



Lundbeck



# 9M Financial results and business update

November 9, 2022

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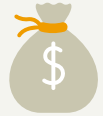
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# 9M performance overview and highlights (reported numbers)



Continued strong revenue performance

**DKK 13.6 billion**  
Revenue up 11%

**+30%**  
Strategic brands revenue

**+105%**  
Vyepti sales (DKK 672 million)



Robust profit growth with slight offsets for launch costs and FX

**DKK 2.4 billion**  
EBIT +22%

**18.1%**  
EBIT margin

**24.9%**  
Core EBIT margin



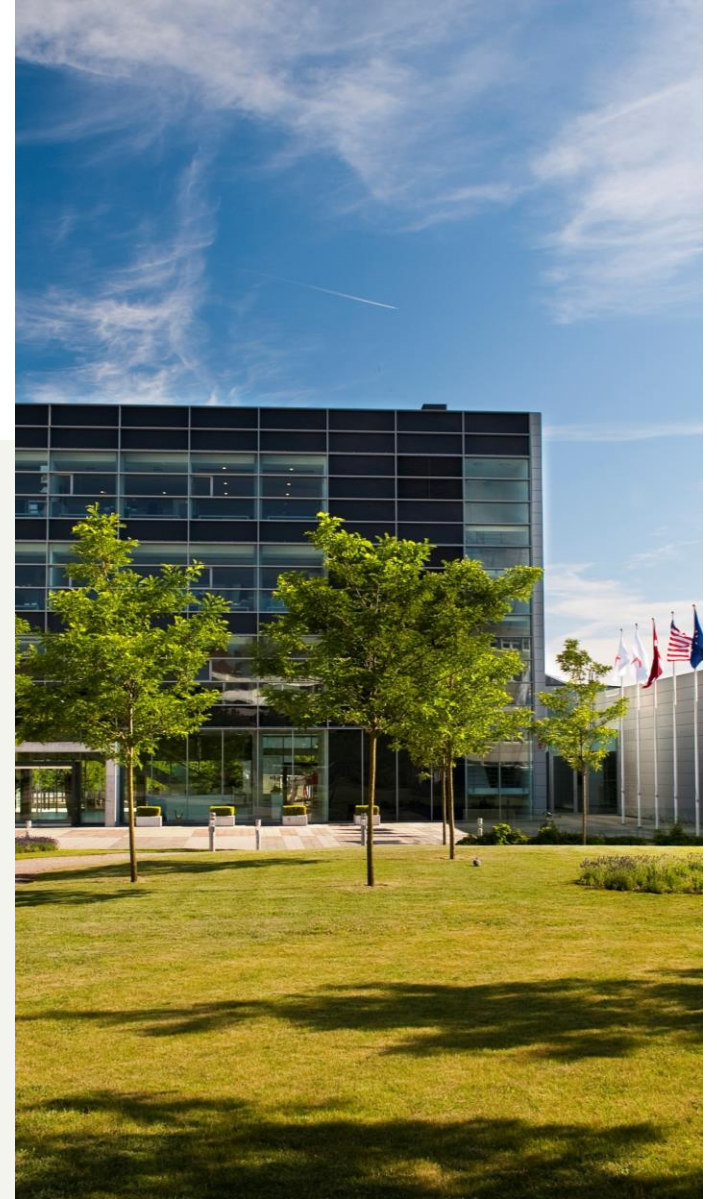
Pipeline continues to progress

Positive *MEMORY* trial in MDD with dementia for **vortioxetine**

**Phase II** study with **Lu AF82422** in MSA finished enrollment

**Brexpiprazole:** Phase III **PTSD** trials progress towards HLR in **H2 2023**

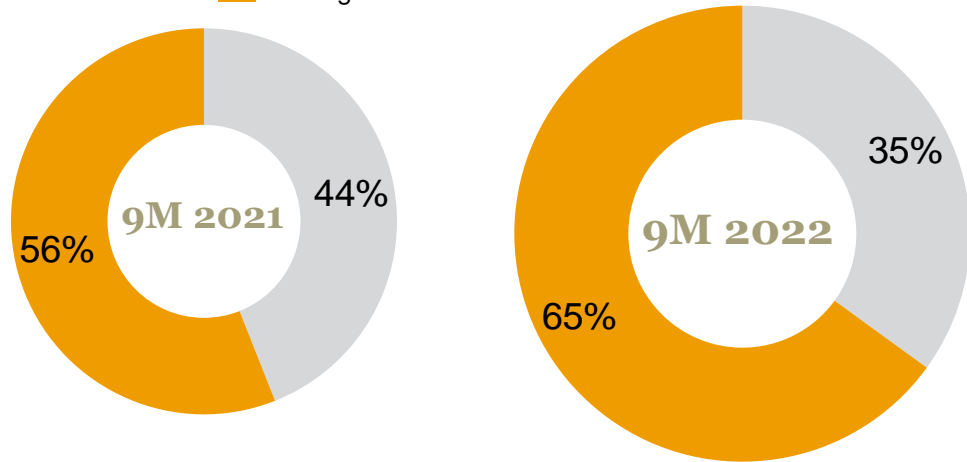
MDD: Major Depressive Disorder; MSA: Multiple System Atrophy; PTSD: Post-Traumatic Stress Disorder; HLR: Headline Results



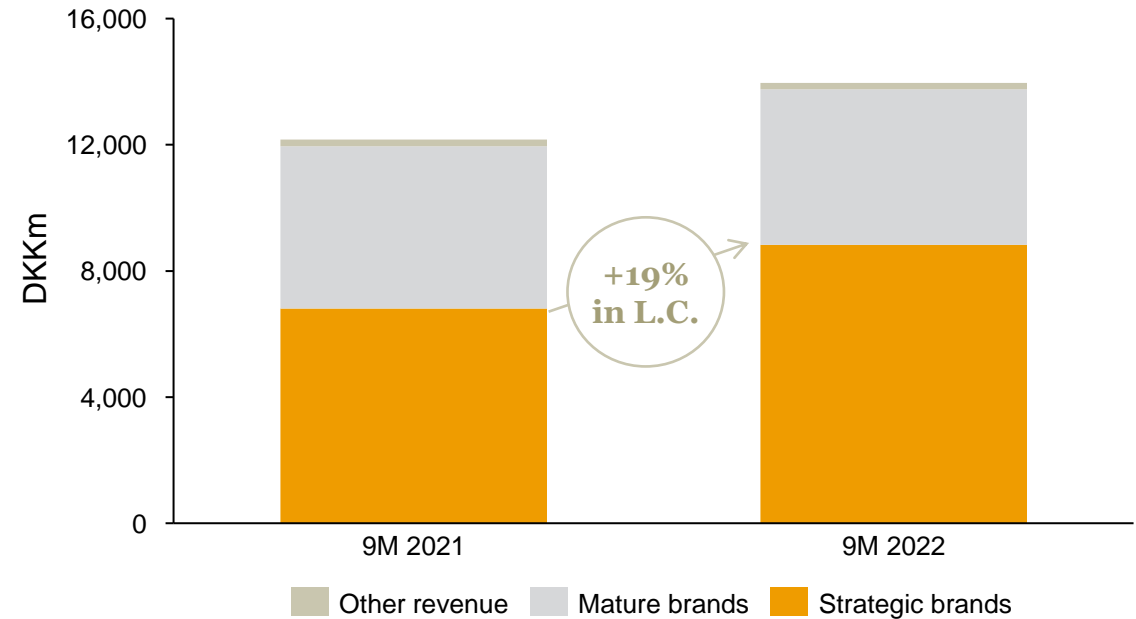
# Strategic brands powering growth across the portfolio

## % Revenue contribution

■ Mature brands incl. Other revenue and hedging  
■ Strategic brands



## Strong growth from strategic brands



Key drivers of revenue in period



### Strategic





Continued double digit growth across all regions

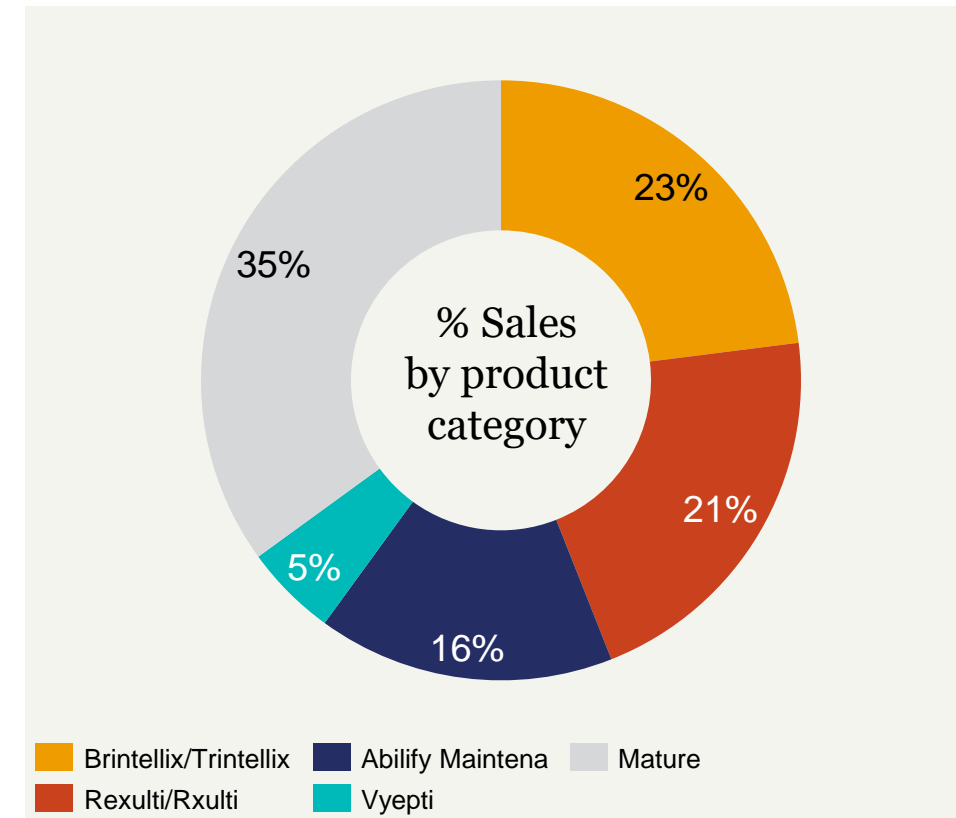


### Mature

- CipraleX/Lexapro continues to be very stable

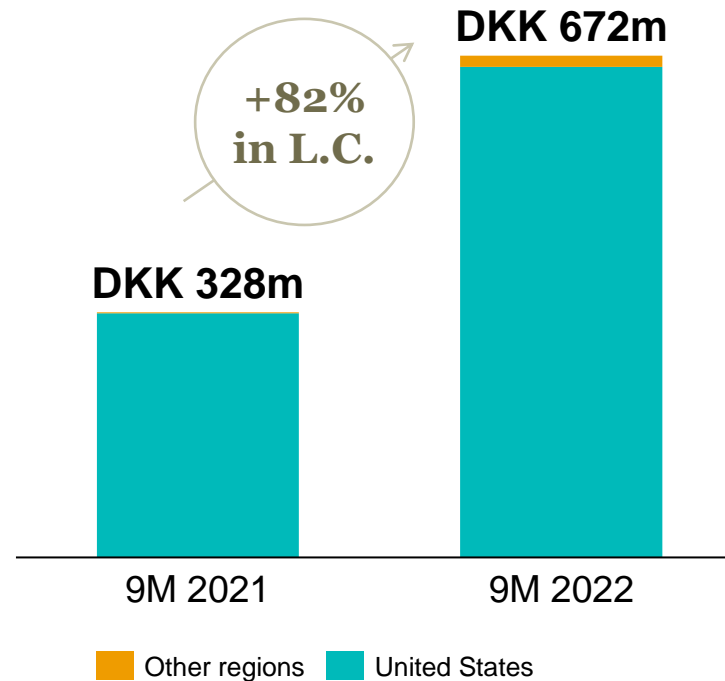
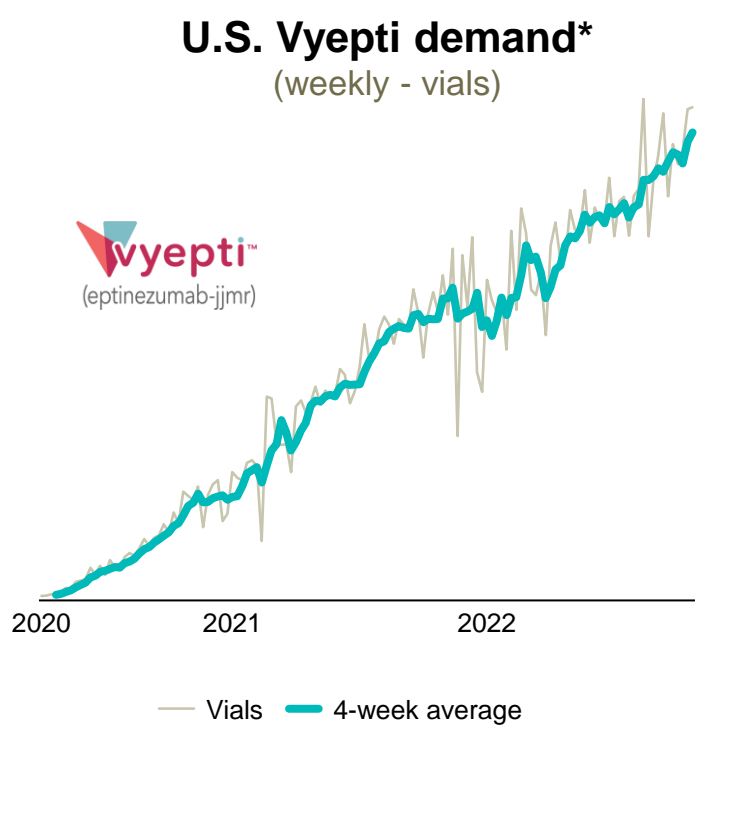
# Strategic brands continue strong double-digit growth

9M 2022 revenue by brand (% in local currencies)	 DKK 3.2bn	 DKK 2.8bn	 DKK 2.2bn	 DKK 672m
	<b>+15%</b>	<b>+19%</b>	<b>+13%</b>	<b>+82%</b>
% Reported	<b>+24%</b>	<b>+33%</b>	<b>+20%</b>	<b>+105%</b>



\*) Abilify Maintena, Brintellix/Trintellix, Rexulti/Rxulti and Vyepti

# Vyepti: Strong growth, global rollout progressing as planned



## Strong adoption across new markets

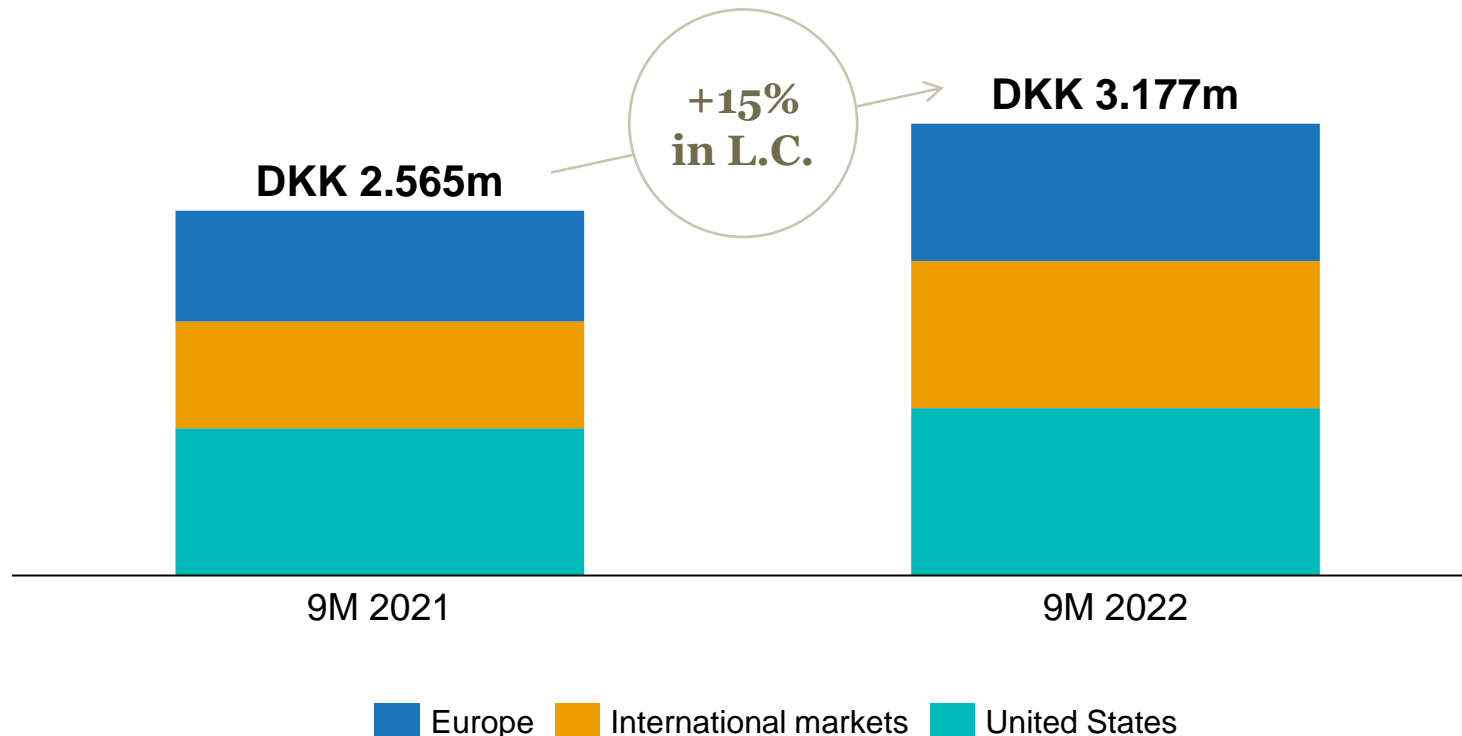
- 13% market share in U.A.E. and 4% in Switzerland\*\*
- Launched in several markets in 2022, namely Australia, Canada, Estonia, Finland, Germany, Singapore, Sweden and Switzerland
- Expected launch in additional 2-3 markets in 2022

## U.S. growth advances

- Prevention market share continues to grow in the U.S.: 5.0%\*\*\*
- Patient persistency on Vyepti exceeds competition

Vyepti was approved by FDA in February 2020 and by the EU Commission in January 2022. \*) Weekly data view through October 28, 2022. \*\*) August and September 2022, respectively. \*\*\*) Thru August 2022

# Strong Brintellix/Trintellix growth underpinned by excellent efficacy profile



Trintellix was approved by FDA September 2013 and Brintellix by EMA December 2013



