

H. LUNDBECK A/S

# Merrill Lynch Global Health Care Conference 2011

14 September, 2011



## Company disclaimer

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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.

# Why invest in Lundbeck?

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- ★ Well-established track-record for innovation and commercialisation in CNS
- ★ Clear therapeutic focus on selected segments
- ★ Substantial unmet medical needs in CNS
- ★ Brand leadership and strong core business support growth opportunities
- ★ Lundbeck at the verge of a new product cycle
- ★ Several potential product launches before 2014
- ★ Strong balance sheet and cash generation provide flexibility



# Our vision - To become a world leader in CNS

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## Lundbeck priorities

- ✦ Maintain focus on the core business and grow the company
- ✦ Advance the pipeline
- ✦ Continue to expand globally
- ✦ Return cash to shareholders

# Building a better Lundbeck

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## **Decisions Now**

Improving organisational efficacy and effectiveness

## **Pipeline**

Advancing clinical programmes

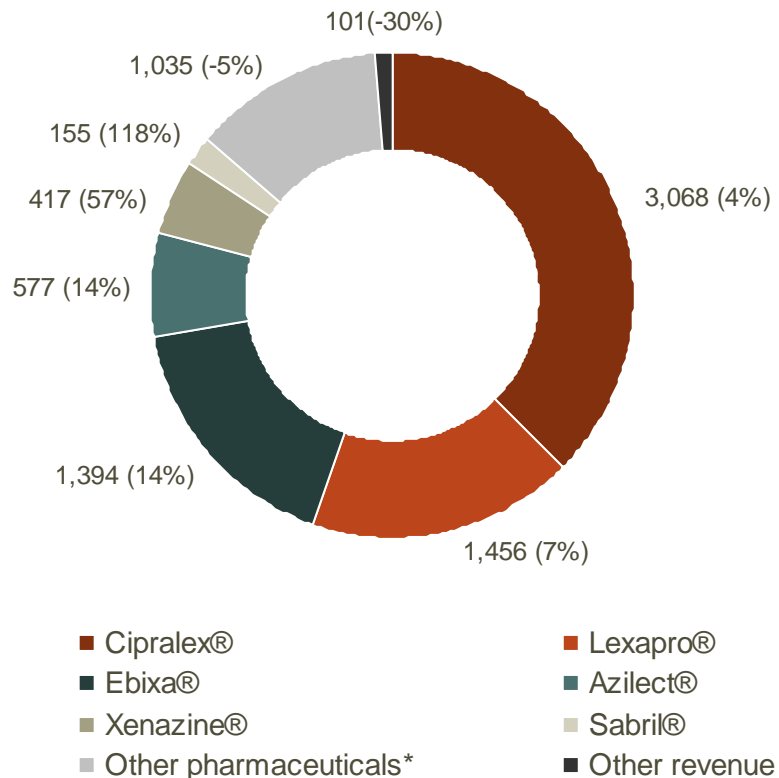


## **Business Development**

New product opportunities

# H1 2011 - commercial review

## Product distribution, H1 2011 (DKKm) (Y/Y growth in brackets)



### Ciprolex®/Lexapro®

- ★ Ciprolex® withdrawn in Germany (public market)
- ★ Market share expansion in Canada continues
- ★ New Chinese sales force in place

### Ebixa®

- ★ Reimbursement in Italy continues to support sales
- ★ Positive development in UK after recommendation from NICE

### Azilect®

- ★ Continued strong growth in France following launch

### Xenazine®

- ★ More than 3,100 patients have now started treatment with Xenazine®

### Sabril®

- ★ Increased compliance rate among existing patients

# Lundbeck – truly global platform for growth

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## North America:

- + New platform for growth
- + Sabril<sup>®</sup>, Xenazine<sup>®</sup> and Onfi<sup>™</sup>
- + Lu AA21004
- + Saphris<sup>®</sup> (Canada)
- + Cephalon brands (Canada)

