% 10% 10% 11%

### R&D
- 19% 20% 21% 21% 23%

### EBIT-margin
- 10% 12% 21% 23% 21%

---

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

- 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

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

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

PAGE 97
Worldwide pharmaceutical market 2013 USD 870 billion (+2%)

- Cardiovascular System; 11%
- General Anti-infectives Systemic; 11%
- Respiratory System; 7%
- Various; 11%
- Musculo-skeletal System; 4%
- Genito-urinary System And Sex Hormones; 5%
- Blood And Blood Forming Organs; 5%
- Antineoplastic And Immunomodulating Agents; 14%
- Alimentary Tract And Metabolism; 13%
- Central nervous system; 15%
- Dermatologicals; 3%

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

PAGE 98
## CNS market overview (2013)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Value (USDbn)</td>
<td>Value Growth</td>
</tr>
<tr>
<td>Total pharma</td>
<td>870</td>
<td>+2%</td>
</tr>
<tr>
<td>Total CNS</td>
<td>129</td>
<td>+1%</td>
</tr>
</tbody>
</table>
| Alcohol therapy (N7E)| 0.34               | +15%                  | +1%            | 5% of men and 1.4% of women in Europe | • Greater resources – number of treatment facilities and trained physicians is inadequate  
• The integration of alcohol treatment into primary care  
• Improved effectiveness  
• Improved compliance | 1. Vivitrol  
2. Campral  
3. Antabuse | $82m  
$52m  
$13m |
| Anti-Alzheimer’s (N7D)| 6.4                | -3%                   | +5%            | >7 million²                      | • Disease modifying treatment  
• Disease slowing agents  
• Improved symptomatic treatments  
• Longer lasting symptomatic treatments | 1. Memantine  
2. Donepezil  
3. Rivastigmine  
4. Galantamine | 46%  
27%  
21%  
7% |
| Anti-depressants (N6A)| 18.2               | -2%                   | +4%            | ~40 million²                     | • Drugs with higher remission rates  
• Increased onset of action  
• Current therapies are relatively well-tolerated but still room for improvement especially on sexual side effects | 1. Duloxetine  
2. Escitalopram  
3. Venlafaxine  
4. Paroxetine | 37%  
11%  
7%  
7% |
| Anti-Parkinson’s (N4A)| 4.3                | +2%                   | +5%            | >3 million²                      | • Therapies that provide neuroprotection and/or neurorestoration  
• An optimal trial design for demonstrating neuroprotection and/or neurorestoration  
• Control of levodopa-induced motor response complications | 1. Levodopa  
2. Pramipexole  
3. Rasagiline  
4. Stalevo  
5. Ropinirole | 22%  
18%  
15%  
10%  
9% |
| Anti-psychotics (N5A)| 21.3               | -6%                   | +4%            | Approx 1% of global population   | • Improved treatment of cognitive dysfunction  
• Improved treatment of negative symptoms  
• Improved treatment of co-morbid depression and anxiety  
• Early stage, definitive diagnostics | 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,$(%)

PAGE 99
### CNS market size – overview (2013)

<table>
<thead>
<tr>
<th>Total market</th>
<th>USA</th>
<th>Europe</th>
<th>Int. Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value (USDbn)</td>
<td>Growth</td>
<td>Share</td>
<td>Growth</td>
</tr>
<tr>
<td>Total pharma</td>
<td>870</td>
<td>2%</td>
<td>38%</td>
</tr>
<tr>
<td>Total CNS</td>
<td>129</td>
<td>1%</td>
<td>47%</td>
</tr>
<tr>
<td>Alcohol</td>
<td>0.3</td>
<td>15%</td>
<td>34%</td>
</tr>
<tr>
<td>Anti-Alzheimer’s</td>
<td>6.4</td>
<td>-3%</td>
<td>42%</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>18.2</td>
<td>-2%</td>
<td>49%</td>
</tr>
<tr>
<td>Anti-epileptics</td>
<td>15.8</td>
<td>9%</td>
<td>44%</td>
</tr>
<tr>
<td>Anti-Parkinson’s</td>
<td>4.3</td>
<td>2%</td>
<td>22%</td>
</tr>
<tr>
<td>Anti-psychotics</td>
<td>21.3</td>
<td>-6%</td>
<td>56%</td>
</tr>
<tr>
<td>Fibrinolytics (incl. stroke)</td>
<td>1.2</td>
<td>12%</td>
<td>55%</td>
</tr>
</tbody>
</table>

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

Appendix

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

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
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 Shares
- **ADR depositary**: 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
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

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