

H. LUNDBECK A/S

7 November 2012



# Teleconference Third quarter results 2012



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# New Products doubled; pipeline supports three additional launches in 2013

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- ★ Revenue was DKK 3,563 million (+2%) for the quarter, excluding Lexapro (US)
- ★ Profit from operations was DKK 661 million for the quarter
- ★ On track to meet financial expectations for 2012
  
- ★ New Products increased 100% for the quarter and now represent 17% of total revenue
  - ★ Lexapro (Japan): DKK 133 million (9M 2012)
  - ★ Onfi: DKK 174 million (9M 2012)
  - ★ Treanda launched in Canada
  
- ★ Pipeline progressions support launch of up to three new products in 2013
  - ★ Vortioxetine filed in the US, Europe and Canada
  - ★ NDA for Abilify Once-Monthly resubmitted to the FDA
  - ★ CHMP feedback for Selincro expected in Q4 2012

# 2012 – an eventful year for Lundbeck

## Commercial operations

- Onfi launched in the US
- Azilect launched in Australia, Hong Kong and Thailand
- Restructuring of European commercial structure
- Treanda approved and launched in Canada

## Regulatory actions

- MAA and NDA for vortioxetine submitted to the EMA and the FDA
- Complete response letter received on Abilify Once-Monthly, NDA resubmitted

## Trial initiations

- Three studies with vortioxetine initiated (cognition, vs. agomelatine, in Asian patients)
- Phase III studies initiated with brexpiprazole in maintenance treatment in schizophrenia
- Two phase III studies with Abilify Once-Monthly initiated (bipolar disorder, acute schizophrenia)

## Data disclosures

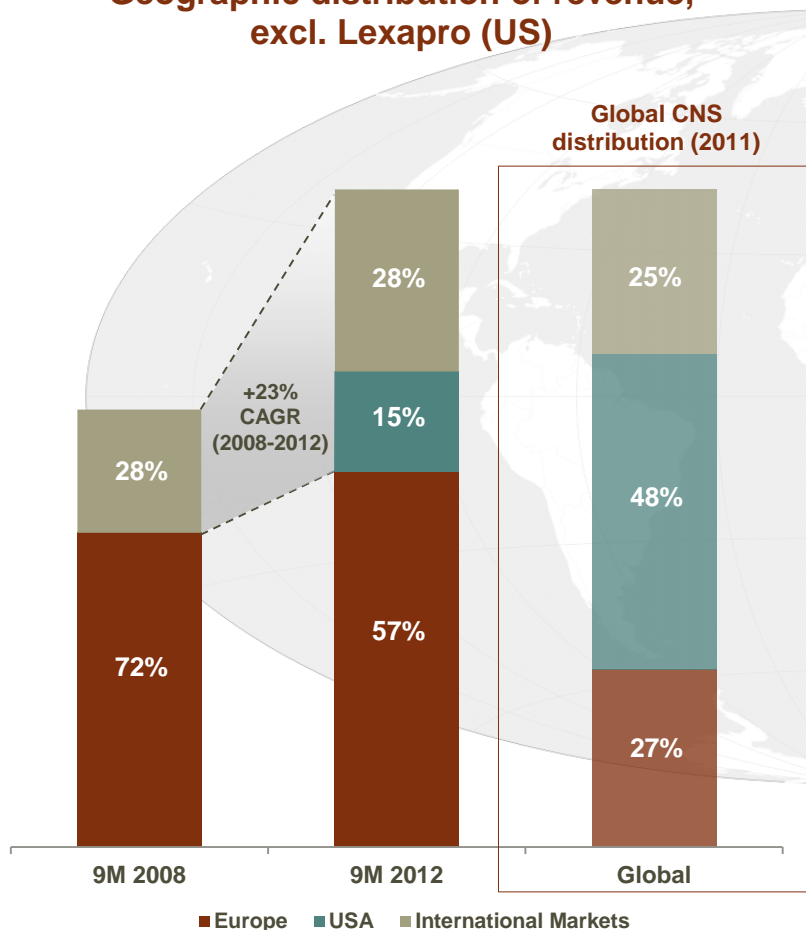
- Positive headlines from “high dose” studies with vortioxetine
- Positive headlines for phase II study with Alzheimer’s agent, Lu AE58054
- Results from phase III trials with Selincro presented at EPA, RSA and ECNP
- Results from phase III trials with Abilify Once-Monthly and vortioxetine presented at APA

