**Corporate Release**
Valby, Denmark, February 7, 2023

**Quarterly corporate release for the period January 1 to December 31, 2022**

# Lundbeck delivers record revenue of DKK 18.2 billion and grows 12% in 2022

## HIGHLIGHTS

The growth of Lundbeck's strategic brands accelerated further with a growth of 31% (+20% in local currencies) in 2022, reaching DKK 12.1 billion, representing 67% of overall revenue.

- Brintellix®/Trintellix®: +21% reported to DKK 4,277 million (+13% in local currencies)
- Rexulti®/Rxulti®: +37% reported to DKK 3,890 million (+21% in local currencies)
- Abilify Maintena®: +22% reported to DKK 2,964 million (+16% in local currencies)
- Vyepti®: +104% reported to DKK 1,004 million (+80% in local currencies)

Total revenue increased by 12% (+7% in local currencies) to DKK 18,246 million, with all markets contributing strongly.

- United States: +22% reported to DKK 9,102 million (+7% in local currencies)
- International Markets: +13% reported to DKK 5,203 million (+6% in local currencies)
- Europe: +11% reported to DKK 4,252 million (+12% in local currencies)

Currency favorability on product sales continued to be partially offset by negative hedging effects of DKK 588 million while specific cost items were significantly impacted by exchange rates. The SG&A costs increased 13% of which the pure organic increase was 4%. The EBITDA margin improved from 22.8% in 2021 to 25.6% for 2022 despite increased investments in marketing and sales costs underpinning the launch of Vyepti in several markets during 2022.

- EBITDA: +25% reported to DKK 4,663 million
- EBIT: +42% reported to DKK 2,852 million
- Core EBIT: +18% reported to DKK 4,155 million
- EPS: +45% reported to DKK 1.93
- Core EPS: +28% reported to DKK 3.22

In line with our dividend policy, it is proposed to pay-out a dividend of DKK 0.58 per share or DKK 578 million which is an increase of 45% compared to 2021.

**In connection with the corporate release, Lundbeck's President and CEO, Deborah Dunsire said:**
*"I am very pleased with our operational performance in 2022. We delivered our best ever revenue result and exceptional growth in profits. Our pipeline continues to progress according to our plans. In 2023, we look forward to continuing to grow our strategic brands and deliver solid results, at the same time we continue to invest into the continued global roll-out of Vyepti, the launch of brexpiprazole in Alzheimer's agitation and the launch of aripiprazole 2M RTU formulation."*

Key figures:

| DKK million | FY 2022 | FY 2021 | *Growth* | Q4 2022 | Q4 2021 | *Growth* |
|---|---|---|---|---|---|---|
| Core Revenue[1] | **18,246** | 16,299 | 12% | **4,680** | 4,053 | *15%* |
| Core EBIT[1] | **4,155** | 3,517 | *18%* | **783** | 544 | *44%* |
| Core EPS[1,2] | **3.22** | 2.51 | *28%* | **0.61** | 0.42 | *45%* |
| *Core EBIT-margin[1]* | ***22.8%*** | *21.6%* | | ***16.7%*** | *13.4%* | |
| | | | | | | |
| Reported Revenue | **18,246** | 16,299 | *12%* | **4,680** | 4,053 | *15%* |
| EBITDA | **4,663** | 3,720 | *25%* | **910** | 440 | *107%* |
| Reported EBIT | **2,852** | 2,010 | *42%* | **403** | 6 | *6,617%* |
| Reported EPS[2] | **1.93** | 1.33 | *45%* | **0.31** | - | |
| *Reported EBIT-margin* | ***15.6%*** | *12.3%* | | ***8.6%*** | *0.1%* | |

1 For definition of the measures "Core Revenue", "Core EBIT", "Core EPS" and "Core EBIT-margin", see note 2 *Core reporting.*
2 The calculation of EPS is based on a share denomination of DKK 1 as a result of the share split completed on June 8, 2022. Comparative figures have been restated to reflect the change in trading unit from a nominal value of DKK 5 to DKK 1.

In January 2023, Lundbeck announced the FDA acceptance and priority review of the sNDA for brexpiprazole for the treatment of agitation associated with Alzheimer's dementia. The FDA target date (PDUFA date) for completion of the review is May 10, 2023.

Lu AG13909 is Lundbeck's first neurohormonal project and has entered clinical phase I in December 2022. Lu AG13909 is a humanized anti-adrenocorticotropic hormone (anti-ACTH) monoclonal antibody that blocks the binding of ACTH to the melanocortin 2 receptor in the adrenal glands, thereby decreasing the neurohormonal signaling of ACTH.

## 2023 GUIDANCE AND MID-TERM TARGETS

In 2023, Lundbeck will continue the global roll-out of Vyepti with around 15 launches. Additionally, Lundbeck plans to launch aripiprazole 2-month ready-to-use (RTU) long-acting injectable (LAI) for both treatment of schizophrenia and the maintenance treatment of bipolar I disorder and brexpiprazole for the significant unmet need for patients with agitation associated with Alzheimer's dementia, pending approvals by the relevant authorities later in 2023.

The financial guidance for 2023 reflects the expected investments needed for these important launches driving significant future growth. Lundbeck continues to expect strong growth for its strategic brands despite continued pricing pressure and loss of exclusivity in some geographies. Inflation will have a significantly higher impact in 2023 than seen in 2022. The financial guidance for 2023 is summarized below:

**Financial guidance**

| DKK | FY 2021 actual | FY 2022 actual | FY 2023 guidance |
|---|---|---|---|
| Revenue | 16,299 million | DKK 18,246 million | **DKK 19.4 – 20.0 billion** |
| EBITDA | 3,720 million | DKK 4,663 million | **DKK 4.8 – 5.2 billion** |

Lundbeck is in a period with limited impact from major regional loss of exclusivity and anticipates solid growth of its strategic brands. We expect that in 2023 and 2024 there will be targeted investments behind the potential blockbuster opportunity for brexpiprazole for the treatment of agitation associated with Alzheimer's dementia. Based on organic growth, we expect revenue to show a mid-single digit compound annual growth rate (CAGR) over the mid-term, (3-4 years). At the same time, we remain focused on driving efficiencies and being prudent in our spending. Based on these assumptions, we target an EBITDA-margin of 30-32% for the current business, excluding any business development activities, by the end of the mid-term period.

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This Corporate release should not be seen as a financial report in accordance with IAS 34 – *Interim Financial Reporting*.

The Annual Report comprising the financial statements for the year ended December 31, 2022, is available for download on: lundbeck.com on February 8, 2023.

Detailed information concerning Lundbeck's Sustainability Strategy can be found in the 2022 Sustainability Report available on: lundbeck.com on February 8, 2023.

# FINANCIAL HIGHLIGHTS AND KEY FIGURES

| | FY 2022 | FY 2021 | Q4 2022 | Q4 2021 |
|---|---|---|---|---|
| **Financial highlights (DKK million)** | | | | |
| Core revenue | **18,246** | 16,299 | **4,680** | 4,053 |
| Core profit from operations (core EBIT) | **4,155** | 3,517 | **783** | 544 |
| | | | | |
| Reported revenue | **18,246** | 16,299 | **4,680** | 4,053 |
| Operating profit before depreciation and amortization (EBITDA) | **4,663** | 3,720 | **910** | 440 |
| Reported profit from operations (EBIT) | **2,852** | 2,010 | **403** | 6 |
| Net financials, expenses | **378** | 429 | **(14)** | 118 |
| Profit before tax | **2,474** | 1,581 | **417** | (112) |
| Tax | **558** | 263 | **106** | (110) |
| Profit for the period | **1,916** | 1,318 | **311** | (2) |
| | | | | |
| Equity | **20,779** | 18,279 | **20,779** | 18,279 |
| Assets | **37,452** | 34,653 | **37,452** | 34,653 |
| | | | | |
| Cash flows from operating and investing activities (free cash flow) | **1,627** | 1,662 | **755** | 105 |
| Purchase of property, plant and equipment, gross | **371** | 410 | **141** | 166 |
| | | | | |
| **Key figures** | | | | |
| EBITDA-margin (%) | **25.6** | 22.8 | **19.4** | 10.9 |
| Core EBIT margin (%) | **22.8** | 21.6 | **16.7** | 13.4 |
| EBIT margin (%) | **15.6** | 12.3 | **8.6** | 0.1 |
| Return on equity (%) | **9.8** | 7.5 | **1.5** | 0.0 |
| Return on equity (%) – rolling four quarters | **9.8** | 7.5 | **9.8** | 7.5 |
| Return on capital invested (%) – rolling four quarters | **9.9** | 7.9 | **9.9** | 7.9 |
| Net debt/EBITDA (x) – rolling four quarters | **0.5** | 0.9 | **0.5** | 0.9 |
| | | | | |
| **Share data** | | | | |
| Number of shares for the calculation of EPS (millions)[1] | **992.9** | 993.3 | **992.8** | 993.2 |
| Number of shares for the calculation of DEPS (millions)[1] | **992.9** | 993.3 | **992.8** | 993.2 |
| Earnings per share, basic (EPS) (DKK)[1] | **1.93** | 1.33 | **0.31** | 0.00 |
| Earnings per share, diluted (DEPS) (DKK)[1] | **1.93** | 1.33 | **0.31** | 0.00 |
| | | | | |
| **Other** | | | | |
| Number of employees (FTE) – end of period | **5,450** | 5,348 | **5,450** | 5,348 |

