

# Investor and analyst presentation

(Autumn 2009)



# Safe Harbour Statement

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.

# Update on recent events

## Strategic

- “*Decisions Now*” process ongoing

## Financials

- Lundbeck records 20% growth (CER) – growth in key products
- Continued strong uptake of Xenazine<sup>®\*</sup> - 20% growth in new patients over Q2

## New products

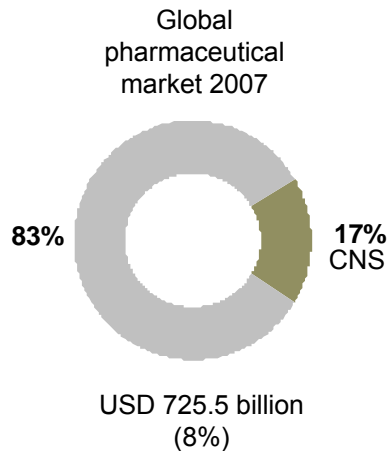
- **Sabril** approved and launched in the US in September
  - Initial feedback shows high level of interest from physicians and medical personnel

# Update on recent events – cont.

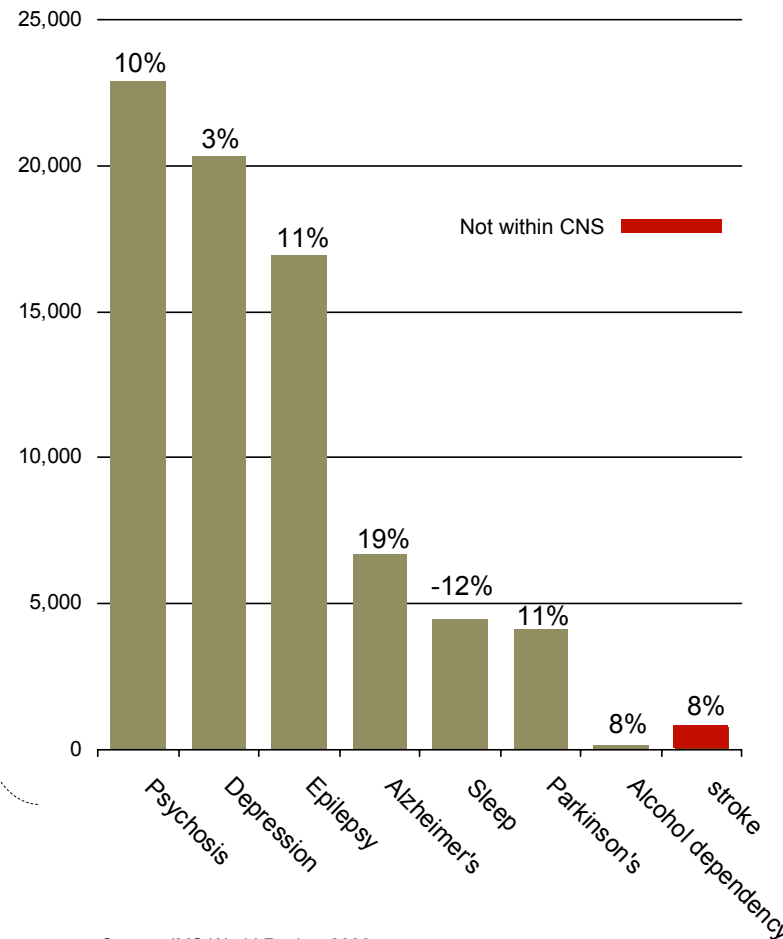
## Pipeline progression

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  - Depending on trial outcome, desmoteplase could be eligible for fast-track
- **Clobazam** and **nalmefene** - phase III efficacy study and the long-term safety study respectively has finished recruiting patients and the programmes are on track
- The discussions and planning of subsequent clinical trials for **Lu AA21004** and **Lu AA24530**, with our partner Takeda Pharmaceuticals, is progressing according to plan
  - Additional clinical work to commence during 2010
- Clinical phase II study using **Lu AE58054** as add-on treatment in Alzheimer's to be initiated
- **Lu AA24493** initiated in clinical phase IIa in Friedreich's ataxia
- New development candidate for Parkinson's, **Lu 02-750**, has entered the pipeline

# Lundbeck – a fully integrated company focusing on CNS



Lundbeck's therapeutic areas (growth 2008 in %)



- CNS, largest therapeutic area, 17% of total pharmaceutical market
- Total CNS market up 8% in 2008 to USD 121.7 billion

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

Rank*	Disease	Drug	Phase
1	Cancer	Cipralelex® / Lexapro®	Launched
2	Unipolar depressive disorder and anxiety	Lu AA21004	Clinical phase III
3	Ischaemic heart disease	Lu AA24530	Clinical phase II
4	Cerebrovascular disease	Lu AA34893	Clinical phase II
5	Chronic obstructive pulmonary disease	Desmoteplase	Clinical phase III
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7	Hearing loss, adult onset		
8	Congenital anomalies	Nalmefene	Clinical phase III
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40	Parkinson's disease	Circadin®	Launched
		Azilect®	Launched
		Lu 02-750	Clinical phase I

\*) DALY=Disability adjusted life years; Global, non-communicable conditions  
Source: Lundbeck based on World Health Report - 2004

## Revenue, yearly figures

DKK million	2004	2005	2006	2007	2008	<b>Growth % 2008</b>	<b>Revenue distribution %</b>
Total revenue	9,733	9,070	9,221	10,985	11,282	3%	100%
Cipralex®	1,661	2,625	3,508	4,094	4,829	18%	43%
Lexapro®	2,420	2,552	1,923	2,594	2,464	(5%)	22%
Ebixa®	722	1,105	1,361	1,655	1,879	14%	17%
Azilect®	-	6	71	168	263	57%	2%
Other pharmaceuticals*	4,299	2,550	1,973	1,750	1,595	(9%)	14%

\* Old anti-psychotics, antidepressants, incl. citalopram

# Engines of growth

## Decisions Now

- **Products** - achieving full potential of marketed pharmaceuticals
- **Pipeline** - maximising the value of new and innovative pharmaceuticals
- **Partners** - intensifying growth through business development and partnerships
- **Performance** - increasing efficiency and reducing costs
- **People** - developing a high performance culture and ensuring consistent targets

## Lundbeck Inc.

- Integration on track
- Positive uptake of **Xenazine®**
- **ATryn®** roll-out
- **Sabril®** launch



## Pipeline

### **Regulatory:**

- Serdolect®

### **Phase III:**







- Lu AA21004
- Nalmefene
- Desmoteplase
- Clobazam
- I.V. carbamazepine

### **Phase II:**

- Lu AA24530
- Ziconapine
- Lu AE58054
- Lu AA39959
- Lu AA34893
- Lu AA24493



# Continued solid performance in major products

	Market share (August 2008)	Market share (August 2009)	Y/Y Change
<b>Ciprallex®</b>			
- Europe	16.2%	<b>19.4%</b>	
<b>Ciprallex®</b>			
- International markets	10.6%	<b>11.8%</b>	
<b>Lexapro®</b>			
- USA	23.0%	<b>23.8%</b>	
<b>Ebixa®</b>			
- Europe	15.9%	<b>16.8%</b>	
<b>Ebixa®</b>			
- International Markets	10.9%	<b>10.5%</b>	
<b>Azilect®</b>			
- Europe	5.7%	<b>7.6%</b>	

Note: All market share data is from IMS Health, August 2009, except International Markets being from Q2 2009

## Ciprallex®

- Continuously better understanding of Ciprallex® as a leading antidepressant
- Venlafaxine patent expiration
- Leading position in 20 European countries - e.g. France, Italy and Spain
- Reimbursement in Canada continues to drive sales
- Patent expiration in Australia
- Changes in health care system in Turkey

## Ebixa®

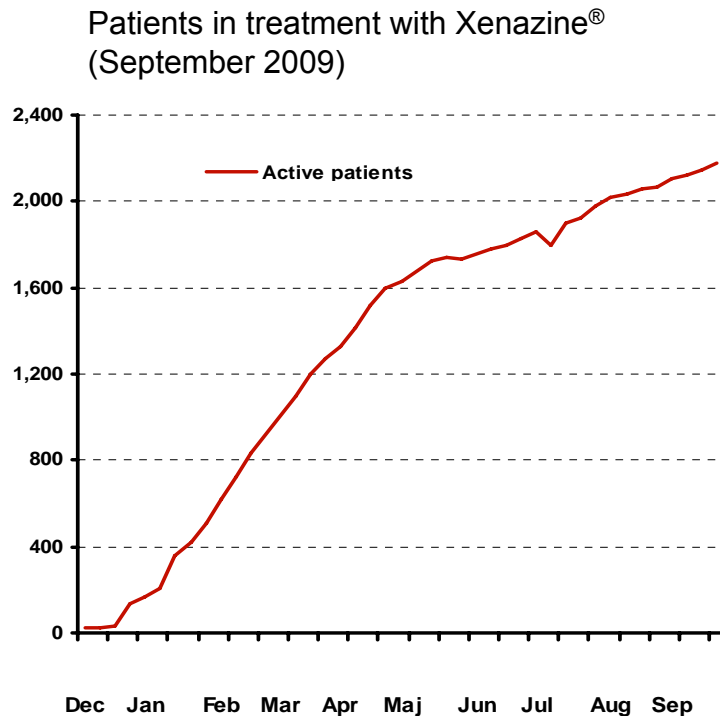
- Strong underlying market growth
- Improved compliance with Ebixa® Once-Daily
  - Now launched in 12 countries
- High growth in Italy driven by public reimbursement in April
- Reduced use of anti-psychotics among Alzheimer's patients provide market opportunities

## Azilect®

- Positive reception of data from the ADAGIO study – now published in New England Journal of Medicine

# Strong uptake for Xenazine®

- acquisition of LifeHealth strengthens Lundbeck position



- Q3 sales of DKK 89 million
- Launched in the US by the end of November 2008
- Xenazine® has been very well received
- Approx 2,200 patients initiated Xenazine® treatment by the end of September 2009
  - Another 300 patients were awaiting to commence treatment

## LifeHealth Limited

- In July 2009 Lundbeck acquired UK-based LifeHealth for USD 147 million
- Strategic investment strengthening the platform in the U.S
- LifeHealth owns rights to 25% of Xenazine® sales in North America
- The deal will be accretive to EBIT from day one

## Sabril® launched

- Approved in August 2009 by the FDA for two indications:
  - Monotherapy for pediatric patients (1 month to 2 years of age) with Infantile Spasms (IS)
  - Adjunctive therapy for adult patients with refractory complex partial seizures (rCPS) who have inadequately responded to several alternative treatments
- Approval accompanied by FDA-mandated Risk Evaluation and Mitigation Strategy (REMS)
  - Only certain physicians can prescribe Sabril®
  - Mandatory risk-benefit assessment at the end of the initial evaluation phase
  - Vision testing at baseline, while on therapy and following discontinuation of therapy
- Launched in the US in September 2009

# Lundbeck pipeline – psychiatry

Compound	Indication	Activity	Phase I	Phase II	Phase III	Regulatory filing
Serdolect® - US	Schizophrenia	Dopamine/serotonin	██████████	██████████	██████████	██████████
Lu AA21004	Depression + GAD	5HT <sub>3</sub> antagonist, 5HT <sub>1a</sub> agonist and 5HT enhancer	██████████	██████████	██████████	2011+
Lu AA24530	Depression	Multiple targets	██████████	██████████		2011+
Lu AA34893 <sup>1)</sup>	Depression/bipolar	Multiple targets	██████████	██████████		2011+
Zicronapine	Psychosis	Monoaminergic	██████████	██████████		2011+
Lu AE58054	Psychosis	Selective 5-HT <sub>6</sub> antagonist	██████████	██████████		2011+
Lu AA39959 <sup>1)</sup>	Psychosis/bipolar	Ion channel modulator	██████████	██████████		2011+

1) Clinical trials currently on hold

# Lundbeck pipeline – neurology, stroke, and other CNS

Compound	Indication	Activity	Phase I	Phase II	Phase III	Regulatory filing
I.V. carbamazepine	Epilepsy	Sodium channel blocker	██████████	██████████	██████████	2011
Nalmefene	Alcohol dependence	Specific opioid receptor antagonist	██████████	██████████	██████████	2011
Clobazam	Lennox-Gastaut syndrome	GABA enhancer	██████████	██████████	██████████	2011
Desmoteplase	Stroke	Plasminogen activator	██████████	██████████	██████████	2011+
Lu AA24493	Stroke/neuronal damage	Tissue protective cytokine	██████████	██████████		2011+
Lu AA38466	Neurological disorders	Ion channel modulator	██████████			2011+
Lu 02-750	Parkinson's	dopaminergic agent	██████████			2011+

# Lu AA24493 in clinical phase IIa in Friedreich's ataxia (FRDA)



## Lu AA24493

- A novel carbamoylated form of human erythropoietin (EPO)
- The modification results in complete loss of haematopoietic effects but maintains the tissue protective effect

### The study:

- The primary objective is both to investigate efficacy signals via biomarkers and to evaluate safety and tolerability
  - Two weeks treatment with a fixed dose Lu AA24493
  - Study to include 35-40 pts with Friedreich's ataxia

## Friedreich's ataxia

- A genetic, neuromuscular degenerative disorder that results in the progressive breakdown of nervous tissue in the spinal cord
- Patients experience a range of symptoms including loss of coordination (ataxia), muscle weakness in the limbs, speech disability, vision and hearing loss, diabetes and heart disease
- The severely debilitating disease most often results in the inability to walk 8-10 years following the onset of symptoms and death by mid-life
- Rare disease affecting about 1 in every 50,000 people in the Caucasian population

## Additional clinical programs in Q4.2009

### Lu AE58054 – clinical phase II

- A pro-cognitive 5HT<sub>6</sub> receptor antagonist
- The primary objective is to explore the effect on cognitive performance after 24 weeks of treatment
  - 270 patients with moderate Alzheimer's
  - Add-on to donepezil
  - 90 mg/day of Lu AE58054 + placebo

### Lu 02-750 – clinical phase I

- Lu 02-750 is a dopaminergic agent acting on brain areas affected in Parkinson's disease
- The placebo-controlled study is expected to enroll up to 150 healthy individuals
- Expectations are that the compound can offer Parkinson's patients a new and higher level of disease control
- Lu 02-750 has been discovered in close collaboration with Professor Håkan Wikström, Groningen University and Axon Biochemicals B.V.

