

Financial report for the period January 1 to March 31, 2021

## Lundbeck delivers a solid EBIT of DKK 882 million and Vyepti is off to a good start

### HIGHLIGHTS

Revenue reached DKK 4,273 million in the first quarter of 2021, a decline of 2% in local currencies. EBIT grew 235% compared to the same period in 2020 and reached DKK 882 million. EBIT margin reached 20.6%. EPS grew by 578% in the quarter thereby reaching DKK 3.13.

The newest product in the portfolio, Vyepti®, grew 49% since the fourth quarter of 2020. The brand continues its strong momentum since launch in the second quarter of 2020. Regulatory review is ongoing in 12 markets.

#### Strategic brand performance:

- Revenue of Abilify Maintena®: DKK 584 million (flat in local currencies, -5% reported)
- Revenue of Brintellix®/Trintellix®: DKK 804 million (up 7% in local currencies, -2% reported)
- Revenue of Rexulti®/Rxulti®: DKK 672 million (up 4% in local currencies, -6% reported)
- Revenue of Vyepti reached DKK 76 million following the launch in the U.S. in April 2020

#### Market performance:

- Revenue in North America: DKK 2,118 million (up 2% in local currencies, -11% reported)
- Revenue in International Markets: DKK 1,162 million (up 4% in local currencies, -6% reported)
- Revenue in Europe: DKK 844 million (-5% and -6% in local currencies and reported, respectively)

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

*"Lundbeck continues to deliver robust financial performance in a world impacted by the pandemic still impeding patient's ability to seek care normally. We are very pleased to see good Vyepti growth in the U.S. as we are gradually able to return to more normal interaction with physicians. We are delighted with the new data on Brintellix/Trintellix, amplifying the strength of its profile as a great choice for people facing depression. Currency headwinds have been impactful as has the loss of exclusivity on Northera."*

#### Key figures:

DKK million	Q1 2021	Q1 2020	Growth
Core Revenue*	4,273	4,564	(6%)
Core EBIT*	1,253	1,357	(8%)
Core EPS*	4.65	4.89	(5%)
Core EBIT margin*	29.3%	29.7%	
Reported Revenue	4,273	4,564	(6%)
Reported EBIT	882	263	235%
Reported EPS	3.13	0.46	578%
Reported EBIT margin	20.6%	5.8%	

For definition of the measures "Core Revenue", "Core EBIT", "Core EBIT margin" and "Core EPS", see note 4 Core reporting

Compared to the first quarter of 2020, which benefitted from extraordinary COVID-19 related stocking in several markets, the first quarter of 2021 saw a return to more normal consumer buying patterns seen pre-pandemic. The increased currency depreciation in key markets had an overall negative impact of 4% on sales growth.

Strong headline results reported from the RECONNECT study in patients with depression and generalized anxiety and from the real-world evidence study RELIEVE both with Brintellix/Trintellix and which support the overall strength of the product.

New data from the RELIEF-study presented at 2021 American Academy of Neurology (AAN) Annual Meeting shows Vyepti demonstrated earlier time to freedom from headache pain and absence of most bothersome symptoms compared to placebo when initiated during migraine attack in patients who were candidates for preventive therapy.

Core EBIT reached DKK 1,253 million and Core EBIT margin reached 29.3%. Profitability was impacted by substantial investments in building our brands which was partly mitigated by a lower activity level in the wake of the COVID-19 pandemic.

The financial guidance for 2021 is maintained. Lundbeck expects revenue to reach DKK 16.3 – 16.9 billion. Core EBIT is expected to reach DKK 3.1 – 3.6 billion and EBIT to reach DKK 1.8 – 2.3 billion.

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## FINANCIAL HIGHLIGHTS AND KEY FIGURES

	Q1 2021	Q1 2020	FY 2020
<b>Financial highlights (DKK million)</b>			
Core revenue	4,273	4,564	17,672
Core profit from operations (core EBIT)	1,253	1,357	4,436
Reported revenue	4,273	4,564	17,672
Operating profit before depreciation and amortization (EBITDA)	1,352	1,427	4,783
Reported profit from operations (EBIT)	882	263	1,990
Net financials, expenses	85	97	84
Profit before tax	797	166	1,906
Tax	176	74	325
Profit for the period	621	92	1,581
Equity	17,223	16,243	16,973
Assets	34,465	37,036	36,029
Cash flows from operating and investing activities (free cash flow)	24	120	3,370
Purchase of property, plant and equipment, gross	61	47	364
<b>Key figures</b>			
Core EBIT margin (%)	29.3	29.7	25.1
EBIT margin (%)	20.6	5.8	11.3
Return on equity (%)	3.6	0.6	9.4
Return on equity (%) – rolling four quarters	12.6	10.1	9.4
Net debt/EBITDA (x) – rolling four quarters	1.0	1.5	0.9
<b>Share data</b>			
Number of shares for the calculation of EPS (millions)	198.7	198.8	198.7
Number of shares for the calculation of DEPS (millions)	198.7	198.8	198.7
Earnings per share, basic (EPS) (DKK)	3.13	0.46	7.95
Earnings per share, diluted (DEPS) (DKK)	3.13	0.46	7.95
<b>Other</b>			
Number of employees (FTE) – end of period	5,551	5,872	5,628

## MANAGEMENT REVIEW

### ***Financial guidance and forward-looking statements***

#### Financial guidance

DKK	FY 2020 actual	2021 guidance
Revenue	17,672 million	DKK 16.3 – 16.9 billion
EBITDA	4,783 million	DKK 3.5 – 4.0 billion
Core EBIT	4,436 million	DKK 3.1 – 3.6 billion
Profit from operations (EBIT)	1,990 million	DKK 1.8 – 2.3 billion

Lundbeck's financial guidance for 2021 is maintained. The results are expected to be driven by the continued growth of Abilify Maintena, Brintellix/Trintellix, Rexulti/Rxulti and the expected strong growth of Vyepti. Northera was exposed to generic competition from February 2021, which is expected to lead to a decline of around 70% of revenue compared to 2020. This is a greater reduction than previously indicated as there have been a greater number of generics that have launched and a more aggressive price erosion.

Lundbeck's main currencies are the USD, CNY and CAD. The financial guidance for 2021 is based on the current hedging rates for our main currencies; i.e. USD/DKK (6.41), CNY/DKK (0.92) and CAD/DKK (4.77) and includes an expected hedging result of approximately DKK 50 million.

Based on our assumptions for product and geographical mix, it is estimated that 5% change of the USD/DKK exchange rate will impact revenue by DKK 250 – 300 million.

#### **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.

### ***COVID-19 impact on Lundbeck's operations***

Lundbeck's priorities during the global pandemic was and continues to be preserving the health and safety of its employees and continuing to safely supply all its medicines to the millions of patients around the world. We have successfully implemented and embraced new ways of working, including less travel activities and switching to virtual meeting solutions. We have seen gradual improvements to more normal working patterns across our operations though the current wave will have some impact on restrictions in various countries. However, the Lundbeck organisation is today much better able to address the situation.

Our product portfolio has generally been very resilient. In the U.S. primary care physicians (PCPs) are still seeing significantly fewer patients than before the pandemic and therefore products such as Brintellix/Trintellix, which have more prescriptions coming from primary care physicians than our other portfolio products, have been impacted by a lower number of new patient starts. While telehealth has seen a significant uptick, physicians are less likely to prescribe new treatments during a telehealth visit versus face-to-face. This impacts our key brands which rely on treatment switches. A significant reduction of in-person patient visits to physician offices significantly reduced the

use of physician-administered therapies in the U.S. across all categories. The launch of Vyepti in April 2020 is significantly impacted by this, but we have seen gradually improvements towards the end of the year.

The COVID-19 pandemic also continues to impact clinical activities causing manageable disruptions especially for new study starts and for our early-stage studies.

Our cash collections continue to be according to our normal trade terms, and days sales outstanding are at normal levels. Lundbeck remains well positioned to meet its ongoing financial obligations and has more than enough liquidity to support our normal business activities.

## Revenue

Revenue reached DKK 4,273 million in the first quarter of 2021 compared to DKK 4,564 million for the same period last year. The performance is impacted by the base effect from the strong first quarter last year. The strategic brands (Abilify Maintena, Brintellix/Trintellix, Rexulti/Rxulti and Vyepti) reached DKK 2,136 million or 51% of total revenue. The first quarter of 2020 was benefitting from patients gaining longer refill prescriptions as well as some stocking of products in many countries in response to the COVID-19 pandemic. The COVID-19 pandemic continues to impact business negatively in many parts of the world. Furthermore, the depreciation of main currencies has significantly impacted growth rates. Lundbeck's biggest markets are the U.S., China, Canada, Japan, Spain, Italy and France.

## Hedging

Lundbeck hedges a significant part of the currency risk for a period of 12 - 18 months. Hedging had a positive impact of DKK 68 million for the first quarter of 2021, compared to a negative impact of DKK 88 million for the first quarter of 2020.

