



# Lundbeck realized 14% growth in revenue (local currencies) and 83% growth in EPS

# HIGHLIGHTS

- Revenue reached DKK 9,288 million in the first six months of 2018 representing an increase of 9% (14% in local currencies) compared to the same period in 2017
  - > Revenue of Abilify Maintena® increased 16% to DKK 771 million (22% in local currencies)
  - > Revenue of Brintellix®/Trintellix® increased 26% to DKK 999 million (36% in local currencies)
  - > Revenue of Northera<sup>®</sup> increased 16% to DKK 849 million (30% in local currency)
  - > Revenue of Onfi<sup>®</sup> increased 19% to DKK 1,762 million (34% in local currency)
  - > Revenue of Rexulti® increased 28% to DKK 752 million (44% in local currencies)
  - Revenue in North America increased 1% to DKK 5,287 million (14% in local currencies)
  - > Revenue in International Markets increased 3% to DKK 1,920 million (11% in local currencies)
  - > Revenue in Europe increased 6% to DKK 1,518 million (7% in local currencies)
- EBIT increased significantly and reached DKK 3,006 million compared to DKK 2,061 million in the first six months of 2017 and the EBIT margin reached 32.4% compared to 24.3% in 2017
- EPS grew 83% to DKK 11.07 in the period compared to DKK 6.05 the year before
- Free cash flow reached DKK 1,999 million representing an increase of 186%, and the net cash position improved to DKK 4,588 million compared to DKK 1,052 million for the same period last year
- Three projects have moved into phase I (Lu AF76432, Lu AF28996 and Lu AF82422) and foliglurax has entered the phase II pipeline in the first half of the year
- The financial guidance for 2018 is revised. Lundbeck now expects revenue to reach DKK 17.6-18.0 billion compared to previously DKK 17.2-18.0 billion. EBIT is now expected to reach DKK 4.9-5.2 billion compared to previously DKK 4.8-5.2 billion
- Dr. Deborah Dunsire appointed new President and CEO of Lundbeck. Deborah will take up her new position 1 September 2018

## In connection with the financial report, Lundbeck's interim CEO and CFO, Anders Götzsche said:

"I am really pleased with the performance. Lundbeck continues the solid financial performance and we are still on track to deliver the best ever results. We have furthermore moved new and innovative projects into clinical development. However, sales in the second half of 2018 will be somewhat lower than realized in the first half of the year as we expect increased generic erosion and destocking."

DKK million	H1 2018	H1 2017	Growth
Reported Revenue	9,288	8,494	9%
Reported EBIT	3,006	2,061	46%
Reported EPS	11.07	6.05	83%
Reported EBIT margin	32.4%	24.3%	-
Core Revenue*	9,288	8,494	9%
Core EBIT*	3,578	2,500	43%
Core EPS*	13.73	8.03	71%
Core EBIT margin*	38.5%	29.4%	-

\*For definition of the measures "Core Revenue", "Core EBIT" and "Core EPS", see note 9 Core reporting

H. Lundbeck A/S Investor Relations Ottiliavej 9 DK-2500 Valby Copenhagen Phone: +45 36 30 13 11 <u>www.lundbeck.com</u> CVR-nr.: 56759913 LEI code: 5493006R4KC2OI5D3470

## CONTENTS

FINANCIAL HIGHLIGHTS AND KEY FIGURES	3
MANAGEMENT REVIEW	4
Financial guidance and forward-looking statements	4
Revenue	4
Expenses and income	10
Cash flow	12
Balance sheet	13
Lundbeck's development portfolio	13
General corporate matters	17
MANAGEMENT STATEMENT	19
FINANCIAL STATEMENTS	20

# FINANCIAL HIGHLIGHTS AND KEY FIGURES

	H1 2018	H1 2017	Q2 2018	Q2 2017	FY 2017
Financial highlights (DKK million)					
Reported revenue	9,288	8,494	4,703	4,283	17,234
Core revenue	9,288	8,494	4,703	4,283	17,234
Operating profit before depreciation and amortization (EBITDA)	3,547	2,649	1,657	1,362	5,424
Reported profit from operations (EBIT)	3,006	2,061	1,350	1,050	4,408
Core profit from operations (core EBIT)	3,578	2,500	1,760	1,287	5,115
Net financials	6	(70)	19	(55)	(131)
Profit before tax	3,012	1,991	1,369	995	4,277
Tax	814	796	370	387	1,653
Profit for the period	2,198	1,195	999	608	2,624
Equity	12,559	10,695	12,559	10,695	12,181
Assets	21,703	19,199	21,703	19,199	19,756
Cash flows from operating and investing activities (free cash flow)	1,999	700	791	19	2,215
Purchase of property, plant and equipment, gross	83	59	51	31	245
Key figures					
EBIT margin (%)	32.4	24.3	28.7	24.5	25.6
Return on invested capital (ROIC) (%)	26.6	13.3	12.0	7.2	30.8
Annualized return on invested capital (ROIC) (%)	53.2	26.6	48.1	28.7	30.8
Cash to earnings (%)	114.1	100.4	129.2	85.4	141.8
Research and development ratio (%)	15.8	15.0	16.2	14.5	15.7
Return on equity (%)	17.8	11.8	8.3	5.9	24.0
Equity ratio (%)	57.9	55.7	57.9	55.7	61.7
Invested capital (DKKm)	7,971	9,643	7,971	9,643	8,504
Net debt/EBITDA	(1.3)	(0.4)	(2.8)	(0.8)	(0.7)
Share data					
Number of shares for the calculation of EPS (millions)	198.6	197.1	198.7	197.3	197.5
Number of shares for the calculation of DEPS (millions)	198.7	197.4	198.7	197.8	197.8
Earnings per share, basic (EPS) (DKK)	11.07	6.05	5.03	3.07	13.28
Earnings per share, diluted (DEPS) (DKK)	11.06	6.04	5.03	3.06	13.26
Cash flow from operating activities per share, diluted (DKK)	16.96	6.15	6.87	2.86	20.45
Net asset value per share, diluted (DKK)	63.18	53.77	63.18	53.77	61.28
Market capitalization (DKK million)	89,276	72,517	89,276	72,517	62,700
Share price end of period (DKK)	448.40	365.40	448.40	365.40	315.00
Proposed dividend per share (DKK)	-	-	-	-	8.00
Other					
Number of employees (FTE) end of period	5,119	4,894	5,119	4,894	4,976
	5,119	4,894	5,119	4,894	

# MANAGEMENT REVIEW

## Financial guidance and forward-looking statements

Lundbeck's results in 2018 are expected to be driven by the continued strong growth of Abilify Maintena, Brintellix/Trintellix, Northera and Rexulti which will more than offset the effect of additional generic erosion on older products and the expected introduction of generic clobazam towards the end of the year. Following the tentative approval by the U.S. FDA (Food and Drug Administration) of several generic versions of clobazam, a significant decline of Onfi has to be expected starting in the fourth quarter of 2018 and continuing into 2019. In the financial guidance for 2018 it's anticipated that Onfi revenue in the fourth quarter will decline with 40-50% compared to the previous quarters in 2018.

Looking at our geographical regions, we expect to realize growth in all three regions, North America, International Markets and Europe, in local currencies.

The financial guidance for 2018 is revised. **Revenue** is expected to reach between DKK 17.6 billion and DKK 18.0 billion in 2018 (previously DKK 17.2-18.0 billion) and Lundbeck's **EBIT** is expected to be in the range between DKK 4.9 billion and DKK 5.2 billion (previously DKK 4.8-5.2 billion). Lundbeck's main currency is the USD, and the guidance is based on the level of the USD as per end of July 2018. As a consequence of the U.S. tax reform, Lundbeck expects the reported **tax rate** to be 26-28% compared to 38.7% in 2017. The financial guidance is summarized below:

#### Financial guidance 2018

DKK	2017 actual	Previous 2018 guidance	Revised 2018 guidance
Revenue	17,234 million	17.2-18.0 billion	17.6-18.0 billion
EBIT	4,408 million	4.8-5.2 billion	4.9-5.2 billion
Tax rate	38.7%	26-28%	26-28%

#### **Forward-looking statements**

Forward-looking statements are subject to risks, uncertainties and inaccurate assumptions. This may cause actual results to differ materially from expectations. Various factors may affect future results, including interest rates and exchange rate fluctuations, delay or failure of development projects, production problems, unexpected contract breaches or terminations, governance-mandated or market-driven price decreases for 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 unexpected growth in expenses.

### Revenue

Revenue for the first six months of 2018 reached DKK 9,288 million compared to DKK 8,494 million for the same period of 2017. The increase of 9% (14% in local currencies) is primarily driven by Abilify Maintena, Brintellix/Trintellix, Northera, Onfi and Rexulti. The revenue development has been positively impacted by seasonality due to shipments generally in International Markets and specifically in China.