## Other important activities

- Remaining rights to desmoteplase acquired
- License agreement regarding Selincro outside of Europe amended

# Lundbeck has a substantial unrealised potential outside Europe

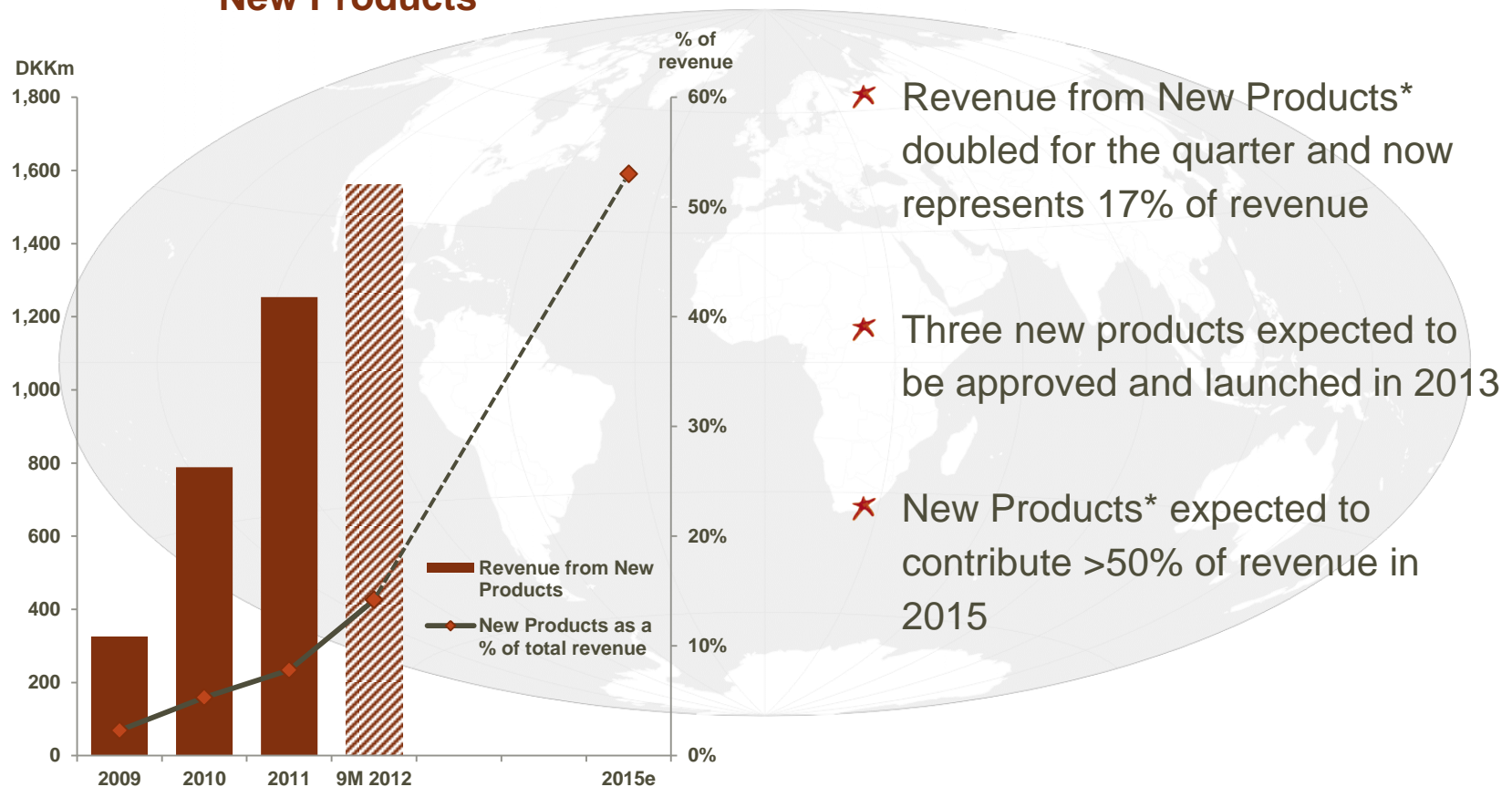
Geographic distribution of revenue, excl. Lexapro (US)