### Revenue - products and regions

DKK million	Q1 2021	Q1 2020	Growth	Growth in local currencies	Q4 2020	FY 2020
Abilify Maintena	584	612	(5%)	-	542	2,271
Brintellix/Trintellix	804	817	(2%)	7%	794	3,102
Cipralex/Lexapro	666	722	(8%)	-	487	2,380
Northera	348	538	(35%)	(29%)	688	2,553
Onfi	146	153	(4%)	5%	156	642
Rexulti	672	713	(6%)	4%	616	2,620
Sabril	167	177	(5%)	4%	193	777
Vyepti	76	-			51	93
Other pharmaceuticals	661	781	(15%)	(11%)	557	2,738
Other revenue	81	139	(41%)	(40%)	136	491
Effects from hedging	68	(88)			55	5
<b>Total revenue</b>	<b>4,273</b>	<b>4,564</b>	<b>(6%)</b>	<b>(2%)</b>	<b>4,275</b>	<b>17,672</b>
North America	2,118	2,385	(11%)	(2%)	2,462	9,790
International Markets	1,162	1,232	(6%)	4%	803	4,057
Europe	844	896	(6%)	(5%)	819	3,329

## Products

**Abilify Maintena** (aripiprazole once-monthly injection) is approved for the treatment of schizophrenia in the EU and for both schizophrenia and bipolar I disorder in the U.S., Canada and Australia. Sales reached DKK 584 million which was unchanged in local currencies compared to the same period in 2020 as especially the U.S. has been impacted in quarterly fluctuations in inventory levels. The regional distribution of sales was 42%, 9% and 49% in North America, International Markets and Europe, respectively. The largest markets are the U.S., Spain, Canada, Australia and France.

**Brintellix/Trintellix** (vortioxetine) is approved for the treatment of major depressive disorder (MDD). Sales grew 7% in local currencies and reached DKK 804 million. The regional distribution of sales was 49%, 22% and 29% in North America, International Markets and Europe, respectively. The largest markets for the product are the U.S., Canada, Spain, Italy and Brazil. Brintellix/Trintellix has been impacted by the reduced promotional activity in many countries as a consequence of the COVID-19 pandemic thereby having impacted new patient enrolment negatively, particularly among primary care physicians.

**Cipraxel®/Lexapro®** (escitalopram) is approved for the treatment of major depressive disorder (MDD). Sales reached DKK 666 million following significant impact from currency depreciations. The regional distribution of sales was 4%, 78% and 18% in North America, International Markets and Europe, respectively. The largest markets are Japan, China, Saudi Arabia, South Korea and Brazil.

**Rexulti/Rxulti** (brexpiprazole) is approved as an adjunctive therapy for the treatment of adults with major depressive disorder and as a treatment for adults with schizophrenia in markets such as the U.S., Canada and Saudi Arabia. In Australia and Europe, the product is approved for schizophrenia. Lundbeck's share of revenue reached DKK 672 million in the quarter. The regional distribution of sales was 96%, 3% and 1% in North America, International Markets and Europe, respectively. Rexulti has especially from the second half of 2020 been impacted by the reduced promotional activity as a consequence of the COVID-19 pandemic thereby having impacted new patient enrolment negatively, particularly among primary care physicians.

**Vyepti** (eptinezumab-ijmr) is approved in the U.S. and Canada for the preventive treatment of migraine in adults. The product was launched in April 2020 in the U.S., and will be launched in Canada later in 2021, and reached sales of DKK 76 million. In the U.S., the permanent J-Code was issued in October 2020 and the Average Selling Price (ASP) was published in January 2021. More than 110 million insured individuals have access to Vyepti without any branded step-edits. In total, 235 million individuals have access to Vyepti.

**Northera** (droxidopa) is approved for the treatment of symptomatic neurogenic orthostatic hypotension (nOH). Sales from Northera reached DKK 348 million. Northera lost exclusivity in February 2021 and currently there are six generics in distribution. Nine have published pricing with generic price discounts from 78% to 97% off Northera's WAC prices (wholesale acquisition cost).

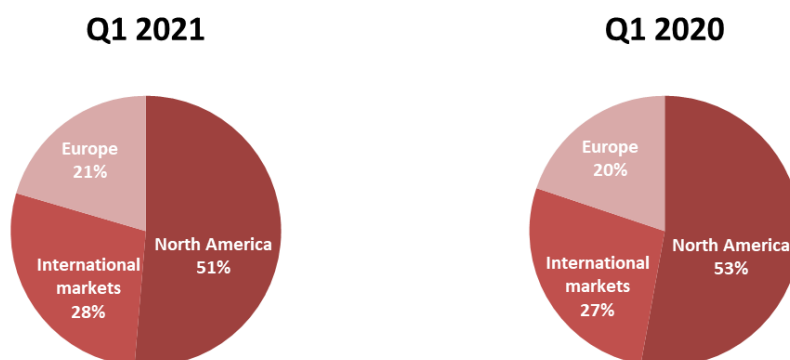
**Onfi** (clobazam) for the treatment of Lennox-Gastaut syndrome, generated revenue of DKK 146 million. Onfi lost exclusivity in October 2018.

**Sabril®** (vigabatrin), for the treatment of refractory complex partial seizures (rCPS) and infantile spasms (IS), faced the first generic competition in the third quarter of 2017. Revenue reached DKK 167 million for the quarter.

Revenue from **Other pharmaceuticals**, which comprise the remainder of Lundbeck's products, reached DKK 661 million compared to DKK 781 million in the first quarter of 2020 following lower sales of mature products such as Azilect®, Ebixa®, Xenazine® and Selincro®. The largest markets are China, France, the U.S., South Korea and Spain.

**Other revenue**, which mainly consists of contract manufacturing, reached DKK 81 million compared to DKK 139 million in the first quarter of 2020. The decline in revenue is due to lower volumes for one of the third-party contracts.

Figure 1 – Revenue per region Q1 2021 vs Q1 2020 (excluding Other revenue and Effects from hedging)



### North America

Revenue reached DKK 2,118 million in the first quarter of 2021 compared to DKK 2,385 million in the first quarter of 2020. Around 5% of revenue in the first quarter of 2020 can be attributed to COVID-19 related stocking. The COVID-19 pandemic continues to impact business in the region and especially Trintellix and Rexulti since they rely heavily on switches and new-to-brand prescriptions which are significantly less likely in telehealth visits. Furthermore, the depreciation of the USD has significantly impacted growth rates. The strategic brands increased by 9% in local currencies and reached DKK 1,359 million or 64% of sales.

### Revenue – North America

DKK million	Q1 2021	Q1 2020	Growth	Growth in local currencies	Q4 2020	FY 2020
Abilify Maintena	243	271	(10%)	(2%)	222	980
Trintellix	394	407	(3%)	6%	440	1,682
Northera	348	538	(35%)	(29%)	688	2,553
Onfi	146	153	(4%)	5%	156	642
Rexulti	646	696	(7%)	2%	593	2,537
Sabril	167	177	(5%)	4%	193	777
Vyepti	76	-	-	-	51	93
Other pharmaceuticals	98	143	(31%)	(25%)	119	526
<b>Total revenue</b>	<b>2,118</b>	<b>2,385</b>	<b>(11%)</b>	<b>(2%)</b>	<b>2,462</b>	<b>9,790</b>

### Products

**Abilify Maintena** revenue reached DKK 243 million, which represents Lundbeck's share of total net sales. Sales are impacted by quarterly fluctuations in inventory levels. In the U.S. Abilify Maintena has a stable volume market share of around 20% and in Canada it reached 31.7% by January 2021 (source: IQVIA) representing a slight increase from October last year.

**Trintellix** sales reached DKK 394 million in revenue for Lundbeck which represented a growth in local currencies of 6%. The volume market share in the U.S. and Canada was unchanged 0.9% and 1.4% of the total anti-depressant market, respectively by January 2021. The value market share of the total anti-depressant market in the U.S. was

24.2%. In Canada, the value market share of the total anti-depressant market was unchanged at 7.7% by January 2021 (source: IQVIA).

Lundbeck's share of **Rexulti** revenue reached DKK 646 with growth of 2% in local currencies. In the U.S., Rexulti has achieved a market share of 2.1% by January 2021 in volume (source: IQVIA) which is unchanged since October. However, the value share has increased to 15.2%. In Canada, the product has reached volume share of 2.6% representing a slight increase. Patient data suggest that more than 3/4 of prescriptions in the U.S. are prescribed for MDD.

**Vyepti** was approved by the U.S. FDA on 21 February 2020 and in Canada in January 2021 for the preventive treatment of migraine in adults. The product was made available in the U.S. on 6 April 2020 and reached sales of DKK 76 million in the first quarter of 2021. Vyepti can be obtained via selected specialty distributors and specialty pharmacies. In the U.S., the permanent J-Code was issued in October 2020 and the Average Selling Price (ASP) was published in January 2021. More than 110 million insured individuals have access to Vyepti without any branded step-edits. In total, 235 million individuals have access to Vyepti. It is still very early in the launch, and the uptake has been affected by general decline in physician-administered medicines during the pandemic. Nonetheless, more patients are being treated with Vyepti, and we are encouraged by the positive feedback from clinicians and patients, who have used the product, on the positive effects and the ease of use.

