

Financial report for the period 1 January to 31 March 2017

# 2017 guidance raised based on strong revenue growth and improved profitability

## **HIGHLIGHTS**

- Revenue reached DKK 4,211 million in the first quarter of 2017 representing an increase of 12% compared to the same period last year
  - > Revenue in North America increased by 21% to DKK 2,437 million (21% in local currency)
  - > Revenue in International Markets increased by 6% to DKK 991 million (3% in local currencies)
  - > Revenue in Europe decreased by 5% to DKK 709 million (6% decline in local currencies)
- Revenue from key products grew 46% (46% in local currencies) to DKK 1,980 million in the period representing 47% of total revenue
  - > Revenue of Abilify Maintena® increased by 22% to DKK 312 million (23% in local currencies)
  - Revenue of Brintellix®/Trintellix® increased by 54% to DKK 367 million (49% in local currencies)
  - Revenue of Northera® increased by 70% to DKK 340 million (73% in local currency)
  - Revenue of Onfi<sup>®</sup> increased by 27% to DKK 690 million (27% in local currency)
  - Revenue of Rexulti<sup>®</sup> increased by 133% to DKK 271 million (136% in local currency)
- EBIT improved significantly reaching DKK 1,011 million from DKK 483 million in 2016 and the EBIT margin reached 24.0% compared to an EBIT margin of 12.8% the year before
- EPS grew more than 200% in the quarter to DKK 2.98 compared to DKK 0.94 in 2016
- The free cash flow reached DKK 681 million compared to a free cash flow of DKK 320 million last year. The
  net cash position has further improved to DKK 975 million compared to net debt of DKK 2,052 million at the
  end of the first guarter of 2016
- Following the solid sales performance for products such as Sabril<sup>®</sup>, Lundbeck now expects revenue to reach DKK 16.5-17.3 billion and profit from operations (EBIT) to reach DKK 3.6-4.0 billion for 2017 compared to previously DKK 16.3-17.1 billion and DKK 3.4-3.8 billion, respectively. The potential gain from the divestiture of properties announced 5 May 2017 is not included in the revised financial guidance
- Brexpiprazole demonstrates improvement of agitation symptoms related to Alzheimer's-type dementia following treatment with brexpiprazole relative to placebo

## In connection with the financial report, Lundbeck's President and CEO, Kåre Schultz said:

"Lundbeck is off to a strong start in 2017 by delivering double-digit revenue growth and more than doubling earnings. I am pleased with the performance and confident that 2017 will be our best financial year ever."

DKK million	Q1 2017	Q1 2016	Growth
Reported Revenue	4,211	3,770	12%
Reported EBIT	1,011	483	109%
Reported EPS	2.98	0.94	217%
Reported EBIT margin	24.0%	12.8%	-
Core Revenue*	4,211	3,770	12%
Core EBIT*	1,213	749	62%
Core EPS*	3.92	2.07	89%
Core EBIT margin*	28.8%	19.9%	-

<sup>\*</sup>For definition of the measures "Core Revenue", "Core EBIT" and "Core EPS", see note 7 Core reporting

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# FINANCIAL HIGHLIGHTS AND KEY FIGURES

	Q1 2017	Q1 2016	FY 2016
Financial highlights (DKK million)			
Reported revenue	4,211	3,770	15,634
Core revenue	4,211	3,770	15,634
Operating profit before depreciation and amortization (EBITDA)	1,287	824	3,846
Reported profit from operations (EBIT)	1,011	483	2,292
Core profit from operations (core EBIT)	1,213	749	3,477
Net financials	(15)	(123)	(135)
Profit before tax	996	360	2,157
Tax	409	174	946
Profit for the period	587	186	1,211
Equity	9,821	8,733	9,694
Assets	20,678	20,614	20,210
Cash flows from operating and investing activities (free cash flow)	681	320	2,789
Purchase of property, plant and equipment, gross	28	21	238
Key figures			
EBIT margin (%)	24.0	12.8	14.7
Return on invested capital (ROIC) (%)	6.6	2.8	13.2
Annualized return on invested capital (ROIC) (%)	26.5	11.3	13.2
Cash-to-earnings (%)	115.9	172.4	230.3
Research and development ratio (%)	15.5	19.4	19.0
Return on equity (%)	6.0	2.1	13.1
Equity ratio (%)	47.5	42.4	48.0
Invested capital (DKKm)	8,846	10,785	9,368
Net debt/EBITDA	(0.8)	2.5	(0.1)
Share data			
Number of shares for the calculation of EPS (millions)	197.3	197.2	197.2
Number of shares for the calculation of DEPS (millions)	197.5	197.5	197.4
Earnings per share, basic (EPS) (DKK)	2.98	0.94	6.14
Earnings per share, diluted (DEPS) (DKK)	2.97	0.94	6.13
Cash flow from operating activities per share, diluted (DKK)	3.29	1.80	15.84
Net asset value per share, diluted (DKK)	49.75	44.18	49.08
Market capitalization (DKK million)	64,114	42,665	56,776
Share price end of period (DKK)	324.40	216.20	287.30
Proposed dividend per share (DKK)		-	2.45
Other			
Number of employees (FTE) end of period	4,921	5,070	4,983

## MANAGEMENT REVIEW

## Financial guidance and forward-looking statements

In outlining the expectations for 2017, Lundbeck has made certain assumptions. Lundbeck expects further decline in sales of Xenazine<sup>®</sup> and the introduction of generic alternatives to Sabril in the US both of which have been included in the assessment of the 2017 guidance. Additionally, Lundbeck's expectations assume continued benefits from the restructuring programme initiated in 2015.