# Financial guidance

	2008	2009* guidance
<b>Revenues</b>	DKK 11,282 million	DKK 13.1-13.6 billion
<b>EBITDA</b>	DKK 3,417 million	DKK 3.5-3.7 billion
<b>EBIT</b>	DKK 2,354 million	DKK 2.8-3.0 billion
<b>Tax rate</b>	27.1%	25-26%
<b>R&amp;D ratio</b>	22%	23-24%

\* Profit of DKK 124m from divestment of shares in LifeCycle Pharma is included in guidance

## 2009 guidance:

- Lundbeck expects EBITDA to be in the higher end of the interval for 2009 following the acquisition of LifeHealth
- Guidance includes a negative EBIT impact of DKK 183m in acquisition accounting (no cash flow effect)



## Key deliverables the next 12 months

### Existing products

- Further enhance Xenazine® market position
- Continued roll out of Sabril® in the US for refractory complex partial seizures (rCPS) and infantile spasms (IS)

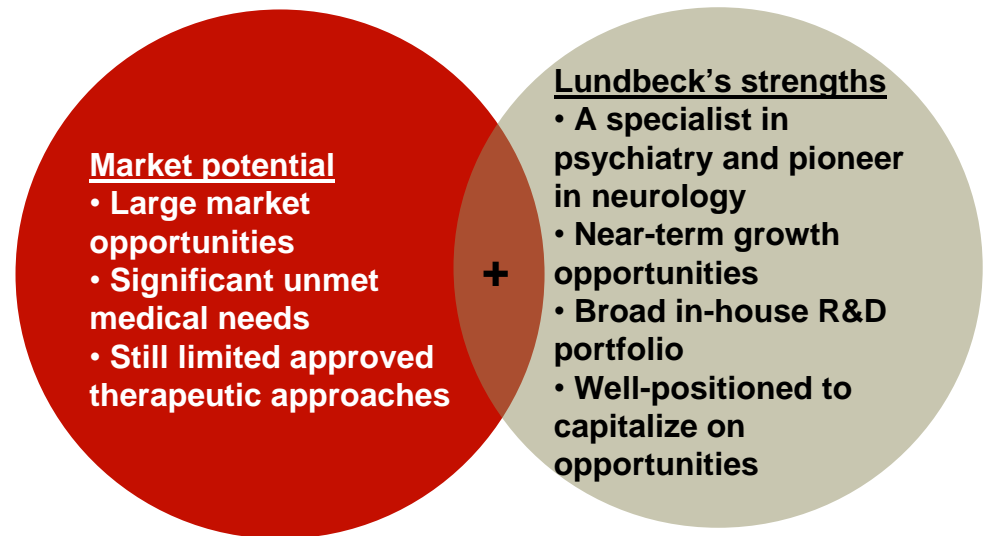
### Pipeline

- Clinical phase II data on ziconapine
- Clinical phase II data on Lu AE58054
- Initiate late-stage development programme for both Lu AA21004 and Lu AA24530
- Finalise pre-clinical investigation on Lu AA34893 and Lu AA39959 in order to continue further development

# Multiple strategies to drive long-term growth

## Our path forward...

- Streamline current business
- Explore opportunities on commercial products
- Delivering on our late-stage portfolio, but...
  - ...focus resources on best opportunities
- Support with business development opportunities
- Managing the total cost structure
- Strong financial foundation



# For more information please contact Investor Relations



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# Agenda

- Lundbeck overview
- Marketed products
- Projects in development
- Financial figures
- Sum-up
- **Back-up slides**

# Back-up slides

- Unmet medical needs
- Projects in development
- Marketed products
- Financial figures
- Therapeutic categories in CNS
- The global IP position
- The Lundbeck share

# Update on recent events

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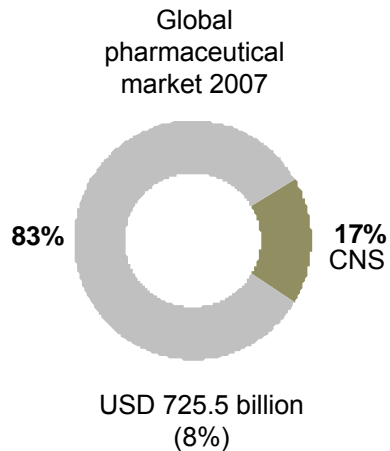
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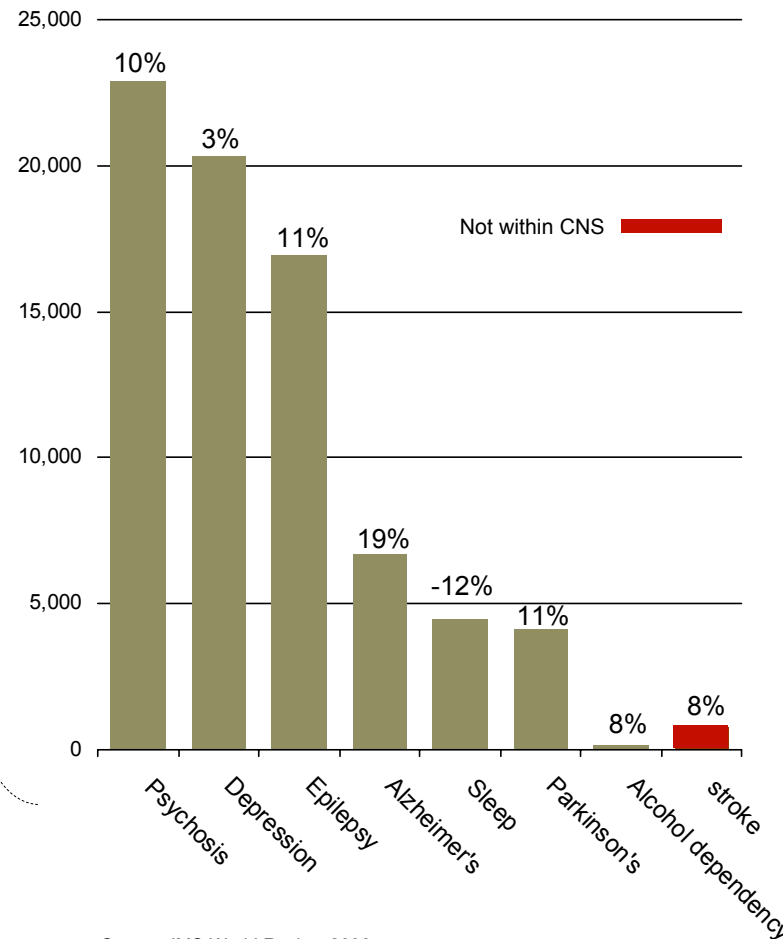
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# It's Lundbeck's aspiration to be a high-growth, research based, CNS company



## Implement strategy to maximize shareholder value in 2011-14

- Ongoing "Decision Now" process
- Integrate Ovation
- Sabril® (rCPS + IS)
- Deliver on the development pipeline
- Serdolect® in the US
- Business development activities

**Optimisation**  
(2009-10)

## Successful product launches

- Lu AA21004 (mood disorders)
- Desmoteplase (stroke)
- Nalmefene (alcohol misuse)
- Zicronapine (psychosis)
- Lu AA24530 (depression)
- Utilize US platform
- Launch first product in Japan
- Business development activities

**Transition**  
(2011-14)

## Leverage on CNS capabilities to develop novel compounds to address unmet medical needs

Potential launch of:

- Lu AA34893 (depression /bipolar)
- Lu AE58054 (cognition)
- Lu AA39959 (psychosis/ bipolar disorders)
- Lu AA24493 (neuronal damages)
- Lu AA38466 (neurological disorders)
- Other early stage projects

**...and beyond**

# Engines of growth

## Decisions Now

- **Products** - achieving full potential of marketed pharmaceuticals
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## Lundbeck Inc.

- Integration on track
- Positive initial uptake of **Xenazine®\***
- **ATryn®** launch
- **Sabril®** launch



## Pipeline

### **Regulatory:**

- Serdolect®

### **Phase III:**

- Lu AA21004
- Nalmefene
- Desmoteplase
- Clobazam
- I.V. Carbamazepine

### **Phase II:**

- Lu AA24530
- Ziconapine
- Lu AE58054
- Lu AA39959
- Lu AA34893
- Lu AA24493

# Back-up slides

- **Unmet medical needs**
- Projects in development
- Marketed products
- Financial figures
- Therapeutic categories in CNS
- The global IP position
- The Lundbeck share

# Alcohol misuse – still substantial unmet medical needs in therapy

Greater resources - the number of treatment facilities and trained physicians is inadequate

Improved effectiveness - 75% of patients relapse within the first year

Improved compliance

More treatment options

Anti-craving medications

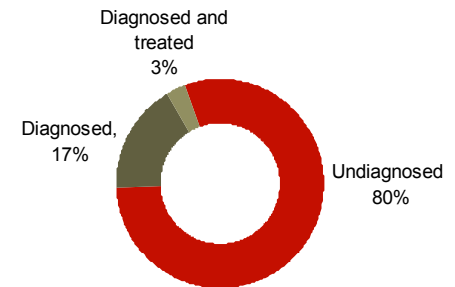
Better awareness/education

Importance

## Unmet medical need:

- Alcohol exerts an influence on the glutamine, gamma-aminobutyric acid (GABA) dopamine, and endogenous opioid systems
  - the release of  $\beta$ -endorphins, coupled with the release of dopamine, results in the pleasurable feelings associated with alcohol consumption
- An estimated 50m people is defined as alcohol misusers in major markets, 3-4% of the total population

- Few people are treated



- Alcohol dependence carries considerable adverse health and social consequences
  - the third leading cause of preventable death in the US

# Bipolar disorder (BPD) – still substantial unmet medical needs in therapy

Mono-therapies that treat depression and manic stage

Improved maintenance therapy - improve remission, prevention of depression

Drugs indicated for bipolar depression

Improve treatment non-compliance

Improved side effect profile – e.g. on manic switching, sedation, weight

Faster onset of therapeutic action

Importance

- The prevalence is estimated around 1%
- Bipolar disorder (or manic-depressive illness is a chronic and debilitating psychiatric illness
  - Recurrent episodes of mania or depression, or a mixture of both
- No single biochemical, genetic, or neuroanatomical hypothesis has been found to account for the condition
- Accurately diagnosing BPD presents a particular challenge.
  - A significant portion of BPD patients remain undiagnosed – up to 50%
  - BPD is often misdiagnosed; up to 30% of BPD patients may be misdiagnosed with unipolar depressive disorder
- Bipolar disorders are today treated with a mix of anti-psychotics, anti-depressants and anti-epileptics

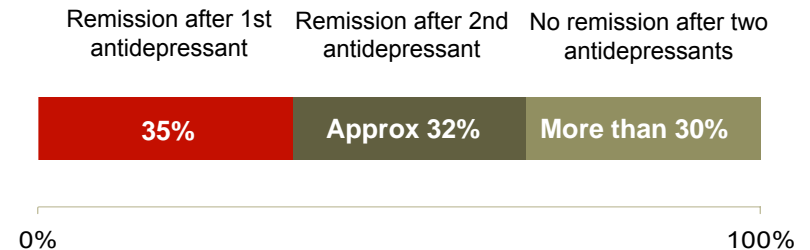
# Depression and anxiety – efficacy and onset of action needs improvement

- Treatment for non-responders - only some 50-60% of patients respond to therapy (higher for escitalopram)
- Drugs with higher remission rates
- Increased onset of action - up to four weeks before patient feels symptom relief
- Current therapies are relatively well-tolerated but still room for improvement especially on sexual side effects
- Treating mood disorders from several angles and/or targeting different sub-types
- Improved patient compliance – via patient education and increased confidence in medication

Importance

- 150m people suffer from depression globally according to WHO
- The world-market for anti-depressants is a USD 20bn opportunity
  - Most prescribed therapeutic category in the US
- Presentation rates of 15–20% for mild MDD, 43–48% for moderate MDD and 74–79% for severe MDD
  - Less than half of the presented patients receive treatment

### Remission rate



# Epilepsy – still substantial unmet medical needs in therapy

New and better treatment for refractory seizures

More choices of drugs, especially with different mechanisms of action and different side-effect profiles

Improved clinical trial design

Better diagnostic tools

Improved patient referrals

Enhanced physician and patient education

Importance

- Prevalence of epilepsy: 1% to 2% of population
- 30% live with seizures uncontrolled by existing therapies
  - Current therapies associated with significant side effects in order to gain seizure control
- Partial seizures constitutes >55% of epileptic seizures
- Complex partial seizures are particularly resistant to available antiepileptic drugs and are the most common seizure type in adults
- Possible complications of refractory complex partial seizures include death and life-altering injuries



# Psychosis – still substantial unmet medical needs in therapy



Improved treatment of cognitive dysfunction

Improved treatment of Negative symptoms

Improved treatment of co-morbid depression and anxiety

Early-stage, definitive diagnostics

More tolerable anti-psychotic therapy

More effective anti-psychotic therapy for treatment of refractory patients

Importance

- The global market for anti-psychotics constitutes USD 21bn
  - In 2007 the US market grew by 12%
  - The European market grew by 9%
- 50-60% of total schizophrenic population receives anti-psychotic treatment
  - 10-20% achieve full recovery
  - 65-70% of patients receive chronic treatment
    - 40% of patient present with persistent negative symptoms
    - 30% of patients are refractory to current therapies

# Stroke – still substantial unmet medical needs in therapy

Thrombolytics with a longer treatment window

Neuroprotectants

Less risk of secondary intra-cranial haemorrhage

Proven combination treatment

Greater clot access for thrombolytics to increase the surface area exposed to thrombolytic drugs

Proof that mechanical recanalization improves outcomes

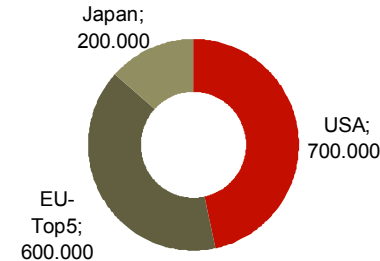
Importance

## Unmet medical need:

- Acute Ischemic stroke (AIS) accounts for 67-85% of all strokes
- AIS is a leading cause of death in the major pharmaceutical markets and the leading cause of severe neurological disability worldwide

Prevalence estimated at 1.5 million patients

Stroke patients



Source: Decision Resources - Acute Ischemic Stroke; August 2007

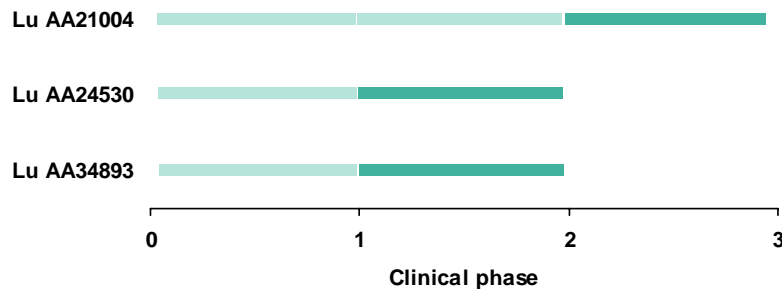
- Approx. 20% of AIS patients at the hospital within three hours from onset
- Less than 3% of diagnosed AIS patients are treated with rt-PA
- Raising stroke awareness is another critical factor to elevating AIS treatment

# Back-up slides

- Unmet medical needs
- **Projects in development**
- Marketed products
- Financial figures
- Therapeutic categories in CNS
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# The portfolio within mood disorders – markedly different to any marketed antidepressants

## Portfolio of three innovative novel compounds



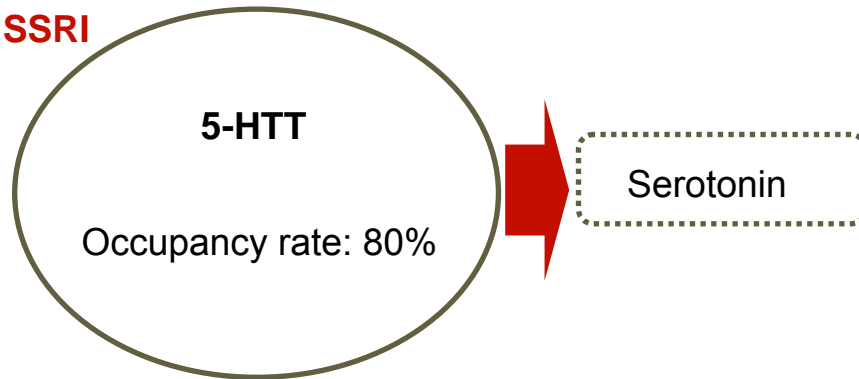
- All three projects has novel mechanism of action
- Targeting a broad spectrum of depression related symptoms
- All compounds a result of Lundbeck's own research
- Lu AA21004 and Lu AA24530 developed and potentially marketed together with Takeda, Japan

### Clinical programme on Lu AA34893:

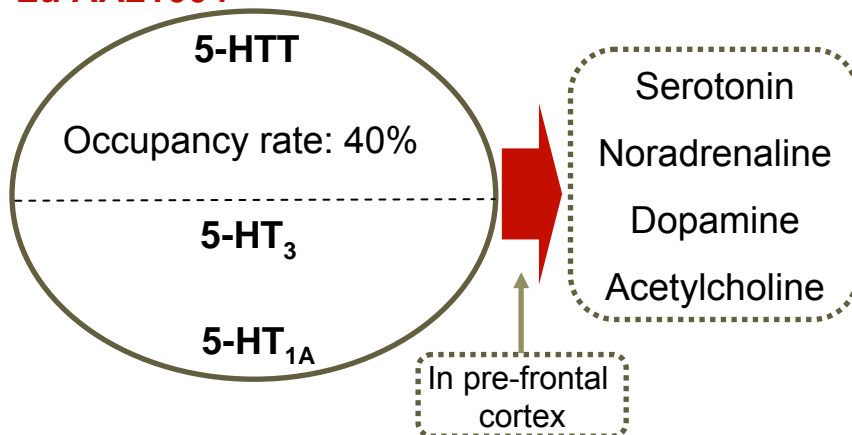
- Clinical phase II programme focus on
  - MDD patients associated with bipolar disorder
  - MDD patients
- Phase II studies started in 2008 – development programme is currently on hold

# Lu AA21004 – receptor profil

## SSRI



## Lu AA21004



## Lu AA21004 offers

- Pharmacological profile different from current antidepressants
  - Increases multiple neuro-transmitters
  - 5-HT<sub>3</sub> antagonist, 5-HT<sub>1A</sub> agonist and 5-HT enhancer
  - Increases 5-HT levels at low 5-HT transporter occupancy
- Increase ACh, NA, DA and 5-HT in regions key for mood regulation
- Strong efficacy at normal dose - MDD
- GAD indication / over 50% mixed anxiety depression symptoms
- 1<sup>st</sup> drug to launch with both MDD and GAD
- Well tolerated / low dropout rates

# Initial clinical phase III data on Lu AA21004

## The study

- Initiated in December 2007 consisting of 14 studies (9 in MDD and 5 in GAD)
- 2,000+ patients in MDD and 2,000+ patients in GAD
- 8 and 52 weeks treatment
- Several doses: 1; 2.5; 5 and 10mg

