# Lundbeck X

Financial report for the period 1 January to 30 June 2014

# Continued solid growth of 36% in New Products - now contributing 27% of revenue

# **HIGHLIGHTS**

- New Products on track and reached DKK 1,901 million in revenue driven by Abilify Maintena<sup>®</sup>, Onfi<sup>®</sup>, Treanda<sup>®</sup> and the recent launch of Brintellix<sup>®</sup>
- US revenue was DKK 1,626 million, an increase of 42% in local currency. Onfi, Sabril<sup>®</sup> and Xenazine<sup>®</sup> continue their solid momentum, increasing 93%, 32% and 17% respectively in local currency and together with the launch uptake from Brintellix and Abilify Maintena all contributing to the strong growth in the US
- Revenue from International Markets increased 10% in local currency, largely driven by markets such as Canada and China
- Brintellix demonstrated a good volume uptake and has reached more than 120,000 prescriptions since the US launch in January 2014
- The market access for Abilify Maintena in Europe is going well and the product has now been launched in Germany, UK and the Nordic countries
- Lundbeck has strengthened its very successful US neurology franchise by the inclusion of Northera<sup>TM</sup> approved for neurogenic orthostatic hypotension
- Significant new data strengthening the clinical profile on Brintellix. A third study on cognition was presented at
  the International College of Neuropsychopharmacology (CINP) World Congress, showing that Brintellix has a
  statistically significant improvement in the cognitive performance assessed by DSST versus placebo
- The US regulatory approval process for brexpiprazole for the treatment of schizophrenia, and as adjunctive therapy for the treatment of major depression, has been initiated
- The first of two phase III clinical studies (DIAS-3) in patients with acute ischaemic stroke did not meet the primary endpoint. However, when analyzing only the patients fulfilling protocol requirements desmoteplase showed an effect relative to placebo
- The financial guidance for 2014 is maintained

# In connection with the interim report, Lundbeck's President and CEO Ulf Wiinberg said:

"The first half of 2014 has shown good progress for Lundbeck, from a strategic, commercial and development point of view. We have reinforced our strategic position as a global player within brain diseases with the recent acquisition of Northera and the regulatory submission of brexpiprazole in the US. We are encouraged by the early launch uptake from our new products and look forward to the second half of 2014 where we will launch Northera in the US and Brintellix, Abilify Maintena and Selincro in some of our major markets."

DKK million	H1 2014	H1 2013	Growth
Core Revenue*	7,035	7,374	(5%)
Core EBIT*	1,168	1,487	(21%)
Core EPS*	3.55	5.75	(38%)
Core EBIT margin	17%	20%	
			(4004)
Reported Revenue	7,035	8,112	(13%)
Reported EBIT	843	1,020	(17%)
Reported EPS	2.42	2.88	(16%)
Reported EBIT margin	12%	13%	

<sup>\*</sup>For definition of the measures "Core Revenue", Core EBIT" and "Core EPS", see page 14 and reconciliation to reported, see page 22

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# FINANCIAL HIGHLIGHTS AND KEY FIGURES

	2014 Q2	2013 Q2	2014 H1	2013 H1	2013 FY
Financial highlights (DKK million)					
Core revenue	3,448	3,536	7,035	7,374	14,242
Reported revenue	3,448	3,536	7,035	8,112	15,258
Operating profit before depreciation and amortization (EBITDA)	540	10	1,364	1,776	2,861
Core profit from operations (core EBIT)	439	566	1,168	1,487	2,282
Reported profit from operations (EBIT)	274	(506)	843	1,020	1,599
Net financials	(34)	(44)	(51)	(46)	(127)
Profit before tax	240	(550)	792	974	1,472
Tax	96	(48)	317	409	617
Profit for the period	144	(502)	475	565	855
Equity	13,406	13,391	13,406	13,391	13,481
Assets	22,954	23,381	22,954	23,381	23,649
Cash flows from operating and investing activities	(2,565)	635	(2,802)	1,178	2,260
Investments in property, plant and equipment, gross	50	68	97	136	311
Key figures					
EBITDA margin (%) <sup>1</sup>	15.6	0.3	19.4	21.9	18.8
EBIT margin (%) <sup>1</sup>	8.0	(14.3)	12.0	12.6	10.5
Return on capital employed (%)	1.9	(3.4)	5.7	7.3	11.4
Research and development ratio (%)	19.4	20.3	18.1	17.0	18.8
Return on equity (%) <sup>1</sup>	1.1	(3.7)	3.5	4.2	6.4
Solvency ratio (%) <sup>1</sup>	58.4	57.3	58.4	57.3	57.0
Capital employed (DKK million)	15,564	15,282	15,564	15,282	15,641
Share data					
Number of shares for the calculation of EPS (millions)	196.1	196.1	196.1	196.1	196.1
Number of shares for the calculation of DEPS (millions)	196.3	196.2	196.3	196.1	196.2
Earnings per share (EPS) (DKK) <sup>1</sup>	0.73	(2.56)	2.42	2.88	4.36
Diluted earnings per share (DEPS) (DKK) <sup>1</sup>	0.73	(2.56)	2.42	2.88	4.36
Cash flow per share (DKK) <sup>1</sup>	2.33	6.86	1.57	10.06	19.16
Net asset value per share (DKK) <sup>1</sup>	68.33	68.24	68.33	68.24	68.66
Market capitalization (DKK million)	26,315	20,046	26,315	20,046	26,879
Share price end of period (DKK)	134.00	102.20	134.00	102.20	137.00
Other					
Number of employees (FTE)	5,703	5,392	5,703	5,392	5,518
1) Definitions according to the Danish Society of Financial Analysts' Recomme	ndations & Financ	rial Patine 2010	n		

<sup>&</sup>lt;sup>1)</sup> Definitions according to the Danish Society of Financial Analysts' *Recommendations & Financial Ratios 2010.* 

# MANAGEMENT REVIEW

## Financial forecast 2014

Lundbeck is investing significantly in product launches and in the late stage development pipeline while being in the midst of a transition period.

As communicated in connection with the full year results on 6 February 2014, this year is a period with an unusual number of variables which elevates the uncertainties for the company. These variables include market access processes in various countries for Lundbeck's new products, launch uptake, timing of generic erosion as well as slope of erosion curves and development in exchange rates.