In January 2021, Vyepti was approved by Health Canada for the preventive treatment of migraine in adults who have at least 4 migraine days per month.

**Northera** sales reached DKK 348 million for the quarter following the launch of several generic versions in February 2021. **Sabril** revenue reached DKK 167 million. In September 2017, the first generic vigabatrin (oral solution) was introduced, and in January 2019 the first generic tablet was approved. **Onfi** revenue reached DKK 146 million. In October 2018, the U.S. FDA approved several versions of generic clobazam; both oral and suspension formulations.

## International Markets

Revenue from International Markets, which comprise all Lundbeck's markets outside of Europe and North America, reached DKK 1,162 million in the first quarter of 2021. The growth of 4% in local currencies was driven by Brintellix, CipraleX/Lexapro and Rexulti. The biggest markets are China, Japan, Brazil, South Korea and Australia. China and Japan constitute approximately 25% and 13%, respectively, of the regional revenue.

### Revenue – International Markets

DKK million	Q1 2021	Q1 2020	Growth	Growth in local currencies	Q4 2020	FY 2020
Abilify Maintena	54	61	(13%)	(14%)	54	210
Brintellix	175	178	(2%)	13%	140	583
CipraleX/Lexapro	516	549	(6%)	4%	328	1,730
Rexulti	21	13	60%	82%	17	65
Other pharmaceuticals	396	431	(8%)	(1%)	264	1,469
<b>Total revenue</b>	<b>1,162</b>	<b>1,232</b>	<b>(6%)</b>	<b>4%</b>	<b>803</b>	<b>4,057</b>

## Products

**Abilify Maintena** reached DKK 54 million in revenue representing a decline of 13% (14% in local currencies) as a consequence of quarterly fluctuations following the very strong sales in the fourth quarter last year. Sales are mainly derived from Australia where Abilify Maintena shows robust sales performance and has a stable volume share of



28.5% by January 2021 (Source: IQVIA). Countries such as Kuwait and United Arab Emirates (U.A.E.) also contributed positively.

**Brintellix/Trintellix** reached DKK 175 million in revenue or an increase of 13% in local currencies. Brintellix realized solid growth across several markets, but the growth is also impacted by quarterly fluctuations. Brazil, China, South Korea, Japan and Mexico are the largest markets for Brintellix in the region. In Japan, Trintellix is showing a very strong momentum and has reached a volume market share of 3.5% by March 2021, 16 months into the launch. Measured by volume market share it is the highest market share globally at this point of the launch.

**Rexulti** reached DKK 21 million in sales and grew by 82% in local currencies. In International Markets, the product has its highest sales in Australia. In Australia, Rexulti has achieved a market share of 2.2% in volume in January 2021 representing a slight increase from October 2020 (source: IQVIA). Rexulti was recently launched in Brazil and has achieved a market share of 0.9%.

**Vyepti** received approval in U.A.E. in December 2020 making it the second country in the world to receive approval within 2020.

**Ciprallex/Lexapro** generated revenue of DKK 516 million representing a growth of 4% in local currencies. The revenue of the product shows solid growth in most countries in the region including Japan and China. Japan, China, Saudi Arabia, South Korea and Brazil are the largest markets for Ciprallex/Lexapro in the region.

**Other pharmaceuticals** generated revenue of DKK 396 million and was positively impacted by timing of shipments.

**Azilect** is promoted by Lundbeck in some countries in Asia. Azilect generated revenue of DKK 33 million following a growth of 19%. **Ebixa** generated revenue of DKK 125 million, which is 20% lower compared to the first quarter of 2020 following the inclusion of Ebixa into VBP (Value-Based Procurement) in China in 2020. Azilect and Ebixa are included in Other pharmaceuticals.

## Europe

Revenue reached DKK 844 million in the first quarter of 2021 compared to DKK 896 million in the same period the year before. Around 4% of sales in the first quarter of 2020 can be attributed to COVID-19-related stocking. In general, Europe sees robust underlying demand offsetting a continuous negative average price development and continued generic erosion on the mature product portfolio.

### Revenue – Europe

DKK million	Q1 2021	Q1 2020	Growth	Growth in local currencies	Q4 2020	FY 2020
Abilify Maintena	287	280	3%	4%	266	1,081
Brintellix	235	232	1%	3%	214	837
Ciprallex	121	139	(13%)	(12%)	133	523
Rexulti/Rxulti	5	4	41%	44%	6	18
Other pharmaceuticals	196	241	(19%)	(18%)	200	870
<b>Total revenue</b>	<b>844</b>	<b>896</b>	<b>(6%)</b>	<b>(5%)</b>	<b>819</b>	<b>3,329</b>

## Products

**Abilify Maintena** is Lundbeck's largest product in the region. Sales uptake of Abilify Maintena is robust with revenue reaching DKK 287 million and is impacted by quarterly fluctuations as the fourth quarter of 2020 was strong. In

Europe, the penetration of long-acting atypical antipsychotics is generally higher than seen in the U.S. (volume). Driven by increasing demand from patients, sales of Abilify Maintena are growing across Europe and the product has achieved a 25% or more market share (volume) in most markets. In some markets the volume market share is approaching or has exceeded 30%. Abilify Maintena is the second most prescribed long acting injectable treatment for patients with schizophrenia in many markets. Spain, France and Italy are the largest European markets for Abilify Maintena.

**Brintellix** revenue grew 3% in local currencies reaching DKK 235 million. Brintellix is Lundbeck's second largest product in Europe and realized solid growth across many markets. In main countries, France, Italy and Spain, the product has achieved value market shares of 10.5%, 9% and 10%, respectively by January 2021 (source: IQVIA). The volume shares are stable or slightly increasing at 3.3%, 3.6% and 3.4%, respectively (source: IQVIA). The solid growth in European markets has in some markets been dampened by a negative impact from the COVID-19 pandemic.

**Rexulti/Rxulti** revenue reached DKK 5 million following a growth of 44% in local currencies. The product was approved for the treatment of adults with schizophrenia in July 2018. The product was recently launched in Italy and Czech Republic and is planned to be launched in Spain later in 2021. Rexulti/Rxulti is co-promoted with Otsuka Pharmaceuticals in most markets.

**Cipralex** generated revenue of DKK 121 million and is impacted by quarterly fluctuations as the fourth quarter of 2020 was strong.

Revenue from **Other pharmaceuticals** was DKK 196 million, a decline of 19% compared to the first quarter of 2020 following continued generic erosion of mature products.

## Expenses and profits

Total costs in the first quarter of 2021 declined by 21% to DKK 3,391 million compared to DKK 4,271 million in the same quarter last year. Adjusted for non-core costs, total costs declined by 6% to DKK 3,020 million mainly as a result of pandemic related cost avoidance.

### Distribution of costs

DKK million	Q1 2021	Q1 2020	Growth	Q4 2020	FY 2020
Cost of sales	946	880	8%	1,021	4,166
<i>COS-ratio</i>	22.1%	19.3%		23.9%	23.6%
Sales and distribution costs	1,318	1,502	(12%)	1,658	5,946
<i>S&amp;D-ratio</i>	30.9%	32.9%		38.8%	33.6%
Administrative expenses	210	218	(3%)	274	966
<i>G&amp;A-ratio</i>	4.9%	4.8%		6.4%	5.5%
Research & development costs	917	1,671	(45%)	883	4,545
<i>R&amp;D-ratio</i>	21.5%	36.6%		20.7%	25.7%
<b>Total costs</b>	<b>3,391</b>	<b>4,271</b>	<b>(21%)</b>	<b>3,836</b>	<b>15,623</b>

**Cost of sales** increased by 8% to DKK 946 million in the first quarter of 2021 and the **gross margin** is 77.9% compared to 80.7% in the same period last year. Cost of sales is impacted by the inclusion of Vyepti amortizations

but also reduced royalty costs. Amortization of product rights was DKK 371 million for the quarter compared to DKK 272 million last year.

**Sales and distribution costs** were DKK 1,318 million, a decline of 12% compared to first quarter 2020 mainly as a consequence of COVID-19 related cost avoidance. Sales and distribution costs correspond to 30.9% of revenue, compared to 32.9% the year before.

**Administrative expenses** declined 3% to DKK 210 million, corresponding to 4.9% of total revenue.

**SG&A** costs for the period were DKK 1,528 million compared to DKK 1,720 million in the first quarter of 2020. The SG&A ratio for the period was 35.8%, compared to 37.7% the prior year.

**Research & development costs** declined 45% to DKK 917 million for the quarter and the R&D ratio reached 21.5%. Adjusted for the impairment of foliglurax of DKK 792 million in the first quarter of 2020, the R&D costs increased by 4% as a result of increased clinical activity for Vyepti.

**Other operating expenses, net** amounted to DKK nil for the first quarter of 2021 compared to DKK 30 million in the first quarter last year.

### Depreciation, amortization and impairment losses

Depreciation, amortization and impairment losses, which are included in the individual expense categories, amounted to DKK 470 million in the first quarter of 2021 compared to DKK 1,164 million in 2020. Amortization of product rights was DKK 371 million for the quarter compared to DKK 272 million last year.