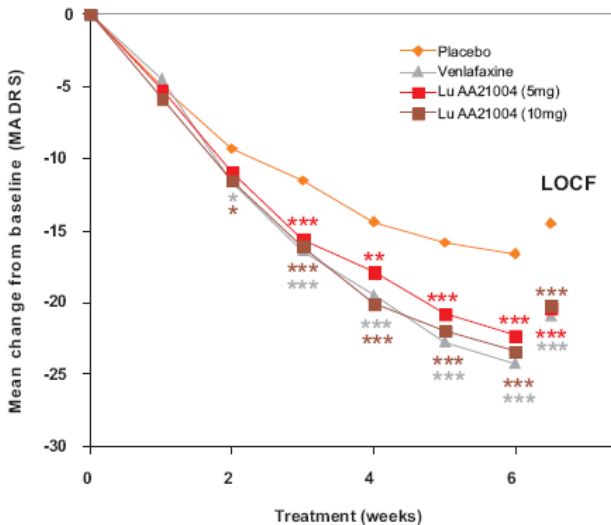
## Initial data

- One study confirmed efficacy of 5 and 10 mg dose. Efficacy of 10 mg appeared more efficacious than 5 mg
- Results from two other phase III studies conducted in the US investigating 5 mg and lower dose did not show efficacy compared to placebo
- Un-blinded clinical phase III data suggests that the higher dose may be more efficacious with an attractive safety profile
- Lu AA21004 was well tolerated in all trials and confirmed the previously observed favourable safety and tolerability profile

## Conclusion:

- Lu AA21004 is the first antidepressant in a new class
- The antidepressant efficacy has been confirmed and supports use in higher dose
- An attractive and now established safety profile
- Ability to dose up is possible
  
- The optimal dose range needs to be explored
- Submission of Lu AA21004 is postponed to allow for inclusion of such studies in the file

# Lu AA21004 - Phase II: MADRS\* total scores from baseline to Week 6



## Clinical phase II concluded in Autumn 2007:

- 6 weeks treatment
- 426 patients
- Two doses: 5 and 10mg
- Active reference: 225mg venlafaxine XL
- Highly significant improvements on the primary efficacy endpoints compared to placebo
- Attractive safety profile
- Data presented on APA in May 2009

## Conclusion:

- At week six, results showed that both doses of Lu AA21004 were statistically significant to placebo ( $p < 0.0001$ ;  $n = 208$ ) ( $n = 105$  is placebo) in mean change from baseline in MADRS total score
- A mean treatment difference to placebo of 5.9 points (5mg;  $n = 108$ ) and 5.7 points (10mg;  $n = 100$ ). Venlafaxine XR ( $n = 113$ ) was significantly superior to placebo ( $p < 0.001$ ).
- The mean MADRS total score decreased in all active treatment groups from 34 at baseline to approximately 14 in the LOCF analysis at Week 6

# Lu AA21004 - Phase II: Well-tolerated with drop-out at placebo level and no sexual dysfunction



Preferred term	Placebo n=105	Lu AA21004 5mg n=108	Lu AA21004 10mg n=100	Venlafaxine 225mg n=113
Withdrawals from study	4%	3%	7%	14%
Patients with AEs	64 (61.0%)	73 (67.6%)	74 (74.0%)	85 (75.2%)
Nausea	10 (9.5%)	32 (29.6%)*	38 (38.0%)*	38 (33.6%)*
Headache	26 (24.8%)	23 (21.3%)	25 (25.0%)	32 (28.3%)
Hyperhidrosis	2 (1.9%)	3 (2.8%)	10 (10.0%)*	17 (15.0%)*
Vomiting	1 (1.0%)	2 (1.9%)	9 (9.0%)*	4 (3.5%)
Dry mouth	7 (6.7%)	8 (7.4%)	8 (8.0%)	19 (16.8%)*
Diarrhoea	5 (4.8%)	9 (8.3%)	7 (7.0%)	5 (4.4%)
Dizziness	8 (7.6%)	7 (6.5%)	7 (7.0%)	14 (12.4%)
Nasopharyngitis	9 (8.6%)	8 (7.4%)	7 (7.0%)	4 (3.5%)
Fatigue	6 (5.7%)	4 (3.7%)	6 (6.0%)	11 (9.7%)
Insomnia	5 (4.8%)	7 (6.5%)	6 (6.0%)	14 (12.4%)
Constipation	1 (1.0%)	1 (0.9%)	3 (3.0%)	11 (9.7%)*
Vision blurred	2 (1.9%)	2 (1.9%)	1 (1.0%)	6 (5.3%)
Anorgasmia	0	0	0	7 (6.2%)*
Ejaculation delayed [men]	0	0	0	4 (7.8%)
Erectile dysfunction [men]	0	0	0	4 (7.8%)
Tremor	3 (2.9%)	5 (4.6%)	0	6 (5.3%)

Source: Francesc Artigas et al: "First double-blind, randomized, placebo-controlled, active-referenced study of Lu AA21004 in patients with major depressive disorder (MDD)" (APA 2009 poster)



# Lu AA24530 – positive results in major clinical phase II study in MDD



## Headline phase II data on Lu AA24530:

- Data support further development of the compound
- Significantly improvement on the primary endpoint and key secondary endpoints compared to placebo
- Lu AA24530 was well-tolerated
  - Drop-out rates due to serious adverse events were low in groups treated with Lu AA24530 and were similar to those of duloxetine

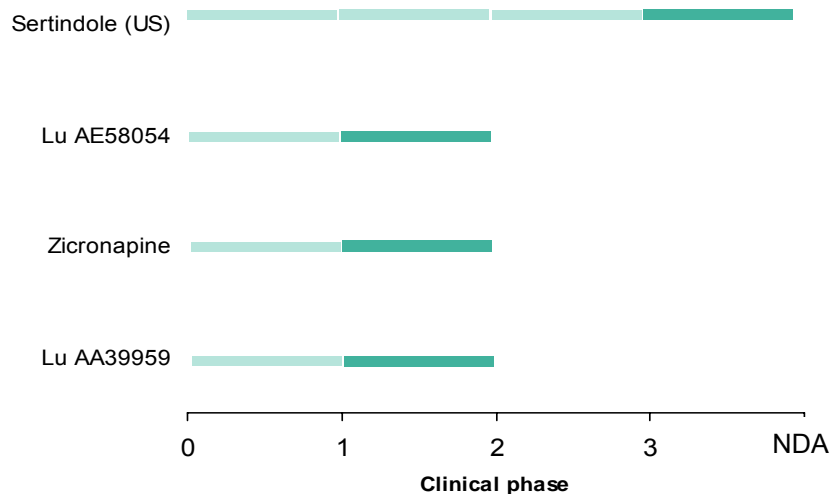
## Lu AA24530:

- A monoamine enhancer
- Reuptake inhibition at monoamine transporters
- Antagonist activity at 5-HT<sub>3</sub> and 5-HT<sub>2c</sub> receptors
- Increases in acetylcholine, noradrenaline, dopamine and 5-HT levels in brain regions that play a key role in the regulation of mood

## Study design:

- 652 patients
- Moderate to severe depression
- 6 weeks treatment
- Several doses: 5; 10 and 20 mg
- Active reference: 60 mg duloxetine
- Primary endpoint measures the difference in change from baseline to end of treatment on the MADRS total score
- Secondary endpoints include response rate, remission rate and safety

# Lundbeck's psychosis portfolio





- Lundbeck's portfolio addresses the patho-physiology with mono and add-on therapies
- The different symptom domains may have a different patho-physiology
  - One compound for all symptoms may not be realistic



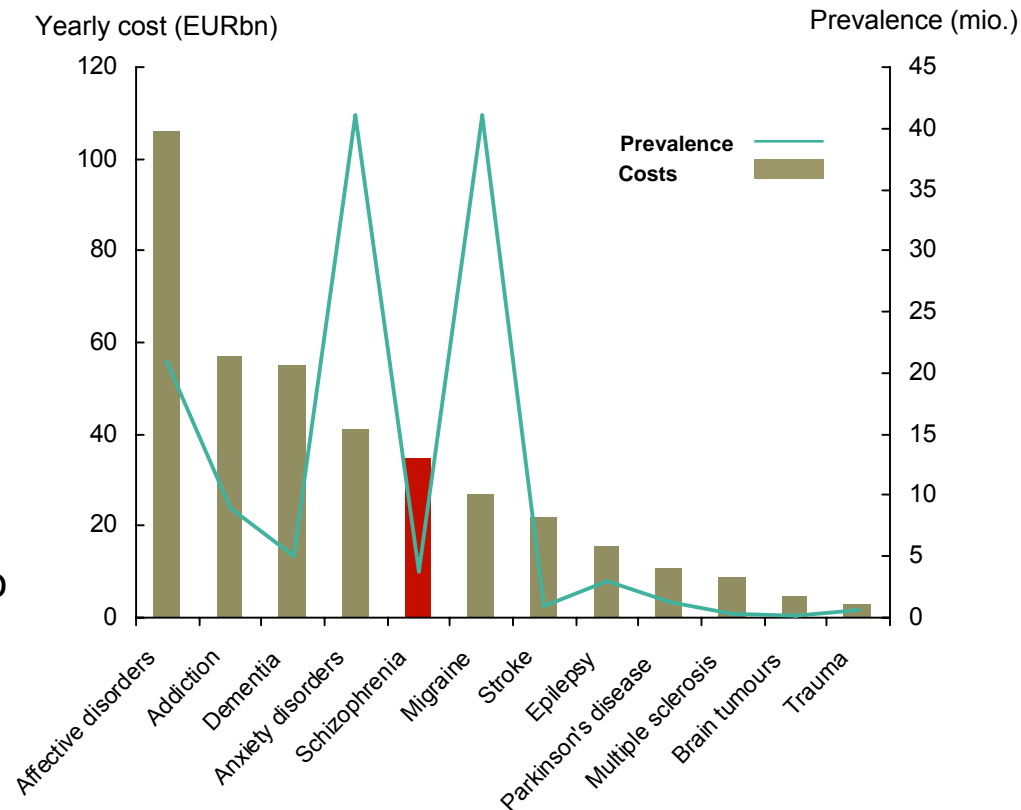
- Develop compounds targeting underlying symptom dimensions

# The burden of schizophrenia is large and multifaceted



- Schizophrenia is heavily stigmatized = create a vicious cycle of discrimination
- 
- Social isolation, unemployment, drug abuse, long-lasting institutionalization, or even homelessness
- 
- All factors that further decrease the chances of recovery and reintegration into normal life

Brain disorders account for 35% of total socio-economic cost of diseases in Europe



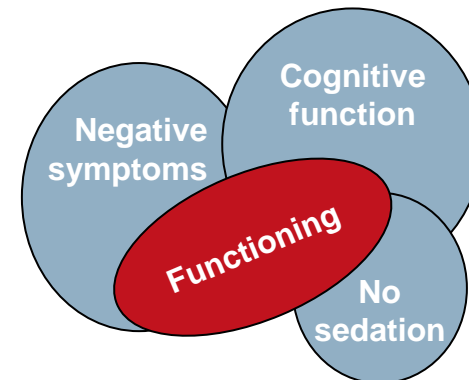
Source: Olesen et al. 2007

# Serdolect® - Complete Response Letter received from the FDA

- NDA submitted in September 2008
- Complete Response Letter received 25 June 2009
  - FDA could not approve Serdolect® based on current application
  - Additional data requested by FDA
  - Lundbeck is currently evaluating the feed back from the FDA
  - The potential launch of Serdolect® in the US postponed to after 2009
- The US anti-psychotics market is valued at USD 12.6bn per year
- Annual growth of around 12%
- Extensive switch opportunities<sup>1)</sup>
  - 74% of patients within 1½ years

**Serdolect**  
sertindole

- Broadly efficacious against positive and negative symptoms
- Low rate of suicide
- Improves cognitive performance
- Placebo-level EPS
- No sedation
- No or limited metabolic effect
- No effect on libido, erection, orgasm
- No anti-cholinergic activity
- QT<sub>c</sub> prolongation – No excess mortality
- Once-daily dosage



<sup>1)</sup> CATIE, NEJM, Sept. 2005

# Zicronapine – pharmacological profile and expected clinical profile

## Zicronapine (Lu 31-130):

Zicronapine has a multi-receptorial profile

- Affinity to monoaminergic receptors
- Potent in vivo antagonistic effects at D<sub>1</sub>, D<sub>2</sub>, and 5-HT<sub>2a</sub> receptors
- Unique in vivo preference for D<sub>1</sub> over D<sub>2</sub> in pre-frontal cortex

Zicronapine is expected to show clear and convincing effects in patients with schizophrenia, likely associated with

- Pro-cognitive effects
- Low potential for EPS side effects
- Benign safety/tolerability profile

## Two Phase II studies ongoing:

### Clinical trial programme 1

- A phase II, placebo controlled, dose-escalation study in 210 patients with schizophrenia
- Preliminary and still blinded data suggest a favourable profile in terms of safety and efficacy
- Good safety data has sparked an interest in extending the study to test higher doses

### Clinical trial programme 2

- A 12-week study in 120 patients with schizophrenia, comparing the effect and safety of 5-7mg zicronapine and 10-15mg olanzapine
- Primary endpoint: PANSS\*; secondary end point include BACS\*\*

These studies will permit a decision of further development by end of 2009

\* The PANSS or the Positive and Negative Syndrome Scale is a medical scale used for measuring symptom severity of patients with schizophrenia.

\*\* BACS or the Brief Assessment of Cognition in Schizophrenia is a newly developed instrument that assesses the aspects of cognition found to be most impaired and most strongly correlated with outcome in patients with schizophrenia.

# Lu AE58054 – pharmacological profile in animal models

## Lu AE58054

Lu AE58054 is a selective 5-HT<sub>6</sub> antagonist

Pharmacological profile of Lu AE58054 suggest multiple paths:

- General schizophrenia (augmentation therapy to anti-psychotics)
- CIAS (augmentation therapy to anti-psychotics)
- Alzheimer's Disease (monotherapy or augmentation therapy)

- Lu AE58054 has been investigated in healthy volunteers and patients with schizophrenia
  - Is generally well tolerated and has a benign side-effect profile
- **Initiation and conduct of clinical studies**
  - General schizophrenia
    - PoC study - Lu AE58054 versus placebo as add-on to risperidone
      - Twice daily oral dose (60 mg BID: total dose 120 mg/day)
      - 120 patients - 60 patients/arm
      - 12 week treatment duration
      - Primary endpoint PANSS\*; secondary endpoint includes BACS\*\*
    - Study to be completed in first half 2010
- **Long-term toxicity studies ongoing to allow for clinical studies of longer duration**

\* The PANSS or the Positive and Negative Syndrome Scale is a medical scale used for measuring symptom severity of patients with schizophrenia.

\*\* BACS or the Brief Assessment of Cognition in Schizophrenia is a newly developed instrument that assesses the aspects of cognition found to be most impaired and most strongly correlated with outcome in patients with schizophrenia.