The acquisition of Chelsea Therapeutics on 23 June 2014 is not expected to have a material positive impact on revenue in 2014. It is expected to be dilutive to both cash flow and EBIT for the year, but cash flow accretive in 2015. The expected impact on Lundbeck's profitability in 2014 will to some extent depend on the timing of the launch of Northera due in the second half of 2014. Lundbeck currently expects to incur incremental costs of up to DKK 500 million related to the acquisition in 2014.

For the fiscal year 2014, Lundbeck is expecting constant currency **revenue** to be around DKK 13.5 billion. The outlook reflects expectations for continued robust performance of the newer product portfolio which partly offsets continued generic erosion, impact from challenging pricing environments and macroeconomic conditions in some major markets. The revenue guidance does not include any significant milestone payments or divestiture gains.

Lundbeck expects **core profit from operations** (core EBIT) in constant currency to be in the range DKK 0.9-1.4 billion for 2014. Expected reported **profit from operations** (EBIT) in constant currency is unchanged at DKK 0.0-0.5 billion for 2014 as a result of the acquisition of Chelsea Therapeutics, increased generic erosion, continued investment in an unprecedented number of product launches and significant costs related to the continued progress of key late-stage clinical development projects. In the guidance, amortization on product rights included in cost of sales are expected to increase to approximately DKK 800 million compared to DKK 590 million in 2013.

As previously communicated the distribution of revenue, and especially EBIT, will be uneven throughout the year, and the expected earnings contributing to the full year result has been recognized in the first half of the year.

The guidance is summarized in the table below:

### Financial forecast 2014

	2013	2014
DKK billion	actual	forecast
Revenue	15.3	~13.5
EBIT	1.6	0.0-0.5
Core EBIT	2.3	0.9-1.4

# **Forward-looking statements**

Forward-looking statements provide current expectations or forecasts for events, such as product launches, product approvals and financial performance. Forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. Actual results may differ from expected results. Factors that may affect future results include fluctuations in interest rates and exchange rates, delay in 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 a competing product, 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 their interpretation and unexpected growth in costs and expenses.

### Revenue

Revenue reached DKK 7,035 million in the first half of 2014 compared to DKK 8,112 million in the same period last year. The decline of 13% is caused by generic competition on Ebixa and recently also on Cipralex in the European markets, as well as the effect of the income from the divestment of the US mature product portfolio in first quarter 2013, all of which has been partly offset by a 36% growth in New Products.

In the second quarter of the year, revenue was DKK 3,448 million corresponding to an increase of 1% in local currency compared to the same quarter last year.

## Revenue from key product and regions

DKK million	Q2 2014	Q2 2013	Growth	Growth in local currency	H1 2014	H1 2013	Growth	Growth in local currency
New Products*	1,014	769	32%	41%	1,901	1,402	36%	43%
Cipralex <sup>®</sup>	1,316	1,511	(13%)	(10%)	2,861	3,048	(6%)	(2%)
Azilect <sup>®</sup>	371	339	9%	9%	747	697	7%	8%
Xenazine	402	372	8%	14%	766	687	11%	16%
Onfi	217	114	90%	102%	387	210	84%	93%
Sabril	176	147	20%	27%	333	265	26%	32%
Brintellix	38	0	-	-	46	0	-	-
Other pharmaceuticals	779	961	(19%)	(16%)	1,650	2,262	(27%)	(24%)
Other revenue	149	92	61%	61%	245	943	(74%)	(74%)
Total revenue	3,448	3,536	(2%)	1%	7,035	8,112	(13%)	(10%)
Europe	1,385	1,817	(24%)	(24%)	2,992	3,813	(22%)	(21%)
US	882	645	37%	44%	1,626	1,191	37%	42%
International Markets	1,032	982	5%	12%	2,172	2,165	0%	10%

<sup>\*</sup>New Products include Xenazine, Sabril, Sycrest, Lexapro (Japan), Onfi, Treanda, Selincro®, Abilify Maintena and Brintellix

**New Products** continues to contribute to the underlying revenue growth and increased by 41% in local currency in the second quarter of 2014 (32% reported). The growth is driven by Abilify Maintena, Brintellix, Onfi, Sycrest, Treanda and the remaining product portfolio in the US.

**Brintellix** (vortioxetine) for the treatment of major depression (MDD) was launched in the US on 20 January 2014 and therefore the product is still very early in the launch phase; revenue recognized by Lundbeck reached DKK 38 million in the second quarter.

**Xenazine**<sup>1</sup> (tetrabenazine) for the treatment of chorea associated with Huntington's disease continues its solid growth into the second quarter with revenue of DKK 402 million compared to DKK 372 million, an increase of 14% in local currency, or 8% reported. Lundbeck has marketing rights for Xenazine in the US.

<sup>&</sup>lt;sup>1</sup> Xenazine is a registered trademark of Biovail Laboratories International (Barbados) S.R.L.

**Onfi** (clobazam) for the treatment of Lennox-Gastaut syndrome continues to show significant growth and generated second quarter revenue of DKK 217 million, an increase of 90%, or 102% in local currency, compared to the same period last year. Lundbeck has marketing rights for Onfi in the US.

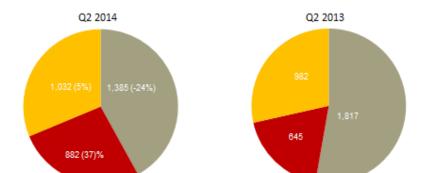
**Sabril** (vigabatrin) for the treatment of refractory complex partial seizures (rCPS) and infantile spasms (IS) generated second quarter revenue of DKK 176 million, increasing 20%, or 27% in local currency, compared to the second quarter of 2013. Lundbeck has marketing rights for Sabril in the US.

**Cipralex** (escitalopram) declined in revenue in the second quarter due to expected generic competition on the European markets. The performance of Cipralex on patent protected markets continues to show solid growth in the quarter.

**Azilect** (rasagiline) for the treatment of Parkinson's disease realized revenue of DKK 371 million, an increase of 9% in local currency. The solid growth is due to continued strong sales uptake in European markets such as France, the UK and Spain, as well the launches of Azilect in Hong Kong, Thailand and Australia.

