

# Investor presentation

(Q1 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.

# Agenda

- **Lundbeck overview**
- Projects in development
- Marketed products
- Financial figures

# Update on recent events

## Strategic

- Integration of US based Ovation Pharmaceuticals, Inc develops according to plan
- “*Decisions Now*” process ongoing

## Financials

- Guidance now includes Lundbeck Inc.
- Continued solid growth in Lundbeck’s key products and regions
- Strong uptake of Xenazine\*

## Pipeline progression

- Supportive outcome of the FDA Advisory Committee (PDAC) meeting on Serdolect®
- Lu AA39959 clinical phase II study paused
- ATryn launched in the US for hereditary anti-thrombin deficiency
- NDA filing for I.V. carbamazepine and clobazam expected during 2010 and 2011 respectively

# 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 initial uptake of **Xenazine\***
- **ATryn** launch
- **Sabril®** launch – FDA decision pending\*\*
- **Serdolect®** launch – FDA decision pending



## Pipeline

### **Regulatory:**

- Sabril®
- Serdolect®

### **Phase III:**

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

### **Phase II:**

- Lu AA24530
- Lu 31-130
- Lu AE58054
- Lu AA39959
- Lu AA34893

\* Xenazine is a registered trademark of Cambridge Laboratories (Ireland) Limited

\*\* Unanimously recommended for approval by the Peripheral and Central Nervous System Drugs Advisory Committee appointed by the US FDA

# 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)
- Bifeprunox (psychosis)
- Nalmefene (alcohol misuse)
- Lu 31-130 (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

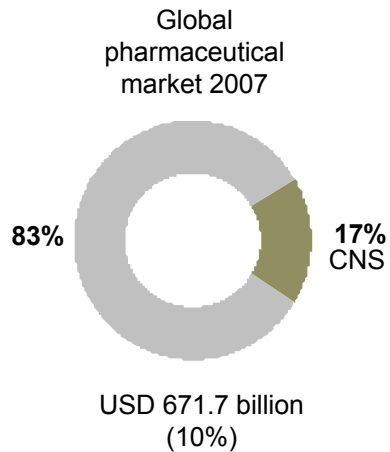
Potential launch of:

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

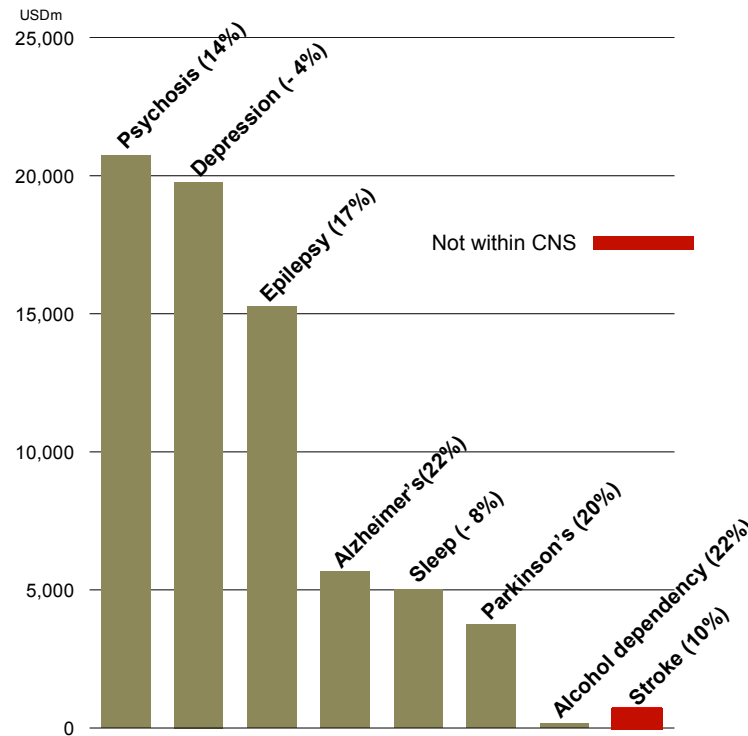
**...and beyond**

\* Sabril filing is being reviewed by FDA. \*\* FDA decision pending

# Lundbeck – a fully integrated company focusing on CNS



Lundbeck's therapeutic areas (growth 2007 in %)



Source: IMS World Review 2008

- CNS, largest therapeutic area, 17% of total pharmaceutical market
- Total CNS market up 10% in 2007 to USD 111.8 billion

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

Rank*	Disease	Drug	Status
1	Cancer	Cipralext <sup>®</sup> / Lexapro <sup>®</sup>	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
6	Refractive errors	Lu AA24493	Clinical phase I
7	Hearing loss, adult onset		
8	Congenital anomalies	Nalmefene	Clinical phase III
9	Alcohol use disorders	Serdolect <sup>®</sup>	Launched
10	Diabetes mellitus	Bifeprunox	Clinical phase III
11	Cataracts	Lu 31-130	Clinical phase II
12	Schizophrenia	Lu AE58054	Clinical phase II
.....	.....		
15	Bipolar disorder	Lu AA34893	Clinical phase II
.....	.....	Lu AA39959	Clinical phase II
17	Alzheimer and other dementias	Lu AE58054	Clinical phase II
...	...		
23	Epilepsy	Ebixa <sup>®</sup>	Launched
...	...		
33	Insomnia	Sabril <sup>®</sup>	NDA**
...	...	Clobazam	Clinical phase III
40	Parkinson's disease	I.V. carbamazepine	Clinical phase III
		Circadin <sup>®</sup>	Launched
		Azilect <sup>®</sup>	Launched

\*) DALY=Disability adjusted life years; Global, non-communicable conditions

\*\*\*) Sabril filing is being reviewed by FDA. FDA decision pending



# Agenda

- Lundbeck overview
- **Projects in development**
- Marketed products
- Financial figures

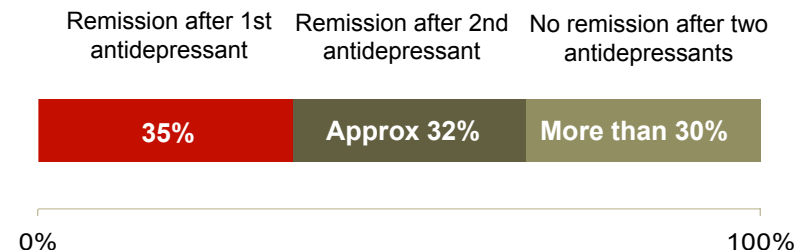
# Depression and anxiety – efficacy and onset of action needs improvement

- 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

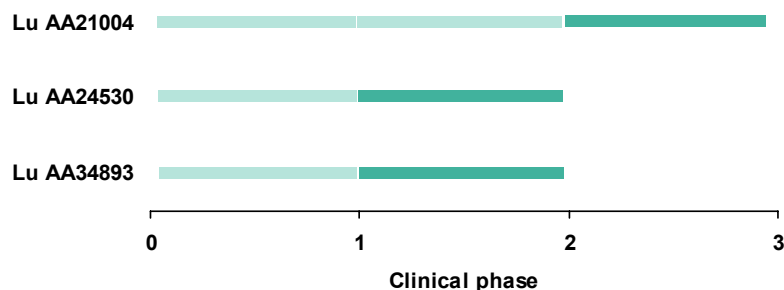
### Remission rate



# The portfolio within mood disorders – markedly different to any marketed antidepressants



## Portfolio of three innovative novel compounds



### Clinical programme on Lu AA24530:

- Clinical phase II programme with Lu AA24530 recruiting 625 patients initiated in October 2007
  - 6 weeks treatment
  - Several doses: 5; 10 and 20mg
  - Active reference: 60mg duloxetine
  - Phase III decision on Lu AA24530 expected mid-2009

### Clinical programme on Lu AA34893:

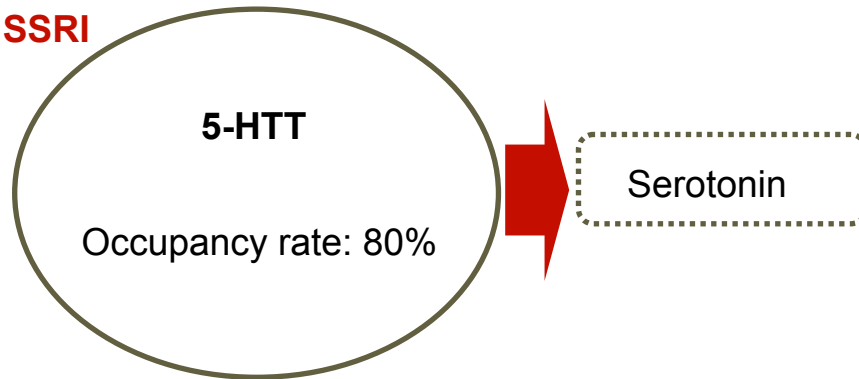
- Phase II studies started in 2008 - is currently on technical hold

### Clinical programme on Lu AA21004:

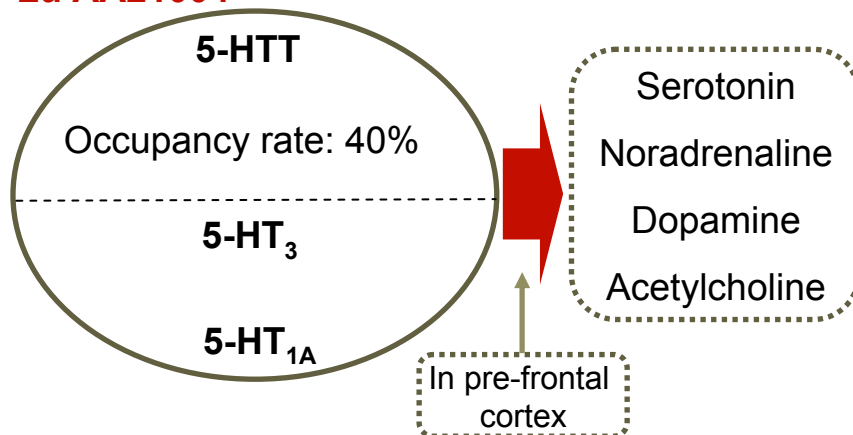
- Clinical phase II concluded in Autumn 2007:
  - 6 weeks treatment
  - 426 patients
  - Two doses: 5 and 10mg
  - Active reference: 225mg venlafaxine XL
  - Highly significant improvements on the primary efficacy endpoints compared to placebo
  - Attractive safety profile
  - Additional data on APA in 19 May 2009
- Ongoing clinical phase III:
  - Initiated in December 2007 currently with 14 active 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
  - Active reference: 60mg duloxetine
  - Headline data by mid-2009

# 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

# 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

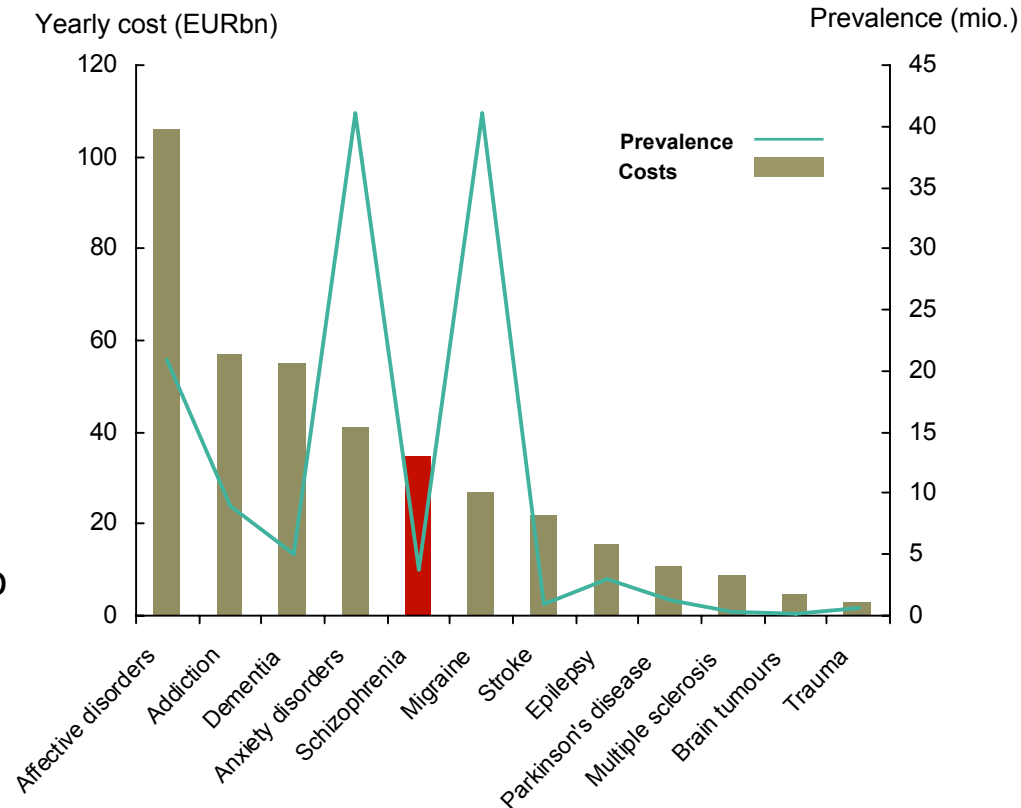
- The global market for anti-psychotics constitutes USD 21bn
  - In 2007 the US market grew by 12%
  - The European market grew by 9%
- 50-60% of total schizophrenic population receives anti-psychotic treatment
  - 10-20% achieve full recovery
  - 65-70% of patients receive chronic treatment
    - 40%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

