

# Lundbeck's revenue increased by 13% (+10% CER) to DKK 10 billion in the first six months of 2023

# **Key highlights**

Lundbeck's revenue increased by 13% (+10% CER¹) to DKK 9,982 million in the first six months of 2023, representing growth in all regions with the U.S. and Europe contributing strongly

- United States: DKK 4,787 million (+16%; +14% CER)
- Europe: DKK 2,333 million (+13%; +13% CER)
- International Markets: DKK 2,736 million (+2%; +5% CER)

The revenue of Lundbeck's strategic brands increased by 18% (+18% CER), reaching DKK 6,632 million, representing 66% of total revenue

- Brintellix®/Trintellix®: DKK 2,156 million (+5%; +6% CER)
- Rexulti<sup>®</sup>/Rxulti<sup>®</sup>: DKK 2,135 million (+21%; +18% CER)
- Abilify Maintena®/Asimtufii: DKK 1,584 million (+14%; +14% CER)
- Vyepti<sup>®</sup>: DKK 757 million (+94%; +91% CER)

Adjusted EBITDA<sup>2</sup> increased to DKK 3,338 million (+46%; +32% CER) and adjusted EBITDA margin reached 33.4% equivalent to an increase of 7.5 percentage points. Adjusted earnings per share (EPS) reached DKK 2.47 equivalent to an increase of 36%.

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

"Lundbeck continues to deliver an excellent performance, achieving the strongest-ever revenue for the first six months of 2023 and having now launched Rexulti® in a potential blockbuster indication in agitation associated with dementia due to Alzheimer's disease (AADAD). I am delighted with Lundbeck's continuous sustainable growth and results. I am fully confident that Lundbeck is well positioned for the future given our successful transformation."

### **Key figures**

DKK million	H1 2023	H1 2022	Change	Change (CER)¹	Q2 2023	Q2 2022	Change	Change (CER) <sup>1</sup>
Revenue	9,982	8,847	13%	10%	4,938	4,475	10%	10%
EBITDA	3,078	2,339	32%	19%	1,334	1,049	27%	16%
Adjusted EBITDA	3,338	2,291	46%	32%	1,493	1,001	49%	35%
EPS (DKK)	1.49	0.92	62%	-	0.60	0.51	18%	-
Adjusted EPS (DKK)	2.47	1.82	36%	-	1.11	0.80	39%	

<sup>&</sup>lt;sup>1</sup> Constant Exchange Rates (CER) previously denominated Local Currency (LC). Change at CER does not include effects from hedging.

<sup>&</sup>lt;sup>2</sup> EBITDA refers to Earnings Before Interest, Taxes, Depreciation and Amortization. Adjusted EBITDA is defined as EBITDA adjusted by certain items, for details see section 4 *Notes*, note 3 *Adjusted EBITDA*.

### **Recent events**

On June 26, 2023, Lundbeck announced that Deborah Dunsire is leaving Lundbeck after having successfully strengthened Lundbeck's position since her appointment in 2018. The Board of Directors has appointed Charl van Zyl as new President and CEO of Lundbeck. Deborah Dunsire will continue to serve as President and CEO until Charl van Zyl assumes the position on September 1, 2023.

On June 16, 2023, Lundbeck released new data confirming long-term benefit of treatment with Vyepti<sup>®</sup> (eptinezumab) in migraine prevention. The findings from the *DELIVER* extension study were presented at the 65<sup>th</sup> Annual Scientific Meeting of the American Headache Society (AHS) on June 15-18, 2023, in Austin, Texas.

On May 11, 2023, Lundbeck and Otsuka Pharmaceutical, Co. Ltd. (Otsuka) announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) of Rexulti® (brexpiprazole) for use in treatment of agitation associated with dementia due to Alzheimer's disease (AADAD). This approval makes Rexulti® the first and only pharmacological treatment approved in the U.S. for agitation associated with dementia due to Alzheimer's disease.

On April 27, 2023, Lundbeck and Otsuka Pharmaceutical, Inc. (Otsuka) announced that FDA approved the New Drug Application (NDA) for Abilify Asimtufii® (aripiprazole) extended-release injectable suspension for intramuscular use, a once-every-two-months injection for the treatment of schizophrenia in adults or for maintenance monotherapy treatment of bipolar I disorder in adults.

### 2023 Guidance

Lundbeck raises its full-year guidance for 2023. Lundbeck now expects revenue to reach DKK 19.5 to 20.1 billion compared to previously DKK 19.4 to 20.0 billion. Adjusted EBITDA is now expected to reach DKK 5.2 to 5.6 billion compared to previously DKK 5.1 to 5.5 billion. Further details are available in section 2.8 *Outlook*.

# **CONTENT**

1 Financial highlights	4
2 Business performance	5
2.1 Revenue by product	5
2.2 Revenue by geographical area	7
2.3 Gross profit	8
2.4 EBIT and adjusted EBITDA	9
2.5 Net profit and adjusted EPS	10
2.6 Cash flow and balance sheet	10
2.7 Summary of the key developments in the second quarter of 2023	11
2.8 Outlook	13
2.9 Lundbeck's development portfolio	14
2.10 Sustainability update	16
2.11 General corporate matters	17
3 Condensed financial statements	20
4 Notes	25
Financial calendar 2023	27

# 1 FINANCIAL HIGHLIGHTS

### For the six months ended June 30

DKK million	H1 2023	H1 2022	Change	Change (CER) <sup>1</sup>
Revenue	9,982	8,847	13%	10%
Gross profit	7,803	7,036	11%	8%
Gross margin	78.2%	79.5%		
Adjusted gross profit <sup>2</sup>	8,975	7,777	15%	12%
Adjusted gross margin	89.9%	87.9%		
Sales and distribution costs	3,501	3,087	13%	14%
S&D ratio	35.1%	34.9%		
Administrative expenses	564	509	11%	11%
Administrative expenses ratio	5.7%	5.8%		
Research and development costs	1,665	1,943	(14%)	(14%)
R&D ratio	16.7%	22.0%		
EBIT (profit from operations)	2,073	1,497	38%	20%
EBIT margin	20.8%	16.9%		
EBITDA <sup>3</sup>	3,078	2,339	32%	19%
EBITDA margin	30.8%	26.4%		
Adjusted EBITDA <sup>4</sup>	3,338	2,291	46%	32%
Adjusted EBITDA margin	33.4%	25.9%		
Net financials, expenses	138	322	(57%)	-
Profit before tax	1,935	1,175	65%	-
Income taxes	455	258	76%	-
Effective tax rate (reported)	23.5%	22.0%		
Net profit	1,480	917	61%	-
Adjusted net profit	2,457	1,804	36%	-
Other key numbers				
Assets	37,242	37,275	0%	-
Equity	21,572	19,596	10%	-
Cash flows from operating and investing activities (free cash flow)	1,384	(516)	(368%)	-
Net cash flow for the period	134	(36)	(472%)	-
Return on invested capital – rolling four quarters	11.2%	7.4%		
Net debt/EBITDA – rolling four quarters	0.3	1.2	(75%)	-

Adjusted earnings per share, basic (DKK) <sup>1</sup> Constant Exchange Rates (CER) previously denominated Local Currency (LC). Change at CER does not include effects from hedging.

Number of shares for the calculation of EPS (millions)

Earnings per share, basic (EPS) (DKK)

993.0

1.49

2.47

992.9

0.92

1.82

62%

36%

<sup>&</sup>lt;sup>2</sup> Adjusted gross profit is the gross profit excluding depreciation and amortization and other adjustments linked to sales.
<sup>3</sup> EBITDA refers to Earnings Before Interest, Taxes, Depreciation and Amortization.

<sup>&</sup>lt;sup>4</sup> EBITDA refers to Earnings Before Interest, Taxes, Depreciation and Amortization. Adjusted EBITDA is defined as EBITDA adjusted by certain items, for details see section 4 Notes, 4.3 Adjusted EBITDA.

# **2 BUSINESS PERFORMANCE**

### 2.1 REVENUE BY PRODUCT

Revenue reached DKK 9,982 million representing a growth of 13% (+10% CER). The revenue growth is driven by the strong performance across the strategic brands (Abilify Maintena®/Asimtufii, Brintellix®/Trintellix®, Rexulti®/Rxulti® and Vyepti®) reaching

DKK 6,632 million, representing a growth of 18% (+18% CER) and equivalent to 66% of total revenue. The largest markets for the strategic brands are the U.S., Canada, Spain, Italy and Australia.