## Europe:

- + Strong market position
- + Sycrest<sup>®</sup>
- + Nalmefene
- + Lu AA21004

## Latin America:

- + Emerging markets
- + Strong commercial platform
- + Saphris<sup>®</sup>
- + Cephalon brands
- + Lu AA21004

## Asia:

- + Emerging markets
- + Lexapro<sup>®</sup> (Japan)
- + Improved commercial platform in China
- + Saphris<sup>®</sup>
- + Azilect<sup>®</sup>
- + Lu AA21004

# Lundbeck product launches 2011/2012

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## New products

- ★ Lundbeck's launch programme for the next 1½ year represents significant opportunities
- ★ Significant investments in commercialisation of new products already in 2011

## ... and expanded collaborations

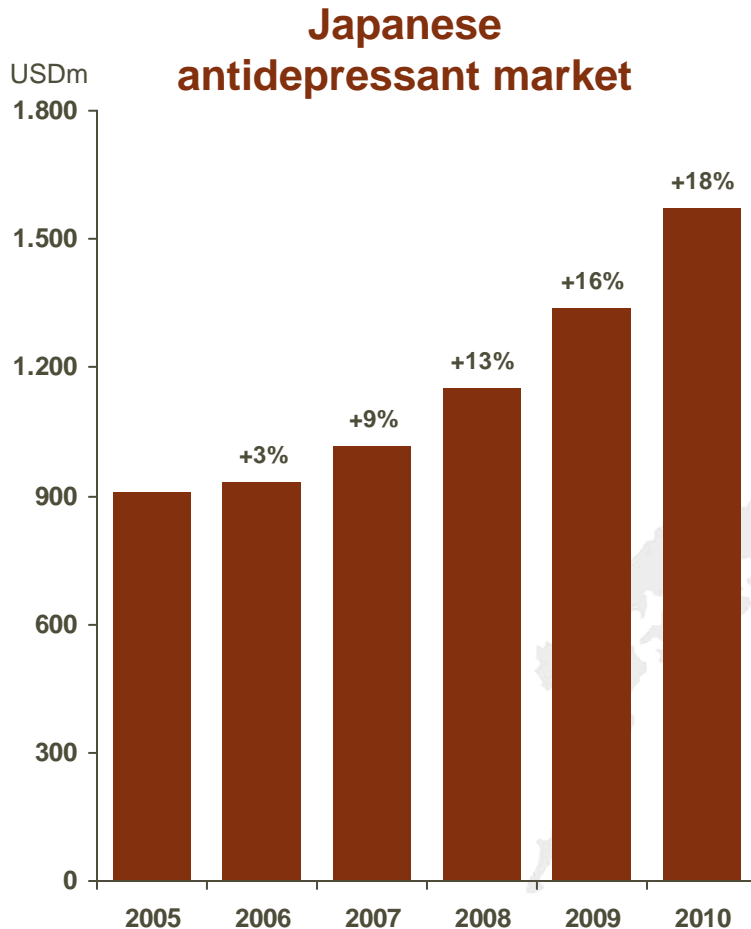
- ★ Positive impact from new co-promotion agreement related to Lexapro® in China
- ★ Azilect® in Asia represents additional opportunity

Products	Potential	First launch
Sycrest®	DKK >1bn	April 2011
Lexapro® (Japan)	DKK >500m <sup>1)</sup>	August 2011
Cephalon products	DKK >500m	2012
Onfi™ (clobazam)	DKK >1bn	H1 2012
Nalmefene	DKK ~2.5bn	2012/13