# The burden of schizophrenia is large and multifaceted



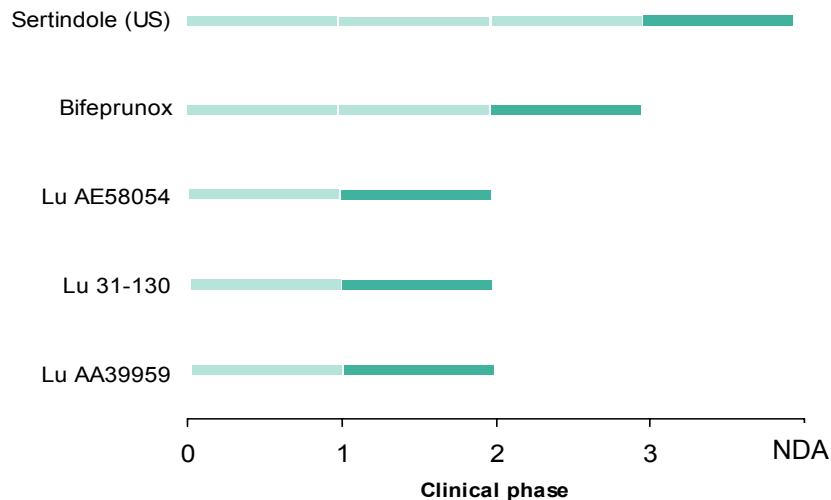
- Schizophrenia is heavily stigmatized = create a vicious cycle of discrimination
- 
- Social isolation, unemployment, drug abuse, long-lasting institutionalization, or even homelessness
- 
- All factors that further decrease the chances of recovery and reintegration into normal life

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



Source: Olesen et al. 2007

# Lundbeck's psychosis portfolio



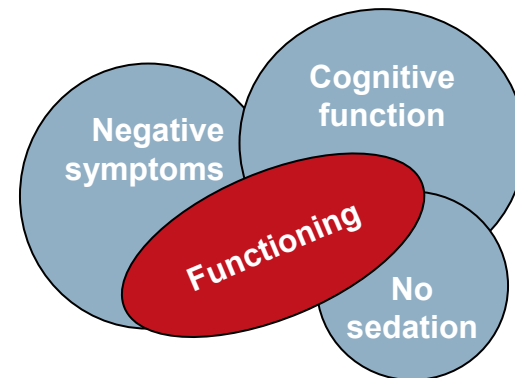
- Lundbeck's portfolio addresses the patho-physiology with mono and add-on therapies
- The different symptom domains may have a different patho-physiology
  - One compound for all symptoms may not be realistic



- Develop compounds targeting underlying symptom dimensions

# Serdolect<sup>®</sup> has market potential in the US

- NDA submitted in September 2008
  - FDA feedback expected in May 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<sup>®</sup> is protected until 2015 in the US



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



## Serdolect® outcome at the PDAC meeting

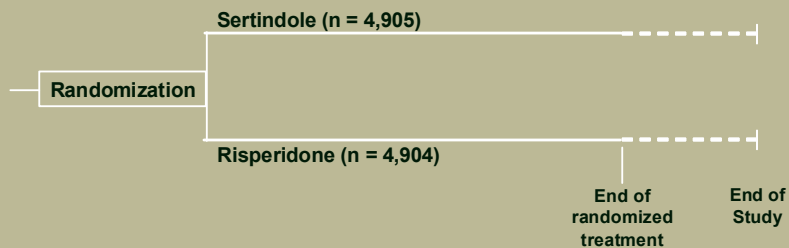
- Serdolect® evaluated by an FDA PDAC on 7 April 2009
- The committee reviewed comprehensive data from clinical trials including the SCoP Study
- The PDAC voted that
  - Serdolect® is efficacious in the treatment of patients with schizophrenia
  - Suicidal behavior as a secondary regulatory claim related to the treatment of schizophrenia was not supported
  - Serdolect® should not be used in a broad schizophrenia population due to safety concerns
  - There may be sub-populations in which the therapy is beneficial with appropriate labeling and risk management tools

### **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

# The Sertindole Cohort Prospective (SCoP) study

## Overall study design



- Designed in close collaboration with CHMP in 2002
- Prospective, randomised, naturalistic, open-label study
- Study objectives:
  - To compare the all-cause mortality of Serdolect® to that of risperidone under normal conditions of use
  - Reduction of suicide and suicide attempts
- Recruiting ~10,000 patients from 38 countries and with ~15,000 years of exposure

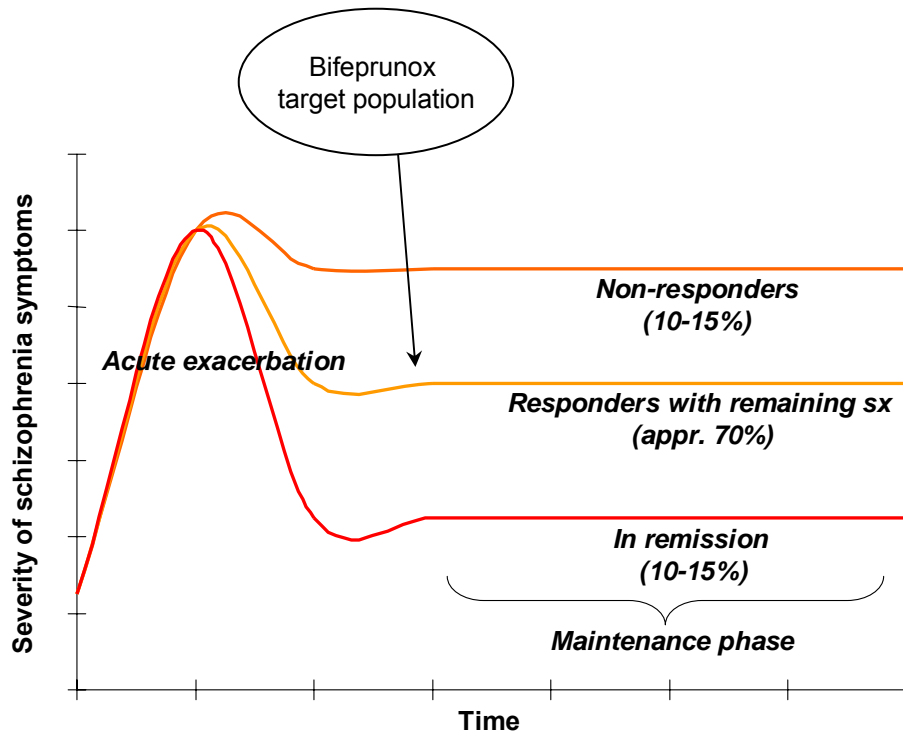
## Overall safety conclusion

- No difference in all-cause mortality between Serdolect® and risperidone
- Very few cases of arrhythmia
  - All confounded by medical history or concomitant treatment
- Serdolect® is well tolerated

## Sertindole is efficacious in reducing risk of suicide attempts

- Reduced risk of suicide attempts (fatal plus non-fatal)
  - Especially in high-risk group
- Effect already observed during first year
- Clinically significant reduction at 6 and 12 months
- Reduced risk of completed suicides
- Confirms observation of low suicide mortality in clinical and epidemiological studies

# Bifeprunox – additional clinical phase III trials initiated



- Bifeprunox is a partial dopamine D<sub>2</sub> and 5-HT<sub>1A</sub> receptor agonist
- IP 2017 + possible extensions

## Clinical trial design

- Two clinical phase III trials; each enrolling 450 patients with schizophrenia inadequately controlled in the maintenance phase
- Two active arms + placebo
  - 20 mg daily
  - 600 mg quetiapine
- Primary objective - efficacy
  - To evaluate the change from baseline to Week 12 between bifeprunox and placebo using PANSS as primary parameter
- The phase III programme is expected to be completed by the end of 2010

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

# Lu 31-130 – pharmacological profile and expected clinical profile

## Lu 31-130

Lu 31-130 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

Lu 31-130 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 Lu 31-130 and 10-15mg olanzapine
- Primary endpoint: PANSS\*; secondary endpoint 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 by the end of 2009
- **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.

# 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

# 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

# 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

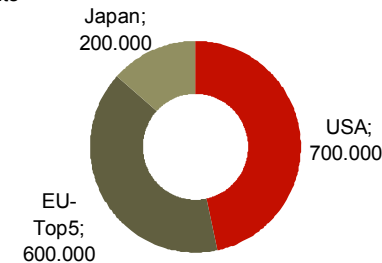
Importance

## 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



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

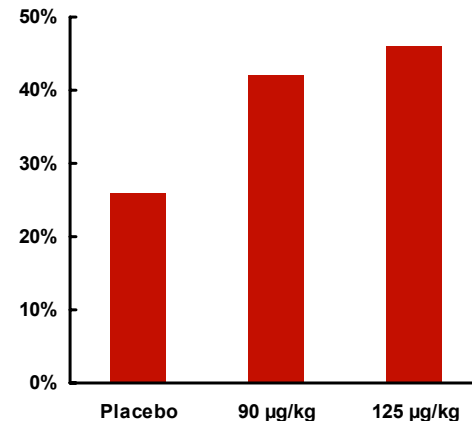
## Desmoteplase

- 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

# 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

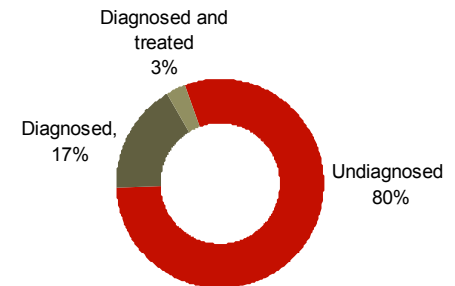
Better awareness/education

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

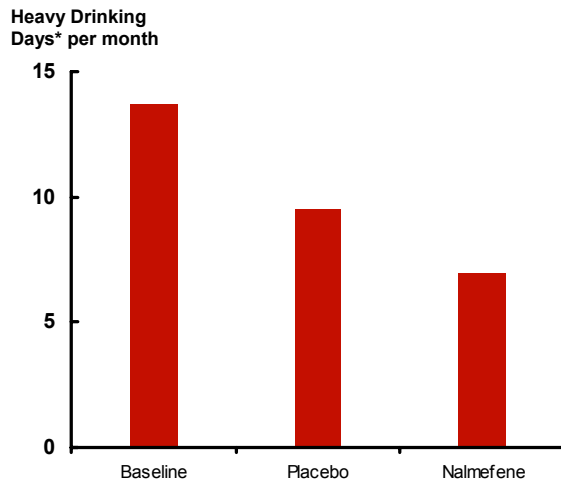


- Alcohol dependence carries considerable adverse health and social consequences
  - the third leading cause of preventable death in the US

# 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



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
- Draft EMEA guidelines in this area consistent with study design

\* 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

# 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

# Sabril® (vigabatrin) in refractory complex partial seizures (rCPS)

## Sabril® \*

- Unique MoA as a selective and irreversible inhibitor of GABA-transaminase
- Unanimous Advisory Committee recommendation for approval on 7 January 2009
  - Committee agreed that approval be accompanied by a Risk Evaluation & Mitigation Strategy (REMS)
- Sabril® currently available in more than 50 countries