Financial guidance for the full year 2017 is revised following better-than-expected sales performance driven by products such as Sabril. For 2017, Lundbeck now expects revenue to reach DKK 16.5-17.3 billion and profit from operations (EBIT) to reach DKK 3.6-4.0 billion with unchanged exchange rates. The financial guidance is summarized below:

#### Financial guidance 2017

DKK	2016 actual	Previous 2017 guidance	Revised 2017 guidance
Revenue	15,634 million	16.3-17.1 billion	16.5-17.3 billion
EBIT	2,292 million	3.4-3.8 billion	3.6-4.0 billion

The revised financial guidance does not include the potential gain from divestiture of properties. In May 2017, Lundbeck signed a conditional agreement regarding the sale of properties in Valby (Copenhagen). Provided that the pre-specified conditions are met, Lundbeck will receive a cash payment of DKK 378 million in December 2017. The payment will be recognized as other operating income in the second half of 2017. Lundbeck anticipates that the transaction will become final and unconditional in the second half of 2017 with a potential positive effect in the income statement and financial guidance of around DKK 200 million everything else being equal. The potential divestiture gain has not been included in the revised financial guidance for 2017. If the required conditions are not fulfilled, the transaction will not be completed and Lundbeck will not receive any payment.

#### **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 quarter of 2017 reached DKK 4,211 million compared to DKK 3,770 million for the same period in 2016. The increase of 12% is driven by a positive development for all our key products (Abilify Maintena, Brintellix/Trintellix, Northera, Onfi and Rexulti) more than mitigating the effect from generic erosion on Xenazine. The currency impact was limited. The growth of our key products was 46% (46% in local currencies) thereby reaching DKK 1,980 million or 47% of total revenue compared to 36% in the first quarter of 2016.

Revenue - products and regions

DKK million	Q1 2017	Q1 2016	Growth	Growth in local currencies	Q4 2016
Abilify Maintena	312	255	22%	23%	309
Brintellix/Trintellix	367	238	54%	49%	332
Cipralex/Lexapro	693	750	(8%)	(12%)	610
Northera	340	199	70%	73%	313
Onfi	690	544	27%	27%	636
Rexulti	271	116	133%	136%	271
Sabril	374	287	30%	30%	406
Xenazine	252	444	(43%)	(43%)	390
Other pharmaceuticals	838	856	(2%)	(2%)	820
Other revenue	74	81	(8%)	(8%)	78
Total revenue	4,211	3,770	12%	11%	4,165
North America	2,437	2,011	21%	21%	2,556
International Markets	991	931	6%	3%	818
Europe	709	747	(5%)	(6%)	713

**Abilify Maintena** (aripiprazole once-monthly injection) for the treatment of schizophrenia shows steady growth. Sales grew 22% and reached DKK 312 million. Abilify Maintena was discovered by Otsuka, is co-marketed by Lundbeck and became available to patients in 2013.

Revenue from **Brintellix/Trintellix** (vortioxetine) for the treatment of depression (MDD) reached DKK 367 million. Growth was driven by continued sales growth in North America and also from countries such as Brazil, Italy and Spain.

Cipralex/Lexapro (escitalopram) for the treatment of depression declined 8% due to generic competition.

**Northera** (droxidopa) for the treatment of symptomatic neurogenic orthostatic hypotension (nOH) was launched in the US in 2014. Sales from Northera showed strong growth and reached DKK 340 million.

**Onfi** (clobazam) for the treatment of Lennox-Gastaut syndrome continues to show strong growth and generated revenue of DKK 690 million, an increase of 27% compared to the same quarter last year.

**Rexulti** (brexpiprazole) is approved by the US Food and Drug Administration (FDA) 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 US in early August 2015. Rexulti was co-developed and is co-marketed by Otsuka and Lundbeck. Lundbeck's share of revenue reached DKK 271 million for the quarter.

**Sabril** (vigabatrin) for the treatment of refractory complex partial seizures (rCPS) and infantile spasms (IS) generated revenue of DKK 374 million, thereby increasing 30%, compared to 2016. Lundbeck has the marketing rights for Sabril in the US.

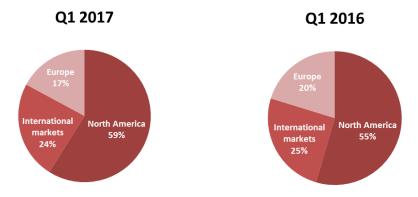
**Xenazine** (tetrabenazine) for the treatment of chorea associated with Huntington's disease saw the first generic introductions in the third quarter of 2015 which have impacted sales negatively. Revenue reached DKK 252 million

compared to DKK 444 million in the first quarter of 2016, a decline of 43%. Lundbeck has the marketing rights for Xenazine in the US.