1) Royalty share



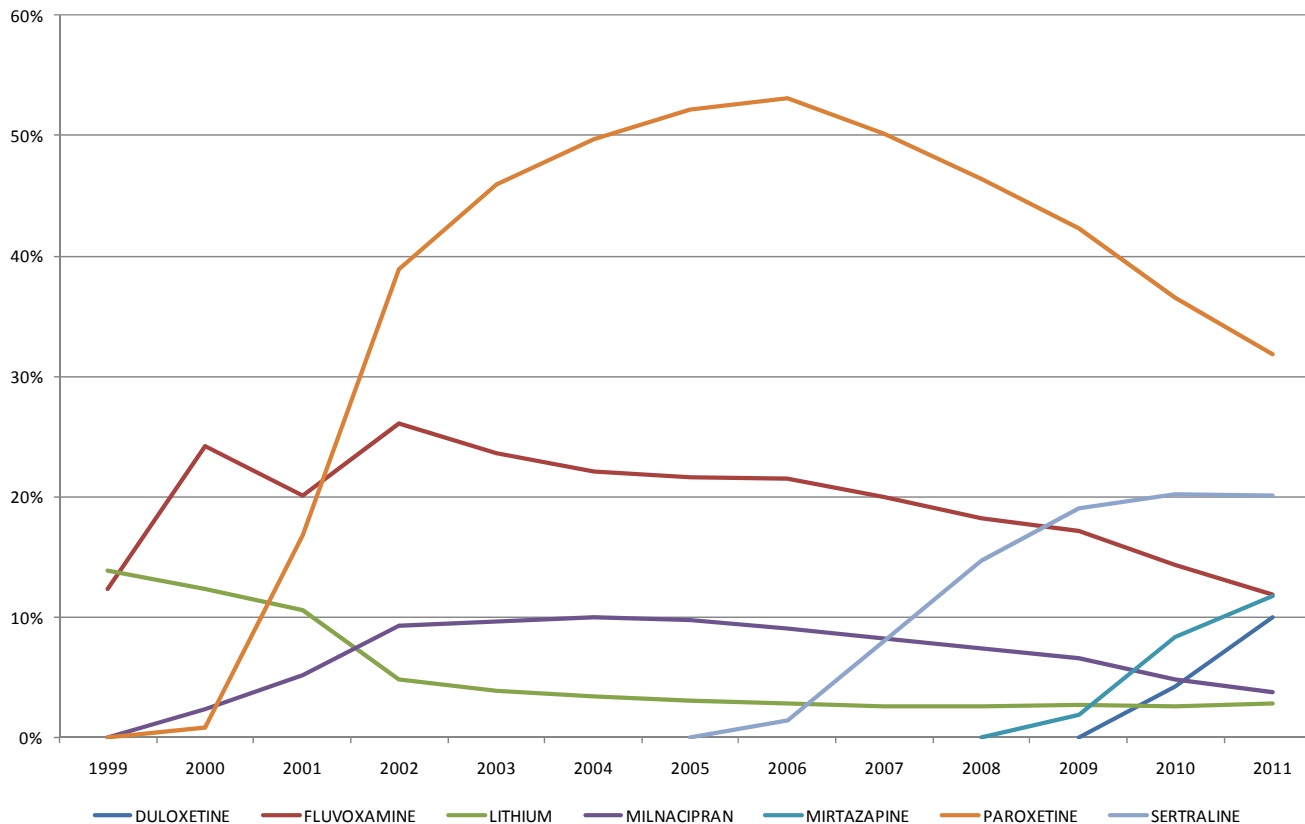
# Lexapro<sup>®</sup> launched in Japan



- ★ Launched in August 2011
- ★ Lexapro<sup>®</sup> in strong position to become no. 1 brand in the market
- ★ Mochida has marketing rights in Japan, in co-promotion with Mitsubishi Tanabe Pharmaceuticals
- ★ NHI Drug Price: JPY 212.00 per tablet
- ★ Mochida and Mitsubishi Tanabe Pharma estimate that sales amounts of Lexapro<sup>®</sup> are JPY 3 billion for the first year of the launch, and...
- ★ ...peak sales of JPY 33.8 billion, in total