DKK million	H1 2023	H1 2022	Growth	Growth (CER)	Q2 2023	Q2 2022	Growth	Growth (CER)
Brintellix®/Trintellix®	2,156	2,051	5%	6%	1,079	1,061	2%	4%
Rexulti <sup>®</sup> /Rxulti <sup>®</sup>	2,135	1,771	21%	18%	1,075	940	14%	16%
Abilify Maintena®/Asimtufii	1,584	1,393	14%	14%	799	716	12%	13%
Vyepti <sup>®</sup>	757	390	94%	91%	406	220	85%	85%
Strategic brands	6,632	5,605	18%	18%	3,359	2,937	14%	16%
Cipralex <sup>®</sup> /Lexapro <sup>®</sup>	1,200	1,254	(4%)	(2%)	536	572	(6%)	(1%)
Sabril <sup>®</sup>	224	322	(30%)	(32%)	114	170	(33%)	(32%)
Other pharmaceuticals	1,800	1,712	5%	6%	837	818	2%	5%
Mature brands	3,224	3,288	(2%)	(1%)	1,487	1,560	(5%)	(1%)
Other revenue	132	156	(15%)	(15%)	69	91	(24%)	(21%)
Total revenue before hedging	9,988	9,049	10%	10%	4,915	4,588	7%	10%
Effects from hedging	(6)	(202)			23	(113)		
Total revenue	9,982	8,847	13%	10%	4,938	4,475	10%	10%

## Strategic brands

 $\textbf{Brintellix}^{\text{@}}/\!\!\!\!\text{Trintellix}^{\text{@}}$  (vortioxetine) is approved for the treatment of major depressive disorder (MDD). Revenue reached DKK 2,156 million representing a growth of 5% (+6% CER) following a continued robust demand in Europe and International Markets mainly in Spain, Canada and Japan partially offset by continued lower demand in the U.S. and China. Increased emphasis on Trintellix® strategic brand positioning focusing on efficacy, together with field force and omnichannel execution, is expected to drive new patient starts and overall demand growth over the near-to-medium term in the U.S. In Japan, the market share of Trintellix® continues to grow with stronger positioning as a first-line treatment being established among psychiatrists. The revenue distribution by region was 32%, 35% and 33% in the U.S., Europe and International Markets, respectively. The largest markets for the product are the U.S., Canada, Spain, Italy and Brazil.

Rexulti®/Rxulti® (brexpiprazole) 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. Further, it is approved for the treatment

of agitation associated with dementia due to Alzheimer's Disease (AADAD) in the U.S. since May 2023. In the early weeks following the approval, the brand has seen an increased usage in 65+ patients versus the pre-AADAD trend. In Australia and Europe, the product is approved only for schizophrenia. Revenue reached DKK 2,135 million representing a growth of 21% (+18% CER) as a result of strong demand and market share growth mainly in the U.S. The revenue distribution by region was 93%, 1% and 6% in the U.S., Europe and International Markets, respectively. The largest markets are the U.S., Canada, Brazil, Australia and Mexico.

Abilify Maintena® (aripiprazole) is approved for the treatment of schizophrenia in Europe and for both schizophrenia and bipolar I disorder in the U.S., Canada and Australia as a once-monthly injection. On April 27, 2023 FDA approved a New Drug Application (NDA) for aripiprazole as an every-two-months injection denominated Abilify Asimtufii® which has been launched in the U.S. in June 2023. Revenue for Abilify Maintena® and Abilify Asimtufii® reached DKK 1,584 million representing a growth of 14% (+14% CER) driven by a combination of strong demand, price increases and timing of shipments. All

regions presented revenue growth in the first six months of 2023. The revenue distribution by region was 37%, 45% and 18% in the U.S., Europe and International Markets, respectively. The largest markets are the U.S., Spain, Canada, Australia and Italy.

Vyepti® (eptinezumab) is approved as preventive treatment of migraine in adults. Vyepti® presented significant performance in the first six months of 2023, almost doubling revenue compared to the same period last year and reached DKK 757 million following a growth of 94% (+91% CER) mainly driven by strong demand in the U.S. The volume market share has increased to 7.0% by June 30, 2023. The product is approved in around 45 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 has since been launched in around 20 markets with the majority of those taking place recently including Spain, the Czech Republic and Hong Kong. The largest markets are the U.S., U.A.E., Germany, Switzerland and Canada. In the second half of 2023, Vyepti® is expected to be launched in around nine additional markets. The revenue distribution by region was 93%, 4% and 3% in the U.S., Europe and International Markets, respectively.

### **Mature brands**

Cipralex®/Lexapro® (escitalopram) is approved for the treatment of MDD. Revenue reached DKK 1,200 million representing a decline of 4% (-2% CER) mainly as a consequence of generic competition in Japan since November 2022. The revenue distribution by region was 70% and 30% in International Markets and Europe, respectively. The largest markets are China, Japan, South Korea, Brazil and Italy.

Revenue from **Other pharmaceuticals**, which comprise the remainder of Lundbeck's products, reached DKK 1,800 million representing a growth of 5% (+6% CER) benefiting from quarterly fluctuations partially offset by lower sales of certain mature products such as Northera<sup>®</sup>. As of January 1, 2023, Onfi<sup>®</sup> is being reported together with Other pharmaceuticals, comparative figures for 2022 have been adjusted accordingly. The largest markets for Other pharmaceuticals are the U.S, China, France and South Korea.

### 2.2 REVENUE BY GEOGRAPHICAL AREA

DKK million	H1 2023	H1 2022	Growth	Growth (CER)	Q2 2023	Q2 2022	Growth	Growth (CER)
United States	111 2023	111 2022	Growan	(OLN)	QZ 2023	QZ ZUZZ	Growan	(OLN)
Rexulti <sup>®</sup>	1,980	1,653	20%	17%	1,001	879	14%	15%
Vyepti <sup>®</sup>	704	387	82%	78%	376	220	71%	72%
Trintellix <sup>®</sup>	695	736	(6%)	(7%)	357	387	(8%)	(7%)
Abilify Maintena®/Asimtufii	580	487	19%	16%	298	255	17%	17%
Strategic brands	3,959	3,263	21%	19%	2,032	1,741	17%	17%
Mature brands	828	869	(5%)	(7%)	418	473	(12%)	(12%)
Revenue – United States	4,787	4,132	16%	14%	2,450	2,214	11%	11%
Europe								
Brintellix <sup>®</sup>	745	630	18%	18%	374	329	14%	15%
Abilify Maintena®	715	657	9%	9%	360	330	9%	9%
Rexulti <sup>®</sup> /Rxulti <sup>®</sup>	28	20	40%	35%	15	9	67%	56%
Vyepti <sup>®</sup>	27	-	-	-	15	-	-	-
Strategic brands	1,515	1,307	16%	16%	764	668	14%	15%
Mature brands	818	759	8%	7%	395	376	5%	7%
Revenue – Europe	2,333	2,066	13%	13%	1,159	1,044	11%	12%
International Markets								
Brintellix <sup>®</sup>	716	685	5%	8%	348	345	1%	7%
Abilify Maintena®	289	249	16%	20%	141	131	8%	15%
Rexulti <sup>®</sup>	127	98	30%	33%	59	52	13%	23%
Vyepti <sup>®</sup>	26	3	767%	767%	15	-	-	-
Strategic brands	1,158	1,035	12%	15%	563	528	7%	14%
Mature brands	1,578	1,660	(5%)	(2%)	674	711	(5%)	2%
Revenue – International Markets	2,736	2,695	2%	5%	1,237	1,239	0%	7%
Other revenue	132	156	(15%)	(15%)	69	91	(24%)	(21%)
Total revenue before hedging	9,988	9,049	10%	10%	4,915	4,588	7%	10%
Effects from hedging	(6)	(202)		/ •	23	(113)	- 70	/ •
Total revenue	9,982	8,847	13%	10%	4,938	4,475	10%	10%

Lundbeck's largest markets are the U.S., China, Canada, Spain and Italy.