Revenue from **Other pharmaceuticals**, which comprise the remainder of Lundbeck's products, was DKK 838 million. Other pharmaceuticals are negatively impacted by the generic competition on Ebixa in Europe which is partly offset by growth in other mature products. **Azilect** (rasagiline) for the treatment of Parkinson's disease, now included in Other Pharmaceuticals, realized revenue of around DKK 50 million.

**Other revenue**, which mainly consists of contract manufacturing, reached DKK 74 million compared to DKK 81 million for the same quarter in 2016.

Figure 1 - Revenue per region 2017 vs 2016 (excluding Other revenue)



#### **North America**

Revenue reached DKK 2,437 million in the first quarter of 2017 which is an increase of 21% compared to DKK 2,011 million for the same quarter in 2016. The growth was driven by the uptake of Rexulti and Northera as well as growth in other products, offsetting the decline in sales of Xenazine. Overall, there has been limited impact from currencies. North America constitutes 59% of revenue (excluding Other revenue) compared to 55% last year.

Revenue - North America

DKK million	Q1 2017	Q1 2016	Growth	Growth in local currencies	Q4 2016
Abilify Maintena	133	119	13%	13%	152
Trintellix	205	161	27%	29%	208
Northera	340	199	70%	73%	313
Onfi	690	544	27%	27%	636
Rexulti	271	116	133%	136%	271
Sabril	374	287	30%	30%	406
Xenazine	246	440	(44%)	(44%)	387
Other pharmaceuticals	178	145	23%	18%	183
Total revenue	2,437	2,011	21%	21%	2,556

**Abilify Maintena** is impacted by quarterly fluctuations and grew 13% in the quarter (13% in local currencies) and reached DKK 133 million for the period, which represents Lundbeck's 20% share of total net sales.

**Trintellix** sales reached DKK 205 million for Lundbeck following a growth of 27% (29% in local currencies) and with solid growth in both the US and in Canada. In the US, Trintellix' share of branded TR<sub>x</sub> (total prescriptions)

volume increased significantly to 38.4% following the loss of exclusivity of Pfizer's Pristiq (desvenlafaxine). The share of branded NR<sub>x</sub> (new prescriptions) volume reached 40.6% by early April 2017.

**Northera** was made available in the US market in the autumn of 2014. Sales from Northera reached DKK 340 million corresponding to a growth of 70% (73% in local currency).

Onfi reached revenue of DKK 690 million corresponding to a growth of 27% (27% in local currency).

Lundbeck's share of **Rexulti** revenue reached DKK 271 million. Rexulti had 11.1% branded  $TR_x$  market share and 12.2% branded  $NR_x$  market share by early April 2017. Patient data suggest that more than  $\frac{3}{4}$  of prescriptions are prescribed for MDD. Rexulti has had close to 23,000 writers since launch. In February 2017, Lundbeck Canada and Otsuka announced that Health Canada issued a Notice of Compliance for Rexulti for the treatment of schizophrenia and the product is expected to become commercially available in Canada this spring. Schizophrenia is estimated to be affecting approximately 1% of the Canadian population – which is more than 350,000 Canadians.

Sabril revenue for the period was DKK 374 million, growing 30% (30% in local currency).

Revenue from **Xenazine** was DKK 246 million. Revenue decreased 44% compared to the previous year. Performance was impacted by the introductions of generic products.

#### **International Markets**

Revenue from International Markets, which comprise all of Lundbeck's markets outside of Europe and North America, reached DKK 991 million in the first quarter of 2017, compared to DKK 931 million in the first quarter last year. In local currencies, sales were up 3% as the positive underlying performance driven by Abilify Maintena and Brintellix is mitigating the reduced revenue from products like Azilect and Cipralex. International Markets constitutes 24% of revenue (excluding Other revenue) compared to 25% last year. The biggest markets are China, Japan, Brazil, South Korea and Australia.

Revenue - International Markets

DKK million	Q1 2017	Q1 2016	Growth	Growth in local currencies	Q4 2016
Abilify Maintena	25	17	47%	37%	24
Brintellix	80	32	152%	129%	57
Cipralex/Lexapro	472	498	(5%)	(10%)	381
Ebixa	176	144	22%	24%	111
Other pharmaceuticals	238	240	(1%)	(2%)	245
Total revenue	991	931	6%	3%	818

Abilify Maintena has so far only been launched in Australia and reached revenue of DKK 25 million.

**Brintellix** reached DKK 80 million following an increase of 152% mainly driven by Brazil following the launch in March 2016. Revenue in Brazil is furthermore positively impacted by some stocking in the quarter. The product has been launched in some 20 countries in the region such as Australia, Brazil, South Africa and Turkey.

**Cipralex/Lexapro** generated revenue of DKK 472 million. Sales decreased 5% compared to the previous year as sales growth in countries such as Brazil, China and South Korea only partly mitigated sales decline in other regions such as the Middle East.

**Ebixa** generated revenue of DKK 176 million representing a growth of 22% reported and 24% in local currencies. Growth is primarily coming from China.