# Anti-depressant market in Japan - a unique opportunity for Lexapro®

## Japanese antidepressant market shares (value)\*



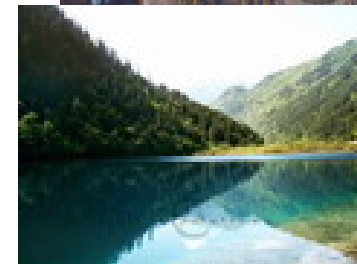
★ Paroxetine and sertraline dominates the market

★ Duloxetine and mirtazapine has recently been launched with high initial uptake

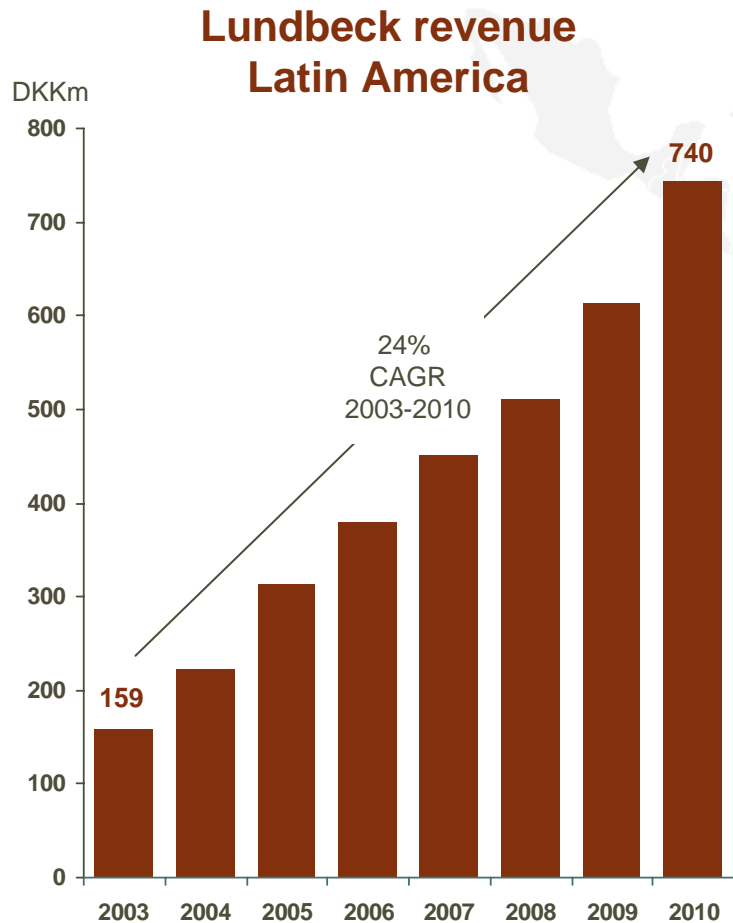
\* 2011 market shares calculated as January-June




# China represents major opportunity for Lundbeck

- ★ The Chinese pharmaceutical market is fast evolving
  - ★ Pharmaceutical market growing by 25+% annually (CER)
- ★ Lundbeck has had products available in China since 1996
- ★ Improved commercial platform following co-promotion agreement with Xian-Janssen regarding Lexapro<sup>®</sup> in China
  - ★ Lexapro<sup>®</sup> promoted by both Xian Janssen and Lundbeck sales force
- ★ Lundbeck's now has 100 sales reps promoting Lexapro<sup>®</sup> and Ebixa<sup>®</sup>
- ★ Launch of Azilect<sup>®</sup> in a couple of years pending approval



# Strong sales growth in Latin America



-  Strong commercial platform
-  Presence in all important markets
-  Significant growth based on Cipralex<sup>®</sup> and Ebixa<sup>®</sup>

