



# Investor Presentation

# Q1 2020

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Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with products that are prescribed for unapproved uses, are made taking into account past performances of other similar drugs for similar disease states or past performance of the same drug in other regions where the products are currently marketed. It is important to note that although physicians may, as part of their freedom to practice medicine in the U.S., prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.



# Lundbeck at a glance

## History

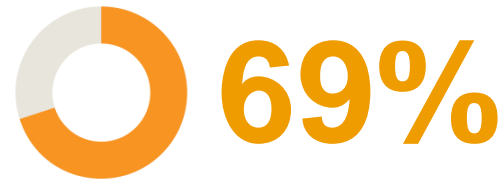
- ★ Lundbeck was founded by Hans Lundbeck in 1915 in Copenhagen



# 1915

## Ownership

- ★ Largest shareholder is the Lundbeck Foundation, which annually grants DKK ~500 million to research



## Specialized in brain health

- ★ ~70 years of expertise in treatments of brain diseases
- ★ Among the first to develop and market antipsychotics

# 70 years

## 2019 Revenue

- ★ ~58% generated in North America
- ★ China 2<sup>nd</sup> largest market



# DKK 17.0bn

(~\$2.5bn)

## Global presence

- ★ Headquartered in Denmark
- ★ 50+ countries

# 50+



## Five strategic brands (55% of rev.)

**Brintellix**  
vortioxetine

**Trintellix**  
vortioxetine

**Northera**  
(droxidopa) capsules

**vyepiti**

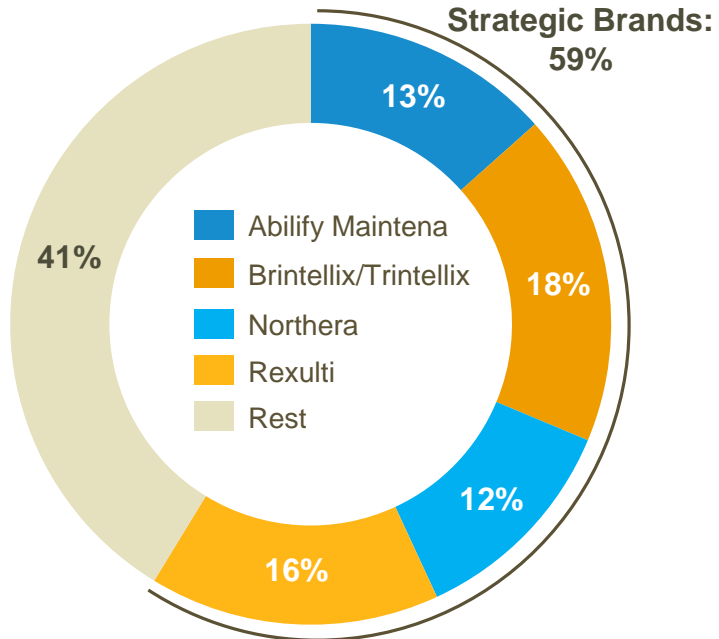
**REXULTI**  
brexpiprazole tablets

**Abilify Maintena**  
(aripiprazole) for extended release injectable suspension

# Diverse portfolio across products and regions with geographical footprint well aligned to global CNS market

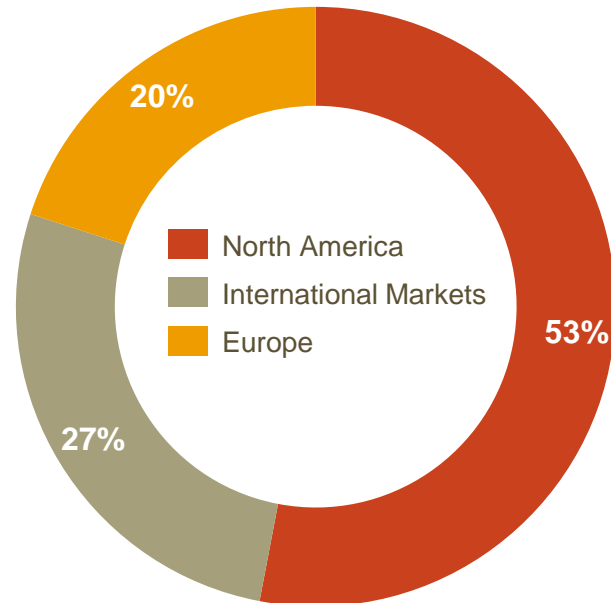
## Lundbeck product diversity

Sales by product (Q1 2020)



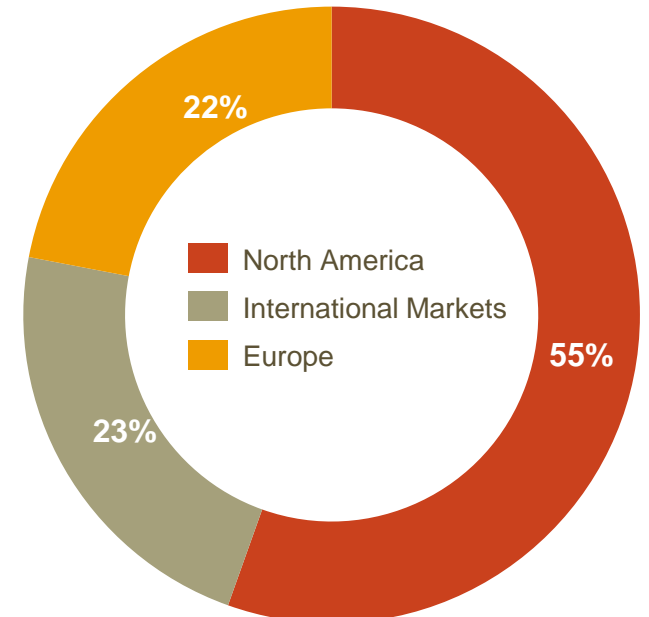
## Lundbeck geographic split

Sales by region (Q1 2020)



## Global CNS market split<sup>(1)</sup>

Sales by region (FY 2018)



1) IQVIA 2018 Data

# Strong financial performance in Q1 2020

## Revenue

DKK 4,564 million  
+8%

## Strategic brands

DKK 2,680 million  
+35%

## Core EBIT

DKK 1,357 million  
-4%

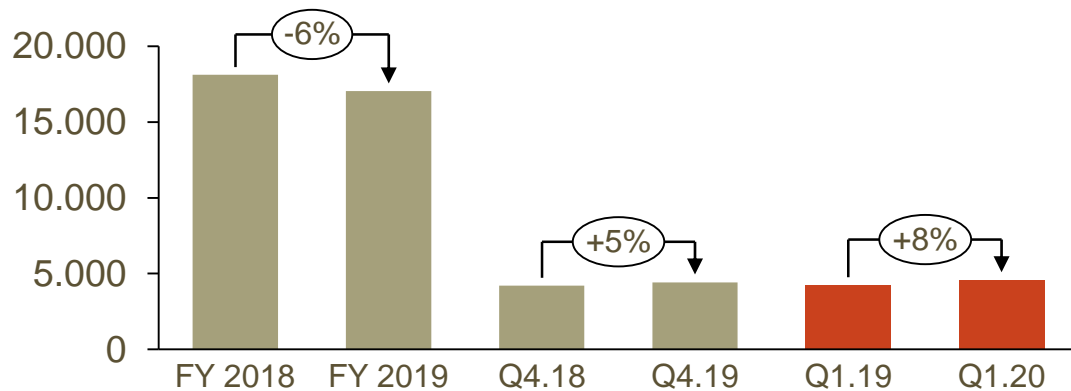
## Core EBIT margin

29.7%  
-3.6pp

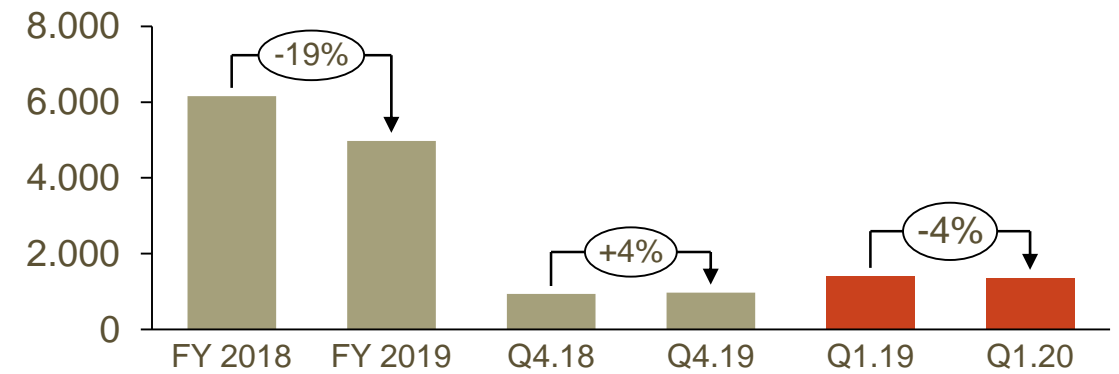
- Revenue grew due to strongly increased demand of medicines
- Growth was partly due to increase in the real demand of products and partly due to inventory increases driven by the COVID-19 pandemic
- Vyepti approved and launched in the U.S. – submitted for approval in Canada, Australia and Switzerland
- Financial guidance for 2020 maintained

# Lundbeck's revenue shows solid growth momentum, earnings impacted by Vyepti launch costs

**Revenue performance**  
(DKKm)



**Core EBIT performance**  
(DKKm)



- Revenue continues to grow as U.S. neurology products are being washed out; the quarter had a positive impact from stocking as a consequence of the COVID-19 pandemic
- In the quarter, core EBIT-margin reaches 29.7% compared to 33.3% the previous year despite investments in commercial infrastructure and added operational costs related to Lundbeck Seattle

# Update on COVID-19

Lundbeck's priorities have been and still are the health and safety of our employees, product supply to ensure patients' access to medicine and business continuity

## Q1 2020:

- Safeguarding product supply, production, logistics and operations
- Positive impact from stocking especially in Europe and the U.S. Some weakness in China
- Several clinical programmes delayed
- Extensive use of technology to support work from home/increased digitalization


## Current business:

- Continued strong momentum for strategic brands
- China reopening and moving towards normal
- Encouraging interest in Vyepiti
- Impact on patient recruitment and new site activation in clinical trials

# Vyepti launch update – very early days, but encouraging interest

- Vyepti was made available to patients on 6 April 2020, and the first patients received therapy on 7 April
- Several key clinics received Vyepti already in the first week and many more since
- Phased launch approach starting with virtual HCP engagement. Customer facing engagement will commence when appropriate
- Encouraging interest in enrolling in the *Vyepti Connect*<sup>1)</sup> and *Vyepti Go*<sup>2)</sup>
- Several payers have issued coverage policies, e.g. Anthem, Highmark, BCBS of NJ, Premera, etc.



 **vyepti**<sup>™</sup>  
(eptinezumab-jjmr)  
100 mg/mL injection

1) Access and reimbursement support program. 2) Patient support program



# Maximising the value of Vyepti

- *RELIEF* study continues to randomize patients. Conclude Q4.20
- Indication expansion in cluster headache planned to start Q4.20
- European market access study (phase IIIb) to start mid-2020
- First phase of Japanese PK/PD study finalized as planned; development strategy for Asia progressing
- Further indication expansion in planning

## Submissions

- Canada: Expected approval Q1 2021
- Australia: Expected approval Q2 2021
- Switzerland: Expected approval Q4 2021



**vyepti**<sup>™</sup>  
(eptinezumab-jjmr)  
100 mg/mL injection

# Robust financial performance in Q1 2020 - Investments in new products and reduced exposure to generic erosion

## Revenue

- Continued strong momentum for strategic brands
- Positive impact from patient refilling and stocking due to COVID-19 pandemic
- Continued erosion of mature U.S. neurology franchise

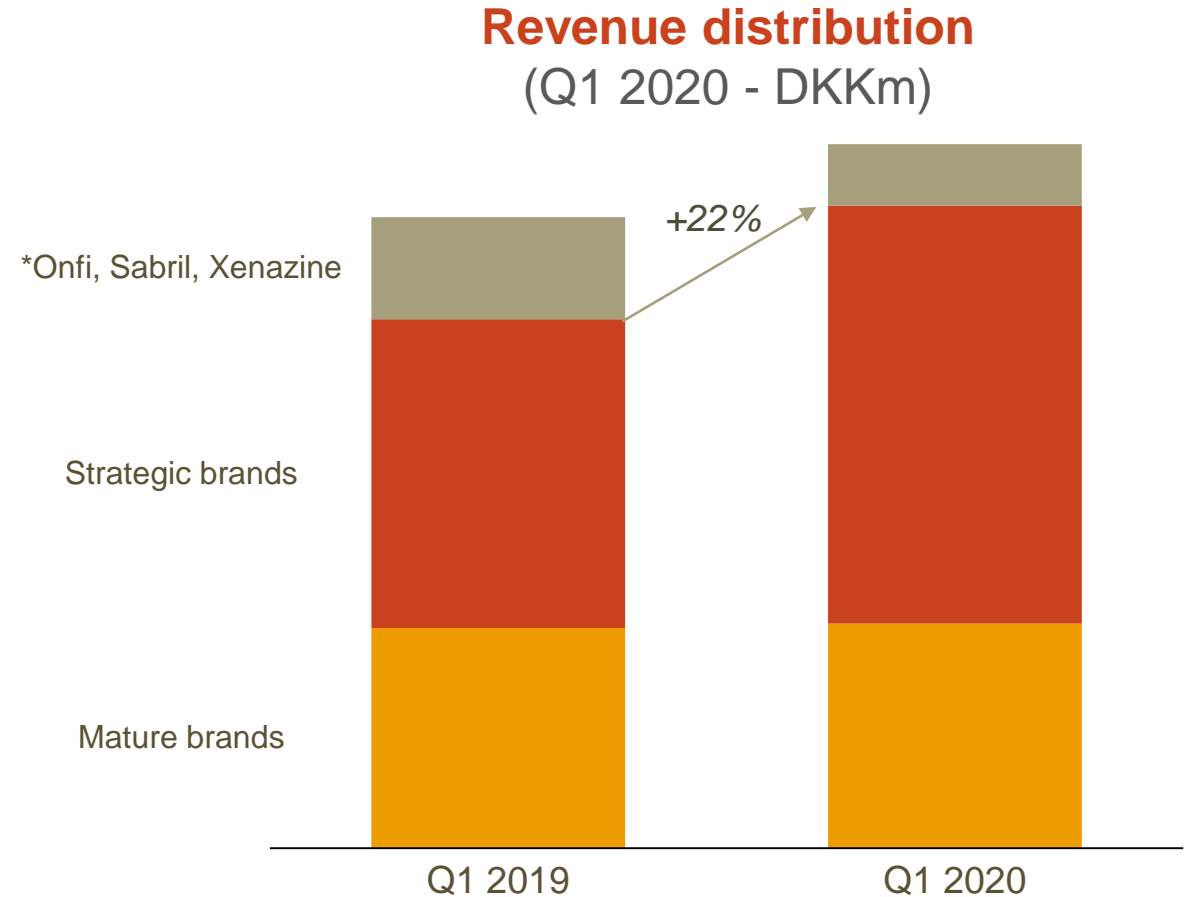
## Margins

- Gross margin in line with expectations
- Operational costs increased as expected and impacted by impairment of foliglurax product rights (EUR 100m)
- Core tax rate 22.8% vs. 24.5% in Q1 2019