# Lu AA39959 – a new class of compounds targeting bipolar disorder

## Lu AA39959

Lu AA39959 has a unique target profile: first in class

- Modulator of selected members in a distinct family of ion channels
- No affinity for other targets

Pre-clinical studies in animal models have shown

- Acute and complete normalisation of pathological levels of dopamine neurotransmission i.e. fast onset potential against psychotic symptoms
- Anti-depressant-like effect in the chronic mild stress model
- No EPS-like side effects

Lu AA39959 is expected to show clear and convincing effects in patients with bipolar disorder, likely associated with

- Benign safety/tolerability profile: mono-therapy
- Additional features, such as fast onset of antipsychotic effect and low mania switch-rate liability and disease-modifying potential

Clinical phase II programme initiated in December 2008

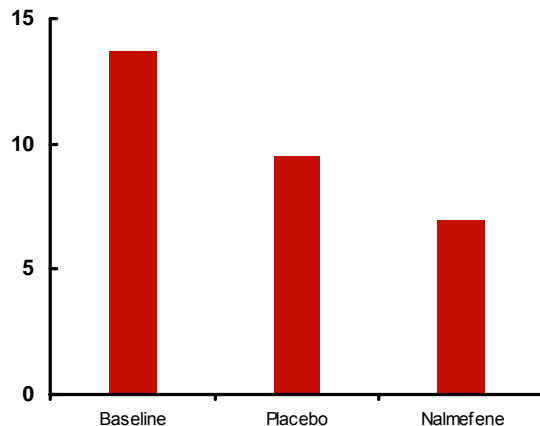
- Focus on treatment of depression in patients with bipolar disorder
- 180 patient in three arms (including placebo and quetiapine)
- The clinical trial is currently paused until emerging data have been fully evaluated
- Study paused in May

# Nalmefene (ph III) – a potential new treatment paradigm

## Nalmefene

- In clinical trials nalmefene reduces
  - Heavy Drinking Days
  - Total consumption
- Nalmefene can leverage on Lundbeck's existing European GP and specialist sales force
  - Co-morbidity to other psychiatric disorders

Heavy Drinking Days\* per month



Results from 403 patients, 28 week study

## Clinical phase III study ongoing:

- Consists of three studies with a total of ~1,800 patients
  - Two placebo-controlled 24-week studies evaluating the effect of 20mg nalmefene each recruiting some 600 patients
  - To evaluate the efficacy of nalmefene on alcohol consumption measured by the monthly number of heavy drinking days and the monthly total consumption
  - The programme will include a 52-week study with focus on safety and tolerability recruiting some 650 patients

\* Heavy drinking is defined by the NIAAA as the consumption of 5 or more drinks in a day for men and 4 or more for women



# Desmoteplase (ph III) – a possible improvement of existing stroke therapy

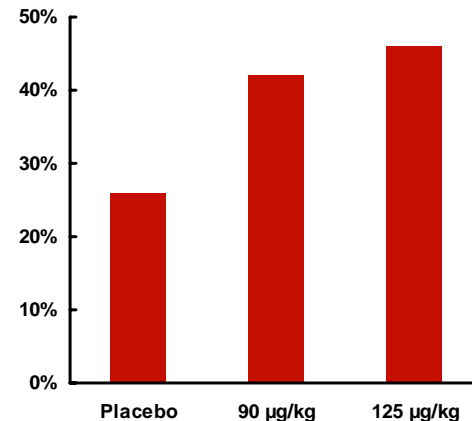
## Desmoteplase

- Nine hour time window increases addressable market
- Potential to decrease bleeding complications
- Potential to improve neurological outcome
- Post-hoc analysis of DIAS-2 supports continued clinical development
  - The mild strokes included in DIAS-2 may explain the unexpectedly high placebo response rate

## Other stroke-related projects:

- Clinical phase I with Lu AA24493 (CEPO) initiated in October 2007
- Lu AA24493 is a novel carba-moylated form of human erythropoietin (EPO) - a modification that results in complete loss of haematopoietic effects but maintains the tissue protective effect

Responder rates  
DIAS/DEDAS DIAS-2 (pooled)



Patients without vessel occlusion or stenosis on baseline angiography excluded from analysis

Source: Data presented at ISC2008, New Orleans

## Clinical phase III study ongoing:

- Consists of two placebo-controlled studies recruiting 320 patients in each
  - Primary endpoint is the effect of a single dose desmoteplase (90µg/kg) in a therapeutic window of 3-9 hours after the incidence
  - The effect will be measured after 90 days

# Intravenous (I.V.) carbamazepine - overview

## **I.V. carbamazepine**

- Niche product used in hospital channels for patients taking oral carbamazepine, but need intravenous treatment
- An intravenous formulation of carbamazepine has historically not been available
- NDA expected in 2010

## **Carbamazepine (CBZ):**

- Oral formulations available in the US and worldwide
- Oral CBZ has been approved for the treatment of partial seizures and generalized tonic-clonic seizures for over 30 years
- Well characterized safety profile
- Oral CBZ has a ~17% market share (vol.)

## **Study design:**

- ~100 patients
- Sequential, open-label study
- Study initiated in July 2007
- Primary objective to assess safety, tolerability and pharmacokinetics of IV CBZ

# Clobazam in clinical phase III development for adjunctive therapy in Lennox-Gastaut Syndrome (LGS)

## Lennox-Gastaut Syndrome (LGS):

- LGS is a complex disease and poses a significant treatment challenge
- Approximately 3-10% of children with epilepsy have LGS
- The mortality rate ranges from 3% to 7%
- Current treatment options provide inadequate seizure control for many patients
- Safety and tolerability issues with most current medications

## Clobazam:

- Clobazam is a GABA enhancer
- Efficacy in LGS demonstrated in phase II
- Generally well tolerated with most AEs being mild or moderate in severity and transient in nature
- Granted orphan drug exclusivity
- NDA expected in 2011

## Study design:

- 304 patients
- Treatment period: 15-18 weeks
- Three active doses of clobazam and placebo
- Twice daily
- Study initiated in August 2007
- Primary endpoint measure reduction in number of drop seizures from the baseline period compared to the maintenance period

# Lu AA24493 in clinical phase IIa in Friedreich's ataxia (FRDA)



## Lu AA24493

- A novel carbamoylated form of human erythropoietin (EPO)
- The modification results in complete loss of haematopoietic effects but maintains the tissue protective effect

### The study:

- The primary objective is both to investigate efficacy signals via biomarkers and to evaluate safety and tolerability
  - Two weeks treatment with a fixed dose Lu AA24493
  - Study to include 35-40 pts with Friedreich's ataxia

## Friedreich's ataxia

- A genetic, neuromuscular degenerative disorder that results in the progressive breakdown of nervous tissue in the spinal cord
- Patients experience a range of symptoms including loss of coordination (ataxia), muscle weakness in the limbs, speech disability, vision and hearing loss, diabetes and heart disease
- The severely debilitating disease most often results in the inability to walk 8-10 years following the onset of symptoms and death by mid-life
- Rare disease affecting about 1 in every 50,000 people in the Caucasian population

## Additional clinical programs in Q4.2009

### Lu AE58054 – clinical phase II

- A pro-cognitive 5HT<sub>6</sub> receptor antagonist
- The primary objective is to explore the effect on cognitive performance after 24 weeks of treatment
  - 270 patients with moderate Alzheimer's
  - Add-on to donepezil
  - 90 mg/day of Lu AE58054 + placebo

### Lu 02-750 – clinical phase I

- Lu 02-750 is a dopaminergic agent acting on brain areas affected in Parkinson's disease
- The placebo-controlled study is expected to enroll up to 150 healthy individuals
- Expectations are that the compound can offer Parkinson's patients a new and higher level of disease control
- Lu 02-750 has been discovered in close collaboration with Professor Håkan Wikström, Groningen University and Axon Biochemicals B.V.

# Lundbeck pipeline – psychiatry

Compound	Indication	Activity	Phase I	Phase II	Phase III	Regulatory filing
Serdolect® - US	Schizophrenia	Dopamine/serotonin	██████████	██████████	██████████	██████████
Lu AA21004	Depression + GAD	5HT <sub>3</sub> antagonist, 5HT <sub>1a</sub> agonist and 5HT enhancer	██████████	██████████	██████████	2011+
Lu AA24530	Depression	Multiple targets	██████████	██████████		2011+
Lu AA34893 <sup>1)</sup>	Depression/bipolar	Multiple targets	██████████	██████████		2011+
Zicronapine	Psychosis	Monoaminergic	██████████	██████████		2011+
Lu AE58054	Psychosis	Selective 5-HT <sub>6</sub> antagonist	██████████	██████████		2011+
Lu AA39959 <sup>1)</sup>	Psychosis/bipolar	Ion channel modulator	██████████	██████████		2011+

1) Clinical trials currently on hold

# Lundbeck pipeline – neurology, stroke, and other CNS

Compound	Indication	Activity	Phase I	Phase II	Phase III	Regulatory filing
I.V. carbamazepine	Epilepsy	Sodium channel blocker	██████████	██████████	██████████	2011
Nalmefene	Alcohol dependence	Specific opioid receptor antagonist	██████████	██████████	██████████	2011
Clobazam	Lennox-Gastaut syndrome	GABA enhancer	██████████	██████████	██████████	2011
Desmoteplase	Stroke	Plasminogen activator	██████████	██████████	██████████	2011+
Lu AA24493	Stroke/neuronal damage	Tissue protective cytokine	██████████	██████████		2011+
Lu AA38466	Neurological disorders	Ion channel modulator	██████████			2011+
Lu 02-750	Parkinson's	dopaminergic agent	██████████			2011+

## Back-up slides

- Unmet medical needs
- Projects in development
- **Marketed products**
- Financial figures
- Therapeutic categories in CNS
- The global IP position
- The Lundbeck share



# Cipralex<sup>®</sup>/Lexapro<sup>®</sup> (escitalopram) - top of the class anti-depressiv



*\*\* "the most important clinical implication of the results is that escitalopram and sertraline might be the best choice when starting a treatment for moderate to severe major depression because they have the best possible balance between efficacy and acceptability"*

The Lancet, January 29, 2009

"Comparative efficacy and acceptability of 12 new-generation antidepressants: a multiple-treatments meta-analysis"

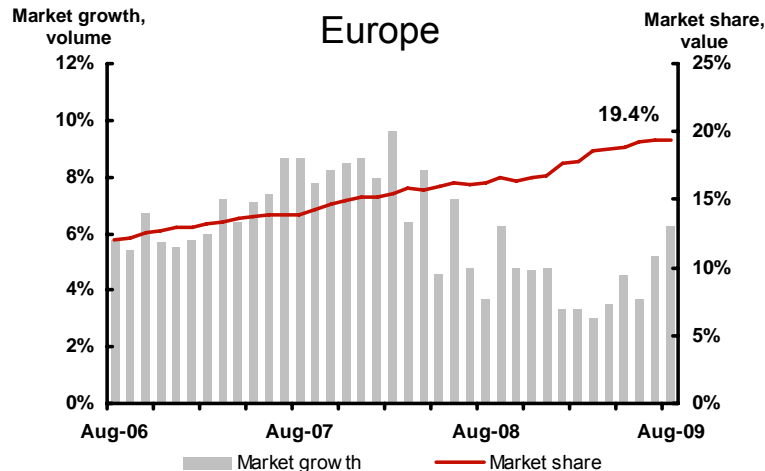
- Cipralex<sup>®</sup> is an ASRI\* with a unique mode of action, Serotonin Dual-action
- Estimated to have treated more than 160 million patients since launch
- Has demonstrated superior efficacy in the treatment of depression and anxiety in numerous post-approval studies
- Provides excellent tolerability and safety profile
- Broad study<sup>1)</sup> proves Cipralex<sup>®</sup> (and sertraline) to be best choice for moderate to severe depression\*\*
- Approved for MDD, PD, GAD, SAD and OCD in EU, and for MDD and GAD in the US

\* allosteric serotonin reuptake inhibitor

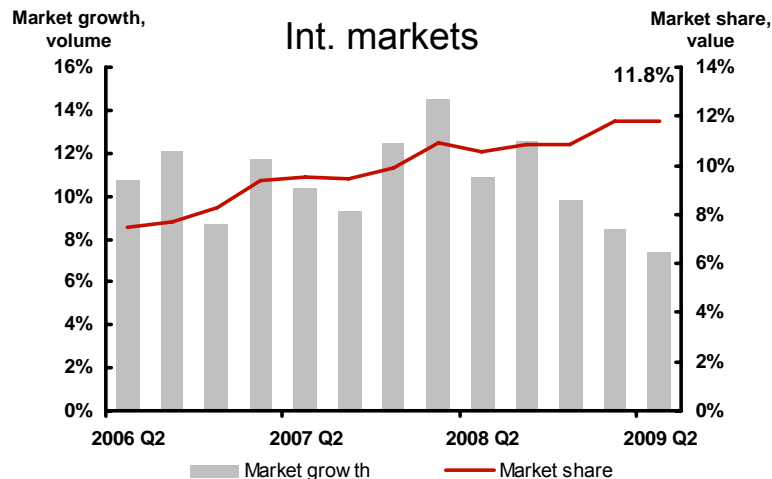
1) Cipriani A, et al. Lancet 2009

# Cipralex<sup>®</sup> (escitalopram) – Continued strong growth in Europe

## Anti-depressant marked



- Cipralex<sup>®</sup> sales in Europe for the quarter was DKK 908m (+8%)
- Cipralex<sup>®</sup> is now the most prescribed antidepressant measured in value, having a 19.4% market share
- The compound is continuously expanding its market share across most countries (value)
- The antidepressant market (value) is contracting due to the patent expiry on venlafaxine
- Patent to expire in the last countries in Europe in June 2014

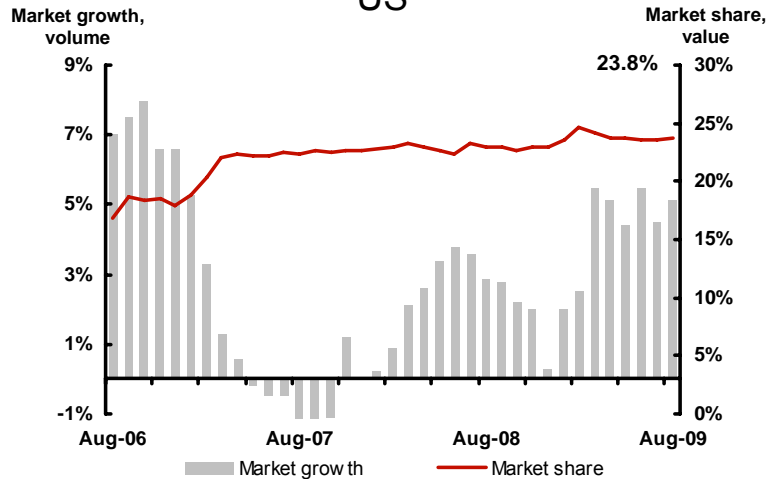


- Int. Markets sales at DKK 350m (-9%)
- Still gaining market shares in international markets despite generic competition in many markets
- Market share expansion continues in Canada following public reimbursement in British Columbia
  - Cipralex<sup>®</sup> market share is now 8.6% compared to 6.5% a year earlier
- Structural changes in the Turkish healthcare system hit Cipralex<sup>®</sup> sales
- Patent expired in June in Australia, as five year extension to patent is denied - decision to be appealed

# Lexapro<sup>®</sup> (escitalopram) – sales pressured by generic competition

## Anti-depressant market

### US



- Lexapro<sup>®</sup> revenue of DKK 600m in Q3 2009, flat compared to 2008
- Market experiencing limited growth – Lexapro<sup>®</sup> revenue pressured by generic competition
- FDA approval of Lexapro<sup>®</sup> for treatment of depression in adolescents expected to support growth
- Lexapro<sup>®</sup> is the most prescribed branded antidepressant in the US
- Marketed by Forest Laboratories, Inc.
- Patent to expire in March 2012

# Ebixa<sup>®</sup> (memantine) – efficacious even in severe Alzheimer's disease



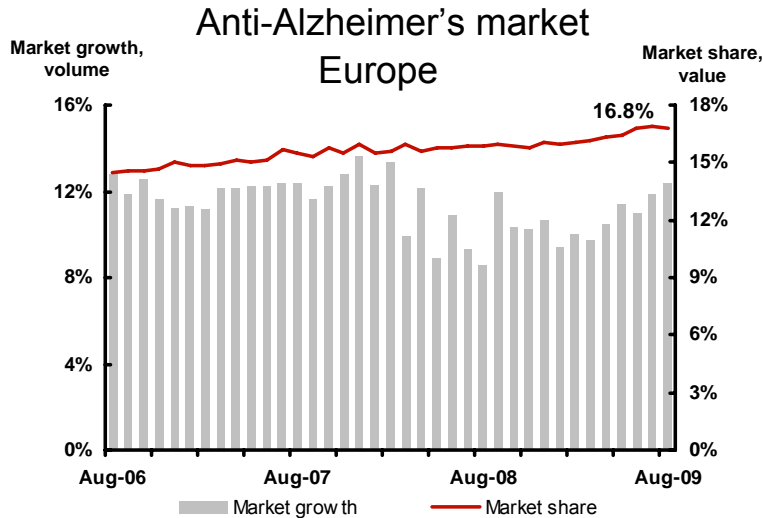
*"It gives me a real opportunity to treat some of the more distressing symptoms that you see emerge in Alzheimer's disease"*

Prof David Wilkinson,  
Memory Assessment and Research Centre, Southampton, UK.