**Rexulti** has been submitted for approval in schizophrenia in Australia in April 2016 and feedback from the authorities is expected mid-2017. Rexulti has also recently been submitted for approval in Saudi Arabia.

**Other pharmaceuticals** generated revenue of DKK 238 million, a decrease of 1% compared to the same period in 2016. The decrease is explained by quarterly fluctuations and is not a permanent trend in the region. In China, however, sales are slightly negatively impacted by generic erosion on Deanxit, an antidepressant sold on behalf of Lundbeck by China Medical System Holdings Ltd.

## **Europe**

Revenue reached DKK 709 million in the first quarter of 2017, which was a decline of 5% compared to DKK 747 million for the period in 2016. The decline is a result of generic erosion on older products. Adjusted for Azilect, key products are replacing the sales decline for other mature products. Europe constitutes 17% of revenue (excluding Other revenue) compared to 20% last year.

#### Revenue - Europe

DKK million	Q1 2017	Q1 2016	Growth	Growth in local currencies	Q4 2016
Abilify Maintena	154	119	29%	31%	133
Brintellix	82	45	84%	65%	67
Cipralex	169	198	(15%)	(18%)	185
Other pharmaceuticals	304	385	(21%)	(20%)	328
Total revenue	709	747	(5%)	(6%)	713

**Abilify Maintena** has been launched in all major markets in Europe. Sales uptake of Abilify Maintena is solid with sales reaching DKK 154 million. Spain, France and Italy are the largest markets.

**Brintellix** grew 84% thereby reaching DKK 82 million and has been launched in most European markets, but the product has only recently achieved market access in some of the major markets. Brintellix realizes solid growth in both Italy and Spain, and in France the product has had an encouraging start since launch in December 2016.

In March 2017, Lundbeck and Otsuka announced that the European Medicines Agency (EMA) has accepted for review a Marketing Authorisation Application (MAA) for **brexpiprazole** to treat schizophrenia in adults. The EMA is anticipated to complete its review in second quarter of 2018. If the EMA grants regulatory approval to brexpiprazole, the brand name of the product in the EU would be **Rxulti**<sup>®</sup>.

Revenue from **Other pharmaceuticals** was DKK 304 million, a decline of 21% compared to the same period the previous year, following continued generic erosion of mature products such as Ebixa and Cipralex.

## Expenses and income

Total costs for the first quarter of 2017 were DKK 3,240 million compared to DKK 3,287 million for the same period last year.

#### Distribution of costs

DKK million	Q1 2017	Q1 2016	Growth	Q4 2016
Cost of sales	965	1,063	(9%)	1,042
COS-ratio	22.9%	28.2%	-	25.0%
Sales and distribution	1,433	1,302	10%	1,418
S&D-ratio	34.0%	34.5%		34.1%
Administration	190	190	0%	240
G&A-ratio	4.5%	5.1%		5.8%
Research and development	652	732	(11%)	714
R&D-ratio	15.5%	19.4%	-	17.1%
Total costs	3,240	3,287	(1%)	3,414

**Cost of sales** decreased 9% to DKK 965 million in the first quarter of 2017. This corresponds to 22.9% of total revenue compared to 28.2% in the previous year. Cost of sales is positively impacted by the change in product mix.

**Sales and distribution costs** were DKK 1,433 million, which was an increase of 10% compared to 2016. Sales and distribution costs correspond to 34.0% of revenue compared to 34.5% the year before.

Administrative expenses were unchanged at DKK 190 million corresponding to 4.5% of total revenue in 2017.

**SG&A** costs were DKK 1,623 million compared to DKK 1,492 million in the same period the previous year. The SG&A ratio for the period was 38.5%, compared to 39.6% in the same period the year before.

**Research and development costs** declined to DKK 652 million in the period. The R&D ratio reached 15.5% of revenue in the period compared to 19.4% last year.

In the first quarter of 2017, **Other operating income** amounted to DKK 40 million and represented a gain from the divesture of office and research facilities in the US.

## Depreciation, amortization and impairment charges

Depreciation, amortization and impairment charges, which are included in the individual expense categories, amounted to DKK 316 million in the first quarter of 2017 compared to DKK 341 million the previous year.

## Depreciation, amortization and impairment charges

DKK million	Q1 2017	Q1 2016	Growth	Q4 2016
Cost of sales	276	306	(10%)	351
Sales and distribution	12	10	12%	12
Administration	6	5	32%	6
Research and development	22	20	9%	42
Total depreciation, amortization and				
impairment charges	316	341	(7%)	411

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

**EBIT** for the first quarter of 2017 reached DKK 1,011 million compared to DKK 483 million for the same period last year. **EBIT margin** increased significantly and reached 24.0% in 2017 compared to 12.8% last year.

**Core EBIT** increased by 62% to DKK 1,213 million in the first quarter of 2017. The increase in EBIT and in Core EBIT is driven by strong sales especially in North America, more than offsetting the loss in revenue due to generic erosion on mature products, and benefits from the restructuring programme initiated in 2015.

For definition of the measures "Core Revenue", "Core EBIT" and "Core EPS", see note 7 Core reporting.