## Clinically meaningful improvements noted

- Complete seizure freedom (7-12%)
- Significant reductions in seizure frequency (> 50% and > 75% criteria)

## Safety profile

- General safety profile is well tolerated
- Peripheral visual field defects: After long term use (>6-9 months) pVFD develops in an estimated 25% of adults

## Refractory complex partial seizures:

- Complex partial seizures are often poorly controlled by current therapies
- Refractory epilepsy is common – 30-36% of patients with epilepsy are refractory, defined as having failed 2 mono-therapies and at least one drug combination
  - Degrades quality of life
  - Is dangerous, and may be fatal
- Favourable drug response is unpredictable
- Patients with uncontrolled seizures have a nearly 40x higher risk of mortality than those whose seizures are adequately controlled

# Sabril® (vigabatrin) in infantile spasms (IS)

## Sabril® \*

Unique MoA as a selective and irreversible inhibitor of GABA-transaminase

Unanimous Advisory Committee recommendation for approval on 8 January 2009

- Committee agreed that approval be accompanied by a Risk Evaluation & Mitigation Strategy (REMS)

## Vigabatrin effective as monotherapy of IS

- Significant spasm cessation
- Most effective dose > 100 mg/kg/day
- Rapid onset—within 2 - 3 weeks
- Effective across aetiologies
- Spasm cessation strongly associated with improved overall function

## Safety profile

- >4,000 patients have received vigabatrin in clinical trials, including 342 patients with IS
- Estimated prevalence of pVFD in infants with IS is 31% - most often mild or moderate

## Infantile spasms (IS) / West syndrome:

- Serious and catastrophic disease with unmet medical need
  - Seizures start early in life, most often in first year
  - Mental retardation is often a consequence - 70% - 90% are intellectually developmentally delayed
  - Mortality of around 5%
  - The infants can suffer from hundreds of seizures a day. Multiple seizures give increased morbidity (i.e. respiratory, developmental, cognitive etc)
- Orphan population in the US
  - ~2,500 patients/year with IS
  - No approved therapies for IS in the US
- Paediatric population: Infants ≤ 3 years of age

\* Sabril filing is being reviewed by FDA. FDA decision pending

# Clobazam and I.V. carbamazepine - overview

## Clobazam

Clobazam is a GABA enhancer

- Efficacy in Lennox-Gastaut Syndrome (LGS) demonstrated in phase II
- Generally well tolerated with most AEs being mild or moderate in severity and transient in nature
- Clobazam in phase III development for LGS
- Granted orphan drug exclusivity
- NDA expected in 2011

## 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

## Intravenous carbamazepine

- Niche product used in hospital channels for patients taking oral carbamazepine, but need intravenous treatment
- Carbamazepine was launched in 1968 and is considered the golden standard for partial seizures being highly efficacious and well-tolerated
- An intravenous formulation of carbamazepine has historically not been available
- Oral carbamazepine has a 17% market share (vol.)
- NDA expected in 2010

# Lundbeck's development pipeline

Compound Indication	Activity	Phase I	Phase II	Phase III	NDA Filing
<b>Sabril®</b> Refractory complex partial seizures/ Infantile spasms	GABA transaminase inhibitor	██████████	██████████	██████████	██████████ *
<b>Serdolect® - US</b> Schizophrenia	Dopamine/serotonin	██████████	██████████	██████████	██████████ **
<b>Lu AA21004</b> Depression + GAD	5-HT <sub>3</sub> antagonist, 5-HT <sub>1A</sub> agonist and 5-HT enhancer	██████████	██████████	██████████	2010
<b>I.V. Carbamazepine</b> Epilepsy	Sodium channel blocker	██████████	██████████	██████████	2010
<b>Bifeprunox</b> Schizophrenia	Dopamine/serotonin	██████████	██████████	██████████	2011
<b>Nalmefene</b> Alcohol dependence	Specific opioid receptor antagonist	██████████	██████████	██████████	2011
<b>Clobazam</b> Lennox-Gastaut syndrome	GABA enhancer	██████████	██████████	██████████	2011
<b>Desmoteplase</b> Stroke	Plasminogen activator	██████████	██████████	██████████	2011+
<b>Lu AA24530</b> Depression	Multiple targets	██████████	██████████		2011+
<b>Lu AA34893</b> Depression/bipolar	Multiple targets	██████████	██████████		2011+
<b>Lu 31-130</b> Psychosis	Monoaminergic	██████████	██████████		2011+
<b>Lu AE58054</b> Psychosis	Selective 5-HT <sub>6</sub> antagonist	██████████	██████████		2011+
<b>Lu AA39959</b> Psychosis/bipolar	Ion channel modulator	██████████	██████████		2011+
<b>Lu AA24493</b> Stroke/neuronal damage	Tissue protective cytokine	██████████			2011+
<b>Lu AA38466</b> Neurological disorders	Ion channel modulator	██████████			2011+

\* Unanimously recommended for approval by the Peripheral and Central Nervous System Drugs Advisory Committee appointed by the US FDA; FDA decision pending

\*\* PDAC concluded 7 April 2009; FDA decision pending



# Agenda

- Lundbeck overview
- Projects in development
- **Marketed products**
- Financial figures

# 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"

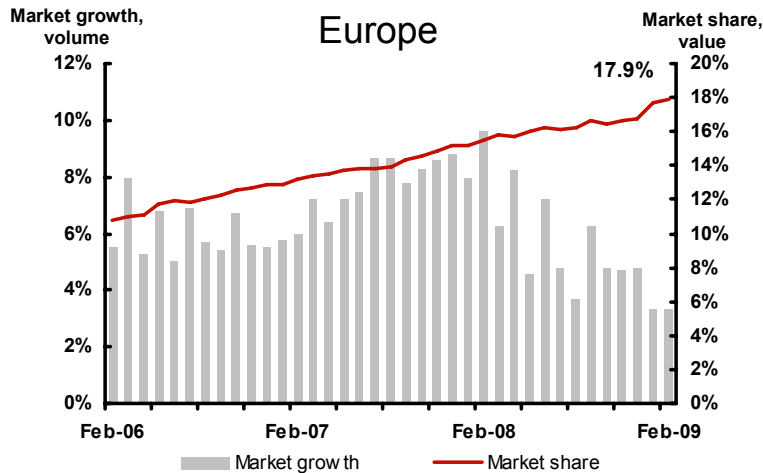
- Cipralex<sup>®</sup> is an ASRI\* with a unique mode of action, Serotonin Dual-action
- Estimated to have treated more than 160 million patients since launch
- Has demonstrated superior efficacy in the treatment of depression and anxiety in numerous post-approval studies
- Provides excellent tolerability 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

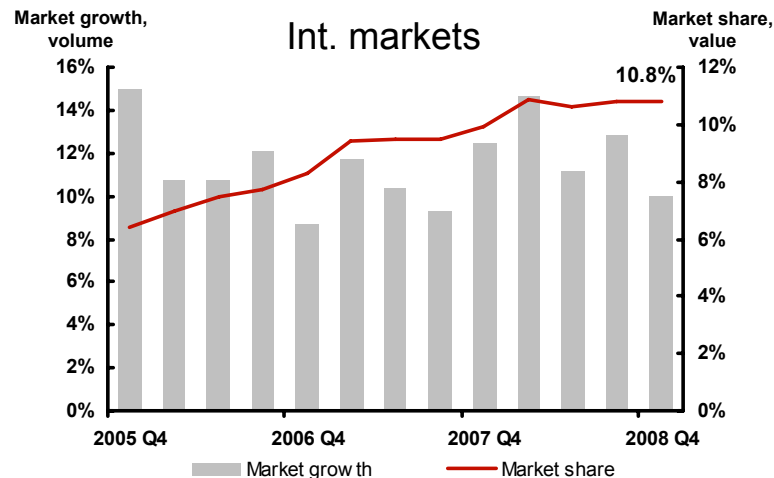
1) Cipriani A, et al. Lancet 2009

# Cipralex<sup>®</sup> (escitalopram) – strong growth in Europe and International Markets

## Anti-depressant market



- Cipralex<sup>®</sup> sales in Europe for the quarter was DKK 913m (+11%)
- Cipralex<sup>®</sup> still the most subscribed branded anti-depressant in Europe
- The compound is continuously expanding its market share across most countries (value)
  - Market leader in around 15 countries (i.e. Spain, Italy, Austria and France)
- Patent to expire in the last countries in Europe in 2014

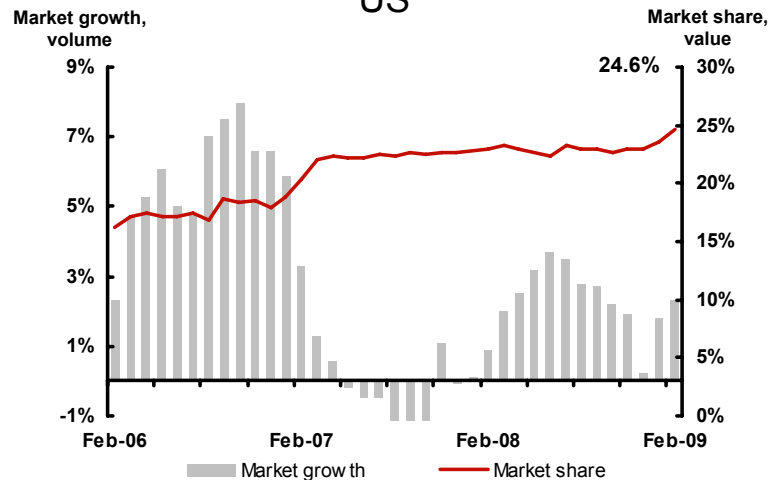


- Int. Markets sales at DKK 450m (+15%)
- Considerable market share expansion in Canada following public reimbursement in the Ontario province
  - Market share now 7.9% compared to 6.5% six month earlier
- Still gaining market shares in international markets despite generic competition in many markets

# Lexapro<sup>®</sup> (escitalopram) – now approved for the treatment of adolescents

## Anti-depressant market

### US



- US revenue of DKK 626m in Q1 2009, down 5% compared to 2008
- Lexapro<sup>®</sup> is the most prescribed branded antidepressant in the US
- Marketed by Forest Laboratories, Inc.
- Recently approved for treatment of major depression in adolescents
  - Additional revenue to Forest is expected to be around USD100m
- Patent to expire in March 2012

# Ebixa® (memantine) – efficacious even in severe Alzheimer's disease



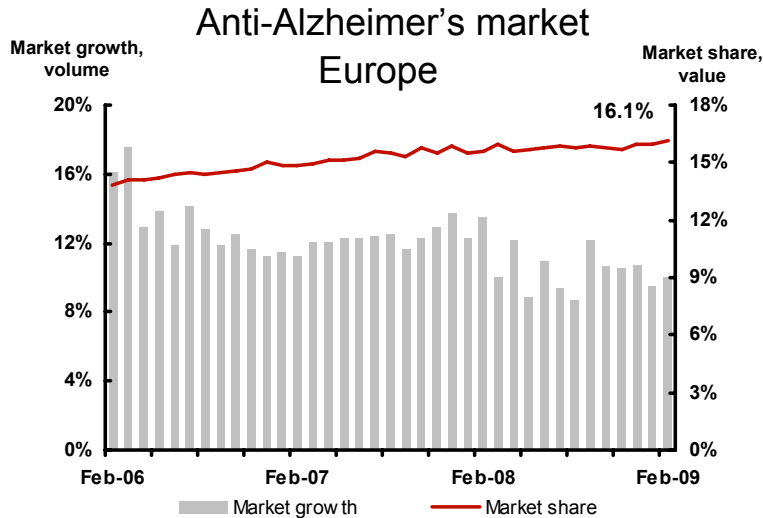
*"It gives me a real opportunity to treat some of the more distressing symptoms that you see emerge in Alzheimer's disease"*