#### Hedging

To establish better transparency regarding the effect of hedging on revenue and profit, Lundbeck has decided to disclose hedging gains/losses (net) in a separate line item in revenue. Previously the effect from hedging was

allocated to the individual products. Lundbeck hedges a significant part of the currency risk for a period of 12-18 months. Hedging had a positive impact of DKK 277 million for the first six months of 2018. The gain from hedging for the full year 2018, is expected to be DKK 200-300 million.

				Growth in local				Growth in local	
DKK million	H1 2018	H1 2017	Growth	currencies	Q2 2018	Q2 2017	Growth	currencies	Q1 2018
Abilify Maintena	771	667	16%	22%	407	351	16%	21%	364
Brintellix/Trintellix	999	794	26%	36%	532	420	27%	36%	467
Cipralex/Lexapro	1,339	1,314	2%	9%	674	624	8%	14%	665
Northera	849	734	16%	30%	453	382	19%	31%	396
Onfi	1,762	1,477	19%	34%	859	767	12%	23%	903
Rexulti	752	587	28%	44%	383	307	25%	37%	369
Sabril	652	780	(16%)	(6%)	311	402	(22%)	(15%)	341
Xenazine	230	551	(58%)	(53%)	118	294	(60%)	(56%)	112
Other pharmaceuticals	1,371	1,606	(15%)	(11%)	704	764	(8%)	(4%)	667
Other revenue	286	137	109%	110%	167	63	165%	166%	119
Hedging	277	(153)	-	-	95	(91)	-	-	182
Total revenue	9,288	8,494	<b>9</b> %	14%	4,703	4,283	10%	13%	4,585
North America	5,287	5,210	1%	14%	2,689	2,707	(1%)	9%	2,598
International Markets	1,920	1,869	3%	11%	979	881	11%	19%	941
Europe	1,518	1,431	6%	7%	773	723	7%	7%	745

#### **Revenue - products and regions**

**Abilify Maintena** (aripiprazole once-monthly injection) for the treatment of schizophrenia and in the U.S. also for bipolar I disorder, shows steady growth. Sales grew 16% (22% in local currencies) and reached DKK 771 million. Abilify Maintena's share of the long-acting market for antipsychotics (atypicals) has increased from 15.2% in the second quarter of 2017 to 17.0% (net sales) in the second quarter of 2018. The regional distribution of sales was 42%, 8% and 50% in North America, International Markets and Europe, respectively. The largest markets are Australia, Canada, France, Spain and the U.S. Abilify Maintena was discovered by Otsuka Pharmaceutical Co., Ltd. (Otsuka), and is co-marketed by Lundbeck and became available to patients in 2013.

Revenue from **Brintellix/Trintellix** (vortioxetine), for the treatment of major depression (MDD), reached DKK 999 million following growth of 26% (36% in local currencies). The regional distribution of sales was 54%, 20% and 26% in North America, International Markets and Europe, respectively. The largest markets are Brazil, Canada, France, Italy, Spain and the U.S. In the U.S., Trintellix is co-marketed by Takeda Pharmaceutical Company Limited (Takeda).

**Cipralex/Lexapro** (escitalopram), for the treatment of depression, increased 2% (9% growth in local currencies) mainly due to large shipments to our partner in China, Xian-Janssen, and revenue reached DKK 1,339 million. The regional distribution of sales was 5%, 71% and 24% in North America, International Markets and Europe, respectively. The largest markets are Brazil, Canada, China, Italy and Japan.

**Northera** (droxidopa), for the treatment of symptomatic neurogenic orthostatic hypotension (nOH), was launched in the U.S. in 2014. Sales from Northera showed growth of 16% (30% in local currencies) and reached DKK 849 million.

**Onfi** (clobazam), for the treatment of Lennox-Gastaut syndrome, continues to show strong growth and generated revenue of DKK 1,762 million, an increase of 19% (34% in local currencies) compared to the same period last year.

**Rexulti** (brexpiprazole) is approved by the U.S. FDA (Food and Drug Administration) as an adjunctive therapy for the treatment of adults with major depressive disorder and as a treatment for adults with schizophrenia, and became available to patients in the U.S. in August 2015, Canada in April 2017 and in Australia in June 2017. Lundbeck's share of revenue reached DKK 752 million for the period, corresponding to a growth of 28% (44% in local currencies). Rexulti was co-developed and is co-marketed by Otsuka and Lundbeck.

**Sabril** (vigabatrin), for the treatment of refractory complex partial seizures (rCPS) and infantile spasms (IS), saw the first generic introduction in the third quarter of 2017. Revenue reached DKK 652 million, thereby declining 16% (6% in local currencies) in the period compared to last year. Lundbeck has the marketing rights for Sabril in the U.S.

**Xenazine** (tetrabenazine) for the treatment of chorea associated with Huntington's disease saw the first generic introduction in the third quarter of 2015 which impacts sales negatively. Revenue reached DKK 230 million compared to DKK 551 million in 2017, a decline of 58%. Lundbeck has the marketing rights for Xenazine in the U.S.

Revenue from **Other pharmaceuticals**, which comprise the remainder of Lundbeck's products, was DKK 1,371 million compared to DKK 1,606 million in first six months of 2017. Other pharmaceuticals are negatively impacted by the hand back of Treanda<sup>®</sup> in Canada and generic competition on Azilect<sup>®</sup> (rasagiline) and Ebixa<sup>®</sup> (memantine) in Europe.

**Other revenue**, which mainly consists of contract manufacturing, reached DKK 286 million compared to DKK 137 million for the period in 2017 following increased contract work at our production sites in France and Italy.



Figure 1 – Revenue per region H1 2018 vs H1 2017 (excluding Other revenue and effects from hedging)

## Key developments in the second quarter of 2018

In the second quarter of 2018, revenue grew 10% (13% in local currencies) and reached DKK 4,703 million compared to DKK 4,283 million the year before as the decline in sales of Xenazine and Sabril was more than mitigated by growth of Abilify Maintena, Brintellix/Trintellix, Northera, Onfi and Rexulti. The quarter is positively impacted by large shipments of Lexapro/Cipralex in International Markets.

## **North America**

Revenue reached DKK 5,287 million in the first six months of 2018 which is an increase of 1% (14% in local currencies) compared to DKK 5,210 million in 2017. The growth was mainly driven by the uptake of Northera, Onfi,

DKK million	H1 2018	H1 2017	Growth	Growth in local currencies	Q2 2018	Q2 2017	Growth	Growth in local currencies	Q1 2018
Abilify Maintena	325	291	12%	24%	174	154	13%	23%	151
Trintellix	542	450	20%	34%	302	237	27%	38%	240
Northera	849	734	16%	30%	453	382	19%	31%	396
Onfi	1,762	1,477	19%	34%	859	767	12%	23%	903
Rexulti	746	587	27%	42%	380	307	24%	36%	366
Sabril	652	780	(16%)	(6%)	311	402	(22%)	(15%)	341
Xenazine	220	538	(59%)	(54%)	113	288	(61%)	(57%)	107
Other pharmaceuticals	191	353	(46%)	(41%)	97	170	(43%)	(40%)	94
Total revenue	5,287	5,210	1%	14%	2,689	2,707	(1%)	9%	2,598

#### Revenue – North America

**Abilify Maintena** revenue grew 12% (24% in local currencies) for the period and reached DKK 325 million, which represents Lundbeck's share of total net sales. In the U.S. Abilify Maintena has a value market share of 18.7% and in Canada it has reached 22.9% by July 2018.

**Trintellix** sales reached DKK 542 million for Lundbeck following a growth of 20% (34% in local currencies). In the U.S., Trintellix' share of branded TR<sub>x</sub> (total prescriptions) volume is still increasing and has reached 53.4% following the loss of exclusivity of Pfizer's Pristiq (desvenlafaxine). The share of branded NR<sub>x</sub> (new prescriptions) volume reached 55.2% by early July 2018. The value market share of the total anti-depressant market in the U.S. was 16.7% and the volume share was 0.7% by July 2018.

**Northera** was made available in the U.S. in the autumn of 2014 for the treatment of Neurogenic Orthostatic Hypotension (nOH). Sales from Northera reached DKK 849 million in the first half of the year, and this performance was impacted by the seasonality component of the disease and the usual phenomenon in the beginning of the year, when drug coverage reauthorization occurs and leads to increased administrative burden for doctors, as well as higher out of pocket costs for patients. Despite these challenges, Northera grew 16% (30% in local currencies), which highlights the unmet need in the nOH market and Northera's strong clinical profile.

**Onfi** reached revenue of DKK 1,762 million corresponding to a growth of 19% (34% in local currency). In March 2018, the U.S. FDA tentatively approved the first version of generic clobazam and additional versions have subsequently been tentatively approved. However, the market exclusivity of Onfi will not expire until October 2018. In the financial guidance for 2018, it is anticipated that Onfi revenue will decline with 40-50% in the fourth quarter compared to the previous quarters in 2018.