#### **Net financials**

Lundbeck generated a net financial expense of DKK 15 million in the first quarter of 2017, compared to a net financial expense of DKK 123 million in the first quarter of 2016.

Net interest expense, including realized and unrealized gains and losses on the bond portfolio, amounted to an expense of DKK 10 million in the first quarter of 2017, compared to an expense of DKK 15 million in the same period in 2016. The lower interest expense is primarily related to the full repayment of the EIB loan in the fourth quarter of 2016.

Net exchange gains/losses amounted to a loss of DKK 3 million in the first quarter of 2017, compared to a loss of DKK 105 million in the first quarter of 2016. The loss in 2016 was primarily related to the recognition of an exchange loss relating to the devaluation in Venezuela.

#### Tax

The effective tax rate for the first quarter of 2017 was 41%. The effective tax rate is 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
- Lundbeck's activity in the US results in a significant profit generated in the US and taxed at a higher tax rate than the Danish tax rate

#### Net profit and EPS for the period

**Net profit** for the first quarter of 2017 reached DKK 587 million compared to DKK 186 million in the first quarter of 2016. The reported net profit corresponds to an **EPS** of DKK 2.98 per share versus an EPS of DKK 0.94 per share for the same period last year. **Core EPS** was DKK 3.92 per share for the first quarter of 2017, compared to a Core EPS of DKK 2.07 per share in the same quarter in 2016.

## **Hedging**

Lundbeck hedges expected income from its products through currency hedging on a rolling basis, up to 18 months in advance. As a result of Lundbeck's currency hedging policy, foreign exchange gains and losses on hedging transactions are allocated directly to the hedged transaction. Hedging had a negative impact on profit of DKK 80 million in the first quarter of 2017, compared with a situation where the income is not hedged and included at the current exchange rates during the period. The effect was positive with DKK 24 million in the first quarter of 2016.

## Cash flow

Lundbeck had a positive cash flow from operating and investing activities of DKK 681 million in the first quarter of 2017 compared to DKK 320 million in the first quarter of 2016. The positive development is driven by the improved profitability which is partly offset by a negative development in working capital.

#### Cash flow

DKK million	Q1 2017	Q1 2016	Q4 2016
Cash flows from operating activities	651	357	1,033
Cash flows from investing activities	30	(37)	(133)
Cash flows from operating and investing activities (free cash			
flow)	681	320	900
Cash flows from financing activities	(157)	(348)	(488)
Net cash flow for the period	524	(28)	412
Cash and bank balance at beginning of period	2,200	1,504	1,785
Unrealized exchange gains/losses on cash and bank balances	4	(93)	3
Net cash flow for the period	524	(28)	412
Cash and bank balances end of period	2,728	1,383	2,200
Net cash/(Net debt)	975	(2,052)	326

Investing activities generated a cash inflow of DKK 30 million in the period following the divestment of office and research facilities in the US. Financing activities generated a cash outflow of DKK 157 million compared to an outflow of DKK 348 million in the first quarter of 2016. The outflow is mainly due to repayment of loans and purchase of treasury shares.

#### Balance sheet

At 31 March 2017, Lundbeck had **total assets** of DKK 20,678 million, compared to DKK 20,210 million at the end of 2016.

Assets held for sale include the carrying amount of properties in Valby (Copenhagen), which were sold conditionally in May 2017. The gain of around DKK 200 million will be recognized in the income statement on the line item other operating income in the second half of 2017.

At 31 March 2017, Lundbeck's **equity** amounted to DKK 9,821 million, corresponding to an equity ratio of 47.5% compared to 48.0% at the end of 2016.

**Interest bearing debt** has been reduced to DKK 1,770 million compared to DKK 1,891 million at the end of 2016. **Net cash** has increased from DKK 326 million at year-end 2016 to DKK 975 million at the end of the first quarter 2017. In the first quarter of 2016, the net debt was DKK 2,052 million.

At the Annual General Meeting in March 2017, the proposed **dividend** for 2016 of DKK 2.45 per share or DKK 484 million was approved. The dividend was paid to the shareholders in April 2017.

## Lundbeck's development portfolio

Lundbeck is developing a number of new and promising pharmaceuticals for the treatment of psychiatric and neurological disorders within the indications of Alzheimer's, depression, Parkinson's and schizophrenia. Pipeline developments are summarized as follows:

## Approved or under regulatory review

In March 2016, Lundbeck and Takeda Pharmaceutical Company (Takeda) announced that the FDA issued a complete response letter (CRL) for the supplemental new drug application (sNDA) to include new data in the clinical trials section of the US label of **Trintellix** for treating certain aspects of cognitive dysfunction in adults with major depressive disorder (MDD). The dialogue with the agency to resolve the CRL is ongoing.