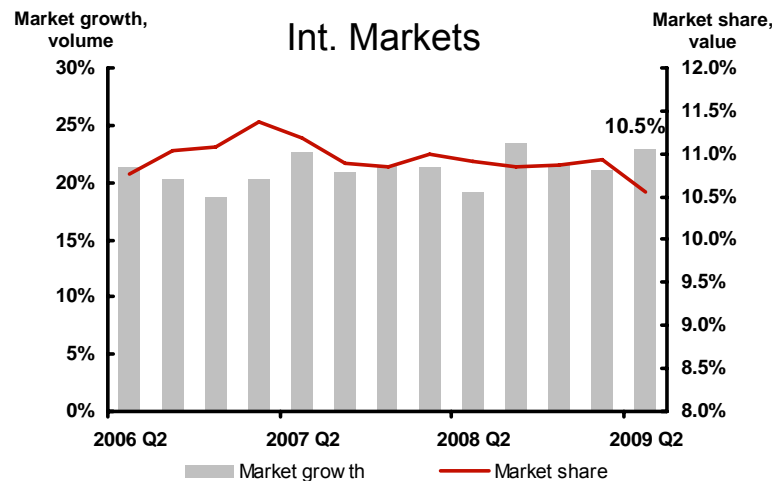
- Ebixa<sup>®</sup> is the only NMDA\* receptor antagonist approved for the treatment of Alzheimer's disease
- A very efficacious, well-tolerated and safe treatment with placebo-like side effects
- Only therapy licensed for the treatment of moderate to severe Alzheimer's in most Lundbeck markets
- Once-daily treatment
- Inlicensed form Merz Pharmaceuticals GmbH (Germany)

\* N-methyl-D-aspartate

# Ebixa<sup>®</sup> (memantine) – sales up 14%



- Ebixa<sup>®</sup> revenue in Europe was DKK 456m (+14%)
- Continues to take market shares in Europe
- High growth in Italy following reimbursement
- Continued roll-out of Ebixa<sup>®</sup> Once-Daily following EU approval in May 2008
- Launched in 2002, data exclusivity to expire in Europe in May 2012



- Int. Markets sales at DKK 93m (+15%)
- Ebixa<sup>®</sup> is losing market shares to cheaper generics
- ... but underlying market growth continues to deliver significant growth
- The market share for Int. Markets were 10.5% in Q2 2009
- New dispenser to be launched end 2009

# Sabril® (vigabatrin) – addressing highly unmet needs



- Unique MoA as a selective and irreversible inhibitor of GABA-transaminase
- Generally well tolerated
- Rapid onset - within 2 - 3 weeks
- Risk of critical vision damage (~ 30% of patients)
- Patent to expire in the US in 2015 (rCPS) and 2016 (IS – orphan drug status)

## Infantile spasms (IS) / West syndrome:

- Serious and catastrophic disease with unmet medical need
  - Mental retardation is often a consequence - 70% - 90% are intellectually developmentally delayed
  - Mortality of around 5%
- ~2,500 patients/year in the US with IS
- Sabril® is the only FDA-approved drug for IS

## Refractory complex partial seizures:

- Complex partial seizures are often poorly controlled by current therapies
  - Degrades quality of life and may be fatal
- ~ 1 million patient in the US
- 30-36% of patients are refractory; defined as having failed 2 mono-therapies and at least one drug combination
- Patients with uncontrolled seizures have a nearly 40x higher risk of mortality than those whose seizures are adequately controlled

## Sabril® launched

- Approved in August 2009 by the FDA for two indications:
  - Monotherapy for pediatric patients (1 month to 2 years of age) with Infantile Spasms (IS)
  - Adjunctive therapy for adult patients with refractory complex partial seizures (rCPS) who have inadequately responded to several alternative treatments
- Approval accompanied by FDA-mandated Risk Evaluation and Mitigation Strategy (REMS)
  - Only certain physicians can prescribe Sabril®
  - Mandatory risk-benefit assessment at the end of the initial evaluation phase
  - Vision testing at baseline, while on therapy and following discontinuation of therapy
- Launched September 2009

# Xenazine® (tetrabenazine) – promising initial launch



*“Xenazine® represents hope for patients and families dealing with this difficult disease. For the first time, there is a treatment that can help patients [ ] gain some quality of life.”*

Timothy Coté, M.D., M.P.H.,  
director of FDA's Office of Orphan Products Development

- Selectively inhibiting vesicular monoamine transporter enzyme (VMAT)-2, thereby depleting pre-synaptic dopamine
- Approved for chorea associated with Huntington's disease
- Only drug approved by FDA specifically for any symptom of HD
- Addresses high unmet medical needs and has shown strong efficacy
- Granted orphan drug exclusivity
- Xenazine® is distributed with a REMS, which includes rigorous education and outreach programmes

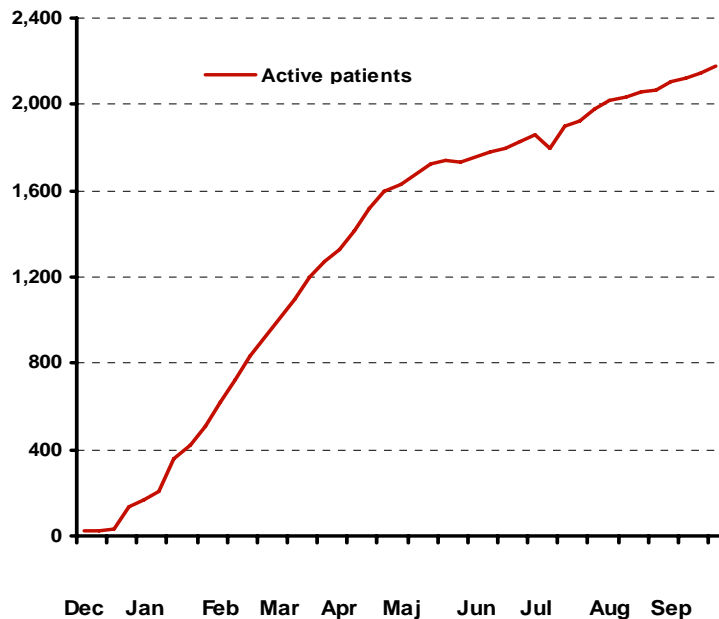
## **Chorea associated with Huntington's disease (HD)**

- Approximately 20,000 to 25,000 people in the US suffer from HD
  - Chorea, a movement disorder characterized by involuntary movements, is the most common symptom of HD (~90%)
- Life expectancy is 15-20 years after onset of disease, death often caused by pneumonia or choking
- Depression is a common co-morbid condition of the disease.
  - Approx 25% of patients attempt suicide



# Strong uptake for Xenazine®

Patients in treatment with Xenazine®  
(September 2009)



- Q3 sales of DKK 89 million
- Launched in the US by the end of November 2008
- Xenazine® has been very well received
- Approx 2,200 patients initiated Xenazine® treatment by the end of September 2009.
  - Another 300 patients were awaiting to commence treatment

## LifeHealth Limited

- In July 2009 Lundbeck acquired UK-based LifeHealth for USD 147 million
- Strategic investment strengthening the platform in the U.S
- LifeHealth owns rights to 25% of Xenazine® sales in North America
- The deal will be accretive to EBIT from day one

# Azilect® (rasagiline) – only treatment of Parkinson's disease proven to slow disease progression



*"The successful outcome of the [ADAGIO] study provides further rationale for the early use of Azilect® among Parkinson's disease patients"*

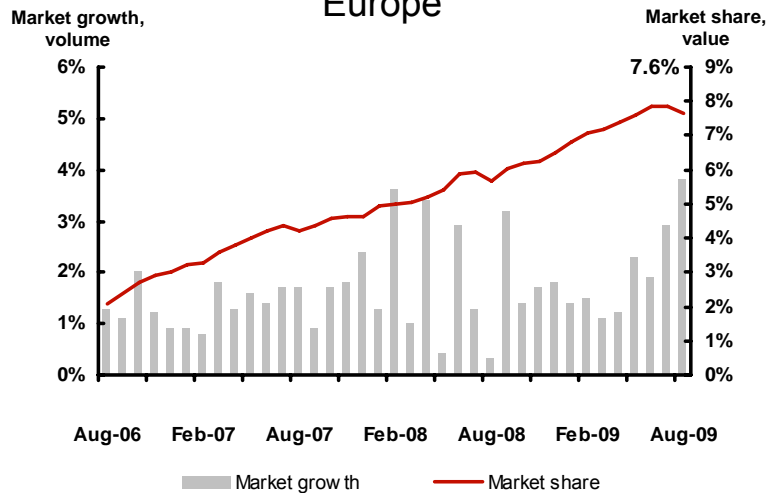
Prof. Rascol, M.D., Ph.D., Principal investigator

- A potent, selective, irreversible monoamine oxidase (MAO) type-B inhibitor
- Approved for monotherapy and adjunct therapy with levodopa treatment
- Azilect® is a well tolerated therapy for early and advanced Parkinson disease patients
- Convenient and simple treatment
  - Single tablet, once-daily
  - No titration
- Only Parkinson's treatment to have proven to have a slowing effect on disease progression
  - ADAGIO study (1,176 patients), data presented at EFNS and ANA in 2008

# Azilect® (rasagiline) – continued expansion of market share

## Anti-Parkinson's market

### Europe



- Azilect® sales rose to DKK 93m in Q3 2009, up 43% compared to 2008
- European sales at DKK 84m (+43%), Int. Markets sales at DKK 9m (+39%)
- Strong ADAGIO result could support further market penetration
  - Data presented in The New England Journal of Medicine in September 2009
- Launched in 2005, data exclusivity until 2015

# ATryn® (recombinant anti-thrombin alpha) - overview

## ATryn®

- Treatment of patients with Hereditary Anti-thrombin Deficiency (HAD) to prevent thrombosis during high risk situations like surgery and obstetrical procedures
- Ovation has an agreement with GTC Biotherapeutics to market the product in the US and pursue further development
- First recombinant anti-thrombin product approved in the world
- First transgenic drug approved in the world
- Granted orphan drug exclusivity
- Launched in the US on 6 May 2009

## Hereditary Anti-thrombin Deficiency (HAD)

- A potentially life-threatening rare disease with limited therapeutic alternatives
  - People with HAD are at increased risk for eg venous blood clots, including pulmonary embolism and deep vein thrombosis
- HAD is a genetic disorder
  - Men and women are equally affected
- Estimated 60,000 HAD patients in the US
  - 3,000-7,500 symptomatic individuals in the US
- Human derived *Thrombate III* is currently the most common therapy for HAD

## Back-up slides

- Unmet medical needs
- Projects in development
- Marketed products
- **Lundbeck Inc.**
- Financial figures
- Therapeutic categories in CNS
- The global IP position
- The Lundbeck share

# Lundbeck, Inc. (former Ovation Pharmaceuticals) overview



- Company was founded by Jeffrey Aronin and started commercial operations in 2002
- Headquartered in Deerfield, IL
- Approximately 300 employees
- Professional interaction with Key Opinion Leaders, patient organisations and FDA
- Strong track record in development and regulatory affairs

## Business model

- Developing and commercialising innovative medicines for severely ill patients suffering from rare diseases with high unmet medical needs

## Key marketed products

### CNS (21% of 2008)

- *Xenazine*<sup>®</sup>: Huntington's chorea
- *Tranxene*<sup>®</sup>: Anxiety disorders
- *Nembutal*<sup>®</sup>: Emergency control of acute convulsive episodes
- *Desoxyn*<sup>®</sup>: ADHD
- *Mebara*<sup>®</sup>: Anxiety, tension
- *Peganone*<sup>®</sup>: Tonic-clonic and complex partial seizures
- *Sabril*<sup>®</sup>: IS and rCPS

### Haematology/Oncology

#### (29% of 2008)

- *Panhematin*<sup>®</sup>: Mod. to sev. attacks associated with acute intermittent porphyria (AIP)
- *Cosmegen*<sup>®</sup>: Treatment of rare childhood cancers
- *Mustargen*<sup>®</sup>: Indicated for palliative treatment of Hodgkin's disease and mycosis fungoides
- *Elspar*<sup>®</sup>: Acute lymphocytic leukaemia
- *ATryn*<sup>®</sup>: hereditary antithrombin deficient patients

### Hospital (50% of 2008)

- *NeoProfen*<sup>®</sup>: Patent ductus arteriosis (PDA), heart problem seen in premature babies
- *Diuril*<sup>®</sup>: Therapy for oedema in congestive heart failure
- *Indocin*<sup>®</sup> IV: PDA
- *Chemet*<sup>®</sup>: Treatment of lead poisoning in paediatric patients
- *Cogentin*<sup>®</sup>: PD

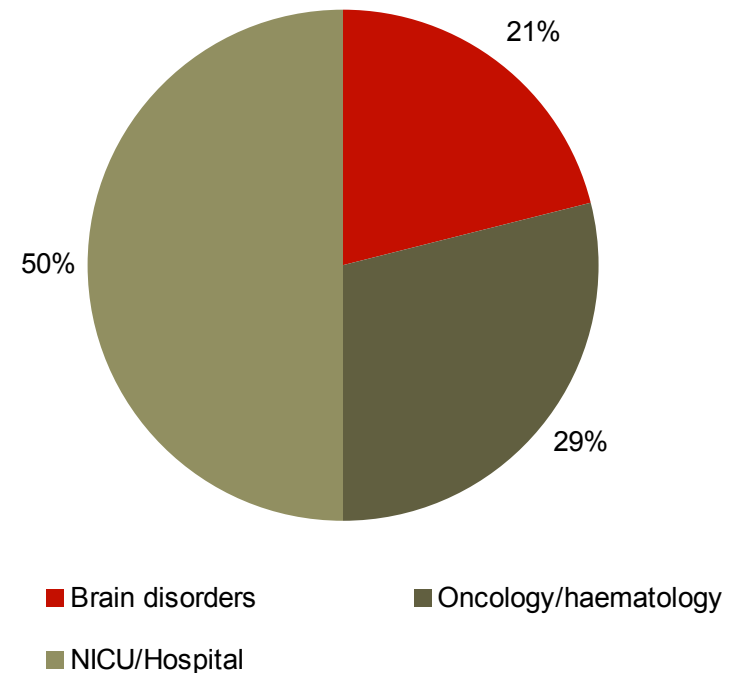
# Ovation P&L (2005-2008)

## Lundbeck Inc. (former Ovation) - historic performance

USDm	2005	2006	2007	2008
Net sales	60.1	142.7	176.1	204.0
Growth %	55%	137%	23%	16%
Gross profit	44.9	117.1	139.5	160.4
Gross margin	75%	82%	79%	79%
SG&A <sup>1)</sup>	21.4	42.1	55.7	65.3
SG&A-ratio	36%	30%	32%	32%
R&D	12.1	14.6	42.8	51.2
R&D-ratio	20%	10%	24%	25%
EBIT	4.5	48.3	31.4	31.6
EBIT-margin	7.3%	33.9%	17.8%	15%

1) SG&A includes Regulatory, Patient Safety and Medical Affairs

Revenue distribution (2008)



## Lundbeck Inc. impact on P&L for 2009

(DKK)	EBIT	Profit before tax
Lundbeck Inc.	~ 150mn	~ 150mn
Acquisition accounting	~ (183)mn	~ (183)mn
Additional amortisations	~ (150)mn	~ (150)mn
Net interests	--	~ (160)mn
<b>Total impact</b>	<b>~ (183)mn</b>	<b>~ (343)mn</b>

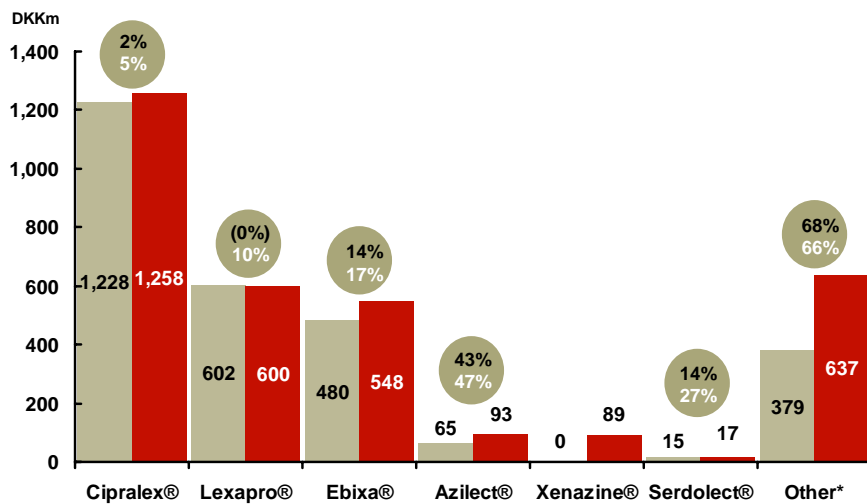
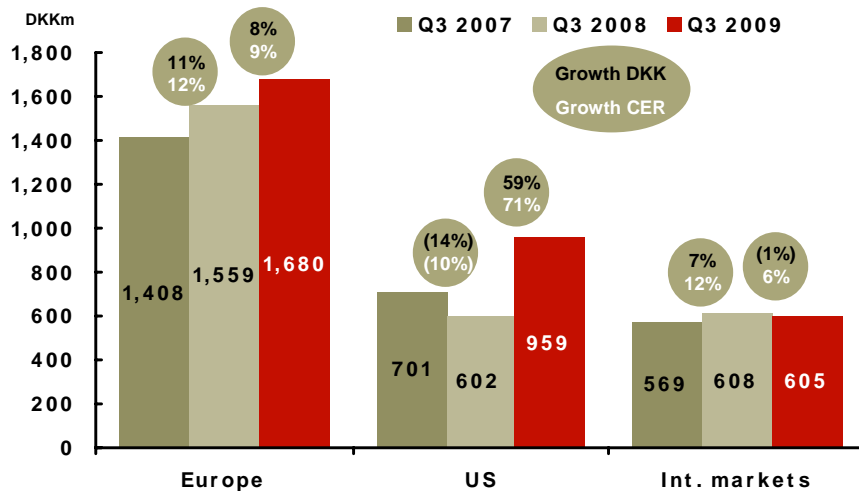
- Lundbeck Inc. has neutral net effect on EBIT excluding acquisition accounting
- Net interests affected negatively with approx DKK 160m due to lower interest income and higher interest expenses due to higher debt