DKKm	Q1 2020	Δ% y/y	FY 2019	Δ% y/y
Revenue	4,564	8%	17,036	(6%)
<i>Gross margin</i>	<b>82.4%</b>	1.9pp	80.1%	-0.8pp
Operational expenses	3,391	53%	9,529	+2%
Other operating items, net	(30)	-	(514)	-
EBIT	338	(72%)	3,608	(32%)
<i>EBIT margin</i>	<b>7.4%</b>	-20.9pp	21.2%	-8.1pp
Core EBIT	1,357	(4%)	4,976	(19%)
<i>Core EBIT margin</i>	<b>29.7%</b>	-3.6pp	29.2%	-4.8pp
Net financials	(97)	-	(127)	-
<i>Effective tax rate</i>	<b>37.5%</b>	-10.5pp	23.4%	-2.7pp
EPS	0.76	(83%)	13.42	(32%)
Core EPS	4.89	(11%)	19.46	(18%)

# Revenue up 22% excluding sales from U.S. neurology products\* currently exposed to impact from LOE

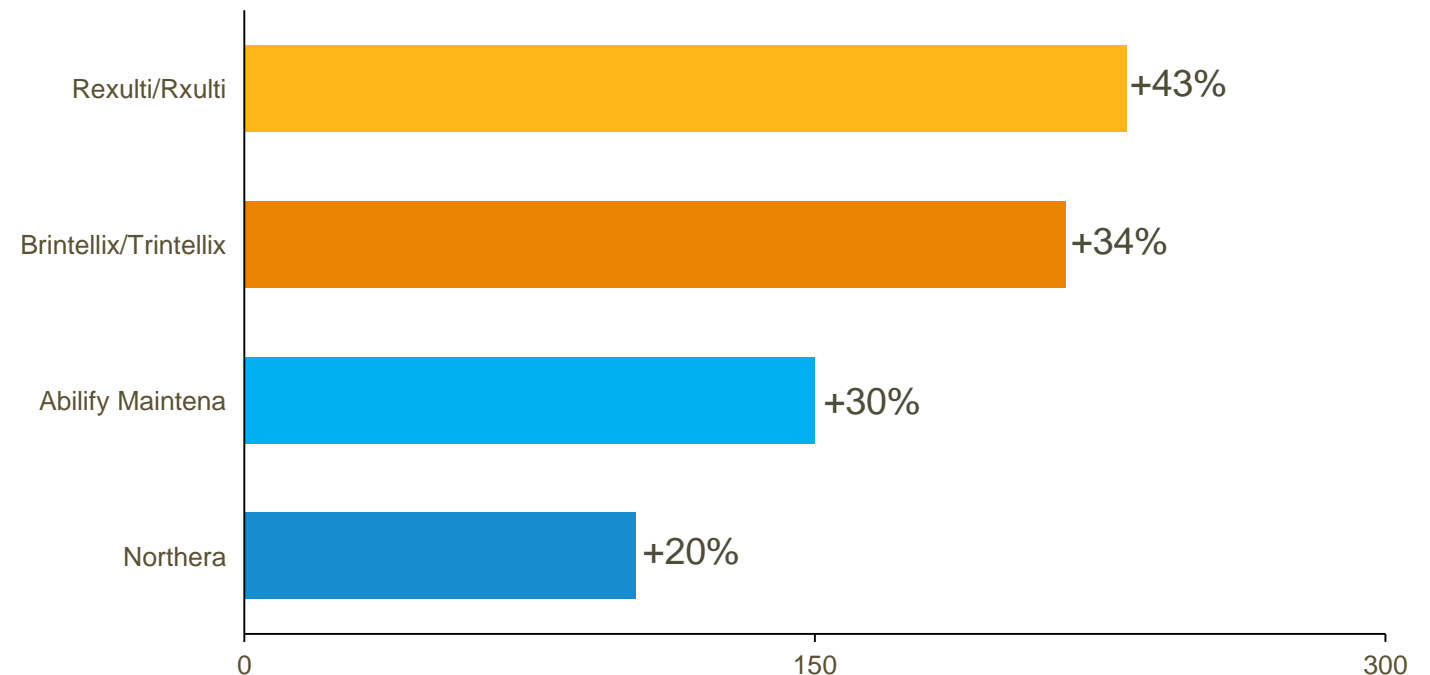
- Strategic brands up 35% in the quarter
- Excluding U.S. neurology products\* with LOE, revenue up by 22%
- Mature brands stable
- Focus on maximizing existing brands has successfully driven strong growth
- Future growth less impacted by decline in U.S. neurology products



# Lundbeck's four strategic brands added DKK 701 million in additional revenue in Q1 2020

- **Strategic brands\***: Up 35% (32% in L.C.) to DKK 2,680 million representing 59% of total revenue
- **Rexulti/Rxulti**: Up 48% to DKK 713 million
- **Brintellix/Trintellix**: Up 36% to DKK 817 million
- **Abilify Maintena**: Up 33% to DKK 612 million
- **Northera**: Up 24% to DKK 538 million
- **Vyepti**: Phased launch commenced in April 2020 in the U.S.

**Strategic brands' growth**  
(Q1 2020 – DKKm and CER growth)

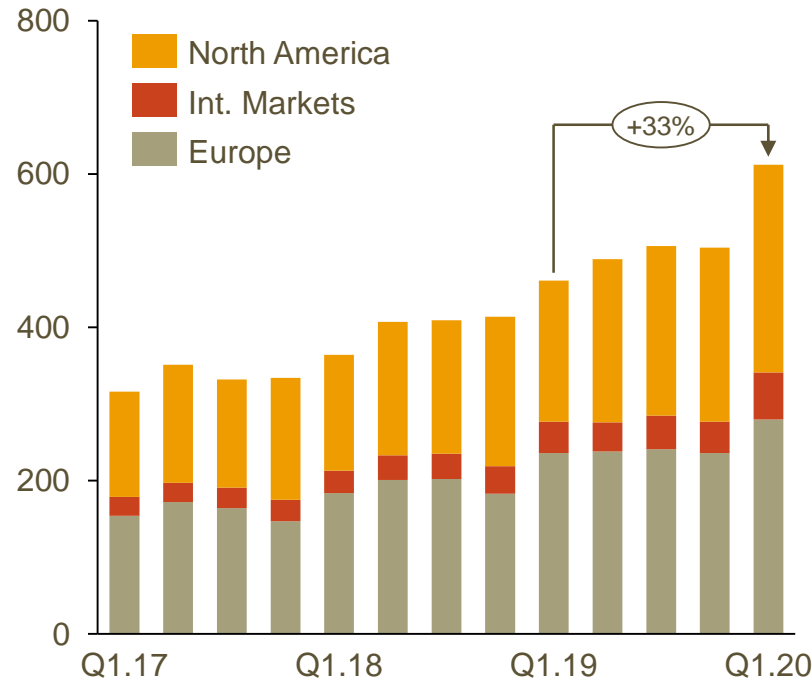


\*) Abilify Maintena, Brintellix/Trintellix, Northera and Rexulti/Rxulti

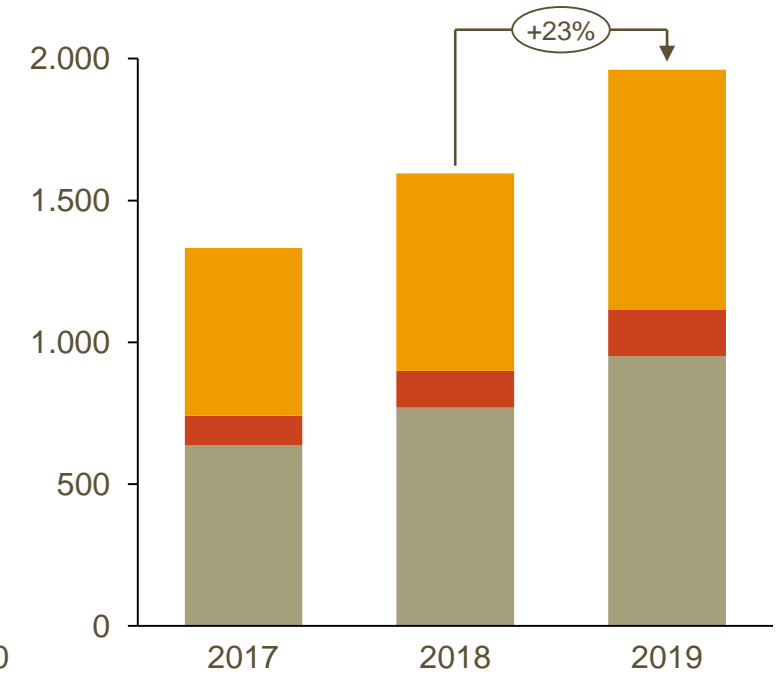
# Abilify Maintena continues its robust growth but also benefitting from inventory increases in the U.S. following COVID-19

- Grew 33% (30% in L.C.) to DKK 612 million in Q1 2020
- Continued solid traction in value share gains
  - >25%: Australia, Canada, Italy, Switzerland and UK
  - >20%: Denmark, Finland, France, Norway, Spain and Sweden
- LAI market continues double-digit growth to USD 1.4bn (Q1.2020) <sup>1)</sup>
- Abilify Maintena’s share of the LAI market is 19.5% compared to 16.6% in Q1.2019<sup>1)</sup>

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



Abilify Maintena sales\*  
(FY - DKKm)



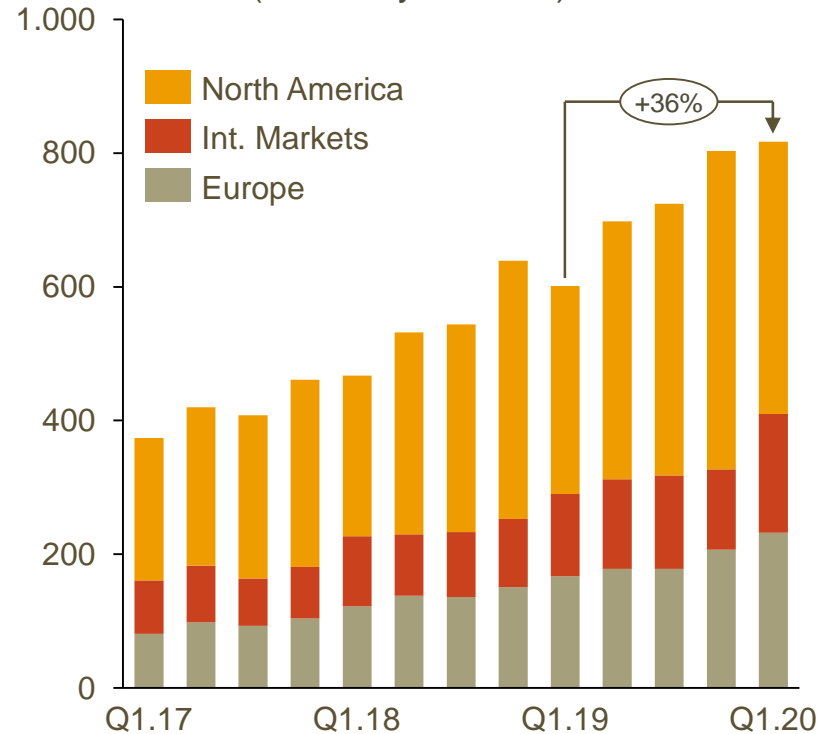
1) Reported net sales of atypical LAIs

\*) Lundbeck’s share of revenue

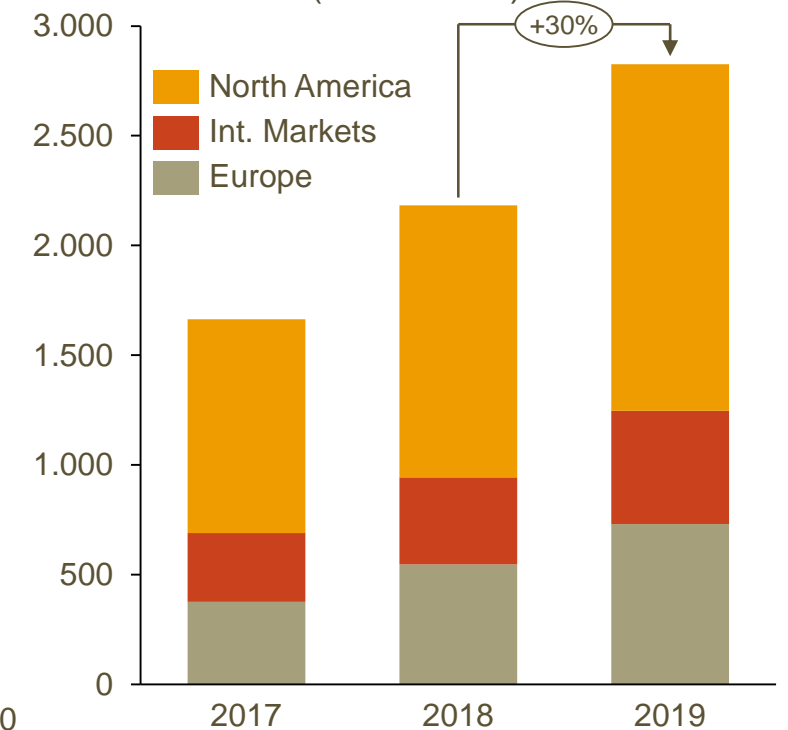
# Brintellix/Trintellix continues its significant growth momentum

- Grew 36% (34% in L.C.) to DKK 817 million in Q1 2020
- Continued solid traction in value share gains<sup>1)</sup>
  - >10%: Finland, France, Italy, Norway, Sweden and the U.S.
  - >7%: Canada, Denmark, Spain
  - >4%: Australia, Mexico, Switzerland and Turkey
- In the U.S., volume is up 15% y/y in Q1 2020<sup>2)</sup>
  - U.S. value share of 22.6%<sup>2)</sup>
- Trintellix launched in Japan in November 2019