1 The calculation of EPS is based on a share denomination of DKK 1 as a result of the share split completed on June 8, 2022. Comparative figures have been restated, to reflect the change in trading unit from a nominal value of DKK 5 to DKK 1.

# MANAGEMENT REVIEW

## *Financial guidance and forward-looking statements*

**Financial guidance**

| DKK | FY 2022 actual | 2023 guidance |
|---|---|---|
| Revenue | 18,246 | **DKK 19.4 – 20.0 billion** |
| EBITDA | 4,663 | **DKK 4.8 – 5.2 billion** |

For the financial guidance for 2023 and going forward, Lundbeck will focus on revenue performance and from first quarter 2023 and onwards, Adjusted EBITDA, providing an improved and more consistent assessment of the underlying business performance.

In 2023, Lundbeck will continue the global roll-out of Vyepti with approximately 15 launches. Additionally, Lundbeck plans to launch aripiprazole 2M RTU and brexpiprazole for significant unmet need for patients with Alzheimer's dementia manifesting the severe symptom of agitation, pending approvals later in 2023.

The financial guidance for 2023 reflects the investments needed in these important launches driving significant future growth.

Lundbeck continues to expect strong growth for its strategic brands despite continued pricing pressure and loss of exclusivity (LoE) in some geographies. Inflation will have a significantly higher impact on 2023 than seen in 2022.

Further, a provision of approximately DKK 300 million for Vyepti inventory obsolescence is reflected in the guidance for 2023.

Lundbeck carries foreign currency risk mainly in USD, CNY and CAD. The financial guidance for 2023 is based on the exchange rates at the end of November 2022. The financial guidance for 2023 is based on current hedging rates for the main currencies, i.e. USD/DKK (7.02), CNY/DKK (1.03) and CAD/DKK (5.26) and the financial guidance for 2023 includes an expected hedging loss of approximately DKK 75 million.

Based on our assumptions for product and geographical mix, it is estimated that a 5% change of the USD/DKK exchange rate will impact revenue by around DKK 350 million.

### Mid-term targets

Lundbeck is in a period with limited impact from major regional losses of exclusivity and anticipates solid growth of its strategic brands.

We expect that in 2023 and 2024 there will be targeted investments behind the potential blockbuster opportunity for brexpiprazole for the treatment of agitation associated with Alzheimer's dementia. Based on organic growth, we expect revenue to show a mid-single digit compound annual growth rate (CAGR) over the mid-term, (3-4 years).

At the same time, we remain focused on driving efficiencies and being prudent in our spending. Based on these assumptions, we target an EBITDA-margin of 30-32% for the current business, excluding any business development activities, by the end of the mid-term period.

### 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.

### Dividend

The Board of Directors proposes to pay a dividend of approximately 30% of net profit for 2022 in line with Lundbeck's pay-out policy of 30 – 60%. This corresponds to DKK 0.58 per share or a total of DKK 578 million compared to DKK 398 million in 2021.

The dividend pay-out is subject to approval at the Annual General Meeting on March 21, 2023.

## *Revenue*

Revenue reached DKK 18,246 million in 2022 compared to DKK 16,299 million in 2021, representing a growth of 7% in local currencies (12% reported). The strategic brands (Abilify Maintena, Brintellix/Trintellix, Rexulti/Rxulti and Vyepti) grew by 31% (+20% in local currencies) and reached DKK 12,135 million or 67% of total revenue. Lundbeck's biggest markets for the strategic brands are the U.S., Canada, Spain, Italy and Australia.

The growth in total sales is primarily due to strong performance of the strategic brands and appreciation of main currencies which to some extent has been offset by the negative effect from hedging. Furthermore, 2022 and especially the fourth quarter has benefitted from reversal of provisions. Lundbeck's biggest markets are the U.S., China, Canada, Spain, Italy and France.

Lundbeck's geographical structure was changed effective January 1, 2022. Following the change, the geographical split of revenue has been subject to modifications. With the new geographical structure, Canada moved from region North America to region International Markets and smaller entities were moved between International Markets and Europe. The North America region has been renamed United States to better reflect its new composition. Comparative figures for 2021 have been adjusted to follow the new geographical structure.

### Hedging

Lundbeck hedges a significant part of the currency risk for a period of 12 - 18 months. Hedging had a negative impact of DKK 588 million in 2022, compared to a positive impact of DKK 53 million in 2021. The negative impact in 2022 is primarily driven by the increase in underlying FX rate for USD.

**Revenue - products and regions**

| DKK million | FY 2022 | FY 2021 | Growth | Growth in local currencies | Q4 2022 | Q4 2021 | Growth | Growth in local currencies | Q3 2022 |
|---|---|---|---|---|---|---|---|---|---|
| Brintellix/Trintellix | **4,277** | 3,526 | *21%* | *13%* | **1,100** | 961 | *14%* | *7%* | 1,126 |
| Rexulti | **3,890** | 2,849 | *37%* | *21%* | **1,073** | 737 | *46%* | *26%* | 1,046 |
| Abilify Maintena | **2,964** | 2,420 | *22%* | *16%* | **800** | 610 | *31%* | *24%* | 771 |
| Vyepti | **1,004** | 492 | *104%* | *80%* | **332** | 164 | *102%* | *77%* | 282 |
| **Strategic brands** | **12,135** | 9,287 | *31%* | *20%* | **3,305** | 2,472 | *34%* | *22%* | 3,225 |
| Cipralex/Lexapro | **2,360** | 2,346 | *1%* | *(2%)* | **486** | 511 | *(5%)* | *(6%)* | 620 |
| Sabril | **636** | 657 | *(3%)* | *(14%)* | **154** | 170 | *(9%)* | *(21%)* | 160 |
| Onfi | **426** | 505 | *(16%)* | *(25%)* | **109** | 123 | *(11%)* | *(24%)* | 108 |
| Other pharmaceuticals | **3,000** | 3,104 | *(3%)* | *(9%)* | **741** | 666 | *11%* | *7%* | 756 |
| Other revenue | **277** | 347 | *(20%)* | *(22%)* | **72** | 136 | *(47%)* | *(49%)* | 49 |
| Effects from hedging | **(588)** | 53 | | | **(187)** | (25) | | | (199) |
| **Total revenue** | **18,246** | **16,299** | ***12%*** | ***7%*** | **4,680** | **4,053** | ***15%*** | ***11%*** | **4,719** |
| United States | **9,102** | 7,481 | *22%* | *7%* | **2,517** | 1,948 | *29%* | *12%* | 2,453 |
| International Markets | **5,203** | 4,597 | *13%* | *6%* | **1,180** | 1,025 | *15%* | *10%* | 1,329 |
| Europe | **4,252** | 3,821 | *11%* | *12%* | **1,098** | 969 | *13%* | *16%* | 1,087 |

## Products

**Brintellix/Trintellix** (vortioxetine) is Lundbeck's largest product and is approved for the treatment of major depressive disorder (MDD). Sales grew by 13% in local currencies (21% reported) and reached DKK 4,277 million following continued strong demand especially in markets outside the U.S. The regional distribution of sales was 39%, 31% and 30% in the U.S., International Markets and Europe, respectively. The largest markets for the product are the U.S., Canada, Spain, Italy and China.