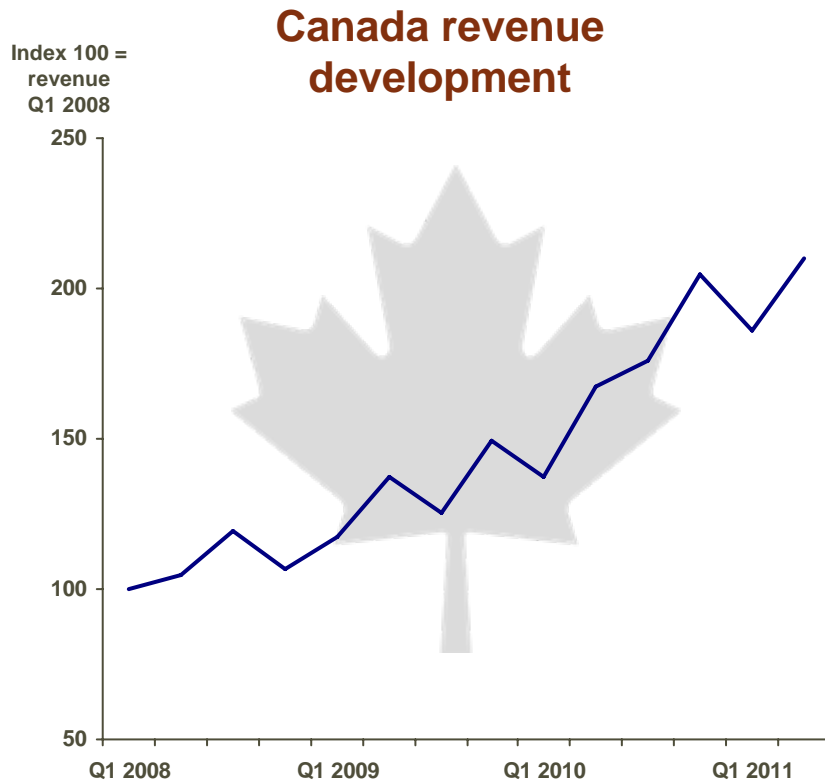
# New products in Latin America

Product	Indication	Expected launch
Saphris® (asenapine)	Bipolar disorder + schizophrenia	2012
Fentora® (fentanyl buccal tablet)	Break-through cancer pain	2013
Myocet® (liposomal-doxorubicin)	Cytotoxin for metastatic breast cancer	*
Provigil® (modafinil) Nuvigil® (armodafinil)	Wakefulness promoting agents (narcolepsy, OSA, SWSD)	2013
Lu AA21004	Mood disorders	2014

\*Myocet® will be amended the agreement with Cephalon at a later stage  
 OSA: obstructive sleep apnea; SWSD: shift work sleep disorder



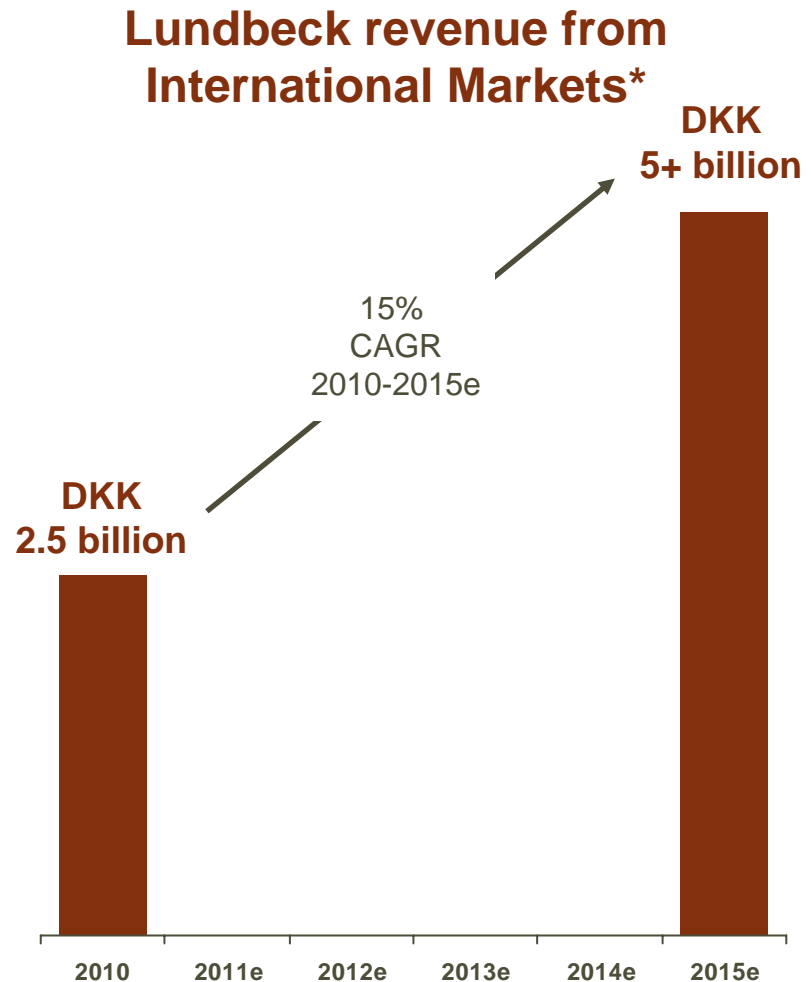
# Canada approaching DKK 1 billion annually in revenue