United States revenue reached DKK 4,787 million representing a growth of 16% (+14% CER). The strategic brands reached DKK 3,959 million increasing by 21% (+19% CER), representing 83% of the revenue for the region. Rexulti® was expanded with the AADAD indication following the approval in May 2023 and Abilify Asimtufii® was launched in June 2023. The revenue growth was driven by strong demand for Rexulti®, Vyepti® and Abilify Maintena®/Asimtufii. Revenue development in the U.S. market was slightly impacted by a decline in Trintellix® and the erosion of mature brands such as Northera® and Sabril®.

**Europe** revenue reached DKK 2,333 million representing a growth of 13% (+13% CER). The strategic brands reached DKK 1,515 million increasing by 16% (+16% CER), representing 65% of revenue. The revenue growth was mainly driven by strong demand for Brintellix® and Abilify Maintena®/Asimtufii. Europe contributed positively to the performance of mature brands reaching DKK 818 million representing a growth of 8% (+7% CER). The largest markets in Europe are Spain, Italy and France.

**International Markets** comprise all Lundbeck's markets outside the U.S. and Europe. Revenue reached DKK 2,736 million representing a growth of 2% (+5% CER) driven by all strategic brands which reached DKK 1,158 million increasing by 12% (+15%

CER), representing 42% of the revenue. The performance in the region was affected by the erosion of certain mature brands. Lexapro in Japan is negatively impacted by the entry of generic versions at the end of 2022. The biggest markets are China, Canada, Brazil, Australia and South Korea. China and Canada constitute approximately 43% of regional revenue.

Lundbeck hedges a significant part of the currency risk for a period of 12 - 18 months. Hedging had a minor negative impact of DKK 6 million in the first six months of 2023, compared to a negative impact of DKK 202 million in the same period last year.

### 2.3 GROSS PROFIT

DKK million	H1 2023	H1 2022	Change	Change (CER)	Q2 2023	Q2 2022	Change	Change (CER)
Revenue	9,982	8,847	13%	10%	4,938	4,475	10%	10%
Cost of sales	2,179	1,811	20%	22%	1,138	966	18%	21%
thereof adjustments	260	-	-	-	159	-	-	-
thereof amortization of product rights	789	624	26%	25%	385	315	22%	22%
thereof depreciation/amortization	123	117	5%	5%	63	58	9%	9%
Gross profit	7,803	7,036	11%	8%	3,800	3,509	8%	7%
Gross margin (%)	78.2%	79.5%			77.0%	78.4%		
Adjusted gross profit	8,975	7,777	15%	12%	4,407	3,882	14%	12%
Adjusted gross margin (%)	89.9%	87.9%			89.2%	86.7%		

Cost of sales reached DKK 2,179 million increasing by 20% (+22% CER), mainly driven by higher revenue, the Vyepti® provision for inventory obsolescence of DKK 245 million, restructuring costs of DKK 15 million due to the closure of the sterile manufacturing line in France and increased Vyepti® amortization recognized in the first six months of 2023 related to the European approval of Vyepti®.

**Gross profit** reached DKK 7,803 million, increasing by 11% (+8% CER) in the first six months of 2023. The **gross margin** was 78.2% representing a decline of 1.3 percentage points.

**Adjusted gross profit** is the gross profit excluding depreciation and amortization and other adjustments linked to sales. The **adjusted gross margin** was 89.9% representing an increase of 2.0 percentage points and in-line with revenue performance.

Amortization of product rights was DKK 789 million, increasing by 26% (+25% CER) driven mainly by an increase in Vyepti® amortization.

### 2.4 EBIT AND ADJUSTED EBITDA

	H1	H1		Change	Q2	Q2		Change
DKK million	2023	2022	Change	(CER)	2023	2022	Change	(CER)
Revenue	9,982	8,847	13%	10%	4,938	4,475	10%	10%
Gross profit	7,803	7,036	11%	8%	3,800	3,509	8%	7%
thereof adjustments	260	-	-	-	159	-	-	-
thereof depreciation/amortization	912	741	23%	22%	448	373	20%	20%
Sales and distribution costs	3,501	3,087	13%	14%	1,828	1,652	11%	13%
thereof adjustments	-	(43)	-	-	-	(43)	-	-
thereof depreciation/amortization	47	47	0%	2%	23	24	(4%)	0%
S&D-ratio	35.1%	34.9%			37.0%	36.9%		
Administrative expenses	564	509	11%	11%	306	273	12%	13%
thereof depreciation/amortization	10	8	25%	25%	5	4	25%	25%
Administrative expenses ratio	5.7%	5.8%			6.2%	6.1%		
Research and development costs	1,665	1,943	(14%)	(14%)	826	962	(14%)	(14%)
thereof adjustments	-	(5)	-	-	-	(5)	-	-
thereof depreciation/amortization	36	46	(22%)	(20%)	18	26	(31%)	(27%)
R&D-ratio	16.7%	22.0%			16.7%	21.5%		
Total operating expenses	5,730	5,539	3%	4%	2,960	2,887	3%	4%
OPEX-ratio	57.4%	62.6%			59.9%	64.5%		
EBIT (profit from operations)	2,073	1,497	38%	20%	840	622	35%	16%
Depreciation/amortization	1,005	842	19%	19%	494	427	16%	16%
EBITDA	3,078	2,339	32%	19%	1,334	1,049	27%	16%
EBITDA margin (%)	30.8%	26.4%			27.0%	23.4%		
Restructuring expenses	15	(48)	(131%)	(131%)	15	(48)	(131%)	(131%)
Other adjustments	245	-	-	-	144	-	-	-
Adjusted EBITDA  Adjusted EBITDA margin (%)	<b>3,338</b> 33.4%	<b>2,291</b> 25.9%	46%	32%	<b>1,493</b> 30.2%	1,001 22.4%	49%	35%

**Total operating expenses** (OPEX) reached DKK 5,730 million corresponding to an increase of 3% (+4% CER) mainly driven by higher sales and distribution costs as well as administrative expenses offset by lower R&D costs. The OPEX-ratio declined by 5.2 percentage points.

Sales and distribution costs reached DKK 3,501 million corresponding to an increase of 13% (+14% CER) driven by higher Vyepti<sup>®</sup> sales activity in the U.S., the global roll-out in 15 countries in 2023 and preparations around the availability as well as promotion activities for Rexulti's<sup>®</sup> additional indication in AADAD in the U.S.

Sales and distribution costs corresponded to 35.1% of revenue, representing an increase of 0.2 percentage points.

**Administrative expenses** reached DKK 564 million increasing by 11% (+11% CER) corresponding to

5.7% of total revenue mainly driven by expenses from digital IT investments, CEO transition and higher legal costs.

Research and development costs reached DKK 1,665 million with an R&D ratio of 16.7%. The decline in R&D costs of 14% (-14% CER) was mainly driven by lower late development and reduced phase IV activities. Last year, the phase IV trials on Brintellix®/Trintellix® were completed and the pivotal trial on Rexulti® was finalized. Further decreases in the first six months of 2023 can be attributed to lower costs for Lu AG09222 (anti-PACAP) phase IIa HOPE trial and Lu AF82422 phase II AMULET, predominantly due to timing of costs.

**EBIT** reached DKK 2,073 million increasing by 38% (+20% CER) reflecting the operating leveraging effect of higher revenue, combined with a lower OPEX-ratio.

Amortization of product rights amounted to DKK 789 million corresponding to an increase of 26% (+25% CER). Total amortization, depreciation and impairment losses reached DKK 1,005 million representing an increase of 19% (+19% CER) mainly driven by an increase of Vyepti® amortization.

Adjusted EBITDA reached DKK 3,338 million representing a growth of 46% (+32% CER) reflecting EBIT and EBITDA development in addition to adjustments of DKK 245 million of Vyepti® inventory obsolescence and DKK 15 million of restructuring costs for the closure of the sterile manufacturing line in France

### 2.5 NET PROFIT AND ADJUSTED EPS

DKK million	H1 2023	H1 2022	Change	Q2 2023	Q2 2022	Change
EBIT (profit from operations)	2,073	1,497	38%	840	622	35%
Net financials, (income)/expenses	138	322	(57%)	55	(25)	(320%)
Profit before tax	1,935	1,175	65%	785	647	21%
Net profit	1,480	917	61%	600	505	19%
thereof other adjustments	260	(48)	(642%)	159	(48)	(431%)
thereof depreciation/amortization	1,005	842	19%	494	427	16%
thereof adjustments on financial items	-	278	-	-	-	-
thereof tax on adjustments	288	185	56%	151	89	70%
EPS (DKK)	1.49	0.92	62%	0.60	0.51	18%
Adjusted net profit	2,457	1,804	36%	1,102	795	39%
Adjusted EPS (DKK)	2.47	1.82	36%	1.11	0.80	39%

### **Net profit**

**Net financial expenses** reached DKK 138 million equivalent to a decline of 57%. The first six months of 2022 was impacted by the European approval of Vyepti<sup>®</sup> which triggered a fair value adjustment of contingent consideration of CVR to former Alder shareholders amounting to DKK 278 million.