**Brintellix/Trintellix sales per region**  
(Quarterly - DKKm)



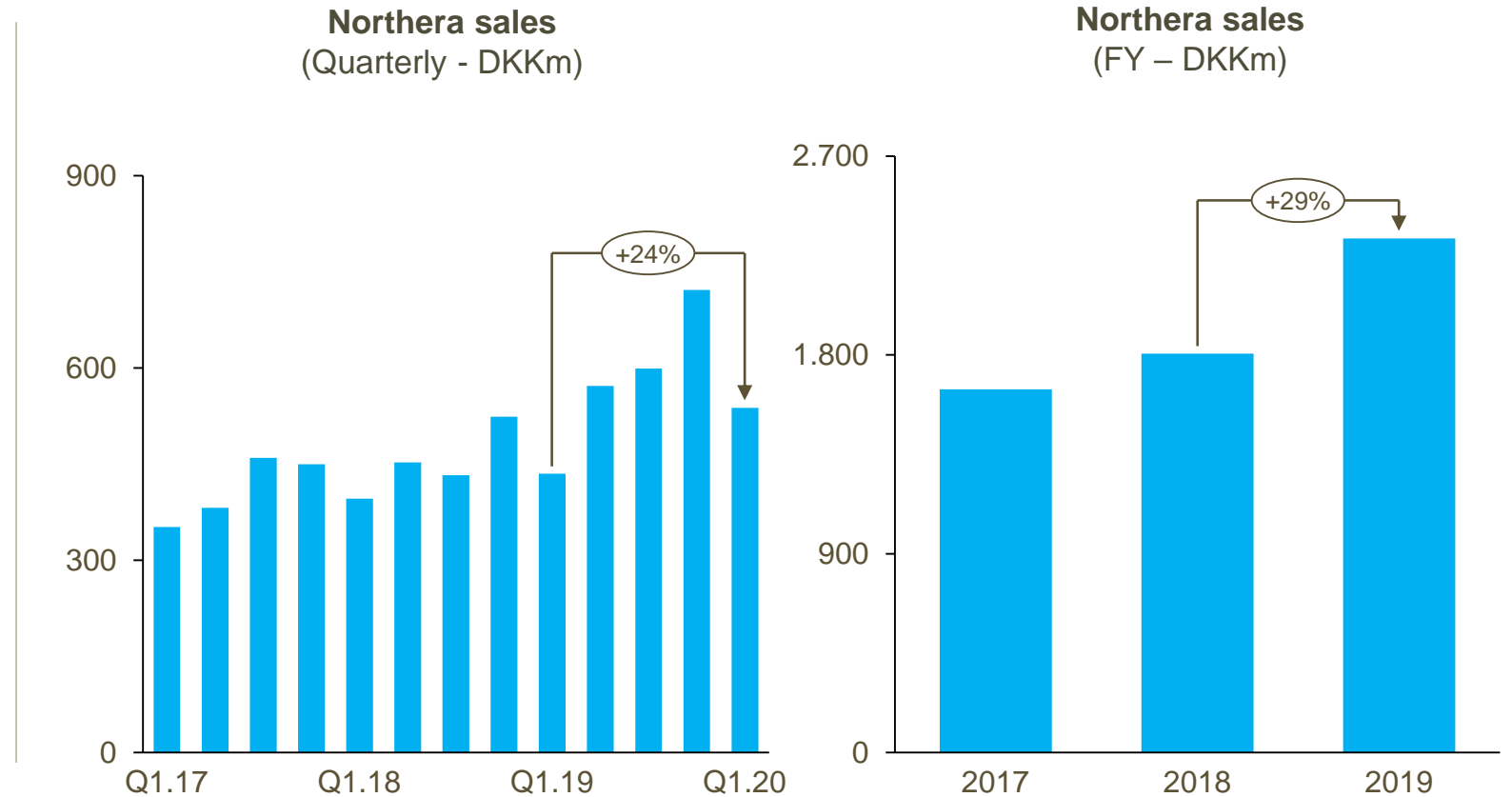
**Brintellix/Trintellix sales**  
(FY - DKKm)



1) IQVIA, February 2020. 2) Symphony Health (c.f. Bloomberg)

# Northera shows solid growth in sales and demand

- Grew 24% (20% in L.C.) to DKK 538 million in Q1 2020
- Volume is up 8%<sup>1)</sup> compared to Q1 2019
- Northera impacted by normal quarterly fluctuations driven by e.g. seasonality and pharmacies' buying pattern
- Lundbeck only promotes Northera in the U.S.

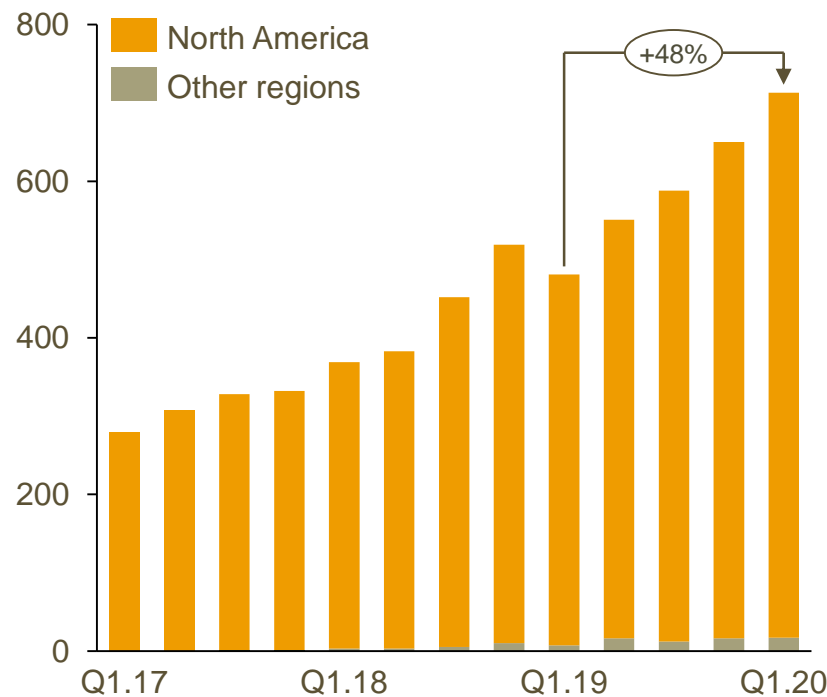


<sup>1)</sup> Symphony Health (c.f. Bloomberg)

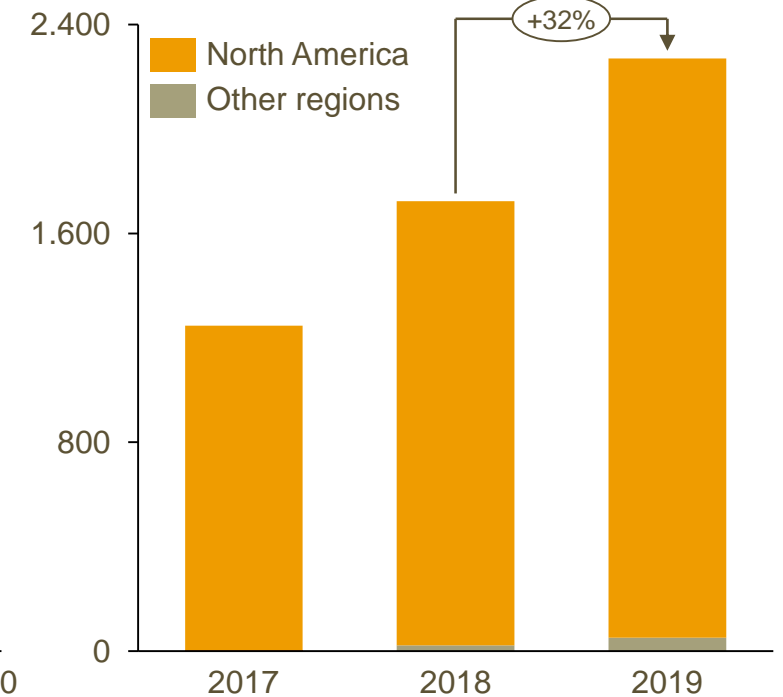
# Rexulti shows significant growth mainly driven by demand, but is also benefitting from inventory increases in the U.S.

- Grew 48% (43% in L.C.) to DKK 713 million in Q1 2020
- In the U.S., volume is up 22% y/y in Q1 2020<sup>1)</sup>
- Continued solid traction in value share gains<sup>2)</sup>
  - >9%: USA
  - >4%: Mexico
  - >2%: Australia, Canada, Mexico, Saudi Arabia
- The Brazilian Regulatory Agency has approved Rexulti as adjunctive treatment in MDD

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



**Rexulti sales\***  
(FY - DKKm)



1) Symphony Health (c.f. Bloomberg). 2) IQVIA, February 2020

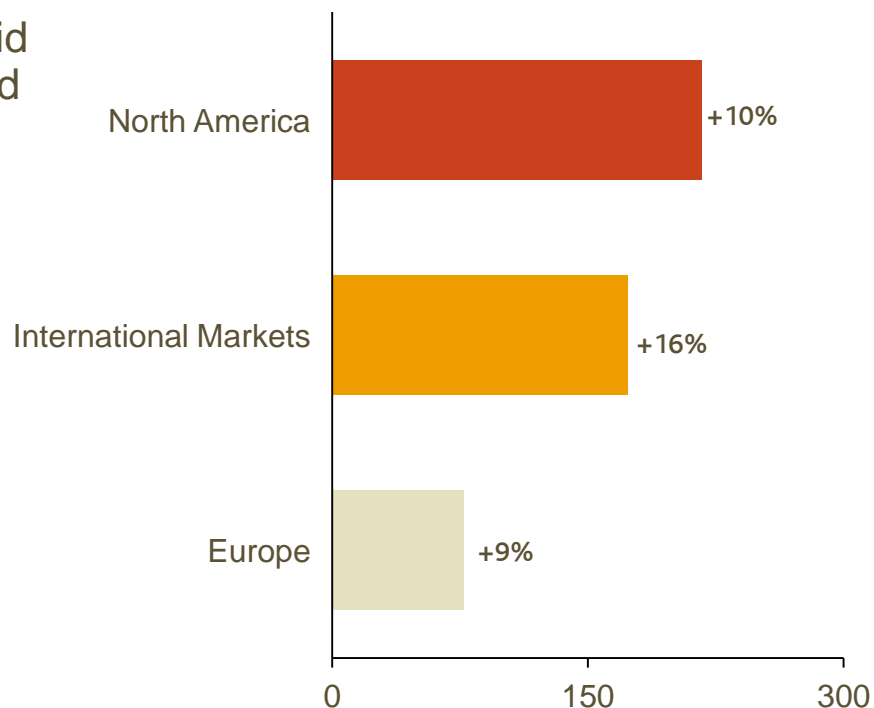
\*) Lundbeck's share of revenue



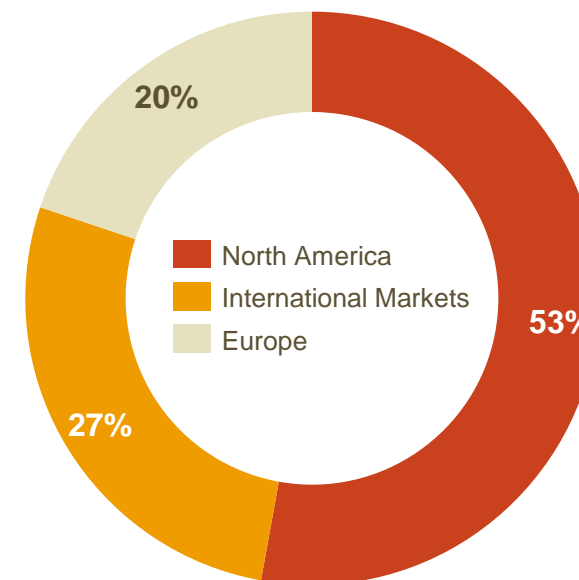
# All regions have returned to solid growth

- Strong improvement in both growth and profitability in **Europe**
- **International Markets** shows solid growth driven by e.g. Australia and Japan
- **North America** impacted by generic erosion, mainly Onfi
  - Growth of 21% excluding Onfi
- Largest markets are the U.S., China, Canada, Spain, Italy, France and Japan constituting >70% of sales<sup>#</sup>

**Regional growth**  
(Q1 2020 - DKKm)



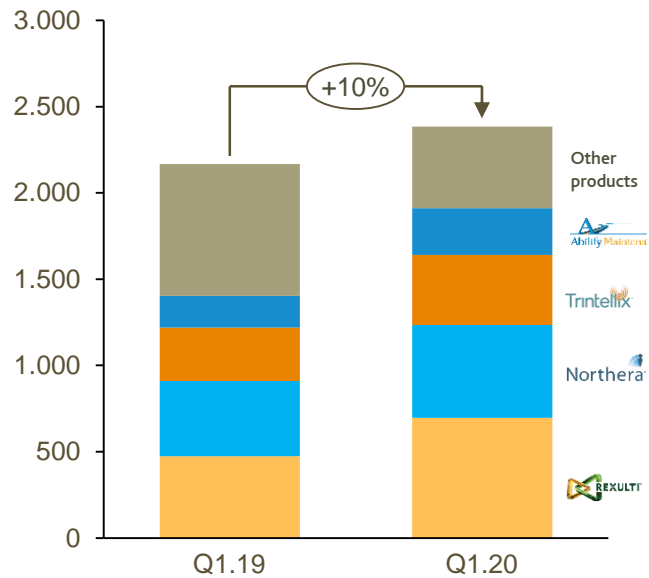
**Sales by region<sup>#</sup>**  
(Q1 2020)



<sup>#</sup>) Excluding Other revenue and effects from hedging

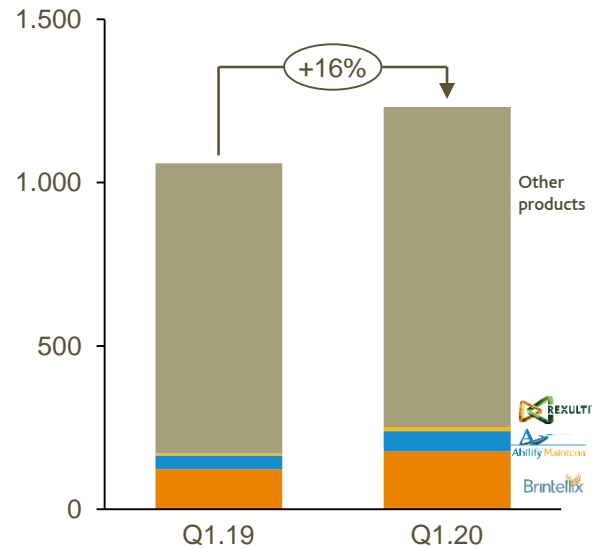
# Solid growth in all three regions

North America revenue  
(Q1 - DKKm)



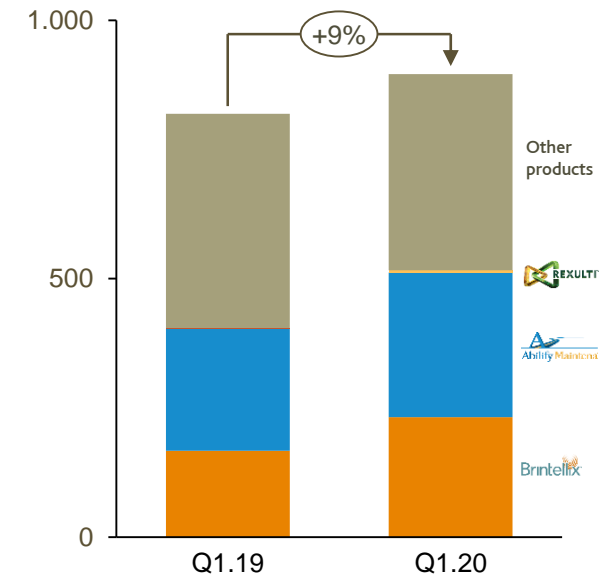
- Strategic brands up 36% to DKK 1,912m
- 32% growth ex. Onfi, Sabril and Xenazine
- Vyepti will add modestly to growth in 2020

International Markets revenue  
(Q1 - DKKm)



- Strategic brands up 47% to DKK 252m
- Cipralelex/Lexapro continues to perform well

Europe revenue  
(Q1 - DKKm)



- Strategic brands up 28% to DKK 516m
- Abilify Maintenance and Brintellix show strong growth in major markets and across other European markets

# Solid financial position

## Selected cash flow figures

DKKm	Q1 2020	Q1 2019	FY 2019
Cash flows from operating activities	188	837	2,609
Cash flows from investing activities	(68)	(63)	(7,755)
Free cash flow	120	774	(5,146)
Cash flows from financing activities	(836)	(2,418)	4,548
Net cash flow for the period	(716)	(1,644)	(598)