- \* Canada revenue up 25% compared to Q2 2010
- \* Now the 2<sup>nd</sup> largest Ciprale<sup>x</sup>® market
  - \* Annual Ciprale<sup>x</sup>® sales of around DKK 650m in 2010
- \* Saphris<sup>®</sup> and Cephalon brands to be launched in 2012

# International Markets - New growth opportunities to boost sales

- ★ Sales from International Markets\* expected to double in five years
- ★ Underlying market growth, market share expansion and new product launches to drive growth
- ★ Lexapro<sup>®</sup> (Japan), Sycrest<sup>®</sup>/Saphris<sup>®</sup> and Cephalon brands to be launched in 2011-12
- ★ Lu AA21004 expected to be launched in 2014



\* Asia (incl. Japan), Australia, Middle East, Africa, Latin America and Canada  
(Reported revenue from International markets include Israel, Russia and Turkey)

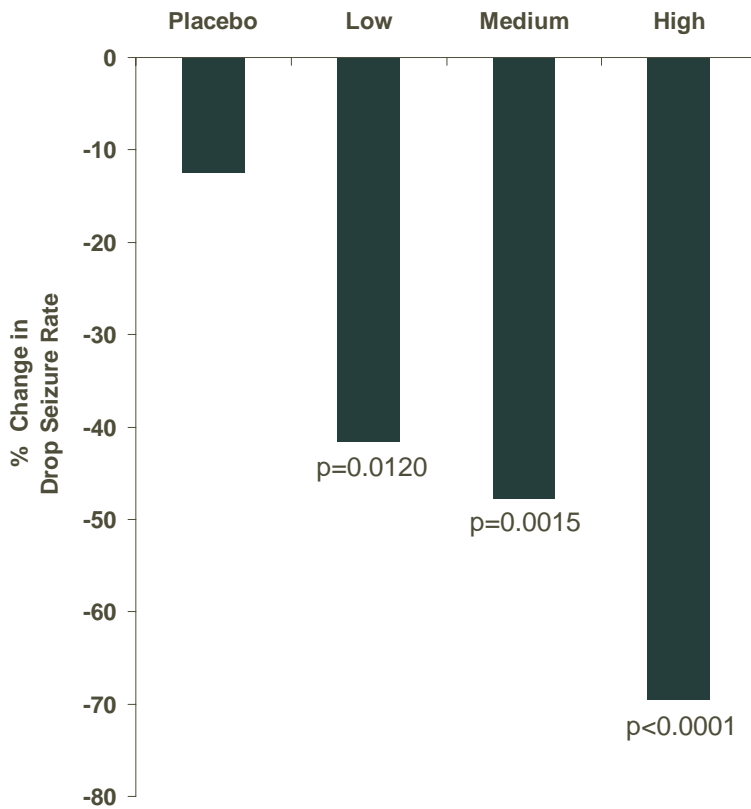
# Lundbeck's mid- to late-stage pipeline