The effective tax rate for the first six months of 2023 was 23.5% (22.0% for the first six months of 2022). The tax rate is in line with the full-year expectation, reflecting the reduced deduction benefit from the Danish research & development incentive of 108% (130% in 2022).

**Net profit** reached DKK 1,480 million corresponding to a growth of 61%.

### Adjusted net profit and EPS

**Adjusted net profit** is the net profit excluding depreciation and amortization and other adjustments, net of taxes. Adjusted net profit reached DKK 2,457 million, representing an increase of 36%. The adjustments mainly relate to the amortization of product rights and the Vyepti<sup>®</sup> provision for obsolescence.

**Adjusted EPS** was DKK 2.47 corresponding to an increase of 36%.

## 2.6 CASH FLOW AND BALANCE SHEET

Cash flows from operating activities amounted to an inflow of DKK 1,649 million compared to an inflow of DKK 711 million in the first six months of 2022. The positive development is primarily driven by higher revenue and EBITDA in 2023 and 2022 being negatively impacted by the milestone connected to the European approval of Vyepti® and offset by higher working capital mainly due to Rexulti® sales milestone payout and inventories.

Lundbeck's **net cash flows from investing activities** were an outflow of DKK 265 million compared to an outflow of DKK 1,227 million in the first six months of 2022, mainly arising from the CVR payment triggered by the European approval of Vyepti<sup>®</sup>.

Lundbeck's **net cash flows from financing activities** were an outflow of DKK 1,250 million compared to an inflow of DKK 480 million in the first six months of 2022. The financing cash flows in 2023

mainly relate to dividend payment approved at the Annual General Meeting in March 2023 as well as repayment of debt. The first six months of 2022 were impacted by a drawdown on a loan to pay the CVR following the European approval of Vyepti<sup>®</sup>.

The net cash inflow reached DKK 134 million compared to an outflow of DKK 36 million in the first six months of 2022.

**Net debt** has decreased from DKK 4,287 million at the end of June 2022 to DKK 1,428 million at the end of June 2023. Net debt/EBITDA ratio declined to 0.3x

at the end of June 2023 compared to 1.2x at the end of June 2022. **Interest-bearing debt** was DKK 5,091 million at the end of June 2023 compared to DKK 6,585 million at the end of June 2022.

On June 30, 2023, Lundbeck's **total assets** amounted to DKK 37,242 million compared to DKK 37.452 million at the end of 2022.

On June 30, 2023, Lundbeck's **equity** amounted to DKK 21,572 million.

### 2.7 SUMMARY OF THE KEY DEVELOPMENTS IN THE SECOND QUARTER OF 2023

### For the quarter ended June 30

DKK million	Q2 2023	Q2 2022	Change	Change (CER) <sup>1</sup>
Revenue	4,938	4,475	10%	10%
Gross profit	3,800	3,509	8%	7%
Gross margin	77.0%	78.4%		
Adjusted gross profit <sup>2</sup>	4,407	3,882	14%	12%
Adjusted gross margin	89.2%	86.7%		
Sales and distribution costs	1,828	1,652	11%	13%
S&D ratio	37.0%	36.9%		
Administrative expenses	306	273	12%	13%
Administrative expenses ratio	6.2%	6.1%		
Research and development costs	826	962	(14%)	(14%)
R&D ratio	16.7%	21.5%		
EBIT (profit from operations)	840	622	35%	16%
EBIT margin	17.0%	13.9%		
EBITDA <sup>3</sup>	1,334	1,049	27%	16%
EBITDA margin	27.0%	23.4%		
Adjusted EBITDA <sup>4</sup>	1,493	1,001	49%	35%
Adjusted EBITDA margin	30.2%	22.4%		
Net financials, expenses	55	(25)	(320%)	
Profit before tax	785	647	21%	
Income taxes	185	142	30%	
Effective tax rate (reported)	23.5%	22.0%		
Net profit	600	505	19%	
Adjusted net profit	1,102	795	39%	

<sup>1</sup> Change at CER does not include effects from hedging.

<sup>2</sup> Adjusted gross profit is the gross profit excluding depreciation and amortization and other adjustments linked to sales.

<sup>3</sup> EBITDA refers to Earnings Before Interest, Taxes, Depreciation and Amortization.

<sup>4</sup> EBITDA refers to Earnings Before Interest, Taxes, Depreciation and Amortization. Adjusted EBITDA is defined as EBITDA adjusted by certain items, for details see section

<sup>4</sup> Notes, note 3 Adjusted EBITDA.

### **REVENUE**

The increase in **revenue** is mainly driven by strong performance across the strategic brands (Abilify Maintena®/Asimtufii, Brintellix®/Trintellix®, Rexulti®/Rxulti® and Vyepti®) reaching DKK 3,359 million, representing a growth of 14% (+16% CER) and equivalent to 68% of total revenue (see section 2.1).

**Rexulti**<sup>®</sup> revenue reached DKK 1,075 million, increasing by 14% (+16 % CER) in the second quarter of the year, driven by higher demand across all regions, with particularly strong growth in the U.S., Europe and South America.

Mature products in the U.S. are mainly impacted by reduced revenue of Sabril® and Northera®.

The U.S. and Europe had strong revenue performance in the second quarter of 2023, reaching DKK 2,450 million (+11%; +11% CER) and DKK 1,159 million (+11%; +12% CER) respectively (see section 2.2).

### **GROSS PROFIT**

In the second quarter of 2023, **gross profit** reached DKK 3,800 million increasing by 8% (+7% CER).

The **gross margin** was 77.0% representing a decline of 1.4 percentage points. **Adjusted gross margin** was 89.2% in the second quarter of 2023 representing an increase of 2.5 percentage points.

Cost of sales increased to DKK 1,138 million, driven by higher revenue, impact from increased Vyepti<sup>®</sup> amortization and provision for Vyepti<sup>®</sup> provision for obsolescence of DKK 144 million recognized in the second quarter of 2023.

### **EBIT AND ADJUSTED EBITDA**

**Total operating expenses** (OPEX) reached DKK 2,960 million corresponding to an increase of 3% (+4% CER) mainly driven by higher sales and distribution costs offset by lower R&D costs. The OPEX-ratio declined by 4.6 percentage points.

Sales and distribution costs reached DKK 1,828 million corresponding to an increase of 11% (+13%

CER) mainly driven by a higher sales activity level for Vyepti<sup>®</sup> and Rexulti<sup>®</sup> across the world.

**Administrative expenses** reached DKK 306 million increasing by 12% (+13% CER) corresponding to 6.2% of total revenue.

Research and development costs reached DKK 826 million with a R&D ratio of 16.7%. The decline in R&D costs of 14% (-14% CER) is due to lower project costs in the second quarter of 2023 as anticipated (see section 2.4).

**EBIT** reached DKK 840 million increasing by 35% (+16% CER) reflecting higher revenue, combined with a lower OPEX-ratio and a negative impact of Vyepti® provision for obsolescence.

Amortization of product rights amounted to DKK 385 million corresponding to an increase of 22% (+22% CER). Total amortization, depreciation and impairment losses reached DKK 494 million representing an increase of 16% (+16% CER) mainly driven by an increase in Vyepti® amortization.

**Adjusted EBITDA** reached DKK 1,493 million representing a growth of 49% (+35% CER) reflecting higher revenue and lower OPEX-ratio.

### **NET PROFIT AND ADJUSTED EPS**

**Net financial (income)/expenses** reached DKK 55 million equivalent to a decline of 320%.

The **effective tax rate** for the second quarter of 2023 was 23.5%.

**Net profit** reached DKK 600 million corresponding to a growth of 19%.

**Adjusted net profit** reached DKK 1,102 million, representing an increase of 39%.

### 2.8 OUTLOOK

### Financial guidance 2023

Lundbeck raises its full year guidance for 2023.