Lundbeck's share of **Rexulti** revenue reached DKK 746 million following a growth of 27% (42% in local currencies). Rexulti had 11.3% value market share (gross sales) in the U.S. by May 2018 compared to 10.1% in December 2017. Rexulti has achieved 17.1% branded TRx market share and 17.5% branded NRx market share and the TRx share of the total atypical market in the U.S. has reached 1.229%. Patient data suggest that more than three quarters of prescriptions are prescribed for MDD. In February 2017, Lundbeck and Otsuka announced that Health Canada issued a Notice of Compliance for Rexulti for the treatment of schizophrenia, and the product became commercially available in Canada during the second quarter of 2017.

**Sabril** revenue for the period was DKK 652 million, declining 16% (6% in local currency). In September 2017, the first generic vigabatrin (oral solution) was introduced, and by early July 2018, generic vigabatrin had 34% of the total sales in volume.

Revenue from **Xenazine** was DKK 220 million. Revenue decreased 59% compared to the previous year. Performance was impacted by the introduction of generic products, and by early July 2018, generic tetrabenazine had 89% of the sales in volume.

**Other pharmaceuticals** are negatively impacted by the hand back of Treanda in Canada in the fourth quarter of 2017, after which Treanda revenue is replaced by a royalty agreement.

### Key developments in the second quarter of 2018

Revenue reached DKK 2,689 million in the second quarter of 2018, which is an increase of 9% in local currencies, but a decline of 1% reported. Revenue in North America contributed 61% of revenue (excluding Other revenue and effects from hedging) compared to 63% in the same period last year.

## **International Markets**

Revenue from International Markets, which comprise all Lundbeck's markets outside of Europe and North America, reached DKK 1,920 million in the first six months of 2018, compared to DKK 1,869 million in 2017. In local currencies, sales were up 11% driven by Brintellix and Cipralex/Lexapro in particular. In general, Lundbeck has realized strong growth in China which is benefitting from stocking of around DKK 150 million. Regions such as the Middle East are also showing solid momentum. International Markets constitutes 22% of revenue (excluding Other revenue and effects from hedging), which is at the same level as last year. The biggest markets are Australia, Brazil, China, Japan, Mexico and South Korea.

DKK million	H1 2018	H1 2017	Growth	Growth in local currencies	Q2 2018	Q2 2017	Growth	Growth in local currencies	Q1 2018
Abilify Maintena	61	50	23%	33%	32	25	30%	41%	29
Brintellix	197	165	20%	35%	92	85	8%	21%	105
Cipralex/Lexapro	945	887	7%	16%	476	418	14%	22%	469
Ebixa	253	280	(10%)	(3%)	112	104	8%	16%	141
Other pharmaceuticals	464	487	(5%)	1%	267	249	7%	13%	197
Total revenue	1,920	1,869	3%	11%	979	881	11%	19%	941

#### **Revenue – International Markets**

**Abilify Maintena** reached DKK 61 million in revenue in the first six months of 2018 representing a growth of 23% (33% in local currencies). Sales are mainly derived from Australia where Abilify Maintena shows solid momentum and has achieved a volume share of 23%.

**Brintellix** reached DKK 197 million in revenue or an increase of 20% (35% in local currencies) mainly driven by Brazil following the launch in March 2016. Brintellix also sees solid growth in countries such as South Korea where Brintellix now has 2.8% volume share and Turkey. The recent launch of Brintellix in China in April 2018 enables Lundbeck to make an even bigger difference for the many patients and caregivers affected by depression. Already today, Lundbeck is the market leader in the anti-depressant market in China as approximately 26% of all medicines prescribed for treating depression in China are invented by Lundbeck. Brazil, South Africa, South Korea and Turkey are the largest markets for Brintellix in the region.

**Cipralex/Lexapro** generated revenue of DKK 945 million representing a growth of 7% (16% in local currencies). Growth is driven by shipments moved forward especially to China and Lundbeck's partner Xian-Janssen in China. Brazil, China, Japan, Saudi Arabia and South Korea are the largest markets for Cipralex/Lexapro in the region.

**Ebixa** generated revenue of DKK 253 million representing a decline of 10% (3% in local currencies) following stocking in China up to license renewal by the end of 2017. China and South Korea are the largest markets for Ebixa in the region.

**Other pharmaceuticals** generated revenue of DKK 464 million, a decrease of 5% (1% growth in local currencies) compared to 2017. The decrease is explained by quarterly fluctuations and is not a permanent trend in the region.

**Rexulti** has been approved for the treatment of schizophrenia in Australia in June 2017 and the product was launched during the third quarter of 2017. In April 2018, Rexulti received regulatory and pricing approval in Saudi Arabia which is the only market other than U.S. so far to approve Rexulti as treatment for both schizophrenia and adjunctive therapy in depression (MDD). In Saudi Arabia, Lundbeck has a leading position with a share of the anti-depressant market of 22%. Rexulti has been submitted for approval in countries such as Brazil, Chile, Malaysia, Mexico and South Africa during 2017.

**Azilect** was approved by the Chinese FDA in late June 2017 and has been launched in October 2017 by Lundbeck. Parkinson's disease is the second most common neurodegenerative disease following Alzheimer's disease in China. Both Rexulti and Azilect are currently included in Other pharmaceuticals for the region.

#### Key developments in the second quarter of 2018

Revenue in the second quarter was DKK 979 million, corresponding to an increase of 11% reported but 19% in local currencies. Sales of Cipralex/Lexapro positively impacted by supply phasing to China as a consequence of stock pilling to address partner's plant reallocation amounting to approximately DKK 100 million. In the second quarter, International Markets constituted 22% of revenue (excluding Other revenue and effects from hedging) representing a slight increase compared to the same period in 2017.

#### **Europe**

Revenue reached DKK 1,518 million in the first half of 2018, representing a growth of 6% (7% in local currencies) compared to DKK 1,431 million in 2017 due to uptake of key products. Europe constitutes 17% of revenue (excluding Other revenue and effects from hedging) which is unchanged from last year.

DKK million	H1 2018	H1 2017	Growth	Growth in local currencies	Q2 2018	Q2 2017	Growth	Growth in local currencies	Q1 2018
Abilify Maintena	385	326	18%	19%	201	172	17%	17%	184
Brintellix	260	179	45%	45%	138	98	40%	41%	122
Cipralex	323	336	(4%)	(3%)	160	168	(5%)	(4%)	163
Other pharmaceuticals	550	590	(7%)	(6%)	274	285	(4%)	(3%)	276
Total revenue	1,518	1,431	6%	7%	773	723	7%	7%	745

#### Revenue – Europe

**Abilify Maintena** has been launched in all major markets in Europe. Sales uptake of Abilify Maintena is solid with sales reaching DKK 385 million. In Europe, the penetration of long-acting atypical antipsychotics is generally higher than seen in the U.S. (volume) and Abilify Maintena has a value share of 18-23% in most markets. Spain, France, Italy and the UK are the largest European markets for Abilify Maintena.

**Brintellix** revenue grew 45% thereby reaching DKK 260 million, and has been launched in most European markets. Brintellix realized solid growth in main countries such as France, Italy and Spain, where the product has achieved value market shares of 6.1%, 6.7% and 5.3%, respectively by July 2018. The volume shares are 1.9%, 2.6% and 1.8%, respectively. France, Italy and Spain are the largest European markets for Brintellix.

**Cipralex** generated revenue of DKK 323 million following a slight decline of 4%. The largest markets are France, Italy and Switzerland.

In July 2018, Lundbeck and Otsuka announced that the European Commission has approved **Rxulti**<sup>®</sup> (brexpiprazole) for the treatment of schizophrenia in adults. Lundbeck and Otsuka will now work with local pricing and reimbursement bodies in countries throughout Europe to help ensure that eligible patients are able to access Rxulti. The medicine is expected to be made available in the first EU markets during first half of 2019.

Revenue from **Other pharmaceuticals** was DKK 550 million, a decline of 7% compared to 2017, following continued generic erosion of mature products such as Azilect and Ebixa.

#### Key developments in the second quarter of 2018

In the second quarter, revenue reached DKK 773 million which was an increase of 7% compared to DKK 723 million in the same period last year. Europe constitutes 17% of revenue (excluding Other revenue and effects from hedging) which is a slight increase from last year.

## Expenses and income

Total costs in the first six months of 2018 were DKK 6,117 million compared to DKK 6,473 million for the same period in 2017 – a decline of 5%.

DKK million	H1 2018	H1 2017	Growth	Q2 2018	Q2 2017	Growth	Q1 2018
Cost of sales	1,711	1,957	(13%)	885	992	(11%)	826
COS-ratio	18.4%	23.1%		18.8%	23.2%		18.0%
Sales and distribution	2,592	2,864	(9%)	1,306	1,431	(9%)	1,286
S&D-ratio	27.9%	33.7%		27.8%	33.4%	-	28.1%
Administration	342	378	(9%)	189	188	1%	153
G&A-ratio	3.7%	4.4%		4.0%	4.4%	-	3.3%
Research and development	1,472	1,274	16%	760	622	22%	712
R&D-ratio	15.8%	15.0%	-	16.2%	14.5%	-	15.5%
Total costs	6,117	6,473	(5%)	3,140	3,233	(3%)	2,977

#### **Distribution of costs**

**Cost of sales** decreased 13% to DKK 1,711 million in the first six months of 2018. Cost of sales corresponds to 18.4% of total revenue compared to 23.1% in the first half of 2017. Cost of sales is positively impacted by the change in product mix, which resulted in reduced royalty costs. Furthermore, amortization of intangibles has declined from DKK 479 million in the first half of 2017 to DKK 407 million in 2018.