#### Depreciation, amortization and impairment losses

DKK million	Q1 2021	Q1 2020	Growth	Q4 2020	FY 2020
Cost of sales	418	320	30%	482	1,758
Sales and distribution cost	23	24	(5%)	37	111
Administrative expenses	5	7	(20%)	32	52
Research & development costs	24	813	(97%)	20	872
<b>Total depreciation, amortization and impairment losses</b>	<b>470</b>	<b>1,164</b>	<b>(60%)</b>	<b>571</b>	<b>2,793</b>

### Profit from operations (EBIT and core EBIT)

**Core EBIT** for the first quarter of 2021 declined 8% to DKK 1,253 million and the **Core EBIT margin** was 29.3%. Reported **EBIT** reached DKK 882 million compared to DKK 263 million in the first quarter of 2020 and the **EBIT margin** increased from 5.8% to 20.6%.

For definition of the measures “Core Revenue”, “Core EBIT”, “Core EBIT margin” and “Core EPS”, see note 4 *Core reporting*.

### Net financials, expenses

Lundbeck generated a **net financial expense** of DKK 85 million for the first quarter of 2021, compared to a net financial expense of DKK 97 million for the first quarter of 2020.

The **net financial items** for the first quarter of 2021 are broken down into financial expenses and financial income. Financial expenses mainly consist of fair value adjustments on contingent considerations, interest costs on the debt portfolio (including interest rate swaps) and banking costs. Financial income mainly consists of net currency gains.

## Tax

The effective tax rate for the first quarter 2021 is 22.0%. The tax rate is negatively impacted by the amortization of Northera product rights, which is not deductible for tax purposes, but this is fully offset by the increase in Danish research & development incentives.

## Profit and EPS for the quarter

**Profit for the quarter** reached DKK 621 million compared to DKK 92 million in the first quarter of 2020. The reported net profit corresponds to an **EPS** of DKK 3.13 versus an EPS of DKK 0.46 last year. **Core EPS** was DKK 4.65 for the first quarter of 2021, compared to a Core EPS of DKK 4.89 in the first quarter of 2020.

## Cash flow

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**Cash flows from operating activities** amounted to DKK 108 million in the first quarter of 2021 compared to DKK 188 million in 2020. The development compared to last year primarily relates to reduced EBITDA and quarterly fluctuations in the working capital.

Lundbeck's **net cash flows from investing activities** was an outflow of DKK 84 million for the first quarter of 2021 compared to an outflow of DKK 68 million in the same period last year. The **free cash flow** reached an inflow of DKK 24 million in the first quarter of 2021 compared to an inflow of DKK 120 million the year before.

In the first quarter of 2021, the **net cash outflow** reached DKK 2,279 million compared to an outflow of DKK 716 million in the first quarter of 2020. The net cash flow is impacted by dividend payout, net of DKK 497 million which was approved at the Annual General Meeting in March 2021 and repayment of bank loans net of DKK 1,752 million.

**Net debt** has increased from DKK 4,106 million at year-end 2020 to DKK 4,711 million at the end of the first quarter of 2021. **Interest bearing debt** was DKK 6,372 million at the end of the first quarter of 2021.

## Financial position

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At 31 March 2021, Lundbeck's **total assets** amounted to DKK 34,465 million compared to DKK 36,029 million at the end of 2020.

At 31 March 2021, Lundbeck's **equity** amounted to DKK 17,223 million, corresponding to an **equity ratio** of 50.0% compared to 47.1% at the end of 2020.

## Lundbeck's development portfolio

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Lundbeck is developing several new and promising medicines for the treatment of brain diseases. Pipeline developments are summarized below.

Project	Area	Phase I	Phase II	Phase III	Filing
<b>Hormonal / neuropeptide signaling:</b>					
Eptinezumab (anti-CGRP-mAb) <sup>1)</sup>	Migraine prevention				
	Episodic cluster headache				
Lu AG09222 (PACAP mAb) <sup>2)</sup>	Migraine				
<b>Circuitry / neuronal biology:</b>					
Brexpirazole <sup>3)</sup>	Agitation in Alzheimer's disease				
	PTSD				
	Borderline personality disorder				
Aripiprazole 2-months injectable	Schizophrenia/bipolar I disorder				Pivotal phase I study finalized
Lu AG06466 (MAGLi) <sup>4)</sup>	PTSD				
	Neurology/psychiatry				3 other phase Ib studies to start during 2021
Lu AG06479 (MAGLi) <sup>4)</sup>	Neurology/psychiatry				
Lu AF28996 (D <sub>1</sub> /D <sub>2</sub> agonist)	Parkinson's disease				
<b>Protein aggregation, folding and clearance:</b>					
Lu AF82422 (alpha-synuclein mAb)	Synucleinopathies				
Lu AF87908 (Tau mAb)	Tauopathies				

1) CGRP: Calcitonin gene-related peptide

2) PACAP: Pituitary adenylate cyclase activating peptide

3) Acts as a partial agonist at 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors at similar potency, and an antagonist at 5-HT<sub>2A</sub> and noradrenaline alpha<sub>1B/2C</sub> receptors.

4) MAGLi: Monoacylglycerol lipase inhibitor ("MAGlipase").

### **Hormonal / neuropeptide signaling:**

#### **Eptinezumab – approved by FDA on 21 February 2020 and by Health Canada in January 2021**

In February 2020, Lundbeck announced that Vyepti (eptinezumab-jjmr) was approved by the U.S. Food and Drug Administration (FDA) for the preventive treatment of frequent episodic and chronic migraine in adults. The recommended dose is 100 mg every 3 months; some patients may benefit from a dose of 300 mg. Vyepti is the first FDA-approved intravenous (IV) treatment for migraine prevention. Furthermore, eptinezumab was approved in U.A.E. in December 2020 and in Canada in January 2021.

Eptinezumab is a monoclonal antibody (mAb) that is administered as a quarterly 30-minute IV infusion. Eptinezumab provides immediate and complete bioavailability and binds to calcitonin gene-related peptide (CGRP), a neuropeptide believed to play a key role in mediating and initiating migraines, with high specificity and potency.

In December 2020, Lundbeck announced the acceptance of the filing for eptinezumab by the European Medicines Agency (EMA) for marketing authorization application (MAA) review. The acceptance of the Vyepti MAA for review marks the beginning of the formal review procedure for this potential new treatment by the EMA's Committee for Medicinal Products for Human Use (CHMP).

In December 2020, Lundbeck initiated *ALLEVIATE*, a phase III clinical study investigating the efficacy of eptinezumab in patients with episodic cluster headache (*ALLEVIATE*). The study (NCT04688775) is planned to recruit around 300 patients that will be randomly assigned to receive, in a blinded manner, two infusions of either eptinezumab or placebo in a cross-over manner during the placebo-controlled period and active treatment period of the study. The total duration of the study is 24 weeks, including a safety follow up period of 8 weeks.

In June 2020, Lundbeck initiated the *DELIVER* study (NCT04418765). The purpose of this study is to evaluate eptinezumab in the prevention of migraine in patients with unsuccessful prior preventive treatments. The patient must have documented evidence of treatment failure (must be supported by medical record or by physician's confirmation specific to each treatment) in the past 10 years of 2-4 different migraine preventive medications and have a history of either previous or active use of triptans for migraine. The total study duration from the screening visit to the completion visit is approximately 76 weeks and includes a screening period (28-30 days), a placebo-controlled treatment period (24 weeks) and a treatment extension period (48 weeks). The patient will start treatment

at the baseline visit and follow a 12-week dosing schedule with either eptinezumab (100 or 300 mg) or placebo by intravenous (IV) infusion. Patients who were assigned to placebo in the placebo-controlled treatment period, will be randomly allocated to one of two treatment groups: eptinezumab 300 mg or eptinezumab 100 mg (n = 840).

Regulatory review is ongoing in 12 markets: Australia, Brazil, Chile, EU, Indonesia, Israel, Kuwait, Philippines, Saudi Arabia, Singapore, Switzerland and Thailand.

#### **Lu AG09222 (former ALD 1910) – phase I commenced in October 2019**

Lu AG09222 is a monoclonal antibody (mAb) designed to bind pituitary adenylate cyclase-activating polypeptide (PACAP), thereby effectively preventing PACAP from activating its receptors. PACAP has emerged as an important signaling molecule in the pathophysiology of migraine and represents an attractive novel target for treating migraine. Lu AG09222 may hold potential as a migraine prevention treatment for those who have an inadequate response to other therapies and could provide another mechanism-specific therapeutic option for migraine patients and their physicians. A phase I double-blind, placebo-controlled study of Lu AG09222 in approximately 100 healthy men and women between the ages of 18 and 55, to assess the safety, tolerability and pharmacokinetic profile at various doses, has completed (NCT04197349).

#### **Circuitry / neuronal biology:**

#### **Brexpiprazole – phase III in Alzheimer's agitation commenced in 2013**

In April 2021 Lundbeck and Otsuka Pharmaceutical announced the decision to continue the recruitment of patients in the phase III clinical trial of brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type (NCT03548584). The decision to continue the trial is based on the results of an independent interim analysis, supporting to progress the trial to the planned full enrollment of 330 patients.