- ★ Significant growth potential outside of Europe
- ★ Geographic diversification on track
  - ★ 43% of revenue now generated outside of Europe
- ★ 9M 2012 revenue from the US (excl. Lexapro) and International Markets increased 28% and 8% y/y respectively

# New Products revenue doubled

## New Products\*



- ★ Revenue from New Products\* doubled for the quarter and now represents 17% of revenue
- ★ Three new products expected to be approved and launched in 2013
- ★ New Products\* expected to contribute >50% of revenue in 2015

\*New Products: Xenazine, Sabril, Sycrest, Lexapro (Japan), Onfi and Treanda

# New Products headlines



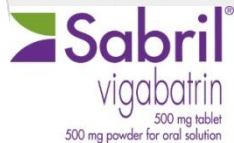
- ★ Xenazine revenue for 9M 2012 was DKK 875 million (+43%)
- ★ The encouraging progress for Xenazine now indicates peak sales exceeding DKK 1.5 billion



- ★ Lexapro in Japan generated revenue of DKK 133 million for 9M 2012
- ★ Lexapro now has a market share of 6.1% in Japan



- ★ Onfi generated revenue of DKK 174 million for 9M 2012
- ★ On track to meet peak sales of more than DKK 1 billion



- ★ Sabril revenue for 9M 2012 was DKK 298 million (+28%)
- ★ More than 1,700 patients now in treatment with Sabril



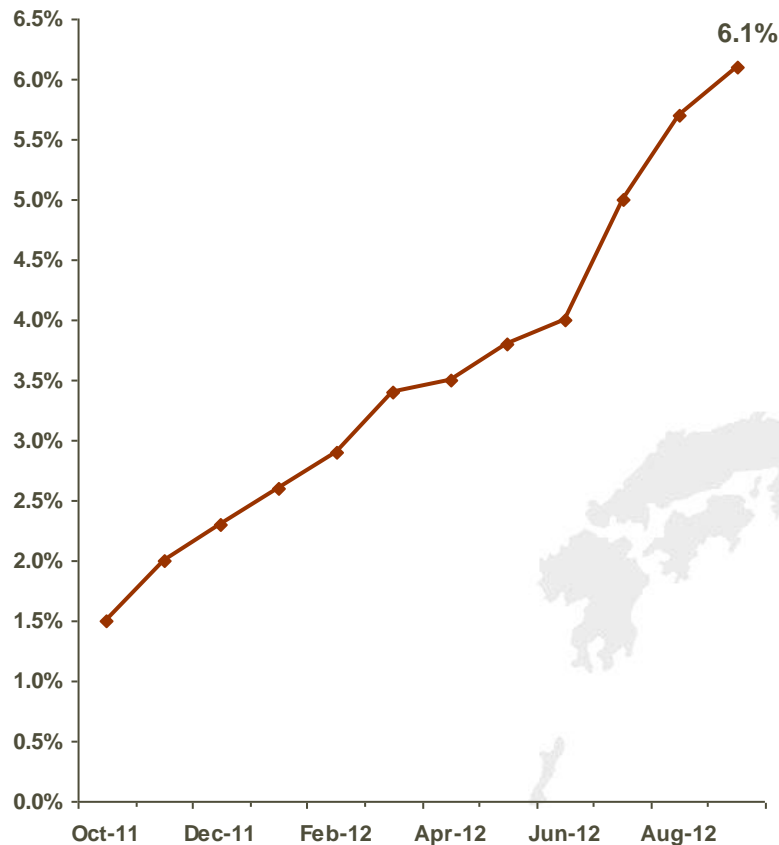
- ★ Treanda launched in Canada in September
- ★ Expected to reach up to USD 100 million in annual sales