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

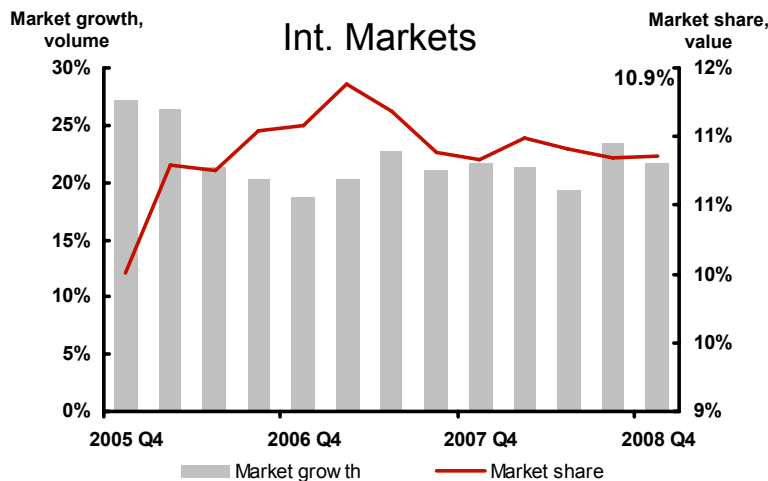
- Ebixa® is the only NMDA\* receptor antagonist approved for the treatment of Alzheimer's disease
- A very efficacious, well-tolerated and safe treatment with placebo-like side effects
- Only therapy licensed for the treatment of moderate to severe Alzheimer's in most Lundbeck markets
- Once-daily treatment
- Post-approval studies to be completed in 2009 and 2010
- Inlicensed form Merz Pharma (Germany)

\* N-methyl-D-aspartate

# Ebixa<sup>®</sup> (memantine) – growth driven by underlying market development



- Ebixa<sup>®</sup> revenue in Europe of DKK 431m (+15%)
- European market share is stable around 16% in a high growth market
- Continued roll-out of Ebixa<sup>®</sup> Once-Daily following EU approval in May 2008
- Now reimbursed in Italy
- Launched in 2002, data exclusivity to expire in Europe in 2012



- Int. Markets sales at DKK 95m (+16%)
- The market share for Int. Markets were 10.9% in Q4 2008
- Several on-going post-approval studies expected to support sales
- New promising dispenser under development

# 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"*

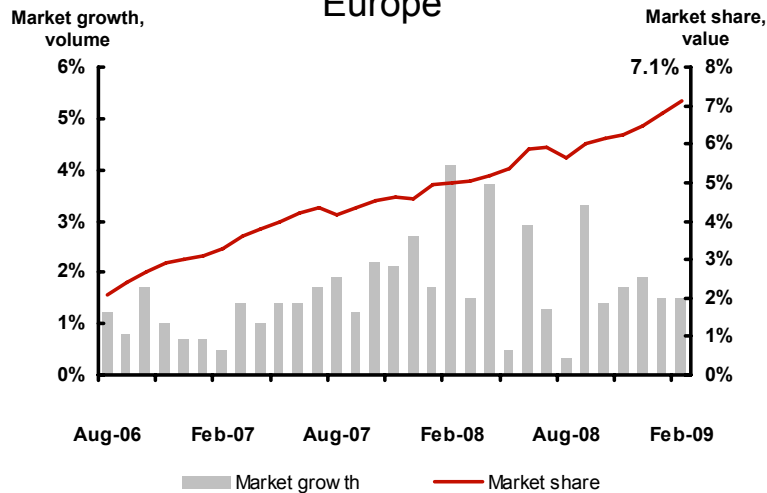
Prof. Rascol, M.D., Ph.D., Principal investigator

- 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, data presented at EFNS and ANA in 2008
  - 1,176 patients enrolled

# Azilect® (rasagiline) – strong growth across all markets

## Anti-Parkinson's market

### Europe



- Azilect® sales rose to DKK 78m in Q1 2009, up 43% compared to 2008
- European sales at DKK 70m (+42%), Int. Markets sales at DKK 7m (+53%)
- European market share continues to increase now having 7.1% of the market
- Strong ADAGIO result expected to drive further market penetration
- Marketed by Lundbeck in close to 30 countries in Europe and International Markets
- Launched in 2005, data exclusivity until 2015



# 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

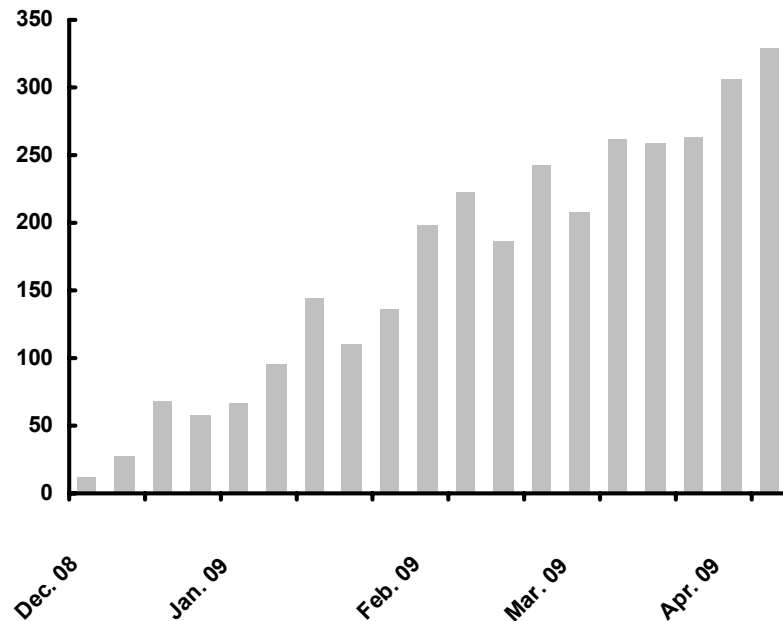
- Selectively inhibiting vesicular monoamine transporter enzyme (VMAT)-2, thereby depleting pre-synaptic dopamine
- Approved for chorea associated with Huntington's disease
- Only drug approved by FDA specifically for any symptom of HD
- Addresses high unmet medical needs and has shown strong efficacy
- 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

# Very strong initial uptake for Xenazine\*

Volume (standard Rx)



- Launched in the US by the end of November 2008
- Xenazine\* has been very well received
- More than 1,300 patients initiated Xenazine\* treatment by the end of Q1 2009
  - Level for renewals higher than expected
- Q1 2009 revenues of USD 10m

# ATryn<sup>®</sup> (recombinant anti-thrombin alpha) - overview

## **ATryn<sup>®</sup>**

- 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

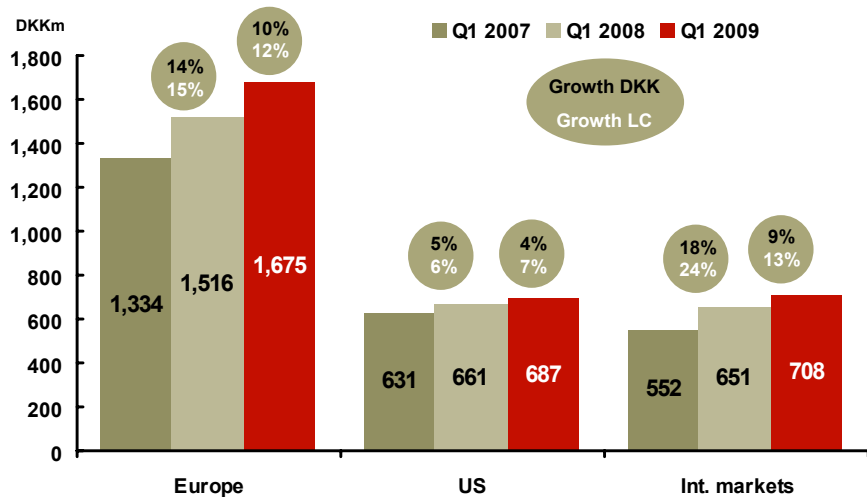
## **Hereditary Anti-thrombin Deficiency (HAD)**

- 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

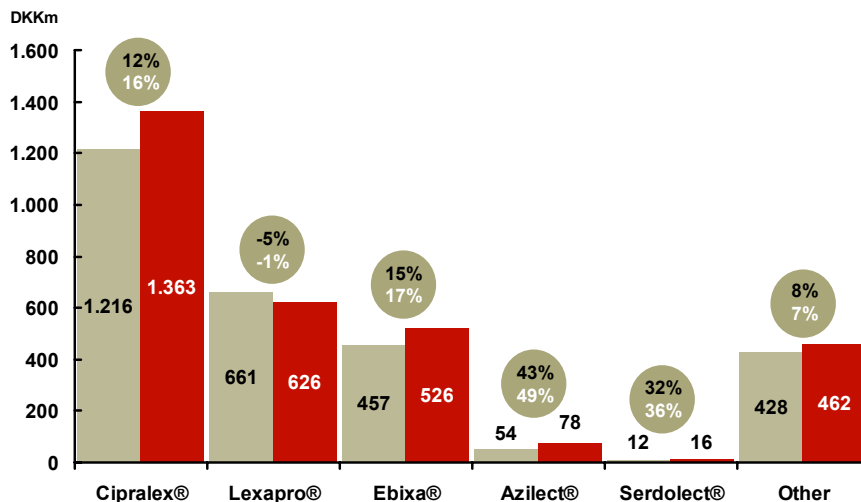
# Agenda

- Lundbeck overview
- Projects in development
- Marketed products
- **Financial figures**

# Financial figures – distribution of revenue in Q1 2009



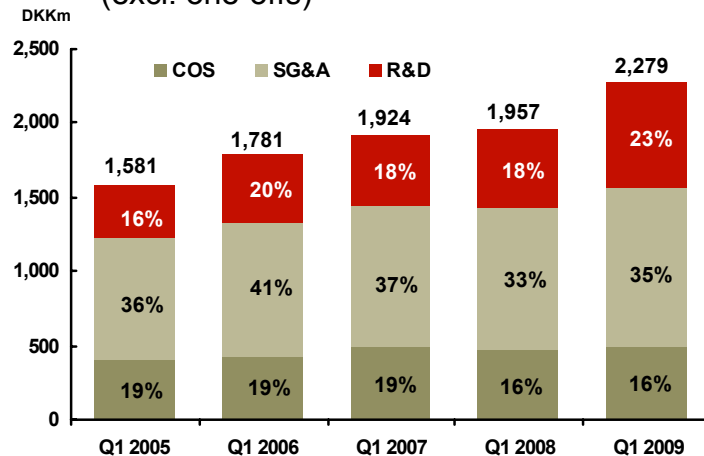
- Lundbeck's revenue excl. the divestment of LifeCycle Pharma (LCP) grew 8% in Q1 2009
- Revenue growth driven by Europe and International Markets were up by 12% and 13%, respectively, at constant exchange rates in Q1 2009 relative to 2008



- Sales of Cipralelex® and Azilect® were up by 16% and 49%, respectively, at constant exchange rates in Q1 2009 compared to 2008. Ebixa® sales rose by 17% at constant exchange rates

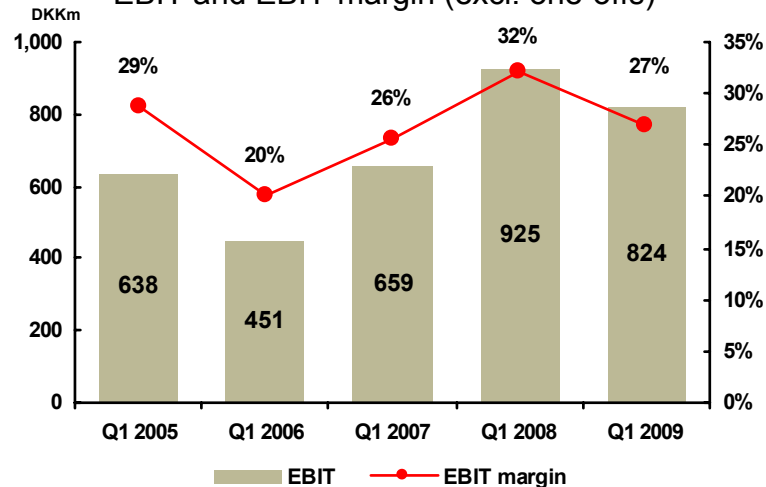
# Financial figures – distribution of costs in Q1 2009

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



- R&D costs for Q1 2009 up 37% compared to 2008, corresponding to 23% of total revenue excl. LCP
- EBIT for Q1 2009, excl. LCP, was down 11% as a result of increased R&D spending

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



# Key deliverables the next 12 months

## Existing products

- FDA decision on Serdolect® in the US for schizophrenia (PDUFA date 15 May 2009)
- Continue the roll-out of ATryn® in the US for hereditary anti-thrombin deficiency
- Further enhance Xenazine's market penetration