The study is designed to assess the safety, tolerability and efficacy of brexpiprazole in the treatment of patients with agitation in Alzheimer's dementia. The trial consists of a continuous 12-week double-blind treatment period with a 30-day follow-up. The trial population is planned to include 330 male and female patients, aged 55–90 years, with a diagnosis of probable Alzheimer's disease.

The continuation of the study enables Lundbeck and Otsuka to further explore the efficacy of brexpiprazole to address the high medical need in patients suffering from agitation in Alzheimer's type dementia. Completion of the trial is expected in the first half of 2022.

The primary outcome in the study is change in the Cohen-Mansfield Agitation Inventory (CMAI) Total score. The key secondary outcome measure is change in the Clinical Global Impression – Severity of Illness (CGI-S) score, as related to symptoms of agitation.

#### **Brexpiprazole – phase III in Post-Traumatic Stress Disorder (PTSD) commenced in October 2019**

Lundbeck and Otsuka Pharmaceutical have initiated a pivotal phase III program (n = ~577) investigating the use of brexpiprazole in combination with sertraline in the treatment of PTSD (NCT04124614) subsequent to an *End of Phase II* meeting with the US Food and Drug Administration (FDA) in May 2019.

PTSD is a psychiatric disorder that can develop as a response to traumatic events, such as interpersonal violence, combat, life-threatening accidents or natural disasters. Core features of PTSD include a variety of symptoms, such as re-experiencing phenomena (i.e. flashbacks and nightmares), avoidance behavior, numbing (i.e. amnesia, anhedonia, withdrawal, negativism) and increased arousal (i.e. insomnia, irritability, poor concentration, hypervigilance). Psychiatric co-morbidities are common, and PTSD sufferers can also present with substance abuse, mood and other anxiety disorders, impulsive and dangerous behavior and self-harm.

Lundbeck and Otsuka Pharmaceutical reported positive phase II data for the combination treatment of brexpiprazole and sertraline for the treatment of PTSD in November 2018.

#### **Brexpiprazole – phase II for borderline personality disorder commenced in October 2019**

Lundbeck and Otsuka Pharmaceutical have initiated a proof-of-concept study (n = ~240) investigating the use of brexpiprazole in the treatment of borderline personality disorder (BPD) subsequent to Type B meeting with the FDA in May 2019 (NCT04100096). BPD is characterized by a pervasive pattern of instability in affect regulation, impulse control, interpersonal relationships, and self-image. The clinical signs of the disorder include emotional dysregulation, impulsive aggression, repeated self-injury, and chronic suicidal tendencies, which make these patients frequent users of mental health resources. There is no medication approved for BPD. In October 2019, FDA has designated as a *Fast Track* development program the investigation of brexpiprazole for borderline personality disorder.

#### **Aripiprazole – 2-Month Injectable (LAI) formulation initiated in July 2019**

In July 2019, Lundbeck and Otsuka Pharmaceutical initiated a pivotal phase 1b study (NCT04030143) to determine the safety, tolerability and pharmacokinetics of multiple-dose administrations of aripiprazole to adult participants with schizophrenia or bipolar I disorder. The study was an open-label, multiple-dose, randomized, parallel-arm, multicenter study. In addition to assessment of safety and tolerability, the objective was to establish the similarity of aripiprazole concentrations on the last day of the dosing interval and the exposure in the last dosing interval following the final administration of aripiprazole into the gluteal muscle site. The study showed that the new 2-Month formulation, while being safe and tolerable, provided effective plasma concentrations of aripiprazole for two months. This implies that the new formulation can be dosed every second month compared to Abilify Maintena which is given on a monthly basis.

Dosing every second month can add important benefits in terms of convenience for the patients and may increase treatment adherence as well as minimizing risk of missing doses and it may reduce the potential need for medication monitoring by healthcare professionals, family and caregivers.

No further clinical studies are expected to be required and as a next step the regulatory agencies in U.S. and EU will be approached. Scale-up of manufacturing capacity is progressing at Otsuka Pharmaceuticals with regulatory submission gated on completing build and validation of new manufacturing capacity at Otsuka. The new 2-Month formulation is an innovative addition to the LAI franchise and has patent protection until the early part of the next decade.

#### **Lu AG06466 (former ABX1431) – phase Ib commenced in September 2020**

Lu AG06466 is an inhibitor of the monoacylglycerol lipase (MAGL) and selective modulator of the endocannabinoid system, and thereby works to reduce excessive neurotransmission and neuroinflammation that are known pathophysiological hallmarks for a range of psychiatric and neurological disorders. The purpose of this study is to investigate the effect of Lu AG06466 after multiple doses in patients with PTSD.

Lundbeck is planning investigational studies in other indications in neurology and psychiatry both with Lu AG06466 and with additional compounds generated by Lundbeck La Jolla Research Center. Trials across the indications will assess a variety of common and innovative biomarkers to develop tools to help guide further late-stage development.



**Lu AG06479 (former ABX1762) – phase I commenced in July 2020**

Lu AG06479 is an inhibitor of the monoacylglycerol lipase (MAGL) and selective modulator of the endocannabinoid system, and thereby works to reduce excessive neurotransmission and neuroinflammation that are known pathophysiological hallmarks for a range of psychiatric and neurological disorders. The purpose of this study is to investigate the safety, tolerability and pharmacokinetic of Lu AG06479 after single dose administration to healthy volunteers (NCT04473651). The distribution profile of this agent differs from Lu AG06466 in that it is only moderately brain penetrant.

**Lu AF28996 – phase I commenced in May 2018**

Lu AF28996 is a small molecule with agonistic properties towards D<sub>1</sub> and D<sub>2</sub> receptors. Continuous D<sub>1</sub> and D<sub>2</sub> dopamine receptor stimulation may play an important role in motor control of Parkinson's disease patients. The ongoing study was initiated in February 2020 with the purpose to investigate the safety of Lu AF28996, how well it is tolerated and what the body does to the drug in patients with Parkinson's disease (NCT04291859).

**Protein aggregation, folding and clearance:****Lu AF82422 – phase I commenced in July 2018**

Lu AF82422 is a monoclonal antibody (mAb) targeting the pathological form of the protein alpha-synuclein that is believed to play a pivotal role in the development and progression of e.g. multiple system atrophy (MSA) and Parkinson's disease and other neurodegenerative disorders. By targeting pathological alpha-synuclein with an antibody that will inhibit aggregation and potentially clear pathological alpha-synuclein from the brain, the project aims to demonstrate delay of disease progression with a therapeutic effect on disease burden and function. The ability to offer a treatment that will change the course of the disease will offer a fundamental improvement compared to currently available symptomatic treatments. Orphan drug designation was granted by EMA in April 2021. The purpose of this study is to investigate the safety of a single dose of Lu AF82422, how well it is tolerated and what the body does to the drug in healthy subjects and patients with Parkinson's disease (NCT03611569).

**Lu AF87908 – phase I commenced in September 2019**

Lu AF87908 is a monoclonal antibody (mAb) targeting the pathological form of the protein tau that is believed to play a pivotal role in the development and progression of Alzheimer's disease and other neurodegenerative disorders. By targeting pathological tau with an antibody that will inhibit aggregation and potentially clear pathological tau from the brain, the project aims to demonstrate delay of disease progression with a therapeutic effect on disease burden and function. The ability to offer a treatment that will change the course of the disease will offer a fundamental improvement compared to currently available symptomatic treatments. The purpose of this study is to investigate the safety of a single dose of Lu AF87908, how well it is tolerated and what the body does to the drug in healthy subjects and patients with Alzheimer's Disease (NCT04149860).

**Other studies**

In November 2017, the real-world study, *RELIEVE* (NCT03555136), was initiated with the aim to examine the real-life effectiveness of **vortioxetine** on functioning, depressive symptom relief, cognition and quality of life. It was an observational, multi-national, study in patients with MDD initiating treatment with vortioxetine. Information was collected by the physician, from the patient and their medical record at three time points - baseline, week 12 and week 24 (end of follow-up). The study was conducted in four countries. In total around 1,000 patients were enrolled. Key results from *RELIEVE* show significant and meaningful improvements by 6.9 points and 8.6 points, respectively after 3 and 6 months on the Sheehan Disability Scale (SDS) compared to prior antidepressant treatment. An improvement equal to or greater than 4 points on the SDS total score is considered to represent a meaningful improvement for patients. The study also met its secondary and exploratory endpoints on health-related quality of life, depressive symptoms, and cognitive symptoms, healthcare resource use and work productivity. Significant improvements were observed in health-related quality of life measured by EQ-5D, depressive symptoms measured



by PHQ-9, cognitive symptoms and performance measured by PDQ-D-5 and DSST, associated with a notable decrease in healthcare resource use and in the number of days lost and unproductive days.