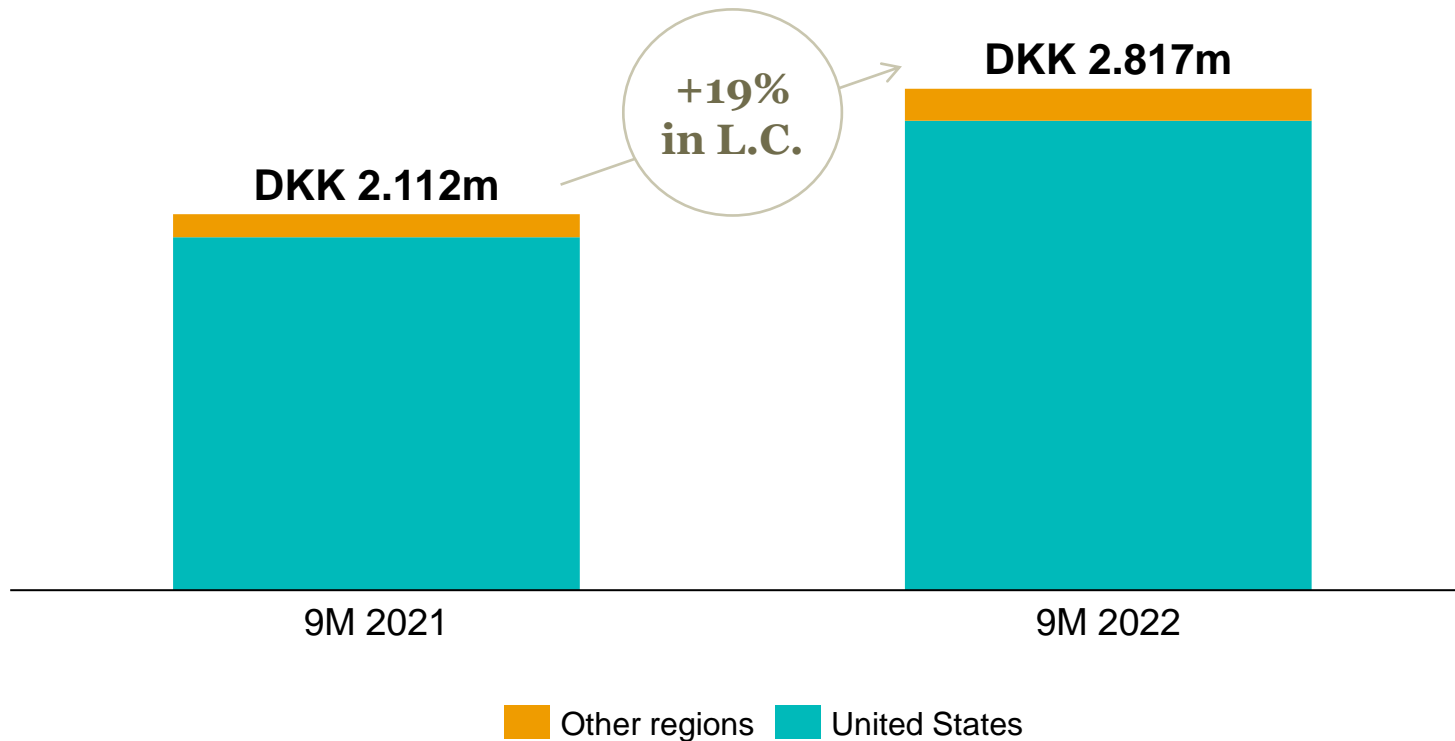
## Continued strong growth in Japan

- 9.1% value market share (up 3.3ppt in 2022)
- Benefitting from stronger positioning due to increased adoption by psychiatrists as a first-line of treatment

## Strong growth continues in Europe and International Markets

- Canada, Spain, China and Italy are growth leaders
- Strong growth in prescribing GPs, e.g. in Spain
- Positive growth across multiple other markets

# Rexulti sales up +33% in 9M driven by strong demand growth



Continued strong growth momentum in the U.S...

- Share at all time high
- Number of R<sub>x</sub> increased with strong in person promotion and DTC offering
- AAD\* launch preparations underway

...and in countries such as Brazil and Canada

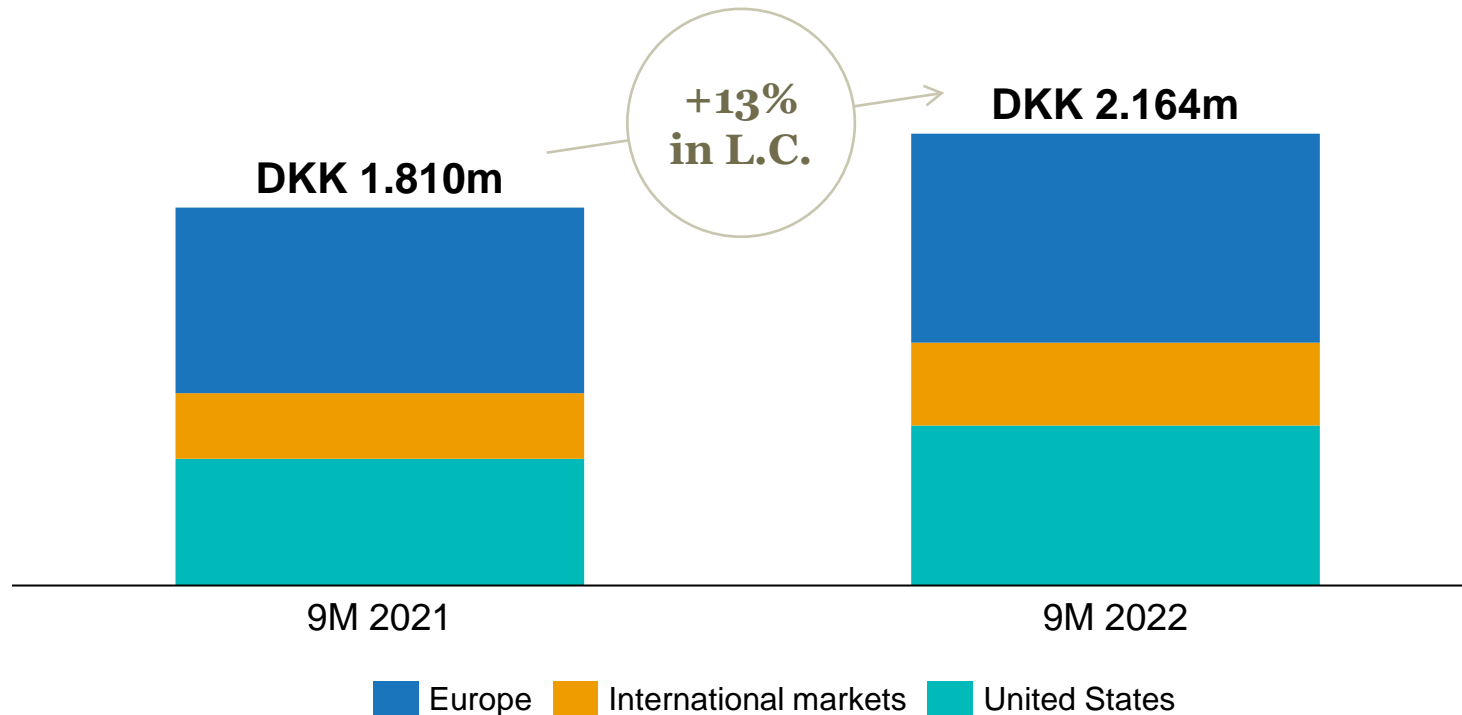
- Dynamic growth in Canada of close to 30% y/y with volume share now at ~3.2%
- Brazil more than doubled sales with volume share now at ~1.8%

Rexulti was approved by the FDA July 2015 and by the EU Commission July 2018. L.C.: Local currencies. \*) AAD: Agitation in Alzheimer's Disease





# Abilify Maintena buoyed by solid growth in North America and Europe



Abilify Maintena was approved by FDA and by the EU Commission in February and November 2013, respectively



## Solid growth in 9M 2022

- Growth mainly driven by the U.S., Spain and Canada

## Strong market share gains in Europe

- Exceeding 30% market share in countries such as Italy, Switzerland and U.K.
- In key markets, Abilify Maintena is growing faster than the aLAI market

## Regulatory process for 2-month formulation initiated

- The FDA target date (PDUFA date) for completion of the review is April 27, 2023

# Financial performance benefitting from growth strategy

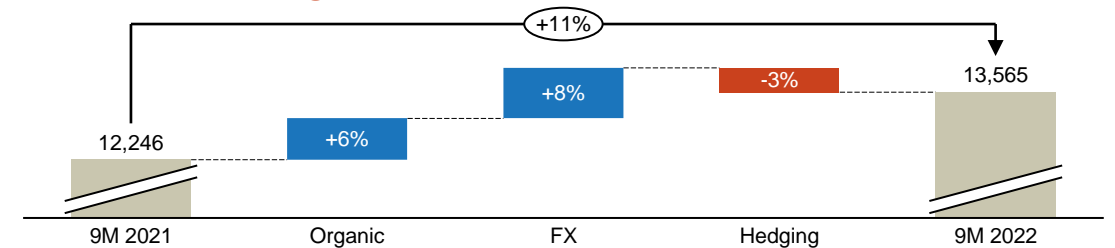
## Key figures

DKKm	9M 2021	9M 2022	Δ
Revenue	12,246	<b>13,566</b>	+11%
SG&A	4,766	<b>5,496</b>	+15%
R&D	2,828	<b>2,849</b>	+1%
EBIT	2,004	<b>2,449</b>	+22%
<i>(in % of revenue)</i>	16.4%	<b>18.1%</b>	+1.7pp
Core EBIT	2,973	<b>3,372</b>	+13%
<i>(in % of revenue)</i>	24.3%	<b>24.9%</b>	+0.6pp
EBITDA	3,280	<b>3,753</b>	+14%
<i>(in % of revenue)</i>	26.8%	<b>27.7%</b>	+0.9pp

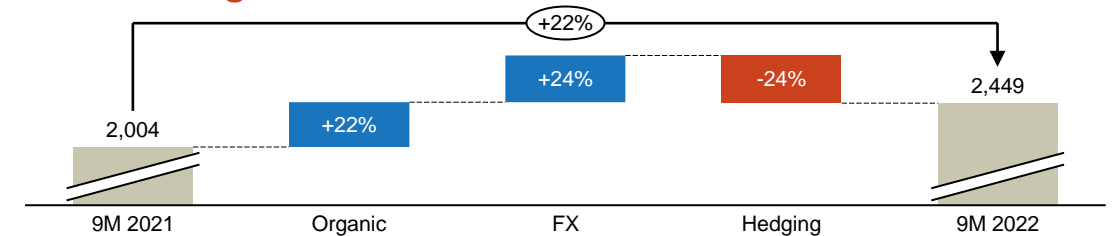
## Comments

- Revenue up +11% in reported with underlying organic growth rate of +6%. FX tailwind of +8% backstopped by hedging impact of -3% on the back of a strengthening U.S. Dollar
- SG&A increase of +15% thereof pure organic increase of +8%. Higher promotion and sales costs due to normalization of activity levels and Vyepti launch costs

## Revenue bridge



## EBIT bridge



- R&D costs favourably impacted by the timing of payments and provision reversal
- Core EBIT growth lower than EBIT growth due to reversal of provisions. Organic growth of +11%
- Organic EBITDA growth of +13%. FX and Hedging net impact account for +1% favourability

# Financial results in 9M 2022

Strong growth of 22% in EBIT

## Reported numbers

DKKm	9M 2021	9M 2022	Δ
EBIT	2,004	<b>2,449</b>	+22%
Net financials, expenses	311	<b>392</b>	+26%
Profit before tax	1,693	<b>2,057</b>	+22%
Income tax	373	<b>452</b>	+21%
<i>Effective tax rate (%)</i>	22%	<b>22%</b>	-
Profit for the period	1,320	<b>1,605</b>	+22%
EPS (DKK)	1.33	<b>1.62</b>	+22%

## Comments

- Underlying organic EBIT growth of +22%
- Increase in net financial expenses predominantly due to Q1 2022 fair value adjustment on CVR for EMA approval of Vyepiti
- Effective tax rate unchanged at 22%
- Net profit and EPS growth reflect EBIT performance

# Solid operational cash flow despite launch and growth investments in Vyepti

DKKm	9M 2021	9M 2022
<b>EBIT</b>	<b>2,004</b>	<b>2,449</b>
Adjustments for non-cash items	636	<b>1,110</b>
Change in Working capital	(214)	<b>(691)</b>
<b>Cash flows from operations</b>	<b>2,426</b>	<b>2,868</b>
Other changes in operating activities	(537)	<b>(636)</b>
Cash flows from investing activities	(332)	<b>(1,360)</b>
<b>Cash flows from operating and investing activities (free cash flow)</b>	<b>1,557</b>	<b>872</b>
Cash flows from financing activities	(2,995)	<b>169</b>
<b>Net cash flow for the period</b>	<b>(1,438)</b>	<b>1,041</b>
Net debt	(3,214)	<b>(3,021)</b>
Net debt/EBITDA (rolling four quarters)	0.8x	<b>0.7x</b>

## Comments

- EBIT growth of 22% drives stronger operational cash flow
- Changes in net working capital driven by higher receivables due to higher sales, increases in inventory and timing of accruals for short-term liabilities
- CVR payment of DKK 1.6bn in Q1 2022 impacts Other changes in operating activities and Cash flows from investing activities
- Change in Cash flows from financing activities driven by loan repayment in 2021 and loans obtained in 2022

# Reaffirming 2022 Revenue guidance

## FY 2022 financial guidance

DKKm

	Revenue	EBITDA	Core EBIT	EBIT
Updated 2022 Guidance (DKKm)	17.9 – 18.2bn	4.4 – 4.6bn	3.9 – 4.1bn	2.6 – 2.8bn
Previous 2022 Guidance (DKKm)	17.2 – 17.7bn	4.2 – 4.5bn	3.8 – 4.1bn	2.4 – 2.7bn

### Other housekeeping items

- Strong momentum of strategic brands to continue
- Strong momentum for Vyepti to continue
- Strong FX impact nearly fully offset by hedging effect of approximately DKK 600m for 2022
- Higher R&D costs due to higher project activity
- Continuous SG&A costs due to FX appreciation, Higher general activity level and spend to support launch and global roll-out of Vyepti

# Continue to build our brands through effective LCM

## Brexpiprazole

- **AAD** – Progression according to plan towards sNDA submission end 2022
- Scientific communications, including CTAD on Dec. 1<sup>st</sup>
- **PTSD** – Based on FDA feedback on program, HLR expected H2 2023

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

- Submitted in the U.S., EU, and Canada
- FDA target date (PDUFA) in April 2023

## Vyepti

- *SUNRISE* trial:
  - Asia pivotal study enrolling well
  - Increasing sample size based on the outcome of *SUNLIGHT*
  - Anticipated HLR in 2025
- *DELIVER* - dose blinded extension
  - >60% of patients reduced their monthly migraine days by at least half following up to 18 months of treatment



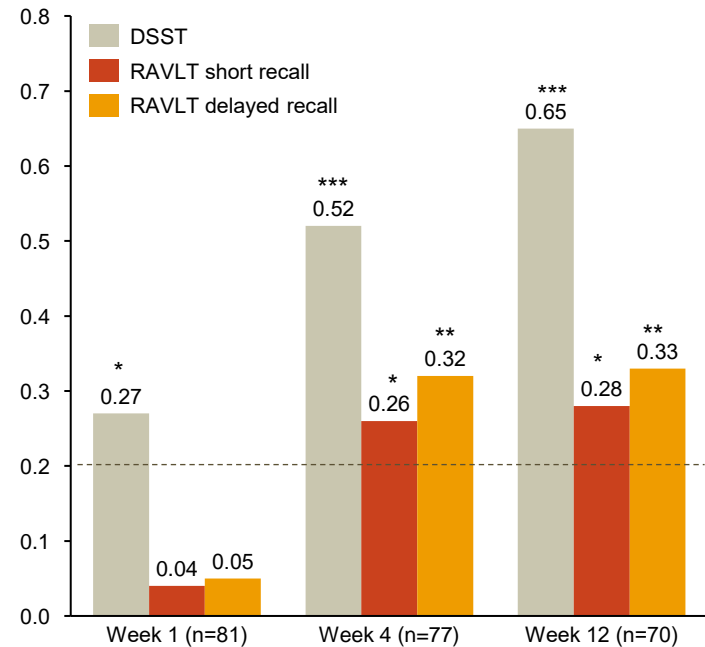
LCM: Life Cycle Management; AAD: Agitation in Alzheimer's Disease; PTSD: Post-Traumatic Stress Disorder; HLR: Headline Results; CTAD: Clinical Trials in Alzheimer's Disease

# Brintellix/Trintellix MEMORY trial: Reduced depressive symptoms and improved cognitive performance in MDD patients with dementia

## MEMORY trial (n=83)

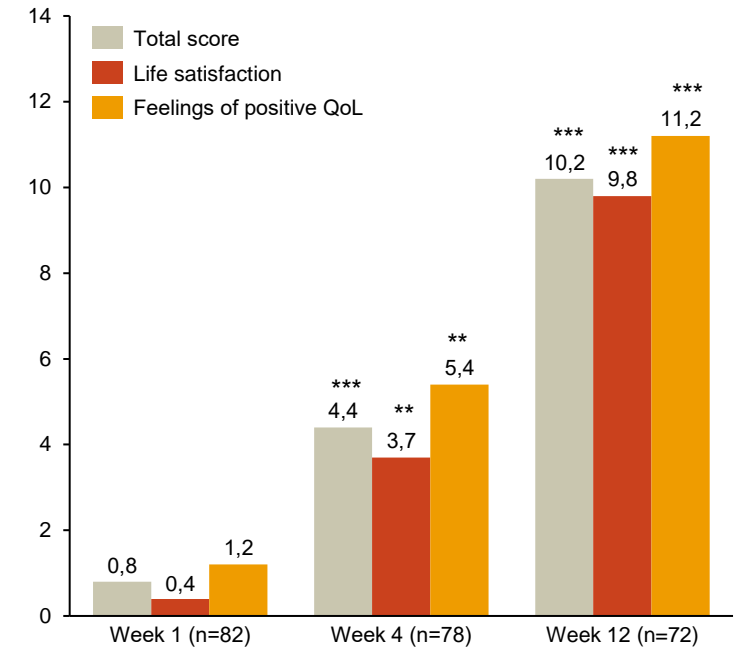
- In patients with **MDD and early dementia** vortioxetine significantly **reduced symptoms of depression** as measured by MADRS already at week 1 and during the 12 weeks of treatment
- Significant **improvement in cognitive performance** observed with DSST already at week 1 and RAVLT (verbal memory) from week 4
- Substantial **improvement in QoL** as measured by BASQID from baseline to week 12

### Cognitive performance



Significant and clinically relevant improvements in cognitive performance were observed as early as Week 1 (DSST) and Week 4 (RAVLT)

