

H. LUNDBECK A/S

8 August 2012 - 2PM CET



# Teleconference Second quarter results 2012



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# Strong operating cash flow post Lexapro patent expiry

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- ★ Flat revenue growth, excluding Lexapro (US), due to pricing and generics
- ★ US revenue excl. Lexapro increases 20% and International Markets increase 8% for the quarter
- ★ Cash flows from operation was DKK 593 million for the quarter
- ★ The 2012 range of the financial guidance maintained
  
- ★ Lundbeck's portfolio of new products\* increased 66% for the quarter and now constitutes 14% of revenue vs. 7% in Q2 2011
  - ★ Lexapro has a market share of 5% in Japan in July
  - ★ Feedback regarding Onfi is positive and sales now exceed DKK 100 million (YTD)
  
- ★ Pipeline progressions supports launch of up to four new products over the next 12-18 months
  - ★ Results from the US vortioxetine trials support filing in the second half of 2012 in EU, Canada and the US
  - ★ No issues or concerns regarding the efficacy, safety, tolerability, or labeling of aripiprazole depot raised by FDA in Complete Response Letter

# Europe: Increasingly challenging environment

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- ★ Challenging environment a result of economic crisis, particularly in the EU
- ★ Significant impact from healthcare reforms, price cuts, etc. on revenue since 2008
- ★ Healthcare reforms/price cuts
  - ★ Sales caps in some countries
  - ★ Several price cuts in the past 4-5 years (France, Italy, Spain, Turkey, etc.)
- ★ Delay in price/reimbursement (Sycrest)



# Restructuring of the commercial organization in Europe

- ★ Maintain cost control and build a flexible commercial infrastructure
- ★ Mitigate pressure from healthcare reforms, generic competition, pricing and reimbursement
- ★ Successful transition of product portfolio in Europe
- ★ Maintain position as a leading CNS specialist

## New sales structure



# Very strong portfolio of potential product launches

## 2011

Sycrest/Saphris- launched  
Lexapro (Japan) – launched

## 2012

Onfi (US) - launched  
Treanda (Canada)

## 2013

Vortioxetine  
Selincro  
Aripiprazole depot (US)  
Other Cephalon products (Canada, Latin America)

