

H. LUNDBECK A/S

# Investor Presentation

## UBS Life Sciences Conference 2011

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?

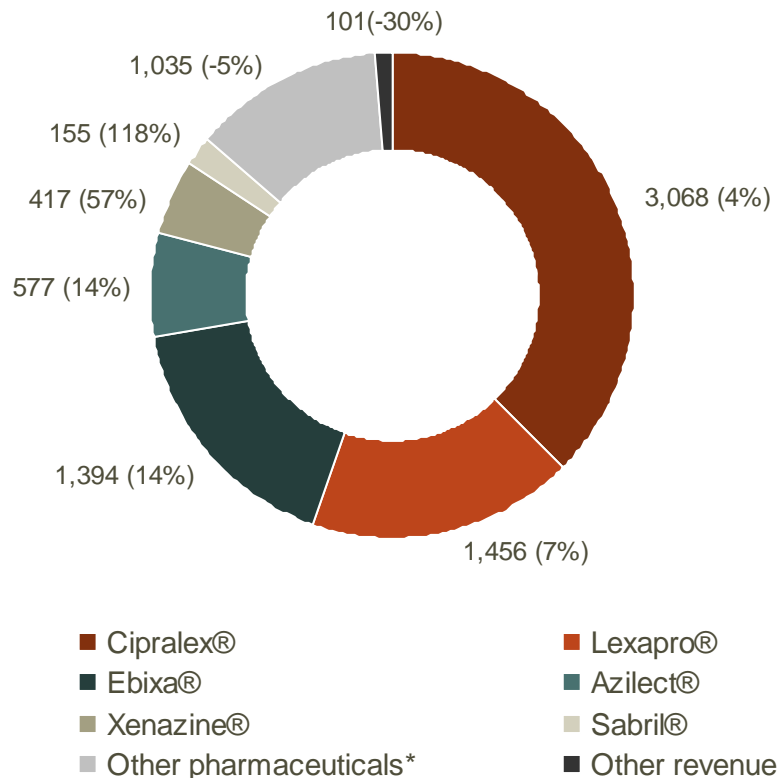
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- ★ Well-established track-record for innovation and commercialisation in CNS
- ★ Clear therapeutic focus on selected segments
- ★ Substantial unmet medical needs in CNS
- ★ Brand leadership and strong core business support growth opportunities
- ★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



# H1 2011 - commercial review

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



### Cipralex®/Lexapro®

- ★ Cipralex® withdrawn in Germany (public market)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

# 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

# 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

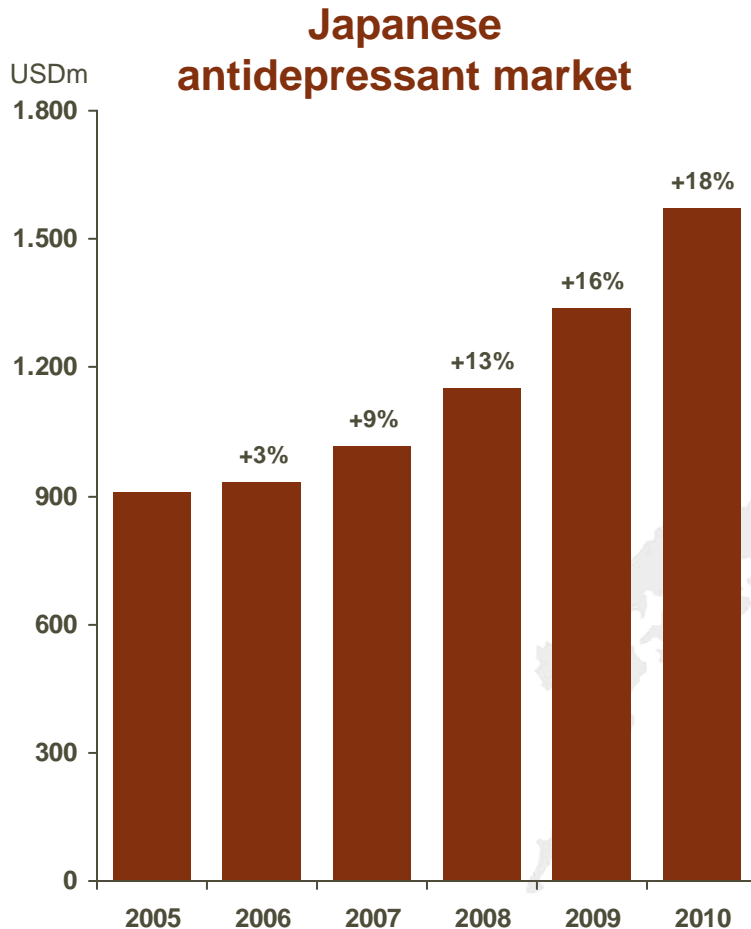
- ★ Positive impact from new co-promotion agreement related to Lexapro® in China
- ★ Azilect® in Asia represents additional opportunity