Revenue from **Other pharmaceuticals**, which comprise the remainder of Lundbeck's products, was DKK 779 million, a decrease of 19% compared to the same quarter last year, which is mainly driven by the generic erosion of Ebixa in Europe. This decrease is partly offset by the sales uptake from products such as Abilify Maintena in the US, Treanda in Canada and Selincro in Europe.

**Other revenue** reached DKK 149 million, compared to DKK 92 million for the same period last year. The growth in other revenue relates to contracted work income.



■ Europe ■ US ■ International Markets

Figure 1 – Revenue per region Q2 2014 (reported growth in brackets) – DKKm

# **Europe**

Revenue declined to DKK 2,992 million in the first half of 2014 compared to DKK 3,813 million in the same period last year caused by the significant, but expected generic erosion of Ebixa following the loss of exclusivity, and the recent entry of generic competition on Cipralex.

Second quarter revenue in Europe was DKK 1,385 million, a decrease of 24% compared to the same quarter last year.

#### Revenue - Europe

				Growth in local					Growth in local
DKK million	Q2 2014	Q2 2013	Growth	currency	Q1 2014	H1 2014	H1 2013	Growth	currency
Cipralex	698	847	(18%)	(17%)	887	1,585	1,703	(7%)	(6%)
Azilect	336	314	7%	7%	344	680	634	7%	7%
Ebixa	144	446	(68%)	(68%)	183	327	1,063	(69%)	(69%)
Other pharmaceuticals	207	210	(1%)	(1%)	193	400	413	(3%)	(3%)
Total revenue	1,385	1,817	(24%)	(24%)	1,607	2,992	3,813	(22%)	(21%)

**Cipralex** generated second quarter revenue of DKK 698 million, a decline of 18% compared with the same period last year. The decline in revenue is due to generic entry in several countries.

Second quarter revenue from **Azilect** amounted to DKK 336 million, an increase of 7% compared to the second quarter of 2013. The growth is mainly driven by the UK, France and Spain.

Revenue from **Ebixa** decreased by 68% to DKK 144 million during the quarter as expected. The decrease is a result of the continued strong generic erosion in all markets, and confirms the 50% decline expected for the group revenue of Ebixa for the full year.

Revenue from **Other pharmaceuticals** was DKK 207 million, a decrease of 1% compared to same quarter last year. Selincro is included in Other pharmaceuticals and contributed in the second quarter with DKK 5 million. The pre-launch and market access activities are ongoing in Europe and to date Selincro has been introduced in more than 20 European markets with limited reimbursement. The rollout of Selincro in additional European markets will continue during 2014. The product was launched in Spain with full reimbursement in July and launches in Germany and France are expected during the remainder of the year. In the UK Selincro has received a positive draft assessment report that is open for public comments.

## US

Revenue reached DKK 1,626 million in the US in the first six months of 2014, which is an increase of 42% in local currency or 37% reported. Lundbeck US continues its solid growth, and thereby confirming this market's strategic importance for Lundbeck. Revenue in the US contributed 23% of total revenue.

In the second quarter, revenue constituted 26% of the total revenue, and the US increased sales with 44% in local currency, or 37% reported, compared to the same quarter last year. Growth is seen for all products.

Revenue - US

				Growth in local					Growth in local
DKK million	Q2 2014	Q2 2013	Growth	currency	Q1 2014	H1 2014	H1 2013	Growth	currency
Xenazine	394	363	9%	14%	362	756	671	13%	17%
Onfi	217	114	90%	102%	170	387	210	84%	93%
Sabril	176	147	20%	27%	157	333	265	26%	32%
Brintellix	38	0	-	-	8	46	0	-	-
Other pharmaceuticals	57	21	177%	178%	47	104	45	136%	145%
Total revenue	882	645	37%	44%	744	1,626	1,191	37%	42%

Revenue from **Xenazine** was DKK 394 million for the quarter, an increase of 14% in local currency, or 9% reported, compared to the second quarter last year. The positive trend from previous quarters continues as Xenazine revenue is progressing well and is on track to meet our expectations.

**Onfi** reached revenue of DKK 217 million in the second quarter, corresponding to a growth of 102% in local currency, or 90% reported.

**Sabril** revenue for the quarter was DKK 176 million, growing 20%, or 27% in local currency, compared to the same quarter last year.

**Brintellix** was launched in the US on 20 January 2014 and therefore the product is still very early in the launch phase, but revenue recognized by Lundbeck reached DKK 38 million in the second quarter.

Second quarter revenue from **Other pharmaceuticals** in the US was DKK 57 million mainly driven by the sales uptake from Abilify Maintena.

# **International Markets**

Revenue from International Markets, which comprise all of Lundbeck's markets outside of Europe and the US, reached DKK 2,172 million in the first half of 2014, compared with DKK 2,165 million same period last year. The flat development in revenue is due to negative currency impact as revenue in local currency increased by 10%. International Markets now constitutes 31% of total revenue compared to 27% for the same period last year.

Revenue in the second quarter was DKK 1,032 million, corresponding to an increase of 12% in local currency (5% reported) compared to the same period last year.

Revenue - International Markets

DKK million	Q2 2014	Q2 2013	Growth	Growth in local currency	Q1 2014	H1 2014	H1 2013	Growth	Growth in local currency
Cipralex/Lexapro	618	664	(7%)	0%	658	1,276	1,345	(5%)	4%
Ebixa	125	113	10%	11%	162	287	285	1%	7%
Treanda	49	22	119%	149%	48	97	33	191%	230%
Azilect	35	25	41%	32%	32	67	63	7%	18%
Other pharmaceuticals	205	158	30%	43%	240	445	439	1%	11%
Total revenue	1,032	982	5%	12%	1,140	2,172	2,165	0%	10%

**Cipralex** generated second quarter revenue of DKK 618 million, which is unchanged compared to the same period last year in local currency, but a decrease of 7% reported. Cipralex continues to grow in Canada and China, but this growth has been partly offset by revenue loss in genericized markets. Lexapro in Japan reached a

market share in value of 9.8% by the end of May 2014 – the market share is relatively volatile, but develops in line with expectations.

**Ebixa** generated second quarter revenue of DKK 125 million representing an increase of 11% in local currency, 10% reported.

**Treanda** for the treatment of indolent Non-Hodgkin lymphoma (iNHL) and chronic lymphocytic leukaemia (CLL) is sold by Lundbeck in Canada and has shown a strong sales uptake reaching DKK 49 million in the second quarter of 2014 compared with DKK 22 million in the same period last year.