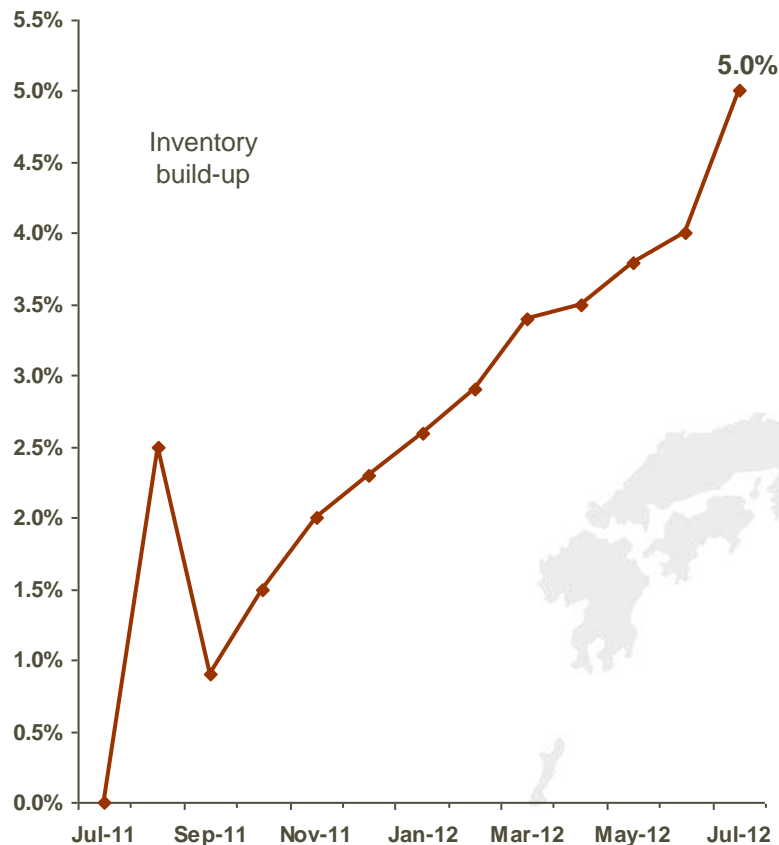
## 2014+

Aripiprazole depot (EU)  
Azilect (Asia)  
Desmoteplase  
OPC-34712  
Zicronapine  
Tedatioxetine  
Lu AE58054



# Solid uptake of Lexapro in Japan

**Lexapro market share  
Japan, value**



- ★ Lexapro in strong position to become no. 1 brand in the market
- ★ Mochida has marketing rights in Japan, in co-promotion with Mitsubishi Tanabe Pharmaceuticals
- ★ Mochida and Mitsubishi Tanabe estimate peak sales of JPY 33.8 billion (or ~ DKK 2.6 billion)
- ★ Market exclusivity until 2019

# Lundbeck invests to grow – a solid late-stage development portfolio

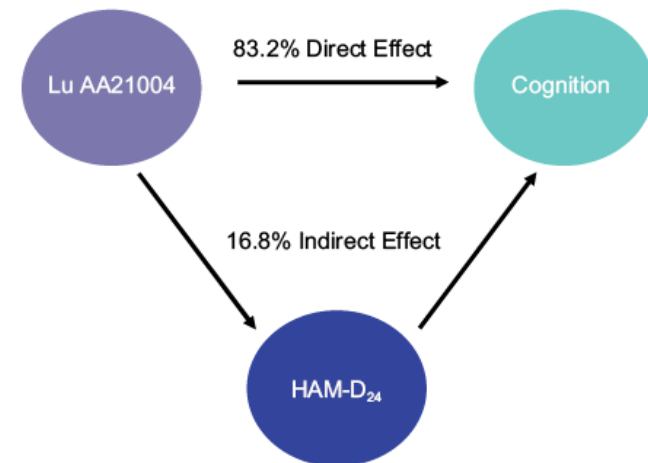
		Phase II	Phase III	Registration app.	
BRAIN DISEASES	PSYCHIATRY	MOOD DISORDERS	Tedatioxetine (Lu AA24530)	Vortioxetine (Lu AA21004)	
		PSYCHOSIS		Aripiprazole depot (EU)	Aripiprazole depot (US)
				Zicronapine	
		ALCOHOL DEPENDENCE			Selincro (nalmefene)
	DEPRESSION/SCHIZOPHRENIA		OPC-34712		
	NEUROLOGY	ALZHEIMER'S DISEASE	Lu AE58054		
		EPILEPSY		IV Carbamazepine	
		OTHER		Desmoteplase (stroke)	



# Statistically significant clinical phase III results of vortioxetine

- ★ High dosage studies demonstrate the efficacy of vortioxetine compared to placebo in the treatment of MDD seen in several previous studies
- ★ Positive top-line results from the three completed phase III clinical studies were achieved using dosages from 10 mg to 20 mg
- ★ Efficacy of vortioxetine is further confirmed in a positive trial in an elderly population, and in a long-term relapse-prevention study in MDD
- ★ NDA and MAA expected to be submitted in US, EU and Canada in H2 2012

## Vortioxetine's treatment effect on cognitive performance\*



# Lu AE58054 meets primary endpoint in large clinical proof of concept study in Alzheimer's

## Positive phase II study

- ★ Statistical significant improvement in cognition (ADAS-cog) in Alzheimer's patients with Lu AE58054 as add-on to donepezil
- ★ Lu AE58054 was well tolerated
- ★ Pivotal programme in planning