- ★ Sycrest generated revenue of more than DKK 75 million for 9M 2012

# Solid uptake of Lexapro in Japan

**Lexapro market share  
Japan, value**



- ★ Lexapro in Japan generated revenue of DKK 133 million for the first nine months of 2012
- ★ Marketing limitations lifted in August
- ★ Phase III studies in social anxiety disorder (SAD) on-going in Japan (555 pts)



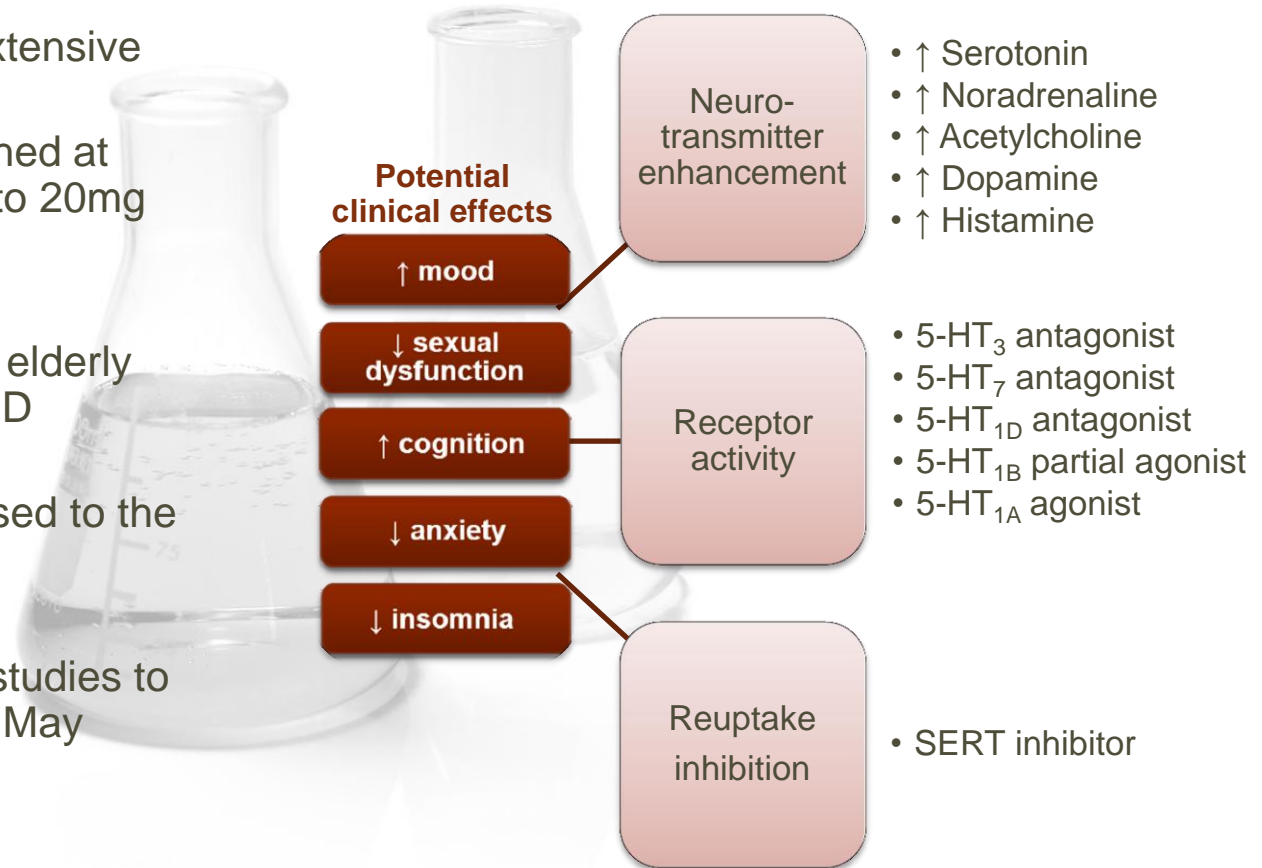
# Lundbeck invests to grow – a solid late-stage development portfolio