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



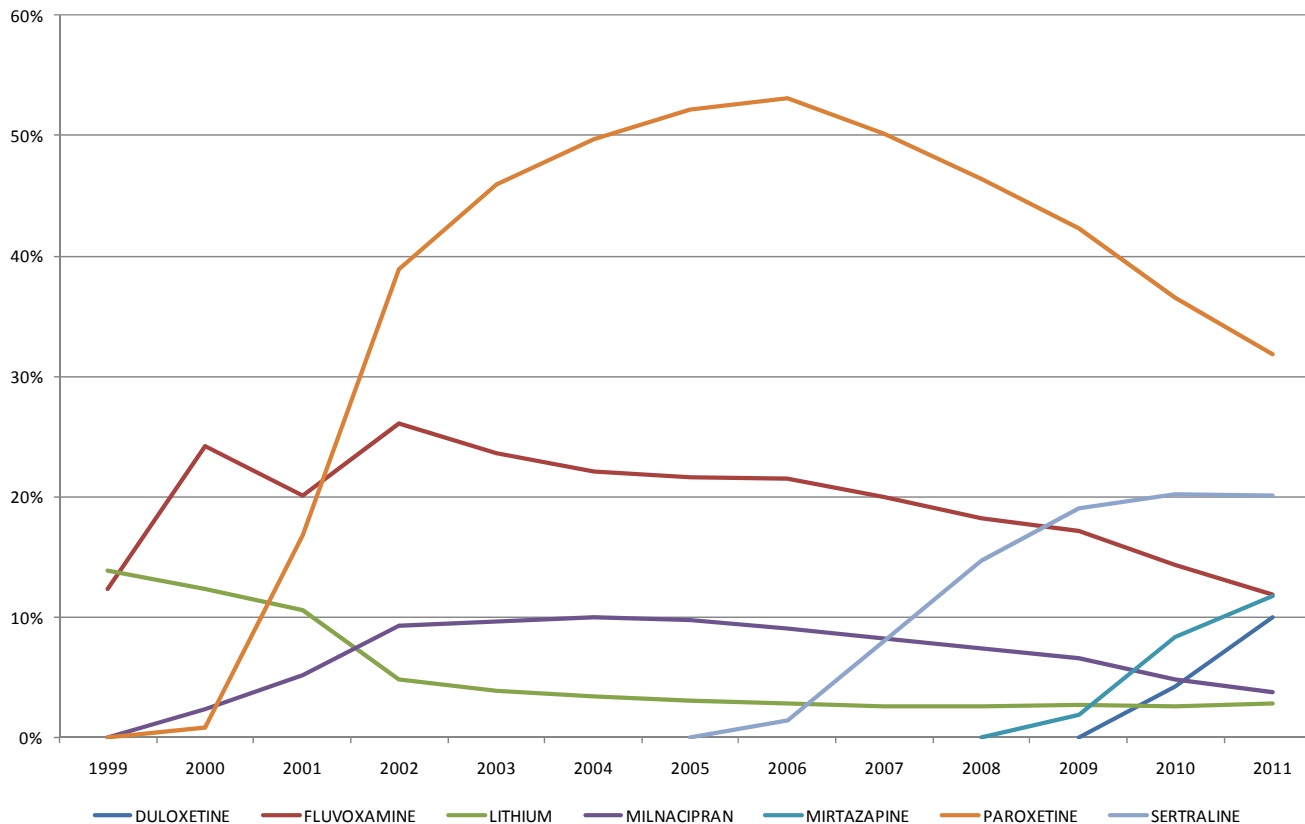
- ★ Launched in August 2011
- ★ Lexapro<sup>®</sup> in strong position to become no. 1 brand in the market
- ★ Mochida has marketing rights in Japan, in co-promotion with Mitsubishi Tanabe Pharmaceuticals
- ★ NHI Drug Price: JPY 212.00 per tablet
- ★ Mochida and Mitsubishi Tanabe Pharma estimate that sales amounts of Lexapro<sup>®</sup> are JPY 3<sup>1)</sup> billion for the first year of the launch, and...
- ★ ...peak sales of JPY 33.8<sup>2)</sup> billion, in total