### Health-related quality of life



A significant and broad improvement in HRQoL was observed as early as Week 4

\*p<0.05; \*\*p<0.01; \*\*\*p<0.0001; <sup>a</sup>Dashed line indicates threshold for clinically relevant standardised effect size (0.2). #: starting dose 5mg/day for the first week  
 HRQoL, health-related quality of life; MADRS: Montgomery-Asberg Depression Rating Scale MDD, major depressive disorder; MMRM, mixed model for repeated measurements; DSST, Digit Symbol Substitution Test; RAVLT, Rey Auditory Verbal Learning Test; BASQID, Bath Assessment of Subjective Quality of Life in Dementia; LS, least squares; SE, standard error; QoL, quality of life  
 Cronquist Christensen M et al. Poster P.0096 presented at the 35th ECNP Congress, Vienna, Austria, 15-18 October 2022

# Strong progression in the early and mid-stage pipeline

## Phase II

- **Lu AF82422** (anti-alpha-synuclein mAb): *AMULET* PoC trial (MSA) in Japan and the U.S. finished enrolment ahead of time
- **Lu AG09222** (PACAP mAb): *HOPE* PoC trial ongoing enrolment

## Phase I (selected)

- **Lu AF28996** (D1/D2 agonist) progressing well towards completion of phase IB
- **Lu AG22515** (CD40L inhibitor) progressing well towards completion of phase I
- Continued flow of new drug candidates from research to clinical



MSA: Multiple System Atrophy; PoC: Proof of Concept; HLR: Headline Results



# Lu AGo9222 holds the potential to be first-in-class with a differentiated approach to migraine prevention

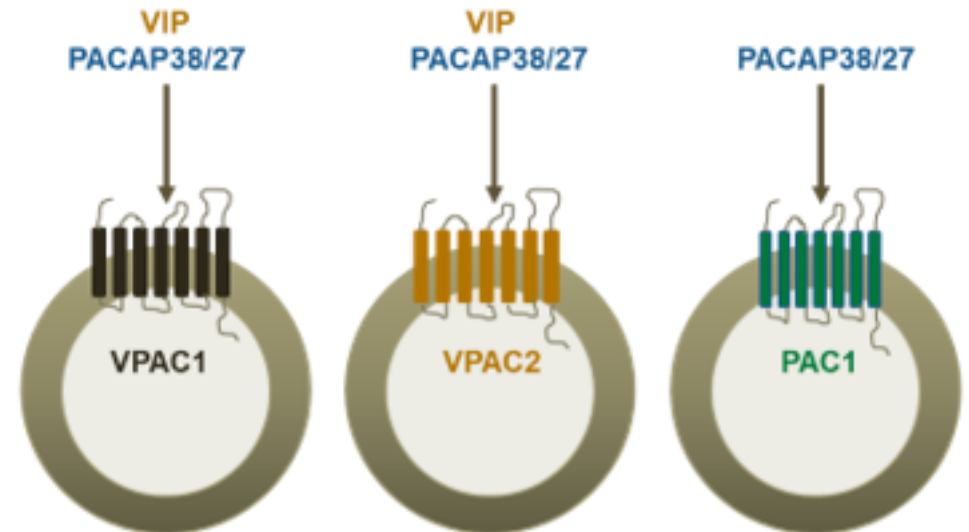
- A differentiated approach to migraine prevention
- Selective PACAP<sup>1)</sup> binding humanized (ligand-binding) IgG1 antibody
- Pre-clinical data<sup>2)</sup> indicate that PACAP and CGRP<sup>3)</sup> may have differentiated involvement in migraine-associated symptoms
- Phase IB study demonstrated target engagement and proof of mechanism
- No safety concerns revealed so far in completed and ongoing trials

## Phase II trial (*HOPE*)<sup>4)</sup>:

- PoC study in adults with migraine who have not been helped by prior preventive treatments
- Trial recruiting well with expected HLR by mid-2023 (n≈230)

## Phase IB trial<sup>5)</sup>

- Multiple-dose safety, pharmacokinetic and pharmacodynamic trial, in subjects with allergic rhinitis



1) Pituitary adenylate cyclase-activating peptide. 2) Moldovan Loomis, C., et al., Pharmacologic Characterization of ALD1910, a Potent Humanized Monoclonal Antibody against the Pituitary Adenylate Cyclase-Activating Peptide. *J Pharmacol Exp Ther*, 2019. 369(1): p. 26-36. 3) Calcitonin gene-related peptide. 4) [Clinicaltrials.gov ID: NCT05133323](https://clinicaltrials.gov/ct2/show/study/NCT05133323). 5) [Clinicaltrials.gov ID: NCT05126316](https://clinicaltrials.gov/ct2/show/study/NCT05126316)

# Focused on driving long term sustainable growth



*Restoring  
Brain Health so  
Every Person  
Can Be Their  
Best*

## Maximize Strategic Brands

- Accelerate and globalize Vyepti
- Maximize Rexulti AAD Launch
- Continue to grow Brintellix and Abilify Maintena
- Capitalize on years with no LOEs

## Continue R&D transformation for mid- and long-term innovation

- Focus in 4 biological clusters for innovation
- Biomarker driven development with active portfolio management: *“Up or out”*

## Secure mid- and late decade growth through BD

- Neuroscience frame
- Leverage commercial and R&D capabilities
- Preference for partnerships, targeted in-licensing or bolt-on M&A
- No use of equity anticipated near term



*Actively  
managing  
for sustainable  
growth*



# Q&A



# Appendix

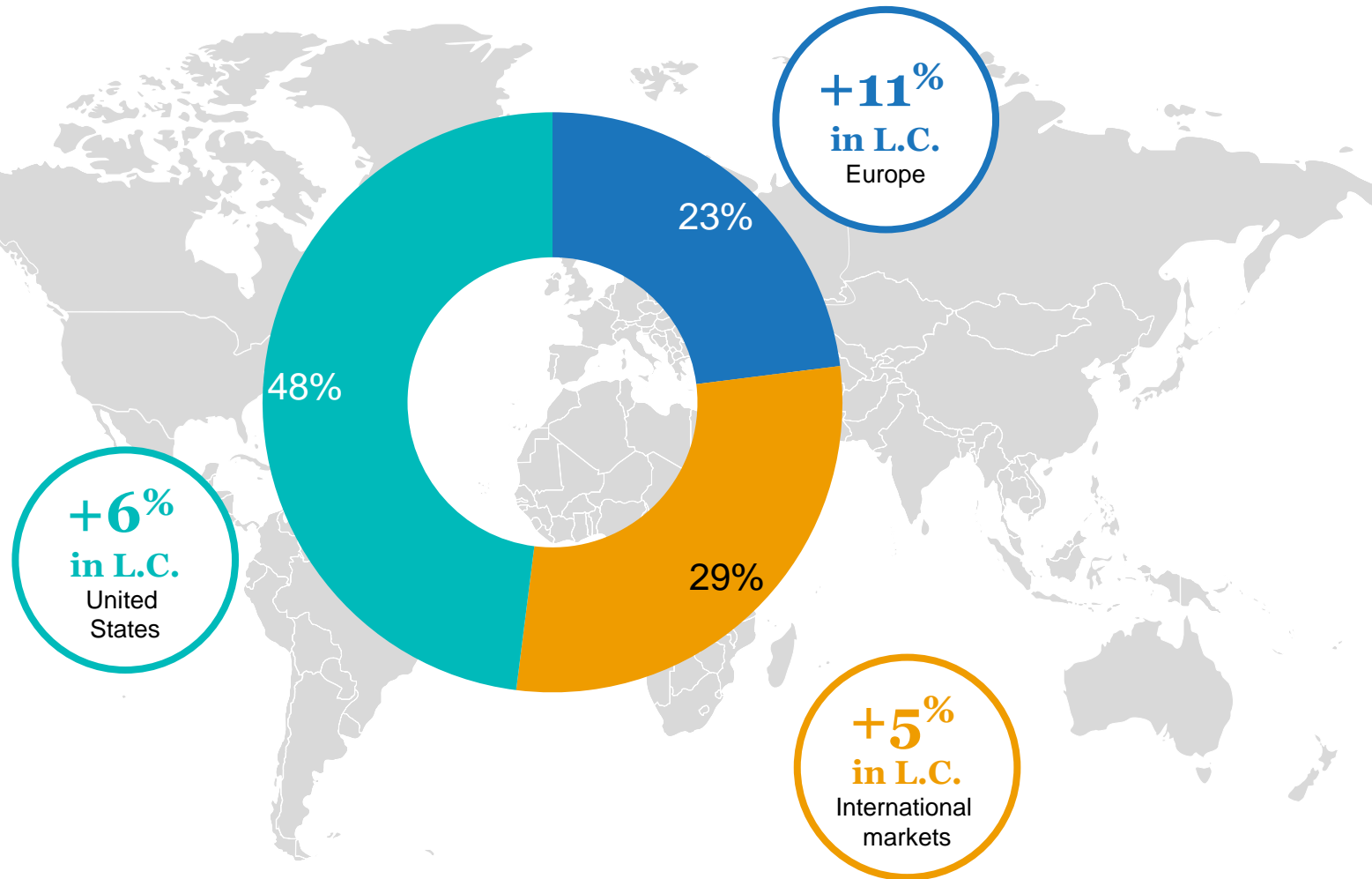
# Product distribution of revenue – 9M 2022 and FY 2021

DKKm	FY 2021	FY 2020	9M 2022	9M 2021	Growth	Growth in local currencies	% of total (9M 2022)
<b>TOTAL:</b>							
Brintellix/Trintellix	3,526	3,102	3,177	2,565	24%	15%	23%
Rexulti/Rxulti	2,849	2,620	2,817	2,112	33%	19%	21%
Abilify Maintena	2,420	2,271	2,164	1,810	20%	13%	16%
Vyepti	492	93	672	328	105%	82%	5%
Cipralex/Lexapro	2,346	2,380	1,874	1,835	2%	0%	14%
Sabril	657	777	482	487	(1%)	(12%)	4%
Onfi	505	642	317	382	(17%)	(26%)	2%
Other pharmaceuticals	3,104	5,219	2,259	2,438	(7%)	(13%)	16%
Other revenue	347	491	205	211	(3%)	(4%)	2%
Effects from hedging	53	5	(401)	78			(3%)
<b>Total revenue</b>	<b>16,299</b>	<b>17,672</b>	<b>13,566</b>	<b>12,246</b>	<b>11%</b>	<b>6%</b>	<b>100%</b>

# Product distribution of revenue – Q3 2022 and FY 2021

DKKm	FY 2021	FY 2020	Q3 2022	Q3 2021	Growth	Growth in local currencies	% of total (Q3 2022)
<b>TOTAL:</b>							
Brintellix/Trintellix	3,526	3,102	1,126	909	24%	13%	24%
Rexulti/Rxulti	2,849	2,620	1,046	734	43%	23%	22%
Abilify Maintena	2,420	2,271	771	613	26%	16%	16%
Vyepti	492	93	282	151	87%	60%	6%
Cipralex/Lexapro	2,346	2,380	620	600	3%	0%	13%
Sabril	657	777	160	151	6%	(9%)	3%
Onfi	505	642	108	97	11%	(4%)	2%
Other pharmaceuticals	3,104	5,219	756	724	4%	(3%)	17%
Other revenue	347	491	49	58	(16%)	(16%)	1%
Effects from hedging	53	5	(199)	(24)			(4%)
<b>Total revenue</b>	<b>16,299</b>	<b>17,672</b>	<b>4,719</b>	<b>4,013</b>	<b>18%</b>	<b>11%</b>	<b>100%</b>

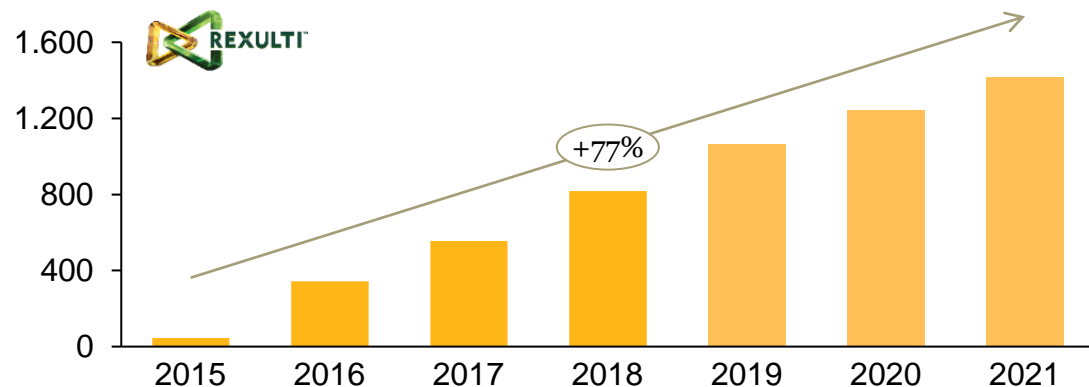
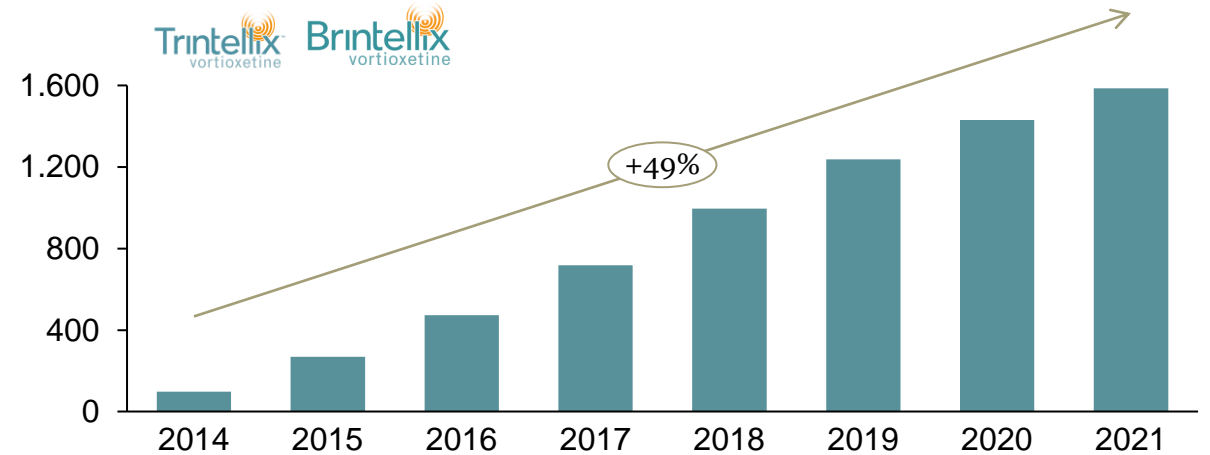
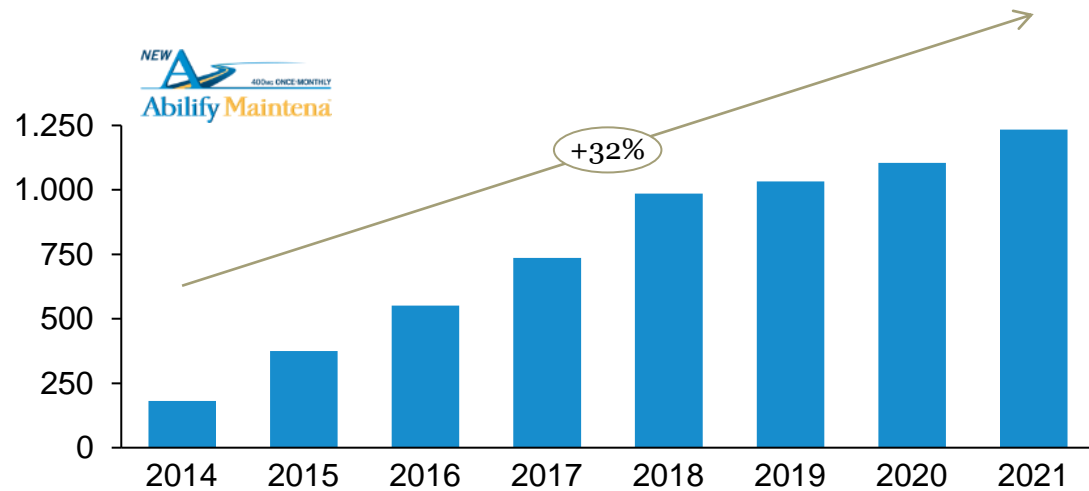
# Seeing double digit growth in all regions