In December 2019, the *RECONNECT*-study (NCT04220996) was initiated to evaluate the effectiveness of **vortioxetine** (10-20 mg/day) on depressive and anxiety symptoms in patients with Major Depressive Episode (MDE) coexisting with a diagnosis of Generalized Anxiety Disorder (GAD). 102 patients with severe depression and anxiety, recruited from psychiatrist outpatient clinics were enrolled in this open-label 8-week study, and 100 patients received treatment. Twenty-three of these patients received vortioxetine as a first treatment for their current MDE (first treatment patients) and 77 patients were switched to vortioxetine due to inadequate response to their current antidepressant medication treatment (switch patients). A significant improvement in symptoms of depression as measured by Montgomery-Åsberg Depression Rating Scale (MADRS) and anxiety as measured by the Hamilton Anxiety Rating Scale (HAM-A) was observed after only one week of treatment; a benefit that continued to increase up until the end of study. At week 8 the MADRS total score was reduced by 17 points and the HAM-A total score by 16 points. Improvement in depressive symptoms and anxiety symptoms was accompanied by a significant and substantial improvement in patient daily function as measured by the Functioning Assessment Short Test (FAST) and health-related quality of life as measured by the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q).

## ***Sustainability update***

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### **Attractive employer**

Lundbeck is a people business, and employees' health and safety have been and continue to be a top priority. In the first quarter of 2021, Lundbeck carried out its annual Employee Satisfaction Survey (ESS) for all employees globally and achieved a record-breaking 95% response rate. Workshops to discuss the input and agree on actions will be conducted locally.

Lundbeck remains in top 5% of comparable, international workplaces on several of the rated parameters, though we do see a slight decrease in some scores from 2020 levels. The ESS scores reflect strong satisfaction with jobs, rewards and recognition, Lundbeck's image and satisfaction with immediate managers. This is also reflected in the fact that we have been awarded several employer recognitions in the first quarter of 2021. The top employer recognitions in 2021 so far are: Lundbeck Italy, Lundbeck Canada, Lundbeck US, Lundbeck China, Lundbeck Valbonne (production site, France).

### **Health & safety**

Lundbeck has seen an increase in work-related accidents with absence to 7 in the first quarter of this year, compared to 5 in the first quarter last year. Each accident has been root cause analyzed and preventive actions have been implemented. Lundbeck does not see trends in the accidents and no common root causes are identified. The target for 2021 is a frequency of lost time accident rate below 5 for the full year and we are confident that we will meet this target.

### **Climate action**

Lundbeck is committed to climate neutrality and setting Science Based Targets. In February, Lundbeck announced a new 15-year climate target approved by the Science Based Target initiative (SBTi), having overperformed on the company's previous Science Based Target. Three elements in Lundbeck's new climate target:

- Commit to carbon neutrality no later than 2050
- Further reduce carbon emissions from production and fleet drastically by almost two-thirds over the next 15 years\*
- Work with our suppliers and customers to reduce our carbon footprint outside our premises by nearly a fifth over the next 15 years\*\*

\* Reduce a share of scope 3 CO<sub>2</sub>e emissions by 19% in 2034 compared to 2019.

\*\* Reduce scope 1 and 2 CO<sub>2</sub>e emissions by 63% in 2034 compared to 2019.

Having already made reduction of more than 70% of emissions from our production since 2006, Lundbeck has achieved most of the incremental reductions possible in both energy use and CO<sub>2</sub> emissions. To reach the new 15-year targets, we will be making investments, evaluate suppliers, etc. which will lead to step-changes. As an example, we have signed a Power Purchase Agreement (PPA) with a solar plant developer which covers our entire electricity consumption for operations located in Denmark and which will come into operation in 2022.

### Business Ethics

We have added two Business Ethics KPI's to our quarterly reporting. The number of Compliance Hotline or whistle blower reports that are investigated in accordance with our global procedures. The number of reports normally show significant variance, while the substantiation rate ranges between 30% and 50%. The other Business Ethics KPI shows the number Due Diligence of Third Parties critical to Lundbeck, that are assessed for conflict of interests, financial crime, promotional misconduct, human rights and environmental aspects. In the first quarter of 2021, 23% of these assessments identified risks that were managed.

Category	Q1 2021	Q1 2020	Change (%)
Energy (MWh)	31,490	29,314	7%
Carbon emissions Scope 1 & 2* (tonnes CO <sub>2</sub> e)	4,317	4,146	4%
Frequency of lost time accidents (Frequency)	7.9	5.4	32%
Work-related accidents with absence (Number)	7	5	29%
Number of employees (FTE)	5,551	5,872	(5%)
Compliance Hotline reports (Number)	9	3	200%
Due diligences of supplier and third parties (Number)	34	24	42%

Note: See Lundbeck Sustainability Report 2020 for accounting principles and definitions.

\*Does not include emissions from fleet of company cars which will be included in year-end results and is included in our SBTi target for Scope 1 & 2.

The 7% increase in total energy consumption is primarily due to more energy used at all sites - except Valbonne and La Jolla – with the most use at site Valby. This is primarily a result of cold weather conditions. Use of ventilation has been increased due to COVID-19 risk mitigation (minimized recirculation of air) resulting in increased heat consumption. The increase is also, but to a lesser extent, due to normal variation in product mix, which determine the energy used for steam cleaning at changeovers.

The 4% increase in total scope 1 and 2 emissions is due to the increase in energy use, as described above. As the largest increases in energy use is low-emission energy sources, the increase in CO<sub>2</sub>e emissions is lower than the increase in energy use.

You can read our most recent sustainability report on <https://www.lundbeck.com/global/sustainability>.

## **General corporate matters**

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### **Pending legal proceedings and regulatory**

The Group is involved in a number of legal proceedings, including patent disputes, the most significant of which are described below. The outcome of these proceedings is not expected to have a material impact on the Group's financial position or cash flows beyond the amount already provided for in the financial statements, or it is too uncertain to make a reliable provision. Such proceedings will, however, develop over time, and new proceedings may occur which could have a material impact on the Group's financial position and/or cash flows.

In June 2013, Lundbeck received the European Commission's decision that agreements concluded with four generic competitors concerning citalopram violated competition law. The decision included fining Lundbeck EUR 93.8 million (approximately DKK 700 million). Lundbeck paid and expensed the fine in the third quarter of 2013. In September 2016 the General Court of the European Union delivered its judgment concerning Lundbeck's appeal against the European Commission's 2013 decision. Lundbeck's appeal was rejected by the General Court and Lundbeck again appealed the judgment to the European Court of Justice. On 25 March 2021 the European Court of Justice rejected Lundbeck's appeal. So-called "follow-on claims" for reimbursement of alleged losses, resulting from alleged violation of competition law, often arise when decisions and fines issued by the European Commission are upheld by the European Court of Justice. Health authorities in the UK and the Netherlands have taken formal protective steps against Lundbeck with the principal purpose of preventing potential claims from being time-barred under the applicable statutes of limitation. Lundbeck expects that these authorities may now decide to pursue their alleged claims.

In Canada, Lundbeck is involved in three product liability class-action lawsuits relating to Cipralex/Celexa<sup>®</sup> (two cases alleging various Celexa-induced birth defects and one case against several SSRI manufacturers (incl. Lundbeck) alleging that SSRI (Celexa/Lexapro) induces autism birth defect), three relating to Abilify Maintena (alleging i.a. failure to warn about compulsive behavior side effects) and one relating to Rexulti (also alleging i.a. failure to warn about compulsive behavior side effects). The cases are in the preliminary stages and as such there is significant uncertainty as to how these lawsuits will be resolved. Lundbeck strongly disagrees with the claims raised.

In 2018, the Group entered into settlements with three of four generic companies involved in an Australian federal court case, in which Lundbeck was pursuing patent infringement and damages claims over the sale of escitalopram products in Australia. Lundbeck received AUD 51.7 million (DKK 242 million) in 2018. In Lundbeck's case against the last of the four generic companies, Sandoz Pty Ltd, the Federal Court found that Sandoz Pty Ltd had infringed Lundbeck's escitalopram patent between 2009 and 2012 and awarded Lundbeck AUD 26.3 million in damages. Sandoz' appeal of the decision was heard in May 2019 and the Full Federal Court has in August 2020 allowed Sandoz' appeal and decided that Sandoz is not liable for damages. Lundbeck's application for special leave to appeal the decision to the High Court was granted in February 2021, and the appeal will be heard later this year.

Together with Takeda, Lundbeck has instituted patent infringement proceedings against 16 generic companies that have applied for marketing authorization for generic versions of Trintellix in the U.S. Two opponents have withdrawn and Lundbeck has now settled with eight opponents. The cases against the six remaining opponents continue. The trial with the six opponents was in late January 2021 and decision is currently expected in third quarter or the beginning of the fourth quarter of 2021. Lundbeck has strong confidence in its vortioxetine patents. The generic companies cannot launch unless they receive a decision in their favor. The compound patent, including patent term extensions, will expire in the U.S. on 17 December 2026. Lundbeck has other patents relating to vortioxetine with expiry in the period until 2032.

Together with Otsuka Pharmaceutical, Lundbeck has instituted patent infringement proceedings against several generic companies that have applied for marketing authorization for generic versions of Rexulti in the U.S. Lundbeck has strong confidence in the Rexulti patents. The FDA cannot grant marketing authorization in the U.S. to the generic companies before the patents expire unless the generic companies receive decisions in their favor. Trial is scheduled to begin on 25 July 2022. The compound patent, including patent term extensions, will expire in the U.S. on 23 June 2029. A patent for the specific formulation used will expire 12 September 2032.