**Rexulti/Rxulti** (brexpiprazole) is Lundbeck's second largest product and is approved as an adjunctive therapy for the treatment of adults with MDD and as a treatment for adults with schizophrenia in markets such as the U.S., Canada, Brazil, and Saudi Arabia. In Australia and Europe, the product is approved for schizophrenia. Lundbeck's share of revenue reached DKK 3,890 million for 2022 representing a growth of 21% in local currencies (37% reported). The regional distribution of sales was 94%, 5% and 1% in the U.S., International Markets and Europe, respectively. The largest markets are the U.S., Canada, Brazil, Australia and Mexico.

**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 2,964 million representing a growth of 16% in local currencies (22% reported). The regional distribution of sales was 35%, 18% and 47% in the U.S., International Markets and Europe, respectively. The largest markets are the U.S., Spain, Canada, Australia and Italy.

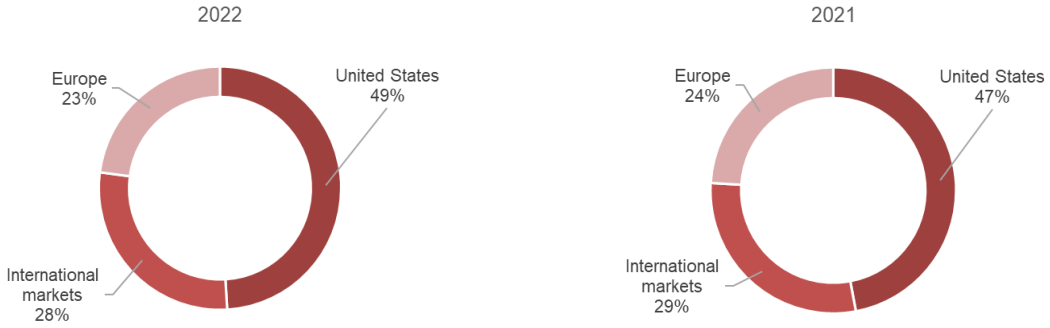
**Vyepti** (eptinezumab) doubled in sales compared to the same period last year and reached DKK 1,004 million in 2022 driven by strong demand. The regional distribution of sales was 98%, 1% and 1% in the U.S., International Markets and Europe, respectively. The product is approved in around 40 markets including the U.S., Australia, Canada and Europe for the preventive treatment of migraine in adults. Vyepti was launched in April 2020 in the U.S., and it has since been launched in Australia, Canada, Denmark, Estonia, Finland, Ireland, Germany, Kuwait, Singapore, Sweden, Switzerland and United Arab Emirates (U.A.E.). In 2023, Vyepti is expected to be launched in around 15 markets.

**Cipralex®/Lexapro®** (escitalopram) is approved for the treatment of MDD. Sales reached DKK 2,360 million in 2022. The regional distribution of sales was 72% and 28% in International Markets and Europe, respectively. The largest markets are Japan, China, South Korea, Italy and Brazil. The market in Japan is now facing generic entries.

Revenue from **Other pharmaceuticals**, which comprise the remainder of Lundbeck's products, reached DKK 3,000 million compared to DKK 3,104 million in 2021 following lower sales of mature products such as Northera. Northera lost exclusivity in February 2021 and is reported together with Other pharmaceuticals. Sales of Northera reached DKK 488 million compared to DKK 665 million in 2021. The largest markets for Other pharmaceuticals are China, the U.S., France, South Korea and Spain.

**Other revenue,** which mainly consists of contract manufacturing, reached DKK 277 million compared to DKK 347 million in 2021.

**Figure 1 – Revenue per region FY 2022 vs FY 2021 (excluding Other revenue and Effects from hedging)**




**Key developments in the fourth quarter of 2022**

In the fourth quarter of 2022, revenue reached DKK 4,680 million compared to DKK 4,053 million in 2021. The strategic brands grew by 22% in local currencies (34% reported) for the period, thereby reaching DKK 3,305 million or 71% of total revenue.

## United States

Revenue reached DKK 9,102 million in 2022 compared to DKK 7,481 million in 2021. The strategic brands increased by 19% in local currency (35% reported) and reached DKK 7,324 million or 80% of sales. The sales growth was driven by strong demand but also positively impacted by the appreciation of the USD and reversal of provisions.

**Revenue – United States**

| DKK million | FY 2022 | FY 2021 | *Growth* | *Growth in local currencies* | Q4 2022 | Q4 2021 | *Growth* | *Growth in local currencies* | Q3 2022 |
|---|---|---|---|---|---|---|---|---|---|
| Rexulti | **3,645** | 2,675 | *36%* | *20%* | **1,009** | 693 | *46%* | *26%* | 983 |
| Trintellix | **1,650** | 1,435 | *15%* | *1%* | **472** | 399 | *18%* | *4%* | 442 |
| Abilify Maintena | **1,047** | 812 | *29%* | *14%* | **281** | 205 | *37%* | *19%* | 279 |
| Vyepti | **982** | 489 | *101%* | *77%* | **325** | 162 | *101%* | *75%* | 270 |
| **Strategic brands** | **7,324** | 5,411 | *35%* | *19%* | **2,087** | 1,459 | *43%* | *24%* | 1,974 |
| Sabril | **636** | 657 | *(3%)* | *(14%)* | **154** | 170 | *(9%)* | *(21%)* | 160 |
| Onfi | **426** | 505 | *(16%)* | *(25%)* | **109** | 123 | *(11%)* | *(24%)* | 108 |
| Other pharmaceuticals | **716** | 908 | *(21%)* | *(30%)* | **167** | 196 | *(15%)* | *(27%)* | 211 |
| **Total revenue** | **9,102** | **7,481** | ***22%*** | ***7%*** | **2,517** | **1,948** | ***29%*** | ***12%*** | **2,453** |

## Products

**Rexulti** is Lundbeck's largest product in the U.S. Lundbeck's share of revenue reached DKK 3,645 million following a growth of 20% in local currency (36% reported). Rexulti volume market share is stable around 2.3% by October 2022 (source: IQVIA). Patient data suggest that more than 3/4 of prescriptions are for major depression (MDD).

**Trintellix** sales reached DKK 1,650 million in revenue for Lundbeck representing a growth of 1% in local currency (15% reported). Prescribing dynamics in the MDD market in the U.S. have been materially impacted by the pandemic, but recent data suggest that NBRx now is above the pre-pandemic level. While Lundbeck and our partner Takeda have optimized the promotional efforts for Trintellix to a lower level over recent years, we are actively addressing the changed prescribing patterns in the U.S. The volume market share is slightly up to 0.9% by November 2022 (source: IQVIA). The value market share of the total anti-depressant market has increased from 24.2% in January 2021 to 30% in October 2022 (source: IQVIA).

**Abilify Maintena** revenue reached DKK 1,047 million, representing Lundbeck's share of total net sales corresponding to a growth of 14% in local currency (29% reported). Abilify Maintena has a stable volume market share of around 23% by October 2022 (source: IQVIA).

**Vyepti** was approved by the U.S. Food and Drug Administration (FDA) on February 21, 2020, for the preventive treatment of migraine in adults. The product was made available in April 2020 and reached a doubling of sales (reported) to DKK 982 million in 2022 compared to 2021. Vyepti has around 5% volume share of the migraine prevention market.

**Sabril®** revenue reached DKK 636 million and **Onfi®** revenue reached DKK 426 million. In Other pharmaceuticals, **Northera** sales reached DKK 488 million for the period compared to DKK 665 million in 2021 following the launch of several generic versions in February 2021.

### Key developments in the fourth quarter of 2022

In the fourth quarter of 2022, revenue reached DKK 2,517 million compared to DKK 1,948 million in 2021. The strategic brands grew by 24% in local currency (43% reported) thereby reaching DKK 2,087 million or 83% of total revenue. Trintellix grew by 4% in local currency (18% reported) mainly driven by price increase and growth in demand.

## International Markets

International Markets, including Canada from January 2022, comprises all Lundbeck's markets outside of Europe and the U.S. Revenue reached DKK 5,203 million in 2022. The revenue growth of 6% in local currencies (13% reported) was mainly driven by Brintellix and Abilify Maintena as well as quarterly fluctuations impacting Deanxit in China. The biggest markets are China, Canada, Japan, Brazil and Australia. China and Japan constitute approximately 33% of regional revenue. The strategic brands increased by 21% in local currencies (30% reported) and reached DKK 2,066 million or 40% of sales.