## Selected balance sheet figures

DKKm	31.03.2020	31.12.2019
Intangible assets	22,652	23,399
Total assets	34,867	35,757
Equity	14,074	14,554
Non-current liabilities	12,928	10,923
Current liabilities	7,865	10,280
Cash, bank balances and securities	2,287	3,012
Interest-bearing debt	(9,638)	(9,578)
Net debt	(7,351)	(6,566)

- **Dividend pay-out, net:** DKK 815m for 2019 or DKK 4.10 per share paid in March 2020
- **Net debt:** Net debt position of around DKK 6 billion expected by the end of 2020
- **Net debt/EBITDA:** Expected to reach 1.5x by end of 2020 vs. 1.4x by the end of 2019

## 2020 guidance maintained

- Continued strong growth for strategic brands
- Increased uncertainty following the COVID-19 pandemic
- Substantial investments in launch and R&D activities for Vyepti
- Expected effects from hedging is a loss of around DKK 150 - 200 million
- Expected net financial expenses of DKK 300-400 million
- Financial guidance based on currency levels end-April 2020\*

### 2020 financial guidance

DKK	FY 2019 actual	FY 2020 guidance
Revenue	17,036m	<b>17.4 – 18.0bn</b>
EBITDA	4,823m	<b>3.9 – 4.4bn</b>
Core EBIT	4,976m	<b>3.5 – 4.0bn</b>
EBIT	3,608m	<b>1.4 – 1.9bn</b>

*\*) Lundbeck's main trading currencies are the USD, CNY, CAD and JPY. The financial guidance is based on the current hedging rates for our main currencies; i.e. USD/DKK (6.57), JPY/DKK (0.0625), CAD/DKK (4.99) and CNY/DKK (0.95)*

# Project status

All studies heavily impacted by COVID-19

Intensive LCM programme for **Rexulti** continues

Continued emphasize on **Lundbeck La Jolla research platform** to reveal full potential of serine hydrolases

- Focused effort for **Lu AG06466** in exploratory clinical studies in psychiatry and neurology, such as MS spasticity and focal epilepsy

No further development in **foliglurax** program

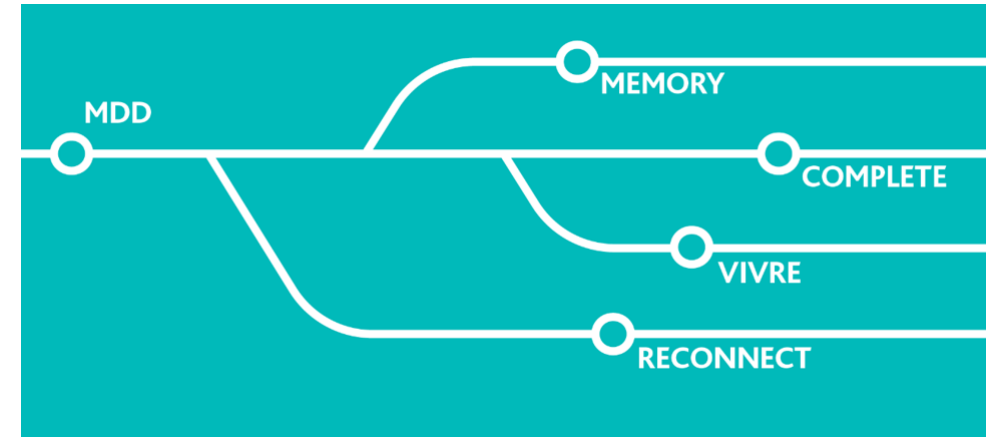
Project	Area	Phase I	Phase II	Phase III	Filing
Eptinezumab (anti-CGRP mAb)	Migraine prevention				★
Brexiprazole	Agitation in Alzheimer's disease			★	~2021
Brexiprazole	PTSD			★	≥2023
Brexiprazole	Borderline Personality Disorder		★		≥2025
Lu AF11167 (PDE 10 inhibitor)	Schizophrenia		★		≥2025
Aripiprazole 2-month injectable	Schizophrenia+bipolar I disorder	★			~2021
Lu AF82422 (alpha-synuclein mAb)	Synucleinopathies	★			>2025
Lu AF28996 (D1/D2 agonist)	Parkinson's disease	★			>2025
Lu AG06466 (MAGLi)	Neurology/psychiatry	★			>2025
Lu AF88434 (PDE1B inhibitor)	Cognitive dysfunction	★			>2025
Lu AG09222 (PACAP mAb)	Migraine	★			>2025
Lu AF87908 (Tau mAb)	Tauopathies	★			>2025

# Brintellix/Trintellix: *COMPLETE* study finalized with significant reduction in emotional blunting in MDD

- Nearly half of patients treated with SSRIs or SNRIs report suffering from 'blunted emotions'
- Blunted emotions have real functional consequences for patients' social, family and work lives
- Evaluated the effectiveness of 10–20 mg/day vortioxetine on emotional blunting in patients with MDD and a partial response to SSRI / SNRI

## Key findings of the *COMPLETE* study:

- 50% report absence of emotional blunting after 8 weeks of treatment with vortioxetine 10 or 20 mg. Highly statistically significant
- Significant effect on emotional blunting observed already after 1 week of treatment
- Improvement in emotional blunting was followed by improvement in overall functioning, motivation and energy (mental and physical)



**Brintellix**  
vortioxetine

**Trintellix**<sup>™</sup>  
vortioxetine  
5mg·10mg·20mg tablets

MDD: Major Depressive Disorder. SSRI: Selective serotonin reuptake inhibitor. SNRI: Serotonin–norepinephrine reuptake inhibitors

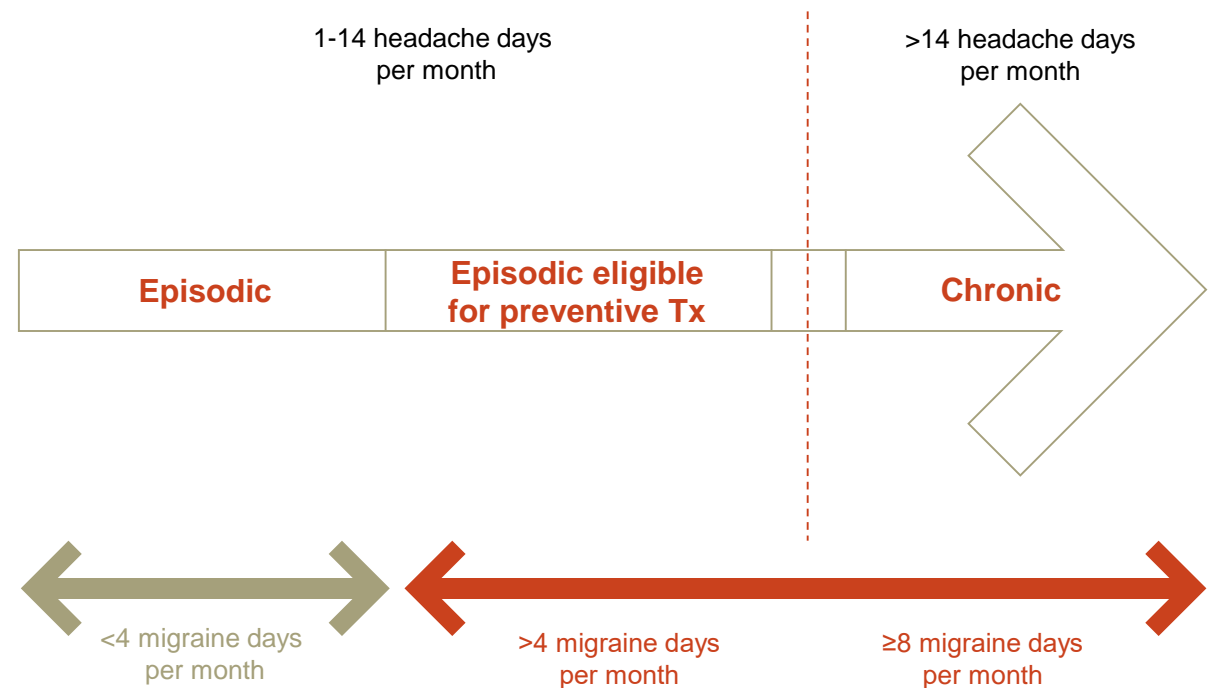
# Migraine prevention represents a large and under served market

## Addressable population (major countries<sup>1</sup>)

- ~134m – Migraine prevalence
- ~41m – Diagnosed patients (30%)
- ~18m – Eligible for prevention (43%)
- ~9m – Currently on prophylactic treatment

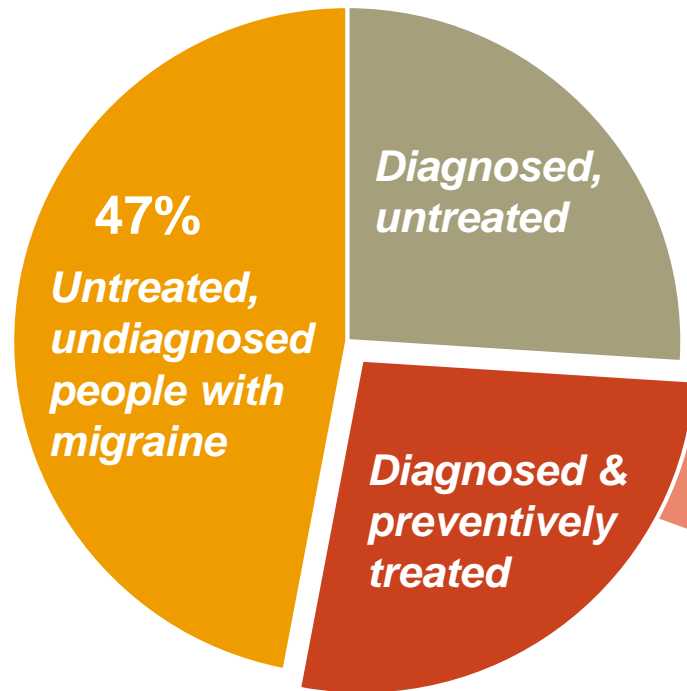
1) Decision Resource, DRG 2018 Migraine Market Report. Covers G7+China

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



# Ready to launch Vyepti in the U.S.

Migraine prevention market: 13.9m<sup>1, 2</sup>



## Breakout of 27% treated group

Preventive Treatment	% of Use <sup>3</sup>
Botox	10%
Anti-CGRPs	5%
Other preventive treatments (Topiramates, beta-blockers, other anti-seizures, amitryptaline)	85%*

As of 9/13/19 IQVIA Xponent PlanTrak data<sup>4</sup>

- ~200K patients are currently on anti-CGRP therapy
- ~25-30K new patients enter the anti-CGRP market

\* Some patients are on combo therapy such as anti-CGRP + topiramates. For purpose of this analysis, patients on multiple therapies are deduped.

1) 2018 DRG Migraine Market Landscape & Forecast. 2) Lipton 2007; 13.9M= 62% 4+ Migraines, 38% 15+. 3) 2019 Truven Health Analytics. 4) IQVIA Xponent PlanTrak 9/13/19



# Two large pivotal studies including ~2,000 patients demonstrated sustained efficacy and good tolerability

## Promise 1

### in Episodic Migraine Patients

(N=888)

- **Primary endpoint:** Change from baseline in MMDs over weeks 1-12
- Baseline: ~9 migraine days/month
- 30mg, 100mg, 300mg or placebo
- Up to 4 quarterly infusions

## Promise 2

### in Chronic Migraine Patients

(N=1,072;)

- **Primary endpoint:** Change from baseline in MMDs over weeks 1-12
- Baseline: ~16 migraine days/month
- 100mg, 300mg or placebo
- Up to 2 quarterly infusions



### Powerful

≥50%, ≥75% and 100% reductions in migraine days

### Fast

Onset of prevention  
Day One post-infusion

### Sustained

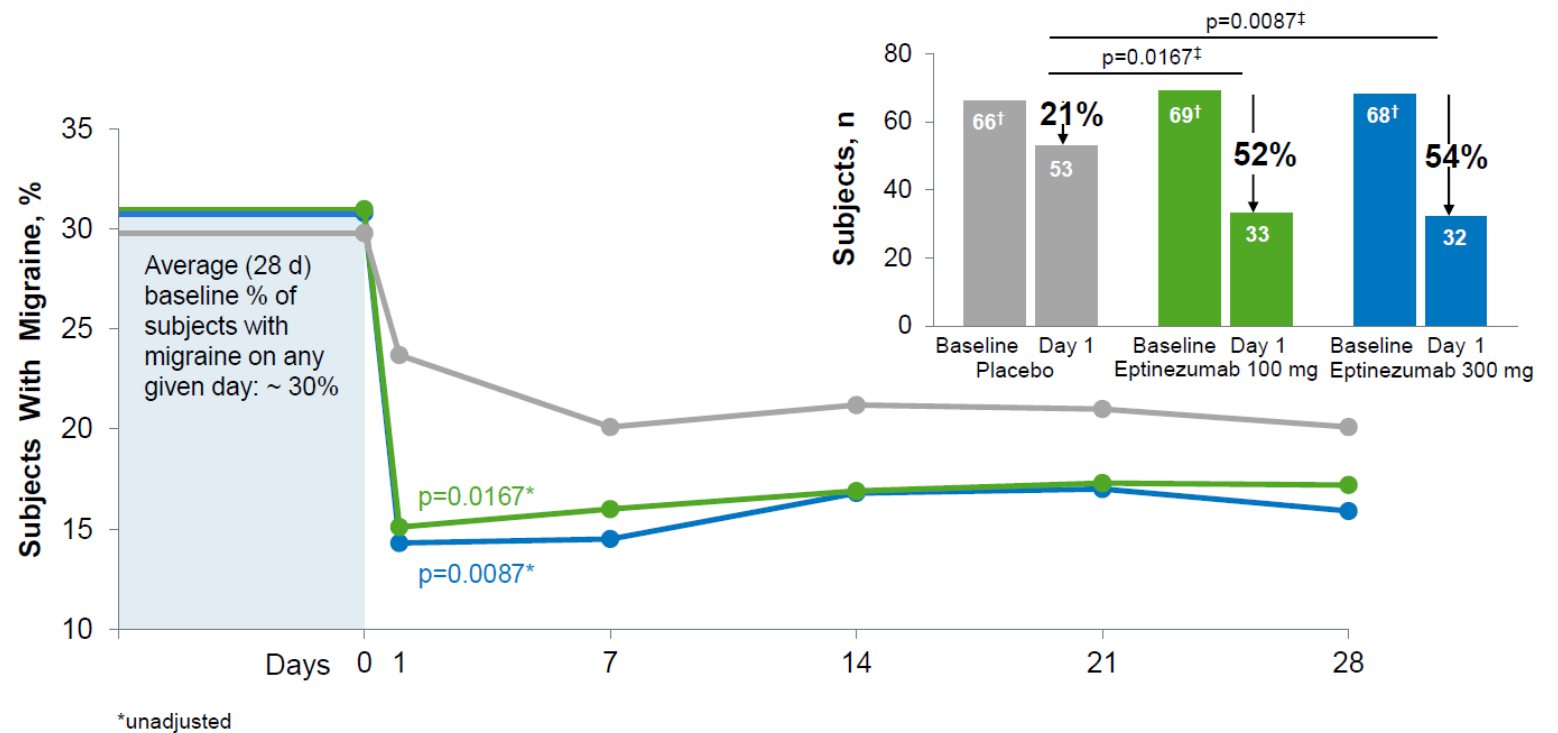
for 3 months following a single administration and sustained or further increased with subsequent infusions

### Meaningful

Significant improvement in patient reported outcome (HIT-6)