Lundbeck now expects revenue to reach DKK 19.5 to 20.1 billion compared to previously DKK 19.4 to 20.0 billion – an implied growth of around 7-10% compared to 2022. The growth is driven by strong demand of the strategic brands which more than offsets the continued erosion of the mature portfolio and despite depreciation of the main currencies when compared to 2022. The revised financial guidance for 2023 is provided based on the exchange rates at the end of June 2023.

For the second half of 2023, Lundbeck expects continued strong growth of the strategic brands. Lundbeck will continue the global roll-out of Vyepti® with approximately nine additional launches. Rexulti® was launched with the additional AADAD indication in May 2023 and Abilify Asimtufii® was launched in June 2023, both in the U.S. Brintellix®/Trintellix® is still impacted by low growth in the U.S. and increased generic pressure in Brazil. Abilify Maintena® was favorably impacted by timing of shipments to the Middle East in the first half of 2023 which is not expected to occur in the second half of 2023.

The mature brands are expected to face stronger generic erosion in the second half of 2023, especially on Cipralex®/Lexapro® in Japan, Deanxit® in China and Sabril® in the U.S. Sabril is expected to be negatively impacted by a potential supply outage as a consequence of a third-party manufacturing quality issue, which is likely to be solved in September. The second half of 2023 is also expected to be dampened when compared to the first half of 2023 by timing of shipments in the first half of the year to countries such as Saudi Arabia and Taiwan. Additionally, currency devaluation in Egypt will constrain Letter of Credit insured shipments, and in Turkey, local inflation levels are expected to reduce local demand.

Lundbeck now expects Adjusted EBITDA to reach DKK 5.2 to 5.6 billion compared to previously DKK 5.1 to 5.5 billion. The financial guidance for 2023 reflects the investments needed in the important launches driving significant future growth. Adjusted EBITDA in the second half of 2023 will be impacted by the required investments in the U.S. to launch Rexulti® in AADAD and Abilify Asimtufii®. Vyepti® will also launch in approximately nine additional countries later this year. R&D investments will rise in the second half of 2023 to develop clinical material ahead of planned initiation of clinical studies for Lu AG09222 (anti-PACAP mAb), Lu AF82422 (anti-α-synuclein mAb) and Lu AG22151 (anti-CD40L blocker).

Lundbeck mainly carries foreign currency risk in USD, CNY and CAD. The financial guidance for 2023 is based on expected hedging rates for the main currencies, i.e. USD/DKK (~7.21), CNY/DKK (~1.02) and CAD/DKK (~5.22) and includes an expected hedging gain of approximately DKK 135 million.

Based on assumptions for product and geographical mix, it is estimated that a 5% change of the USD/DKK exchange rate will impact revenue by approximately DKK 150 million for the remaining period of 2023.

The previously communicated expected provision of approximately DKK 300 million for Vyepti® provision for obsolescence was reflected in the EBITDA guidance for 2023. Of the total expected provision, DKK 245 million has been recognized in the first six months of 2023.

		Previous	Revised
	FY 2022 actual	FY 2023 guidance	FY 2023 guidance
Revenue	DKK 18,246 million	DKK 19.4 - 20.0 billion	DKK 19.5 - 20.1 billion
Adjusted EBITDA	DKK 4,823 million	DKK 5.1 - 5.5 billion	DKK 5.2 - 5.6 billion

### Mid-term targets are confirmed

Lundbeck is in a period with limited impact from major regional losses of exclusivity and anticipates solid growth of its strategic brands. In 2023 and 2024, we plan targeted investments behind the potential blockbuster opportunity for Rexulti® in the treatment of AADAD. Based on organic growth, we expect revenue to show a midsingle 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 adjusted 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.

### 2.9 LUNDBECK'S DEVELOPMENT PORTFOLIO

Lundbeck is developing several new and promising medicines for the treatment of brain diseases.

The pipeline developments are summarized below.

Project	Area	Phase I	Phase II	Phase III	Filing/ Launch
Hormonal / neuropeptide signaling:					
Eptinezumab (anti-CGRP) <sup>1</sup>	Migraine prevention			SUN-studies <sup>2</sup>	PROMISE 1 & 2
	Cluster headache		CHRONICLE <sup>3</sup>	ALLEVIATE	
'222/Lu AG09222 (anti-PACAP mAb)4	Migraine prevention		HOPE		
'909/Lu AG13909 (anti-ACTH mAb) <sup>5</sup>	Neuro-hormonal dysfunctions				
Circuitry / neuronal biology:					
Brexpiprazole <sup>6</sup>	Agitation in Alzheimer's disease8				
	PTSD				
Aripiprazole 2-months injectable	Schizophrenia/bipolar I disorder8				
MAGLi program <sup>7</sup>	Neurology/Psychiatry				
'996/Lu AF28996 (D <sub>1</sub> /D <sub>2</sub> agonist)	Parkinson's disease				
Protein aggregation, folding and clearar	ice:				
'422/Lu AF82422 (anti-α-synuclein mAb)	Multiple system atrophy		AMULET		
'908/Lu AF87908 (anti-Tau mAb)	Tauopathies				
Neuroinflammation / neuroimmunology:					
<b>151</b> /Lu AG22151 (anti-CD40L blocker)	Neurology				

<sup>&</sup>lt;sup>↑</sup> CGRP: Calcitonin gene-related peptide. <sup>2</sup> Two phase III clinical trials, supporting registration in Asia, including China and Japan: SUNRISE, and SUNSET trials. <sup>3</sup> Long-term safety study. <sup>4</sup> PACAP: Pituitary adenylate cyclase activating peptide. <sup>5</sup> Adrenocorticotropic hormone. <sup>6</sup> 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. <sup>7</sup> Monoacylglycerol lipase inhibitor ("MAGlipase") previously denominated 466/Lu AG06466. <sup>8</sup> Approved in the U.S.

### Hormonal / neuropeptide signaling

# Eptinezumab - development and regulatory status

In December 2020, Lundbeck initiated a phase III clinical trial investigating the efficacy of eptinezumab in patients with episodic cluster headache (ALLEVIATE). In this trial (NCT04688775), patients 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 one-year safety and tolerability trial in participants with chronic cluster headache (CHRONICLE). The study (NCT05064397) recently completed recruitment.

### Lu AG09222 ('222) - phase II

'222 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 November 2021, Lundbeck initiated the *HOPE*-trial, a randomized, double-blind, phase II, proof of concept study to assess efficacy, safety, and tolerability of '222 as a treatment for the prevention of migraine (NCT05133323) which recently reported results. The target population for this trial was defined as patients diagnosed with migraine as outlined in the

International Classification of Headache Disorders Third Edition (ICHD-3) and with unsuccessful prior preventive treatments. A total of 237 patients were randomly allocated to one of three treatment groups: high/low dose of '222 or placebo. The primary analysis concluded that there was a statistically significant difference (p=0.01) between '222 and placebo in the mean change from baseline in the number of monthly migraine days over weeks 1 to 4. '222 was generally well tolerated. As of the next steps, a phase IIb study to start in second half of 2024 to establish the full dose range and subcutaneous efficacy.

### Circuitry / neuronal biology

# Brexpiprazole – phase III in patients with agitation associated with dementia due to Alzheimer's Disease

On May 10, 2023, the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) of brexpiprazole for use in the treatment of agitation associated with dementia due to Alzheimer's disease.

The approval was based on two positive phase III, 12-week, randomized, double-blind, placebo-controlled fixed-dose studies that evaluated the frequency of agitation symptoms in patients with dementia due to Alzheimer's disease based on the Cohen-Mansfield Agitation Inventory (CMAI) total score, making brexpiprazole the first and only pharmacological treatment approved in the U.S. for agitation associated with dementia due to Alzheimer's disease.

Further, a supplemental New Drug Submission (sNDS) was formally accepted by Health Canada for review as of April 12, 2023, with anticipated action in 2024, while a joint application using the Access pathway was submitted on May 31, 2023 for Australia, Singapore and Switzerland with anticipated action in the second quarter of 2024.

# Brexpiprazole – phase III in adolescent patients (13-17 years old) with schizophrenia

The phase III trial 331-10-234 in adolescent patients with schizophrenia (NCT03198078) read out during the second quarter of 2023, with the trial meeting its primary endpoint, as measured by the PANSS total score change from baseline to week 6 and demonstrated a significant improvement for brexpiprazole compared to placebo (p<0.05).