Lundbeck launched **Azilect** in Hong Kong, Australia and Thailand during the first half of 2012, thereby contributing to the growth of 41%.

**Other pharmaceuticals** generated revenue of DKK 205 million during the quarter, an increase of 30%, or 43% in local currency, compared to the same quarter last year. The increase is explained by quarterly fluctuations in sales of mature products in the region.

# Expenses and income

Total cost for the first half of 2014 was DKK 6,192 compared to DKK 7,092 million for the same period last year. The decrease of 13% is explained by the fine from the European Commission and the impairment of Sycrest rights that was recognized in first half of 2013, which combined was approximately DKK 900 million. Adjusting for these "one-off" costs, the development in costs has been flat as a result of increased sales and distribution costs for new product launches offset by costs savings from Project "Fit-for-the-Future".

Total cost for the second quarter was DKK 3,174 million, a decrease of 21% compared to second quarter last vear.

### **Distribution of costs**

DKK million	Q2 2014	Q2 2013	Growth	Q1 2014	H1 2014	H1 2013	Growth
Cost of sales	994	1,170	(15%)	987	1,981	2,227	(11%)
Sales and distribution	1,151	1,011	14%	1,070	2,221	1,925	15%
Administration	362	1,143	(68%)	352	714	1,562	(54%)
Research and development	667	718	(7%)	609	1,276	1,378	(7%)
Total costs	3,174	4,042	(21%)	3,018	6,192	7,092	(13%)

Cost of sales decreased 15% to DKK 994 million. This corresponds to 29% of Lundbeck's total revenue, a decrease from 33% compared to same quarter last year. Last year was adversely impacted by impairment of Sycrest product rights of DKK 210 million. Excluding the impairment, cost of sales increased in the quarter from 27% last year to 29% of the total revenue.

Sales and distribution costs were DKK 1,151 million, corresponding to 33% of revenue and an increase of 14% compared to second quarter last year. The launch of Brintellix in US as well as launches of Abilify Maintena and Selincro was the main reasons for the increase.

Administrative expenses were DKK 362 million compared to DKK 1,143 million in the same quarter last year, a decrease of 68% and corresponding to 11% of revenue for the period. Excluding the fine from the European

Commission in June 2013 of approximately DKK 700 million, administrative expenses decreased by 18%. The decrease is partly related to savings due to Project "Fit-for-the-Future" as well as general cost awareness efforts.

SG&A cost was DKK 1,513 million compared to DKK 2,154 million in the same period last year. The SG&A margin for the period was 44% compared to 61% in the same period last year. In 2013, the SG&A margin was negatively impacted by the fine from the European Commission. Excluding this, the SG&A margin for the same period last year was 41%.

Research and development costs for the quarter were DKK 667 million compared to DKK 718 million in the same period last year.

# Operating profit before depreciation and amortization (EBITDA)

EBITDA was DKK 540 million compared to DKK 10 million for the second quarter last year. The EBITDA margin for the period was 15.6% compared to 0.3% in the same quarter last year. Excluding the fine from the European Commission last year, the EBITDA margin was 20% last year. The decrease in the EBITDA margin is related to generic impact on Ebixa and Cipralex in 2014.

# Depreciation, amortization and impairment charges

Depreciation, amortization and impairment charges, which are included in the individual expense categories, amounted to DKK 266 million.

## Depreciation, amortization and impairment charges

DKK million	Q2 2014	Q2 2013	Growth	Q1 2014	H1 2014	H1 2013	Growth
Cost of sales	207	416	(50%)	200	407	596	(32%)
Sales and distribution	9	7	44%	7	16	13	29%
Administration	16	16	(3%)	14	30	31	(4%)
Research and development	34	77	(56%)	34	68	116	(42%)
Total depreciation, amortization							
and impairment charges	266	516	(49%)	255	521	756	(31%)

The decrease in cost of sales compared to last year is due to impairment of Sycrest product rights in June 2013 of DKK 210 million. The decrease in research and development costs compared to last year is mainly due to the write-down of patents on two research projects last year.

# **Profit from operations (EBIT)**

Core EBIT for the second quarter was DKK 439 million compared with DKK 566 million in the same quarter in 2013. The decrease of 22% is driven by the loss in revenue due to the patent expiry for Ebixa and Cipralex in Europe and increased launch costs for new products.

Reported EBIT for the second quarter of 2014 amounted to DKK 274 million, compared to a loss of DKK 506 million in the same quarter in 2013. The increase in profit from operations is primarily due to the fine from the European commission and impairment of Sycrest product rights recognized in the second quarter 2013.

The reported EBIT margin for the period was 8.0%, compared to -14.3% in the same period last year. The core EBIT margin was 13% compared with 16% in the same quarter in 2013. The slight decrease in the core EBIT margin from 2013 to 2014 shows a continuous profitability from the underlying business, despite considerable generic erosion and investments in new product launches.

#### **Net financials**

Lundbeck generated a net financial expense of DKK 34 million in the second quarter of 2014, compared to a net financial expense of DKK 44 million in the second quarter of 2013.

Net interest income, including realized and unrealized gains and losses on the bond portfolio, amounted to a net expense of DKK 18 million, compared to a net expense of DKK 17 million in the same period in 2013.

Net exchange losses amounted to DKK 10 million, compared to DKK 26 million in the second quarter last year. This decrease was primarily due to fluctuations in exchange rate translations of intercompany balances.

#### Tax

The effective tax rate for the full year 2014 is expected to increase significantly compared to the 40% communicated in connection with first quarter results and is expected to be extremely volatile. This is mainly due to the following:

- 1) The acquisition of Chelsea Therapeutics Ltd.; amortization which is not deductible for tax purposes creating a permanent difference impacting the tax rate upwards.
- 2) The now lower expected reported profit before tax, resulting in an extremely volatile effective tax rate.
- 3) The effective tax rate being highly dependent on the mix of revenue for the full year.

## Profit for the period

Profit for the period was DKK 144 million, compared to a loss of DKK 502 million in the same period last year. The reason for the improvement is the negative impact on profit last year due to the fine from the European Commission and the impairment of Sycrest product rights. The profit in the second quarter 2014 corresponds to an EPS of DKK 0.73 per share versus an EPS of DKK -2.56 per share for the same period last year.