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

# Regulatory process initiated for vortioxetine in major regions

## Vortioxetine's multimodal profile

- ★ Filing supported by extensive data package
  - ★ Efficacy established at dosages from 5 to 20mg
  - ★ Positive relapse prevention study
  - ★ Positive study in elderly patients with MDD
  - ★ More than 7,500 individuals exposed to the drug
  
- ★ Data from high dose studies to be presented at APA, May 2013

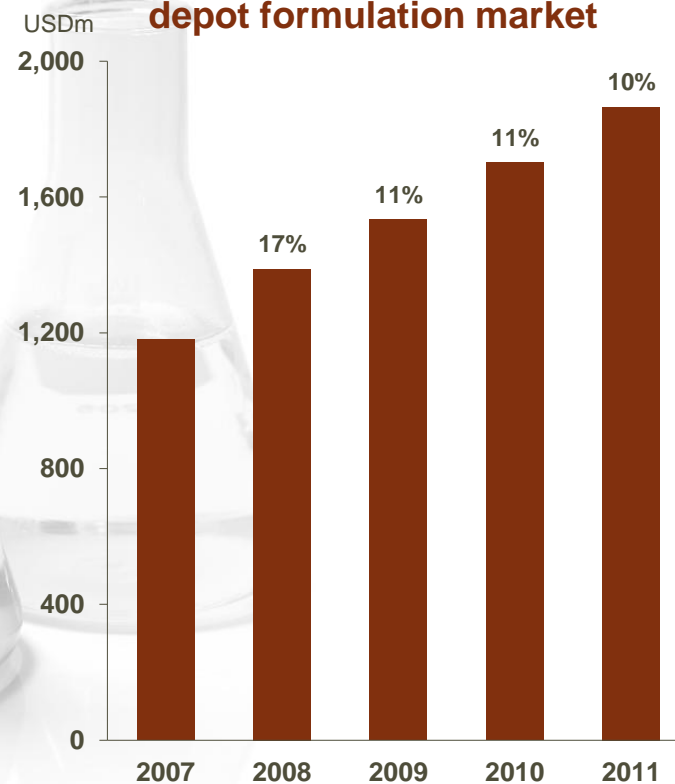


# Abilify Once-Monthly - a treatment aimed at improving compliance

## Abilify Once-Monthly status

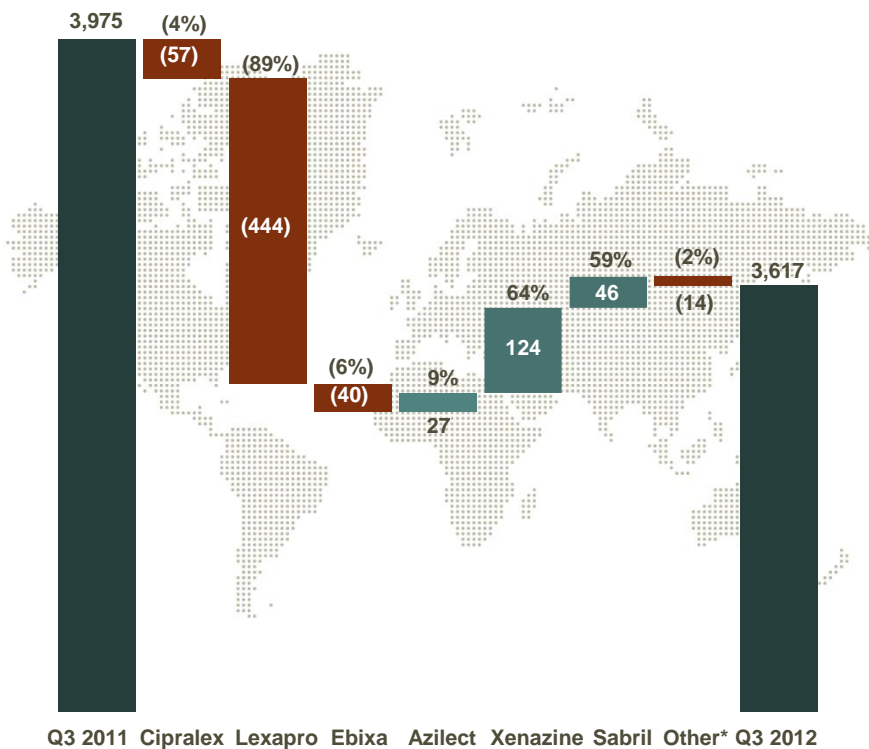
- ★ NDA resubmitted to the FDA in September
- ★ Submission of MAA in Europe is on track and expected around year-end 2012
- ★ Phase III studies initiated in acute schizophrenia (310 pts) and bipolar I disorder (600 pts)