## Product launches

- Potential launch of Sabril® in the US for refractory complex partial seizures (rCPS) and infantile spasms (IS)
- Potential launch of Serdolect® for schizophrenia in the US

## Pipeline

- FDA decision on Sabril® for rCPS and IS
- Headline phase III data on Lu AA21004
- Headline phase II data on Lu AA24530
- Clinical phase II data on Lu 31-130
- Clinical phase II data on Lu AE58054

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

(DKK)	Revenue	EBIT	Profit before tax
Lundbeck Inc.	~ 1.1bn	~ 150mn	~ 150mn
Acquisition accounting	--	~ (183)mn	~ (183)mn
Additional amortisations	--	~ (150)mn	~ (150)mn
Net interests	--	--	~ (160)mn
<b>Total impact</b>	<b>~ 1.1bn</b>	<b>~ (183)mn</b>	<b>~ (343)mn</b>

- Lundbeck Inc. is expected to generate approx DKK 1.1bn in revenue
- 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



# Financial guidance

	2008 (DKKm)	2009* Previous guidance (DKKbn)	2009* New guidance (DKKbn)
<b>Revenues</b>	11,282	12-12.5	13.1-13.6
<b>EBITDA</b>	3,417	--	3.5-3.7
<b>EBIT</b>	2,354	3-3.2	2.8-3.0
<b>Tax rate</b>	27.1%	28%	~ 28%
<b>R&amp;D ratio</b>	22%	23-24%	23-24%

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

## New guidance

- Unchanged expectations for Lundbeck excl. Lundbeck Inc.
- Significant contribution from Lundbeck Inc. sales
- EBITDA added to guidance
- EBIT guidance lowered as a consequence of acquisition accounting

## Balance sheet and cash position

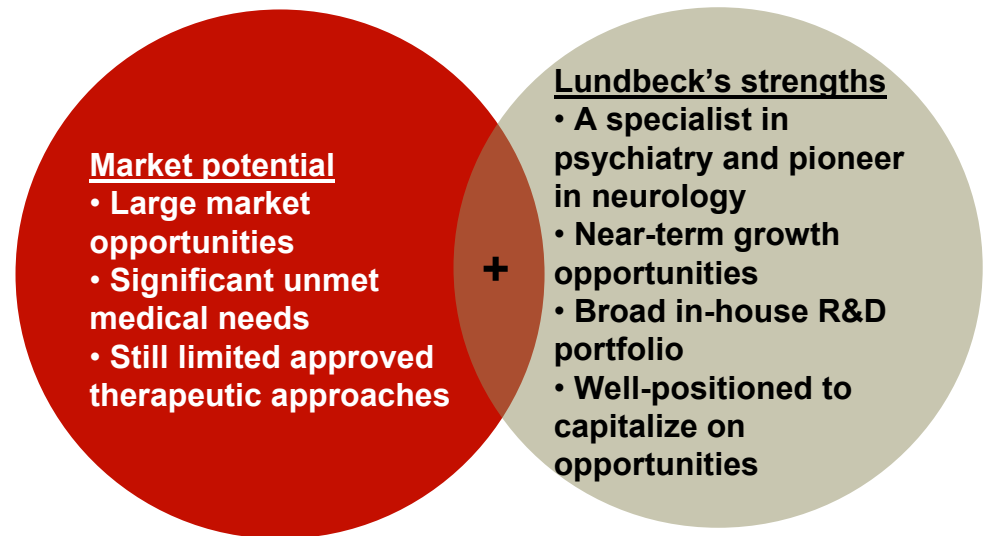
(DKKm)	31.12.2008	31.03.2009
Intangible assets	2,016	7,552
Other non-current assets	3,370	3,380
Current assets	7,140	5,068
<b>Assets</b>	<b>12,526</b>	<b>16,000</b>
Equity	7,511	8,115
Non current liabilities	2,594	3,240
Current liabilities	2,421	4,645
<b>Equity &amp; Liabilities</b>	<b>12,526</b>	<b>16,000</b>
Cash position	2,921	1,123
Securities	955	53
Interest bearing debt	1,927	1,942
<b>Interest bearing net debt (cash)</b>	<b>(1,949)</b>	<b>766</b>

- Intangible assets related to the acquisition amounts to DKK 5.8bn
- DKK 3.5bn of the transaction has been paid, the remaining DKK 1.7bn depends on Sabril® approval
- Remainder of transaction price booked as “other payables” under current liabilities
- Net debt end Q1 of DKK 766mn

# 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



**Jacob Tolstrup**

Director; IR and Communication

Tel: +45 36 43 30 79

Fax: +45 36 43 82 62

[jtl@lundbeck.com](mailto:jtl@lundbeck.com)



**Palle Holm Olesen**

Head of Investor Relations

Tel: +45 36 43 24 26

Fax: +45 36 43 82 62

[palo@lundbeck.com](mailto:palo@lundbeck.com)



**Joan Loua**

Investor Relations coordinator

Tel: +45 36 43 45 98

Fax: +45 36 43 82 62

[julo@lundbeck.com](mailto:julo@lundbeck.com)

# Appendix

# Lundbeck share

## Share information:

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

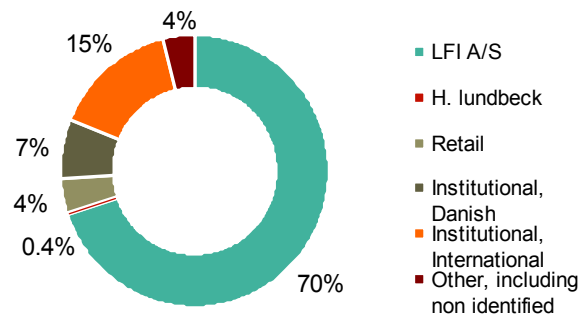
## Trading code:

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

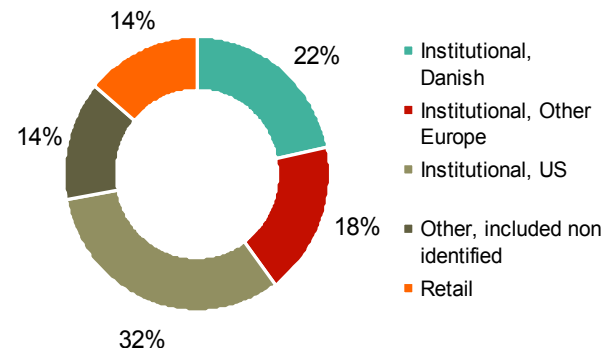
## Index examples:

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







## Ownership, total outstanding



## Ownership, of free float



# Continued solid performance in all products

	Market share (Feb 2009)	Y/Y Change
<b>Cipralex®</b>		
- Europe	17.9%	
<b>Cipralex®</b>		
- International markets	10.8%	
<b>Lexapro®</b>		
- USA	24.6%	
<b>Ebixa®</b>		
- Europe	16.1%	
<b>Ebixa®</b>		
- International Markets	10.9%	
<b>Azilect®</b>		
- Europe	7.1%	

Note: All market share data is from IMS Health, February 2009, except International Markets being from Q4, 2008

## Cipralex®

- Results from a multiple-treatments meta-analysis comparing efficacy and acceptability of 2 new-generation antidepressants support Cipralex<sup>1)</sup>
- “*Decisions Now*”
- Venlafaxine patent expiration
- Leading position in 15 countries - e.g. France, Italy, Spain and Turkey
- Improved reimbursement situation in Canada

## Ebixa®

- Strong underlying market growth
- Improved compliance with Ebixa Once-Daily
  - Now launched in 11 countries
- Reimbursement in Italy
- Reduced use of anti-psychotics among alzheimer’s patients provide market opportunities

## Azilect®

- Further market share gains following ADAGIO

1) Cipriani A, et al. Lancet 2009

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

	Total		Europe		USA		International Markets	
	Q1 2009	Q1 2008	Q1 2009	Q1 2008	Q1 2009	Q1 2008	Q1 2009	Q1 2008
DKKkm								
Total revenue	3,226	2,882	1,675	1,516	687	661	708	651
<i>Growth</i>	<i>12%</i>		<i>10%</i>		<i>4%</i>		<i>9%</i>	
Ciprallex®	1,363	1,216	913	823	-	-	450	393
<i>Growth</i>	<i>12%</i>		<i>11%</i>		<i>-</i>		<i>15%</i>	
Lexapro®	626	661	-	-	626	661	-	-
<i>Growth</i>	<i>(5%)</i>		<i>-</i>		<i>(5%)</i>		<i>-</i>	
Ebixa®	526	457	431	375	-	-	95	82
<i>Growth</i>	<i>15%</i>		<i>15%</i>		<i>-</i>		<i>16%</i>	
Azilect®	78	54	70	50	-	-	7	5
<i>Growth</i>	<i>43%</i>		<i>42%</i>		<i>-</i>		<i>53%</i>	
Serdolect®	16	12	11	7	-	-	5	5
<i>Growth</i>	<i>32%</i>		<i>44%</i>		<i>-</i>		<i>11%</i>	
Other pharmaceuticals	462	428	250	262	61	-	151	166
<i>Growth</i>	<i>8%</i>		<i>(5%)</i>		<i>-</i>		<i>(9%)</i>	
Other revenue	155	54						
<i>Growth</i>	<i>185%</i>							



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

DKKkM	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>	
Ciprallex®	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>-100%</i>		<i>-6%</i>	
Other revenue	195	690	-	-	-	-	-	-
<i>Growth</i>	<i>-72%</i>							

## Revenue, quarterly figures

	Revenue, DKK million				Growth, Y/Y, %			
	Q2 2008	Q3 2008	Q4 2008	Q1 2009	Q2 2008	Q3 2008	Q4 2008	Q1 2009
Total revenue	2,938	2,810	2,653	3,226	12%	(5%)	(6%)	12%
Cipralex®	1,234	1,228	1,151	1,363	20%	17%	12%	12%
Lexapro®	692	602	509	626	8%	(14%)	(19%)	(5%)
Ebixa®	467	480	475	526	14%	11%	12%	15%
Azilect®	63	65	80	78	58%	40%	69%	43%
Serdolect®	14	15	17	16	121%	43%	107%	32%
Other pharmaceuticals*	416	379	371	462	(4%)	(15%)	(9%)	8%
Other revenue	51	40	49	155	(10%)	(86%)	(83%)	185%

\* Old anti-psychotics, anti-depressants, incl. Citalopram and Lundbeck Inc.

## 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, %			
	Q2 2008	Q3 2008	Q4 2008	Q1 2009	Q2 2008	Q3 2008	Q4 2008	Q1 2009
Revenue	2,938	2,810	2,653	3,226	12%	(5%)	(6%)	12%
Production costs	468	433	460	487	18%	(5%)	(46%)	2%
Distribution costs	632	571	689	673	7%	(2%)	5%	19%
Administrative expenses	427	385	437	401	12%	8%	15%	2%
R&D	1,046	568	854	717	91%	18%	24%	37%
EBIT	365	852	212	947	(47%)	(21%)	(17%)	2%

### Costs, % of revenue

Production costs	16%	15%	17%	15%	-	-	-	-
Distribution costs	22%	20%	26%	21%	-	-	-	-
Administrative expenses	15%	14%	16%	12%	-	-	-	-
R&D	36%	20%	32%	22%	-	-	-	-