Core EPS was DKK 1.30 per share for the second quarter in 2014, compared to a core EPS of DKK 2.37 per share in the same quarter in 2013. The decrease of 45% in core EPS is due to lower profit from operations (EBIT) in 2014.

# Hedging

Lundbeck hedges expected income from its products through currency hedging on a rolling basis, up to 12 months in advance. As a result of Lundbeck's currency hedging policy, foreign exchange gain and losses on hedging transactions are allocated directly to the hedged transaction. Hedging had a positive impact on profit of DKK 18 million in the second quarter of 2014, compared with a situation where the income is not hedged and included at the current exchange rates during the period. The effect was a DKK 22 million gain in the second quarter of 2013.

# Cash flow

Lundbeck had a negative cash flow during the quarter of DKK 3,136 million, compared to a positive cash flow of DKK 637 million in the same period last year.

#### Cash flow

DKK million	Q2 2014	Q2 2013	FY 2013
Cash flows from operating activities	459	1,346	3,760
Cash flows from investing activities	(3,024)	(711)	(1,500)
Cash flows from operating and investing activities	(2,565)	635	2,260
Cash flows from financing activities	(571)	2	(141)
Change in cash	(3,136)	637	2,119
Cash at beginning of period	4,551	2,869	2,747
Unrealized currency translation adjustments for the period	9	(21)	(49)
Change for the period	(3,136)	637	2,119
Cash at end of period	1,424	3,485	4,817
Securities	18	1,041	1,042
Interest-bearing debt	(2,158)	(1,891)	(2,160)
Interest-bearing net cash and cash equivalents, end of period	(716)	2,635	3,699

Operating activities during the second quarter generated cash inflow of DKK 459 million, compared to an inflow of DKK 1,346 million in the same period last year. The development compared to the same period last year was mainly related to working capital items primarily due to prepayment for Lu AE58054 from Otsuka (USD 150 million) in second quarter last year.

Investing activities during the second quarter generated cash outflow of DKK 3,024 million, compared to an outflow of DKK 711 million in the same period last year. The main event causing this cash outflow was the acquisition of Chelsea Therapeutics in June 2014.

Cash at 30 June 2014 was DKK 1,424 million compared to DKK 3,485 million at 30 June 2013. Lundbeck's net debt position at 30 June 2014 was DKK 716 million, compared to a net cash position of DKK 2,635 million at 30 June 2013.

## Balance sheet

As of 30 June 2014, Lundbeck had total assets of DKK 22,954 million, compared to DKK 23,381 million at the end of the second quarter 2013.

As of 30 June 2014, Lundbeck's equity amounted to DKK 13,406 million, corresponding to a solvency ratio of 58.4% compared to 57.3% at the end of the second quarter 2013.

At the Annual General Meeting in March, the proposed dividend for 2013 of DKK 2.77 per share or DKK 544 million (DKK 2.00 per share or DKK 392 million for 2012) was approved. The dividend was paid out to the shareholders on 1 April 2014.

# Lundbeck's development portfolio

Lundbeck is developing a number of new and promising pharmaceuticals for the treatment of brain diseases. The pipeline projects are targeting areas in which Lundbeck currently has a market presence, such as depression, anxiety and other psychiatric disorders, as well as new areas such as stroke. Pipeline development is summarized as follows:

#### Approved or under regulatory review

**Brintellix** (vortioxetine) is a new antidepressant which was launched together with our partner Takeda in the US in January 2014 and approved in Europe on 27 December 2013. More recently in April 2014, the Australian Therapeutic Goods Administration (TGA) approved Brintellix for the treatment of Major Depressive Disorders. Launches outside the US are expected to commence in the second half of 2014 following market access procedures. At the recent International College of Neuropsychopharmacology (CINP) World Congress in Vancouver, Canada, several new studies were presented.

- Brintellix 10-20 mg/day met the primary study endpoint in adult patients with major depression and showed a statistically significant improvement in cognitive performance as assessed by DSST versus placebo. The study also met several secondary endpoints measuring symptoms of depression and patient outcomes; Brintellix was generally well tolerated. The study results are consistent with results from previous studies of Brintellix that demonstrated an improvement in cognitive performance in adult and in elderly patients with major depression.
- Brintellix demonstrated a statistically significantly superior improvement compared to escitalopram in improving sexual functioning in well treated patients suffering from depression and experiencing treatment-emergent sexual dysfunction (TESD).
- Results of the SOLUTION trial conducted in Asian patients suffering from major depression. In this headto-head study, Brintellix was at least as efficacious as venlafaxine on the primary efficacy endpoint and was better tolerated than venlafaxine.

Abilify Maintena (aripiprazole) for extended-release injectable suspension was launched in the US in 2013 and in Europe in March 2014. In April, the US Food and Drug Administration (FDA) accepted for review a supplemental New Drug Application (sNDA) for the proposed expanded labelling of Abilify Maintena to support broader use of the drug for treatment of patients in the acute phase of schizophrenia. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of 7 December 2014 to complete its review. Currently two studies are ongoing using Abilify Maintena in bipolar I disorder with a total of 1,600 patients. This program is expected to be finalised in 2016. Additional development projects are ongoing including a new administration device. Abilify Maintena is part of Lundbeck's collaboration with Otsuka Pharmaceutical Co., Ltd. (Otsuka), and Lundbeck has co-development and co-promotional rights to the product.

Intravenous carbamazepine (IV CBZ) is in development in the US for short-term replacement of oral carbamazepine in adult patients with epilepsy. Carbella™ is the proposed US trade name for intravenous carbamazepine. In March 2014, Lundbeck announced that the US FDA had accepted a New Drug Application (NDA) for Carbella for review. An action letter is anticipated before the end of 2014. In June 2013, Lundbeck received FDA Orphan drug status for this product.

**Brexpiprazole** is a novel investigational psychotropic compound discovered by Otsuka and under codevelopment with Lundbeck. In July 2014, Lundbeck announced the submission of a NDA to the US FDA for brexpiprazole for the treatment of schizophrenia and as adjunctive treatment of major depressive disorder (MDD). The clinical development program included data from more than 6,500 participants of whom more than 5,300 received brexpiprazole. Following the submission the US FDA will determine if the NDA is sufficiently complete to

allow for a substantive review of the data; a decision from the US FDA on initiation of the substantive review is expected in September 2014.