The active reference for the study, aripiprazole, also separated from placebo on the primary efficacy analysis, thus validating the study methodology and patient population.

Brexpiprazole was generally well tolerated in the trial, and the safety profile was similar to that observed in adult patients with schizophrenia.

The trial forms part of the brexpiprazole EMA Paediatric Investigation Plan (PIP), as well as an FDA Post Marketing Requirement (PMR) following the U.S. approval of brexpiprazole for treatment of schizophrenia in adolescent patients. The U.S. indication was obtained in December 2021 based on pediatric PK comparability data and extrapolation of adult efficacy data. For Europe, results of the study will be submitted to EMA later in 2023.

The EMA PIP includes two further studies that are currently ongoing:

- A phase III open-label 2-year extension study 331-10-236 (NCT03238326) enrolling patients completing Trial 234
- 2) An extrapolation study 3331-201-00185 assessing the long-term efficacy in adolescent subjects with schizophrenia, by extrapolating data from completed brexpiprazole trials in both adolescents and adult subjects with schizophrenia.

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

Following an exploratory phase II trial, Lundbeck and Otsuka 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 FDA in May 2019. The execution of those two ongoing studies was challenged by the COVID-19 pandemic, primarily impacting enrollment rates. After FDA feedback, it was decided that the two trials will be concluded with reduced sample size. Recruitment of both studies concluded in April 2023 and headline results are expected in the second half of 2023.

# Aripiprazole – 2-month Injectable (LAI) formulation

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 submitted the Marketing Authorization Application (MAA) for aripiprazole as an every-two months ready-to-use (RTU) long-acting injectable for the maintenance treatment of schizophrenia in adult patients stabilized with aripiprazole to the European Medicines Agency (EMA) on May 26, 2022. Due to a Committee for

Medicinal Products for Human Use (CHMP) procedural objection, Lundbeck withdrew its MAA under the "hybrid" procedure and re-submitted to EMA in June 2023, under the "line-extension" procedure instead. This change is procedural only, and unrelated to product quality or safety.

A supplemental New Drug Submission (sNDS) was filed with Health Canada for the treatment of schizophrenia and bipolar I disorder in the third quarter of 2022. In July 2023, following a CMC related Notice of Deficiency (NOD) from Health Canada, the submission will enter a new review cycle.

### Protein aggregation, folding and clearance Lu AF82422 ('422) – phase II

'422 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 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. '422 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) was initiated in November 2021 (NCT05104476) and is presently fully accrued with ongoing follow-up in the U.S. and Japan. The primary objective of the study is to evaluate the efficacy of '422 versus placebo on disease progression in patients with MSA.

Orphan drug designation for MSA was granted by EMA in April 2021 and SAKIGAKE pioneering drug designation was granted by the Japanese Health Authorities in March 2023.

### **Neuroinflammation / neuroimmunology**

### Lu AG22515 ('515)- phase I

In October 2021, Lundbeck acquired an exclusive license to '515 (formerly APB-A1) from AprilBio Co. Ltd in South Korea. '515 is a CD40L/serum-albumin bispecific antibody-fragment that blocks CD40L/CD40 pathway through direct neutralization of CD40L, thereby affecting adaptive and innate immune responses. '515 holds potential in the treatment of autoimmune-related CNS disorders and neurological diseases with autoreactive T-cells, Bcells and marked presence of autoantibodies and inflammation Α First-in-Human study (NCT05136053) testing single ascending doses of '515 in healthy volunteers was initiated in the U.S. in March 2022.

### 2.10 SUSTAINABILITY UPDATE

Category <sup>1</sup>	H1 2023	H1 2022	Change (%)
Scope 1 GHGs (Tonne CO <sub>2</sub> .e) <sup>2</sup>	11,597	11,590	0%
Scope 2 GHGs – market based (Tonne CO <sub>2</sub> -e) <sup>2</sup>	1,947	2,065	(6%)
Scope 1+2 GHGs (Tonne CO <sub>2</sub> .e) <sup>2</sup>	13,544	13,655	(1%)
Scope 3 GHG's: Purchased goods and services (Tonne CO <sub>2</sub> .e) <sup>2</sup>	39,919	46,162	(14%)
Scope 3 GHG's: Up-stream transportation and distribution (Tonne CO <sub>2</sub> .e) <sup>2</sup>	3,618	3,603	0%
Scope 3 GHG's: Business travel (Tonne CO <sub>2</sub> .e) <sup>2</sup>	4,194	3,628	16%
Energy consumption (MWh) <sup>2</sup>	55,565	56,996	(3%)
Recycling rate – General waste (%)	74	66.4	11%
Frequency of lost time accidents (Frequency) <sup>3</sup>	2.9	6.2	N/A
Work-related accidents with absence (Number) 3	14	11	N/A
Compliance Hotline reports (Number)	40	50	(20%)
Due Diligence screenings of suppliers and Third Parties (Number)	107	67	60%

See Lundbeck Sustainability Report 2022 for accounting policies and definitions.
 Comparative figures were updated to reflect changes in our estimates.

<sup>3</sup> Scope for accidents has changed to include sales force. The previous scope for frequency would be 6.2 considering a total of 11 accidents in the first six months of 2023.

### 2.11 GENERAL CORPORATE MATTERS

### **Pending legal proceedings**

Legal cases and proceedings for which it is either not probable that there will be an outflow of resources or for which it is not practicable or possible to make a reliable estimate is disclosed in this section and is considered contingent liabilities.

Lundbeck is involved in a number of cases and legal proceedings, including patent disputes, the most significant of which are described below. Some of these involve significant amounts and are subject to considerable uncertainty. Management continuously assesses the risks associated with the cases and legal proceedings, and their likely outcome. It is the opinion of the management that, apart from items recognized in the financial statements, the outcome of these cases and disputes are not probable or cannot be reliably estimated in terms of amount or timing. Such proceedings may, however, develop over time, and new proceedings may occur, in a way 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 March 2021, the European Court of Justice rejected Lundbeck's final appeal of the European Commission's decision. So-called "follow-on claims" for reimbursement of alleged losses, resulting from violation of competition law, often arise when decisions and fines issued by the European Commission are upheld by the European Court of Justice. The below mentioned "follow-on claims" are ongoing or threatened. Lundbeck disagrees with all claims and intends to defend itself against them.

At the end of first quarter 2023, the UK health authorities served their claim form on Lundbeck and several generic companies. Lundbeck has handed in its defense and an initial Case Management Conference is scheduled for the third quarter of 2023.

In late October 2021, Lundbeck received a writ of summons from a German health care company claiming compensation for an alleged loss of profit plus interest payments, allegedly resulting from Lundbeck's conclusion of agreements with two of the four generic competitors, which were comprised by the EU Court of Justice ruling. Lundbeck filed its first defense in May 2022 and the parties have subsequently exchanged additional pleadings. The first instance court hearing is scheduled for the third quarter of 2023, and a first instance ruling is expected within a few weeks thereafter. It may take several years before a final conclusion is reached by the German courts.

Lundbeck has been informed about potential claims in other European countries, however, it is still uncertain whether the potential claims will be actively pursued.

In Canada, Lundbeck is involved in three product class-action lawsuits relating Cipralex®/Celexa® (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, Lundbeck 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. Lundbeck's case against the last of the four generic companies, Sandoz Pty Ltd, went up to the High Court of Australia, who has now decided that Sandoz Pty Ltd infringed Lundbeck's escitalopram patent between 2009 and 2012. The High Court has now sent the case back to the first instance court for recalculation of the damages awarded to Lundbeck in first instance which amounted to AUD 26.3 million. In the meantime, Lundbeck's appeal of the Australian Patent Office's decision to grant Sandoz a license is restarted and if a license is maintained in any form, the first instance court will have to decide if such a license can have impact on the damage awarded by the High Court.