Strategic brands continues to show **robust demand growth** across most markets

**Vyepti** is an increasing contributor to growth as **global roll out ramps up**

# Total molecule sales (gross) - USDm



**Abilify Maintena:** U.S. approval (Feb. 2013); EU approval (Nov. 2013)

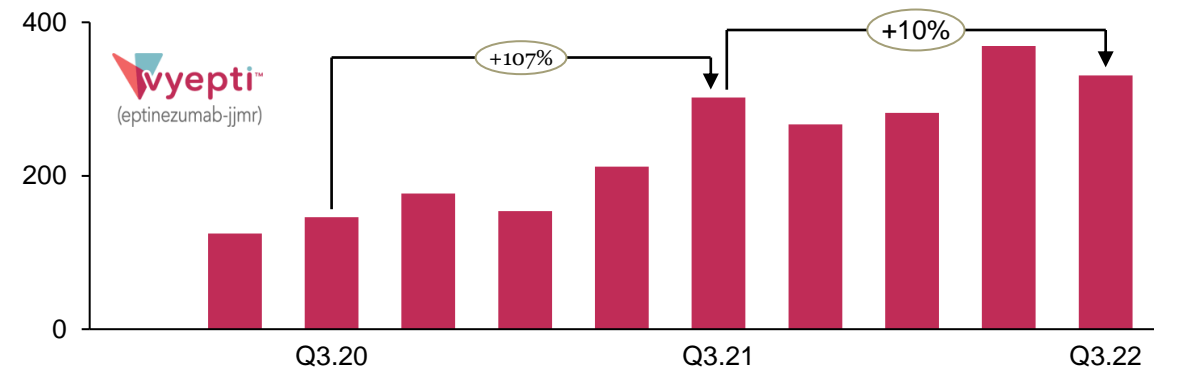
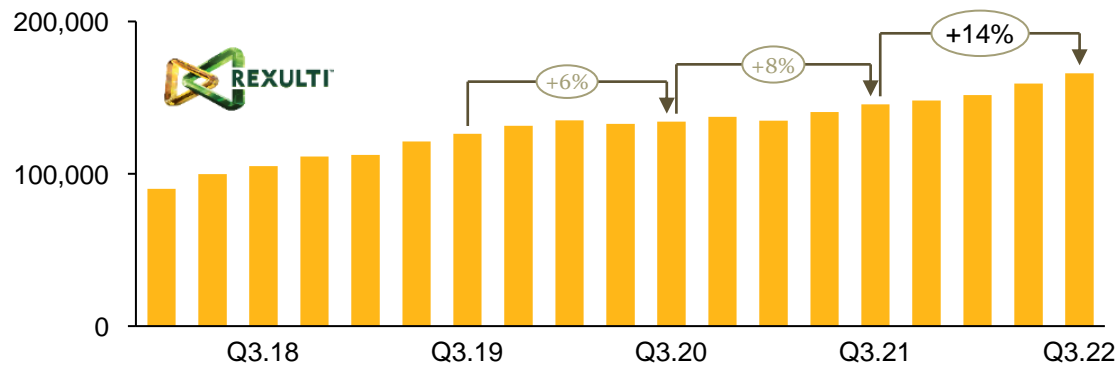
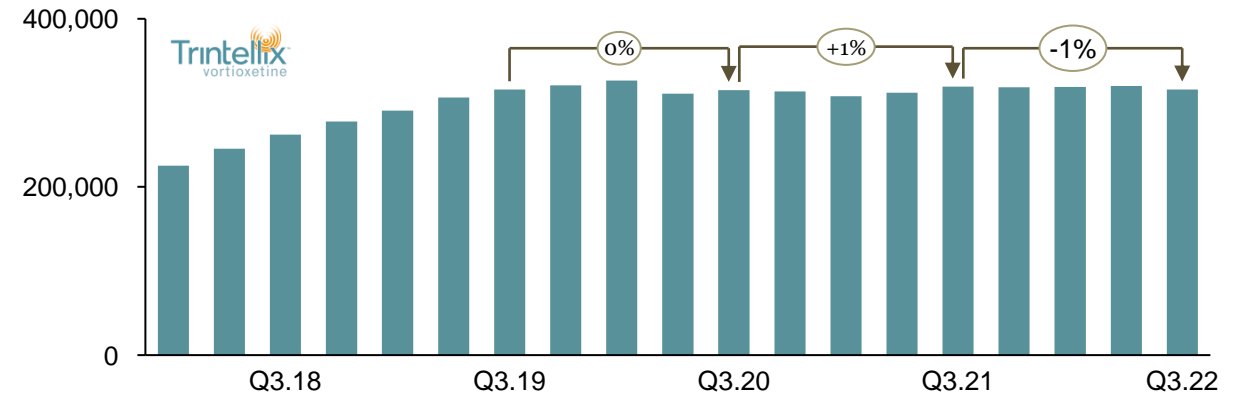
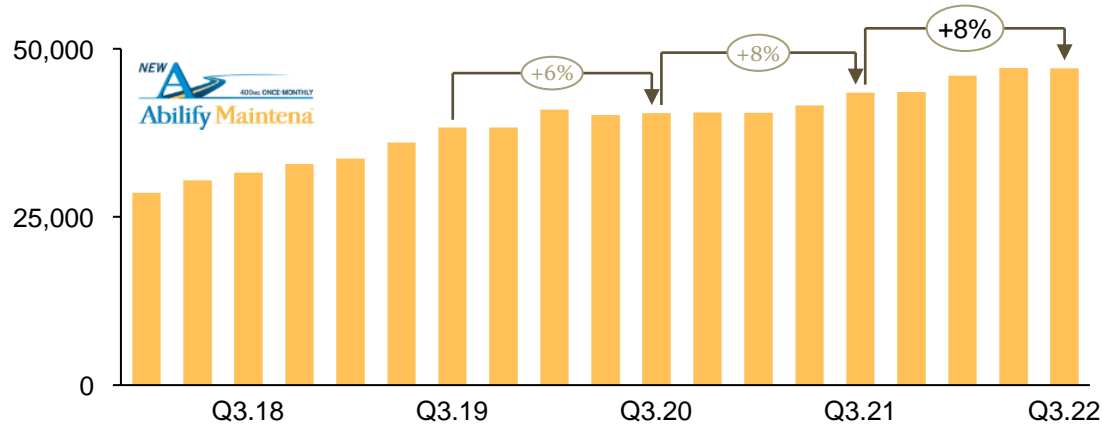
**Brintellix/Trintellix:** U.S. approval (Oct. 2013); EU approval (Dec. 2013); Japan approval (Sep. 2019)

**Rexulti:** U.S. approval (Jul. 2015); EU approval (Jul. 2018); Japan approval (Jan. 2018 – NOT Lundbeck territory)

Source: IQVIA 2021 Data



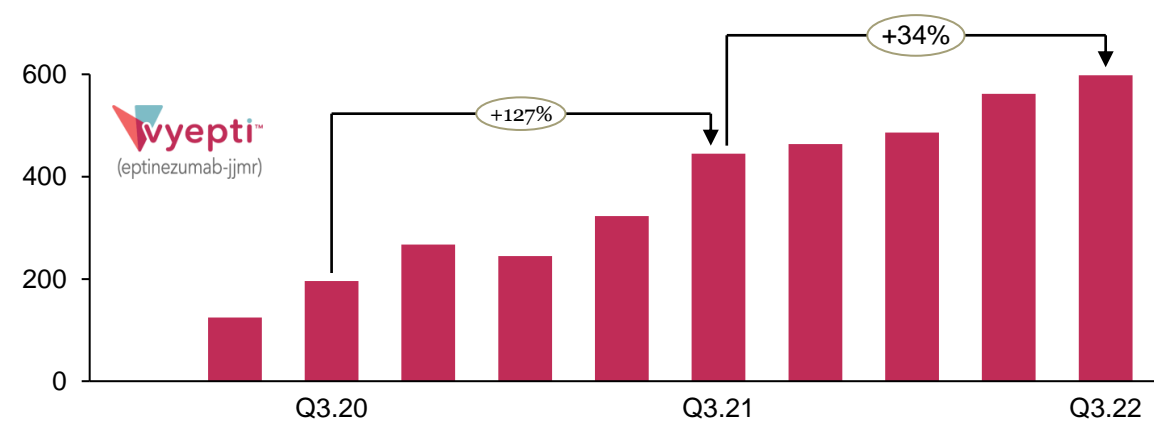
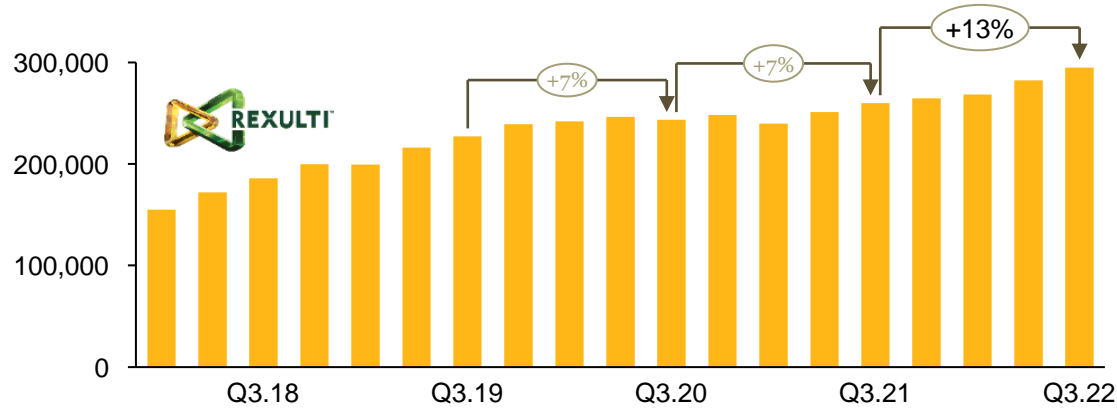
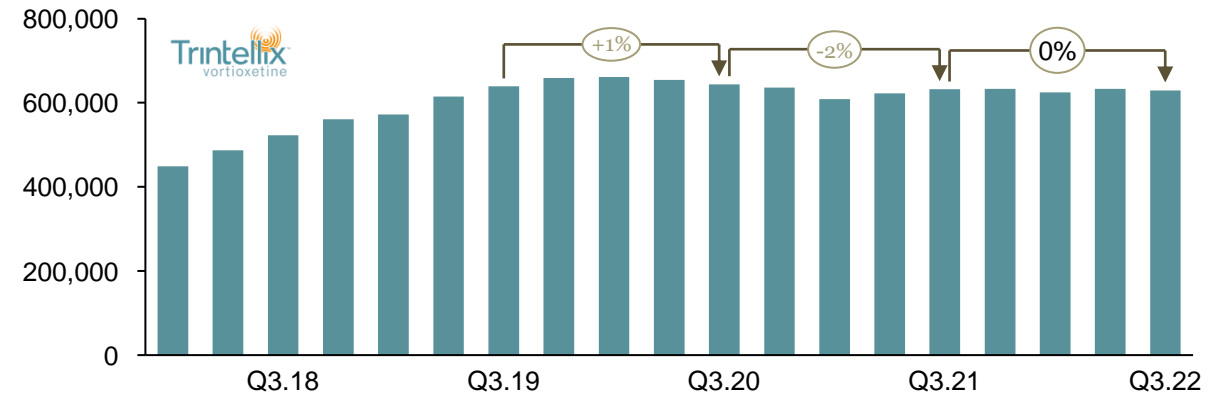
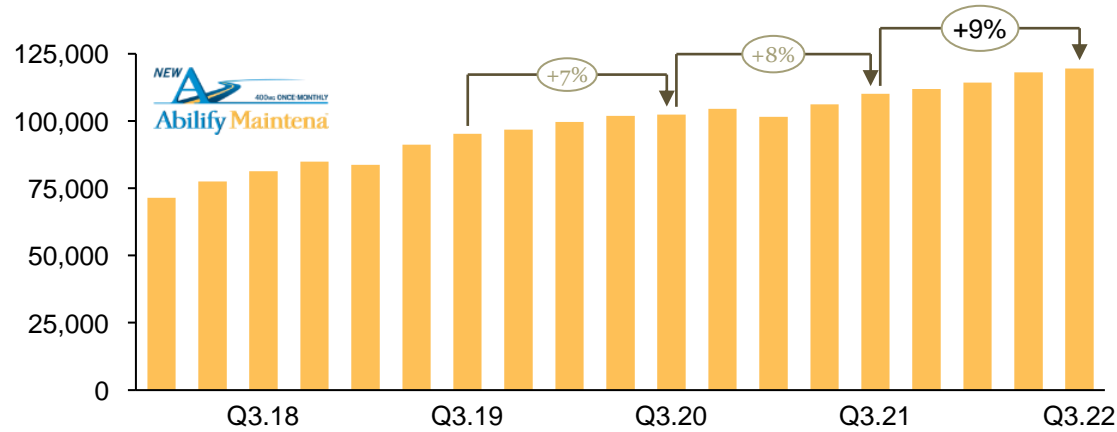
# Volume growth in the U.S. impacted by the pandemic (NRx Count)



Source: Symphony Health (ref Bloomberg)



# Volume growth in the U.S. impacted by the pandemic (TRx Count)

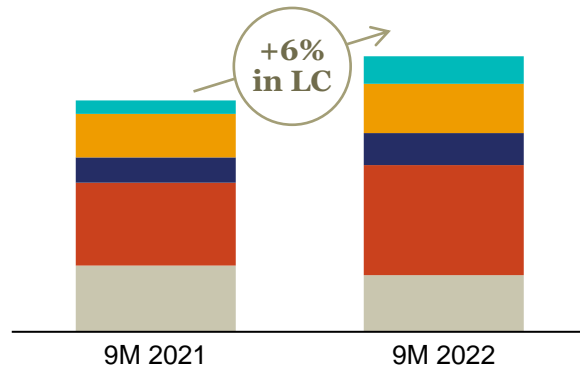


Source: Symphony Health (ref Bloomberg)



# Strong strategic brands growth globally

## United States

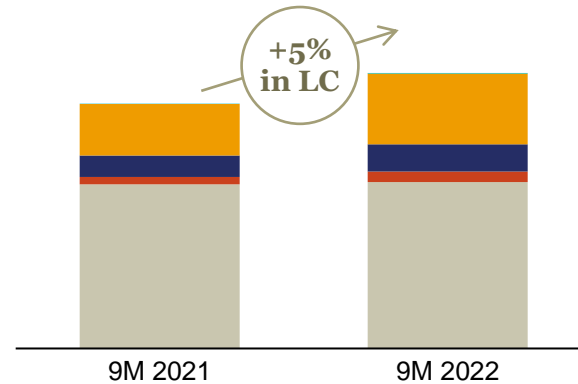


Strategic brands  
up 33%\* to DKK 5.2bn –  
80% of sales

**Vyepti** and **Rexulti** key contributors to growth

United States accounts for almost  
**50% of total revenue**

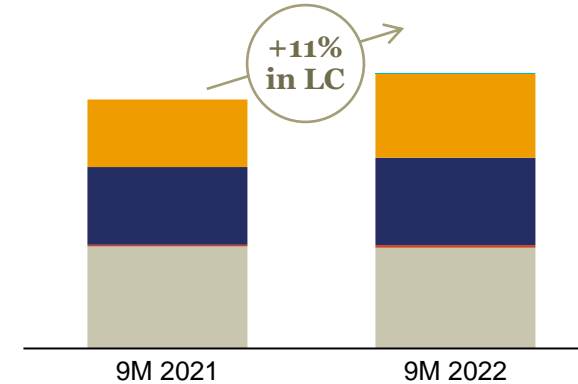
## International markets



Strategic brands  
up 35%\* to DKK 1.6bn –  
40% of sales

**Vyepti** roll-out started

## Europe



Strategic brands  
up 19%\* to DKK 2.0bn –  
63% of sales

Strategic brands show  
**robust growth**  
**across most markets**  
driven by demand

**Solid**  
underlying growth  
in Europe and  
International markets  
driven by demand



**U.S. Canada,**  
**Spain, Italy and**  
**Australia**  
are the largest markets  
for strategic brands

■ Vyepti ■ Trintellix ■ Abilify/Maintena ■ Rexulti ■ Other products

# Strategic brands are major revenue contributors, continuing strong growth momentum

+30%



Strategic brands sales growth (+19% in L.C.)

DKK 8.8bn

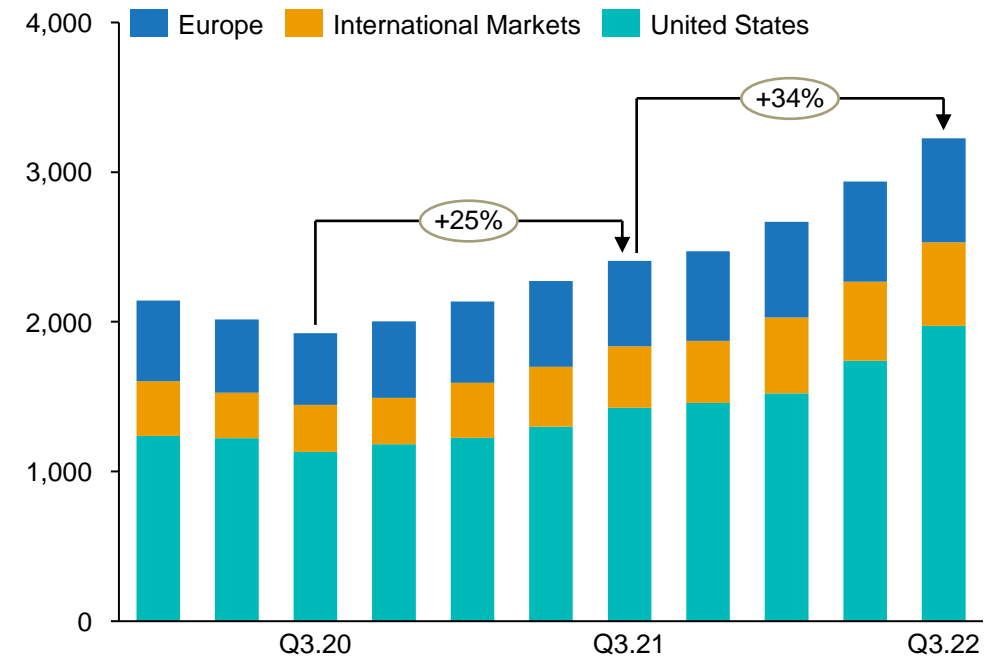
Global Lundbeck sales in 9M 2022 (65% of total Lundbeck sales)

- All four strategic brands showed double-digit growth in 9M 2022
- Strategic brands grew significantly in all regions
  - 33%, 35% and 19% in the United States, International Markets and Europe, respectively
- Strong growth momentum is expected to continue
- Some benefit from FX



\*) Abilify Maintena, Brintellix/Trintellix, Rexulti/Rxulti and Vyepti. L.C.: Local currencies

Strategic brands\* revenue  
(Quarterly - DKKm)



# Vyepti: Robust uptake continues



Grew 105% (82% in L.C.)  
to DKK 672m in 9M 2022

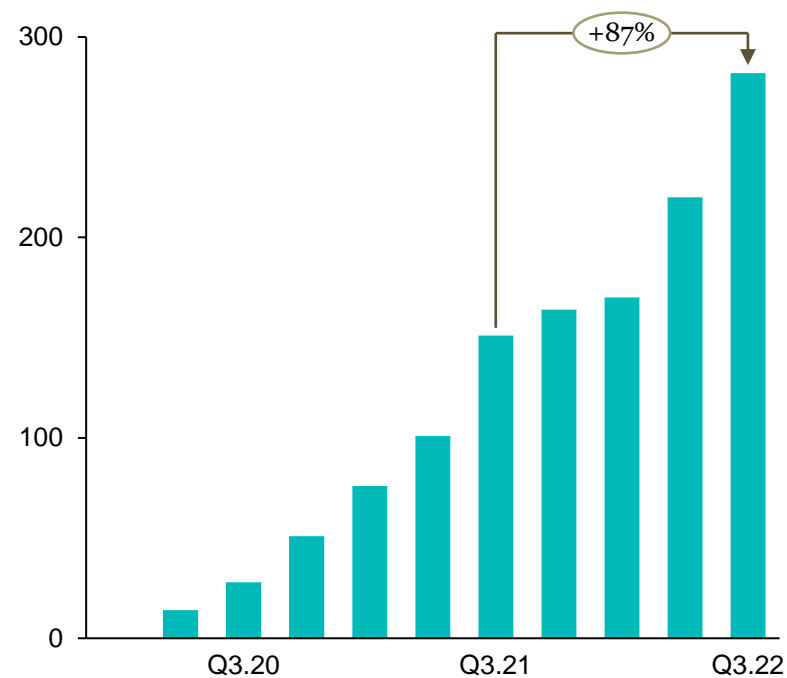
Launched in the U.S.,  
Australia, Canada, Estonia, Finland,  
Germany, Kuwait, Singapore,  
Sweden, Switzerland and U.A.E.