#### Clinical phase III

Desmoteplase is being developed for the treatment of ischaemic strokes with an extended treatment window of three to nine hours after the incidence. In June, Lundbeck announced the initial headline conclusions from DIAS-3, the first of two phase III clinical trials of desmoteplase for the treatment of adult patients with acute ischaemic stroke. The study did not meet the primary endpoint. The DIAS-3 study confirmed the favourable safety profile of desmoteplase by providing excellent safety and tolerability data. However, the DIAS-3 study protocol defined the target population as patients with symptoms of stroke and treatable ischaemic stroke pathology (proximal cerebral vessel occlusion/high-grade stenosis without signs of extensive infarction, intracranial haemorrhage or sub-acute infarction). Analyzing only the patients fulfilling the protocol requirements (per protocol population) a favourable effect of desmoteplase was observed relative to placebo. As a consequence of the failure to meet the primary outcome, but considering the efficacy signal in the per protocol population and the excellent safety and tolerability, further development will be evaluated with advice from key clinical and regulatory experts during the next few months in order to evaluate if a path forward is feasible.

Lu AE58054 is a potent and selective so-called 5-HT6 receptor antagonist in development as adjunctive symptomatic therapy in Alzheimer's disease. In March 2013, Lundbeck and Otsuka further expanded their alliance and entered into collaboration for the development and commercialization of Lu AE58054. The first three out of currently four planned studies in the clinical phase III program are now recruiting patients. The clinical program is scheduled to include four trials including approximately 3,000 patients worldwide and is expected to provide headline conclusions during 2016.

# General corporate matters

# **Accounting policies**

The interim report is presented in accordance with IAS 34 *Interim financial reporting* as adopted by the EU and additional Danish disclosure requirements for the interim report of listed companies.

Accounting policies remain unchanged compared to the annual report for 2013, which contains a more detailed description of the Group's accounting policies.

# Lundbeck core results reporting

Lundbeck has implemented core result reporting as we believe this approach provides a clearer view of the underlying performance of the business and should make cLundbeck's results more comparable with the majority of its peers. In general, Lundbeck adjusts for each non-recurring item, including milestones that are, or are expected to accumulate exceeding DKK 100 million thresholds (approximately USD 20 million) within the year that the Lundbeck's management deems exceptional.

Lundbeck's core results - including core operating income (core EBIT) and core EPS - exclude:

Amortization and impairments:

Amortization and impairment of intangible assets

Acquisitions and integration activities:

 Acquisition accounting adjustments relating to the consolidation of material acquisitions, disposals of associates, products and businesses Major costs associated with the integration of companies

#### Divestments and reorganizations:

- Income/expenses from discontinued operations
- Gains/losses on divestments of assets, and received or expensed upfront-, sales-, and development milestones
- Termination costs
- Major restructuring charges and expenses

#### Legal and litigation costs:

- · Legal costs (external) related to settlement of litigations, government investigations and other disputes
- Legal charges (net of insurance recoveries) and expenses on the settlement of litigation and government investigations

The adjusted core result is taxed at the underlying corporate tax rate.

These core financial measures are used by Lundbeck's management to make operating decisions because they facilitate internal comparisons of Lundbeck's performance to historical results and to peer companies.

For this same reason, Lundbeck believes that investors' understanding of the company's performance is enhanced by disclosing core measures. Excluding these exceptional items which may vary significantly from year to year also increases comparability across years.

These core measures should not be considered in isolation from, as substitutes for, or superior to the reported results prepared in accordance with IFRS.

### Acquisition of Chelsea Therapeutics International, Ltd

In the second quarter of 2014, Lundbeck completed the purchase of all shares of Chelsea Therapeutics International, Ltd. for USD 6.44 per share in cash and non-transferable contingent value rights (CVRs) that may pay up to an additional USD 1.50 per share upon achievement of certain sales milestones. The acquisition is considered a purchase of assets, mainly the Northera product rights and tax assets.

#### Incentive plans in the Lundbeck Group

Lundbeck operates with Long-Term Incentive schemes (LTI) for the Executive Management and key employees in Denmark and abroad. To fund the programs granted in 2011, during the first half of 2014 Lundbeck has purchased treasury shares with a value of DKK 70 million, corresponding to 459,072 shares.

## Executive Management

In May the Executive Management were granted 1,355,000 warrants in H. Lundbeck A/S. All of the warrants will vest 3 years after grant, subject to the Board of Directors' decision on vesting (having regard to i.e. the financial situation of the Lundbeck Group) and subject to the Executive Management members' continued employment in the Lundbeck Group during the vesting period. The warrants may be exercised during certain windows in the period from 3-6 years after the date of grant. The market value of the warrants are calculated using the Black-Scholes method and is based on a volatility of 23.68%, a dividend yield of 2.00%, a risk free interest rate of 0.50%, a vesting period of 3 years and a share price of DKK 157.30. The total value of the program at the time of grant is DKK 35 million.

#### Key employees

In June, key employees were granted 204,981 restricted shares in H. Lundbeck A/S. All of the restricted shares will vest in 2017, 3 years after grant, subject to Lundbeck achieving its financial targets for vesting and subject to

their continued employment with the Lundbeck Group for the period from the grant in 2014 until the restricted shares have vested in 2017. Key employees in the US subsidiaries were granted Restricted Cash Units (RCUs) on terms and conditions similar to those that apply for the Restricted Share Unit program. The market value of the Restricted Share Units and the Restricted Cash Units are calculated using the Black-Scholes method and is based on a volatility of 26.08%, a dividend yield of 2.00%, a risk free interest rate of 0.19%, a vesting period of 3 years and a share price of DKK 147.40. The total value of the programs at the time of grant is DKK 30 million.

## Protection of patents and other intellectual property rights

Intellectual property rights are a prerequisite for Lundbeck's continued investments in innovative pharmaceuticals. It is Lundbeck's policy to enforce its granted intellectual property rights wherever they may be violated. Lundbeck is involved in a number of trials around the world related to defending its intellectual property rights. With regards to escitalopram, Lundbeck is presently involved in pending court trials in Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, Hungary, Lebanon, the Netherlands, Norway, Portugal, Saudi Arabia, Singapore and Turkey.

## **Conference call**

Today at 2.00 pm (CET), Lundbeck will be hosting a conference call for the financial community. You can listen to the call online at www.lundbeck.com under the investor section.