1) Approx. USD 40m; 2) Approx. USD 440m

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

## Japanese antidepressant market shares (value)\*



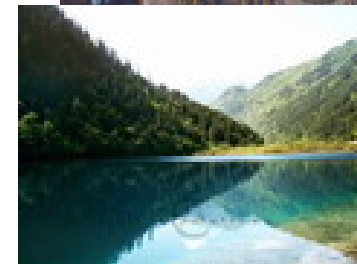
\* Paroxetine and sertraline dominates the market

\* 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



# The Cephalon portfolio represents new growth opportunities in Canada and Latin America

- ★ The Cephalon products will significantly strengthen our position in Canada and Latin America while leveraging existing sales and marketing capabilities
- ★ Treanda<sup>®</sup> and Nuvigil<sup>®</sup> in particular represent attractive product opportunities adding significant sales in the 2012+ timeframe
- ★ Well known products already launched in the US and/or Europe

Product	Region
Provigil <sup>®</sup> (modafinil), Nuvigil <sup>®</sup> (armodafinil)	Canada (Nuvigil <sup>®</sup> only) and Latin America
Treanda <sup>®</sup> (bendamustine HCl)	Canada
Fentora <sup>®</sup> (fentanyl buccal tablet)	Canada and Latin America
Trisenox <sup>®</sup> (arsenic trioxide)	Canada
Myocet <sup>®</sup> (liposomal- doxorubicin) <sup>1)</sup>	Latin America

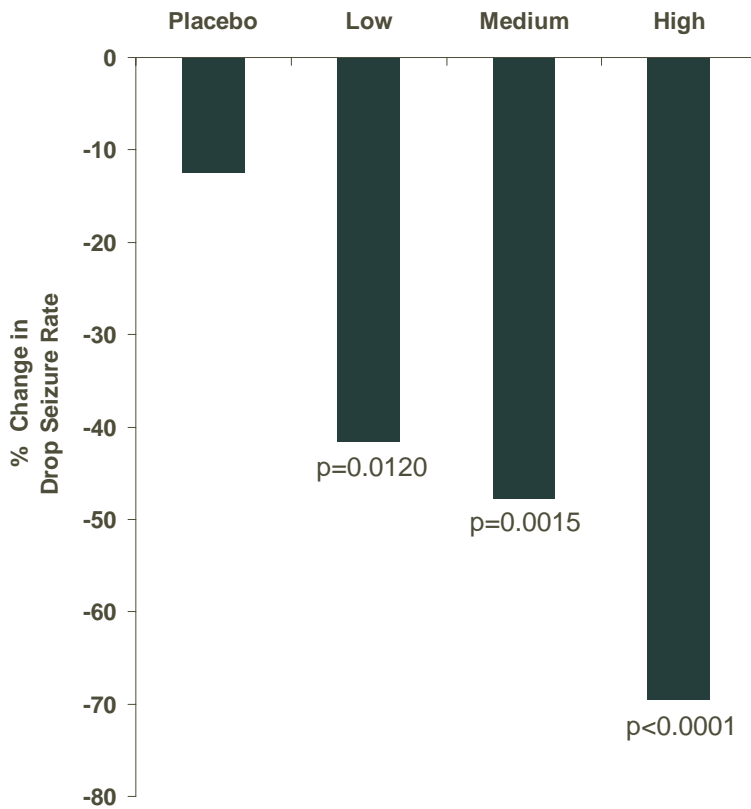
1) Myocet<sup>®</sup> will be included in the agreement at a later stage

# 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



## 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

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

# Current treatment of alcohol dependence – time for a treatment paradigm shift?

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## Today's Abstinence Concept