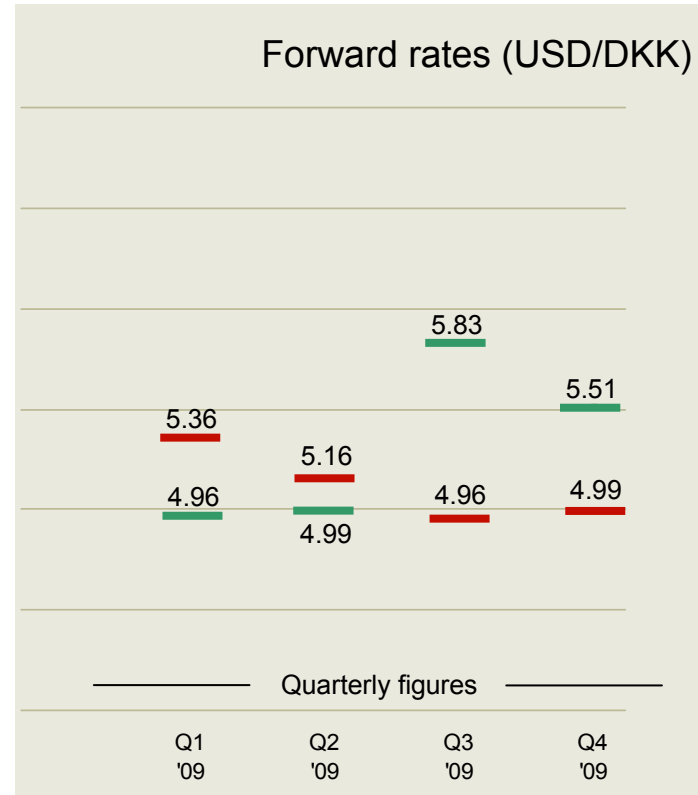
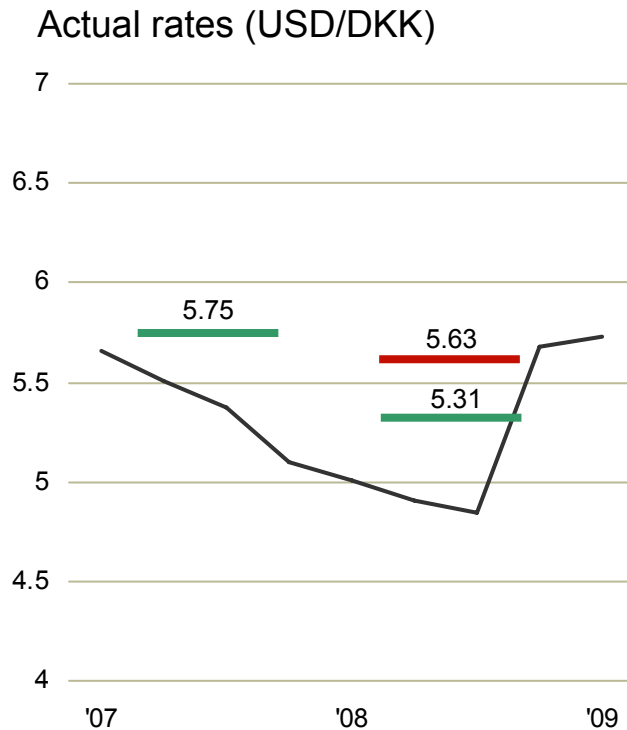
## Costs, yearly figures

	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	1,725	1,488	1,646	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.	1,364	1,303	1,419	1,514	1,651	-5%	9%	7%	9%
R&D	1,776	1,782	1,958	2,187	2,992	0%	10%	12%	37%
Other oper. exp., net	12	-8	-4	-18	-9	-	-	-	-
EBIT	2,554	2,170	1,784	2,695	2,352	-15%	-18%	51%	-13%

### Costs, % of revenue

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

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



Average USD exchange rate (quarterly)

Average hedging USD rate (cash)

Average hedging USD rate (reporting)



# Ovation (now Lundbeck, inc.) 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 2008e)

- *Xenazine*\*: 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

### Haematology/Oncology

#### (29% of 2008e)

- *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

### Hospital (50% of 2008e)

- *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

\* Xenazine is a registered trademark of Cambridge Laboratories (Ireland) Limited

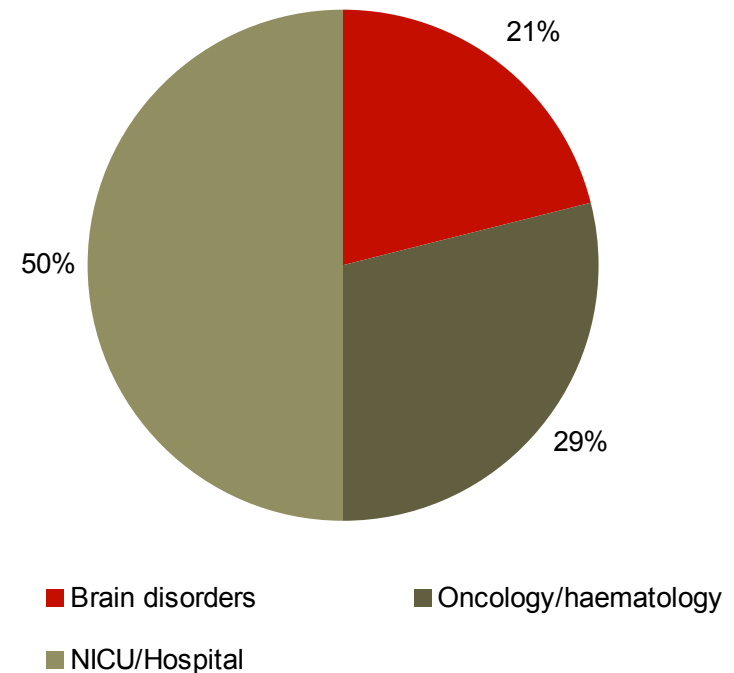
# Solid historic performance in Ovation – Brain disorders to be key future revenue driver

## 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)





# Global IP position



## USA

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

Sertindole: Use patent to April 2010, excl. extensions

Anti-thrombin Alfa: 2021

Xenazine: Orphan Drug exclusivity through 15 August 2015

## International Markets

Bifeprunox: Compound patent in major markets to Feb. 2017

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

Bifeprunox: Compound patent in majority of countries to Feb. 2017 (excl. extension)

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

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

Rasagiline: Compound patent to 2011 (excl. possibility of 5 year extension); data exclusivity until 2015

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

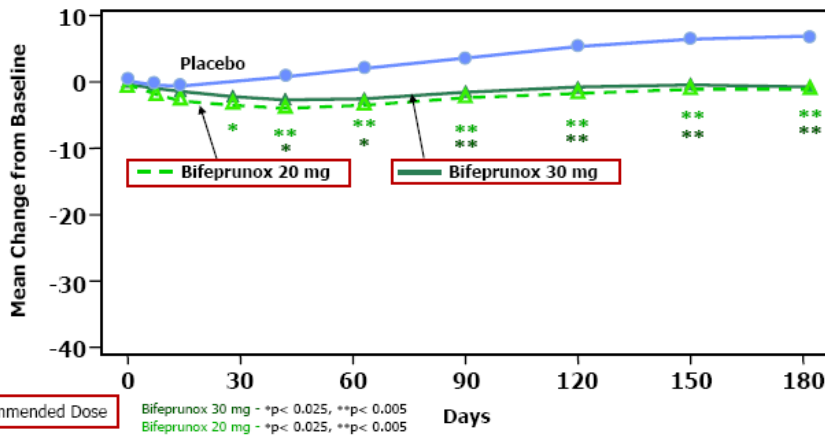
Circadin®: Data exclusivity to 2017

# Bifeprunox is expected to improve schizophrenia symptoms over the long-term



Symptoms were stable over 6 months on bifeprunox treatment in a time-to-deterioration trial

Mean PANSS Score



	Bifeprunox 20mg	Bifeprunox 30mg	Placebo
Proportion of patients with $\geq 7\%$ increase in weight (%)	2.5	2.3	2.4
Proportion of patients with $\geq 7\%$ decrease in weight (%)	9.4	9.3	8.4

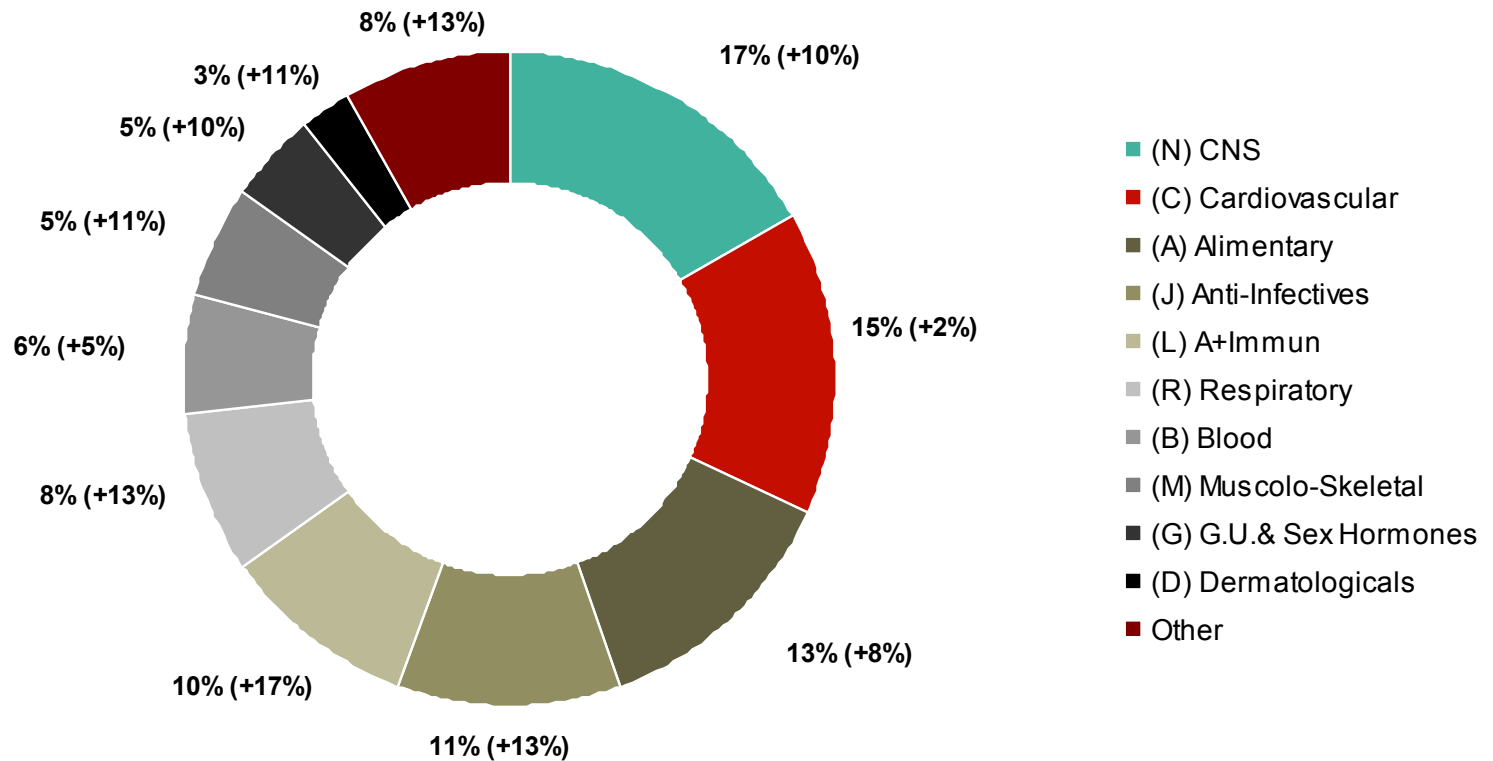
The proportion of patients with clinically relevant ( $\geq 7\%$ ) increase or decrease in weight was comparable between bifeprunox and placebo during long-term treatment (6 months)

In clinical trials bifeprunox has shown:

- Anti-psychotic effect (acute+chronic)
  - In chronic, stabilised schizophrenia, bifeprunox delayed the time to deterioration
- Generally low EPS potential
- No QTc prolongation at therapeutic dose levels
- Favourable metabolic data
  - Weight reduction compared to placebo (6 months):
    - Placebo: -0.8 kg; BX20: -1.3 kg; BX30: -1.5 kg
    - Treatment with bifeprunox may be beneficial to stable patients where long-term concerns exist related to weight gain
  - Favourable effects on lipids, neutral on glucose
- No prolactin increase
- Prolonged and cross-tapered titration schedule expected to improve tolerability/reduce (high) early withdrawal