Together with Takeda, Lundbeck instituted patent infringement proceedings against 16 generic companies in response to their filing of Abbreviated New Drug Applications ("ANDAs") with the FDA seeking to obtain marketing approval for generic versions of Trintellix® in the U.S. Two opponents have since withdrawn and Lundbeck has settled with eight opponents. As communicated by Lundbeck in company release no. 706 dated October 1, 2021, the cases against the six remaining opponents (the "ANDA Filers") have been decided by the U.S. District Court for the District of Delaware (the 'Court'). The Court found that Lundbeck's compound patent (U.S. Patent No. 7,144,884) is valid. The compound patent expires on June 17, 2026, with an expected sixmonth pediatric exclusivity period extending to December 17, 2026. Assuming the ruling is confirmed at appeal, final approval will not be granted to the relevant ANDA Filers until after expiration of the compound patent, including any extension or additional periods of exclusivity. A total of seven other patents asserted at trial were found by the Court to be valid or their validity was not challenged during the trial. The Court decided that none of the seven other patents were infringed by the relevant ANDA Filers, except that Lupin was found to infringe a patent covering Lundbeck's process for manufacturing Trintellix®. Unless and until the Court's ruling is reversed on appeal, the patents found not infringed by a particular ANDA Filer will not prevent that ANDA Filer from receiving final approval. For details on each of the patents comprised by the case, please see company release no. 706. The Court's decision has been appealed by Lundbeck to the U.S. Court of Appeals for the Federal Circuit. Lupin has appealed with respect to the process patent and the ANDA Filers have cross appealed with respect to the validity of two of the seven other patents. The validity of the compound patent has not been challenged under the appeal. The appeal hearing has been scheduled for the third quarter of 2023.

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 (including the

promotional speaker program) of Trintellix<sup>®</sup>. Lundbeck is cooperating with the DOJ.

Lundbeck and Otsuka have received a Paragraph IV certification from Mylan Pharmaceuticals with respect to certain of the patent listed for Abilify Maintena® in the U.S., and Lundbeck and Otsuka have instituted patent infringement proceedings against Mylan and Viatris Inc. The FDA cannot grant marketing authorization in the U.S. to Mylan or Viatris Inc. before the patents expire unless they receive a decision in their favor. The trial has been scheduled to start on April 1, 2024 and a District Court decision is currently expected by August 2024. Abilify Maintena® is covered by several U.S. patents relating specific forms of the active ingredient, formulations, processes, devices, indications and methods of use, which will expire in different years, with the latest patent expiry date in the U.S. being in

In June 2022 in the U.S., several entities created for the purpose of receiving assignment of claims from payors providing health insurance coverage pursuant to Medicare Parts C and D and Medicaid filed a complaint against Lundbeck and others. The complaint alleges that Lundbeck and the other defendants conspired to increase the unit price and quantity dispensed of Xenazine®. Lundbeck denies the allegations in the complaint and intends to defend itself.

In June 2023 in the U.S., Humana Inc., an insurer, filed a complaint against Lundbeck U.S. legal entities. The complaint alleges that Lundbeck engaged in an illegal kickback scheme to increase the sales and sale price of Lundbeck's Xenazine<sup>®</sup>. The complaint alleges that Lundbeck's activities targeted Humana Inc. and other private Medicare insurers who were forced to bear the costs of the alleged illegally subsidized drug sales. Lundbeck denies the allegations in the complaint and intends to defend itself

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

The Board of Directors and the Registered Executive Management have discussed and adopted the financial report of H. Lundbeck A/S for the period January 1 to June 30, 2023. The financial report is presented in accordance with IAS 34 Interim Financial Reporting, as adopted by the EU and additional Danish disclosure requirements for interim financial reports of listed companies.

We consider the accounting policies applied to be appropriate. Accordingly, the financial report gives a true and fair view of the Group's assets, liabilities and financial position as of June 30, 2023, and of the results of the Group's operations and cash flows for the period, which ended on June 30, 2023.

In our opinion, the Management's Review (pages 5-18) 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 2022.

The financial report has not been subject to audit or reviewed by the company's independent auditors.

Valby, August 16, 2023

### **Registered Executive Management**

Deborah Dunsire	Lars Bang	Joerg Hornstein	Per Johan Luthman
President and CEO	Executive Vice President,	Executive Vice President,	Executive Vice President,
	Product Development & Supply	CFO	Research & Development

Jacob Tolstrup Executive Vice President, Commercial Operations

### **Board of Directors**

Lars Søren Rasmussen Chair of the Board	Lene Skole-Sørensen Deputy Chair of the Board	Santiago Arroyo	Jeffrey Berkowitz
Lars Erik Holmqvist	Jeremy Max Levin	Jakob Riis	Ilse Dorothea Wenzel
Hossein Armandi Employee representative	Dorte Clausen Employee representative	Lasse Skibsbye Employee representative	Camilla Gram Andersson Employee representative

# **3 CONDENSED FINANCIAL STATEMENTS**

# **CONDENSED STATEMENT OF PROFIT OR LOSS**

DKK million	H1 2023	H1 2022	Q2 2023	Q2 2022
Revenue	9,982	8,847	4,938	4,475
Cost of sales	2,179	1,811	1,138	966
Gross profit	7,803	7,036	3,800	3,509
Sales and distribution costs	3,501	3,087	1,828	1,652
Administrative expenses	564	509	306	273
Research and development costs	1,665	1,943	826	962
Profit from operations (EBIT)	2,073	1,497	840	622
Net financials, expenses	138	322	55	(25)
Profit before tax	1,935	1,175	785	647
Tax on profit for the period	455	258	185	142
Profit for the period	1,480	917	600	505
Earnings per share, basic (EPS) (DKK)	1.49	0.92	0.60	0.51
Earnings per share, diluted (DEPS) (DKK)	1.49	0.92	0.60	0.51

### STATEMENT OF COMPREHENSIVE INCOME

DKK million	H1 2023	H1 2022	Q2 2023	Q2 2022
Profit for the period	1,480	917	600	505
Actuarial gains/losses	-	-	-	-
Tax	-	-	-	-
Items that will not be reclassified subsequently to profit or loss	-	-	-	-
Exchange rate gains/losses on investments in foreign subsidiaries	(125)	1,017	45	779
Exchange rate gains/losses on additions to net investments in foreign subsidiaries	(40)	(48)	(39)	(40)
Hedging of net investments in foreign subsidiaries	17	(168)	(1)	(142)
Deferred gains/losses on cash flow hedge, exchange rate	123	(408)	(11)	(265)
Deferred gains/losses on cash flow hedge, interest rate	(16)	39	(7)	14
Deferred gains/losses on cash flow hedge, price	(41)	140	-	140
Exchange gains/losses, hedging (transferred to the hedged items)	6	202	(23)	113
Tax	(11)	55	17	41
Items that may be reclassified subsequently to profit or loss	(87)	829	(19)	640
Other comprehensive income	(87)	829	(19)	640
Comprehensive income	1,393	1,746	581	1,145

# **CONDENSED STATEMENT OF FINANCIAL POSITION**

DKK million	30.06.2023	31.12.2022
Assets		
Intangible assets	21,643	22,500
Property, plant and equipment	2,483	2,515
Right-of-use assets	387	427
Other financial assets	137	173
Other receivables	215	195
Deferred tax assets	227	230
Non-current assets	25,092	26,040
Inventories	4,276	4,046
Receivables	4,211	3,818
Cash and bank balances	3,663	3,548
Current assets	12,150	11,412
Assets	37,242	37,452
Equity and liabilities		
Share capital	996	996
Foreign currency translation reserve	1,294	1,438
Hedging reserve	213	156
Retained earnings	19,069	18,189
Equity	21,572	20,779
Retirement benefit obligations	205	213
Deferred tax liabilities	2,277	2,152
Provisions	216	190
Bank debt and bond debt	4,499	5,096
Lease liabilities	362	395
Other payables	421	428
Non-current liabilities	7,980	8,474
Retirement benefit obligations	1	1
Provisions	1,180	1,132
Trade payables	4,052	4,251
Lease liabilities	81	88
Income taxes payable	630	535
Other payables	1,746	2,192
Current liabilities	7,690	8,199
Liabilities	15,670	16,673
Equity and liabilities	37,242	37,452

# STATEMENT OF CHANGES IN EQUITY

DKK million	Share capital	Foreign currency translation reserve	Hedging reserve	Retained earnings	Total equity
Equity at January 1, 2023	996	1,438	156	18,189	20,779
Profit for the period	-	-	-	1,480	1,480
Other comprehensive income	-	(144)	57	-	(87)
Comprehensive income	-	(144)	57	1,480	1,393
Distributed dividends, gross	-	-	-	(578)	(578)
Dividends received, treasury shares	-	-	-	2	2
Buyback of treasury shares	-	-	-	(43)	(43)
Incentive programs	-	-	-	18	18
Tax on other transactions in equity	-	-	-	1	1
Other transactions	-	-	-	(600)	(600)
Equity at June 30, 2023	996	1,294	213	19,069	21,572