Lundbeck received a Civil Investigative Demand (“CID”) from the U.S. Department of Justice (“DOJ”) in March 2020. The CID seeks information regarding the sales, marketing, and promotion of Trintellix. Lundbeck is cooperating with the DOJ.

**Conference call**

Today at 13.00 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](http://www.lundbeck.com) under the Investor section.

## STATEMENT OF THE BOARD OF DIRECTORS AND THE REGISTERED EXECUTIVE MANAGEMENT

The Board of Directors and the registered Executive Management have discussed and adopted the interim report of H. Lundbeck A/S for the period January 1 - March 31, 2021. 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 March 31, 2021, and of the results of the Group's operations and cash flows for the period, which ended on March 31, 2021.

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 relative to the disclosures in the Annual Report 2020.

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

Valby, May 11, 2021

### Registered Executive Management

Deborah Dunsire  
President and CEO

Lars Bang  
Executive Vice President,  
Product Development & Supply

Anders Götzsche  
Executive Vice President,  
CFO

Per Johan Luthman  
Executive Vice President,  
Research & Development

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

Santiago Arroyo

Jeffrey Berkowitz

Lars Erik Holmqvist

Jeremy Max Levin

Ilse Dorothea Wenzel

Rikke Kruse Andreasen  
Employee representative

Henrik Sindal Jensen  
Employee representative

Ludovic Tranholm Otterbein  
Employee representative

## CONDENSED FINANCIAL STATEMENTS

### Statement of profit or loss

DKK million	Q1 2021	Q1 2020	FY 2020
Revenue	4,273	4,564	17,672
Cost of sales	946	880	4,166
<b>Gross profit</b>	<b>3,327</b>	<b>3,684</b>	<b>13,506</b>
Sales and distribution costs	1,318	1,502	5,946
Administrative expenses	210	218	966
Research and development costs	917	1,671	4,545
Other operating expenses, net	-	30	59
<b>Profit from operations (EBIT)</b>	<b>882</b>	<b>263</b>	<b>1,990</b>
Net financials, expenses	85	97	84
<b>Profit before tax</b>	<b>797</b>	<b>166</b>	<b>1,906</b>
Tax on profit for the period	176	74	325
<b>Profit for the period</b>	<b>621</b>	<b>92</b>	<b>1,581</b>
Earnings per share, basic (EPS) (DKK)	3.13	0.46	7.95
Earnings per share, diluted (DEPS) (DKK)	3.13	0.46	7.95

### Statement of comprehensive income

DKK million	Q1 2021	Q1 2020	FY 2020
<b>Profit for the period</b>	<b>621</b>	<b>92</b>	<b>1,581</b>
Actuarial gains/losses	-	-	(1)
Tax	-	-	1
<b>Items that will not be reclassified subsequently to profit or loss</b>	<b>-</b>	<b>-</b>	<b>-</b>
Exchange rate gains/losses on investments in foreign subsidiaries	476	192	(1,007)
Exchange rate gains/losses on additions to net investments in foreign subsidiaries	(104)	137	(21)
Hedging of net investments in foreign subsidiaries	(90)	(131)	356
Deferred exchange gains/losses, hedging	(162)	5	313
Deferred fair value of interest rate swaps	4	(122)	(90)
Exchange gains/losses, hedging (transferred to the hedged items)	(68)	88	(5)
Tax	46	5	(124)
<b>Items that may be reclassified subsequently to profit or loss</b>	<b>102</b>	<b>174</b>	<b>(578)</b>
<b>Other comprehensive income</b>	<b>102</b>	<b>174</b>	<b>(578)</b>
<b>Comprehensive income</b>	<b>723</b>	<b>266</b>	<b>1,003</b>

**Condensed statement of financial position**

DKK million	31.03.2021	31.03.2020	31.12.2020
<b>Assets</b>			
Intangible assets	23,133	25,432	22,738
Property, plant and equipment	2,758	2,639	2,733
Other financial assets	82	55	116
Other receivables	119	112	104
Deferred tax assets	266	137	233
<b>Non-current assets</b>	<b>26,358</b>	<b>28,375</b>	<b>25,924</b>
Inventories	2,582	2,349	2,163
Receivables	3,864	4,025	4,018
Securities	-	4	-
Cash and bank balances	1,661	2,283	3,924
<b>Current assets</b>	<b>8,107</b>	<b>8,661</b>	<b>10,105</b>
<b>Assets</b>	<b>34,465</b>	<b>37,036</b>	<b>36,029</b>
<b>Equity and liabilities</b>			
Share capital	996	996	996
Foreign currency translation reserve	412	1,078	134
Hedging reserve	(81)	(97)	95
Retained earnings	15,896	14,266	15,748
<b>Equity</b>	<b>17,223</b>	<b>16,243</b>	<b>16,973</b>
Retirement benefit obligations	288	295	288
Deferred tax liabilities	1,522	1,564	1,614
Provisions	142	262	139
Bank debt and bond debt	5,314	9,143	5,397
Lease liabilities	438	417	416
Other payables	1,574	1,247	1,190
<b>Non-current liabilities</b>	<b>9,278</b>	<b>12,928</b>	<b>9,044</b>
Retirement benefit obligations	2	-	2
Provisions	1,485	1,908	1,672
Bank debt	400	-	2,000
Trade payables	3,667	3,631	3,740
Lease liabilities	79	77	77
Income taxes payable	834	712	675
Other payables	1,497	1,537	1,846
<b>Current liabilities</b>	<b>7,964</b>	<b>7,865</b>	<b>10,012</b>
<b>Liabilities</b>	<b>17,242</b>	<b>20,793</b>	<b>19,056</b>
<b>Equity and liabilities</b>	<b>34,465</b>	<b>37,036</b>	<b>36,029</b>

## Statement of changes in equity

DKK million	Share capital	Foreign currency translation reserve	Hedging reserve	Retained earnings	Total equity
<b>Equity at 1 January 2021</b>	<b>996</b>	<b>134</b>	<b>95</b>	<b>15,748</b>	<b>16,973</b>
Profit for the period	-	-	-	621	621
Other comprehensive income	-	278	(176)	-	102
<b>Comprehensive income</b>	<b>-</b>	<b>278</b>	<b>(176)</b>	<b>621</b>	<b>723</b>
Distributed dividends, gross	-	-	-	(498)	(498)
Dividends received, treasury shares	-	-	-	1	1
Buyback of treasury shares	-	-	-	(34)	(34)
Incentive programmes	-	-	-	10	10
Tax on other transactions in equity	-	-	-	48	48
<b>Other transactions</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(473)</b>	<b>(473)</b>
<b>Equity at 31 March 2021</b>	<b>996</b>	<b>412</b>	<b>(81)</b>	<b>15,896</b>	<b>17,223</b>

DKK million	Share capital	Foreign currency translation reserve	Hedging reserve	Retained earnings	Total equity
<b>Equity at 1 January 2020</b>	<b>996</b>	<b>882</b>	<b>(75)</b>	<b>14,979</b>	<b>16,782</b>
Profit for the period	-	-	-	92	92
Other comprehensive income	-	196	(22)	-	174
<b>Comprehensive income</b>	<b>-</b>	<b>196</b>	<b>(22)</b>	<b>92</b>	<b>266</b>
Distribution of dividends, gross	-	-	-	(816)	(816)
Dividends received, treasury shares	-	-	-	1	1
Capital increase through exercise of warrants	-	-	-	1	1
Incentive programmes	-	-	-	8	8
Tax on other transactions in equity	-	-	-	1	1
<b>Other transactions</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(805)</b>	<b>(805)</b>
<b>Equity at 31 March 2020</b>	<b>996</b>	<b>1,078</b>	<b>(97)</b>	<b>14,266</b>	<b>16,243</b>