**Revenue – International Markets**

| DKK million | FY 2022 | FY 2021 | Growth | Growth in local currencies | Q4 2022 | Q4 2021 | Growth | Growth in local currencies | Q3 2022 |
|---|---|---|---|---|---|---|---|---|---|
| Brintellix | **1,316** | 1,013 | *30%* | *21%* | **282** | 261 | *8%* | *3%* | 349 |
| Abilify Maintena | **535** | 427 | *25%* | *16%* | **138** | 113 | *22%* | *16%* | 148 |
| Rexulti | **204** | 148 | *38%* | *27%* | **53** | 38 | *39%* | *26%* | 53 |
| Vyepti | **11** | 3 | *267%* | *233%* | **1** | 2 | *(50%)* | *(50%)* | 7 |
| **Strategic brands** | **2,066** | 1,591 | *30%* | *21%* | **474** | 414 | *14%* | *8%* | 557 |
| Cipralex/Lexapro | **1,698** | 1,662 | *2%* | *(2%)* | **337** | 346 | *(3%)* | *(7%)* | 444 |
| Other pharmaceuticals | **1,439** | 1,344 | *7%* | *0%* | **369** | 265 | *39%* | *34%* | 328 |
| **Total revenue** | **5,203** | **4,597** | ***13%*** | ***6%*** | **1,180** | **1,025** | ***15%*** | ***10%*** | **1,329** |

## Products

**Brintellix/Trintellix** is Lundbeck's second largest product in the region. Sales reached DKK 1,316 million or an increase of 21% in local currencies (30% reported). Brintellix realized exceptional growth in Japan, achieving a 7.5% (volume) and 10.1% (Value) market share in its third year after launch, up from 5.8% in December of 2021 (Source: IQVIA). Other markets including Brazil, China and Canada, showed solid growth but saw impacts from quarterly fluctuations in shipments. Brintellix is not included in the National Reimbursement Drug List (NRDL) in China but continues to grow well. Canada, China, Brazil, Japan and South Korea are the largest markets for Brintellix in the region.

**Abilify Maintena** reached DKK 535 million in revenue representing a growth of 16% in local currencies (25% reported). Sales are mainly derived from Canada and Australia, where Abilify Maintena shows robust sales performance. In Australia and Canada, the volume share is stable around 31% and 34%, respectively by October 2022 (source: IQVIA). Countries such as Saudi Arabia and U.A.E. also contributed positively.

**Rexulti** reached DKK 204 million in sales and grew by 27% in local currencies (38% reported). In International Markets, the product has its highest sales in Canada followed by Australia and Brazil. In Canada, Rexulti's volume share has increased to 3.7% by October 2022 compared to 3.2% in December 2021 (source: IQVIA). In Australia, Rexulti has maintained a market share of around 2.3% in volume by October 2022 (source: IQVIA). In Brazil, Rexulti has a stable market share of around 1.8% (source: IQVIA) and most of the product growth in the region came from Brazil.

**Vyepti** was launched in Australia, Canada and Singapore in 2022. Sales reached DKK 11 million in 2022. Vyepti was launched in the U.A.E as the first market outside the U.S. in 2020 and has obtained a volume market share among the other aCGRP's and gepants of around 13%.

**Cipralex/Lexapro** continues to be Lundbeck's largest product in the region. The product generated revenue of DKK 1,698 million representing a decline of 2% in local currencies (up 2% reported). Japan, China, South Korea, Brazil and Canada are the largest markets for Cipralex/Lexapro in the region.

**Other pharmaceuticals** generated revenue of DKK 1,439 million. **Azilect** is promoted by Lundbeck in some countries in Asia. Azilect generated revenue of DKK 196 million while **Ebixa** generated revenue of DKK 439 million.

**Key developments in the fourth quarter of 2022**

In the fourth quarter of 2022, revenue increased by 10% in local currencies (15% reported) and reached DKK 1,180 million. The strategic brands grew by 8% in local currencies (14% reported), thereby reaching DKK 474 million or 40% of total revenue.

## Europe

Revenue reached DKK 4,252 million in 2022 compared to DKK 3,821 million in 2021, which represents a growth of 12% in local currencies. The strategic brands increased by 20% both in local currencies and reported and reached DKK 2,745 million or 65% of sales. In general, Europe continues to realize robust underlying demand countering a continuous negative average price development and continued generic erosion on the mature product portfolio but has also benefitted in adjustments in the payment of medicine tax in several countries. The largest markets in Europe are Spain, Italy, France, Switzerland and United Kingdom.

**Revenue – Europe**

| DKK million | FY 2022 | FY 2021 | Growth | Growth in local currencies | Q4 2022 | Q4 2021 | Growth | Growth in local currencies | Q3 2022 |
|---|---|---|---|---|---|---|---|---|---|
| Abilify Maintena | **1,382** | 1,181 | *17%* | *17%* | **381** | 292 | *30%* | *30%* | 344 |
| Brintellix | **1,311** | 1,078 | *22%* | *22%* | **346** | 301 | *15%* | *17%* | 335 |
| Rexulti/Rxulti | **41** | 26 | *58%* | *50%* | **11** | 6 | *83%* | *83%* | 10 |
| Vyepti | **11** | - | - | - | **6** | - | - | - | 5 |
| **Strategic brands** | **2,745** | 2,285 | *20%* | *20%* | **744** | 599 | *24%* | *25%* | 694 |
| Cipralex | **662** | 684 | *(3%)* | *0%* | **149** | 165 | *(10%)* | *(4%)* | 176 |
| Other pharmaceuticals | **845** | 852 | *(1%)* | *0%* | **205** | 205 | *0%* | *3%* | 217 |
| **Total revenue** | **4,252** | **3,821** | ***11%*** | ***12%*** | **1,098** | **969** | ***13%*** | ***16%*** | **1,087** |

## Products

**Abilify Maintena** is Lundbeck's largest product in the region. Sales uptake of Abilify Maintena is robust with revenue reaching DKK 1,382 million, a growth of 17% in local currencies compared to 2021. Driven by increasing demand, sales of Abilify Maintena are growing across Europe. The market share is still increasing in some markets and the product has achieved 25% or more market share (volume) in most markets (source: IQVIA). In some markets including Italy and Switzerland, the volume market share in October 2022 is approaching or has exceeded 35% (source: IQVIA). Abilify Maintena is the second most prescribed long-acting injectable treatment for patients with schizophrenia in many markets. Spain, Italy and France are the largest European markets for Abilify Maintena.

**Brintellix** revenue grew by 22% reaching DKK 1,311 million. Brintellix is Lundbeck's second largest product in Europe and realized solid growth across many markets. In main countries, Spain, Italy and France, the product has increased value market shares to 13.8%, 11.5% and 11.4%, respectively by October 2022 (source: IQVIA). The volume shares are stable around 4.7%, 4.4% and 4.0%, respectively (source: IQVIA).

**Rexulti/Rxulti** revenue reached DKK 41 million following a growth of 50% in local currencies compared to 2021. The product is launched in 10 markets in Europe for the treatment of schizophrenia and is expected to be launched in Ukraine and Hungary later in 2023. Rexulti/Rxulti is co-promoted with Otsuka Pharmaceuticals in most markets in Europe.

**Vyepti** was granted marketing authorization in the European Union (EU) in January 2022 for the prophylactic treatment of migraine in adults who have at least four migraine days per month. The formal EU approval means that the milestone for the Contingent Value Rights (CVRs) of USD 2 per share relating to the acquisition of Alder BioPharmaceuticals, Inc. in 2019 was met. The amount payable by Lundbeck to the CVR holders totaled approximately USD 230 million (DKK ~1.5 billion) and was paid in the first quarter of 2022. Vyepti is now launched in Denmark, Estonia, Finland, Germany, Ireland, Sweden and Switzerland. Lundbeck plans to launch in additional markets in the EU in 2023 and onwards including France and the UK following pricing and market access discussions in each market. Sales reached DKK 11 million in 2022. Early launch experiences from the markets indicate that the launches are going well and in Switzerland where the product was first launched in Europe the volume market share among the CGRP products have reached around 6%. In Germany, Vyepti has achieved around 1% of the prevention market.