## Back-up slides

- Unmet medical needs
- Projects in development
- Marketed products
- Lundbeck Inc.
- **Financial figures**
- Therapeutic categories in CNS
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# Financial figures – distribution of revenue in Q3 2009

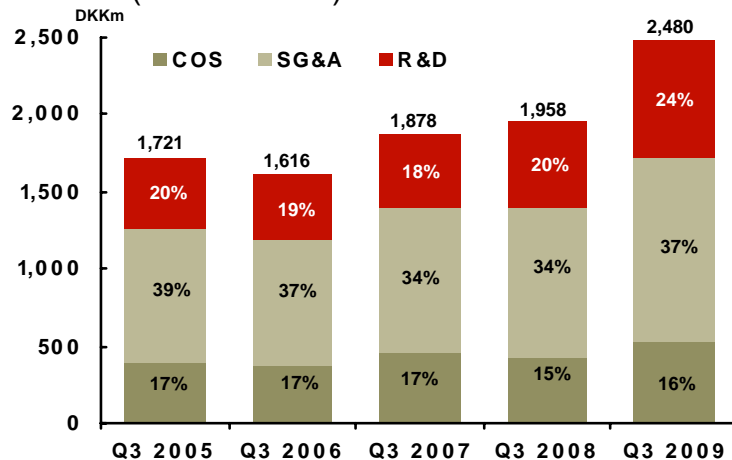


- Lundbeck's revenue was DKK 3,264 million and grew 20% in constant exchange rates compared to Q3 2008
- US sales were up 71% (CER) driven by the inclusion of Lundbeck Inc., contributing DKK 359 million in the quarter
- Sales in International Markets grew 6% (CER) despite escitalopram generics in Australia and changes in the health care system in Turkey
- Cipralextm grew 9% (CER) in Europe, as positive perception among prescribers continues to grow
- Ebixa and Azilect both showed double digit growth during the quarter
- Xenazine sales were DKK 89 million in the quarter

\* Old anti-psychotics, anti-depressants incl. citalopram and Lundbeck Inc. (excl. Xenazine)

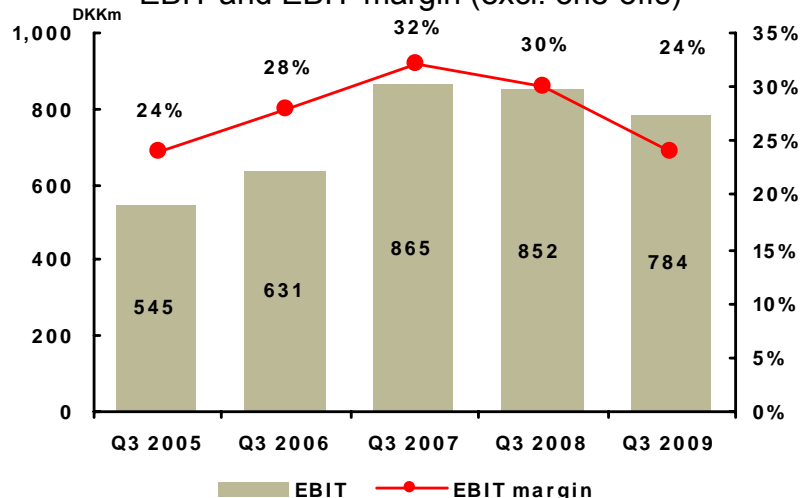
# Financial figures – distribution of costs in Q3 2009

Costs in % of total revenue and total costs (excl. one-offs)



- Costs continue to be under control. Excl. costs related to Lundbeck Inc. and a staff reduction in September, total costs grew with a single digit percentage compared with third quarter last year.
- Third quarter R&D costs were up 35% as a result of continued high spending on phase III studies

EBIT and EBIT-margin (excl. one-offs)



- EBIT for the third quarter was DKK 784 million - excl. approx DKK 50 million in costs related to a staff reduction in September and costs of DKK 32 million related to acquisition accounting, EBIT was on level with Q3 2008.

## Revenue – by product / by region (quarterly)

DKKm	Total		Europe		USA		International Markets	
	Q3 2009	Q3 2008	Q3 2009	Q3 2008	Q3 2009	Q3 2008	Q3 2009	Q3 2008
Total revenue	3,264	2,810	1,680	1,559	959	602	605	608
<i>Growth</i>	<i>16%</i>		<i>8%</i>		<i>59%</i>		<i>(1%)</i>	
Cipralex®	1,258	1,228	908	844	-	-	350	384
<i>Growth</i>	<i>2%</i>		<i>8%</i>				<i>(9%)</i>	
Lexapro®	600	602	-	-	600	602	-	-
<i>Growth</i>	<i>(0%)</i>				<i>(0%)</i>			
Ebixa®	548	480	456	399	-	-	93	81
<i>Growth</i>	<i>14%</i>		<i>14%</i>				<i>15%</i>	
Azilect®	93	65	84	59	-	-	9	6
<i>Growth</i>	<i>43%</i>		<i>43%</i>				<i>39%</i>	
Xenazine®	89	-	-	-	89	-	-	-
<i>Growth</i>	<i>-</i>				<i>-</i>			
Serdolect®	17	15	11	9	-	-	6	6
<i>Growth</i>	<i>14%</i>		<i>17%</i>				<i>9%</i>	
Other pharmaceuticals	637	379	221	248	269	-	147	132
<i>Growth</i>	<i>68%</i>		<i>(11%)</i>		<i>-</i>		<i>12%</i>	
Other revenue	21	40	-	-	-	-	-	-
<i>Growth</i>	<i>(48%)</i>							

## Revenue – by product / by region (yearly)

DKKm	Total		Europe		USA		International Markets	
	2008	2007	2008	2007	2008	2007	2008	2007
Total revenue	11,282	10,985	6,213	5,501	2,464	2,599	2,409	2,194
<i>Growth</i>	<i>3%</i>		<i>13%</i>		<i>(5%)</i>		<i>10%</i>	
Cipralex®	4,829	4,094	3,355	2,827	-	-	1,474	1,267
<i>Growth</i>	<i>18%</i>		<i>19%</i>				<i>16%</i>	
Lexapro®	2,464	2,594	-	-	2,464	2,594	-	-
<i>Growth</i>	<i>(5%)</i>				<i>(5%)</i>			
Ebixa®	1,879	1,655	1,557	1,359	-	-	321	295
<i>Growth</i>	<i>14%</i>		<i>15%</i>				<i>9%</i>	
Azilect®	263	168	241	156	-	-	22	11
<i>Growth</i>	<i>57%</i>		<i>54%</i>				<i>89%</i>	
Serdolect®	58	34	36	24	-	-	22	11
<i>Growth</i>	<i>68%</i>		<i>50%</i>				<i>108%</i>	
Other pharmaceuticals	1,595	1,750	1,025	1,135	-	6	570	609
<i>Growth</i>	<i>(9%)</i>		<i>(10%)</i>		<i>-</i>		<i>(6%)</i>	
Other revenue	195	690	-	-	-	-	-	-
<i>Growth</i>	<i>(72%)</i>							

## Revenue, quarterly figures

	Revenue, DKK million				Growth, Y/Y, %			
	Q4 2008	Q1 2009	Q2 2009	Q3 2009	Q4 2008	Q1 2009	Q2 2009	Q3 2009
Total revenue	2,653	3,226	3,432	3,264	(6%)	12%	17%	16%
Cipralex®	1,151	1,363	1,345	1,258	12%	12%	9%	2%
Lexapro®	509	626	625	600	(19%)	(5%)	(10%)	(0%)
Ebixa®	475	526	539	548	12%	15%	15%	14%
Azilect®	80	78	88	93	69%	43%	40%	43%
Xenazine®	-	12	81	89	-	-	-	-
Serdolect®	17	16	17	17	107%	32%	17%	14%
Other pharmaceuticals*	371	450	713	637	(9%)	5%	71%	68%
Other revenue	49	155	24	21	(83%)	185%	(53%)	(48%)

\* Old anti-psychotics, anti-depressants incl. citalopram and Lundbeck Inc. (excl. Xenazine®)

## Revenue, yearly figures

	Revenue, DKK million					Growth, Y/Y, %			
	2004	2005	2006	2007	2008	2005	2006	2007	2008
Total revenue	9,733	9,070	9,221	10,985	11,282	(7%)	2%	19%	3%
Cipralex®	1,661	2,625	3,508	4,094	4,829	58%	34%	17%	18%
Lexapro®	2,420	2,552	1,923	2,594	2,464	5%	(25%)	35%	(5%)
Ebixa®	722	1,105	1,361	1,655	1,879	53%	23%	22%	14%
Azilect®	-	6	71	168	263	-	1,068%	136%	57%
Serdolect®	-	-	10	34	58	-	-	250%	68%
Other pharmaceuticals*	4,299	2,550	1,973	1,750	1,595	(41%)	(23%)	(11%)	(9%)
Other revenue	631	232	375	690	195	(63%)	61%	84%	(72%)

\* Old anti-psychotics, anti-depressants incl. citalopram

## Costs, quarterly figures

	DKK million				Growth, Y/Y, %			
	Q4 2008	Q1 2009	Q2 2009	Q3 2009	Q4 2008	Q1 2009	Q2 2009	Q3 2009
Revenue	2,653	3,226	3,432	3,264	(6%)	12%	17%	16%
Production costs	460	487	623	519	(46%)	2%	33%	20%
Distribution costs	689	673	799	712	5%	19%	26%	25%
Administrative expenses	437	401	464	480	15%	2%	9%	25%
R&D	854	717	826	769	24%	37%	(21%)	35%
EBIT	212	947	719	784	(17%)	2%	97%	(8%)

### Costs, % of revenue

Production costs	17%	15%	18%	16%
Distribution costs	26%	21%	23%	22%
Administrative expenses	16%	12%	14%	15%
R&D	32%	22%	24%	24%



## Costs, yearly figures

	DKK million					Growth, Y/Y, %			
	2004	2005	2006	2007	2008	2005	2006	2007	2008
Revenue	9,733	9,070	9,221	10,985	11,282	(7%)	2%	19%	3%
Production costs	1,717	1,483	1,643	2,198	1,837	(14%)	11%	34%	(16%)
Distribution costs	2,302	2,337	2,419	2,409	2,459	2%	4%	0%	2%
Administrative exp.	1,377	1,294	1,415	1,496	1,642	(6%)	9%	6%	10%
R&D	1,772	1,782	1,956	2,193	2,990	1%	10%	12%	36%
EBIT	2,567	2,174	1,789	2,690	2,354	(15%)	(18%)	50%	(13%)

### Costs, % of revenue

Production costs	18%	16%	18%	20%	16%
Distribution costs	24%	26%	26%	22%	22%
Administrative exp.	14%	14%	15%	14%	15%
R&D	18%	20%	21%	20%	27%

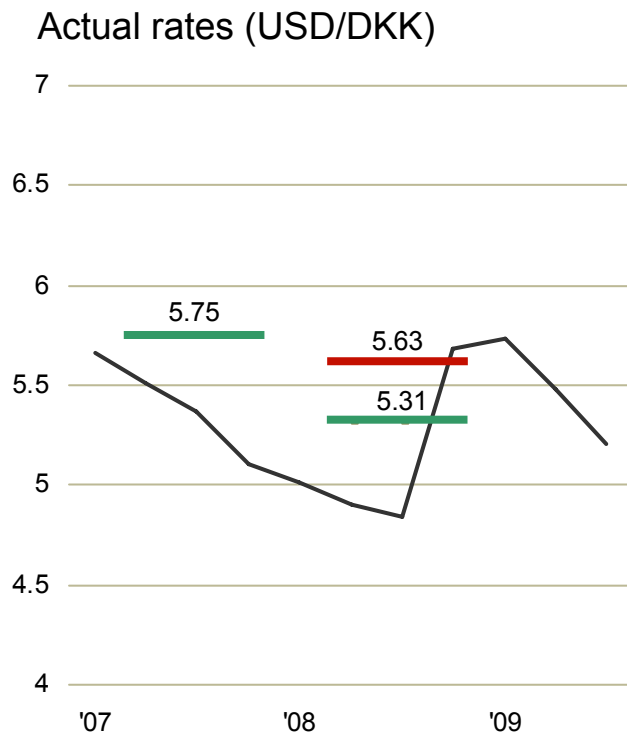
## Balance sheet and cash position

(DKKm)	31.12.2008	30.06.2009	30.09.2009
Intangible assets	2,016	7,219	7,688
Other non-current assets	3,370	3,283	3,250
Current assets	7,140	6,482	6,792
<b>Assets</b>	<b>12,526</b>	<b>16,984</b>	<b>17,729</b>
Equity	7,511	8,101	8,512
Non current liabilities	2,594	3,242	3,785
Current liabilities	2,421	5,640	5,432
<b>Equity &amp; Liabilities</b>	<b>12,526</b>	<b>16,984</b>	<b>17,729</b>
Cash	2,921	2,256	2,554
Securities	955	50	48
Interest-bearing debt	(1,927)	(2,670)	(4,421)
<b>Interest-bearing net cash (debt)</b>	<b>1,949</b>	<b>(365)</b>	<b>(1,818)</b>

# Cash flow

(DKKm)	FY 2008	Q3 2008	Q3 2009
Cash flow from operating activities	2,780	1,032	907
Cash flow from investing activities	(587)	(116)	(2,363)
<b>Cash flow from operating and investing activities</b>	<b>2,193</b>	<b>916</b>	<b>(1,456)</b>
Cash flow from financing activities	(1,016)	(3)	1,752
<b>Change in cash</b>	<b>1,177</b>	<b>913</b>	<b>297</b>
Cash at beginning of period	1,772	1,955	2,256
Unrealised gains	(28)	(2)	2
<b>Cash at the end of period</b>	<b>2,921</b>	<b>2,867</b>	<b>2,554</b>

# Average US\$ hedging rates of USD/DKK 5.36 (cash) and USD/DKK 5.13 (reporting) for 2009



Forward rates (USD/DKK)

Quarter	Forward Rate (USD/DKK)
Q3 '09	5.83
Q4 '09	5.59
Q1 '10	5.83
Q2 '10	5.59

Quarterly figures

Quarter	Forward Rate (USD/DKK)
Q3 '09	4.96
Q4 '09	4.99
Q1 '10	5.73
Q2 '10	5.30

Average USD exchange rate (quarterly)

Average hedging USD rate (cash)

Average hedging USD rate (reporting)

# Financial guidance

	2008	2009* guidance
<b>Revenues</b>	DKK 11,282 million	DKK 13.1-13.6 billion
<b>EBITDA</b>	DKK 3,417 million	DKK 3.5-3.7 billion
<b>EBIT</b>	DKK 2,354 million	DKK 2.8-3.0 billion
<b>Tax rate</b>	27.1%	25-26%
<b>R&amp;D ratio</b>	22%	23-24%

\* Profit of DKK 124m from divestment of shares in LifeCycle Pharma is included in guidance

## 2009 guidance:

- The acquisition of LifeHealth will have a positive impact on EBITDA and to a lesser degree EBIT
- Lundbeck Inc. expected to generate significant sales (approx DKK 1.1bn)
- Following the acquisition of LifeHealth Lundbeck expects EBITDA to be in the higher end of the interval for 2009
- EBIT negatively effected by DKK 183m due to acquisition accounting (no cash flow effect)

# Key deliverables the next 12 months

## Existing products

- Decision on Serdolect® in the US for schizophrenia
- Continue the roll-out of ATryn® in the US for hereditary anti-thrombin deficiency
- Further enhance Xenazine® market penetration

## Product launches

- Launch of Sabril® in the US for refractory complex partial seizures (rCPS) and infantile spasms (IS)

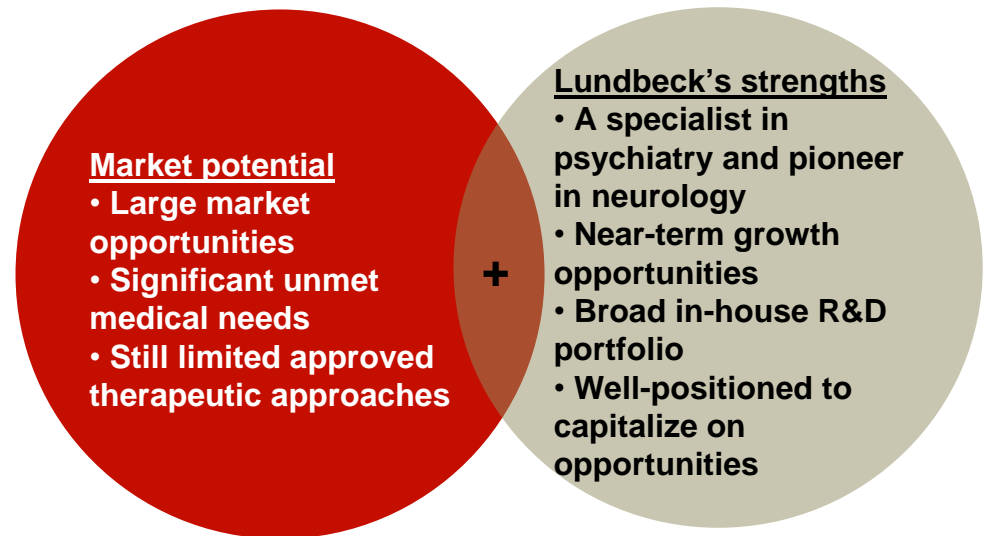
## Pipeline

- Clinical phase II data on ziconapine
- Clinical phase II data on Lu AE58054
- Development programme for:  
Lu AA21004, Lu AA24530, Lu AA34893 and Lu AA39959