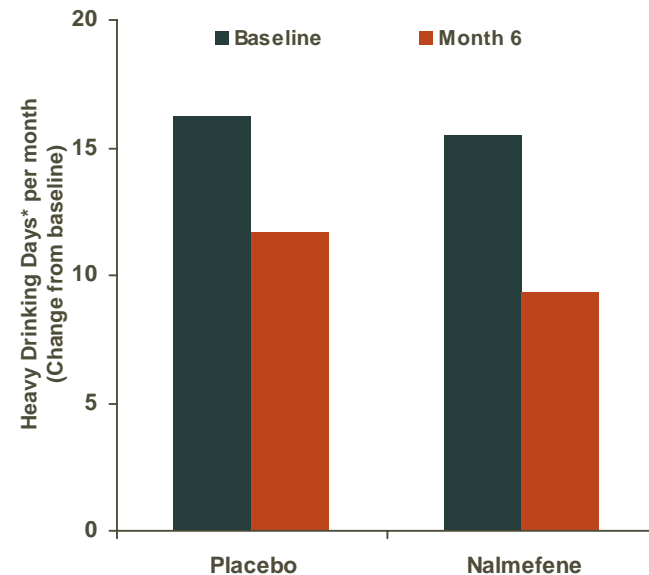
- ★ Currently approved therapies have been developed to target abstinence as the only treatment goal
- ★ For many patients, abstinence is an unacceptable treatment goal
- ★ Alcohol dependence remains a highly stigmatized, under-diagnosed and undertreated disease
  - ★ Market is significantly underdeveloped and under-commercialized
  - ★ Clear unmet medical need for effective treatment and integration of alcohol treatment into primary care



# 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.



# Lu AA21004 - Why does society need a new antidepressant?

## The need for new anti-depressants is there:

- ★ Prevalent as ever
- ★ High level of non- and insufficient response to first-line treatments
- ★ Disorder driving suffering and social issues both for individuals and relatives
- ★ High mortality
- ★ Long-term outcomes still not satisfactory



## Willingness to prescribe/pay:

- ★ New MoA gives promise
- ★ Important to provide clear benefits compared to standard care
- ★ Clinical benefits that translate into e.g.:
  - ★ Increased productivity
  - ★ Decreased sick-leaves
  - ★ Decreased hospitalisations
  - ★ Reduced relapses



## Lu AA21004 - a solution?

- ★ Unique pharmacological profile
- ★ Effects on multiple neurotransmitter systems
- ★ Potential therapeutic dose range of 5-20 mg (QID)
- ★ Positive safety and tolerability profile

Strong partnership with **Takeda**

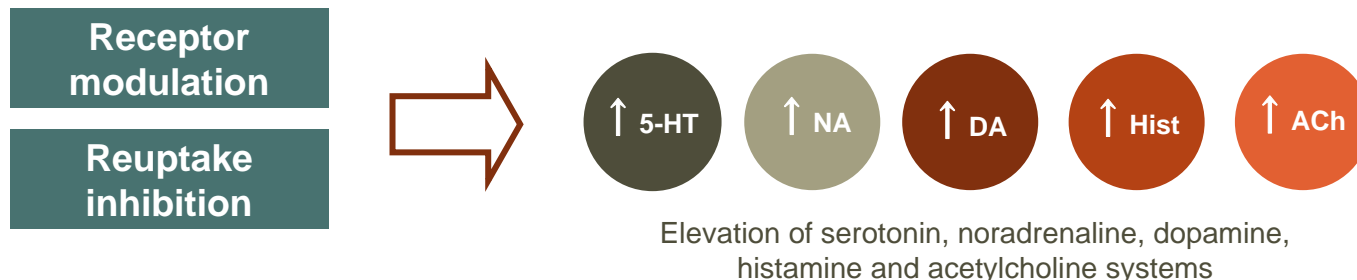
# Lu AA21004 – a unique pharmacological profile

## 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

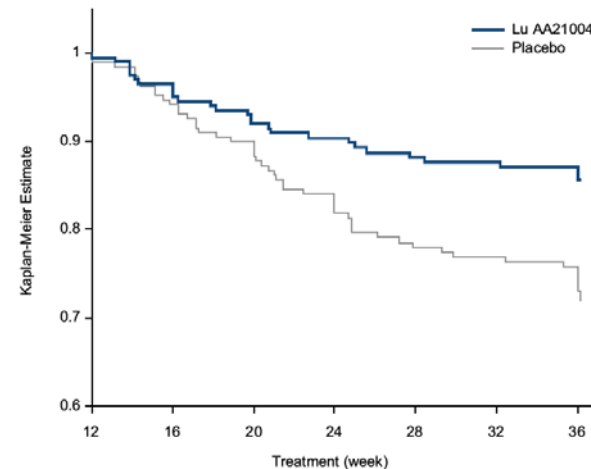
- ★ More than 2,000 patients with moderate to severe depression
- ★ Doses are 10, 15 and 20 mg
- ★ Additional profiling studies ongoing
  - ★ Effect of Lu AA21004 vs escitalopram on sexual functioning in people with well-treated MDD
    - ★ 440 patients
    - ★ 10-20mg
  - ★ Efficacy study of Lu AA21004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