# PROMISE 1: A phase III study to evaluate the efficacy and safety of eptinezumab for prevention of frequent episodic migraine

- Eptinezumab reaching statistical significance for the primary and all key secondary endpoints
- Migraine day prevalence dropped over 50% on Day 1 and reduction was sustained through Day 28
- Subjects experienced significantly fewer days with migraine
- Responder rates further improved with subsequent infusions for the 300 mg dose group

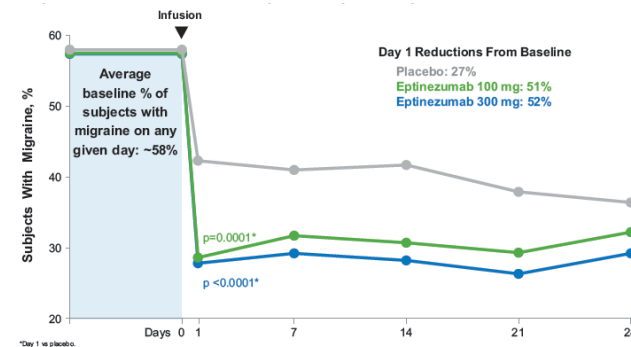


1) Clinicaltrials.gov ID: NCT04082325

# Eptinezumab achieved meaningful reductions in migraine activity as early as Day 1 that were sustained through Week 12: results from PROMISE 2 phase III trial in chronic migraine

- In subjects with chronic migraine beginning on the 1st day post-infusion, a single infusion of eptinezumab significantly reduced migraine activity for 3 months
- >61% of subjects' migraine days were reduced by ≥75% and, on average, 38% experienced a ≥75% reduction over 3 months
- The % of subjects with a migraine on Day 1 was reduced >50% following eptinezumab infusion and the reduction was sustained for 1 month

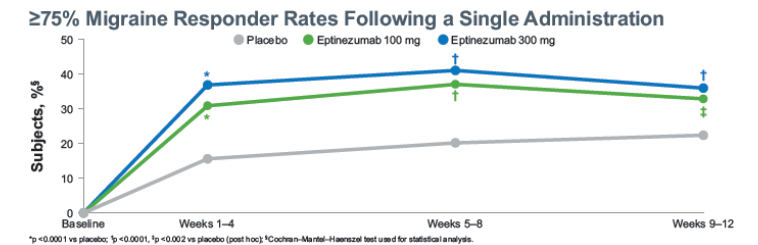
## Day 1 Reductions from baseline in percentages of subjects with a migraine maintained on average through 28 Days



• At Day 1 following eptinezumab infusion, migraine risk was reduced by 52%

• At Day 1 following eptinezumab infusion, migraine risk was reduced by 52%

## ≥75% Migraine Responder Rates (RR) following a single administration



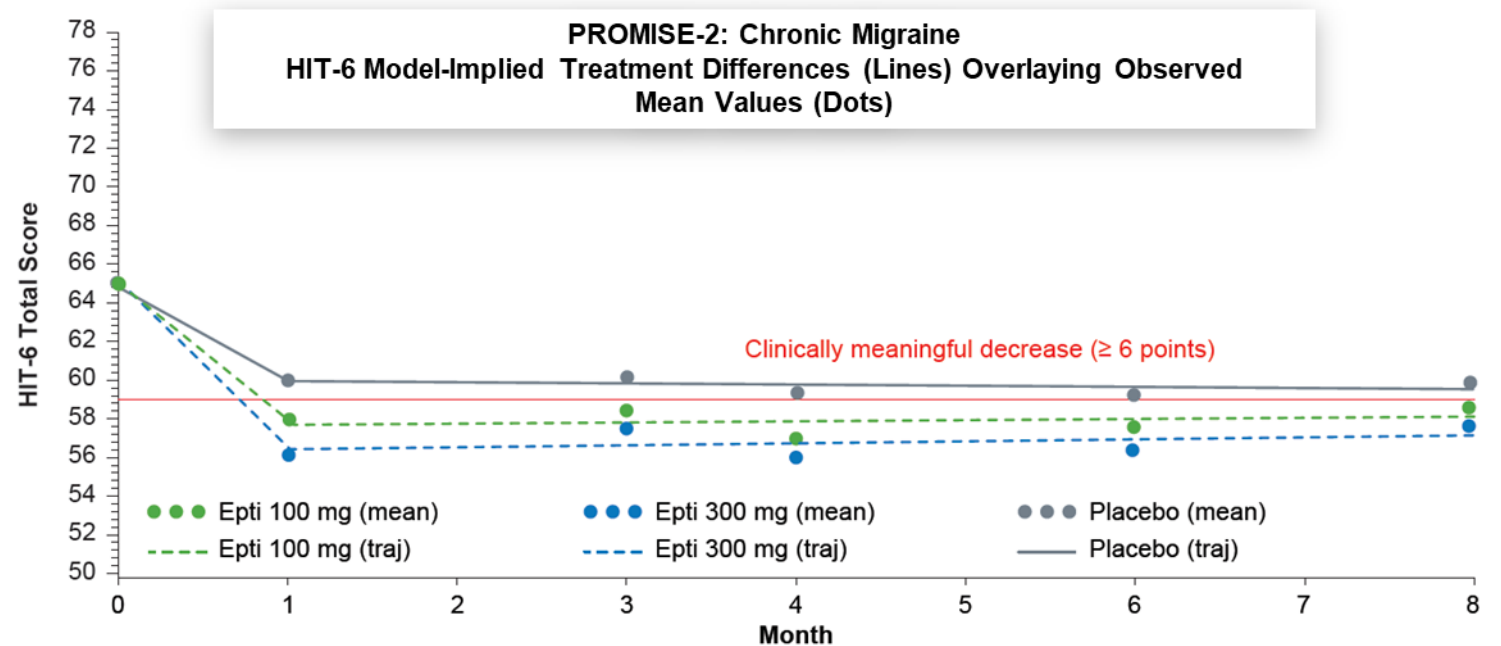
• An average of 38% of subjects treated with eptinezumab achieved a ≥75% reduction in monthly migraine over 3 months

• This RR benefit was obtained as early as Weeks 1-4 and was maintained through Weeks 9-12

# HIT-6 is a widely used patient-reported outcome measure in headache and migraine research

- General measure of impact of headache on daily life<sup>1</sup>
- Six-item scale (severe pain, limits daily activities, lie down, too tired, felt fed up or irritated, limits concentration)<sup>1</sup>
- Scoring<sup>2</sup>:
  - $\geq 60$ : severe impact
- A reduction in total HIT-6 score of  $\geq 6$  points has been reported to be clinically meaningful<sup>3</sup>
- 300 mg significant at  $p < 0.0001$

1. Kosinski M et al. *Qual Life Res* 2003;12(8):963-974. 2. Yang M et al. *Cephalgia* 2010;31(3):357-367. 3. Cady R, et al. Presented at 13th European Headache Congress; May 30–June 1, 2019; Athens, Greece. 4. Lipton RB, McGinley J, Houts CR, Wirth RJ, Cady R. Presented at: AHS 61st Annual Meeting, July 11-14, 2019; Philadelphia, PA.



Note: The red line demarcates an approximate 6-point decrease from baseline (clinically meaningful change threshold). Epti, eptinezumab; traj, model-implied trajectory.

# RELIEF-study: Starting migraine prevention during attack

- Enrollment commenced in November 2019 (n=450 subjects who are candidates for preventive therapy)\*
- Single-dose study with a 4-week follow-up period
- Study planned to complete by the end of 2020

## Eptinezumab has...

- ...throughout its development programme for preventive migraine treatment, consistently demonstrated a reduction in the percentage of subjects with a migraine on Day 1 after infusion, a measure that provides information on the early onset of efficacy for the preventive treatment of migraine
- ...the potential to impact ongoing migraine attacks and at the same time, provide a sustained preventive benefit

\*) *Clinicaltrials.gov ID: NCT04152083*

**100 mg eptinezumab  
vs. placebo**

## Co-primary endpoints

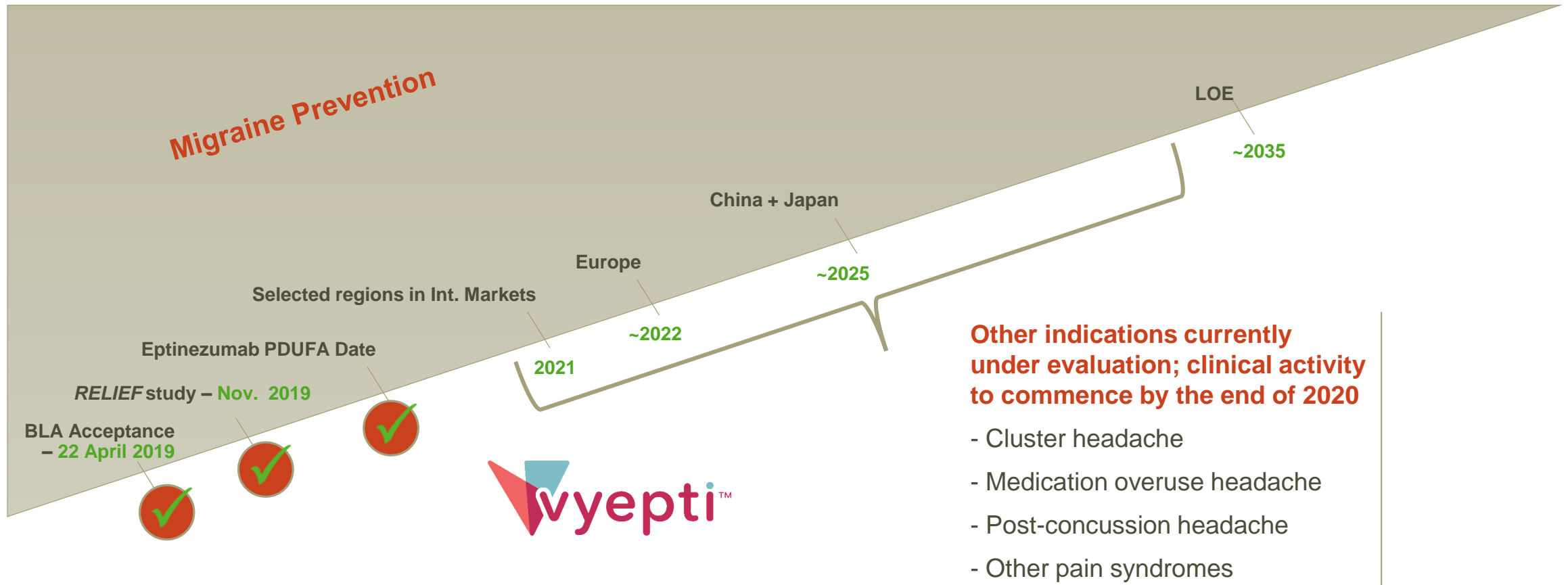
- Time to headache pain freedom
- Time to absence of most bothersome symptom

## Key secondary endpoints

*Measured 2 hours after start of treatment*

- Patients achieving freedom from pain
- Absence of most bothersome symptom

# Success for Vyepti is a marathon, not a sprint



# Third study in brexpiprazole pivotal programme in Agitation in Alzheimer's progresses as planned

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

To compare the efficacy of 2 doses of brexpiprazole with placebo in subjects with agitation associated with dementia of the Alzheimer's type

## Third study out of three in the pivotal programme (phase III):

Brexpiprazole (fixed dose 2mg and 3mg) and placebo

**Primary endpoint:** Cohen-Mansfield Agitation Inventory (CMAI) total score (Week 12)

**Secondary endpoint:** Clinical Global Impression Severity of Illness (CGI-S) score

Study started in May 2018

Fast Track designation granted February 2016

1) *Clinicaltrials.gov ID: NCT03548584*

# Brexpiprazole in pivotal programme for the treatment of agitation in Alzheimer's disease

## Alzheimer's Disease (AD)

50 million people worldwide have dementia (Alzheimer's is the most common cause of dementia contributing 60-70% of cases)

It is predicted that the number of people affected by dementia will almost double every 20 years

People with Alzheimer's live an average of 8 years after their symptoms become noticeable to others

The total global societal costs of dementia are estimated to be USD 600 billion

## Agitation in Alzheimer's disease (AAD)

>20% of individuals in a community setting and >50% of nursing home residents with dementia have agitation

1.5-2m dementia patients in the U.S. with agitation / aggression

No FDA approved medication

## Associated with:

Increased caregiver burden leading to increased cost to the healthcare system

Decreased functioning

Earlier nursing home placement



# PTSD offers an exciting opportunity for brexpiprazole

## PTSD epidemiology

>8m – U.S. prevalence  
(2.5%-3.6%)<sup>1, 2</sup>

~3m – Severe  
(36.6%)<sup>2</sup>

~1.8m – pharmacological  
treatment rate  
(~60%)<sup>2</sup>

1) Nature Reviews Disease Primers; Vol 1, 2015. 2) National Institute of Mental Health 3) Clinician-Administered PTSD Scale for DSM-5 (CAPS-5).

## Post-traumatic Stress Disorder (PTSD)

~8.6m U.S. adults affected, but  
~80% estimated to be undiagnosed

Growing economic and social  
burden of care

Inadequate response with  
approved SSRIs - polypharmacy  
the norm

## PoC study<sup>4</sup> showed...

Combination of brexpiprazole and  
sertraline demonstrated  
improvement in symptoms of  
PTSD versus placebo ( $p<0.01$ ) on  
the primary endpoint (CAPS-5 total  
score<sup>3</sup>)

The efficacy supported by multiple  
secondary endpoints

The overall safety and tolerability  
of brexpiprazole were good

# Both studies in brexpiprazole pivotal programme 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 (n = 577 and 733)

1) [Clinicaltrials.gov ID: NCT04124614](https://clinicaltrials.gov/ct2/show/study/NCT04124614) and [NCT04174170](https://clinicaltrials.gov/ct2/show/study/NCT04174170)

## 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

First study started in October 2019 and the second in November 2019

U.S. dedicated study

# Borderline Personality Disorder (BPD) offers an exciting opportunity for brexpiprazole

## BPD epidemiology

~5m – U.S. prevalence  
(1.6%, but likely higher)<sup>1)</sup>

~2.4m – diagnosis rate  
(45%)

~1.7m – pharmacological  
treatment rate  
(~70%)<sup>2)</sup>

## Borderline Personality Disorder (BPD)

Dysfunctions in the serotonergic and dopaminergic systems is considered as possible causes for symptoms associated with BPD<sup>3)</sup>

Pharmacotherapy focuses on key symptoms (aggression, irritability, depressed mood, behavioural dyscontrol and affective dysregulation, anxiety, psychoticism and hostility) which brexpiprazole is hypothesized to address

No drugs approved for BPD

1. Grant BF, Chou SP, Goldstein RB, et al. Prevalence, correlates, disability, and comorbidity of DSM-IV borderline personality disorder: results from the Wave 2 National Epidemiologic Survey on Alcohol and Related Conditions. *J Clin Psychiatry* 2008; 69:533. | 2. Bridler et al (2015) and Zaanarini et al. (2004 and 2015) | 3. Friedel RO: Dopamine dysfunction in borderline personality disorder: a hypothesis. *Neuropsychopharmacology* 2004; 29:1029–1039 and Hansenne M et al: 5-HT1A dysfunction in borderline personality disorder. *Psychol Med* 2002; 32:935–941