**Sales and distribution costs** were DKK 2,592 million, which was a decrease of 9% compared to 2017. Sales and distribution costs correspond to 27.9% of revenue, compared to 33.7% the year before.

Administrative expenses declined 9% to DKK 342 million, corresponding to 3.7% of total revenue in 2018.

**SG&A** costs for the period were DKK 2,934 million, compared to DKK 3,242 million in first half of 2017. The SG&A ratio for the period was 31.6%, compared to 38.1% in the same period the year before.

**Research and development costs** increased by 16% to DKK 1,472 million for the period. The R&D ratio reached 15.8% compared to 15.0% last year.

**Other operating items, net** amounted to an expense of DKK 165 million. In June 2018, Lundbeck LLC reached an agreement in principle to resolve the U.S. Department of Justice (DOJ) investigation related to Lundbeck LLC's relationship with and donations to independent patient assistance charitable foundations. As part of the agreement, Lundbeck LLC will pay DOJ USD 52.6 million (DKK 334 million). The settlement is recognized in Other operating items, net which also includes the gain from divestment of buildings in Copenhagen realized in the first quarter of 2018 and income from settlements in Australia.

## Key developments in the second quarter of 2018

In the second quarter of 2018, total costs amounted to DKK 3,140 million, which is a slight decrease compared to the same quarter last year.

## Depreciation, amortization and impairment charges

Depreciation, amortization and impairment charges, which are included in the individual expense categories, amounted to DKK 589 million in the first six months of 2018, compared to DKK 628 million the previous year. R&D is impacted by a write-down of the product rights for Carnexiv<sup>™</sup>.

-		-					
DKK million	H1 2018	H1 2017	Growth	Q2 2018	Q2 2017	Growth	Q1 2018
Cost of sales	485	546	(11%)	236	270	(13%)	249
Sales and distribution	21	24	(14%)	10	12	(21%)	11
Administration	10	14	(29%)	6	8	(30%)	4
Research and development	73	44	68%	55	22	150%	18
Total depreciation, amortization							
and impairment charges	589	628	(6%)	307	312	(2%)	282

#### Depreciation, amortization and impairment charges

### **Profit from operations (EBIT)**

**EBIT** for the first six months of 2018 reached DKK 3,006 million compared to DKK 2,061 million for the same period last year – a growth of 46%, but was to some extend impacted by stocking in International Markets. The **EBIT margin** increased significantly and reached 32.4% in 2018 compared to 24.3% last year.

**Core EBIT** increased 43% to DKK 3,578 million and the **Core EBIT margin** improved to 38.5% in the period. The increase in EBIT and in Core EBIT is driven by solid sales development and the margin is also benefitting from hedging gains of DKK 277 million.

#### Key developments in the second quarter of 2018

In the second quarter of 2018, EBIT amounted to DKK 1,350 million, which is an increase of 29% compared to the same quarter last year. The EBIT margin increased to 28.7% in the quarter compared to 24.5% last year.

For definition of the measures "Core Revenue", "Core EBIT" and "Core EPS", see note 9 Core reporting.

## **Net financials**

Lundbeck generated **net financial income** of DKK 6 million in the first half year of 2018, compared to a net expense of DKK 70 million in the first half year of 2017.

**Net interest income**, including realized and unrealized gains and losses on the bond portfolio, amounted to an income of DKK 19 million in the first half of 2018, compared to an expense of DKK 33 million in the same period in 2017. The interest income in 2018 primarily relates to income received from the Danish tax authorities regarding tax reassessments in the U.S. and Italy.

**Net exchange gains/losses** amounted to a loss of DKK 4 million in the first half of 2018, compared to a loss of DKK 31 million in the first half of 2017.

**Fair value adjustment** relating to other financial assets amounted to a net loss of DKK 6 million in the first half of 2018.

## Тах

The effective tax rate for the first half of 2018 is 27.0%. The effective tax rate has decreased significantly compared to 2017 due to the reduced U.S. federal tax rate. The effective tax rate is still higher than the Danish income tax rate due to amortization of Northera product rights, which is not deductible for tax purposes and thus creates a permanent difference.

### Net profit and EPS for the period

**Net profit** for the first six months of 2018 reached DKK 2,198 million compared to DKK 1,195 million for the same period last year. The reported net profit corresponds to an **EPS** of DKK 11.07 per share versus an EPS of DKK 6.05 per share for the same period last year. **Core EPS** was DKK 13.73 per share for the first six months of 2018, compared to a Core EPS of DKK 8.03 per share in 2017 – a growth of 71%.

In the second quarter of 2018, **Net profit** increased by 65% y/y thereby reaching DKK 999 million. **Core EPS** increased from DKK 4.11 to DKK 6.93, representing a growth of 69%.

## **Cash flow**

**Cash flows from operating activities** amounted to DKK 3,369 million in the first six months of 2018, against DKK 1,217 million in 2017. The increase of 177% follows the significant increase in profitability and improved working capital e.g. following the agreement in principle with the DOJ.

Lundbeck's **net cash flow from investing activities** was an outflow of DKK 1,370 million in the first six months of 2018 as a result of the acquisition of Prexton Therapeutics BV in March 2018 and of purchase of securities. **The free cash flow** reached DKK 1,999 million for the period compared to DKK 700 million for 2017.

In the first six months of 2018, the **net cash flow** reached DKK 416 million compared to an outflow of DKK 742 million for the same period of 2017. The net cash flow is furthermore impacted by dividend payout of DKK 1.6 billion.

At the Annual General Meeting in March 2018, the proposed **dividend** for 2017 of DKK 8.00 per share or DKK 1,592 million was approved. The dividend was paid to the shareholders in March 2018.

At 30 June 2018, Lundbeck's **total assets** amounted to DKK 21,703 million, compared to DKK 19,756 million at the end of 2017.

At 30 June 2018, Lundbeck's **equity** amounted to DKK 12,559 million, corresponding to an **equity ratio** of 57.9% compared to 61.7% at the end of 2017.

**Interest bearing debt** was reduced to DKK 0 during 2017. **Net cash** has increased from DKK 3,677 million at yearend 2017 to DKK 4,588 million at the end of the second quarter of 2018.

Return on invested capital (annualized) has increased to 53.2% compared to 30.8% by the end of 2017.

## Lundbeck's development portfolio

Lundbeck is developing several new and promising medicines for the treatment of psychiatric and neurological disorders within the indications of Alzheimer's, depression, Parkinson's and schizophrenia. Pipeline developments are summarized below.

#### Aripiprazole for prolonged release injectable suspension (Abilify Maintena)

- Abilify Maintena is an atypical anti-psychotic for intra-muscular, once-monthly use and a dopamine D<sub>2</sub> partial agonist
- Approved in the U.S. and in Europe in February and November 2013, respectively, for the treatment of adults with schizophrenia
- Invented by Otsuka in Japan and has been co-developed and co-commercialized by Otsuka and Lundbeck

November 2017: Lundbeck Canada and Otsuka Pharmaceutical Canada announced that Health Canada issued a Notice of Compliance for Abilify Maintena, approving a new indication for the maintenance monotherapy treatment of bipolar I disorder in adult patients.

July 2017: Lundbeck and Otsuka announced the U.S. FDA approval of Abilify Maintena for the maintenance monotherapy treatment of bipolar I disorder (BP-I). The approval is based on results from a 52-week, phase III, double-blind, randomized-withdrawal study in adults (aged 18 to 65) with BP-I (NCT01567527).

June 2017: Lundbeck together with Otsuka, initiated a phase I, open-label study to determine the pharmacokinetics and tolerability of aripiprazole 2-month intramuscular depot administered gluteal in adult subjects with schizophrenia.

## **Brexpiprazole (Rexulti)**

- The efficacy of brexpiprazole may be mediated through a combination of partial agonist activity at serotonin 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors, and antagonist activity at serotonin 5-HT<sub>2A</sub> receptors. Brexpiprazole exhibits high affinity (sub-nanomolar) for these receptors as well as for noradrenaline alpha<sub>1B/2C</sub> receptors
- Brexpiprazole was approved by the U.S. FDA in July 2015 for treating patients with schizophrenia and as an adjunctive treatment for patients with MDD
- Brexpiprazole was also approved in February 2017 by Health Canada, and in May 2017 by the Australian Department of Health, for the treatment of schizophrenia

- Brexpiprazole is distributed and marketed under the brand name Rexulti
- Discovered by Otsuka and co-developed and co-commercialized by Otsuka and Lundbeck

July 2018: Lundbeck and Otsuka Pharmaceutical announced that the European Commission has approved Rxulti (brexpiprazole) for the treatment of schizophrenia in adults. The approval follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) on 31 May 2018.