# Multiple strategies to drive long-term growth

## Our path forward...

- Streamline current business
- Explore opportunities on commercial products
- Delivering on our late-stage portfolio, but...
  - ...focus resources on best opportunities
- Support with business development opportunities
- Managing the total cost structure
- Strong financial foundation



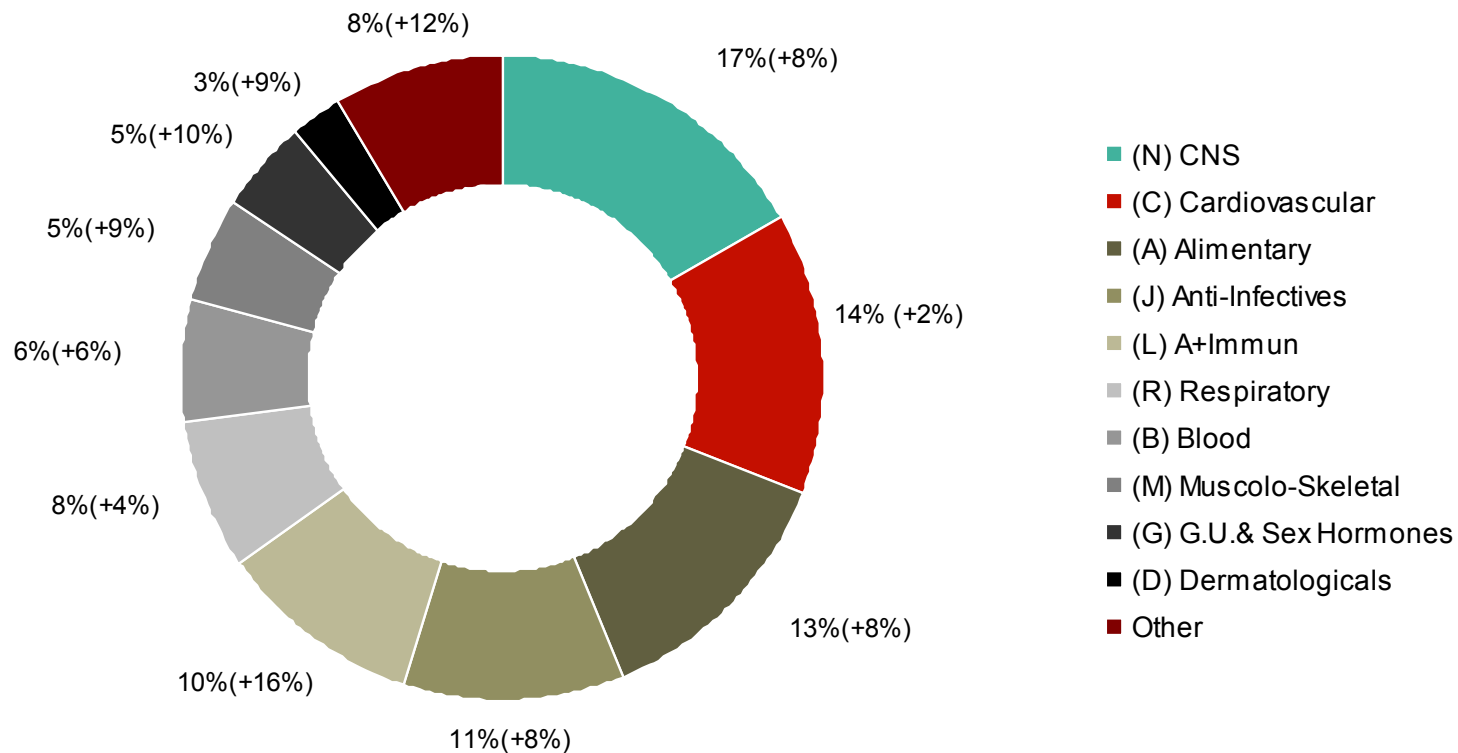
## Back-up slides

- Unmet medical needs
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# Worldwide pharmaceutical market 2008

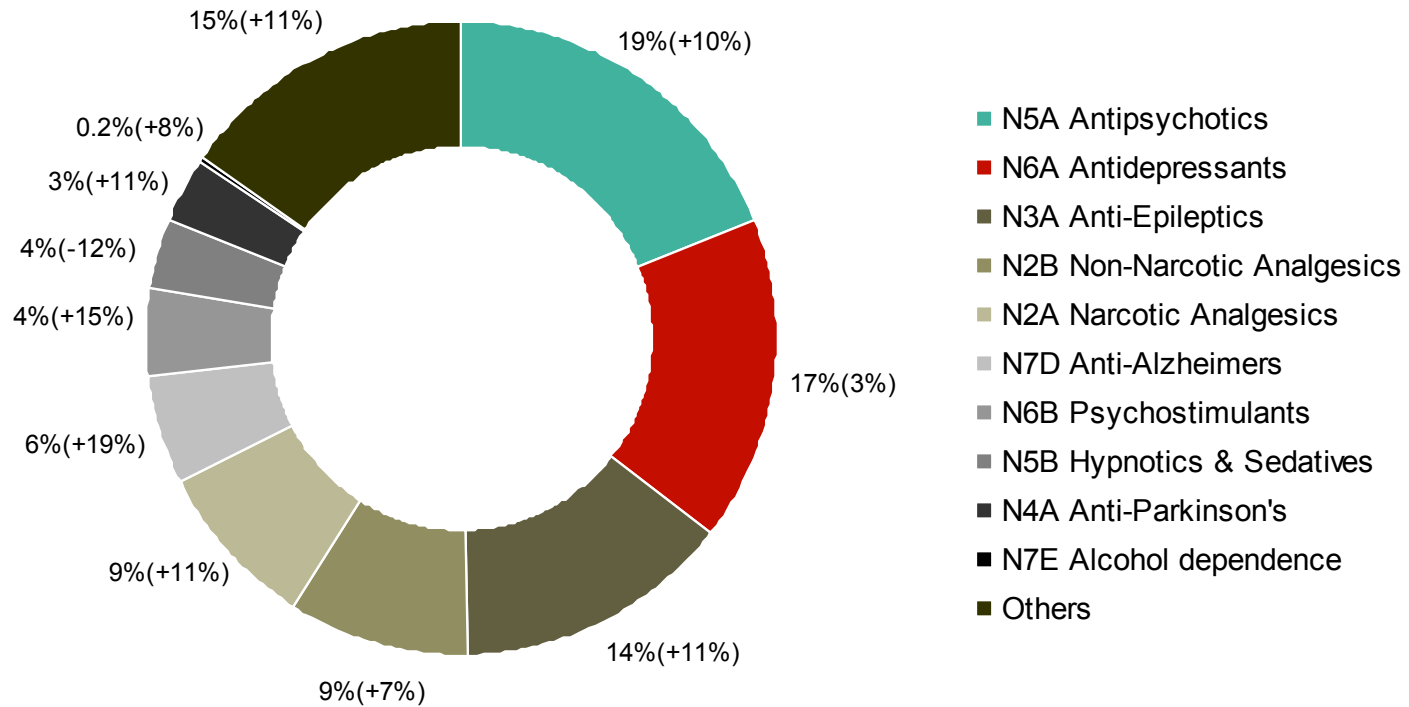
– USD 725.5 billion (+8%)



Source: IMS World Review 2009  
2007-2008 growth in \$ in brackets

# Worldwide CNS market 2008

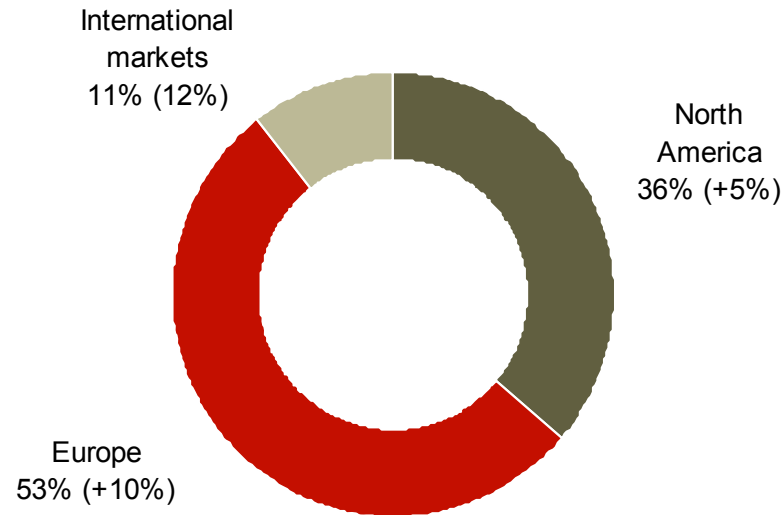
– USD 121.2 billion (+8%)



Source: IMS World Review 2009

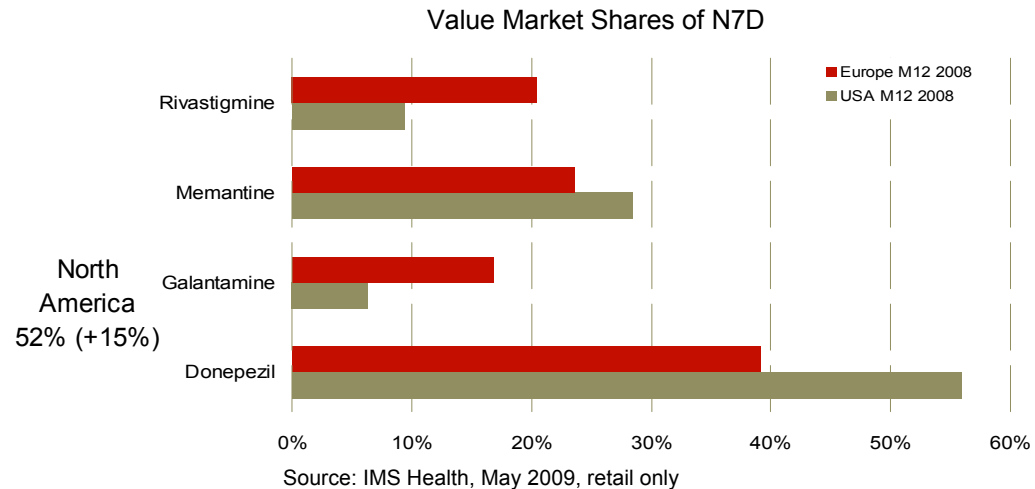
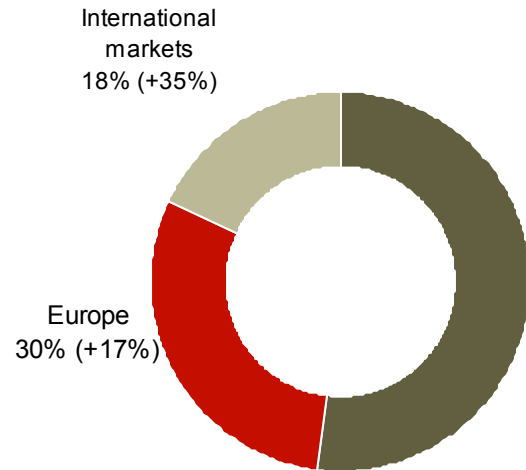
# Alcohol (N7E-2008)

– USD 189 million (+8%)



Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Campral®	Merck	76	4
Antabuse®	Barr/Sanofi-Aventis	28	12
Vivitrol®	Cephalon	15	-2
Nemexin®	Bristol-Myers Squibb	11	-2

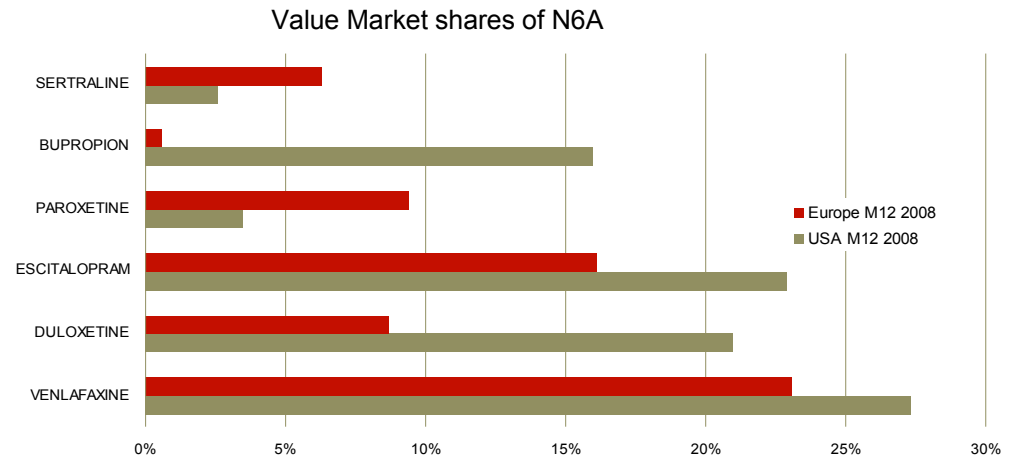
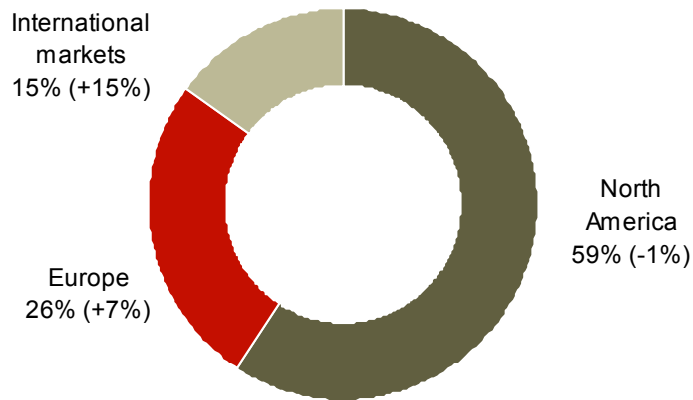
# Anti-Alzheimer's (N7D-2008) – USD 6.7 billion (+19%)



Leading product	Marketing Corporation	Sales 2008 (USDm)	Growth in %
Aricept®	Eisai/Pfizer	3,543	19
Namenda®	Forest	952	15
Exelon®	Novartis	777	29
Reminyl®//Razadyne®	Johnson & Johnson	605	1
Ebixa®	Lundbeck	381	21

# Anti-depressants (N6A-2008)

– USD 20.3 billion (3%)

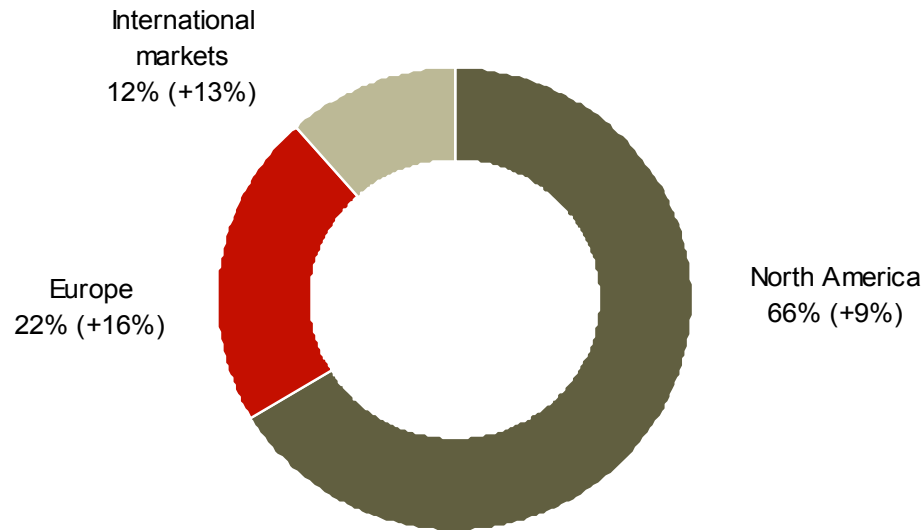


Source: IMS Health, May 2009, retail only.