**Cipralex** generated revenue of DKK 662 million in 2022.

Revenue from **Other pharmaceuticals** was DKK 845 million.

**Key developments in the fourth quarter of 2022**
In the fourth quarter of 2022, revenue increased by 16% in local currencies (13% reported) and reached DKK 1,098 million compared to DKK 969 million in 2021. The strategic brands grew by 25% in local currencies, thereby reaching DKK 744 million or 68% of total revenue. Spain and Italy are key drivers of growth and especially Brintellix benefits from continued strong growth in these markets.

## *Expenses and profit*

In 2022, total costs increased by 8% to DKK 15,394 million compared to DKK 14,289 million in 2021. The individual cost items have partly been driven by the exchange rate appreciation. Revenue increased 12% in the same period and 7% in local currencies.

**Distribution of costs**

| DKK million | FY 2022 | FY 2021 | *Growth* | Q4 2022 | Q4 2021 | *Growth* | Q3 2022 |
|---|---|---|---|---|---|---|---|
| Cost of sales | **3,951** | 3,648 | *8%* | **1,179** | 1,000 | *18%* | 961 |
| *COS-ratio* | ***21.7%*** | *22.4%* | | ***25.2%*** | *24.7%* | | *20.4%* |
| Sales and distribution costs | **6,610** | 5,885 | *12%* | **1,870** | 1,782 | *5%* | 1,653 |
| *S&D-ratio* | ***36.2%*** | *36.1%* | | ***40.0%*** | *44.0%* | | *35.0%* |
| Administrative expenses | **1,079** | 933 | *16%* | **323** | 270 | *20%* | 247 |
| *G&A-ratio* | ***5.9%*** | *5.7%* | | ***6.9%*** | *6.7%* | | *5.2%* |
| Research & development costs | **3,754** | 3,823 | *(2%)* | **905** | 995 | *(9%)* | 906 |
| *R&D-ratio* | ***20.6%*** | *23.5%* | | ***19.3%*** | *24.5%* | | *19.2%* |
| **Total costs** | **15,394** | **14,289** | ***8%*** | **4,277** | **4,047** | ***6%*** | **3,767** |

Cost of sales increased by 8% to DKK 3,951 million in 2022 and the gross margin was 78.3% compared to 77.6% for 2021. Part of cost of sales relates to amortization of product rights which was DKK 1,371 million compared to DKK 1,274 million in 2021. Amortizations have increased due to appreciation of USD and additional amortization of Vyepti following the European approval. Core gross margin increased from 85.7% to 85.9%.

**Sales and distribution costs** were DKK 6,610 million in 2022, an increase of 12% compared to 2021 driven by FX appreciation and an increasing activity level especially for Vyepti development and launch preparation and patient activation programs in the U.S. Sales and distribution costs corresponded to 36.2% of revenue in 2022, compared to 36.1% in 2021.

**Administrative expenses** increased by 16% to DKK 1,079 million compared to 2021, corresponding to 5.9% of total revenue. The increase is mainly a result of legal costs, cloud-based software that is recognized directly in the income statement, FX development and a donation to Red Cross communicated in the financial report for the first half of 2022.

**Research & development costs** were DKK 3,754 million in 2022 with an R&D ratio of 20.6%. The lower R&D spend is due to lower project related cost related to marketed products such as Brintellix/Trintellix and Rexulti.

Total **operational costs** (OPEX) reached DKK 11,443 million in 2022 compared to DKK 10,641 million in 2021 corresponding to an increase of 8%.

**Key developments in the fourth quarter of 2022**
In the fourth quarter of 2022, total costs amounted to DKK 4,277 million, representing an increase of 6%

compared to 2021 compared to a revenue growth of 15%.

Fourth quarter of 2022 was impacted by a DKK 228 million provision for Vyepti inventory obsolescence has been recognized in Cost of sales. The provision is a consequence of

- a fixed batch quantity supply agreement effective for five years up to June 30, 2023, which was inherited as part of the acquisition of Alder BioPharmaceuticals Inc.
- higher than originally expected production yields from the current pichia-based production cell line
- recent progress in the likelihood of success of the planned transition of the antibody cell line to a modern, CHO-based, higher yield and lower cost production cell line.

Furthermore, a reversal of restructuring cost of DKK 90 million was recognized in Sales and distribution costs and Administrative expenses, which was adjusted in core EBIT.

**Core gross margin** decreased from 83.8% to 83.4% in the fourth quarter of 2022.

## Depreciation, amortization and impairment losses

Depreciation, amortization and impairment losses, which are included in the individual expense categories, amounted to DKK 1,811 million in 2022 compared to DKK 1,710 million in 2021. The increase is driven by FX and increased Vyepti amortizations.

Amortization of product rights was DKK 1,371 million in 2022 compared to DKK 1,274 million in 2021.

**Depreciation, amortization and impairment charges**

| DKK million | FY 2022 | FY 2021 | *Growth* | Q4 2022 | Q4 2021 | *Growth* | Q3 2022 |
|---|---|---|---|---|---|---|---|
| Cost of sales | 1,610 | 1,485 | *8%* | 460 | 374 | *23%* | 409 |
| Sales and distribution cost | 99 | 95 | *4%* | 22 | 24 | *(8%)* | 30 |
| Administrative expenses | 16 | 29 | *(45%)* | 4 | 7 | *(43%)* | 4 |
| Research & development costs | 86 | 101 | *(15%)* | 21 | 29 | *(28%)* | 19 |
| **Total depreciation, amortization and impairment charges** | **1,811** | **1,710** | ***6%*** | **507** | **434** | ***17%*** | **462** |

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

Following the solid growth in revenue and prudent cost spend, **EBITDA** increased by 25%, reaching DKK 4,663 million. **EBITDA-margin** increased from 23% to 26%.

Reported **EBIT** grew by 42%, reaching DKK 2,852 million in 2022. The **EBIT margin** reached 15.6% compared to 12.3% for the same period in 2021. **Core EBIT** increased by 18% to DKK 4,155 million compared to 2021 and **Core EBIT margin** was 22.8% compared to 21.6% in 2021.

In the fourth quarter of 2022, **EBITDA** reached DKK 910 million representing a growth of 107% compared to 2021. The **EBITDA margin** increased from 11% to 19%. **EBIT** reached DKK 403 million and **Core EBIT** reached DKK 783 million. The **Core EBIT margin** increased from 13.4% to 16.7%.

For definitions of the measures “Core Revenue”, “Core EBIT”, “Core EPS” and “Core EBIT margin”, see note 2 *Core reporting*.

## Net financials, expenses

Lundbeck generated a net financial expense of DKK 378 million in 2022 compared to a net financial expense of DKK 429 million in 2021.

Fair value adjustments on contingent consideration have negative impact of DKK 229 million primarily derived from the European Medicines Agency’s (EMA) approval of Vyepti. Interest costs are lower compared to last year driven by positive development in deposit rates and banking costs.

### Tax

The effective tax rate in 2022 is 22.6%. The effective tax rate has increased significantly compared to 2021, as 2021 was positively impacted by recognition of tax credits not previously recognized. The tax rate for 2022 is negatively impacted by the non-deductible CVR payment regarding Vyepti EMA approval however this is partially offset by the Danish research and development incentive.

### Profit and EPS

**Profit** reached DKK 1,916 million for 2022 compared to DKK 1,318 million in 2021. The reported net profit corresponded to an **EPS** of DKK 1.93 versus an EPS of DKK 1.33 in 2021. **Core EPS** reached DKK 3.22 in 2022, compared to a Core EPS of DKK 2.51 in 2021. The calculation of EPS is based on a share denomination of DKK 1 as a result of the share split completed on June 8, 2022. Comparative figures have been restated to reflect the change in trading unit from a nominal value of DKK 5 to DKK 1.

## *Cash flows*

**Cash flows from operating activities** amounted to an inflow of DKK 3,519 million in 2022 compared to an inflow of DKK 2,272 million in 2021. The development compared to 2021 is impacted by higher EBITDA, offset by the realized financial expense in connection with the payment of the contingent consideration for the EMA approval of Vyepti. The EMA approval of Vyepti triggered a payment to former Alder shareholders of USD 2 per share. This resulted in a payment of DKK 1,566 million, consisting of DKK 490 million in operating activities and DKK 1,076 million in investing activities.