## Study design

- ★ The primary objective was to explore the effect on cognitive performance after 24 weeks of treatment
  - ★ Placebo controlled study with 278 patients with moderate Alzheimer's disease
  - ★ Add-on to donepezil
  - ★ Fixed dose

## Lu AE58054 - profile

- ★ Lu AE58054 is a potent, selective pro-cognitive 5-HT<sub>6</sub> antagonist
- ★ A number of early trials have demonstrated that a 5-HT<sub>6</sub>-receptor antagonist could offer potential in the treatment of disorders such as Alzheimer's disease
  - ★ Is known to enhance cholinergic and glutaminergic neuronal function
- ★ Is generally well tolerated with a benign side-effect profile

# Aripiprazole depot - a treatment aimed at improving compliance

## The US

- ★ Complete Response Letter received from the FDA in July
- ★ No additional clinical data requested
- ★ No issues or concerns regarding the efficacy, safety, tolerability, or labeling raised by FDA
- ★ Only issue cited was related to deficiencies found at a third party supplier

## Europe

- ★ Submission of MAA in Europe is on track and expected around year-end 2012

Figure 2. Time from randomization to impending relapse during double-blind treatment (final analysis)

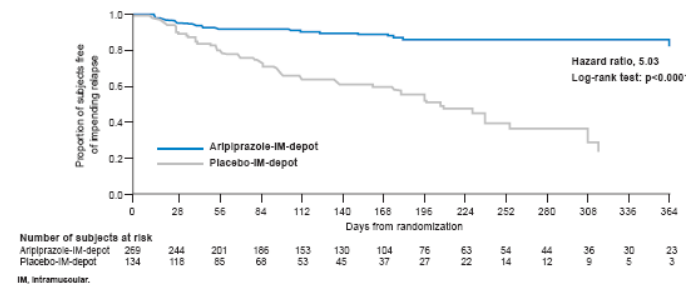
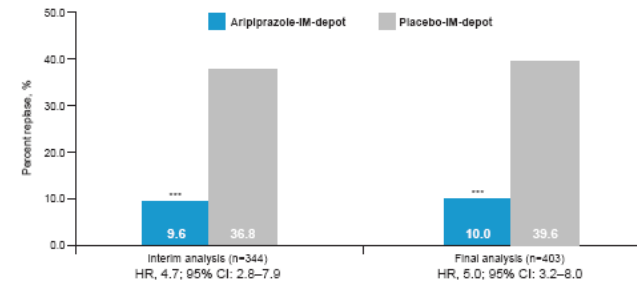
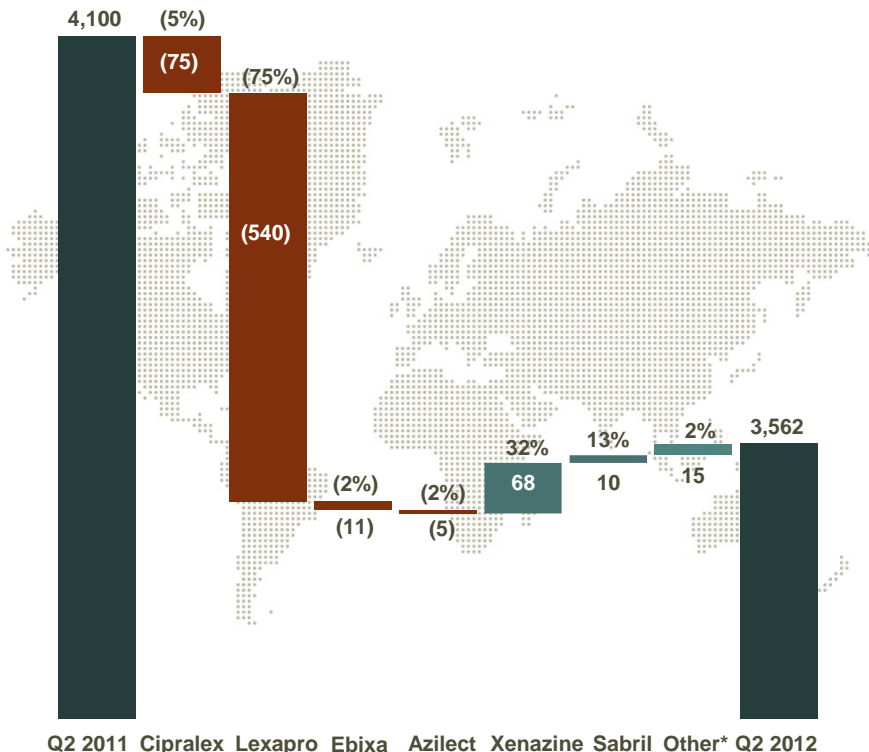