		Phase II	Phase III	Regulatory filing	
BRAIN DISEASES	PSYCHIATRY	MOOD DISORDERS	Lu AA24530	Lu AA21004	
		ALCOHOL DEPENDENCE		Nalmefene	
		PSYCHOSIS		Zicronapine	
	NEUROLOGY	ALZHEIMER'S DISEASE	Lu AE58054		
		EPILEPSY		IV carbamazepine	Onfi™ (Clobazam)
		OTHER		Desmoteplase (stroke)	



# Onfi™ (clobazam) – addresses clear unmet medical need

## Reduction in weekly drop seizure rate by dose



Source: Joan A. Conry, Yu-Tze Ng, Rebecca Drummond, Julie Stolle, Stephen M. Sagar. Data presented at the American Epilepsy Society 64th Annual Meeting, 2010, San Antonio, Texas

## Lennox-Gastaut syndrome (LGS)

- ✖ Clear unmet medical needs
- ✖ Only 10% of cases experiencing full seizure remission with available therapies
- ✖ Clobazam has been granted orphan drug status

## Positive clinical phase III study

- ✖ Clobazam significantly decreased average weekly rates of drop seizures and total seizures
- ✖ Both physicians' and parents'/caregivers' assessments indicated that clobazam improved symptoms of LGS
- ✖ No new safety issues were identified

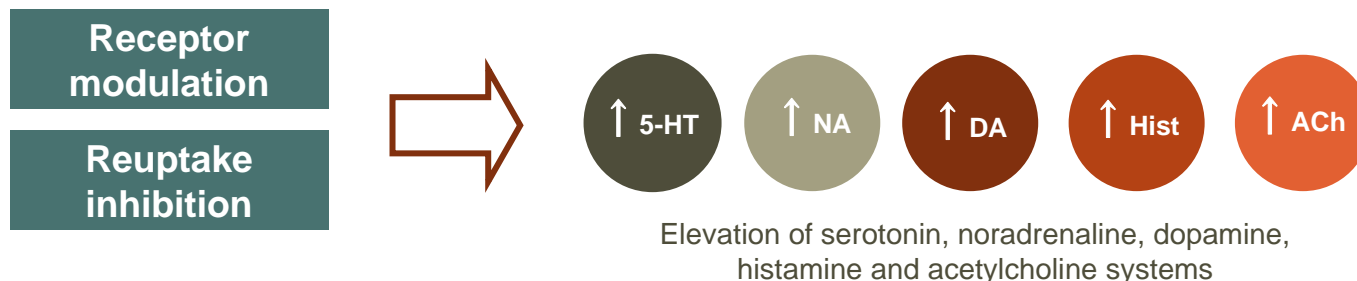
# Lu AA21004 – a unique pharmacological profile

## Lu AA21004

- ★ Novel mechanism of action
  - ★ Multimodal enhancer\* - enhances levels of serotonin, noradrenaline, dopamine, acetylcholine and histamine
- ★ Potential dose range in label 5-20 mg
- ★ Tolerability
  - ★ Sexual side effects at placebo level
  - ★ Nausea levels on par with SSRIs, better than SNRIs
  - ★ Weight neutral