# Worldwide pharmaceutical market 2007

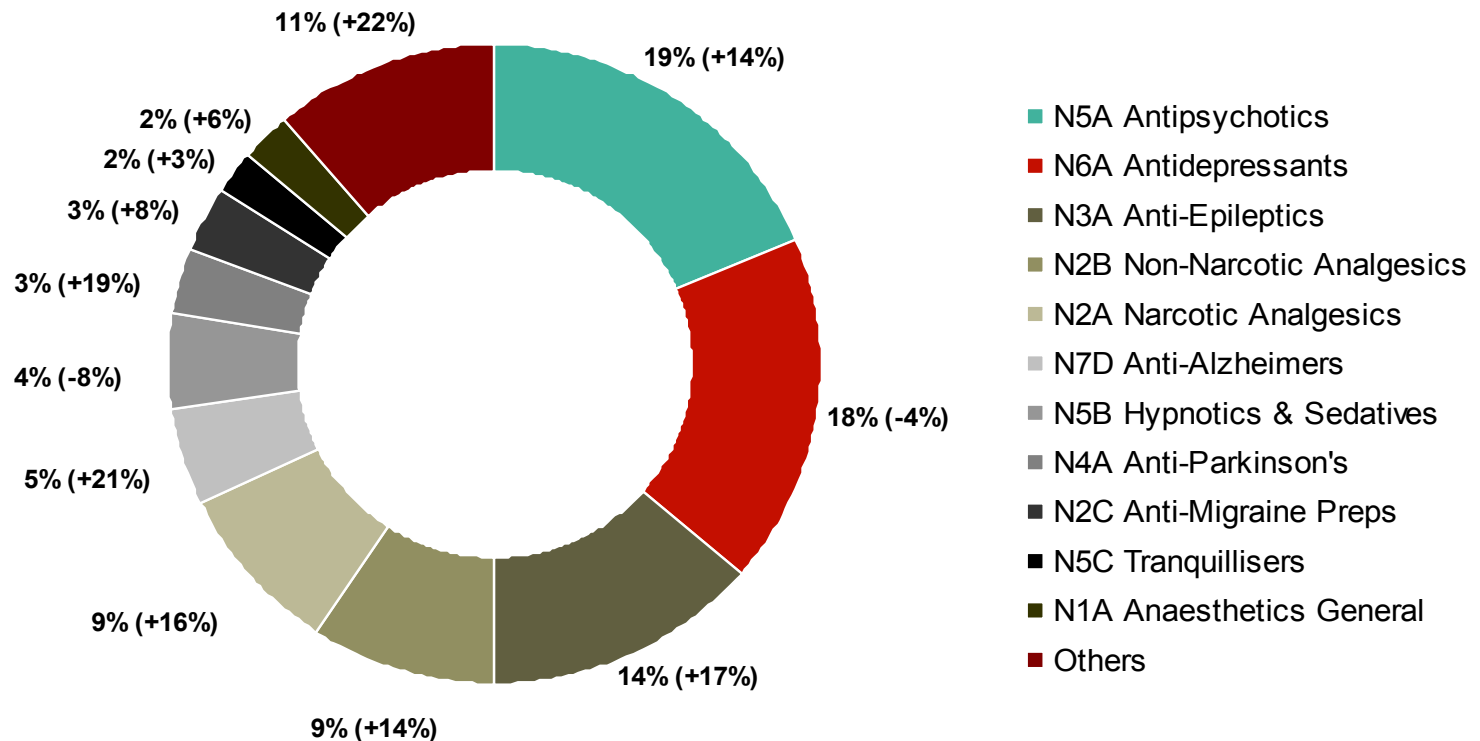
– USD 671.7 billion (+10%)



Source: IMS World Review 2008,  
2006-2007 growth in \$ in brackets

# Worldwide CNS market 2007

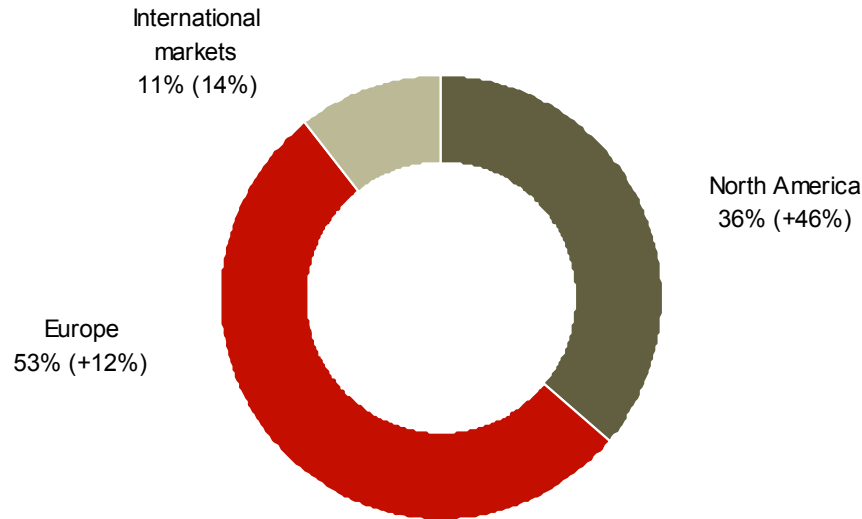
– USD 111.8 billion (+10%)



Source: IMS World Review 2008,  
2006-2007 growth in \$ in brackets

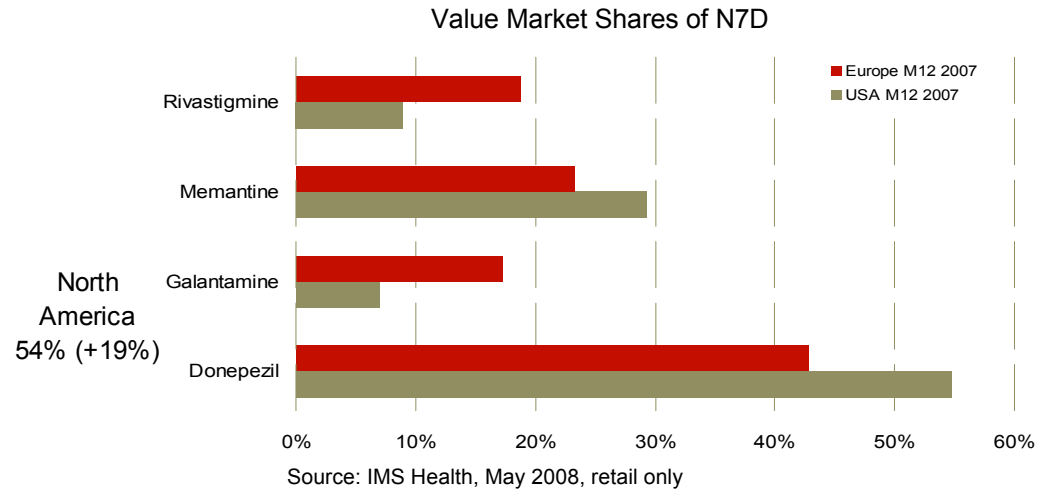
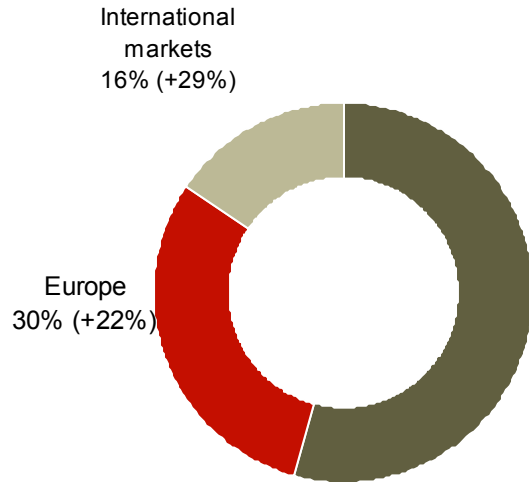
# Alcohol (N7E-2007)

– USD 172 million (+22%)



Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Campral®	Merck	74	11
Antabuse®	Barr/Sanofi-Aventis	26	48
Nemexin®	BMS/Cephalon	11	7
Vivitrol®	BMS/Cephalon	11	479

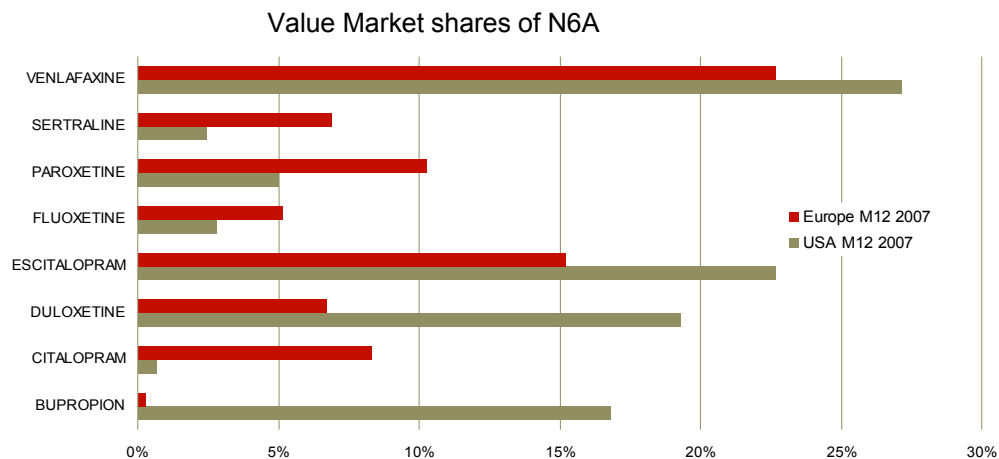
# Anti-Alzheimer's (N7D-2007) – USD 5.6 billion (+21%)



Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Aricept®	Pfizer/Eisai	3,003	20
Namenda®	Forest	838	28
Exelon®	Novartis	608	16
Reminyl®//Razadone®	Johnson & Johnson	602	15
Ebixa®	Lundbeck	318	31

# Anti-depressants (N6A-2007)

## – USD 19.8 billion (- 4%)



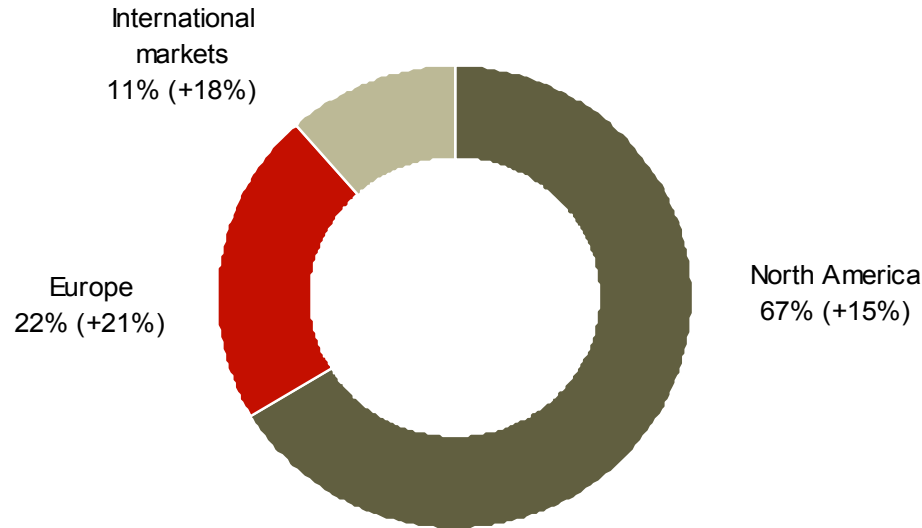
Source: IMS Health, May 2008, retail only.

Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Effexor®	Wyeth	4,071	2
Lexapro®/Cipralextm	Lundbeck/Forest	3,321	10
Cymbalta®/ Yentreve®	Lilly	2,154	61
Wellbutrin®	GlaxoSmithKline	1,176	(40)
Seroxat®/Paxil®	GlaxoSmithKline	1,102	(4)
Zoloft®	Pfizer	579	(76)
Sertraline® (branded generic)	Pfizer	202	(56)

# Anti-epileptics (N3A - 2007)

## – USD 15.3 billion (+17%)

PLEASE NOTE: Ovation acquisition subject to approval by FTC

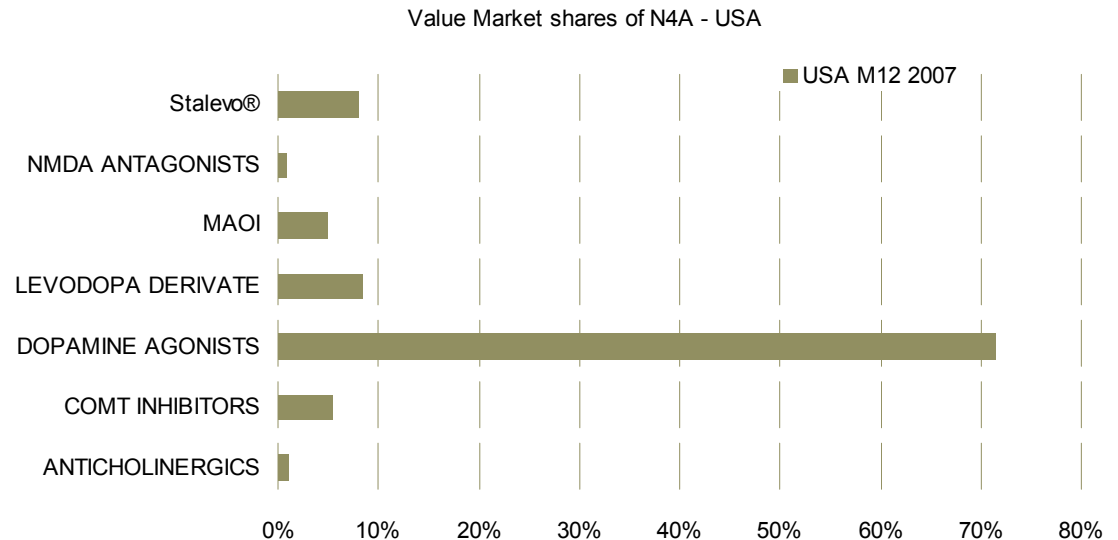
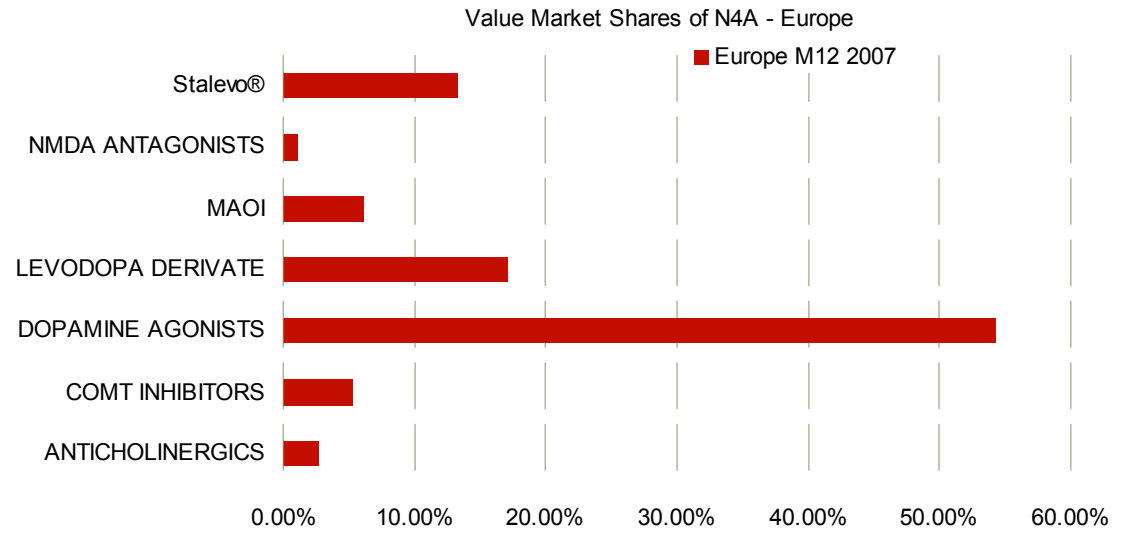
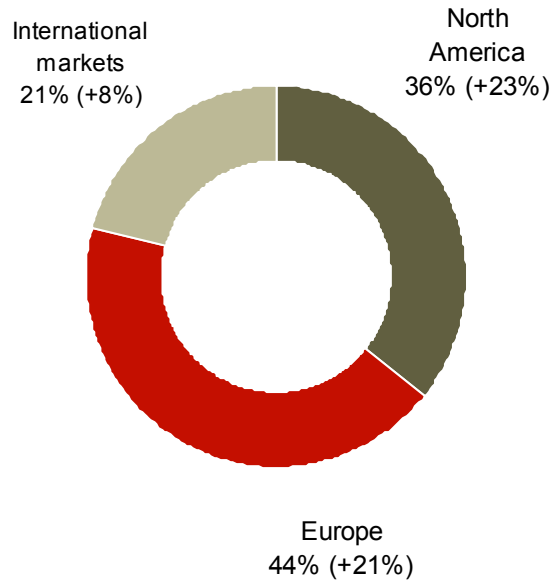


Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Topamax®	J&J	2496	17
Lamictal®	GlaxoSmithKleine	2468	21
Lyrica®	Pfizer	1899	59
Valcote®	Abbott	1695	8
Keppra®	UCB	1505	44
Tileptal®	Novartis	848	4



# Anti-Parkinson's (N4A - 2007)

## – USD 3.7 billion (+19%)

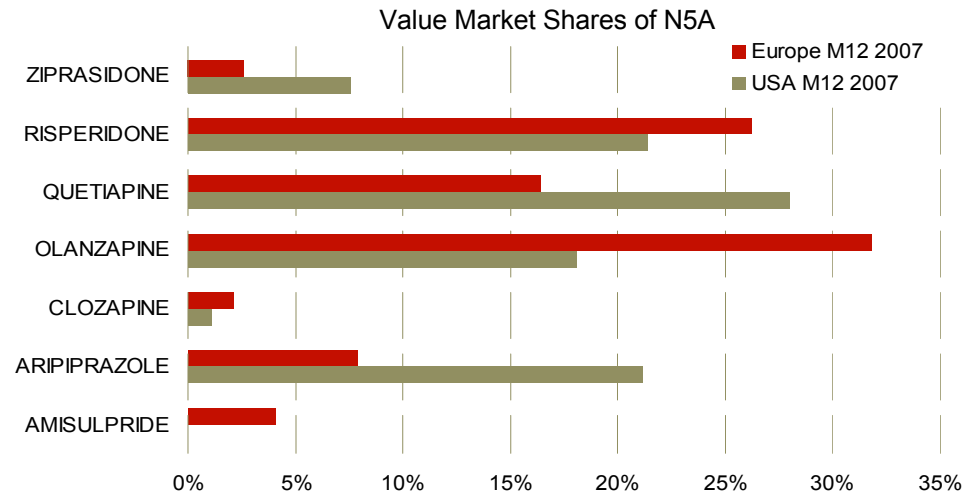
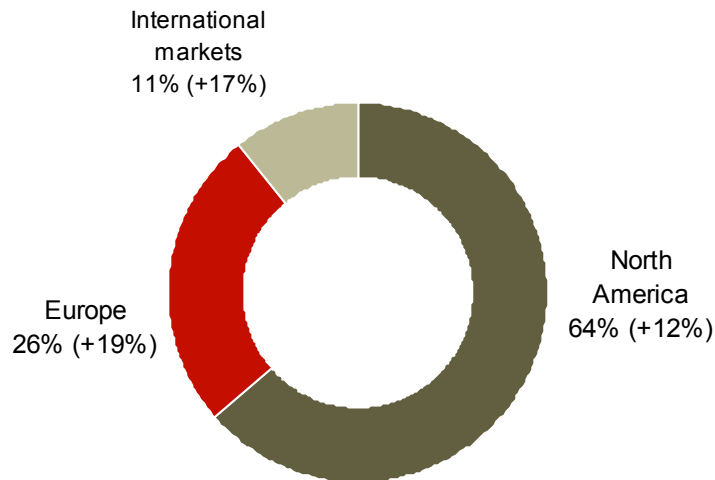


Source: IMS World Review 2008

Source: IMS Health, May 2008, retail.

# Anti-psychotics (N5A-2007)

## – USD 20.8 billion (+14%)

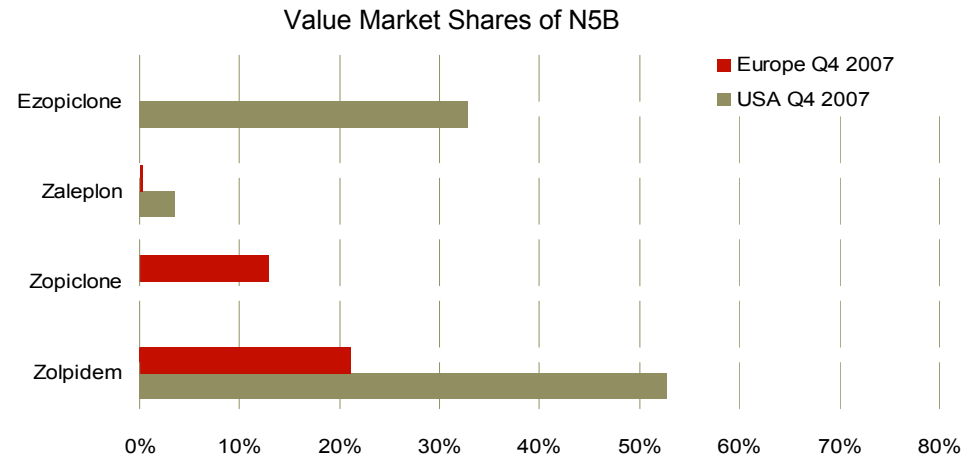
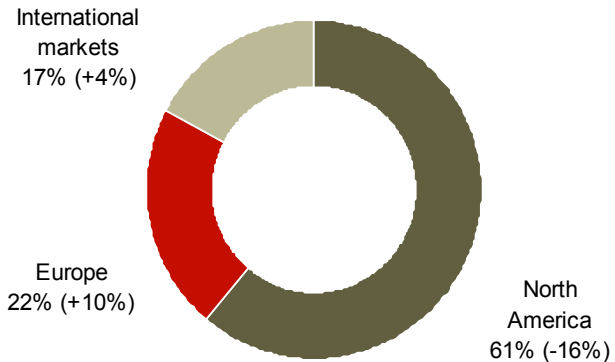


Source: IMS Health, May 2008, retail

Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Zyprexa®	Eli Lilly	5,019	5
Risperdal®	Johnson & Johnson	4,947	7
Seroquel®	AstraZeneca	4,645	18
Abilify®	Otsuka/BMS	2,760	27
Zeldox® /Geodon®	Pfizer	1,036	21
Leponex®	Novartis	224	(1)
Solian®	Sanofi-Aventis	205	6

# Hypnotics (N5B-2007)

– USD 5.0 billion (- 8%)



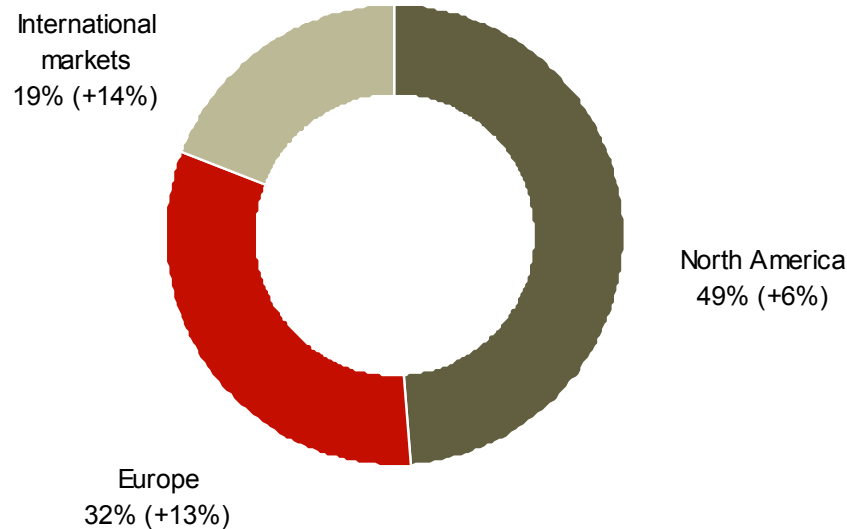
Source: IMS Health, May 2008, retail

Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Stilnox®	Sanofi-Aventis	2,211	(27)
Lunesta®	Sepracor	726	20
Lendormin®	Boehringer Ingelheim	120	2
Sonata®	Wyeth	92	(14)
Rozerem®	Takeda	119	61
Imovane®	Aventis	79	1

Source: IMS World Review 2008 & IMS Knowledge link

# Stroke, Fibrinolytics (B1D-2007)

## – USD 743 million (+10%)



Leading product	Marketing Corporation	Sales 2007 (USDm)	Growth in %
Activase®/Actilyse®	Roche/Boehringer	365	20
Metalyse®/Tnkase	Roche/Boehringer	166	(1)
Retavase®/Rapilysin®	PDL biopharma/Rosche	50	(14)