#### Clinical phase III

In August 2012, Lundbeck and Otsuka Pharmaceuticals (Otsuka) initiated a randomized, double-blind, placebo-controlled trial (NCT01567527) to assess the time to recurrence of any mood episode in stabilized patients with bipolar I disorder randomized to 52 weeks of treatment with either placebo or **Abilify Maintena**. The clinical phase III maintenance study, which enrolled in total 731 patients, met its primary endpoint and data was presented at the 2016 Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Hollywood, Florida in December 2016. In November 2016, Lundbeck and Otsuka announced that the FDA had determined that the supplemental New Drug Application (sNDA) for the expanded labeling of Abilify Maintena for the maintenance treatment of Bipolar I disorder in adult patients is sufficiently complete to permit a substantive review and is considered filed. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of 28 July 2017, to complete its review.

In April 2015, our partner Takeda started a new clinical phase III study (NCT02389816) with **Brintellix** in Japanese individuals. The study is planned to recruit 480 patients who will receive Brintellix (10 or 20 mg) or placebo. The study is expected to be finalized in 2018.

In the second half of 2013, Lundbeck and Otsuka initiated two pivotal studies with **brexpiprazole** in individuals with agitation associated with dementia of the Alzheimer's type (NCT01862640, NCT01922258). In May 2017, Lundbeck and Otsuka announced top-line results from the clinical trials. 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 CMAI (p>0.05) appeared less robust than the improvements on the key secondary endpoint of CGI-S (p<0.05). In both studies, there was variability in the data from different countries, perhaps associated with differing standards of care; the data from Russian sites showed especially poor separation between placebo and drug.

Regarding safety 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 (MDD). The most common adverse events in patients receiving brexpiprazole versus placebo (incidence >3% and greater than placebo) were insomnia (4.7% vs. 3.3%), agitation (3.5% vs. 2.9%), and somnolence (3.3% vs. 2.2%). Overall mortality during the studies was low (0.86%) and none of the deaths were considered to be related to the treatment. FDA has granted Fast Track designation for this programme.

In 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*, (NCT02717195) is planned to enrol approximately 1,000 patients in approximately 15 countries including the US and Canada and is expected to last around 2½ years. Lu AF35700 has been granted Fast Track designation in treatment resistant schizophrenia by the FDA. Additionally, a long-term open label safety study was initiated (NCT02892422) in August 2016.

For **Selincro** (nalmefene) a clinical phase III study (NCT02364947) was initiated in Japan in December 2014. The study is run by Otsuka and is expected to recruit some 660 patients. The study is planned to finalize during 2017. Additionally, a long-term open label extension study has been initiated in Japan (NCT02382276) which is planned to finalise in 2018.

#### Clinical phase II

In 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.

## **Early programmes**

In January 2017, Lundbeck together with Otsuka initiated a phase I open-label study (NCT02968121) to determine the pharmacokinetics and tolerability of **brexpiprazole LAI** (long-acting injectable) administered subcutaneously or intramuscularly. The study is expected to enrol 110 adult patients with schizophrenia.

In March 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. Lu AF20513 is an active vaccine inducing high affinity polyclonal antibodies that target beta-amyloid, for the potential injectable prevention of progression of Alzheimer's. Lundbeck is developing Lu AF20513 in a phase I trial collaboration with Otsuka.

## General corporate matters

Lundbeck is involved in legal proceedings in a number of countries against a number of businesses, including patent disputes. In the Annual Report 2016 (page 52), Lundbeck provided an overview of pending legal proceedings.

#### Purchase of treasury shares

To fund Lundbeck's long-term incentive programmes granted to key employees in Denmark and abroad, Lundbeck purchased 120,000 shares at a value of DKK 35 million in the first guarter of 2017.

#### Conference call

Today at 13.00 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 – 31 March 2017. 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 31 March 2017, and of the results of the Group's operations and cash flows for the first three months of 2017, which ended on 31 March 2017.

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, 10 May 2017

## **Executive Management**

Kåre Schultz Lars Bang Anders Götzsche

President and CEO Executive Vice President, Supply Executive Vice President, CFO

Operations & Engineering

Anders Gersel Pedersen Staffan Schüberg Jacob Tolstrup

Executive Vice President, R&D Executive Vice President, CCO Executive Vice President,

Corporate Functions

**Board of Directors** 

Employee representative

Lars Søren Rasmussen Lene Skole-Sørensen Mona Elisabeth Elster
Chairman of the Board Deputy Chairman of the Board Employee representative

Lars Erik Holmqvist Henrik Sindal Jensen Jeremy Max Levin

Employee representative

Jørn Møller Mayntzhusen Jesper Jens Ovesen

# FINANCIAL STATEMENTS

## **Income statement**

DKK million	Q1 2017	Q1 2016	FY 2016
Revenue	4,211	3,770	15,634
Cost of sales	965	1,063	4,082
Gross profit	3,246	2,707	11,552
Sales and distribution costs	1,433	1,302	5,488
Administrative expenses	190	190	805
Research and development costs	652	732	2,967
Other operating income	40	-	-
Profit from operations (EBIT)	1,011	483	2,292
Net financials	(15)	(123)	(135)
Profit before tax	996	360	2,157
Tax on profit for the period	409	174	946
Profit for the period	587	186	1,211
Earnings per share, basic (EPS) (DKK)	2.98	0.94	6.14
Earnings per share, diluted (DEPS) (DKK)	2.97	0.94	6.13