# Brexpiprazole PoC study in Borderline Personality Disorder (BPD) ongoing

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

To evaluate the efficacy and safety of 12-week brexpiprazole for the treatment of subjects diagnosed with BPD (n = ~240) to provide a pharmacological treatment for BPD

## Phase II

Brexpiprazole (flexible dose 2-3mg) and placebo

**Primary endpoint:** Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD) total score (Week 12)

**Secondary endpoints:** Clinical Global Impression - Severity of Illness (CGI-S); Patient's Global Impression of Severity (PGI-S); Patient's Global Impression of Change (PGI-C) Scale; Clinical Global Impression - Improvement (CGI-I) Scale

Fast Track designation granted October 2019

Study initiated in October 2019

1) *Clinicaltrials.gov ID: NCT04100096*

# Lundbeck La Jolla has access to an exciting biology platform exploring serine hydrolases starting with the endocannabinoid system

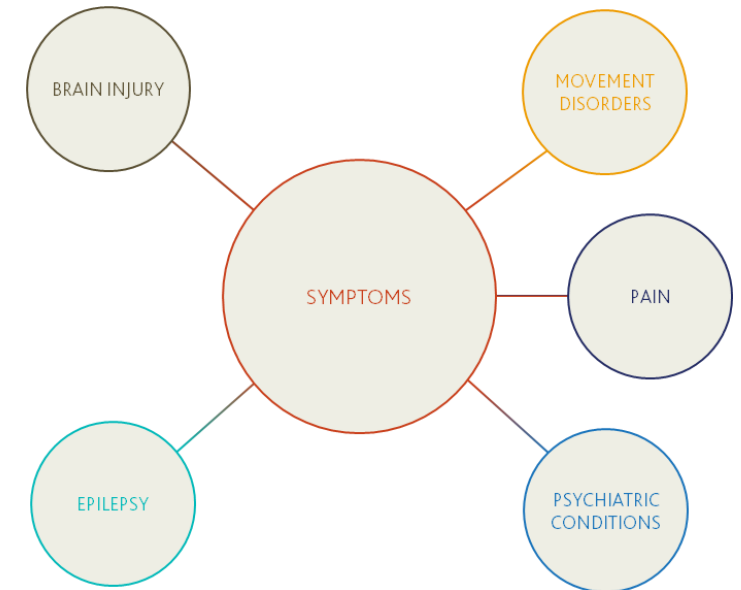
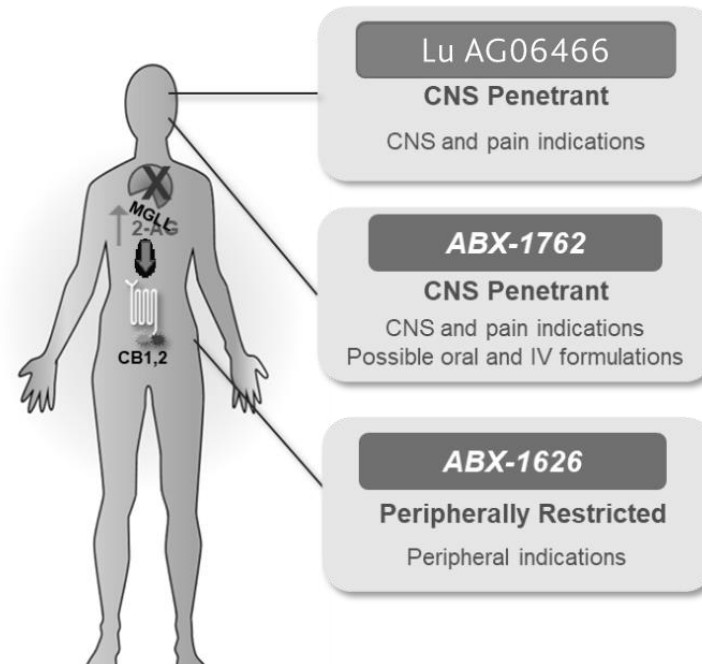
Access to world class MAG-lipase development candidates to bolster our portfolio

Pipeline in a drug – many potential indications

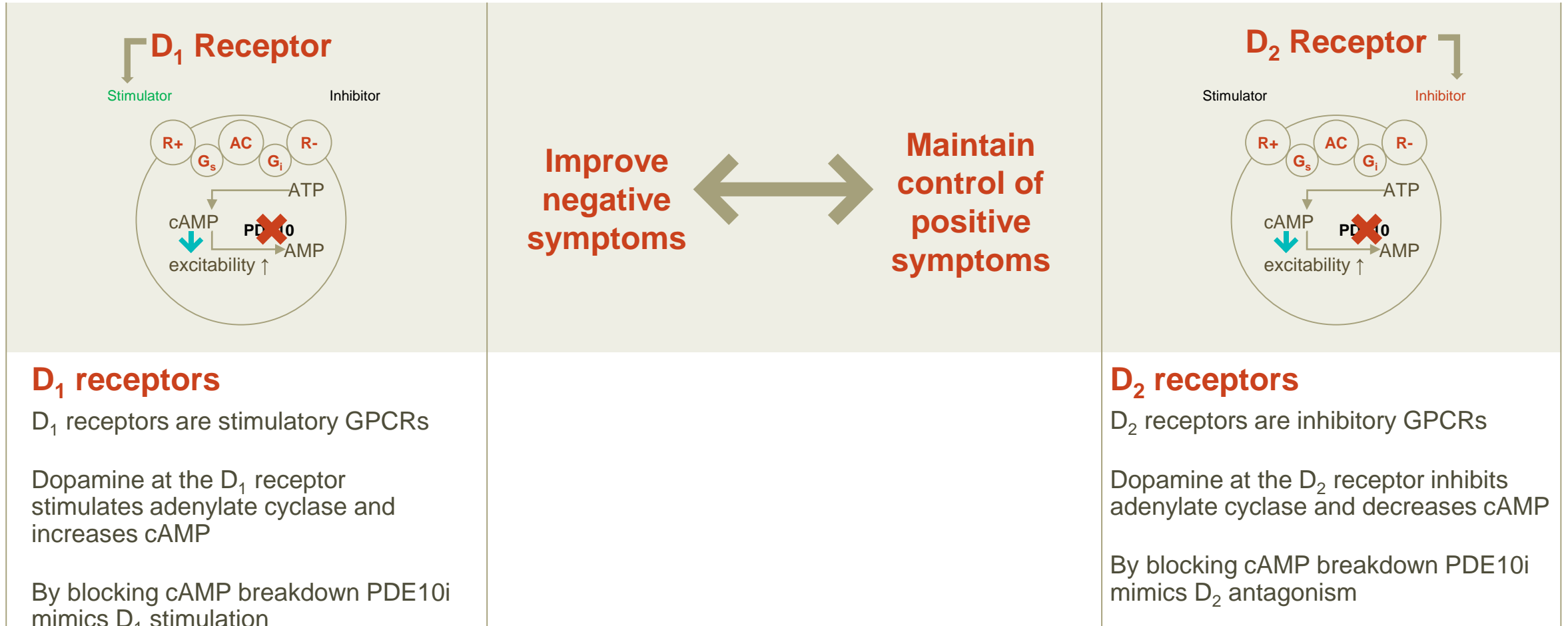
Discovery site in U.S.

World class platform to expand to novel biological targets

Chemical biology tool box to compliment the Lundbeck neuroscience and modality expertise



# PDE10 inhibition: A new approach to obtain a combined D<sub>1</sub> agonist-like effect and D<sub>2</sub> antagonist-like effect



## D<sub>1</sub> receptors

D<sub>1</sub> receptors are stimulatory GPCRs

Dopamine at the D<sub>1</sub> receptor stimulates adenylate cyclase and increases cAMP

By blocking cAMP breakdown PDE10i mimics D<sub>1</sub> stimulation

## D<sub>2</sub> receptors

D<sub>2</sub> receptors are inhibitory GPCRs

Dopamine at the D<sub>2</sub> receptor inhibits adenylate cyclase and decreases cAMP

By blocking cAMP breakdown PDE10i mimics D<sub>2</sub> antagonism

# Proof-of-concept study commenced in December 2018

## Monotherapy\*

Two fixed-flexible doses, once daily

1-2mg/day

3-4mg/day

placebo

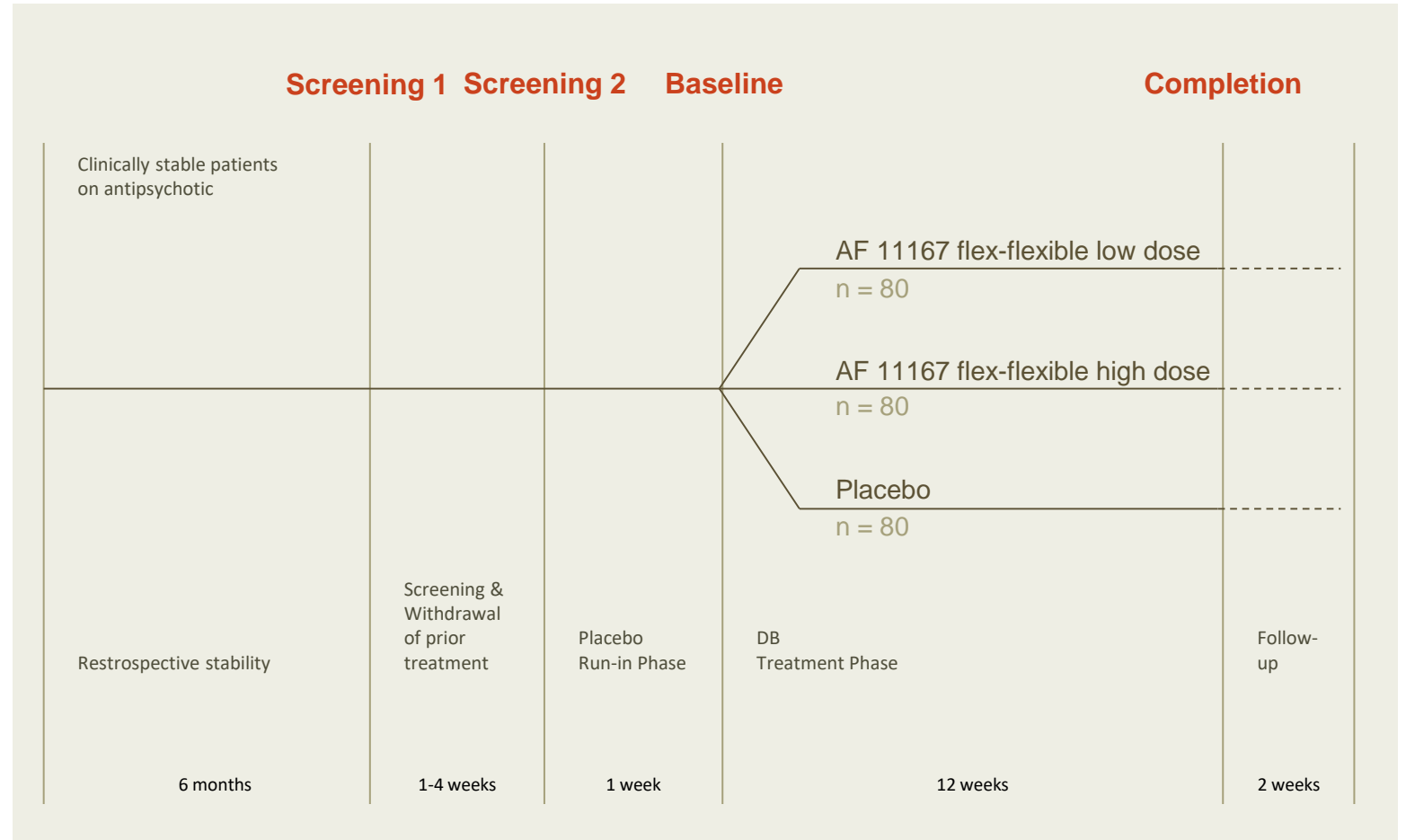
N = ~250 patients

**Primary endpoint:** Change from baseline to Week 12 in BNSS total score\*\*

Several secondary endpoints

\*) *Clinicaltrials.gov ID: NCT03793712*

\*\*) *Brief negative symptom scale (BNSS)*



# Negative symptoms represent a major unmet medical need

Schizophrenia has three core symptoms: Positive, cognitive and negative symptoms

Negative symptoms together with impaired cognition are the major cause of the marked functional disability

Negative symptoms are thus a key contributor to the enormous costs of schizophrenia

No pharmacological treatment

40 - 50% of patients with schizophrenia are clinically stable outpatients; of those 40% experience at least two prominent negative symptoms (~ 20% of the total schizophrenia population)

## Prevalence<sup>1)</sup> (major countries)

**4.7m**

Prevalence of schizophrenia (G7)

**3.5m**

Treatment prevalence (75%)

**1.7m**

Clinical stable outpatients (50%)

**0.8m**

Negative symptoms (40%)

1) Decision Ressource: Schizophrenia. Landscape & Forecast 2018



# Pipeline – investing for the future

Project	Area	Phase I	Phase II	Phase III	Filing
Eptinezumab (anti-CGRP mAb)	Migraine prevention				★
Brexpiprazole <sup>1)</sup>	Agitation in Alzheimer's disease			★	≥2021
Brexpiprazole <sup>1)</sup>	PTSD			★	≥2023
Brexpiprazole <sup>1)</sup>	Borderline Personality Disorder		★		≥2025
Lu AF11167 (PDE 10 inhibitor)	Schizophrenia		★		≥2025
Aripiprazole 2-month injectable	Schizophrenia+bipolar I disorder	★			~2021
Lu AF82422 (alpha-synuclein mAb)	Synucleinopathies	★			>2025
Lu AF28996 (D1/D2 agonist)	Parkinson's disease	★			>2025
Lu AG06466 (MAGLi) <sup>2)</sup>	Neurology/psychiatry	★			>2025
Lu AF88434 (PDE1B inhibitor)	Cognitive dysfunction	★			>2025
Lu AG09222 (PACAP mAb) <sup>3)</sup>	Migraine	★			>2025
Lu AF87908 (Tau mAb)	Tauopathies	★			>2025

1) 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 alpha1B/2C receptors.