Figure 3. Proportion of subjects meeting impending-relapse criteria in Phase 4



# New products now 14% of revenue

## Revenue development Q2 2012 (DKKm)



- ★ Excl. Lexapro (US) revenue was DKK 3,387 million and unchanged compared to Q2 2011
- ★ New products increased 66% and now constitutes 14% of revenue vs. 7% in Q2 2011
- ★ Europe impacted by generic competition and a challenging economic environment
- ★ US revenue excl. Lexapro increased 20% driven by Onfi, Sabril and Xenazine
- ★ International Markets grew 8%

\*Other includes Other pharmaceuticals and Other revenue

# Financial figures Q2 2012

## Income statement

DKKm	Q2 2012	Q2 2011	Growth
Revenue	3,562	4,100	(13%)
Cost of sales	806	726	11%
- as % of revenue	23%	18%	
SG&A costs	2,190	1,580	39%
- as % of revenue	61%	38%	
R&D costs	684	692	(1%)
- as % of revenue	19%	17%	
Total costs	3,680	2,998	23%
- as % of revenue	103%	73%	
EBIT	(118)	1,102	(111%)
- margin	(3.3%)	26.9%	
EBITDA	119	1,250	(90%)
- margin	3.4%	30.5%	
Net profit	(85)	797	(111%)

- ★ Excl. restructuring costs, total costs increased 6%
- ★ Cost of sales increased due to net gain of DKK 95m in Q2 2011 related to the sale of Seal Sands
- ★ SG&A costs were impacted by a provision of DKK 500m concerning the restructuring plan
- ★ EBIT excl. restructuring costs DKK 382 million for the quarter

# Q2 2012 – Continued satisfactory cash generation

## Key cash flow figures

DKKm	Q2 2012	Q2 2011
Cash flows from operating activities	593	1,257
Cash and securities at 30 June	2,694	3,550
<b>Interest-bearing net cash and cash equivalents</b>	<b>786</b>	<b>1,632</b>

- ★ Cash flow from investing activities was a net outflow of DKK 771m related to milestone payment to Otsuka
- ★ Cash flow decreased due to lower profits
- ★ The decrease in cash is due to the strategic collaboration with Otsuka

# Financial guidance

## 2012 financial guidance

	Reported 2011	Guidance 2012
DKK		
Revenue	16,007m	14.5-15.2bn
EBITDA	4,628m	3.0-3.5bn
EBIT	3,393m	2.0-2.5bn

- ★ The range for the financial guidance maintained excluding costs related to the restructuring plans announced in June 2012
- ★ A provision of DKK 500 million concerning the restructuring was included in the second quarter results
- ★ Revenue likely to be in the lower end of the guided range, due to the increased pressure from health care reforms



## Expected main events next 12 months

### H2 2012

- Lundbeck to submit MAA for vortioxetine in Europe and Canada
- Lundbeck and Takeda to submit NDA for vortioxetine in the US
- Feedback from CHMP on Selincro
- Approval of Treanda by Health Canada
- Submission of MAA for aripiprazole depot (EU) (around year-end)

### H1 2013

- Approval of Selincro by EU Commission
- Presentation of vortioxetine data at APA 2012 on 18-22 May, San Francisco

**Thank you...**

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