# MANAGEMENT STATEMENT

The Board of Directors and the Executive Management have discussed and adopted the interim report of H. Lundbeck A/S for the period 1 January - 30 June 2014. The interim report is presented in accordance with IAS 34 Interim financial reporting, as adopted by the EU and additional Danish disclosure requirements for the interim reports of listed companies.

We consider the accounting policies applied to be appropriate. Accordingly, the interim report gives a true and fair view of the Group's assets, liabilities and financial position as of 30 June 2014, and of the results of the Group's operations and cash flows for the second quarter of 2014, which ended on 30 June 2014.

In our opinion, the Management's report gives a true and fair view of activity developments, the Group's general financial position and the results for the period. It also gives a fair account of the significant risks and uncertainty factors that may affect the Group.

The interim report has not been subject to audit or review.

Valby, 7 August 2014

# **Executive Management**

**Ulf Wiinberg** President and CEO

Anders Götzsche Anders Gersel Pedersen Executive Vice President, CFO Executive Vice President, R&D

## **Board of Directors**

Christian Dyvig Håkan Björklund Terrie Curran

Chairman Deputy Chairman

Mona Elisabeth Elster Henrik Sindal Jensen Thorleif Krarup

Melanie G. Lee Jørn Mayntzhusen Lars Rasmussen

# **FINANCIAL STATEMENTS**

# Income statement

DKK million	2014 Q2	2013 Q2	2014 H1	2013 H1	2013 FY
Revenue	3,448	3,536	7,035	8,112	15,258
Cost of sales	994	1,170	1,981	2,227	4,038
Gross profit	2,454	2,366	5,054	5,885	11,220
Sales and distribution costs	1,151	1,011	2,221	1,925	4,200
Administrative expenses	362	1,143	714	1,562	2,549
Research and development costs	667	718	1,276	1,378	2,872
Profit from operations	274	(506)	843	1,020	1,599
Net financials	(34)	(44)	(51)	(46)	(127)
Profit before tax	240	(550)	792	974	1,472
Tax on profit for the period	96	(48)	317	409	617
Profit for the period	144	(502)	475	565	855
Earnings per share (EPS) (DKK)	0.73	(2.56)	2.42	2.88	4.36
Diluted earnings per share (DEPS) (DKK)	0.73	(2.56)	2.42	2.88	4.36

# Statement of comprehensive income

	2014	2013	2014	2013	2013
DKK million	Q2	Q2	H1	H1	FY
Profit for the period	144	(502)	475	565	855
Actuarial gains/losses	-	-	-	-	15
Tax	-	-	-	-	(4)
Items that will not subsequently be reclassified to profit or	-	-	-	-	11
loss					
Currency translation, foreign subsidiaries	48	(68)	62	(21)	(115)
Currency translation concerning additions to net investments in					
foreign subsidiaries	(3)	(82)	(6)	8	(145)
Realized exchange gains/losses concerning additions to net					
investments in foreign subsidiaries (transferred to the income					
statement)	-	4	-	(19)	(8)
Adjustments, deferred exchange gains/losses, hedging	(57)	75	(45)	98	142
Exchange gains/losses, hedging (transferred to the hedged items)	37	(23)	1	(43)	(126)
Fair value adjustment of available-for-sale financial assets	(3)	(3)	(11)	(9)	(25)
Tax	6	8	15	(9)	38
Items that may subsequently be reclassified to profit or loss	28	(89)	16	5	(239)
Other comprehensive income	28	(89)	16	5	(228)
Comprehensive income	172	(591)	491	570	627

# **Balance** sheet

**Equity and liabilities** 

DKK	mil	lion
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Assets	30.06.2014	30.06.2013	31.12.2013
Intangible assets	12,535	9,117	9,077
Property, plant and equipment	2,722	2,773	2,778
Financial assets	728	981	431
Non-current assets	15,985	12,871	12,286
Inventories	1,749	1,611	1,893
Receivables	3,778	4,373	3,611
Securities	18	1,041	1,042
Cash	1,424	3,485	4,817
Current assets	6,969	10,510	11,363
Assets	22,954	23,381	23,649
Equity and liabilities			
Share capital	982	980	981
Share premium	251	227	232
Currency translation reserve	(383)	(240)	(441)
Currency hedging reserve	(18)	44	15
Retained earnings	12,574	12,380	12,694
Equity	13,406	13,391	13,481
Provisions	1,605	1,469	1,509
Debt	2,149	1,873	2,141
Non-current liabilities	3,754	3,342	3,650
Provisions	306	269	364
Debt	9	18	19
Trade payables	1,763	1,528	1,967
Other payables	3,716	4,833	4,168
Current liabilities	5,794	6,648	6,518
Liabilities	9,548	9,990	10,168

22,954

23,381

23,649

# Statement of changes in equity

DKK million						
2014	Share capital	Share premium	Currency translation reserve	Currency hedging reserve	Retained earnings	Equity
Equity at 01.01.2014	981	232	(441)	15	12,694	13,481
Profit for the period	-	-	-	-	475	475
Other comprehensive income	-	-	58	(33)	(9)	16
Comprehensive income	-	-	58	(33)	466	491
Distributed dividends	-	-	-	-	(544)	(544)
Capital increase through exercise of warrants	1	19	-	-	-	20
Buyback of treasury shares	-	-	-	-	(70)	(70)
Incentive programmes	-	-	-	-	28	28
Other transactions	1	19	-	-	(586)	(566)
Equity at 30.06.2014	982	251	(383)	(18)	12,574	13,406
2013						
Equity at 01.01.2013	980	226	(211)	3	12,200	13,198
Profit for the period	-	-	-	-	565	565
Other comprehensive income	-	-	(29)	41	(7)	5
Comprehensive income	-	-	(29)	41	558	570
Distributed dividends		-	-	-	(392)	(392)
Capital increase through exercise of warrants	-	1	-	-	-	1
Buyback of treasury shares	-	-	-	-	(7)	(7)
Incentive programmes	-	-	-	-	21	21
Other transactions	-	1	-	-	(378)	(377)
Equity at 30.06.2013	980					