**Condensed statement of cash flows**

DKK million	Q1 2021	Q1 2020	FY 2020
<b>Profit from operations (EBIT)</b>	<b>882</b>	<b>263</b>	<b>1,990</b>
Adjustments for non-cash items	213	1,118	2,477
Change in working capital	(915)	(1,052)	(18)
<b>Cash flows from operations before financial receipts and payments</b>	<b>180</b>	<b>329</b>	<b>4,449</b>
Financial receipts and payments	(4)	(74)	(287)
<b>Cash flows from ordinary activities</b>	<b>176</b>	<b>255</b>	<b>4,162</b>
Income taxes paid	(68)	(67)	(325)
<b>Cash flows from operating activities</b>	<b>108</b>	<b>188</b>	<b>3,837</b>
Purchase and sale of securities and other financial assets	-	-	10
Purchase and sale of intangible assets and property, plant and equipment	(84)	(68)	(477)
<b>Cash flows from investing activities</b>	<b>(84)</b>	<b>(68)</b>	<b>(467)</b>
<b>Cash flows from operating and investing activities (free cash flow)</b>	<b>24</b>	<b>120</b>	<b>3,370</b>
Proceeds from loans and issue of bonds	400	-	3,701
Repayment of bank loans and borrowings	(2,152)	-	(5,169)
Capital increase through exercise of warrants	-	1	1
Dividends paid in the financial year, net	(497)	(815)	(815)
Other financing activities	(54)	(22)	(112)
<b>Cash flows from financing activities</b>	<b>(2,303)</b>	<b>(836)</b>	<b>(2,394)</b>
<b>Net cash flow for the period</b>	<b>(2,279)</b>	<b>(716)</b>	<b>976</b>
Cash and bank balances at beginning of period	3,924	3,008	3,008
Unrealized exchange gains/losses on cash and bank balances	16	(9)	(60)
Net cash flow for the period	(2,279)	(716)	976
<b>Cash and bank balances at end of period</b>	<b>1,661</b>	<b>2,283</b>	<b>3,924</b>
<b>Interest-bearing debt, cash, bank balances and securities, net, is composed as follows:</b>			
Cash and bank balances	1,661	2,283	3,924
Securities	-	4	-
Interest-bearing debt	(6,372)	(9,638)	(8,030)
<b>Net cash/(net debt)</b>	<b>(4,711)</b>	<b>(7,351)</b>	<b>(4,106)</b>

## Statement of profit or loss – Core results reconciliation (Q1)

### Q1 2021

DKK million	Reported result	Amortization of product rights	Impairment and inventory valuation	Major restructuring	Acquisition and integration costs	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	4,273	-	-	-	-	-	-	4,273
Cost of sales	946	(371)	-	-	-	-	-	575
<b>Gross profit</b>	<b>3,327</b>	<b>371</b>	-	-	-	-	-	<b>3,698</b>
Sales and distribution costs	1,318	-	-	-	-	-	-	1,318
Administrative expenses	210	-	-	-	-	-	-	210
Research and development costs	917	-	-	-	-	-	-	917
Other operating expenses, net	-	-	-	-	-	-	-	-
<b>Profit from operations (EBIT)</b>	<b>882</b>	<b>371</b>	-	-	-	-	-	<b>1,253</b>
Net financials, expenses	85	-	-	-	-	-	-	85
<b>Profit before tax</b>	<b>797</b>	<b>371</b>	-	-	-	-	-	<b>1,168</b>
Tax on profit for the period	176	68	-	-	-	-	-	244
<b>Profit for the period</b>	<b>621</b>	<b>303</b>	-	-	-	-	-	<b>924</b>
Earnings per share, basic (EPS)	3.13	1.52	-	-	-	-	-	4.65

### Q1 2020

DKK million	Reported result	Amortization of product rights	Impairment and inventory valuation	Major restructuring	Acquisition and integration costs	Legal fees and settlements	Divestments / sales milestones	Core result
Revenue	4,564	-	-	-	-	-	-	4,564
Cost of sales	880	(272)	-	-	-	-	-	608
<b>Gross profit</b>	<b>3,684</b>	<b>272</b>	-	-	-	-	-	<b>3,956</b>
Sales and distribution costs	1,502	-	-	-	-	-	-	1,502
Administrative expenses	218	-	-	-	-	-	-	218
Research and development costs	1,671	-	(792)	-	-	-	-	879
Other operating expenses, net	30	-	-	-	(30)	-	-	-
<b>Profit from operations (EBIT)</b>	<b>263</b>	<b>272</b>	<b>792</b>	-	<b>30</b>	-	-	<b>1,357</b>
Net financials, expenses	97	-	-	-	-	-	-	97
<b>Profit before tax</b>	<b>166</b>	<b>272</b>	<b>792</b>	-	<b>30</b>	-	-	<b>1,260</b>
Tax on profit for the period	74	32	174	-	7	-	-	287
<b>Profit for the period</b>	<b>92</b>	<b>240</b>	<b>618</b>	-	<b>23</b>	-	-	<b>973</b>
Earnings per share, basic (EPS)	0.46	1.21	3.11	-	0.11	-	-	4.89

## Notes

### Note 1: Accounting policies

Lundbeck's accounting policies and methods of computation are unchanged and explained in detail in the 2020 Annual Report published February 4, 2021. A number of new amendments came into effect from January 1, 2021. None of the amendments are expected to have a material impact on the accounting policies and/or on the condensed consolidated financial statements.

The comparative figures for the first quarter of 2020 are adjusted to reflect the changes related to the reversal of the impairment loss of the product rights of Rexulti and related amortization as well as other reclassifications to better reflect the company's financial position.

### Note 2: Fair value measurement

Financial assets and financial liabilities measured or disclosed at fair value	Level 1 (DKKm)	Level 2 (DKKm)	Level 3 (DKKm)
2021:			
<b>Financial assets</b>			
Other financial assets <sup>1</sup>	44	-	37
Derivatives <sup>1</sup>	-	158	-
<b>Total</b>	<b>44</b>	<b>158</b>	<b>37</b>
<b>Financial liabilities</b>			
Contingent consideration <sup>1</sup>	-	-	1,477
Derivatives <sup>1</sup>	-	261	-
Bank debt <sup>2</sup>	-	2,017	-
Bond debt <sup>2</sup>	3,766	-	-
<b>Total</b>	<b>3,766</b>	<b>2,278</b>	<b>1,477</b>
2020:			
<b>Financial assets</b>			
Securities <sup>1</sup>	4	-	-
Other financial assets <sup>1</sup>	15	-	40
Derivatives <sup>1</sup>	-	110	-
<b>Total</b>	<b>19</b>	<b>110</b>	<b>40</b>
<b>Financial liabilities</b>			
Contingent consideration <sup>1</sup>	-	-	1,178
Derivatives <sup>1</sup>	-	249	-
Bank debt <sup>2</sup>	-	9,143	-
<b>Total</b>	<b>-</b>	<b>9,392</b>	<b>1,178</b>

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

The fair value of securities is based on publicly quoted prices of the invested assets. The fair value of derivatives is calculated by applying recognized measurement techniques, whereby assumptions are based on the market conditions prevailing at the balance sheet date. The fair value of contingent consideration is calculated as the discounted cash outflows (DCF method) from future milestone payments, taking probability of success into consideration. The fair value adjustment of contingent consideration amounts to a net loss of DKK 48 million and is the result of changes in the time value of the contingent value rights and the milestone relating to the phase IIa study results of Lu AG06466 not being met. Total contingent consideration amounted to DKK 1,477 million at 31 March 2021 (DKK 1,178 million at 31 March 2020). Besides the fair value adjustment, the only change in contingent consideration is exchange rate adjustments of DKK 53 million.

The fair value related to future milestones in Alder BioPharmaceuticals (subsequently changed to Lundbeck Seattle BioPharmaceuticals, Inc.) has been reassessed generating an increase in the financial liabilities of DKK 273 million against goodwill and deferred taxes.

The carrying amount of other receivables, trade receivables, prepayments, bank debt, other debt, trade payables and other payables is believed to be equal to or close to fair value.

### Note 3: EBITDA calculation

DKK million	Q1 2021	Q1 2020	FY 2020
EBIT	882	263	1,990
+ Depreciation, amortization and impairment losses	470	1,164	2,793
= EBITDA	1,352	1,427	4,783

### Note 4: Core reporting

As a general rule, Lundbeck adjusts for amortization of product rights and for each non-recurring item that Management deems exceptional and which accumulates or is expected to accumulate to an amount exceeding a DKK 100 million threshold. 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 of product rights*

*Impairment of intangible assets and property, plant and equipment as well as inventory valuation adjustment*

*Major restructuring costs*

*Acquisition and integration costs, including:*

- Accounting adjustments relating to the consolidation of material acquisitions and disposals of associates, products and businesses
- Costs associated with the integration of newly acquired companies
- Retention costs
- Transaction costs

*Legal fees and settlements, including:*

- Legal costs (external), charges (net of insurance recoveries) and expenses related to settlement of litigations, government investigations and other disputes
- Income from settlements of litigations and other disputes

*Divestments/milestones, including:*

- Income/expenses from discontinued operations
- Gains/losses on divestments of assets
- Received or expensed upfront sales and development milestones

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

## FINANCIAL CALENDAR 2021

August 18, 2021: Financial statements for the first six months of 2021  
November 10, 2021: Financial statements for the first nine months of 2021

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### About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUY) is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of neuroscience research. We are tirelessly dedicated to restoring brain health, so every person can be their best.

Millions of people worldwide live with brain diseases, and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement, and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with brain diseases – we call this *Progress in Mind*.

Our approximately 5,600 employees in more than 50 countries are engaged in the entire value chain throughout research, development, production, marketing, and sales. Our pipeline consists of several R&D programmes, and our products are available in more than 100 countries. We have research centers in Denmark and the U.S., and our production facilities are located in Denmark, France and Italy. Lundbeck generated revenue of DKK 17.7 billion in 2020 (EUR ~2.4 billion; USD ~2.7 billion).

For additional information, we encourage you to visit our corporate site [www.lundbeck.com](http://www.lundbeck.com), and connect with us on Twitter at @Lundbeck and via LinkedIn.