Additional launches planned for 2022  
and 2023

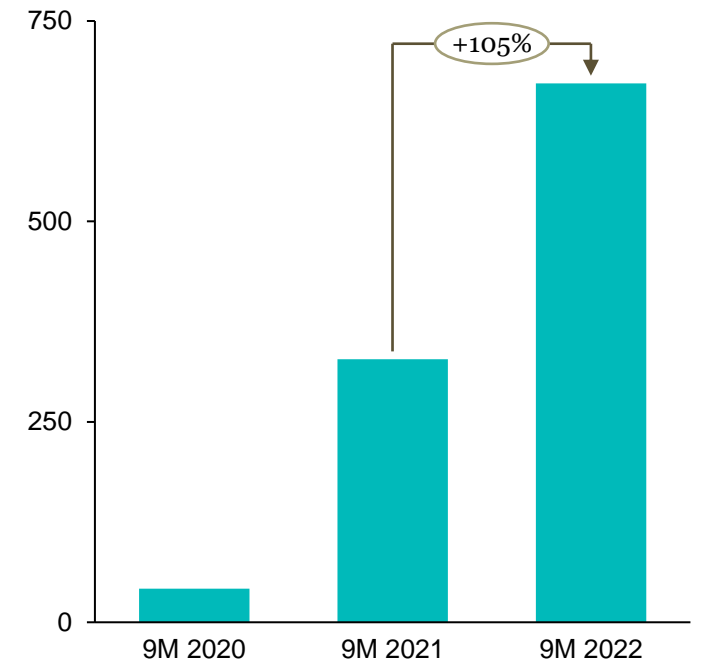
Vyepti franchise protected  
for several years:

- Patents issued lasting to Q3 2037
- U.S. Composition of matter patent expires in Q2 2034 (including extensions)

Vyepti sales  
(Quarterly - DKKm)



Vyepti sales  
(9M - DKKm)



Vyepti was approved by the FDA February 2020 and by the EU Commission January 2022. \*) aCGRPs Normalized Units IQVIA NPA retail + DDD non-retail. By November 2021.



# Brintellix/Trintellix: Solid underlying performance driven by strong clinical profile

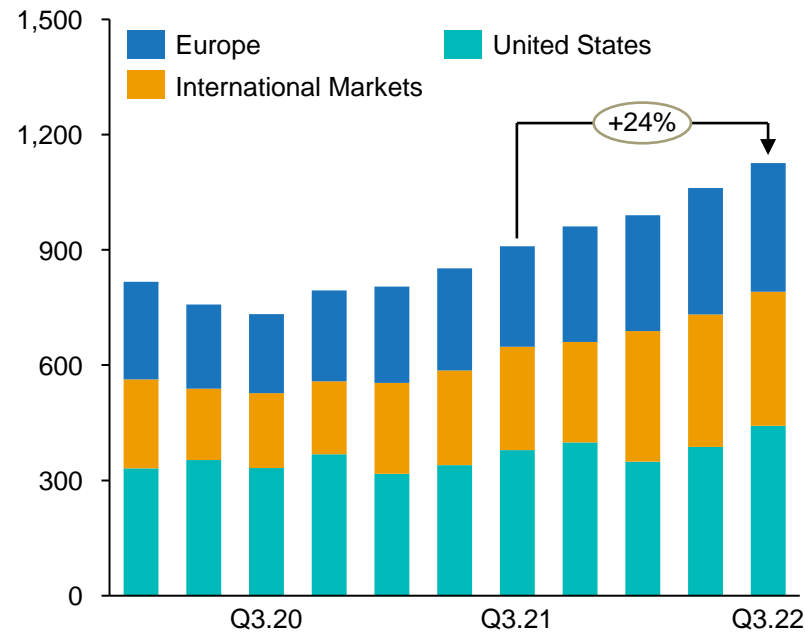
Grew 15% (L.C.) to DKK 3.2bn in 9M 2022

Volume share sustained or increased in most markets\*)

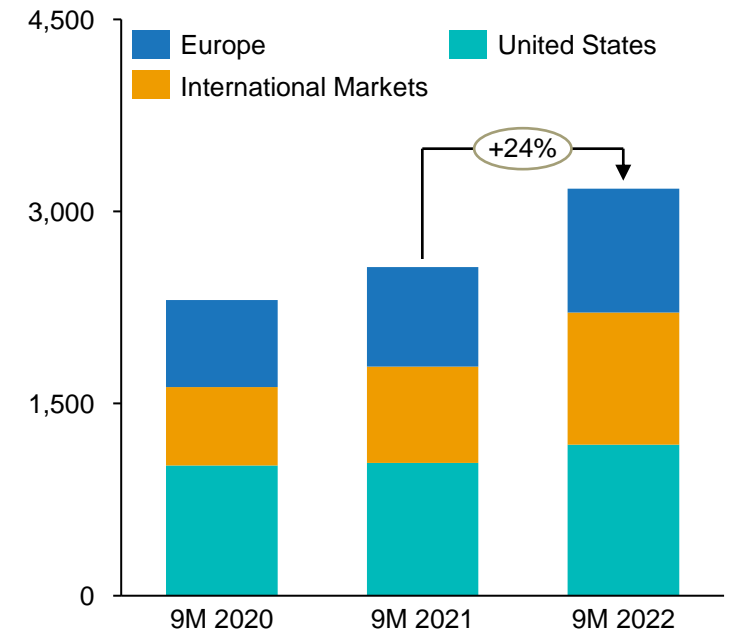
Brintellix/Trintellix franchise protected for several years:

- Patents issued lasting to March 2032
- Composition of matter patent expires in December 2026 (including extensions)

Brintellix/Trintellix sales per region  
(Quarterly - DKKm)



Brintellix/Trintellix  
(9M - DKKm)



Trintellix was approved by FDA September 2013 and Brintellix by EMA December 2013





# Rexulti: Growing 33% – an effective drug that is meeting patient needs

Grew 19% in L.C. to DKK 2.8bn in 9M 2022

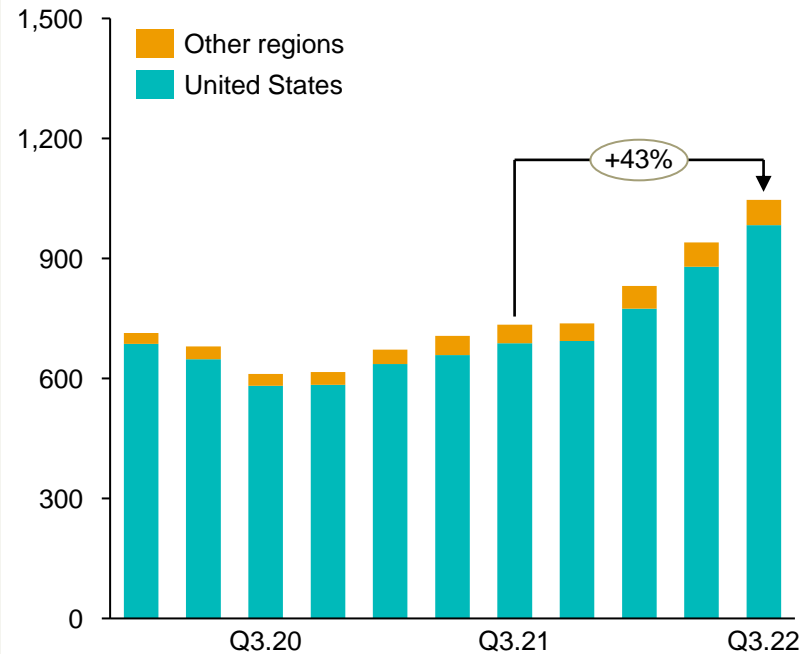
Continued solid traction in market shares

In the U.S., volume (TRx) is up 13% y/y in Q3 2022, NRx up 14%\*

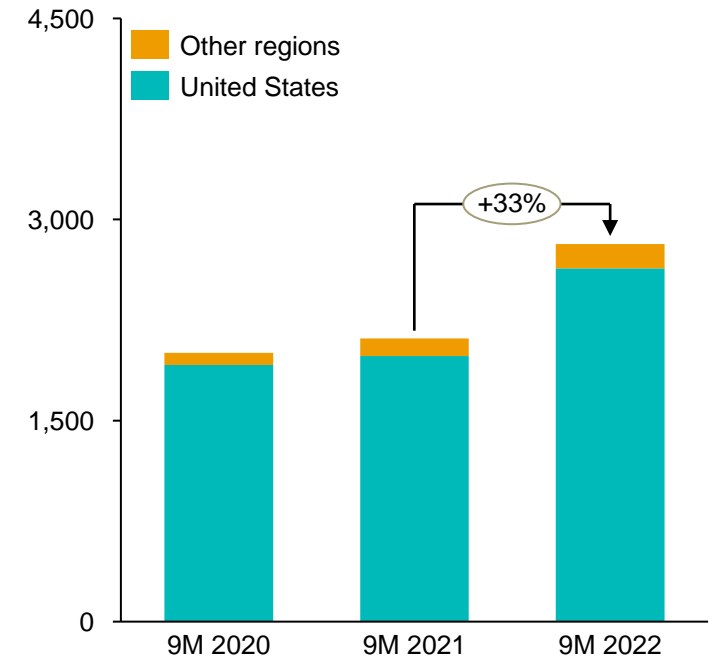
Rexulti franchise protected for several years:

- Composition of matter patent expires in June 2029 (including extensions)
- Patents issued lasting to Nov. 2032

Rexulti sales per region\*\*  
(Quarterly - DKKm)



Rexulti sales\*\*  
(9M - DKKm)



\*) Symphony Health (c.f. Bloomberg). \*\*) Lundbeck's share of revenue  
Rexulti was approved by the FDA July 2015 and by the EU Commission July 2018



# Abilify Maintena: Growing 20% in 9M 2022

Grew 13% (L.C.) to DKK 2.2bn in 9M 2022

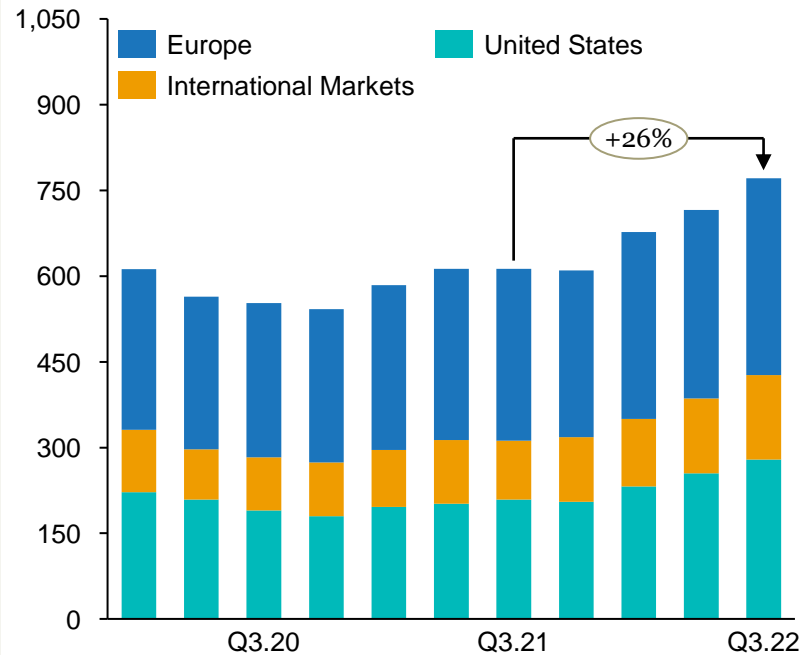
Global LAI market up 4% to USD 4.6bn (9M 2022)\*

- Continued robust traction in value share\*
- Abilify Maintena's share of the global LAI market was 19.5% in 9M 2022 vs. 18.4% in 2021\*

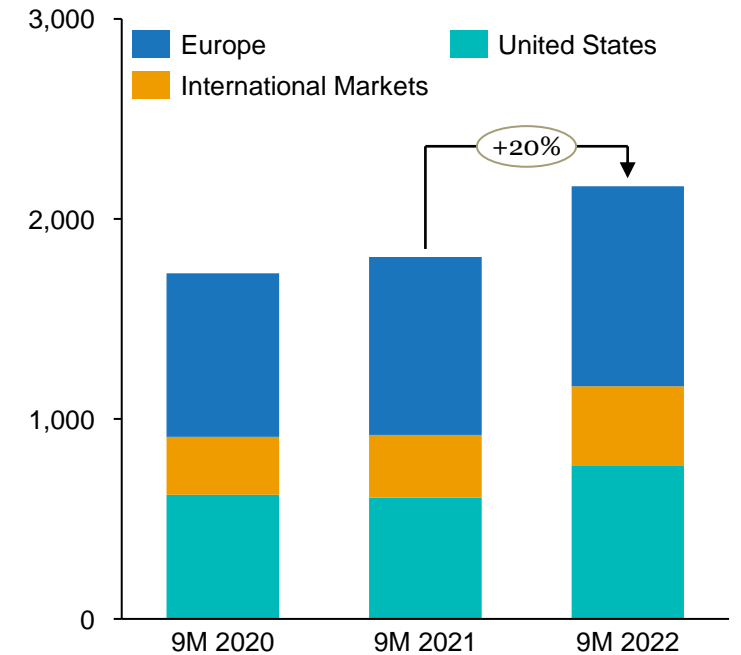
Abilify Maintena franchise protected for several years:

- 1-month formulation: Orange Book listed patents until March 2034. In RoW formulation patent expires Oct. 2024
- 2-month formulation protected until mid-2030's

Abilify Maintena sales per region\*\*  
(Quarterly - DKKm)



Abilify Maintena  
(9M - DKKm)



\*) Reported net sales of atypical LAIs. \*\*) Lundbeck's share of revenue. Abilify Maintena was approved by FDA and by the EU Commission in February and November 2013, respectively



# Cipralex/Lexapro: Sales grew 2% in 9M 2022



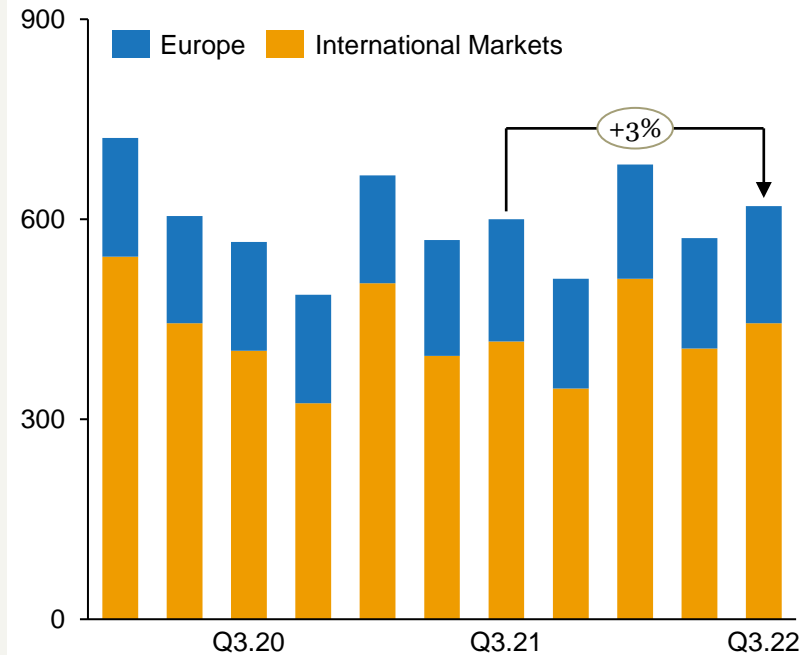
Grew 2% (unchanged in L.C.) to DKK 1.9bn in 9M 2022

The biggest markets are Japan, China, South Korea, Italy and Brazil

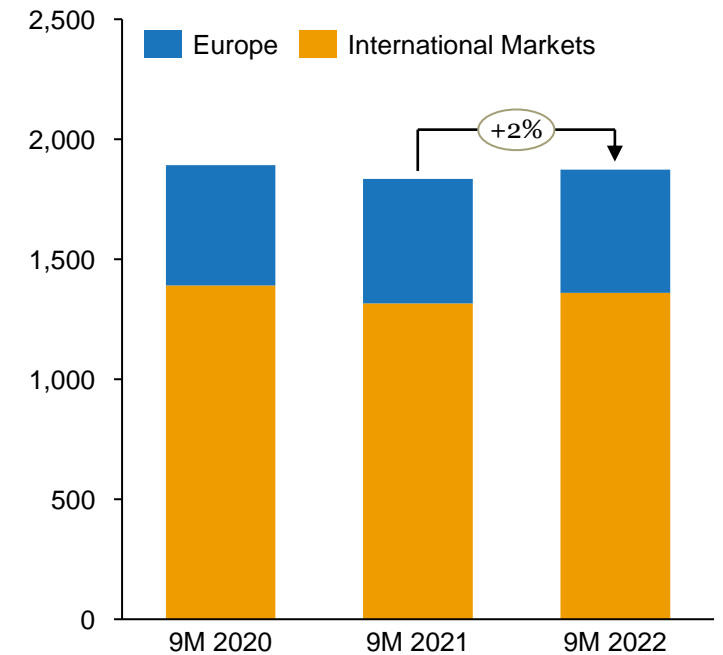
The patent expired in 2012 (U.S.) and in 2014 (most of RoW)\*

Market exclusivity in Japan expired April 2021

Cipralex/Lexapro  
(Quarterly - DKKm)



Cipralex/Lexapro  
(9M- DKKm)



*\*) Generic launches were seen in 2009-2010 in countries such as Australia, Brazil, Canada, Finland, Norway and Spain as a consequence of different patent extension rules at the time.*



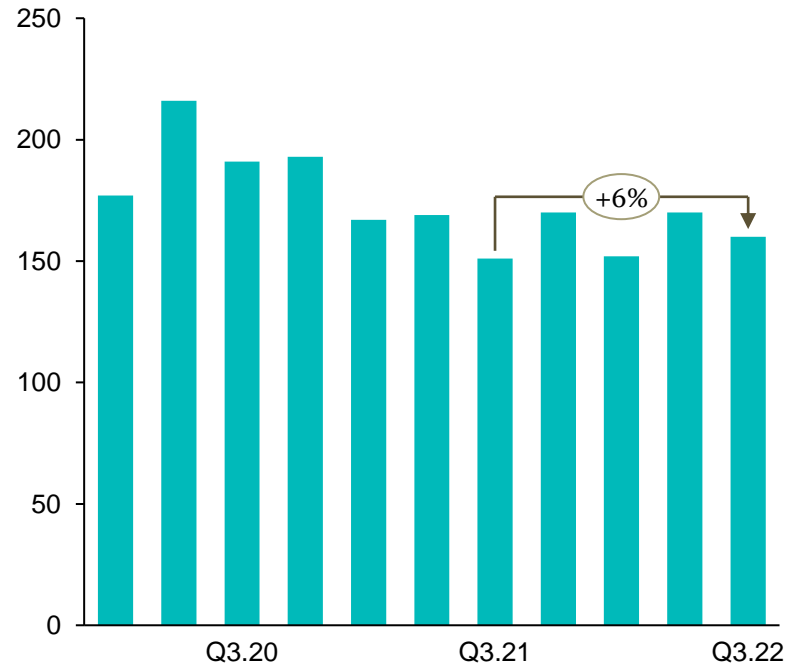
# Sabril: Sales impacted by generic erosion from Q3 2017



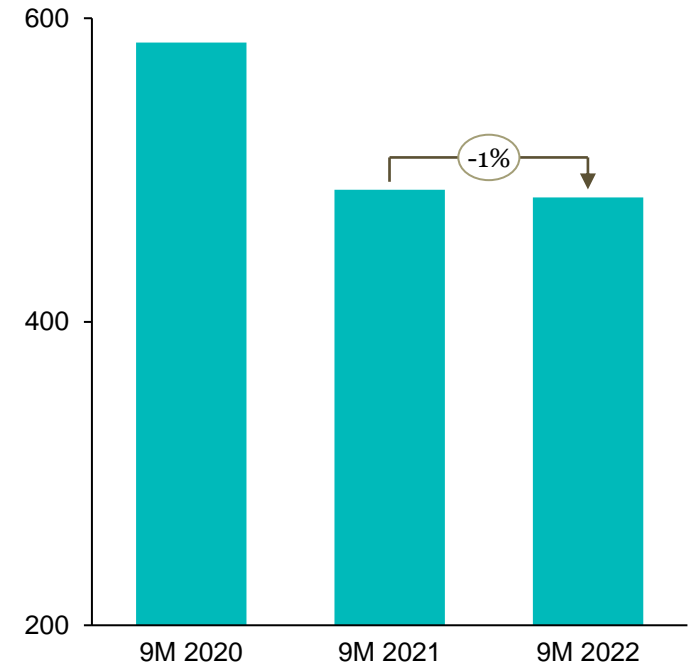
Grew 6% (down 9% in L.C.) to DKK 160m in Q3 2022

Declined 1% (12% in L.C.) to DKK 482m in 9M 2022

Sabril sales  
(Quarterly - DKKm)



Sabril sales  
(9M - DKKm)



Sabril was approved by the FDA in August 2009. Lundbeck has only promoted Sabril in the U.S.