Lundbeck's **net cash flows from investing activities** were an outflow of DKK 1,892 million in 2022 compared to an outflow of DKK 610 million in 2021. In 2022, the cash flow was primarily driven by the payment of contingent consideration related to the EMA approval of Vyepti.

The **cash flows from financing activities** were an inflow of DKK 387 million in 2022 compared to an outflow of DKK 3,336 million in 2021. The cash inflow mainly related to the drawing on the RCF needed for the payment triggered by the EMA approval of Vyepti and a DKK 397 million dividend payout.

In 2022, the **net cash inflow** reached DKK 1,240 million compared to an outflow of DKK 1,674 million in 2021 which included repayment of a DKK 2.0 billion loan. The net cash flow in 2022 is impacted by the EMA approval of Vyepti and the dividend payout of DKK 398 million which was approved at the Annual General Meeting in March 2022.

**Selected cash flow figures**

| DKK million | FY 2022 | FY 2021 | Q4 2022 | Q4 2021 |
|---|---|---|---|---|
| **Profit from operations (EBIT)** | **2,852** | **2,010** | **403** | **6** |
| Cash flows from operating activities | 3,519 | 2,272 | 1,287 | 424 |
| Cash flows from investing activities | (1,892) | (610) | (532) | (319) |
| **Cash flows from operating and investing activities (free cash flow)** | **1,627** | **1,662** | **755** | **105** |
| Cash flows from financing activities | (387) | (3,336) | (556) | (341) |
| **Net cash flow for the period** | **1,240** | **(1,674)** | **199** | **(236)** |

## *Financial position*

At December 31, 2022, Lundbeck's **total assets** amounted to DKK 37,452 million compared to DKK 34,653 million at the end of 2021.

In November 2022, Rexulti® achieved a sales milestone of USD 1 billion triggering the recognition of an addition in the product rights of Rexulti of DKK 359 million (USD 50 million) and a corresponding liability. The milestone will be paid in the first quarter of 2023

At December 31, 2022, Lundbeck's **equity** amounted to DKK 20,779 million, corresponding to an **equity ratio** of 55.5% compared to 52.7% at the end of 2021.

**Net debt** has been reduced from DKK 3,189 million at the end of December 2021 to DKK 2,183 million at the end of December 2022. **Interest bearing debt** was DKK 5,731 million at the end of December 2022 compared to DKK 5,468 million at the end of December 2021.

**Selected balance sheet figures**

| DKK million | FY 2022 | FY 2021 |
|---|---|---|
| **Total assets** | **37,452** | **34,653** |
| Lundbeck's share of equity | 20,779 | 18,279 |
| Net-interest bearing debt | 2,183 | 3,189 |
| **Invested capital, end of period** | **14,490** | **13,185** |

## *Lundbeck's development portfolio*

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/ Launch |
|---|---|---|---|---|---|
| **Hormonal / neuropeptide signaling:** | | | | | |
| Eptinezumab (anti-CGRP)[1)] | Migraine prevention[2)] | | | *SUN-studies* | *PROMISE 1 & 2* |
| | Cluster headache | | *CHRONICLE* | *ALLEVIATE* | |
| Lu AG09222 (anti-PACAP mAb)[4)] | Migraine prevention | | *HOPE* | | |
| Lu AG13909 (anti-ACTH mAb)[5)] | Neurohormonal dysfunctions | | | | |
| **Circuitry / neuronal biology:** | | | | | |
| Brexpiprazole[6)] | Agitation in Alzheimer's disease | | | | |
| | PTSD | | | | |
| Aripiprazole 2-months injectable | Schizophrenia/bipolar I disorder | | | | |
| Lu AG06466[7)] | PTSD | | | | |
| Lu AF28996 ($D_1/D_2$ agonist) | Parkinson's disease | | | | |
| **Protein aggregation, folding and clearance:** | | | | | |
| Lu AF82422 (anti-α-synuclein mAb) | Multiple system atrophy | | *AMULET* | | |
| Lu AF87908 (anti-Tau mAb) | Tauopathies | | | | |
| **Neuroinflammation / neuroimmunology:** | | | | | |
| Lu AG22151 (CD40L inhibitor) | Neurology | | | | |

1) CGRP: Calcitonin gene-related peptide. 2) Two phase III clinical trials, supporting registration in Asia, including China and Japan: *SUNRISE*, and *SUNSET* trials. 3) Long-term safety study. 4) PACAP: Pituitary adenylate cyclase activating peptide. 5) Adrenocorticotropic hormone. 6) Acts as a partial agonist at 5-HT1A and dopamine D2 receptors at similar potency, and an antagonist at 5-HT2A and noradrenaline alpha1B/2C receptors. 7) Monoacylglycerol lipase inhibitor ("MAGlipase").

**Hormonal / neuropeptide signaling:**

**Eptinezumab - development and regulatory status**

Eptinezumab is a monoclonal antibody (mAb) that 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. Eptinezumab is administered as a 30-minute intravenous (IV) infusion, providing immediate and complete bioavailability.

In February 2020, Vyepti (eptinezumab-jjmr) was approved by the U.S. Food and Drug Administration (FDA) as the first FDA-approved IV treatment for the treatment of migraine in adults. In January 2022, Lundbeck announced that the European Commission has granted marketing authorization for Vyepti in the European Union (EU) for the prophylactic treatment of migraine in adults who have at least four migraine days per month. The EU marketing authorization is valid in all EU Member States, Iceland, Norway, and Liechtenstein.

Furthermore, Vyepti has been approved in U.A.E., Canada, Kuwait, Australia, Singapore, Switzerland, Israel. In 2022 additional approvals were obtained in Great Britain, Brazil, Indonesia, Mexico, Saudi Arabia and Hong Kong.

Eptinezumab has been submitted for regulatory review in other markets.

During 2021, Lundbeck initiated phase III clinical trials supporting registration in Asia, the *SUNLIGHT* trial (NCT04772742) was a smaller trial designed to test the efficacy of eptinezumab to prevent migraine and headache in patients with the combined diagnosis of chronic migraine and medication overuse headache. The study did not reach statistically significant separation from placebo for the primary endpoint but numerically favored the eptinezumab arm for the primary and key secondary endpoints.

The *SUNRISE* trial (NCT04921384) evaluates the efficacy of eptinezumab to prevent migraine and headache in patients with chronic migraine. This study forms the base case for Asian approval across Japan, China and Korea. Based on the outcome of the SUNLIGHT trial the sample size of this study has been adjusted. Patients are randomly allocated to placebo or two treatment groups: eptinezumab 100 mg or 300 mg given by IV infusion (n=945). The total study duration is either approximately 36 weeks, including screening period and safety follow-up; or 24 weeks for patients in Japan that enter a separate open label extension trial, the *SUNSET* trial (NCT05064371). The *SUNSET* study will enroll approximately 100 patients with a total study duration of approximately 68 weeks.

In December 2020, Lundbeck initiated 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 treatment consisting of two infusions of either eptinezumab or placebo in a cross-over manner. The total duration of the study is 24 weeks, including a safety follow-up period of 8 weeks. During 2021, Lundbeck further initiated a 1-year safety and tolerability trial in participants with chronic cluster headache (*CHRONICLE*, NCT05064397).

In 2022, Lundbeck initiated an explorative, randomized, pragmatic open label study to evaluate the comparative effectiveness of eptinezumab against other advanced preventive medications in a real-world community setting in adult participants with episodic or chronic migraine (*EVEC*, NCT05284019). The objectives included exploring the comparative effectiveness on patient-reported outcomes. The study planned to enroll 200 patients, but as operational execution has been challenging, this study will be closed.

Also, in 2022, Lundbeck initiated a phase IV study investigating the add-on efficacy of eptinezumab treatment to brief educational intervention, for the preventive treatment of migraine in patients with a dual diagnosis of migraine and medication overuse headache (*RESOLUTION*). The study (NCT05452239) is planned to recruit around 570 patients that will be randomly assigned to receive either eptinezumab (100mg) or placebo administered

by IV infusion. The total study duration is approximately 36 weeks including screening period and safety follow-up.

**Lu AG09222 – phase II**

Lu AG09222 represents a potential new therapeutic option for the treatment of migraine, which unlike the recently available calcitonin gene-related peptide (CGRP) migraine treatment drug class, targets pituitary adenylate cyclase-activating polypeptide (PACAP). PACAP and its receptors are broadly expressed in the nervous system, including at sites implicated in migraine pathophysiology. In pre-clinical and clinical studies in healthy subjects, Lu AG09222 has been shown to bind with high affinity to PACAP, thereby preventing PACAP from activating its receptors.