	Share	Foreign currency translation	Hedging	Retained	Total
DKK million	capital	reserve	reserve	earnings	equity
Equity at January 1, 2022	996	874	(162)	16,571	18,279
Profit for the period	-	-	-	917	917
Other comprehensive income	-	850	(21)	-	829
Comprehensive income	-	850	(21)	917	1,746
Distribution of dividends, gross	-	-	-	(398)	(398)
Dividends received, treasury shares	-	-	-	1	1
Buyback of treasury shares	-	-	-	(45)	(45)
Incentive programs	-	-	-	13	13
Tax on other transactions in equity	-	-	-	-	-
Other transactions	-	-	-	(429)	(429)
Equity at June 30, 2022	996	1,724	(183)	17,059	19,596

# **CONDENSED STATEMENT OF CASH FLOWS**

DKK million	H1 2023	H1 2022	Q2 2023	Q2 2022
Profit from operations (EBIT)	2,073	1,497	840	622
Adjustments for non-cash items	1,368	636	745	288
Change in working capital	(1,481)	(816)	(120)	63
Cash flows from operations before financial receipts and payments	1,960	1,317	1,465	973
p-7				
Financial receipts and payments	(85)	(488)	(34)	(3)
Cash flows from ordinary activities	1,875	829	1,431	970
Income taxes paid	(226)	(118)	(160)	(54)
Cash flows from operating activities	1,649	711	1,271	916
Contingent consideration, payment from acquisition of company	-	(1,076)	-	-
Purchase and sale of intangible assets and property, plant and equipment	(265)	(151)	(188)	(64)
Cash flows from investing activities	(265)	(1,227)	(188)	(64)
•	` ,	, ,	, ,	, ,
Cash flows from operating and investing activities	1,384	(516)	1,083	852
(free cash flow)	1,304	(310)	1,003	032
Decreeds from bears and factor of heads		4.004		
Proceeds from loans and issue of bonds	- (500)	1,234	(074)	- (4.00)
Repayment of bank loans and borrowings  Dividends paid in the financial year, net	(588) (576)	(266) (397)	(274)	(168)
Other financing activities	(86)	(91)	(21)	(21)
Cash flows from financing activities	(1,250)	480	(295)	(189)
oddi nows nom manong douvides	(1,200)	400	(200)	(100)
Net cash flow for the period	134	(36)	788	663
·		, ,		
Cash and bank balances at beginning of period	3,548	2,279	2,882	1,614
Unrealized exchange gains/losses on cash and bank balances	(19)	55	(7)	21
Net cash flow for the period	134	(36)	788	663
Cash and bank balances at end of period	3,663	2,298	3,663	2,298
Interest-bearing debt, cash, bank balances and securities, net, is composed as follows:				
Cash and bank balances	3,663	2,298	3,663	2,298
Interest-bearing debt	(5,091)	(6,585)	(5,091)	(6,585)
Net cash/(net debt)	(1,428)	(4,287)	(1,428)	(4,287)
` '	( , )	` ' '	( , )	. , ,

## STATEMENT OF PROFIT OR LOSS - ADJUSTED EBITDA RECONCILIATION (H1 AND Q2)

H1 2023 H1 2022 Reported DKK million Adjusted Adjusted Reported Revenue 9,982 9,982 8,847 8,847 Cost of sales 2,179 1,007 1,811 1,070 **Gross profit** 7,803 8,975 7,036 7,777 3,501 3,087 3,083 Sales and distribution costs 3,454 Administrative expenses 564 509 501 554 Research and development costs 1,665 1,629 1,943 1,902 Profit from operations (EBIT) 2,073 1,497 Depreciation/amortization 1,005 842 **EBITDA** 3,078 3,338 2,339 2,291 EBITDA margin 30.8% 33.4% 26.4% 25.9% Adjustments to EBITDA Integration costs 15 Restructuring expenses (48)Gains/losses on divestment of businesses Acquisition expenses Other adjustments 245 Adjusted EBITDA 3,338 2,291 3,338 2,291 Adjusted EBITDA margin 33.4% 33.4% 25.9% 25.9%

	Q2 2023		Q2 2022	
DKK million	Reported	Adjusted	Reported	Adjusted
Revenue	4,938	4,938	4,475	4,475
Cost of sales	1,138	531	966	593
Gross profit	3,800	4,407	3,509	3,882
Sales and distribution costs	1,828	1,805	1,652	1,671
Administrative expenses	306	301	273	269
Research and development costs	826	808	962	941
Profit from operations (EBIT)	840	-	622	-
Depreciation/amortization	494	-	427	-
EBITDA	1,334	1,493	1,049	1,001
EBITDA margin	27.0%	30.2%	23.4%	22.4%
Adjustments to EBITDA				
Integration costs	-	-	-	-
Restructuring expenses	15	-	(48)	-
Gains/losses on divestment of businesses	-	-	-	-
Acquisition expenses	-	-	-	-
Other adjustments	144	-	-	-
Adjusted EBITDA	1,493	1,493	1,001	1,001
Adjusted EBITDA margin	30.2%	30.2%	22.4%	22.4%

# **4 NOTES**

### 4.1 BASIS OF PREPARATION

The interim condensed consolidated financial statements for the six months ended June 30, 2023, have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU and additional Danish disclosure requirements for interim financial reporting of listed companies. The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements and should be read in conjunction with the Group's annual consolidated financial statements at December 31, 2022, published February 8, 2023. The accounting policies, judgements and significant estimates are consistent with those applied in the Annual Report 2022.

Further IAS 34 disclosure requirements for interim financial reporting are included in section 2, *Business Performance*. For disclosures regarding revenue and segment information see section 2.1 *Revenue by product* and section 2.2 *Revenue by geographical area*, for disclosures regarding inventory obsolescence see section 2.3 *Gross profit* and for disclosures regarding pending legal proceedings (contingent liabilities), see section 2.11 *General corporate matters*.

A number of new amendments came into effect from January 1, 2023. The Group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these amended standards.

### **4.2 FAIR VALUE MEASUREMENT**

Financial assets and financial liabilities measured or disclosed at fair value

DKK million			
June 30, 2023	Level 1	Level 2	Level 3
Financial assets			
Other financial assets <sup>1</sup>	42	-	27
Derivatives <sup>1</sup>	-	295	86
Total	42	295	113
Financial liabilities			
Contingent consideration <sup>1</sup>	-	-	340
Derivatives <sup>1</sup>	-	109	-
Bank debt <sup>2</sup>	-	789	-
Bond debt <sup>2</sup>	3,232	-	-
Total	3,232	898	340

<sup>1</sup> Measured at fair value

The fair value of listed 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 of other financial assets is calculated through the financial performance of the market inputs (i.e. interest swap rates) and other market conditions prevailing at the balance sheet date.

### **4.3 ADJUSTED EBITDA**

For the financial guidance for 2023 and onwards, Lundbeck will focus on revenue performance and adjusted FBITDA

Lundbeck's previous performance measure (Core EBIT) adjusted for amortization of product rights and for each non-recurring item that Management deemed exceptional and/or which accumulates or was expected to accumulate to DKK 100 million.

Adjusted EBITDA provides an improved and more consistent indicator, measuring the underlying operational profitability. Adjusted EBITDA enables a better understanding of the underlying operational performance, as the operating result is adjusted to exclude depreciation and amortization, impairment losses and reversals of impairment losses, as well as adjustments restricted to the following categories:

- Integration expenses,
- Restructuring expenses,
- Gains/losses on divestment of businesses,
- Acquisition expenses,
- Other adjustments.

Adjusted EBITDA, adjusted gross profit and adjusted EPS are non-IFRS performance measures.

# FINANCIAL CALENDAR 2023

November 8, 2023: Financial statements for the first nine months of 2023

February 7, 2024: Financial statements for 2023

### Lundbeck contacts

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### **About Lundbeck**

H. Lundbeck A/S (HLUNa / HLUNb, HLUNA DC / HLUNB DC) 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 5,600 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) and via LinkedIn.