May 2018: Lundbeck and Otsuka Pharmaceutical announced that the two companies' third clinical phase III study (NCT03548584) of brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type commenced in June. Approximately 300 patients are expected to be enrolled in this 12-week, randomized, doubleblind, placebo-controlled trial. The decision to initiate a third trial follows discussions with the U.S. Food and Drug Administration (FDA) regarding two phase III clinical trials for the agitation in Alzheimer's disease indication that were completed by Otsuka and Lundbeck in 2017. Results for the two completed trials were announced in May of last year and presented in poster sessions at the American Association for Geriatric Psychiatry annual meeting in March of this year.

October 2017: Lundbeck and Otsuka Pharmaceutical announced that patient enrolment has been initiated in two global phase III clinical trials (NCT03259555 and NCT03257865) to evaluate brexpiprazole for the treatment of patients with manic episodes associated with bipolar I disorder. Both studies are expected to recruit around 320 patients, and are planned to finalize in the beginning of 2019.

May 2017: Lundbeck and Otsuka announced top-line results from two pivotal studies with brexpiprazole in individuals with agitation associated with dementia of the Alzheimer's type (NCT01862640, NCT01922258). In both studies, patients treated with brexpiprazole showed improvements in symptoms of agitation relative to placebo. In the first study, the improvements in the primary endpoint of CMAI for 2 mg brexpiprazole were statistically better than placebo (p<0.05) and appeared more robust than the improvements on the key secondary endpoint of CGI-S (p>0.05). In the second study, the improvements in the primary endpoint of CGI-S (p<0.05) appeared less robust than the improvements on the key secondary and tolerability, both studies confirmed the profile of brexpiprazole as observed in the clinical trials for schizophrenia and for adjunctive treatment of major depressive disorder. U.S. FDA has granted Fast Track designation for this programme.

January 2017: A phase II trial (NCT03033069) using brexpiprazole as monotherapy, or as combination therapy in the treatment of adults with Post-Traumatic Stress Disorder (PTSD) was initiated. The study is expected to enrol around 330 patients.

January 2017: A phase I open-label study (NCT02968121) to determine the pharmacokinetics and tolerability of **brexpiprazole LAI** (long-acting injectable) administered subcutaneously or intramuscularly was initiated. Part A of the study was completed per protocol. Evaluation of Part A data and subsequent clinical program is ongoing.

#### Carnexiv (carbamazepine) injection

In October 2016, the U.S. FDA approved Carnexiv (carbamazepine) injection as a short-term replacement therapy for oral carbamazepine formulations in adults with certain seizure types when oral administration is temporarily not feasible. In our preparation for the launch of Carnexiv, we discovered a manufacturing challenge that impacted our commercialization of the product. Since that time, we have worked diligently to determine the root cause of the manufacturing challenge and to identify the appropriate resolution; however, at this time, we do not have an adequate solution. Therefore, Lundbeck has decided to cease further activities on the product and will be exploring divestment opportunities.

## Nalmefene (Selincro)

- Nalmefene is an opioid receptor antagonist
- Nalmefene has been marketed in Europe by Lundbeck since April 2013 under the brand name Selincro as treatment for the reduction of alcohol consumption
- In October 2013, Otsuka was named as Lundbeck's partner for nalmefene in Japan
- A clinical phase III study (NCT02364947) was initiated in Japan in December 2014
- It is estimated that 800,000 people in Japan have been diagnosed with alcohol dependency

October 2017: Lundbeck (Japan) and Otsuka announced the Japanese submission by Otsuka of a new drug application (NDA) for nalmefene for patients with alcohol dependency.

June 2017: Lundbeck (Japan) and Otsuka announced positive topline results from the comparative clinical trial and a follow-on, long-term extension study in participants with an alcohol dependency.

## Vortioxetine (Brintellix/Trintellix)

- Vortioxetine is an inhibitor of serotonin (5-HT) reuptake and that is thought to be a mechanism of its action. It is also an agonist at 5-HT<sub>1A</sub> receptors, a partial agonist at 5-HT<sub>1B</sub> receptors and an antagonist at 5-HT<sub>3</sub>, 5-HT<sub>1D</sub> and 5-HT<sub>7</sub> receptors
- Vortioxetine is considered to be the first and only compound with this combination of pharmacodynamic activity
- Vortioxetine was discovered by Lundbeck. The clinical trial program in the U.S. was conducted jointly by Lundbeck and Takeda, and Takeda holds the new drug application for the U.S. market
- The U.S. FDA approved vortioxetine for the treatment of MDD in adults in 2013. Vortioxetine is furthermore approved in more than 77 markets (including Europe, Brazil, Canada, Chile, China, Mexico, Argentina, South Korea, Turkey, Australia, Hong Kong, Singapore and South Africa)

June 2018: Lundbeck and Takeda Pharmaceutical announced positive results from the pivotal study with vortioxetine in adults with Major Depressive Disorder conducted in Japan. Both companies intend to move forward with regulatory filing of vortioxetine later this year to the Ministry of Health, Labor and Welfare in Japan. Lundbeck plans to co-promote the product together with Takeda.

May 2018: Lundbeck and Takeda Pharmaceutical announced that U.S. FDA has approved a supplemental new drug application for Trintellix. The clinical trials section of the U.S. label now includes data from the largest replicated clinical studies on an important aspect of cognitive function in acute major depressive disorder (MDD, depression). The *FOCUS* and *CONNECT* studies show Trintellix has a positive effect on processing speed, an important aspect of cognitive function observed in some patients with MDD. Additionally, a sNDA has been submitted in the U.S. for Trintellix to include data on treatment emergent sexual dysfunction in depression (TESD). PDUFA is scheduled on 21 October 2018.

December 2017: Lundbeck announced that it further enhances its leading position within treatments for Major Depressive Disorder (depression) in China as Brintellix (vortioxetine) has been approved by China Food and Drug Administration.

## Lu AF35700 – phase III

• Lu AF35700 has a novel pharmacological profile with predominant D<sub>1</sub> vs. D<sub>2</sub> dopamine receptor occupancy, and a high occupancy of 5-HT<sub>2A</sub> and 5-HT<sub>6</sub> serotonin receptors

- The relatively low dopamine D<sub>2</sub> receptor occupancy of Lu AF35700 is expected to result in reduced burden of adverse events, such as extrapyramidal symptoms (EPS), prolactin elevation, dysphoria/anhedonia, and depressed mood
- In completed safety trials, Lu AF35700 was generally well tolerated with a beneficial safety profile
- U.S. FDA has granted Fast Track designation for Lu AF35700 a first important step to ensure a potential expedited approval of the compound

July 2017: Lundbeck initiated the *Anew*-study (NCT03230864) to evaluate the efficacy of 10 mg/day Lu AF35700 on symptoms of schizophrenia in patients with early-in-disease (ED) or late-in-disease (LD) treatment-resistant schizophrenia. The study is expected to recruit around 300 patients and is planned to finalize during 2019.

August 2016: Lundbeck initiated an open-label, flexible-dose, long-term safety study of Lu AF35700 in adult patients with schizophrenia (NCT02892422).

March 2016: Lundbeck initiated the phase III programme on Lu AF35700 which is currently planned to consist of two pivotal trials. Two doses of Lu AF35700 (10 and 20 mg) will be tested in patients with treatment resistant schizophrenia. The first study, *DayBreak I* (NCT02717195) is planned to enrol around 1,000 patients in approximately 15 countries including the U.S. and Canada.

## Foliglurax – phase II

- Foliglurax works by stimulating a specific glutamatergic target (mGluR4), which activates a compensatory
  neuronal system in the brain which is largely unaffected in Parkinson's disease. Animal models have
  convincingly demonstrated positive effects in models of Parkinson's disease. The aim is to treat the motor
  symptoms of Parkinson's disease, such as resting tremor, muscle rigidity and uncontrolled movements
  (dyskinesia)
- A single- and multiple-ascending oral dose phase I trial (NCT02639221) in healthy volunteers using foliglurax was successfully completed in 2016. The results showed that foliglurax appears well-tolerated with a satisfactory pharmacokinetic profile
- In July 2017, Prexton initiated a phase II clinical trial (NCT03162874) with foliglurax. The trial will enroll
  around 165 Parkinson's patients in sites across six European countries (U.K., Germany, France, Austria,
  Spain, and Italy). The double-blinded, randomized, placebo-controlled, parallel-arm study will assess the
  effectiveness, safety, and tolerability of foliglurax in reducing motor complications of levodopa therapy in
  patients experiencing end-of-dose wearing-off and levodopa-induced dyskinesia

March 2018: Lundbeck announced signing of a definitive agreement in which Lundbeck acquires Prexton Therapeutics BV. Under terms of the agreement, Lundbeck paid EUR 100 million (DKK 745 million) upfront and is required to pay up to EUR 805 million (approximately DKK 6 billion) under certain conditions in development and sales milestones to the group of former owners. More than half of the EUR 805 million is connected to sales milestones. The upfront payment was capitalized in the balance sheet as an intangible asset and will be tested for impairment annually or whenever there is indication of impairment.