In 2021, Lundbeck completed a study confirming the target engagement of Lu AG09222 with PACAP (NCT04976309). In this study, the preventive effect of Lu AG09222 on vasodilation induced by PACAP was investigated and confirmed. Subsequently, in November 2021, Lundbeck initiated the HOPE study, a randomized, double-blind, phase II, proof of concept study to assess efficacy, safety, and tolerability of Lu AG09222 as a treatment for the prevention of migraine (NCT05133323) with headline results planned for mid-year 2023. A total of 230 patients, recruited from specialist settings, have been randomly allocated to one of three treatment groups: high/low dose of Lu AG09222 or placebo. This study has completed enrollment.Recently, Lundbeck completed a multi-dose study conducted in allergic rhinitis subjects (NCT05126316) demonstrating dose-proportionality following sub-cutaneous administration of Lu AG09222 and further validating its good safety and tolerability profile. Also, exploratory readout of pharmacodynamic (PD) allergic responses were obtained guiding the compound's further development.

**Lu AG13909 – phase I**

Lu AG13909 is a novel approach to target neuro-hormonal dysfunctions of the hypothalamic–pituitary–adrenal (HPA) axis caused by elevated levels of adrenocorticotropic hormone (ACTH) produced in the pituitary gland. Lu AG13909 is a humanized anti-ACTH IgG1 monoclonal antibody that neutralizes ACTH-induced signaling in the adrenal glands by blocking ACTH binding to the (melanocortin 2 receptor (MC2R).

A phase I first in human trial (NCT05669950) has been initiated December 2022 in patients with Congenital Adrenal Hyperplasia (CAH), which encompasses a group of autosomal recessive rare disorders. The phase I trial aims at establishing the safety and efficacy profile of Lu AG13909 after single and multiple doses.

**Circuitry / neuronal biology:**

**Brexpiprazole – phase III in Alzheimer's agitation**

In June 2022, Lundbeck and Otsuka Pharmaceutical reported positive results showing reduced agitation in patients with Alzheimer's dementia treated with brexpiprazole. In the study, the improvements from baseline on the primary endpoint of Cohen-Mansfield Agitation Inventory (CMAI) scale for patients receiving brexpiprazole or 2 mg/day or 3 mg/day were statistically greater than for those receiving placebo (p=0.0026). This result was supported by a statistically superior improvement on the key secondary endpoint of CGI-S, as related to agitation (p=0.0055).

Brexpiprazole was generally well tolerated, and no new safety signals were observed. The only Treatment Emergent Adverse Event (TEAE) with more than 5% incidence in patients treated with brexpiprazole was headache (6.6% vs. 6.9% for placebo). The following TEAEs occurred at an incidence of at least 2% in brexpiprazole treatment group and greater than that of placebo: somnolence, nasopharyngitis, dizziness, diarrhea, urinary tract infection, and asthenia. There was one death observed in the 3 mg/day treatment group, assessed by the investigator as not related to treatment.

Based on this outcome, Lundbeck and Otsuka Pharmaceutical submitted a supplemental New Drug Application (sNDA) for brexpiprazole in the treatment of agitation associated with Alzheimer's dementia on November 10, 2022. On January 6, 2023, the application was accepted and filed by the FDA under Priority review with an FDA target date (PDUFA date)

for completion of the review of May 10, 2023. Lundbeck has also been informed that FDA is currently planning to hold a Psychopharmacologic Drugs Advisory Committee meeting to discuss the application. The sNDA is comprised of this study as well as two earlier phase III studies. If approved, brexpiprazole would be the first pharmacological treatment indicated for agitation in patients with Alzheimer's dementia in the U.S.

**Brexpiprazole – phase III in Post-Traumatic Stress Disorder (PTSD)**

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.

In November 2018, Lundbeck and Otsuka Pharmaceutical reported data from an explorative phase II study in PTSD, with positive findings from the treatment arm that examined a combination treatment of brexpiprazole and sertraline. On basis of these data, Lundbeck and Otsuka Pharmaceutical initiated two pivotal phase III trials (NCT04124614; n=577 and NCT04174170; n=733), investigating the use of brexpiprazole in combination with sertraline in the treatment of PTSD, subsequent to an End of Phase II meeting with the U.S. FDA in May 2019. The execution of those two ongoing studies was challenged by the COVID-19 pandemic, primarily impacting enrollment rates. Therefore, Lundbeck and Otsuka Pharmaceutical have been seeking phase III program advice from the U.S. FDA. Given the obtained FDA guidance, the program will continue, with a slightly reduced sample size and with estimated headline results in the second half of 2023.

**Aripiprazole – 2-Month Injectable (LAI) formulation**

In July 2019, Lundbeck and Otsuka Pharmaceutical initiated a pivotal phase Ib 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 provided effective plasma concentrations of aripiprazole for two months, while being safe and tolerable.

A long-acting injectable formulation ensures continuous exposure to medication and through a simplified treatment regimen, many of the challenges with poor treatment adherence may be mitigated, resulting in a potential positive impact on patient outcomes.

The new 2-month formulation is an innovative addition to the long-acting injectable (LAI) franchise and has patent protection until the early part of the next decade.

Lundbeck and Otsuka Pharmaceutical have submitted the Marketing Authorization Application (MAA) for aripiprazole as a 2-month ready-to-use (RTU) long-acting injectable (LAI) for the maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole to the European Medicines Agency (EMA) as well as to the U.S FDA and Health Canada for the treatment of schizophrenia and bipolar disorder. The MAA was submitted May 26, 2022. The U.S. NDA was submitted June 27, 2022 – PDUFA date April 27, 2023.

**Lu AG06466 – phase Ib**

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.

A phase Ib study was initiated in September 2020 with the purpose to investigate the effect of Lu AG06466 after multiple doses in patients with PTSD (NCT04597450). This exploratory study using biomarkers and clinical outcome measures will, together with previous studies conducted in small phase Ib patient population, guide decision making for future development of Lu AG06466 and other molecules of the MAGL inhibitor class that the company has in the pipeline,

### Lu AF28996 – phase I

Lu AF28996 is a small molecule with agonistic properties towards D1 and D2 receptors. Continuous D1 and D2 dopamine receptor stimulation may play an important role in motor control of Parkinson's disease patients. A phase Ib study was initiated in February 2020 with the purpose to investigate the safety and tolerability as well as pharmacokinetics of Lu AF28996 in patients with Parkinson's disease (NCT04291859).

## Protein aggregation, folding and clearance:

### Lu AF82422 – phase II

Lu AF82422 is a humanized monoclonal IgG1 antibody targeting the pathological form of the protein alpha-synuclein that is believed to play a pivotal role in the development and progression of neurodegenerative diseases such as multiple system atrophy (MSA), Parkinson's disease (PD), and other synucleinopathies. 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 and therapeutic effect on disease burden and function. Lu AF82422 has been demonstrated to be well-tolerated in a phase I single-ascending dose study, which was completed in July 2021. A phase II study (*AMULET*, NCT05104476) was initiated in November 2021, and completed enrollment in 2022. The primary objective of the study is to evaluate the efficacy of Lu AF82422 versus placebo on disease progression in patients with MSA. Headline results are expected in first half of 2024.

A natural history study (*TALISMAN*, NCT05453058) for patients with early MSA has been initiated in China in June 2022 and is expected to open for recruitment in the EU in 2023.

Orphan drug designation for MSA was granted by EMA April 2021.

### Lu AF87908 – phase I

Lu AF87908 is an IgG1 monoclonal antibody (mAb) targeting the pathological form of the hyper-phosphorylated tau protein, which is believed to play a pivotal role in the development and progression of Alzheimer's disease and other tau-driven neurodegenerative disorders (primary tauopathies). Lu AF87908 binds to a specific tau epitope (pS396-tau) which is a dominating phosphorylation site in pathological tau. A phase I program on Lu AF87908 was initiated in September 2019 to investigate the safety and tolerability as well as pharmacokinetics of a single dose of Lu AF87908, in healthy subjects and patients with Alzheimer's Disease (NCT04149860). Trial execution has been delayed as accrual of patients has been impacted by COVID-19.