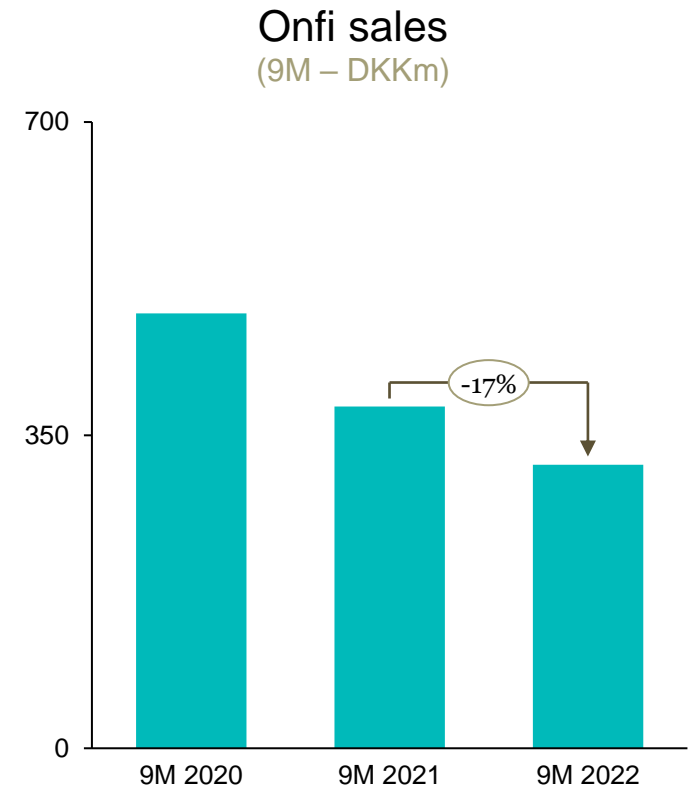
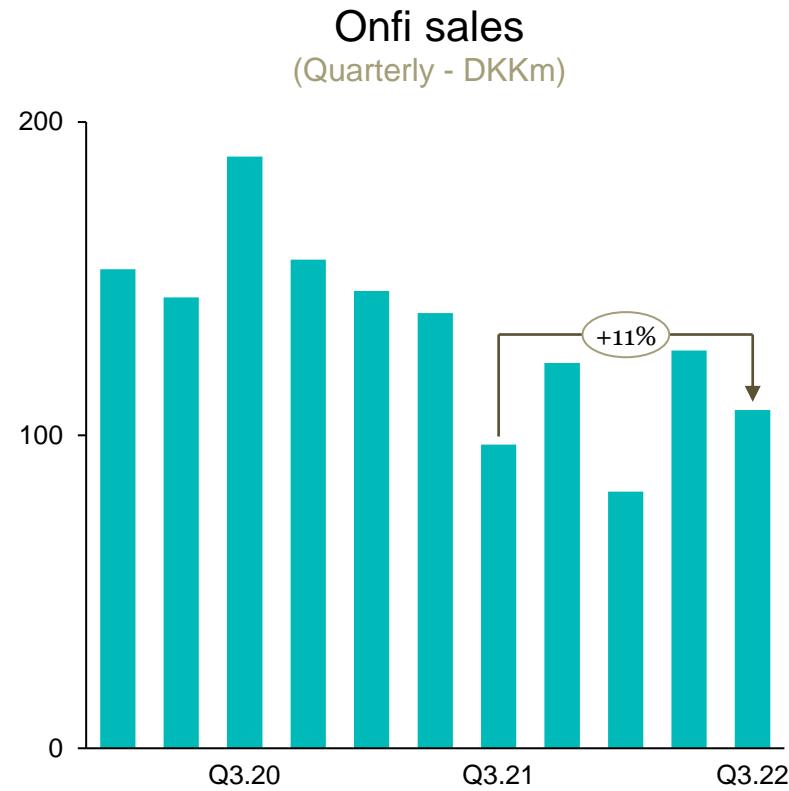


# Onfi: Sales impacted by generic erosion from October 2018



Increased 11% (down 4% in L.C.) to DKK 108m in Q3 2022

Declined 17% (26% in L.C.) to DKK 317m in 9M 2022



Onfi was approved by the FDA October 2011. Lundbeck has only promoted Onfi in the U.S.



# Other pharmaceuticals

Grew 4% (down 3% in L.C.) to DKK 756m in Q3 2022

Declined 7% (13% in L.C.) to DKK 2.3bn in 9M 2022

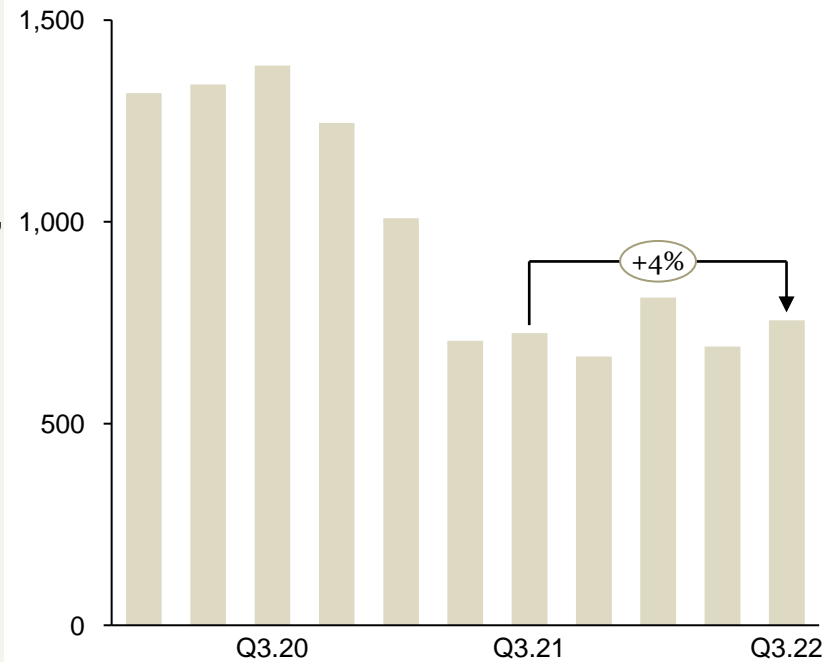
Around 15 mature products included

Biggest products are Azilect, Cipramil, Cisordinol, Deanxit, Ebixa, Fluanxol, Northera, Selincro, Xenazine

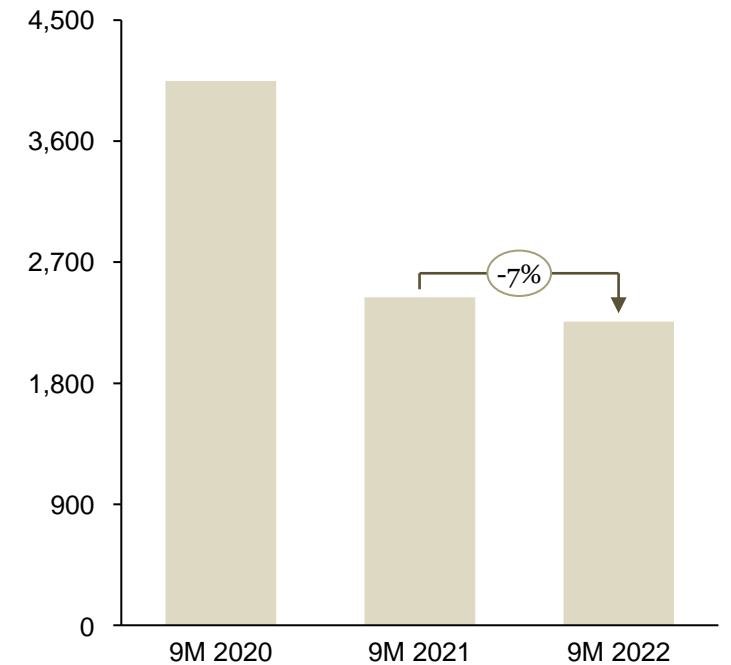
Ebixa impacted by VBP in China from Q4 2020

International Markets constitutes around 50% of sales

Other pharmaceuticals  
(Quarterly - DKKm)



Other pharmaceuticals  
(9M - DKKm)

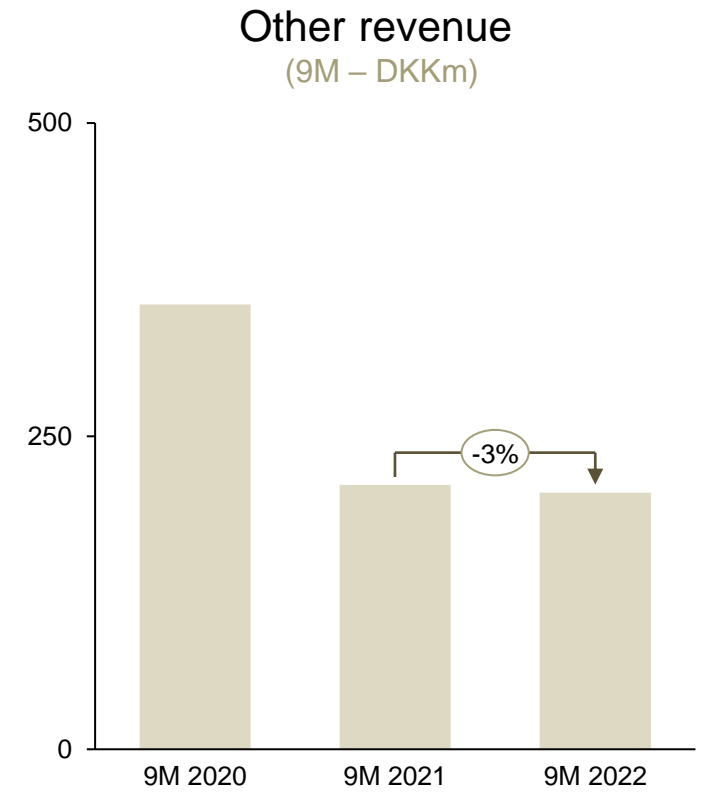
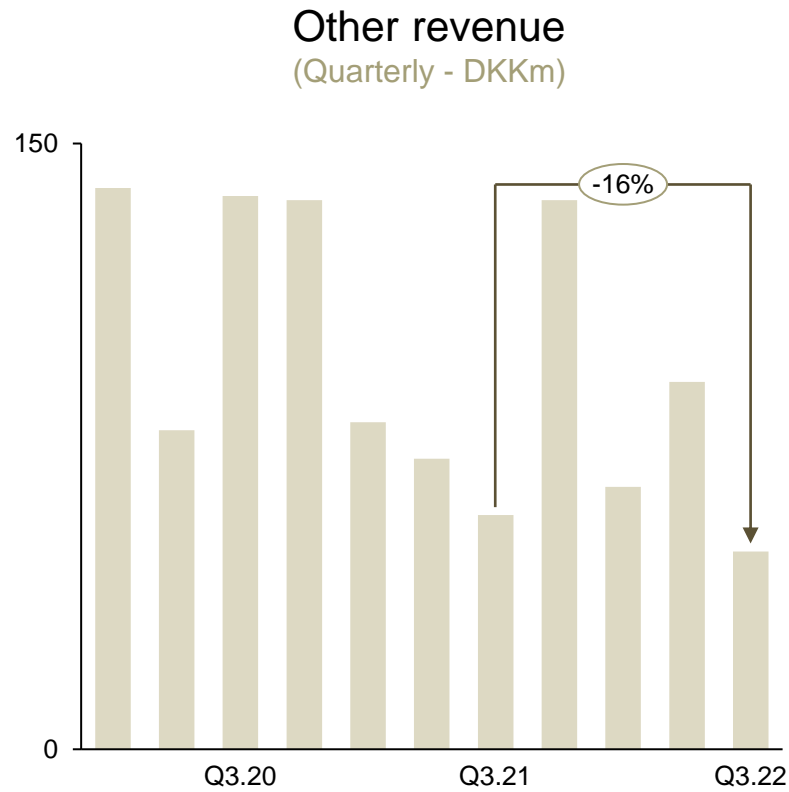


# Other revenue

Declined 16% (down 16% in L.C.) to DKK 49m in Q3 2022

Declined 3% (down 4% in L.C.) to DKK 205m in 9M 2022

Mostly contract manufacturing to third-party



# Core operating profit maintained at robust level

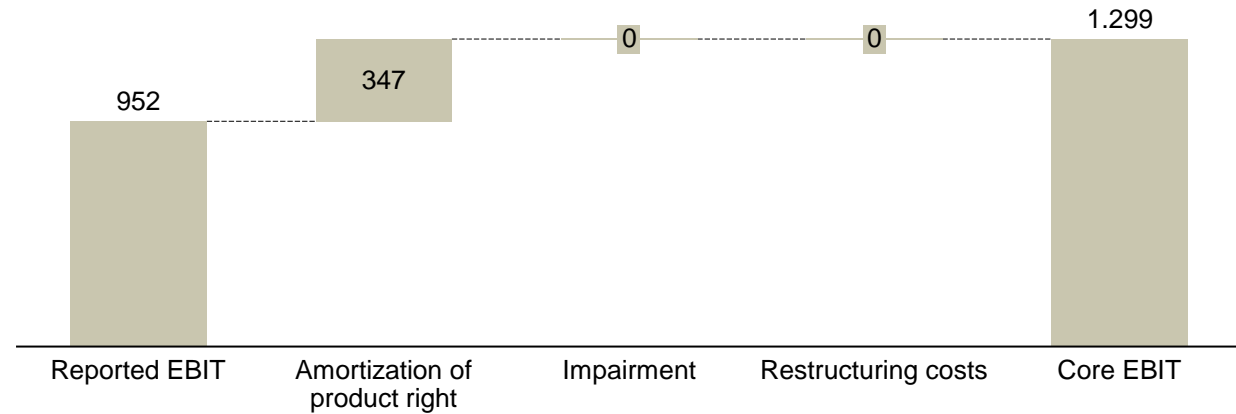
## Q3 2022

- Core EBIT reached DKK 1,299 million in Q3 2022
- Amortizations increased from DKK 300 million in Q3 2021 to DKK 347 million due to the appreciating USD

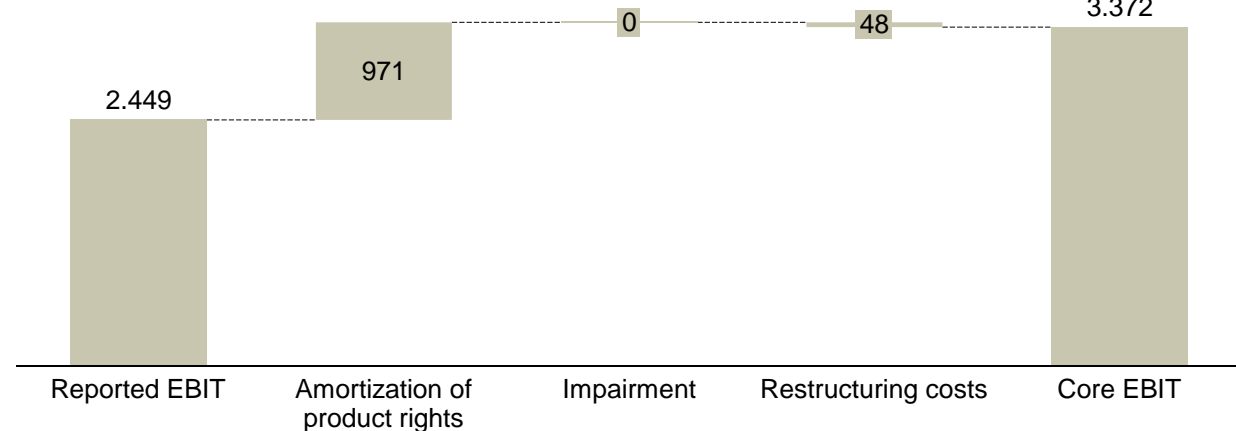
## 9M 2022

- Core EBIT reached DKK 3,372 million in 9M 2022
- Amortizations increased slightly from DKK 969 million (9M 2021) to DKK 971 million due to Northera LoE partly offsetting the impact from the USD-appreciation and Vyepti rest of world amortization