## Lu AF20513 – phase I

- Lu AF20513 is an active vaccine inducing high affinity polyclonal antibodies that target beta-amyloid (Aß), for the potential injectable prevention of progression of Alzheimer's
- Lu AF20513 is expected to provide an enhanced and heterogeneous immunogenic response towards Aβ
  peptides in comparison to mono-clonal antibody treatment strategies as it may activate the body's immune
  system to fight the formation of the plaques which are believed to be involved in the disease

May 2015: An open-label, dose escalation, multiple immunisation phase I study (NCT02388152) was initiated, to assess the safety, tolerability and immunogenicity of Lu AF20513 in patients with mild Alzheimer's disease.

December 2013: Lundbeck and Otsuka announced that they will further expand their collaboration to include the development of Lu AF20513. The agreement covers the development of Lu AF20513 through clinical phase I.

#### Lu AF76432 – phase I

- Phosphodiesterase type 1 (PDE1) is an enzyme naturally present in the human brain where it plays an
  important role in the communication between brain cells. Inhibiting the enzyme increases the presence of
  a chemical messenger within the cells that improves the communication, in turn improving the cognitive
  function
- Addresses impaired communication between cells in certain parts of the brain that causes cognitive/functional deficits, e.g. the loss of concentration, loss of memory, the ability to learn and planning of daily tasks. Such cognitive symptoms are prominent in diseases like schizophrenia and Alzheimer's disease, and Lu AF76432 has the potential to help ease these symptoms in patients suffering from these diseases

May 2018: A phase I-study (NCT03531229) in healthy volunteers (n = -48) with the compound, invented by Lundbeck, has just begun. The phase I-study is designed to provide information about safety and tolerability, general pharmacokinetic characteristics and to identify maximum tolerated dose.

#### Lu AF28996 - phase I

In June 2018, Lundbeck initiated a phase I study (NCT03565094) of a potential new treatment of Parkinson's disease (n =  $\sim$ 20 healthy young men).

Lu AF28996 is a  $D_1/D_2$  agonist with the potential to treat common symptoms in patients with moderate/advanced Parkinson's disease. Typically, patients gradually develop fluctuations in the control of their symptoms with poor or absent motor function (so called *OFF* episodes) and experience involuntary movements (dyskinesia). Both these symptoms are thought to be treated effectively with Lu AF28996.

### Lu AF82422 – phase I

In August 2018, Lundbeck initiated a single-ascending-dose (SAD), first-in-human study (n=~45) to evaluate the safety and tolerability of Lu AF82422 in healthy volunteers and Parkinson's patients.

Lu AF82422 is a human IgG1 mAb that recognizes all major alpha-synuclein forms including aggregated/misfolded forms involved in the pathogenesis of Parkinson's. There is compelling evidence that alpha-synuclein may play a role in progression of Parkinson's and other synucleinopathies.

## General corporate matters

Lundbeck is involved in legal proceedings in several countries against a number of businesses, including patent disputes. In the Annual Report 2017 (page 50), Lundbeck provided an overview of pending legal proceedings.

In June 2013, Lundbeck received the European Commission's decision that the company's agreements concluded with four generic competitors concerning citalopram violated competition law. The decision included fining Lundbeck EUR 93.8 million (approximately DKK 700 million). On 8 September 2016, Lundbeck announced that the General

Court of the European Union had delivered its judgment concerning Lundbeck's appeal against the European Commission's 2013 decision. Lundbeck's appeal was rejected by the General Court. Lundbeck has appealed the judgment to the European Court of Justice. Lundbeck paid and expensed the fine in the third quarter of 2013. A final judgment is expected during 2019.

In December 2011, the Brazilian antitrust authorities SDE (Secretariat of Economic Law) initiated administrative proceedings to investigate whether Lundbeck's enforcement of data protection rights could be viewed as anticompetitive conduct. In January 2012, Lundbeck submitted a response to the authorities. Due to a change in the Brazilian Antitrust Law, handling of the case has shifted from SDE to CADE (Administrative Council for Economic Defense). In April, May and June 2018 CADE's Superintendence, CADE's General Attorney and the Federal Public Prosecutor, respectively, issued opinions stating that Lundbeck in defending its data protection rights had not acted in violation of Brazilian competition law regulation. All three authorities therefore recommended that the case should be closed without any consequences for Lundbeck. The final decision on the matter will be made by CADE's Tribunal and is expected during 2018.

H. Lundbeck A/S and Lundbeck Canada Inc. are involved in three product liability class-action lawsuits relating to Cipralex<sup>®</sup>/Celexa<sup>®</sup> and four relating to Abilify Maintena in Canada. The cases are in the preliminary stages and as such associated with significant uncertainties. Lundbeck strongly disagrees with the claims raised.

In June 2018 Lundbeck announced that its U.S. subsidiary Lundbeck LLC has reached an agreement in principle to resolve the U.S. Department of Justice (DOJ) investigation related to Lundbeck LLC's relationship with and donations to independent patient assistance charitable foundations. The final terms of agreement are subject to further negotiation with DOJ. As part of the agreement, Lundbeck LLC will pay DOJ USD 52.6 million (DKK 334 million). Lundbeck LLC is pleased to have reached an agreement that will allow the company to put this matter behind it. The agreement does not include any admission by Lundbeck LLC that it violated any law. The agreement will allow Lundbeck LLC to continue its focus on providing innovative medications to the patients.

#### **Conference call**

Today at 11.30 CET, Lundbeck will be hosting a conference call for the financial community. You can find dial-ins and a link for webcast online at www.lundbeck.com under the Investor section.

# MANAGEMENT STATEMENT

The Board of Directors and the registered Executive Management have discussed and adopted the interim report of H. Lundbeck A/S for the period 1 January - 30 June 2018. 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 2018, and of the results of the Group's operations and cash flows for the period, which ended on 30 June 2018.

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 view of the significant risks and uncertainty factors that may affect the Group.

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

Valby, 8 August 2018

### **Registered Executive Management**

Anders Götzsche Interim CEO, Executive Vice President and CFO	Lars Bang Executive Vice President, Supply Operations & Engineering	
Anders Gersel Pedersen Executive Vice President, R&D	Jacob Tolstrup Executive Vice President, Commercial Operations	
Board of Directors		
Lars Søren Rasmussen Chairman of the Board	Lene Skole-Sørensen Deputy Chairman of the Board	Henrik Andersen
Jeffrey Berkowitz	Lars Erik Holmqvist	Jeremy Max Levin
Rikke Kruse Andreasen Employee representative	Jørn Møller Mayntzhusen Employee representative	Ludovic Tranholm Otterbein Employee representative

# FINANCIAL STATEMENTS

## Income statement

DKK million	H1 2018	H1 2017	Q2 2018	Q2 2017	FY 2017
Revenue	9,288	8,494	4,703	4,283	17,234
Cost of sales	1,711	1,957	885	992	3,881
Gross profit	7,577	6,537	3,818	3,291	13,353
Sales and distribution costs	2,592	2,864	1,306	1,431	5,649
Administrative expenses	342	378	189	188	833
Research and development costs	1,472	1,274	760	622	2,705
Other operating items, net	(165)	40	(213)	-	242
Profit from operations (EBIT)	3,006	2,061	1,350	1,050	4,408
Net financials	6	(70)	19	(55)	(131)
Profit before tax	3,012	1,991	1,369	995	4,277
Tax on profit for the period	814	796	370	387	1,653
Profit for the period	2,198	1,195	999	608	2,624
Earnings per share, basic (EPS) (DKK)	11.07	6.05	5.03	3.07	13.28
Earnings per share, diluted (DEPS) (DKK)	11.06	6.04	5.03	3.06	13.26

# Statement of comprehensive income

DKK million	H1 2018	H1 2017	Q2 2018	Q2 2017	FY 2017
Profit for the period	2,198	1,195	999	608	2,624
Actuarial gains/losses	-	-	-	-	33
Тах	-	-	-	-	(5)
Items that will not be reclassified					
subsequently to profit or loss	-	-	-	-	28
Exchange rate gains/losses on investments in					
foreign subsidiaries	171	(284)	254	(247)	(447)
Exchange rate gains/losses on additions to net					
investments in foreign subsidiaries	(94)	(86)	(84)	(61)	(107)
Deferred exchange gains/losses, hedging	(180)	561	(264)	514	817
Exchange gains/losses, hedging (transferred to					
the hedged items)	(277)	100	(95)	20	(33)
Fair value adjustment of available-for-sale					
financial assets	-	16	-	21	16
Tax	121	(122)	97	(100)	(143)
Items that may be reclassified subsequently					
to profit or loss	(259)	185	(92)	147	103
Other comprehensive income	(259)	185	(92)	147	131
Comprehensive income	1,939	1,380	907	755	2,755