# Cash flow statement

DKK million	2014 Q2	2013 Q2	2014 H1	2013 H1	2013 FY
Profit from operations	274	(506)	843	1,020	1,599
Adjustments for non-cash operating items etc.	181	522	474	725	1,375
Working capital changes	119	1,553	(742)	595	1,079
Cash flows from operations before financial					
receipts and payments	574	1,569	575	2,340	4,053
Financial receipts and payments	2	(50)	(20)	(53)	(89)
Cash flows from ordinary activities	576	1,519	555	2,287	3,964
Income tax paid	(117)	(173)	(247)	(314)	(204)
Cash flows from operating activities	459	1,346	308	1,973	3,760
Acquisition <sup>1</sup>	(2,831)	_	(2,831)	_	
Investments in and sale of bonds and other financial	, ,		( , ,		
assets	1,016	14	998	14	10
Investments in and sale of intangible assets and					
property, plant and equipment	(1,209)	(725)	(1,277)	(809)	(1,510)
Cash flows from investing activities	(3,024)	(711)	(3,110)	(795)	(1,500)
Cash flows from operating and investing activities	(2,565)	635	(2,802)	1,178	2,260
Capital contributions	14	1	20	1	7
Dividends paid in the financial year	(544)	-	(544)	(392)	(392)
Other financing activities	(41)	1	(72)	(24)	244
Cash flows from financing activities	(571)	2	(596)	(415)	(141)
Change in cash	(3,136)	637	(3,398)	763	2,119
Cash at beginning of period	4,551	2,869	4,817	2,747	2,747
Unrealized currency translation adjustments for the					
period	9	(21)	5	(25)	(49)
Change for the period	(3,136)	637	(3,398)	763	2,119
Cash at end of period	1,424	3,485	1,424	3,485	4,817

<sup>&</sup>lt;sup>1</sup> The acquisition of Chelsea Therapeutics, which is considered a purchase of assets, consists of the Northera product rights valued at DKK 2,600 million, tax assets of DKK 272 million, as well as net liabilities totalling DKK 41 million. A cash balance of DKK 145 million was also acquired and this amount is included in the change in cash for the period.

# Interest-bearing net cash and cash equivalents is composed as follows:

Cash	1,424	3,485	1,424	3,485	4,817
Securities	18	1,041	18	1,041	1,042
Interest-bearing debt	(2,158)	(1,891)	(2,158)	(1,891)	(2,160)
Interest-bearing net cash and cash equivalents,					
end of period	(716)	2,635	(716)	2,635	3,699

# Income statement – Core results reconciliation

# Q2 2014

	Reported	Intangible	Intangible	Major	Legal fees and	Divestments/ sales	
DKK million	result	amortization		restructuring	settlements	milestones	Core result
Revenue	3,448	-	-	-	-	-	3,448
Cost of sales	994	(165)	-	-	-	-	829
Gross profit	2,454	165	-	-	-	-	2,619
Sales and distribution costs	1,151	-	-	-	-	-	1,151
Administrative expenses	362	-	-	-	-	-	362
Research and development costs	667	-	-	-	-	-	667
Profit from operations	274	165	-	-	-	-	439
Net financials	(34)	-	-	-	-	-	(34)
Profit before tax	240	165	-	-	-	-	405
Tax on profit for the period	96	53	-	-	-	-	149
Profit for the period	144	112	-	-	-	-	256
Earnings per share (EPS)(DKK)	0.73	0.57	-	-	-	-	1.30

# Q2 2013

DKK million	Reported	Intangible	Intangible	Major	and	Divestments/ sales	
Distribution .	result	amortization	impairment	restructuring	settlements	milestones	Core result
Revenue	3,536	-	-	-	-	-	3,536
Cost of sales	1,170	(163)	(210)	-	-	-	797
Gross profit	2,366	163	210	-	-	-	2,739
Sales and distribution costs	1,011	-	-	-	-	-	1,011
Administrative expenses	1,143	-	-	-	(699)	-	444
Research and development costs	718	-	-	-	-	-	718
Profit from operations	(506)	163	210	-	699	-	566
Net financials	(44)	-	-	-	-	-	(44)
Profit before tax	(550)	163	210	-	699	-	522
Tax on profit for the period	(48)	53	53	-	-	-	58
Profit for the period	(502)	110	157	-	699	-	464
Earnings per share (EPS)(DKK)	(2.56)	0.56	0.80	-	3.57	-	2.37

# **FINANCIAL CALENDAR 2014**

5 Nov 2014 Third quarter results 2014

# Corporate releases since the first quarter report

May 8 2014	Lundbeck to acquire Chelsea Therapeutics
May 21 2014	H. Lundbeck A/S increases its share capital by 115,722 shares (0.0590% of outstanding shares) as a result of employee warrant exercise
May 23 2014	Lundbeck commences tender offer for all outstanding shares of Chelsea Therapeutics
May 31 2014	Total number of voting rights and share capital in H. Lundbeck A/S as of 31 May 2014
Jun 4 2014	New incentive plans in the Lundbeck Group
Jun 16 2014	New study shows that Brintellix (vortioxetine) improves cognitive performance and function in adult patients with major depression
Jun 23 2014	Lundbeck successfully completes tender offer for Chelsea Therapeutics
Jun 27 2014	Lundbeck provides update on the development program for desmoteplase
Jul 14 2014	Otsuka and Lundbeck submit New Drug Application for brexpiprazole for the treatment of schizophrenia and as adjunctive therapy for the treatment of major depression

For more information, please visit www. http://investor.lundbeck.com/releases.cfm.

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# About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in brain diseases. For more than 50 years, we have been at the forefront of research within neuroscience. Our key areas of focus are alcohol dependence, Alzheimer's disease, bipolar disorder, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia, stroke and symptomatic neurogenic orthostatic hypotension (NOH).

An estimated 700 million people worldwide are living with brain disease and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary

consequences. Every day, we strive for improved treatment and a better life for people living with brain disease – we call this Progress in Mind.

Read more at www.lundbeck.com/global/about-us/progress-in-mind.

Our approximately 6,000 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales. Our pipeline consists of several late-stage development programs and our products are available in more 100 countries. We have research centers in China, Denmark and the United States and production facilities in China, Denmark, France and Italy. Lundbeck generated revenue of approximately DKK 15.3 billion in 2013 (EUR 2.0 billion; USD 2.7 billion).

For additional information, we encourage you to visit our corporate site <a href="www.lundbeck.com">www.lundbeck.com</a>.