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

3) PACAP: inhibits pituitary adenylate cyclase-activating polypeptide

Most advanced stage shown

# Maintaining focus on our role and responsibility in society

## During the recent quarter, the COVID-19 pandemic challenged the global community affecting everyone

- We have adapted our ways of working to preserve employee safety while ensuring business continuity
- Focused on maintain stable supply of medicines to help people suffering from brain diseases
- Provided financial and medical support to eligible not-for-profit groups providing pandemic and mental health across the globe
- Expanded virtual resources for people whose mental health has been impacted
- Working with the Danish Medicines Agency on pandemic preparedness

## Our focus on progressing to carbon-neutrality has not diminished

- Part of Danish Climate Partnership on Business Ambition 70%

Category	Q1 2020	Q1 2019	Δ% y/y
Energy (MWh)	27,748	27,256	1.8%
CO2 (tonnes)	4,426	4,361	1.5%
Work related accidents	5.4	8.9	(39%)
No. Of employees (FTE)	5,872	5,442	7.9%



# Commitment to the UN Global Compact Principles and to the Sustainable Development Goals (SDG) underpins our business

- Contribute to solving societal challenges where we can

Tirelessly dedicated to restoring brain health, so every person can be their best

<b>PARTNERING FOR IMPACT</b>	<b>DEDICATED TO RESTORING BRAIN HEALTH</b>	<b>3 GOOD HEALTH AND WELL-BEING</b> 	<b>PURSuing A ZERO EMISSIONS FUTURE</b>	<b>13 CLIMATE ACTION</b> 	
<b>17 PARTNERSHIPS FOR THE GOALS</b> 	<b>USING OUR INFLUENCE TO PROMOTE CHANGE</b>	<b>5 GENDER EQUALITY</b> 	<b>8 DECENT WORK AND ECONOMIC GROWTH</b> 	<b>12 RESPONSIBLE CONSUMPTION AND PRODUCTION</b> 	<b>16 PEACE, JUSTICE AND STRONG INSTITUTIONS</b> 

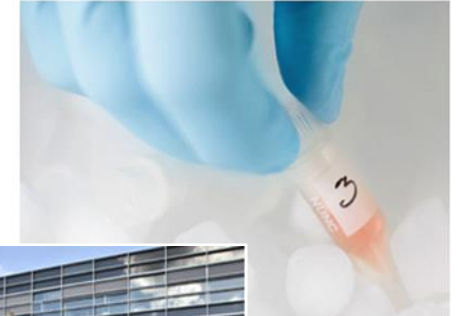
## Overview of our ambitions, initiatives and targets

SUSTAINABLE DEVELOPMENT GOALS		LUNDBECK'S SUSTAINABILITY - 2020 TARGETS
SDG 3	Good health and well-being	<ul style="list-style-type: none"> <li>• Engage all Lundbeck offices in local World Mental Health Day activities</li> <li>• Establish a product donation partnership</li> </ul>
SDG 5	Gender equality	<ul style="list-style-type: none"> <li>• Strive to maintain an overall equal gender split for people managers globally</li> </ul>
SDG 8	Decent work and economic growth	<ul style="list-style-type: none"> <li>• Reduce lost time accident frequency ≤ 5</li> </ul>
SDG 12	Responsible consumption and production	<ul style="list-style-type: none"> <li>• Recycle 55% of the solvents used in chemical production</li> <li>• Zero environmental incidents</li> </ul>
SDG 13	Climate action	<ul style="list-style-type: none"> <li>• Reduce CO<sub>2</sub> emission by 4% in 2020 compared to 2019</li> <li>• Obtain 'Science Based Targets initiative (SBTi)' approval of new climate target</li> </ul>
SDG 16	Peace, justice and strong institutions	<ul style="list-style-type: none"> <li>• Annual Code of Conduct training completed by all employees at work globally</li> <li>• Work to increase proportion of healthcare professionals supporting disclosure of collaborations compared to the previous reporting year</li> </ul>

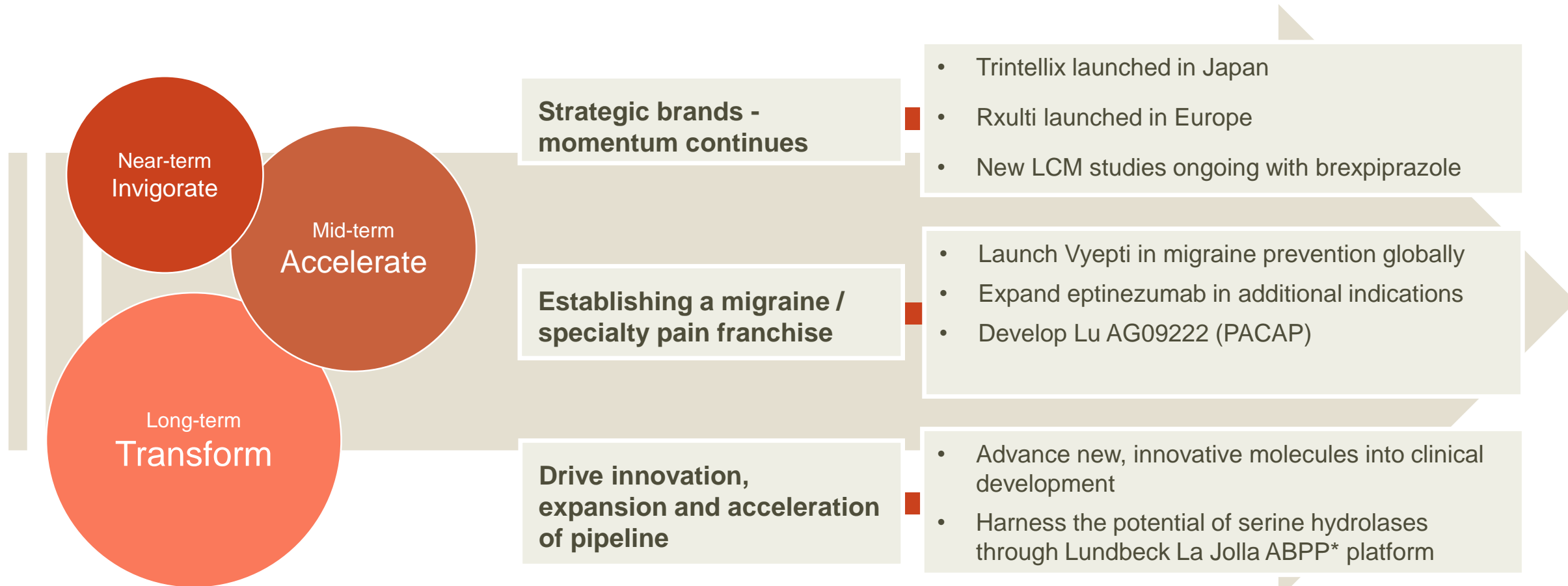
More detailed information about our sustainability policies, efforts and results is available on [www.lundbeck.com](http://www.lundbeck.com)

## Near-term priorities

- Manage the impact from COVID-19 internally and externally
- Secure supply of medicines to patients
- Ensure strong continued momentum for the strategic brands
- Vyepti launch in the U.S., regulatory submissions and indication expansion
- Prepare to restart and accelerate clinical activities
- Continue to execute on *Expand and Invest to Grow*



# Readying Lundbeck for a new growth phase – 2020 and beyond



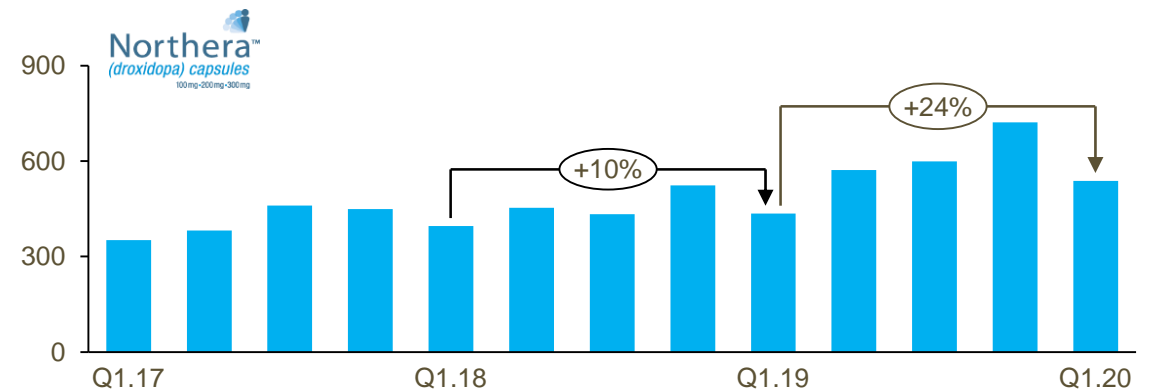
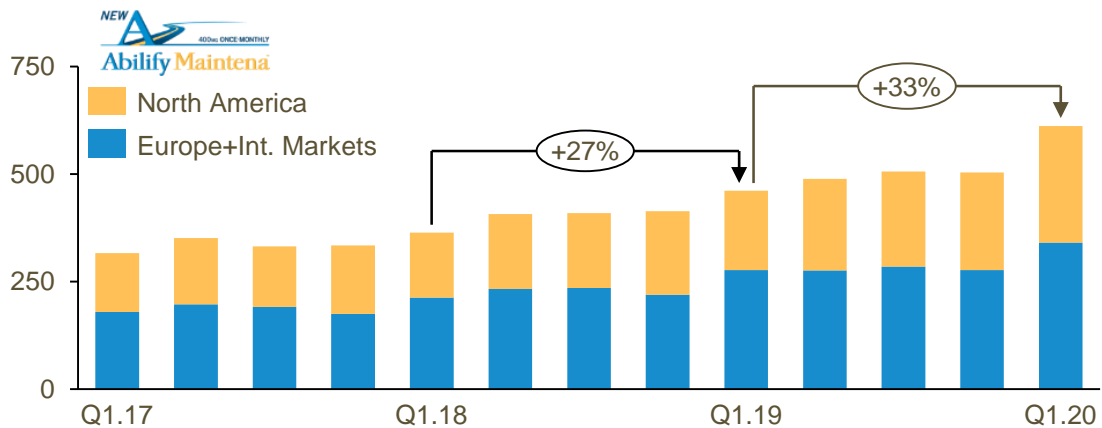
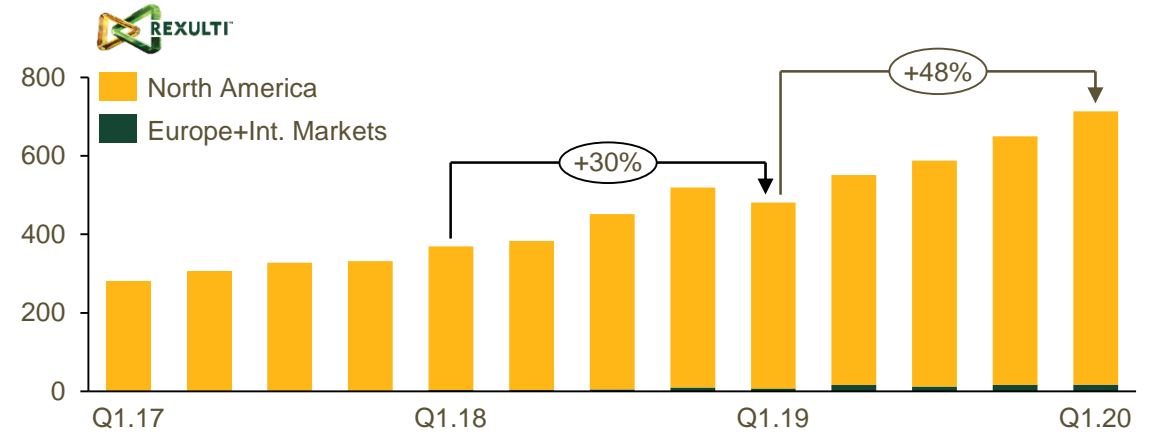
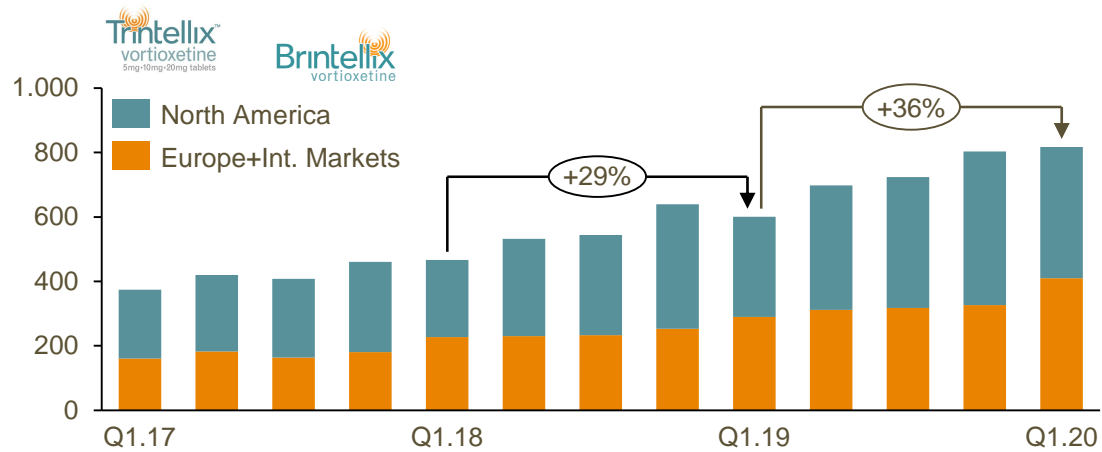
\*) Activity-Based Protein Profiling

Thank you

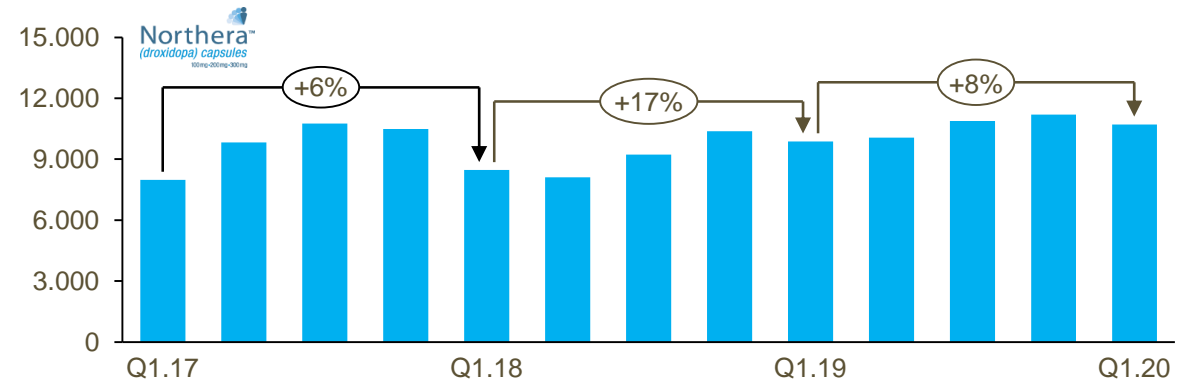
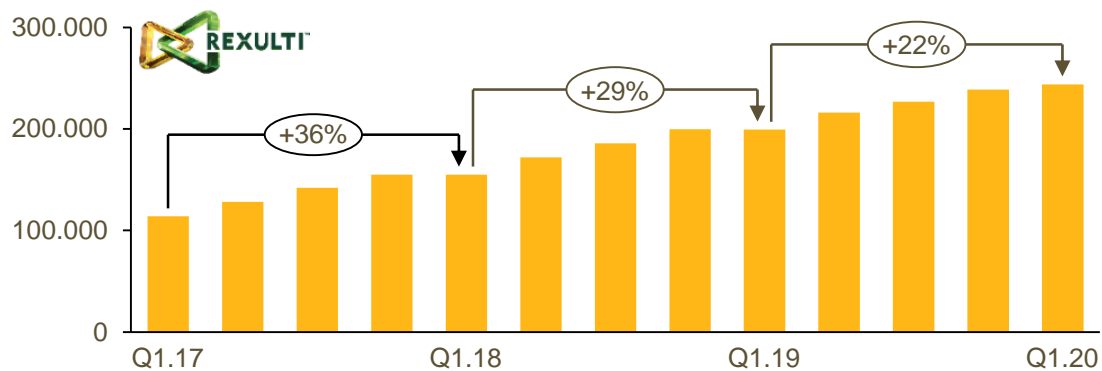
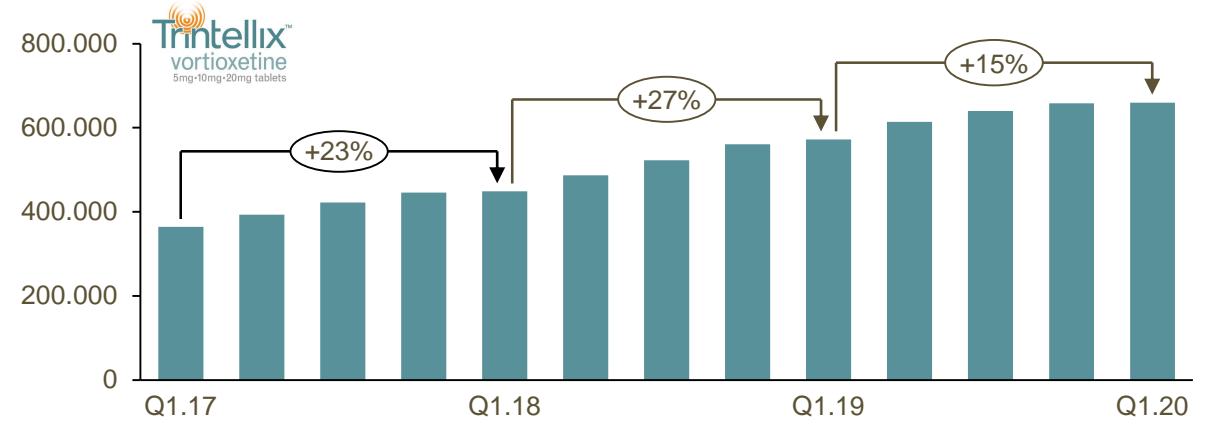
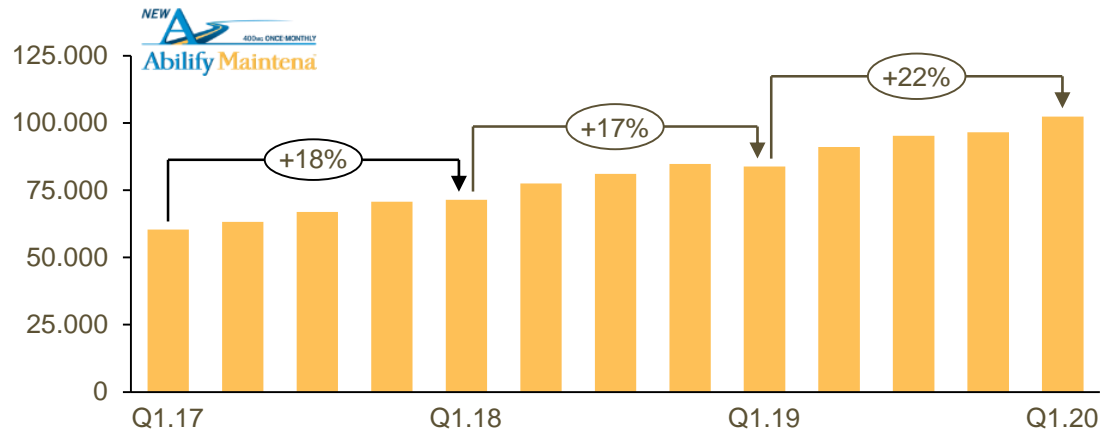
Lundbeck