### Q3 2022 core EBIT reconciliation (DKK m)



### 9M 2022 core EBIT reconciliation (DKK m)



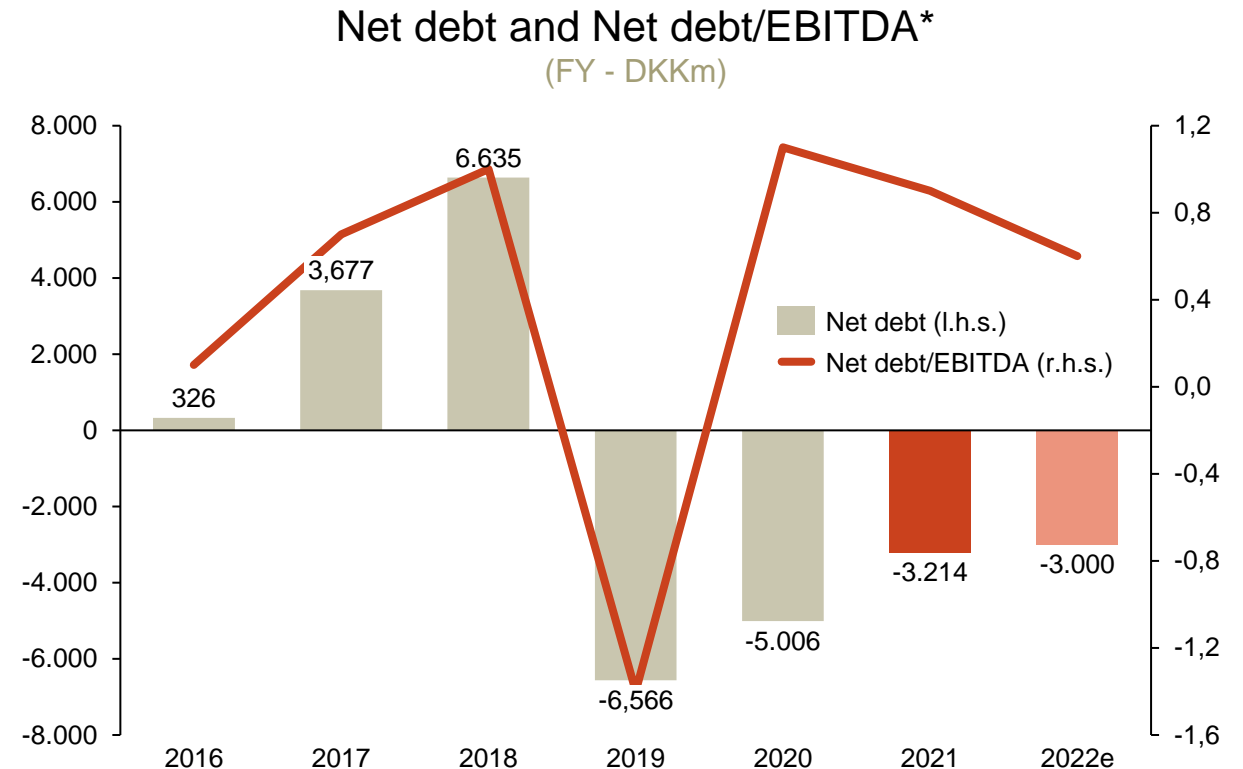
# Solid financial foundation from which to execute on our strategy

**FY 2022:** Cash flow negatively impacted by:

- Significant milestone payment for EMA approval of Vyepti
- Dividend
- CAPEX investments
- Inventory build-up of Vyepti in preparation for launch in additional markets

**Net debt** expected to reach around DKK 3.0bn by end-2022 and Net debt/EBITDA expected to stay unchanged from 2021 at ~0.7

**Lundbeck is solidly funded** with its current facilities



# Cash position, funding and debt maturity

A diversified and long-term balanced debt portfolio is a priority to Lundbeck

This includes access to various funding sources as well as a balanced maturity profile to support the *Expand and Invest to Grow* strategy

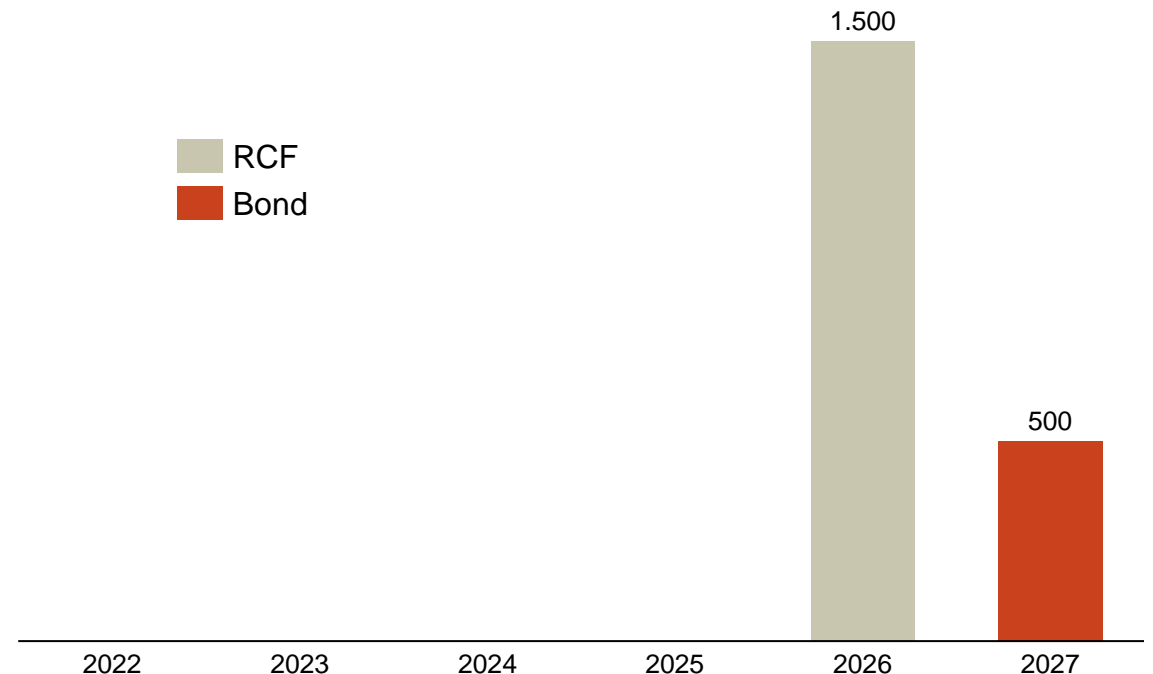
The EUR 1.5bn RCF was established in June 2019, extended in 2020, 2021, 2022 and matures 2026

The EUR 0.5bn bond was issued in October 2020, and is a 7-year fixed interest rate long-term funding instrument which will be repaid in 2027

Overall Lundbeck is solidly funded with its current bank facilities and newly issued bond

RCF: Revolving Credit Facility

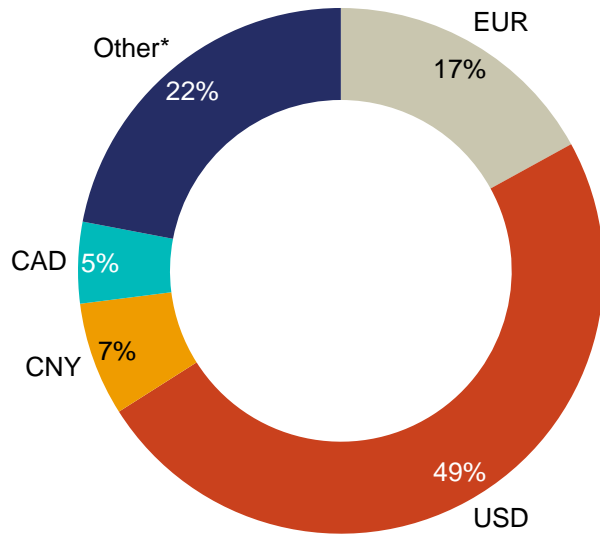
Debt maturity profile  
(EURm equivalent)



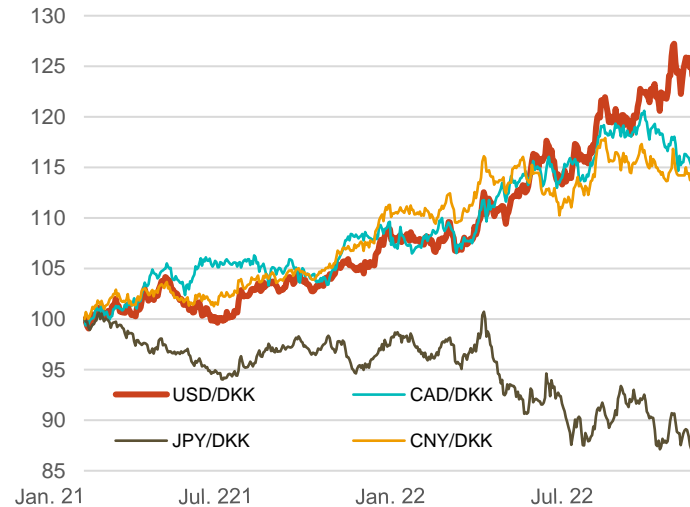


# 9M 2022 impacted by appreciation of main currencies

9M 2022 sales by currency



Main currencies\*\*  
(January 1, 2021 = index 100)



	Spot Oct. 24, 2022	Lundbeck's hedging rate	Avg. 9M 2021	Avg. 9M 2022	Avg. Q2 2022	Avg. Q3 2022
USD	752.14	645	621.87	700.90	681.13	738.59
CAD	552.86	508	497.01	545.93	535.72	566.36
CNY	103.6	101	95.82	105.86	104.96	107.77

- ~80% of sales in non-EUR currencies
- USD directly represents ~50% of sales
- The three main currencies make up ~70% of net exposure
- 5% change in USD will impact revenue by DKK ~85m
- In 9M 2022 effects from hedging reach a loss of DKK 401m vs a gain of DKK 78m in 9M 2021

\*) Other includes JPY, AUD and other currencies. Excluding effects from hedging. \*\*) Source: Bloomberg – data until October 24, 2022



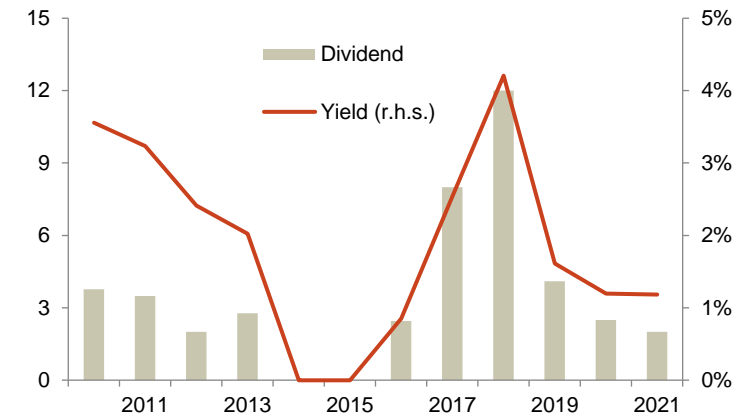
# Cash generation

DKKm	9M 2022	9M 2021	FY 2021	FY 2020	FY 2019
Cash flows from operating activities	2,232	1,889	2,272	3,837	2,609
Cash flows from investing activities	(1,360)	(332)	(610)	(467)	(7,755)
<b>Cash flows from operating and investing activities (free cash flow)</b>	<b>872</b>	<b>1,557</b>	<b>1,662</b>	<b>3,370</b>	<b>(5,146)</b>
Cash flows from financing activities	169	(2,995)	(3,336)	(2,394)	4,548
<b>Net cash flow for the period</b>	<b>1,041</b>	<b>(1,438)</b>	<b>(1,674)</b>	<b>976</b>	<b>(598)</b>
Cash, bank balances and securities, end of period	3,406	2,504	2,279	3,924	3,012
Interest-bearing debt	(6,427)	(5,718)	(5,468)	(8,030)	(9,578)
<b>Net cash/(net debt)</b>	<b>(3,021)</b>	<b>(3,214)</b>	<b>(3,189)</b>	<b>(4,106)</b>	<b>(6,566)</b>

# Financial position and dividend

DKKm	30.09.2022	31.12.2021
Intangible assets	23,765	22,750
Other non-current assets	3,506	3,291
Current assets	12,034	8,612
<b>Assets</b>	<b>39,305</b>	<b>34,653</b>
Equity	20,919	18,279
Non-current liabilities	9,250	7,556
Current liabilities	9,136	8,818
<b>Equity and liabilities</b>	<b>39,305</b>	<b>34,653</b>
<b>Interest-bearing debt, cash, bank balances and securities, net, end of year</b>	<b>(3,021)</b>	<b>(3,189)</b>

## Dividend (DKK)



- ★ Dividend payout of DKK 2.0 per share paid-out for 2021, corresponding to a payout ratio of approx. 30%
- ★ A total of DKK 398 million and a yield of 1.2%\*
- ★ Dividend policy: Pay-out ratio of 30-60% from 2019

\*Based on the share price of DKK 168.85

# Costs – Full year figures

DKKm	2021	2020	2019	2021 ( $\Delta\%$ )	2020 ( $\Delta\%$ )
Revenue	16,299	17,672	17,036	(8%)	4%
Cost of sales	3,648	4,166	3,840	(12%)	8%
Sales & Distribution costs	5,885	5,946	5,514	(1%)	8%
Administrative expenses	933	966	899	(3%)	7%
R&D costs	3,823	4,545	3,116	(16%)	46%
<b>Total costs</b>	<b>14,289</b>	<b>15,623</b>	<b>13,369</b>	<b>(9%)</b>	<b>17%</b>
EBITDA	3,720	4,783	4,823	(22%)	(1%)
EBIT <sup>1)</sup>	2,010	1,990	3,153	1%	(37%)
Core EBIT	3,517	4,436	4,976	(21%)	(11%)
<i>Cost of sales</i>	<b>22.4%</b>	23.6%	22.5%	-	-
<i>Sales &amp; Distribution costs</i>	<b>36.1%</b>	33.6%	32.4%	-	-
<i>Administrative expenses</i>	<b>5.7%</b>	5.5%	5.3%	-	-
<i>R&amp;D costs</i>	<b>23.5%</b>	25.7%	18.3%	-	-
<i>EBIT margin</i>	<b>12.3%</b>	11.3%	18.5%	-	-
<i>Core EBIT margin</i>	<b>21.6%</b>	25.1%	29.2%	-	-

1) Includes Other operating expenses, net

# Migraine prevention represents a large and underserved market

## Addressable population (major countries)

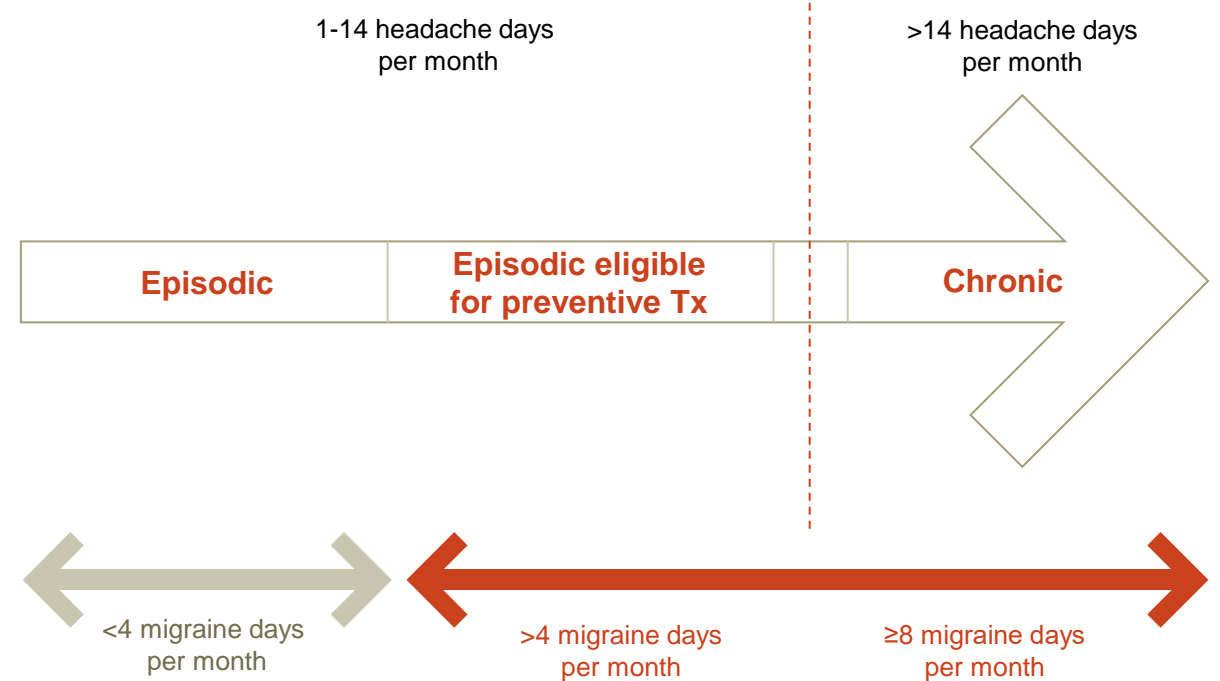
~135m – Migraine prevalence

~55m – Diagnosed patients (~40%)

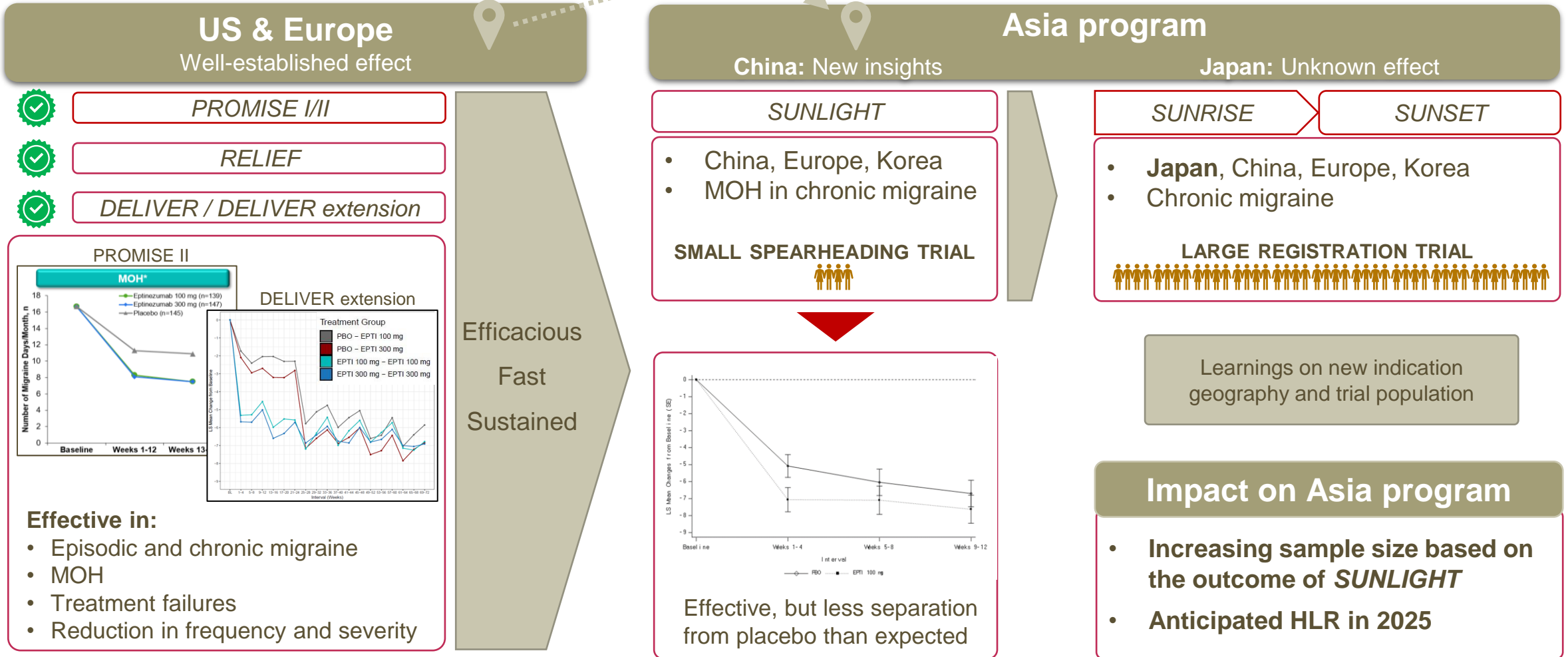
~33m – Eligible for prevention (~60%)