# Lu AA21004 data presented at APA 2011

- ★ Four phase III studies presented at APA 2011 in May
- ★ Two European studies showed strong efficacy
- ★ All studies confirmed the positive safety profile of Lu AA21004
- ★ Timeline for NDA and MAA submission in 2012 on track

## Analysis of relapse over 24 weeks after 12-weeks open label treatment with Lu AA21004



Source: Boulenger, J. et al, relapse study, 400 patients. (APA 2011 poster)

## Adverse events occurring in ≥ 5% in any treatment group

Adverse event	Placebo	Lu AA21004		
		1mg	5mg	10mg
Nausea	4.3%	7.9%	15.7%	12.9%
Headache	7.9%	6.4%	11.4%	5.0%
Nasopharyngitis*	5.7%	3.6%	5.0%	2.2%
Dizziness	2.1%	0.7%	3.6%	6.5%

\* common cold

Source: Henigsberg, N. et al, 8 week study, 560 patients. (APA 2011 poster)

# Financials

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# Strong cash flow generation in Q2 2011

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## Key cash flow figures

DKKm	Q2 2011	Q2 2010
Cash flow from operating activities	1,257	1,245
Cash and securities at end of the period	3,550	1,976
<b>Interest-bearing net cash</b>	<b>1,632</b>	<b>13</b>

- ★ Continued strong cash flow generation in the quarter
- ★ Operating activities generated a cash flow of DKK 1,257 million
- ★ Cash flow from financing activities was an outflow of DKK 737 million mainly due to dividend pay
- ★ Interest-bearing net cash of DKK 1,632 million at the end of the quarter
  - ★ Now positive compared to same quarter last year

## 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







# For more information please contact Investor Relations

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# Clinical programme using Lu AA21004 in MDD

Clinicaltrials.gov identifier	Estimated enrolment	Study start	Intervention
NCT01140906	600 (non-US)	May 2010	8 wks. Lu AA21004 (15+20mg); duloxetine (60mg); Placebo
NCT01255787	615 (non-US)	November 2010	8 wks. Lu AA21004 (5+10+20mg); placebo
NCT01323478	300 (non-US)	April 2011	52 wks extension. Lu AA21004 (15+20mg)
NCT01163266	450 (US)	July 2010	8 wks. Lu AA21004 (10+20mg); placebo
NCT01153009	600 (US)	June 2010	8 wks. Lu AA21004 (15+20mg); duloxetine (60mg); placebo
NCT01179516	450 (US)	August 2010	8 wks. Lu AA21004 (10+20mg); placebo
NCT01152996	1,000 (US)	September 2010	52 wks extension. Lu AA21004 (15+20mg) –by invitation only
NCT01355081	360 (Japan)	May 2011	8 wks. Lu AA21004 (5+10mg); placebo
NCT01364649 (sexual funct.)	440 (US+Canada)	May 2011	Lu AA21004 (10-20mg); escitalopram (10-20mg)
NCT00635219 (*)	766 (non-US)	April 2009	8 wks. Lu AA21004 (2.5+5+10mg); duloxetine (60mg); placebo
NCT00735709 (*)	560 (non-US)	August 2008	8 wks. Lu AA21004 (1+5+10mg); placebo
NCT00672620	611 (US)	April 2008	8 wks. Lu AA21004 (2.5+5 mg), duloxetine (60mg); placebo
NCT00672958 (*)	600 (US)	April 2008	6 wks. Lu AA21004 (5mg); placebo
NCT00694304 (safety)	536 (non-US)	May 2008	52 wks. Lu AA21004 (2.5-10mg flexible dose)
NCT00596817 (relapse) (*)	400 (non-US)	December 2007	<76 wks. Lu AA21004 (5+10mg); placebo
NCT00707980	836 (non-US)	June 2008	<52 wks. Lu AA21004 (2.5+5+10mg)
NCT00811252 (elderly)	453 (US)	January 2009	8 wks. Lu AA21004 (5mg); duloxetine (60mg); placebo
NCT00761306 (safety)	74 (non-US)	June 2007	52 wks. Lu AA21004 (5+10mg)
NCT00839423 (phase II) (*)	429 (non-US)	August 2006	8wks. Lu AA21004 (5+10mg); venlafaxine XL (225mg); placebo