## The current clinical programme

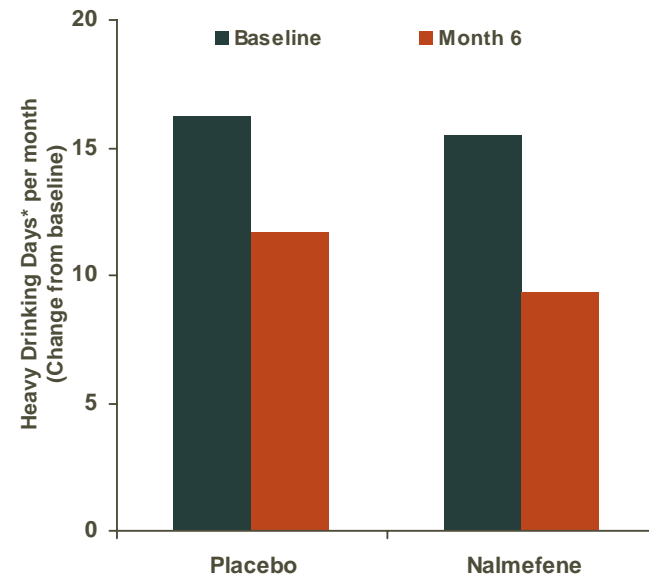
- ★ More than 2,000 patients with moderate to severe depression
- ★ Doses are 10, 15 and 20 mg
- ★ Additional profiling studies ongoing
  - ★ Effect of Lu AA21004 vs. escitalopram on sexual functioning in people with well-treated MDD
    - ★ 440 patients
    - ★ 10-20mg
  - ★ Efficacy study of Lu AA21004 on cognitive dysfunction in MDD
    - ★ 600 patients
    - ★ 10 mg, 20 mg and placebo



# Nalmefene – a novel concept for treating alcohol dependence

- ★ Completed phase III studies confirm nalmefene profile
  - ★ On track for MAA\* submission in Europe towards year-end 2011
  
- ★ First treatment to target reduction of alcohol consumption
  - ★ More than 50% reduction of alcohol consumption observed in studies
  - ★ Effect seen within one month of treatment and maintained after 12 months
  - ★ Safe and well tolerated
  
- ★ Convenient treatment regime
  - ★ Tablet taken as needed
  - ★ No need for extensive counseling program

## Efficacy shown in published Finnish phase III study



Significant change in HDD vs placebo,  $p = 0.0065$ , OC analysis; source: results from 28-week study (N=403); published in Alcohol Clin Exp Res, Vol 31, No 7, 2007

Heavy drinking days defined as the consumption of 5 or more drinks per day for men, and 4 or more for women.

## 2011 financial guidance adjusted

- ★ Revenue and EBITDA now expected to be in the high end of the guidance range
- ★ Write offs related to reduction in R&D of DKK 300-400 million now included in guidance

### 2011-2014 guidance

	Reported 2010	Guidance 2011	Floor guidance			
			2011e	2012e	2013e	2014e
DKK						
Revenue	14,765m	15.3-15.8bn	>14.5bn	>14bn	>14bn	>14bn
SG&A ratio	36.6%		36-37%	37-40%	37-40%	37-40%
R&D ratio	20.6%		~20%	~20%	~20%	~20%
EBITDA	4,393m	4.3-4.6bn	-	-	-	-
EBIT	3,357m	3.3-3.6bn	>3bn	>2bn	>2bn	>2bn
Net profit	2,466m	2.3-2.6bn	-	-	-	-

# Key priorities for 2011

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## Operations

- ★ Continue the roll out of **Sycrest**<sup>®</sup>
- ★ Approval and preparation for launch of **Cephalon** products
- ★ Preparations for successful launch of **nalmefene** and **Onfi**<sup>™</sup>
- ★ Continue expansion in **China**

## Pipeline

- ★ **Onfi**<sup>™</sup> (clobazam) FDA approval – Action Day in Q4
- ★ Ensure optimal execution of the phase III studies with **Lu AA21004**
- ★ Initiation of the registration process for **nalmefene**

## Sum-up

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- ★ Solid first half of the year
- ★ Lundbeck is increasingly diversified
  - ★ More products on the market
  - ★ More balanced geographic distribution
  - ★ More projects in development
- ★ Staying highly profitable during transition period
  - ★ Positive cash flow
  - ★ Continuing dividend policy
- ★ Return to growth from 2015



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