~10m – Currently on prophylactic treatment

Migraine is divided into two major categories, episodic and chronic depending on the frequency of headaches



# Vyepti: Moving into new frontiers; adapting based on learnings



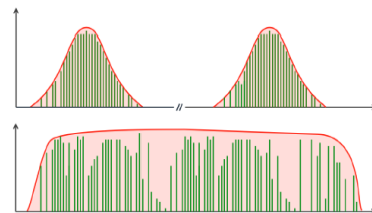
# Eptinezumab: Phase III study for treatment of cluster headache, a crippling pain with few effective medications currently available

Cluster headache affects approximately one in 1,000 people across the world

These are severe attacks of one-sided pain in the head, much stronger than a normal headache

Cluster Headaches are also known as “*Suicide Headaches*” due to the intensity of pain leading to frequent suicide ideation

Duration	15-180 min
Frequency	1-8 times a day
Age of onset	20-40 yrs.
Prevalence	1:1,000
Episodic/chronic ratio	6:1
Male/female ratio	4.3:1



## *ALLEVIATE* phase III study to evaluate eptinezumab in episodic Cluster Headache (eCH)

- Eptinezumab intravenous in ~300 patients with eCH
- Primary endpoint: Change from baseline in number of weekly attacks (Weeks 1–2)
- FPFV commenced in December 2020\*

## *CHRONICLE* phase III study to evaluate safety of eptinezumab in chronic Cluster Headache (cCH)

- Eptinezumab intravenous in ~125 patients with cCH
- Primary endpoint: Number of participants with adverse events
- FPFV commenced in September 2021\*\*

\*) *ClinicalTrials.gov* Identifier: NCT04688775. \*\*) NCT05064397

# Aripiprazole 2M RTU submitted in the U.S., Canada and EU: Potential to further maximize the franchise

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

Clinical study has shown that the new 2-Month LAI formulation provides effective plasma concentrations of aripiprazole over two months, while being well-tolerated

The new 2-Month LAI formulation is an innovative addition to the LAI franchise and has patent protection until the early part of the next decade

Novel formulation with its own IP  
Not a patent extension of Abilify Maintena  
Cannot be substituted by generic Abilify Maintena



**2M** duration in a pre-filled syringe (PFS) will be differentiating as there will be no generic 2M Abilify Maintena on the market



# Two studies in brexpiprazole pivotal program in PTSD ongoing

## Study objective<sup>1</sup>

To evaluate the efficacy, safety, and tolerability of 12-week brexpiprazole + sertraline combination treatment in adult subjects with PTSD

## Two studies initiated in the pivotal programme (phase III)

Brexpiprazole (fixed 2, 3mg and flexible dose up to 3mg) in combination with sertraline

- **Primary endpoint:** Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total score
- **Secondary endpoints:** Change in Clinical Global Impression – Severity (CGI-S) score; Change in Brief Inventory or Psychosocial Functions (B-IPF) score

Lundbeck and Otsuka Pharmaceutical have been seeking phase III program advice from the U.S. FDA

Given FDA guidance, the program will continue with reduced sample size with estimated headline results H2 2023

1) [Clinicaltrials.gov](https://clinicaltrials.gov) ID: NCT04124614 and NCT04174170

# Lu AF82422 (anti alpha-synuclein mAb) in phase II for the devastating disease Multiple System Atrophy (MSA)

MSA – a rare, aggressive, disease with a high unmet medical need<sup>1</sup>

Synucleinopathy; classified as an “atypical parkinsonism” disorder

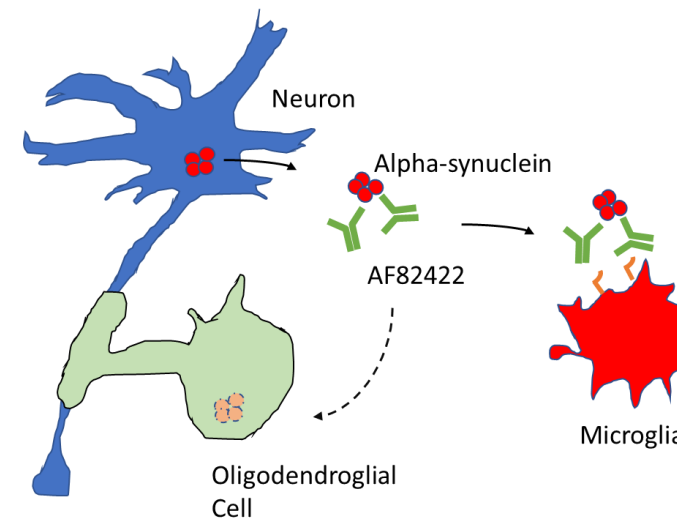
Average time from first symptoms to death 6-9 years

Impacts 4-5 out of 100,000 people

Currently only symptomatic and supportive therapies available

Lu AF82422 has potential to become first therapy capable of delaying disease progression

## Mechanism of Action



- Lu AF82422 inhibits seeding of pathological forms of  $\alpha$ -synuclein in both in vitro and in vivo models
- Potential to induce immune-mediated clearance of pathological  $\alpha$ -synuclein species

1) Krismer F, Wenning GK. Multiple system atrophy: insights into a rare and debilitating movement disorder. *Nat Rev Neurol.* 2017;13(4):232-243

# Lu AF82422: Innovative development program

## Phase II study (*AMULET*)<sup>1)</sup>:

PoC study investigating the effect of Lu AF82422 on disease progression in patients with early multiple system atrophy (MSA)

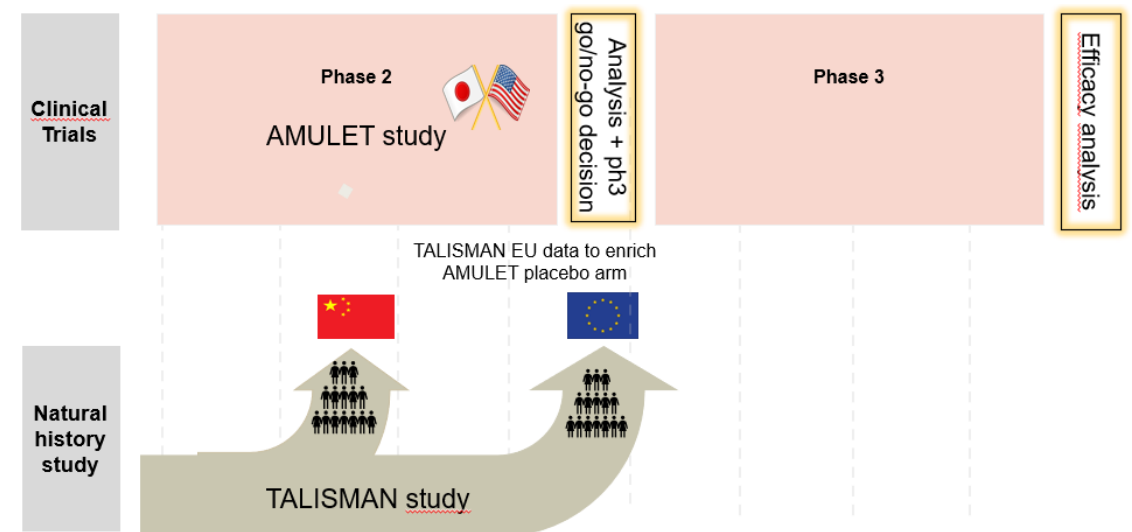
- Biomarker-supported study
- Commenced November 2021

## Primary endpoint:

Change from baseline in the UMSARS<sup>3)</sup> Part I and Part II Total Score (UMSARS TS) at the end of 48-72 weeks of treatment

- N = 60 patients randomized 2:1 (active vs placebo)
- Placebo arm to be enriched with data from the so far largest natural history study (*TALISMAN*) conducted in early MSA<sup>4)</sup>

Phase III study to be guided by phase II data which may influence current assumptions on trial design, sample size, study duration, dose-selection etc.



- The *TALISMAN* study (n≈140) is an observational, retro-prospective, international, multicenter cohort study, which will explore disease progression and related biomarkers in a cohort of relatively early stage MSA patients.
- The *TALISMAN* study will help to better understand the epidemiology of the early stages of the disease over a longer period, compared to previous studies.

1) [Clinicaltrials.gov ID: NCT05104476](https://clinicaltrials.gov/ct2/show/study/NCT05104476). 2) PoC: Proof of Concept. 3) UMSARS: Unified Multiple System Atrophy Rating Scale. 4) [ClinicalTrials.gov Identifier: NCT05453058](https://clinicaltrials.gov/ct2/show/study/NCT05453058)

# Broad MAGLipase program ongoing

## Lu AG06466

Inhibitor of the monoacylglycerol lipase (MAGL) and selective modulator of the endocannabinoid system

CNS penetrant

Ongoing phase Ib studies

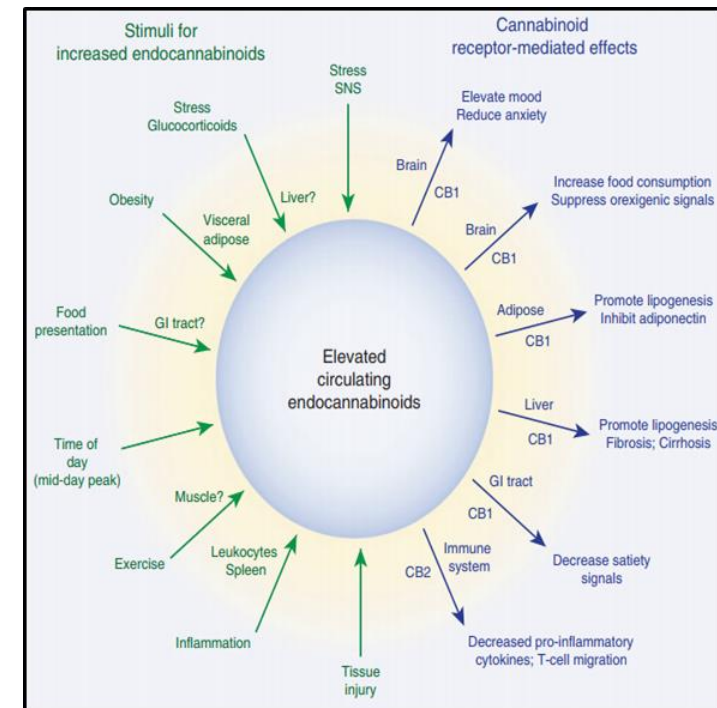
- Spasticity in participants with multiple sclerosis (n=78)<sup>1)</sup>
- PTSD (n=30)<sup>2)</sup>

Phase Ib study in treatment resistant focal epilepsy terminated due to recruitment challenges (July 2022)<sup>3)</sup>

## Lu AG06474

Peripherally restricted

Phase I study initiated in August 2021<sup>4)</sup>



Cecilia J. Hillard; Neuropsychopharmacology REVIEWS (2018) 43, 155–172

1) ) [ClinicalTrials.gov Identifier: NCT04990219](https://clinicaltrials.gov/ct2/show/study/NCT04990219). 2) [ClinicalTrials.gov Identifier: NCT04597450](https://clinicaltrials.gov/ct2/show/study/NCT04597450). 3) [ClinicalTrials.gov Identifier: NCT05081518](https://clinicaltrials.gov/ct2/show/study/NCT05081518). 4) [ClinicalTrials.gov Identifier NCT05003687](https://clinicaltrials.gov/ct2/show/study/NCT05003687)

# Lu AF28996: A potentially new oral treatment for Parkinson's patients experiencing motor fluctuations

## D<sub>1</sub>/D<sub>2</sub>-type agonists

Known to be highly efficacious even in the later stages of Parkinson's (PD), but the currently available agonist (apomorphine) cannot be delivered by oral route

Improving the treatment of fluctuating PD patients answers a strong unmet need and is an attractive commercial target

## Lu AF28996

A highly potent agonist at the D<sub>1</sub>- and D<sub>2</sub>-type dopamine receptors

Designed to solve a long-standing challenge of oral delivery of D<sub>1</sub>/D<sub>2</sub>-type agonists such as apomorphine

Parkinson's disease (moderate to advanced) as adjunct to L-DOPA (or monotherapy pending data)

Further expansion of patient population and symptoms (including non-motor symptoms) are being considered

## Phase I studies:

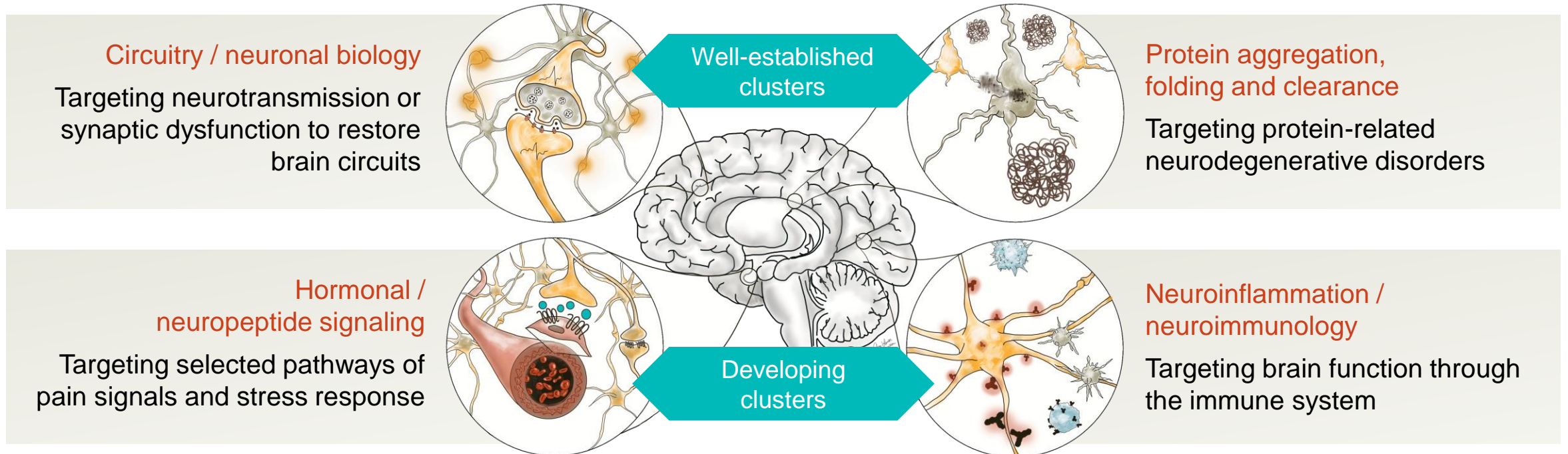
- Single- and sequential-ascending-dose of Lu AF28996 to healthy young men
- Open-label study investigating the safety, tolerability and pharmacokinetic profile of Lu AF28996 in patients with PD
- Phase Ia initiated in May 2018, completed in August 2019<sup>1)</sup>
- Phase Ib initiated Q1 2020<sup>2)</sup>

1) [Clinicaltrials.gov ID: NCT03565094](https://clinicaltrials.gov/ct2/show/study/NCT03565094). 2) [NCT04291859](https://clinicaltrials.gov/ct2/show/study/NCT04291859)

# Focus on promising biology

## Selected four biology clusters feeding into our strategy

Scientifically well-described areas still rich in targets with untapped potential  
 High feasibility for early de-risking and maintaining a competitive edge



# Broad pipeline to sustain future growth

Biology	Project	Area	Phase I	Phase II	Phase III	Filing/launch
Hormonal / neuropeptide signaling	Eptinezumab (anti-CGRP mAb) <sup>1)</sup>	Migraine prevention	SUN-studies			PROMISE 1 & 2
	Eptinezumab (anti-CGRP mAb) <sup>1)</sup>	Episodic cluster headache	ALLEVIATE			
	Eptinezumab (anti-CGRP mAb) <sup>1)</sup>	Chronic cluster headache	CHRONICLE			
	Lu AG09222 (anti-PACAP mAb) <sup>2)</sup>	Migraine prevention	HOPE			
Circuitry / neuronal biology	Brexiprazole <sup>3)</sup>	Agitation in Alzheimer's disease				
	Brexiprazole <sup>3)</sup>	PTSD				
	Aripiprazole 2-month injectable formulation <sup>4)</sup>	Schizophrenia & bipolar I disorder				
	Lu AF28996 (D1/D2 agonist)	Parkinson's disease				
	Lu AG06466 (MAGL inhibitor) <sup>5)</sup>	MS spasticity, PTSD				
Protein aggregation, folding and clearance	Lu AF82422 (anti alpha-synuclein mAb)	Synucleinopathies (MSA)	AMULET			
	Lu AF87908 (anti-Tau mAb)	Tauopathies				
Neuroinflammation / neuroimmunology	Lu AG22515 (CD40L inhibitor)	Neurology				

1) CGRP: Calcitonin gene-related peptide. 2) PACAP: Pituitary adenylate cyclase-activating polypeptide. 3) Acts as a partial agonist at 5-HT<sub>1A</sub> and dopamine D<sub>2</sub> receptors at similar potency, and an antagonist at 5-HT<sub>2A</sub> and noradrenaline alpha<sub>1B/2C</sub> receptors. 4) Life cycle management in partnership with Otsuka Pharmaceuticals. 5) MAGL: Monoacylglycerol lipase

# For more information, please contact Investor Relations

Listed on the Copenhagen Stock Exchange since June 18, 1999

For additional company information, please visit Lundbeck at: [www.lundbeck.com](http://www.lundbeck.com)

Number of A-shares	199,148,222
Number of B-shares	796,592,888
Total	<u>995,741,110</u>
Treasury shares <sup>1</sup>	502,115 (0.25%)
Insider holdings <sup>1</sup>	156,348 (0.08%)
Classes of shares	2
Restrictions	None
ISIN code	DK0061804697 (A) DK0061804770 (B)
Bloomberg ticker symbol	HLUNA DC and HLUNB DC

1) 2021 Annual Report. Data based on one share class

## IR contact

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## Financial calendar

<b>FY 2022</b>	February 8, 2023
<b>Q1 2023</b>	May 10, 2023
<b>Q2 2023</b>	August 16, 2023
<b>Q3 2023</b>	November 8, 2023