Leading product	Marketing Corporation	Sales 2008 (USDm)	Growth in %
Effexor®	Wyeth	4,241	5
Lexapro®/Cipralextm	Lundbeck/Forest	3,556	8
Cymbalta®/Yentreve®	Lilly	2,775	30
Seroxat®/Paxil®	GlaxoSmithKline	945	(14)
Wellbutrin®	GlaxoSmithKline	773	(33)
Budeprion®	Teva	650	11
Zoloft®	Pfizer	542	(5)

# Anti-epileptics (N3A - 2008)

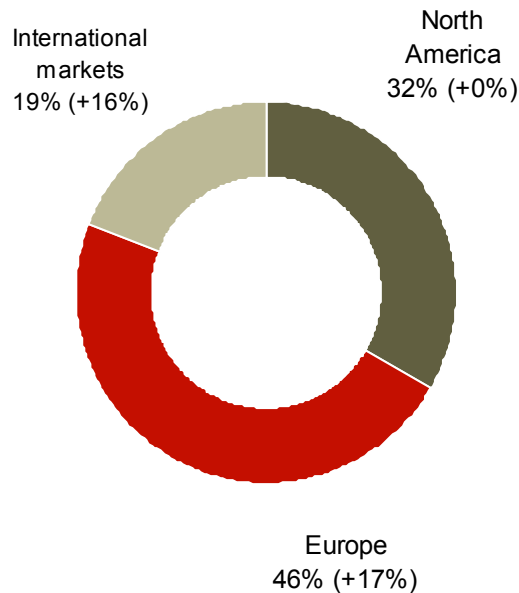
## – USD 16.9 billion (+11%)



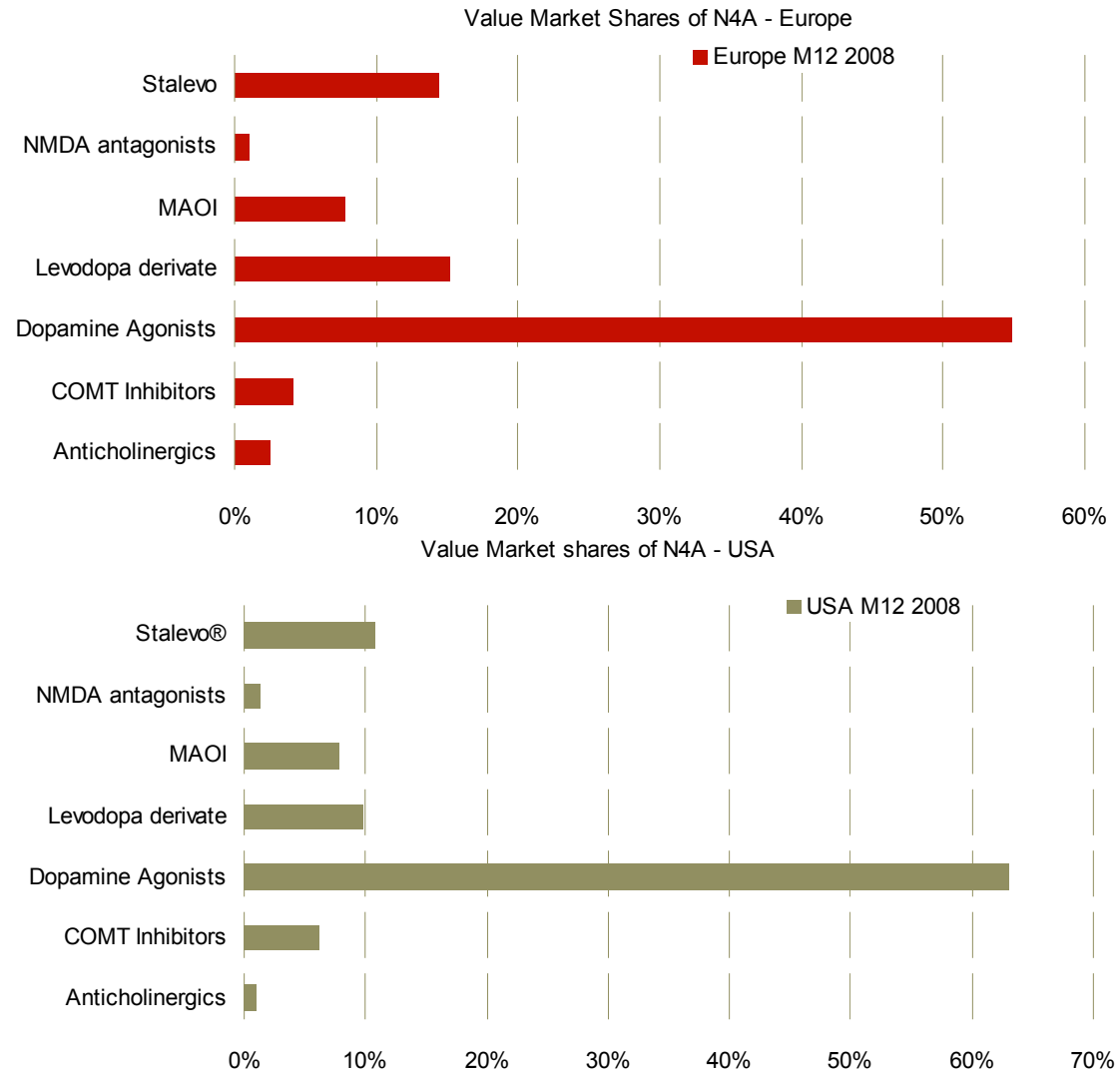
Leading product	Marketing Corporation	Sales 2008 (USDm)	Growth in %
Topamax®	Johnson & Johnson	2824	14
Lyrica®	Pfizer	2612	38
Lamictal®	GSK	2116	(13)
Keppra®	UCB	1964	32
Valcote®	Abbott	1592	(4)
Lamotrigine®	Teva	679	-

# Anti-Parkinson's (N4A - 2008)

## – USD 4.1 billion (+11%)



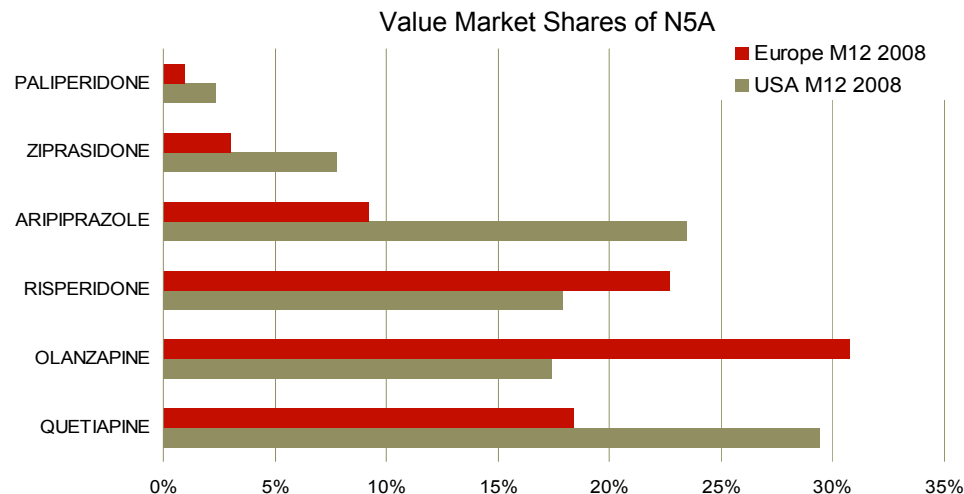
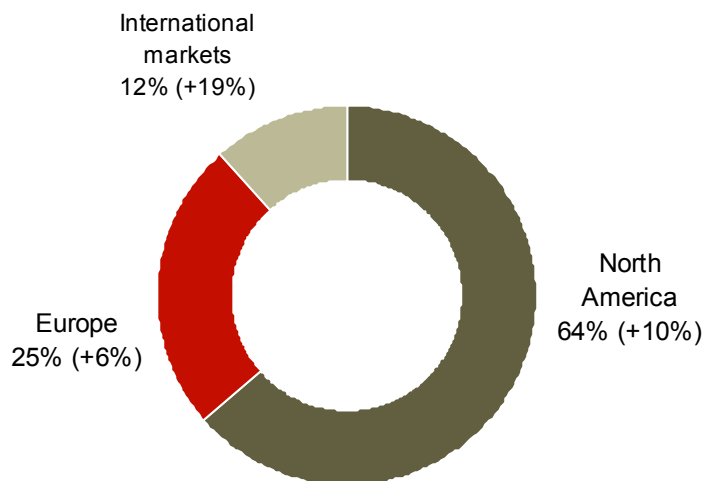
Source: IMS World Review 2009



Source: IMS Health, May 2009, retail.

# Anti-psychotics (N5A-2008)

– USD 22.8 billion (+10%)



Source: IMS Health, May 2009, retail

Leading product	Marketing Corporation	Sales 2008 (USDm)	Growth in %
Seroquel®	AstraZeneca	5,340	16
Zyprexa®	Eli Lilly	4,956	0
Risperdal®	Johnson & Johnson	3,843	(22)
Abilify®	Otsuka/BMS	3,561	31
Zeldox®/Geodon®	Pfizer	1,170	15
Invega®	Johnson & Johnson	357	115

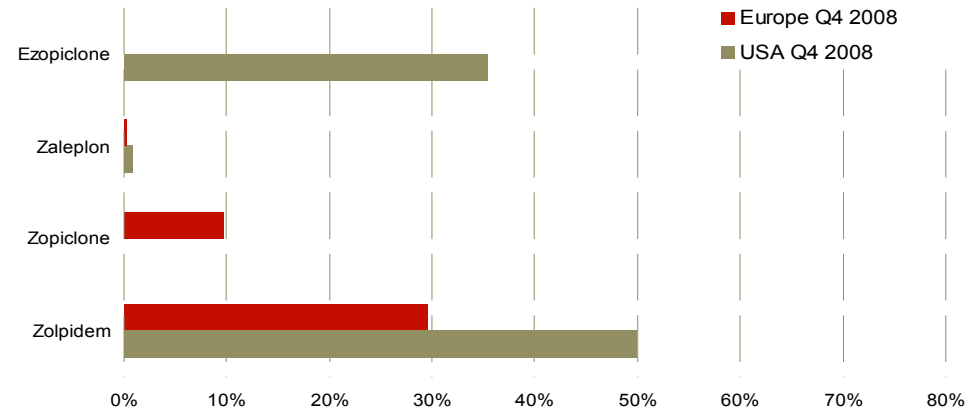
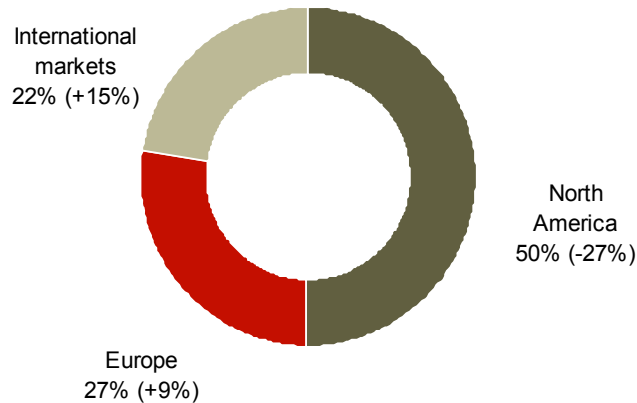


# Hypnotics (N5B-2008)

– USD 4.4 billion (- 12%)



Value Market Shares of N5B



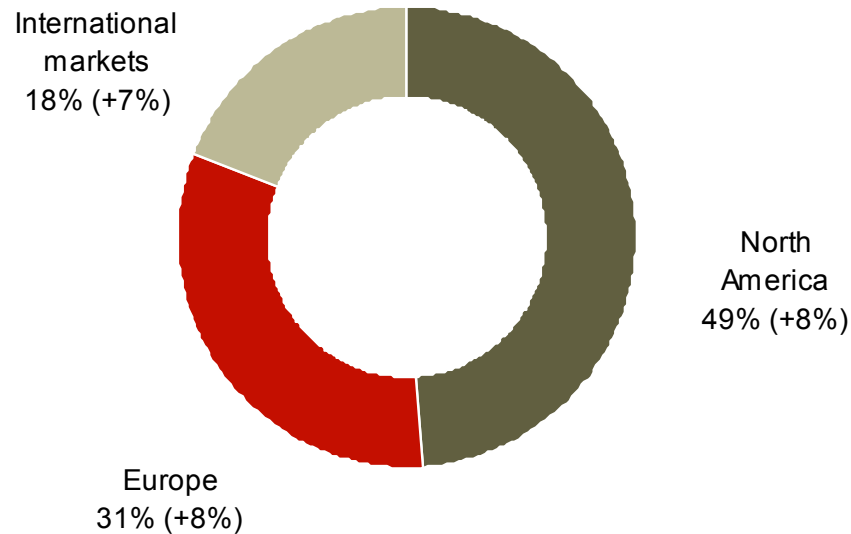
Source: IMS Health, May 2009, retail

Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Stilnox <sup>®</sup>	Sanofi-Aventis	1,429	(34)
Lunesta <sup>®</sup>	Sepracor	755	5
Lendormin <sup>®</sup>	Boehringer Ingelheim	141	18
Imovane <sup>®</sup>	Sanofi-Aventis	114	41
Rozerem <sup>®</sup>	Takeda	100	(15)
Halcion <sup>®</sup>	Pfizer	94	12

Source: IMS World Review 2009 & IMS Knowledge link

# Stroke, Fibrinolytics (B1D-2008)

– USD 796 million (+8%)



Leading product	Marketing Corporation	Sales 2008 (USDm)	Growth in %
Activase®/Actilyse®	Roche/Boehringer	427	18
Metalyse®/Tnkase®	Roche/Boehringer	160	(1)
Retavase®/Rapilysin®	PDL biopharma/Rosche	37	(22)

## Back-up slides

- Unmet medical needs
- Projects in development
- Marketed products
- Financial figures
- Therapeutic categories in CNS
- **The global IP position**
- The Lundbeck share

# Global IP position



## USA

Escitalopram: Compound patent to March 2012 (incl. extension)

Sertindole: Use patent to April 2010, excl. extensions

Anti-thrombin alfa: 2021

Tetrabenazine: Orphan Drug exclusivity through 15 August 2015

Vigabatrin:  
 Infantile spasms  
 - Orphan drug exclusivity to 2016  
 Refractory complex partial seizures  
 - Data exclusivity to 2015

## International Markets

Escitalopram: Compound patent in major markets to 2009, excl. extensions

Memantine: Use patent to April 2010

Rasagiline: Compound patent to 2011, excl. extensions

Sertindole: Use patent in major markets to March/April 2010, excl. extensions

## Europe

Escitalopram: Compound patent in majority of countries to May-June 2014. Process patent in majority of countries to June 2014

Memantine: Data exclusivity until May 2012; use patent until 2014 (incl. extensions).

Rasagiline: Compound patent to 2011; data exclusivity until 2015

Sertindole: Compound patent in majority of countries to March 2011 (incl. extension)

Melatonin: Data exclusivity to 2017

## Back-up slides

- Unmet medical needs
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# The Lundbeck Foundation

- 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
  - To provide financial support for research of the highest quality in biomedical and natural sciences
- The Foundation's commercial activities are carried out through the wholly-owned subsidiary LFI a/s
  - As of 30 April 2009, LFI a/s held 70% of the capital and voting rights in H. Lundbeck A/S, and 38% of the capital and 66% of the voting rights in ALK-Abelló A/S
- The Foundation's equity in terms of market value amounted to DKK 27.6bn at the end of 2008
  - Free resources of DKK 10.8bn
- The Foundation expects to award grants of approx. DKK 1bn in the years 2008 to 2010, primarily to projects in biomedical and natural sciences
  - It awarded DKK 328mn in grants in 2008

**LUNDBECKFONDEN**

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# Lundbeck share

## Share information:

- Free float (approximately 60m shares) is traded 1.5+ time over annually (daily trade of approximately 0.35m)

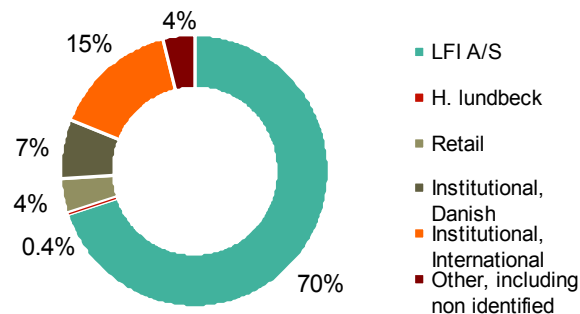
## Trading code:

- Reuters (LUN.CO) / Bloomberg (LUN DC)
- ISIN Number DK0010287234
- Unsponsored ADR programmes HLUKY, CUSIP 40422M107

## Index examples:

- End of 2008 weight of 4.7% in OMXC20
- Member of FTSE4Good

## Ownership, total outstanding



## Ownership, of free float