## Statement of comprehensive income

DKK million	Q1 2017	Q1 2016	FY 2016
Profit for the period	587	186	1,211
Actuarial gains/losses	-	-	(42)
Tax	-	-	3
Items that will not be reclassified subsequently to profit or loss	-	-	(39)
Exchange rate gains/losses on investments in foreign subsidiaries	(37)	(269)	(180)
Exchange rate gains/losses on additions to net investments in foreign			
subsidiaries	(25)	(47)	241
Deferred exchange gains/losses, hedging	47	118	(308)
Exchange gains/losses, hedging (transferred to the hedged items)	80	(24)	15
Exchange gains/losses, transferred from hedging to financial items	-	-	3
Fair value adjustment of available-for-sale financial assets	(5)	16	8
Tax	(22)	(14)	8
Items that may be reclassified subsequently to profit or loss	38	(220)	(213)
Other comprehensive income	38	(220)	(252)
Comprehensive income	625	(34)	959

## **Balance sheet**

DKK million	31.03.2017	31.03.2016	31.12.2016
Assets			
Intangible assets	8,507	9,234	8,839
Property, plant and equipment	1,974	2,202	2,162
Financial assets	1,463	1,487	1,685
Non-current assets	11,944	12,923	12,686
Inventories	2,130	2,259	1,528
Receivables	3,734	4,032	3,779
Securities	17	17	17
Cash and bank balances	2,728	1,383	2,200
Assets held for sale	125	-	-
Current assets	8,734	7,691	7,524
Assets	20,678	20,614	20,210
Equity and liabilities			
Share capital	988	987	988
Share premium	-	353	-
Foreign currency translation reserve	1,108	852	1,164
Currency hedging reserve	(131)	69	(230)
Retained earnings	7,856	6,472	7,772
Equity	9,821	8,733	9,694
Provisions	1,032	1,038	1,032
Debt	1,690	3,369	1,708
Non-current liabilities	2,722	4,407	2,740
Provisions	701	749	745
Debt	85	83	188
Trade payables	3,829	4,111	3,650
Other payables	3,520	2,531	3,193
Current liabilities	8,135	7,474	7,776
Liabilities	10,857	11,881	10,516
Equity and liabilities	20,678	20,614	20,210

# Statement of changes in equity

DKK million	Share capital	Share premium	Foreign currency translation reserve	Currency hedging reserve	Retained earnings	Equity
Equity at 1 January 2017	988	-	1,164	(230)	7,772	9,694
Profit for the period	-	-	-	-	587	587
Other comprehensive income	-	-	(56)	99	(5)	38
Comprehensive income	-	-	(56)	99	582	625
Distribution of dividends, gross	-	-	-	-	(484)	(484)
Distribution of dividends, treasury shares	-	-	-	-	1	1
Capital increase through exercise of warrants	-	-	-	-	2	2
Buyback of treasury shares	-	-	-	-	(35)	(35)
Incentive programmes	-	-	-	-	18	18
Other transactions	-	-	-	-	(498)	(498)
Equity at 31 March 2017	988	-	1,108	(131)	7,856	9,821

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Equity at 1 January 2016	987	349	1,157	(4)	6,296	8,785
Profit for the period	-	-	-	-	186	186
Other comprehensive income	-	-	(305)	73	12	(220)
Comprehensive income	-	-	(305)	73	198	(34)
Capital increase through exercise of warrants	-	4	-	-	-	4
Buyback of treasury shares	-	-	-	-	(31)	(31)
Incentive programmes	-	-	-	-	9	9
Other transactions	-	4	-	-	(22)	(18)
Equity at 31 March 2016	987	353	852	69	6,472	8,733

## Cash flow statement

DKK million	Q1 2017	Q1 2016	FY 2016
Profit from operations (EBIT)	1,011	483	2,292
A Produce of Comments and Comments of Comments	270	70	4.454
Adjustments for non-cash operating items etc.	270	70	1,154
Change in working capital	(484)	(149)	463
Cash flows from operations before financial receipts and payments	797	404	3,909
Financial receipts and payments	(12)	(16)	(63)
Cash flows from ordinary activities	785	388	3,846
Income taxes paid	(134)	(31)	(720)
Cash flows from operating activities	651	357	3,126
Cash none from operating doublines	301	001	0,120
Purchase of and proceeds from sale of bonds and other financial assets	(4)	-	(3)
Purchase of and proceeds from sale of intangible assets and property,			
plant and equipment	34	(37)	(334)
Cash flows from investing activities	30	(37)	(337)
Cash flows from operating and investing activities (free cash flow)	681	320	2,789
Capital increase through exercise of warrants	2	4	37
Other financing activities	(159)	(352)	(2,043)
Cash flows from financing activities	(157)	(348)	(2,006)
Net cash flow for the period	524	(28)	783
			4.504
Cash and bank balances at beginning of period	2,200	1,504	1,504
Unrealized exchange gains/losses on cash and bank balances	4	(93)	(87)
Net cash flow for the period	524	(28)	783
Cash and bank balances at end of period	2,728	1,383	2,200
Interest-bearing debt, cash, bank balances and securities, net is			
composed as follows:			
Cash and bank balances	2,728	1,383	2,200
Securities	17	17	17
Interest-bearing debt	(1,770)	(3,452)	(1,891)
Interest-bearing debt, cash, bank balances and securities, net end of period – Net cash/(Net debt)	975	(2,052)	326
		,	