## **Balance sheet**

DKK million	30.06.2018	30.06.2017	31.12.2017
Assets			
Intangible assets	7,989	7,880	7,565
Property, plant and equipment	1,946	1,938	1,990
Financial assets	1,253	1,373	1,357
Non-current assets	11,188	11,191	10,912
Inventories	1,971	1,807	1,376
Receivables	3,956	4,115	3,791
Securities	2,027	518	1,522
Cash and bank balances	2,561	1,443	2,155
Assets held for sale	-	125	
Current assets	10,515	8,008	8,844
Assets	21,703	19,199	19,756
Equity and liabilities			
Share capital	995	992	995
Foreign currency translation reserve	732	813	634
Currency hedging reserve	25	286	382
Retained earnings	10,807	8,604	10,170
Equity	12,559	10,695	12,181
Provisions	1,024	991	1,039
Debt	68	870	57
Non-current liabilities	1,092	1,861	1,096
Provisions	557	634	491
Debt	-	43	
Trade payables	4,057	3,200	3,203
Other payables	3,438	2,766	2,785
Current liabilities	8,052	6,643	6,479
Liabilities	9,144	8,504	7,57
Equity and liabilities	21,703	19,199	19,756

# Statement of changes in equity

DKK million	Share capital	currency translation reserve	Currency hedging reserve	Retained earnings	Equ
Equity at 1 January 2018	995	634	382	10,170	12,18
Profit for the period	-	-	-	2,198	2,19
Other comprehensive income	-	98	(357)	-	(259
Comprehensive income	-	98	(357)	2,198	1,93
Distributed dividends, gross	-	-	-	(1,592)	(1,592
Dividends received, treasury shares	-	-	-	3	
Capital increase through exercise of warrants	-	-	-	6	
Incentive programmes	-	-	-	14	1
Tax on other transactions in equity	-	-	-	8	
Other transactions	-	-	-	(1,561)	(1,56 <sup>-</sup>
Equity at 30 June 2018	995	732	25	10,807	12,55
Equity at 30 June 2018 DKK million Equity at 1 January 2017	995 988	1,164	(230)	7,772	
DKK million					9,69
DKK million Equity at 1 January 2017	988	1,164	(230)	7,772	<b>9,69</b> 1,19
DKK million Equity at 1 January 2017 Profit for the period	988	1,164	(230)	<b>7,772</b> 1,195	<b>9,69</b> 1,19 18
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income	988	<b>1,164</b> (351)	<b>(230)</b> - 516	<b>7,772</b> 1,195 20	<b>9,69</b> 1,19 18 <b>1,38</b>
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income Comprehensive income	988 - - -	<b>1,164</b> (351) <b>(351)</b>	<b>(230)</b> 516 <b>516</b>	<b>7,772</b> 1,195 20 <b>1,215</b>	<b>9,69</b> 1,19 18 <b>1,38</b> (484
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income Comprehensive income Distribution of dividends, gross	988 - - -	<b>1,164</b> (351) <b>(351)</b>	<b>(230)</b> - 516 <b>516</b> -	<b>7,772</b> 1,195 20 <b>1,215</b> (484)	<b>9,69</b> 1,19 18 <b>1,38</b> (484
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income Comprehensive income Distribution of dividends, gross Dividends received, treasury shares	988 - - - - -	<b>1,164</b> (351) (351)	(230) - 516 516 - -	<b>7,772</b> 1,195 20 <b>1,215</b> (484) 1	<b>9,69</b> 1,19 18 <b>1,38</b> (484 (484
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income Comprehensive income Distribution of dividends, gross Dividends received, treasury shares Capital increase through exercise of warrants	988 - - - - -	<b>1,164</b> (351) (351)	(230) - 516 516 - - - -	<b>7,772</b> 1,195 20 <b>1,215</b> (484) 1 120	<b>9,69</b> 1,19 1,38 (484 (484 (93) (93) 2
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income Comprehensive income Distribution of dividends, gross Dividends received, treasury shares Capital increase through exercise of warrants Buyback of treasury shares	988 - - - - - 4 -	<b>1,164</b> (351) ( <b>351)</b> - - - -	(230) - 516 516 - - - - - -	<b>7,772</b> 1,195 20 <b>1,215</b> (484) 1 120 (93)	<b>9,69</b> 1,19 18 <b>1,38</b> (484 12 (93
DKK million Equity at 1 January 2017 Profit for the period Other comprehensive income Comprehensive income Distribution of dividends, gross Dividends received, treasury shares Capital increase through exercise of warrants Buyback of treasury shares Incentive programmes	988 - - - - - 4 - -	<b>1,164</b> (351) ( <b>351)</b> - - - -	(230) - 516 516 - - - - - -	<b>7,772</b> 1,195 20 <b>1,215</b> (484) 1 120 (93) 28	<b>9,69</b> 1,19 18 <b>1,38</b> (48- 12 (93) 2

# **Cash flow statement**

DKK million	H1 2018	H1 2017	Q2 2018	Q2 2017	FY 201
Profit from operations (EBIT)	3,006	2,061	1,350	1,050	4,408
Adjustments for non-cash operating items etc.	609	509	268	239	871
Change in working capital	81	(646)	5	(162)	291
Cash flows from operations before financial receipts					
and payments	3,696	1,924	1,623	1,127	5,570
Financial receipts and payments	8	(41)	12	(29)	(96
Cash flows from ordinary activities	3,704	1,883	1,635	1,098	5,474
Income taxes paid	(335)	(666)	(269)	(532)	(1,429
Cash flows from operating activities	3,369	1,217	1,366	566	4,045
Acquisition of subsidiary*	(745)	-	-	-	
Purchase and sale of securities and other financial assets	(508)	(504)	(501)	(500)	(1,509
Purchase and sale of intangible assets and property, plant					
and equipment	(117)	(13)	(74)	(47)	(321
Cash flows from investing activities	(1,370)	(517)	(575)	(547)	(1,830
Cash flows from operating and investing activities					
(free cash flow)	1,999	700	791	19	2,21
Capital increase through exercise of warrants	6	124	5	122	21
Dividends paid in the financial year, net	(1,589)	(483)	-	(483)	(483
Other financing activities	-	(1,083)	-	(924)	(1,966
Cash flows from financing activities	(1,583)	(1,442)	5	(1,285)	(2,235
Net cash flow for the period	416	(742)	796	(1,266)	(20
Cash and bank balances at beginning of period	2,155	2,200	1,771	2,728	2,20
Unrealized exchange gains/losses on cash and bank					
balances	(10)	(15)	(6)	(19)	(25
Net cash flow for the period	416	(742)	796	(1,266)	(20
Cash and bank balances at end of period	2,561	1,443	2,561	1,443	2,15
Interest-bearing debt, cash, bank balances and securities, net is composed as follows:					
Cash and bank balances	2,561	1,443	2,561	1,443	2,15
Securities	2,027	518	2,027	518	1,52
Interest-bearing debt	-	(909)	-	(909)	*
Interest-bearing debt, cash, bank balances and		(/		· · · · /	
securities, net end of period – Net cash/(net debt)	4,588	1,052	4,588	1,052	3,67

\*) The acquisition of Prexton Therapeutics BV, which is considered a purchase of assets, consists of the foliglurax product rights valued at DKK 712 million, tax assets of DKK 39 million, as well as net liabilities totaling DKK 6 million.

# Income statement – Core results reconciliation (first half)

## H1 2018

DKK million	Reported result	Intangible amortization	Impairment	Major restructuring	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	9,288	-	-	-	-	-	9,288
Cost of sales	1,711	(407)	-	-	-	-	1,304
Gross profit	7,577	407	-	-	-	-	7,984
Sales and distribution costs	2,592	-	-	-	-	-	2,592
Administrative expenses	342	-	-	-	-	-	342
Research and development costs	1,472	-	-	-	-	-	1,472
Other operating items, net	(165)	-	-	-	213	(48)	-
Profit from operations (EBIT)	3,006	407	-	-	213	(48)	3,578
Net financials	6	-	-	-	-	-	6
Profit before tax	3,012	407	-	-	213	(48)	3,584
Tax on profit for the period	814	41	-	-	13	(11)	857
Profit for the period	2,198	366	-	-	200	(37)	2,727
Earnings per share, basic (EPS) (DKK)	11.07	1.84	-	-	1.00	(0.18)	13.73