Global anti-psychotic depot formulation market



# New Products doubled for the quarter

## Revenue development Q3 2012 (DKKm)



- ★ Excl. Lexapro (US) revenue was DKK 3,563 million, an increase of 2% compared to Q3 2011
- ★ New Products increased 100% and now constitutes 17% of revenue vs. 8% in Q3 2011
- ★ US revenue excl. Lexapro increased 44% driven by Onfi, Sabril and Xenazine
- ★ Europe decreased 2% impacted by generic competition and a challenging economic environment
- ★ International Markets was unchanged for the quarter

\*Other includes Other pharmaceuticals and Other revenue

# Financial figures Q3 2012

## Income statement

DKKm	Q3 2012	Q3 2011	Growth
Revenue	3,617	3,975	(9%)
Cost of sales	873	790	10%
- as % of revenue	24%	20%	
SG&A costs	1,399	1,423	(2%)
- as % of revenue	39%	35%	
R&D costs	684	1,102	(38%)
- as % of revenue	19%	28%	
Total costs	2,956	3,315	(11%)
- as % of revenue	82%	83%	
EBIT	661	660	0%
- margin	18.2%	16.6%	
EBITDA	846	1,260	(33%)
- margin	23.4%	31.7%	
Net profit	426	352	21%

- ★ Total costs increased 2% for the quarter, excluding restructuring costs in R&D booked in Q3 2011
- ★ Cost of sales increased 10% due to change in product mix
- ★ SG&A costs impacted by high launch costs
- ★ R&D was unchanged compared to Q3 2011, excl. R&D restructuring costs
- ★ Gain from Proximagen divesture included in EBIT

# Q3 2012 – Continued solid cash generation

## Key cash flow figures

DKKm	Q3 2012	Q3 2011
Cash flows from operating activities	541	1,303
Cash and securities at 30 September	3,249	4,685
<b>Interest-bearing net cash and cash equivalents</b>	<b>1,340</b>	<b>2,766</b>

- ★ Cash flow from operating activities decreased due to lower profits
- ★ Cash flow from investing activities was a net inflow of DKK 15 million impacted by the divestment of Proximagen
- ★ The decrease in cash compared to 2011 is due to the milestone payments related to the 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

- ★ Financial guidance maintained excluding restructuring costs as announced in June
- ★ Provision of DKK 500 million concerning the restructuring 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 2012-2013

### Q4 2012

- Feedback from CHMP on Selincro
- Submission of MAA for Abilify Once-Monthly (EU) (around year-end)
- FDA acceptance of NDA for vortioxetine
- Presentation of Abilify Once-Monthly data on ACNP

### H1 2013

- Approval of Abilify Once-Monthly in the US
- Approval of Selincro by EU Commission
- Presentation of vortioxetine data at APA 2013 on 18-22 May, San Francisco

### H2 2013

- Approval of vortioxetine in Europe and the US
- Headline conclusion on brexpiprazole phase III studies
- Headline conclusions on desmoteplase phase III study (DIAS 3)
- Approval of Abilify Once-Monthly (EU)
- Presentation of Lu AE58054 data at AAIC 2013 in July in Boston



## Conclusions

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- ★ Financial expectations for 2012 maintained
- ★ Strategic growth drivers on track
  - ★ Product diversification and geographic expansion progressing as planned
- ★ High investment levels in launch activities and R&D to continue
- ★ Solid news flow the next 12-15 months

**Thank you...**

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