## Income statement – Core results reconciliation (Q1)

## Q1 2017

DKK million	Reported result	Intangible amortization	Impairment	Major restructuring	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	4,211	-	-	-	-	-	4,211
Cost of sales	965	(242)	-	-	-	-	723
Gross profit	3,246	242	-	-	-	-	3,488
Sales and distribution costs	1,433	-	-	-	-	-	1,433
Administrative expenses	190	-	-	-	-	-	190
Research and development costs	652	-	-	-	-	-	652
Other operating income	40	-	-	-	-	(40)	-
Profit from operations (EBIT)	1,011	242	-	-	-	(40)	1,213
Net financials	(15)	-	-	-	-	-	(15)
Profit before tax	996	242	-	-	-	(40)	1,198
Tax on profit for the period	409	33	-	-	-	(16)	426
Profit for the period	587	209	-	-	-	(24)	772
Earnings per share, basic (EPS) (DKK)	2.98	1.06	-	-	-	(0.12)	3.92

## Q1 2016

DKK million	Reported result	Intangible amortization	Impairment	Major restructuring	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	3,770	-	-	-	-	-	3,770
Cost of sales	1,063	(266)	-	-	-	-	797
Gross profit	2,707	266	-	-	-	-	2,973
Sales and distribution costs	1,302	-	-	-	-	-	1,302
Administrative expenses	190	-	-	-	-	-	190
Research and development costs	732	-	-	-	-	-	732
Profit from operations (EBIT)	483	266	-	-	-	-	749
Net financials	(123)	-	-	-	-	-	(123)
Profit before tax	360	266	-	-	-	-	626
Tax on profit for the period	174	43	-	-	-	-	217
Profit for the period	186	223	-	-	-	-	409
Earnings per share, basic (EPS) (DKK)	0.94	1.13	-	_	-	-	2.07

# 2016 quarterly figures restated to new regional structure

Q2 2016	North America	International	Europe	Total
DKK million	North America	markets	Luiope	Total
	400	18	133	070
Abilify Maintena	128			279
Brintellix/Trintellix	153	41	50	244
Cipralex/Lexapro	44	358	181	583
Northera	250	-	-	250
Onfi	584	-	-	584
Rexulti	193	-	-	193
Sabril	317	-	-	317
Xenazine	375	-	5	380
Other pharmaceuticals	135	335	337	807
Other revenue				114
Total	2,179	752	706	3,751
Q3 2016	North America	International	Europe	Total
DKK million		markets		
Abilify Maintena	127	21	123	271

Q3 2016	North America	International	Europe	Total
DKK million		markets		
Abilify Maintena	127	21	123	271
Brintellix/Trintellix	184	49	58	291
Cipralex/Lexapro	45	334	196	575
Northera	325	-	-	325
Onfi	645	-	-	645
Rexulti	246	-	-	246
Sabril	332	-	-	332
Xenazine	355	-	2	357
Other pharmaceuticals	117	370	367	854
Other revenue				52
Total	2,376	774	746	3,948

Q4 2016	North America	International	Europe	Total
DKK million		markets		
Abilify Maintena	152	24	133	309
Brintellix/Trintellix	208	57	67	332
Cipralex/Lexapro	44	381	185	610
Northera	313	-	-	313
Onfi	636	-	-	636
Rexulti	271	-	-	271
Sabril	406	-	-	406
Xenazine	387	-	3	390
Other pharmaceuticals	139	356	325	820
Other revenue				78
Total	2,556	818	713	4,165

#### **Notes**

#### Note 1 Accounting policies

Lundbeck's accounting policies are explained in detail in the 2016 Annual Report published 8 February 2017.

#### Note 2 Other operating income

Please see Expenses and income; page 9.

#### Note 3 Assets held for sale

Please see Balance sheet; page 11.

#### Note 4 Dividends for 2016

Please see Balance sheet; page 11.

#### Note 5 Events after the balance sheet date

Please refer to section on page 12 and corporate release no 613 for H. Lundbeck A/S and Otsuka Pharmaceutical Co., Ltd. announcement on top-line results from two phase III clinical trials evaluating the efficacy, safety and tolerability of brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type.

Properties in Valby (Copenhagen) were sold conditionally in May 2017. Lundbeck anticipates that the transaction will become final and unconditional in the second half of 2017 with a potential positive effect in the income statement and financial guidance of around DKK 200 million everything else being equal. Please see corporate release no 614.

#### Note 6 EBITDA calculation

DKK million	Q1 2017	Q1 2016
EBIT	1,011	483
+ Depreciation, amortization and impairment charges	316	341
- Other operating income	40	-
= EBITDA	1,287	824

## Note 7 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 2017

9 August 2017: Second quarter results 20178 November 2017: Third quarter results 2017

#### Lundbeck contacts

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#### **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 15.6 billion in 2016 (EUR 2.1 billion; USD 2.2 billion).

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