## Neuroinflammation / neuroimmunology:

Lu AG22515 is a CD40L/serum-albumin bispecific antibody-fragment that blocks the CD40L/CD40 pathway through direct neutralization of CD40L, thereby affecting adaptive and innate immune responses. Lu AG22515 holds strong promise in the treatment of a wide range of autoimmune-related CNS disorders and neurological diseases with autoreactive T-cells, B-cells and marked presence of autoantibodies and inflammation. A First-in-Human study (NCT05136053) testing single ascending doses of Lu AG22515 in healthy volunteers was initiated in the U.S. in March 2022.

### 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 under the Investor section.

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

### FY 2022

| 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 | 18,246 | - | - | - | - | - | - | 18,246 |
| Cost of Sales | 3,951 | (1,371) | - | - | - | - | - | 2,580 |
| **Gross profit** | **14,295** | **1,371** | **-** | **-** | **-** | **-** | **-** | **15,666** |
| Sales and distribution costs | 6,610 | - | - | 126 | - | - | - | 6,736 |
| Administrative expenses | 1,079 | - | - | 7 | - | (70) | - | 1,016 |
| Research and development costs | 3,754 | - | - | 5 | - | - | - | 3,759 |
| **Profit from operations (EBIT)** | **2,852** | **1,371** | **-** | **(138)** | **-** | **70** | **-** | **4,155** |
| Net financials, expenses | 378 | - | - | - | - | - | (278) | 100 |
| **Profit before tax** | **2,474** | **1,371** | **-** | **(138)** | **-** | **70** | **278** | **4,055** |
| Tax on profit for the period | 558 | 315 | - | (30) | - | 15 | - | 858 |
| **Profit for the period** | **1,916** | **1,056** | **-** | **(108)** | **-** | **55** | **278** | **3,197** |
| Earnings per share, basic (EPS)[1] | 1.93 | 1.06 | - | (0.11) | - | 0.06 | 0.28 | 3.22 |

### FY 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 | 16,299 | - | - | - | - | - | - | 16,299 |
| Cost of sales | 3,648 | (1,274) | - | (37) | - | - | - | 2,337 |
| **Gross profit** | **12,651** | **1,274** | **-** | **37** | **-** | **-** | **-** | **13,962** |
| Sales and distribution costs | 5,885 | - | - | (162) | - | - | - | 5,723 |
| Administrative expenses | 933 | - | - | (31) | - | - | - | 902 |
| Research and development costs | 3,823 | - | - | (3) | - | - | - | 3,820 |
| **Profit from operations (EBIT)** | **2,010** | **1,274** | **-** | **233** | **-** | **-** | **-** | **3,517** |
| Net financials, expenses | 429 | - | - | - | - | - | - | 429 |
| **Profit before tax** | **1,581** | **1,274** | **-** | **233** | **-** | **-** | **-** | **3,088** |
| Tax on profit for the period | 263 | 276 | - | 51 | - | - | - | 590 |
| **Profit for the period** | **1,318** | **998** | **-** | **182** | **-** | **-** | **-** | **2,498** |
| Earnings per share, basic (EPS)[1] | 1.33 | 1.00 | - | 0.18 | - | - | - | 2.51 |

1 The calculation of EPS is based on a share denomination of DKK 1 as a result of the share split completed on June 8, 2022. Comparative figures have been restated, to reflect the change in trading unit from a nominal value of DKK 5 to DKK 1.

## *Statement of profit or loss – Core results reconciliation (Q4)*

### Q4 2022

| 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 | 4,680 | - | - | - | - | - | - | 4,680 |
| Cost of Sales | 1,179 | (400) | - | - | - | - | - | 779 |
| **Gross profit** | **3,501** | **400** | **-** | **-** | **-** | **-** | **-** | **3,901** |
| Sales and distribution costs | 1,870 | - | - | 83 | - | - | - | 1,953 |
| Administrative expenses | 323 | - | - | 7 | - | (70) | - | 260 |
| Research and development costs | 905 | - | - | - | - | - | - | 905 |
| **Profit from operations (EBIT)** | **403** | **400** | **-** | **(90)** | **-** | **70** | **-** | **783** |
| Net financials, expenses | (14) | - | - | - | - | - | - | (14) |
| **Profit before tax** | **417** | **400** | **-** | **(90)** | **-** | **70** | **-** | **797** |
| Tax on profit for the period | 106 | 91 | - | (20) | - | 15 | - | 192 |
| **Profit for the period** | **311** | **309** | **-** | **(70)** | **-** | **55** | **-** | **605** |
| Earnings per share, basic (EPS)[1] | 0.31 | 0.31 | - | (0.07) | - | 0.06 | - | 0.61 |

### Q4 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 | 4,053 | - | - | - | - | - | - | 4,053 |
| Cost of sales | 1,000 | (305) | - | (37) | - | - | - | 658 |
| **Gross profit** | **3,053** | **305** | **-** | **37** | **-** | **-** | **-** | **3,395** |
| Sales and distribution costs | 1,782 | - | - | (162) | - | - | - | 1,620 |
| Administrative expenses | 270 | - | - | (31) | - | - | - | 239 |
| Research and development costs | 995 | - | - | (3) | - | - | - | 992 |
| **Profit from operations (EBIT)** | **6** | **305** | **-** | **233** | **-** | **-** | **-** | **544** |
| Net financials, expenses | 118 | - | - | - | - | - | - | 118 |
| **Profit before tax** | **(112)** | **305** | **-** | **233** | **-** | **-** | **-** | **426** |
| Tax on profit for the period | (110) | 70 | - | 51 | - | - | - | 11 |
| **Profit for the period** | **(2)** | **235** | **-** | **182** | **-** | **-** | **-** | **415** |
| Earnings per share, basic (EPS)[1] | - | 0.24 | - | 0.18 | - | - | - | 0.42 |

1 The calculation of EPS is based on a share denomination of DKK 1 as a result of the share split completed on June 8, 2022. Comparative figures have been restated, to reflect the change in trading unit from a nominal value of DKK 5 to DKK 1.

## Notes

### Note 1: EBITDA calculation

| DKK million | FY 2022 | FY 2021 | Q4 2022 | Q4 2021 |
|---|---|---|---|---|
| EBIT | 2,852 | 2,010 | 403 | 6 |
| + Depreciation, amortization and impairment losses | 1,811 | 1,710 | 507 | 434 |
| **= EBITDA** | **4,663** | **3,720** | **910** | **910** |

### Note 2: Core reporting

As a general rule, Lundbeck adjusts for amortization of product rights and for each non-recurring item that Management deems exceptional and/or 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 adjustments*

*Major restructurings*

*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
- Adjustments in probability of success embedded in milestone calculations

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

# FINANCIAL CALENDAR 2023

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|---|---|
| February 8, 2023: | Annual Report 2022 (PDF) |
| March 21, 2023: | Lundbeck Annual General Meeting 2022 |
| March 24, 2023: | Dividends for 2022 at the disposal of shareholders |
| May 10, 2023: | Financial statements for the first three months of 2023 |
| August 16, 2023: | Financial statements for the first six months of 2023 |
| November 8, 2023: | Financial statements for the first nine months of 2023 |

## Lundbeck contacts

**Investors:**

Palle Holm Olesen
Vice President, Investor Relations
PALO@lundbeck.com
+45 30 83 24 26

**Media:**

Thomas Mikkel Mortensen
Media Relations Lead, Corporate Communication
THMR@lundbeck.com
+45 30 83 30 24

## About Lundbeck

H. Lundbeck A/S (LUN.CO, LUN DC, HLUYY) 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.

Too many people worldwide live with brain diseases – complex conditions often invisible to others that nonetheless take a tremendous toll on individuals, families and societies. We are committed to fighting stigma and discrimination against people living with brain diseases and advocating for broader social acceptance of people with brain health conditions. Every day, we strive for improved treatment and a better life for people living with brain disease.

We have approximately 5,400 employees in more than 50 countries, and our products are available in more than 100 countries. Our research programs tackle some of the most complex challenges in neuroscience, and our pipeline is focused on bringing forward transformative treatments for brain diseases for which there are few, if any therapeutic options. We have research facilities in Denmark and the United States, and our production facilities are located in Denmark, France, and Italy. Lundbeck generated revenue of DKK 18.2 billion in 2022 (EUR ~2.5 billion; USD ~2.6 billion).

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