## H1 2017

DKK million	Reported result	Intangible amortization	Impairment	Major restructuring	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	8,494	-	-	-	-	-	8,494
Cost of sales	1,957	(479)	-	-	-	-	1,478
Gross profit	6,537	479	-	-	-	-	7,016
Sales and distribution costs	2,864	-	-	-	-	-	2,864
Administrative expenses	378	-	-	-	-	-	378
Research and development costs	1,274	-	-	-	-	-	1,274
Other operating items, net	40	-	-	-	-	(40)	-
Profit from operations (EBIT)	2,061	479	-	-	-	(40)	2,500
Net financials	(70)	-	-	-	-	-	(70)
Profit before tax	1,991	479	-	-	-	(40)	2,430
Tax on profit for the period	796	65	-	-	-	(16)	845
Profit for the period	1,195	414	-	-	-	(24)	1,585
Earnings per share, basic (EPS) (DKK)	6.05	2.10	-	-	-	(0.12)	8.03

# Income statement – Core results reconciliation (Q2)

## Q2 2018

DKK million	Reported result	Intangible amortization	Impairment	Major restructuring	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	4,703	-	-	-	-	-	4,703
Cost of sales	885	(197)	-	-	-		688
Gross profit	3,818	197	-	-	-	-	4,015
Sales and distribution costs	1,306	-	-	-	-	-	1,306
Administrative expenses	189	-	-	-	-	-	189
Research and development costs	760	-	-	-	-	-	760
Other operating items, net	(213)	-	-	-	213	-	-
Profit from operations (EBIT)	1,350	197	-	-	213	-	1,760
Net financials	19	-	-	-	-	-	19
Profit before tax	1,369	197	-	-	213	-	1,779
Tax on profit for the period	370	19	-	-	13	-	402
Profit for the period	999	178	-	-	200		1,377
Earnings per share, basic (EPS) (DKK)	5.03	0.90	-	-	1.00	-	6.93

## Q2 2017

DKK million	Reported result	Intangible amortization	Impairment	Major restructuring	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	4,283	-	-	-	-	-	4,283
Cost of sales	992	(237)	-	-	-	-	755
Gross profit	3,291	237	-	-	-	-	3,528
Sales and distribution costs	1,431	-	-	-	-	-	1,431
Administrative expenses	188	-	-	-	-	-	188
Research and development costs	622	-	-	-	-	-	622
Other operating items, net	-	-	-	-	-	-	-
Profit from operations (EBIT)	1,050	237	-	-	-	-	1,287
Net financials	(55)	-	-	-	-	-	(55)
Profit before tax	995	237	-	-	-	-	1,232
Tax on profit for the period	387	32	-	-	-	-	419
Profit for the period	608	205	-	-	-	-	813
Earnings per share, basic (EPS) (DKK)	3.07	1.04	-	-	-	-	4.11

## **Notes**

#### Note 1 Accounting policies

The Financial Report for the period 1 January – 30 June 2018 has been prepared in accordance with IAS 34 *Interim Financial Reporting* as endorsed by the EU and additional Danish disclosure requirements for interim reports for listed companies.

As of 1 January 2018, Lundbeck has implemented IFRS 9 Financial Instruments.

The implementation has an impact on the presentation of fair value adjustments on equity investments previously classified as available-for-sale financial assets. These fair value adjustments were previously recognized in other comprehensive income. As from 1 January 2018, Lundbeck will irrevocably and on an individual basis classify such fair value adjustments of each equity investment either in the income statement under financial items or in other comprehensive income. For all equity investments held at 1 January 2018, Lundbeck has decided to recognize fair value adjustments in the income statement under financial items. Comparative figures have not been restated. However, if IFRS 9 *Financial Instruments* had been implemented for the financial year 2017, profit for the year would have been DKK 20 million higher, but the implementation would not have had any impact on total comprehensive income, total equity or total assets and liabilities.

Further, in accordance with IFRS 9 *Financial Instruments* write-downs on receivables are calculated using the 'full lifetime expected credit losses'-method, whereby the likelihood of non-fulfilment is taken into consideration. Comparative figures have not been restated as the change does not have any impact.

The implementation of IFRS 9 Financial Instruments does not have any impact on hedging.

In addition, also as of 1 January 2018, Lundbeck has implemented IFRS 15 *Revenue from Contracts with Customers*. The new standard does not have any impact on current revenue contracts except for the timing of recognition of some future milestone payments from collaborations and licensing arrangements. Earlier recognition may apply when it is highly probable that no significant reversal of the revenue will occur. We do not expect this to have any material impact in 2018.

Further, Lundbeck has changed the accounting policies for 'Translation of foreign currency' and 'Net financials'. The previous exception whereby currency translation related to hedged items was recognized in the same item as the hedged items no longer applies and such exchange differences are now recognized in financial items. Comparative figures have not been restated as the impact is considered immaterial.

Apart from the above, accounting policies remain unchanged compared to the 2017 Annual Report, to which reference is made.

For accounting estimates, see note 2 Significant accounting estimates and judgements in the 2017 Annual Report.

For risks, see the 2017 Annual Report.

### Note 2 Other operating items, net

Please see Expenses and income; page 10.

### Note 3 Acquisition of Prexton Therapeutics BV

In March 2018, Lundbeck announced signing of a definitive agreement in which Lundbeck acquired Prexton Therapeutics BV. Under terms of the agreement, Lundbeck paid EUR 100 million (DKK 745 million) upfront and is furthermore required to later pay up to EUR 805 million (approximately DKK 6 billion) under certain conditions in development and sales milestones to the group of former owners. The acquisition is considered a purchase of assets, mainly the foliglurax product rights and tax assets.

## Note 4 Dividends for 2017

Please see Cash flow; page 12.

## Note 5 Fair value measurement

Financial assets and financial liabilities measured or disclosed at fair value	Level 1	Level 2	Level 3
2018:			
Financial assets			
Securities <sup>1</sup>	2,027	-	-
Other financial assets <sup>1</sup>	26	-	34
Derivatives <sup>1</sup>	-	141	-
Total	2,053	141	34
Financial liabilities			
Derivatives <sup>1</sup>	-	109	-
Total	-	109	-
2017:			
Financial assets			
Securities <sup>1</sup>	518	-	-
Available-for-sale financial assets <sup>1</sup>	35	-	32
Derivatives <sup>1</sup>	-	379	-
Total	553	379	32
Financial liabilities			
Mortgage debt <sup>2</sup>	883	-	-
Derivatives <sup>1</sup>	-	11	-
Total	883	11	-

1) Measured at fair value. 2) Disclosed at fair value

The fair value of securities is based on publicly quoted prices on the invested assets.

The fair value of derivatives is calculated by applying recognized measurement techniques, whereby the Group makes assumptions that are based on the market conditions prevailing on the closing date.

## Note 6 Contingent assets and contingent liabilities

Except for the agreement reached in principle to resolve the U.S. Department of Justice (DOJ) investigation as mentioned in the section General corporate matters (page 17), no material changes to contingent assets and contingent liabilities have occurred since 31 December 2017.

#### Note 7 Events after the balance sheet date

2 July 2018: Lundbeck announced that the Board of Directors of the company has appointed Dr. Deborah Dunsire as new president and CEO of Lundbeck. Dr. Dunsire will take up her new position on 1 September 2018. From 1 September 2018, Anders Götzsche, interim CEO and CFO in Lundbeck will resume his position as EVP and CFO for the company.

## **Note 8 EBITDA calculation**

DKK million	H1 2018	H1 2017	Q2 2018	Q2 2017
EBIT	3,006	2,061	1,350	1,050
+ Depreciation, amortization and impairment charges	589	628	307	312
- Gain from divestment of properties recognized in Other				
operating items, net	(48)	(40)	-	-
= EBITDA	3,547	2,649	1,657	1,362

## **Note 9 Core reporting**

In general, Lundbeck has adjusted for each non-recurring item, including milestones that are accumulated, or are expected to accumulate, to an amount exceeding a DKK 100 million threshold within the year that Lundbeck's management deems it exceptional. Lundbeck's core reporting is a non-IFRS performance measurement. Lundbeck's core results – including core operating income (core EBIT) and core EPS – exclude:

Amortization and impairments:

- Amortization of intangible assets
- Impairment of intangible assets and property, plant and equipment

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.

## Financial calendar 2018

7 November 2018: Financial statements for the first nine months of 2018

## Lundbeck contacts

Investors:	Media:
Palle Holm Olesen	Mads Kronborg
Vice President, Investor Relations	Senior Director, Corporate Communication
palo@lundbeck.com	mavk@lundbeck.com
+45 30 83 24 26	+45 36 43 40 00

## About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) is a global pharmaceutical company specialized in psychiatric and neurological disorders. For more than 70 years, we have been at the forefront of research within neuroscience. Our key areas of focus are Alzheimer's disease, depression, Parkinson's disease and schizophrenia.

Our approximately 5,000 employees in 55 countries are engaged in the entire value chain throughout research, development, manufacturing, marketing and sales. Our pipeline consists of several late-stage development programmes and our products are available in more than 100 countries. We have production facilities in Denmark, France and Italy. Lundbeck generated revenue of DKK 17.2 billion in 2017 (EUR 2.3 billion; USD 2.6 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us on Twitter at @Lundbeck.