# Continued excellence in commercial execution delivers double-digit revenue growth in all regions for the four strategic brands



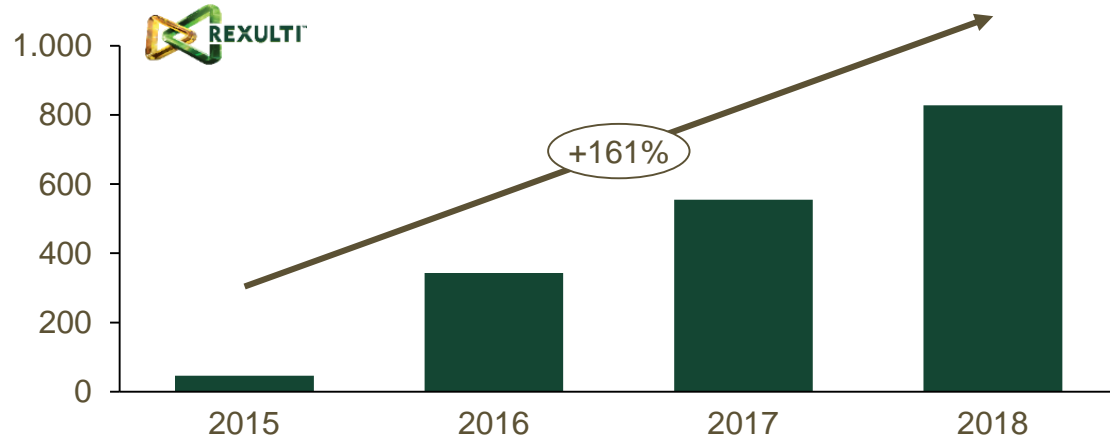
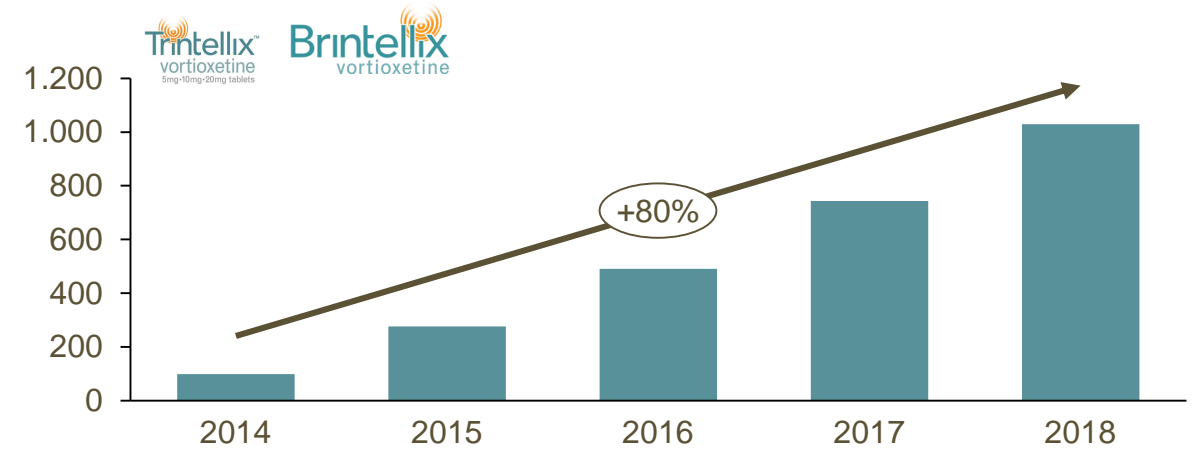
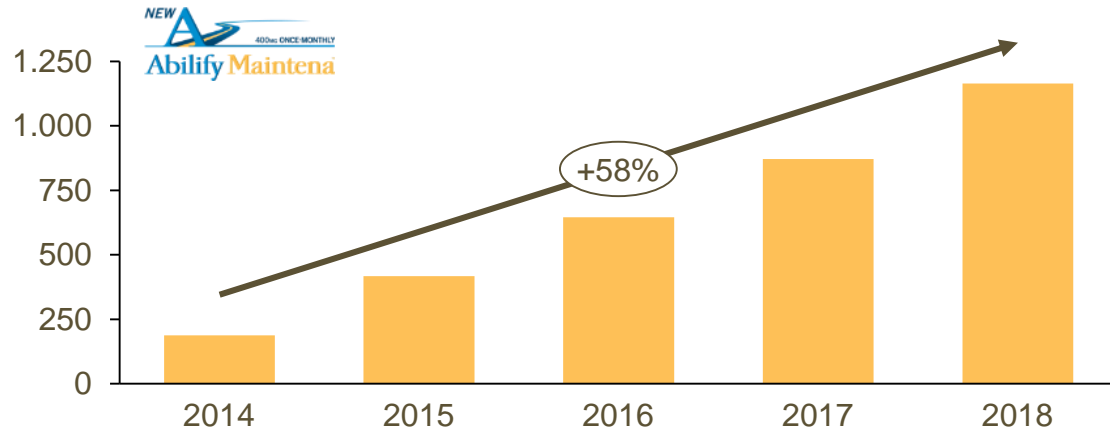
# Solid volume growth in the U.S. for all strategic brands



Source: Symphony Health (ref Bloomberg)



# 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: IMS

# 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, but the currently available agonist (apomorphine) cannot be delivered by oral route

Improving the treatment of fluctuating Parkinson's 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<sup>1</sup>:

- 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
- Phase Ia initiated in May 2018, completed in August 2019
- Phase Ib was planned to be initiated Q1 2020

1) *Clinicaltrials.gov* ID: NCT03565094

# Lu AF82422: Potential disease modifying antibody for Parkinson's disease

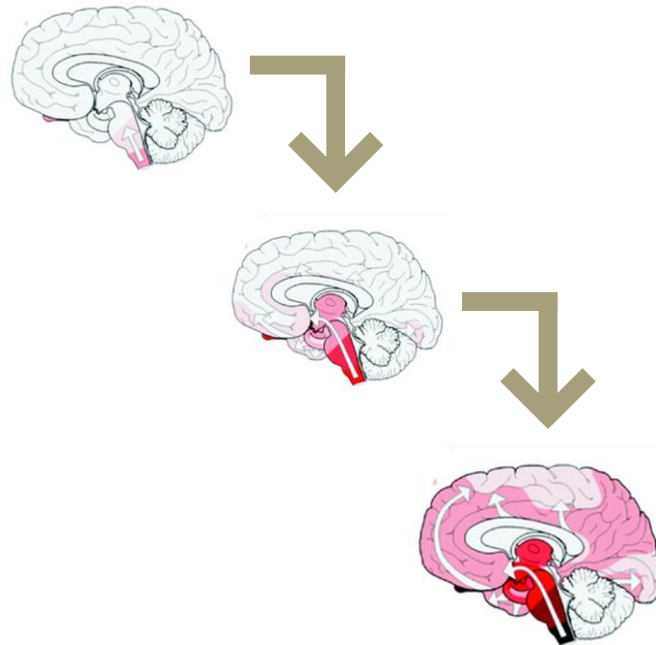
Pathological alpha-synuclein is released to extracellular space upon cell death and can mediate seeding and aggregation of alpha-synuclein in healthy neurons<sup>1</sup>

This process is considered to be central in the disease progression of Parkinson's, Multiple System Atrophy and other synucleopathies<sup>2</sup>

Lu AF82422 is able to inhibit seeding of pathological form(s) of alpha-synuclein in in vitro and in vivo models

Has the potential to induce immune-mediated clearance of alpha-synuclein/mAb complexes

## Pathogenesis of Parkinson's



## Ongoing phase I study<sup>3</sup>:

- Healthy non-Japanese and Japanese subjects and in patients with Parkinson's
- **Primary endpoint:** Number of patients with incidence of Treatment-Emergent Adverse Events (safety and tolerability) from dosing to Day 84
- Study initiated in July 2018

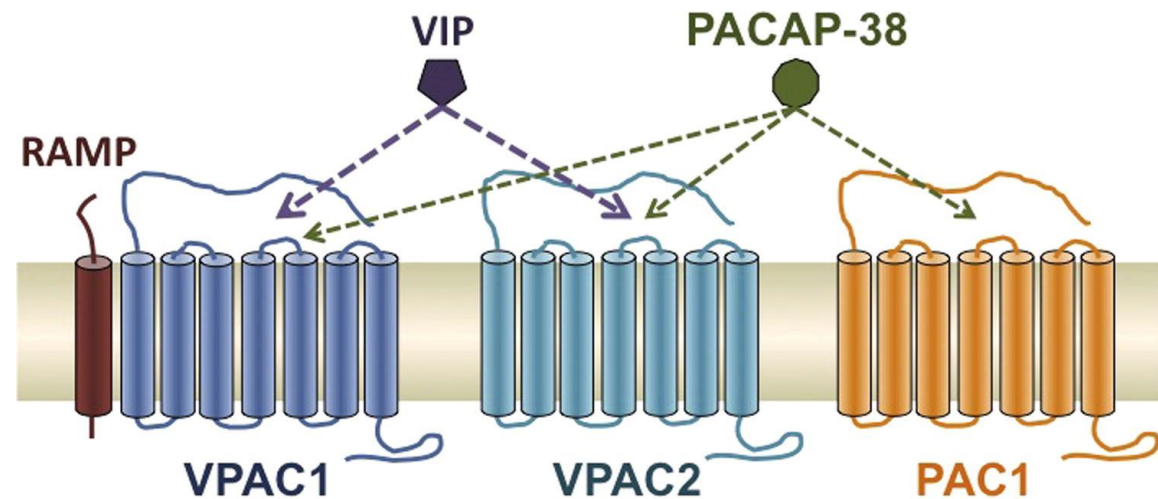
1) Poewe et al Nature Reviews Disease Primers vol. 3 17013 (2017) <https://www.nature.com/articles/nrdp201713> 2. Krismer and Wenning (2017) Nat Rev Neurol 13(4):232-243 <https://www.ncbi.nlm.nih.gov/pubmed/28303913> 3) Clinicaltrials.gov ID: NCT03611569

# Lu AG09222: Potential to build a migraine franchise in the future with early-stage PACAP<sup>2</sup> inhibitor mAb

## A differentiated approach to migraine prevention

- Highly potent and selective humanized PACAP binding antibody
- Preclinical data<sup>1</sup> indicate that PACAP<sup>2</sup> and CGRP<sup>3</sup> have differentiated pharmacology with respect to migraine-associated symptoms
- Potential for mono-therapy in non-CGRP<sup>3</sup> induced migraine or combination therapy with eptinezumab

1) Loomis et al: Pharmacologic characterization of ALD1910, a potent humanized monoclonal antibody against the pituitary adenylate cyclase-activating peptide, JPET Fast Forward 2) Pituitary adenylate cyclase-activating peptide 3) Calcitonin gene-related peptide. Clinicaltrials.gov ID: NCT04197349



# Projects with new MoAs in clinical development

## Lu AF88434

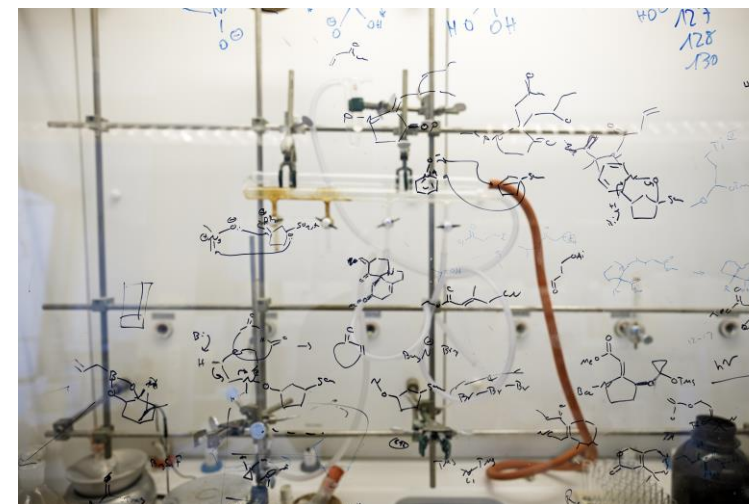
- Potent and selective phosphodiesterase PDE1B inhibitor
- PDE1 is an intracellular enzyme responsible for the degradation of cGMP and cAMP
- cGMP is a critical intracellular signalling molecule that regulates neuronal functions like synaptic plasticity, cognitive function, neuronal survival and axonal regeneration
- FIH study\* initiated in July 2019 to investigating the safety, tolerability, PK/PD properties

\*) *Clinicaltrials.gov* ID: NCT04082325

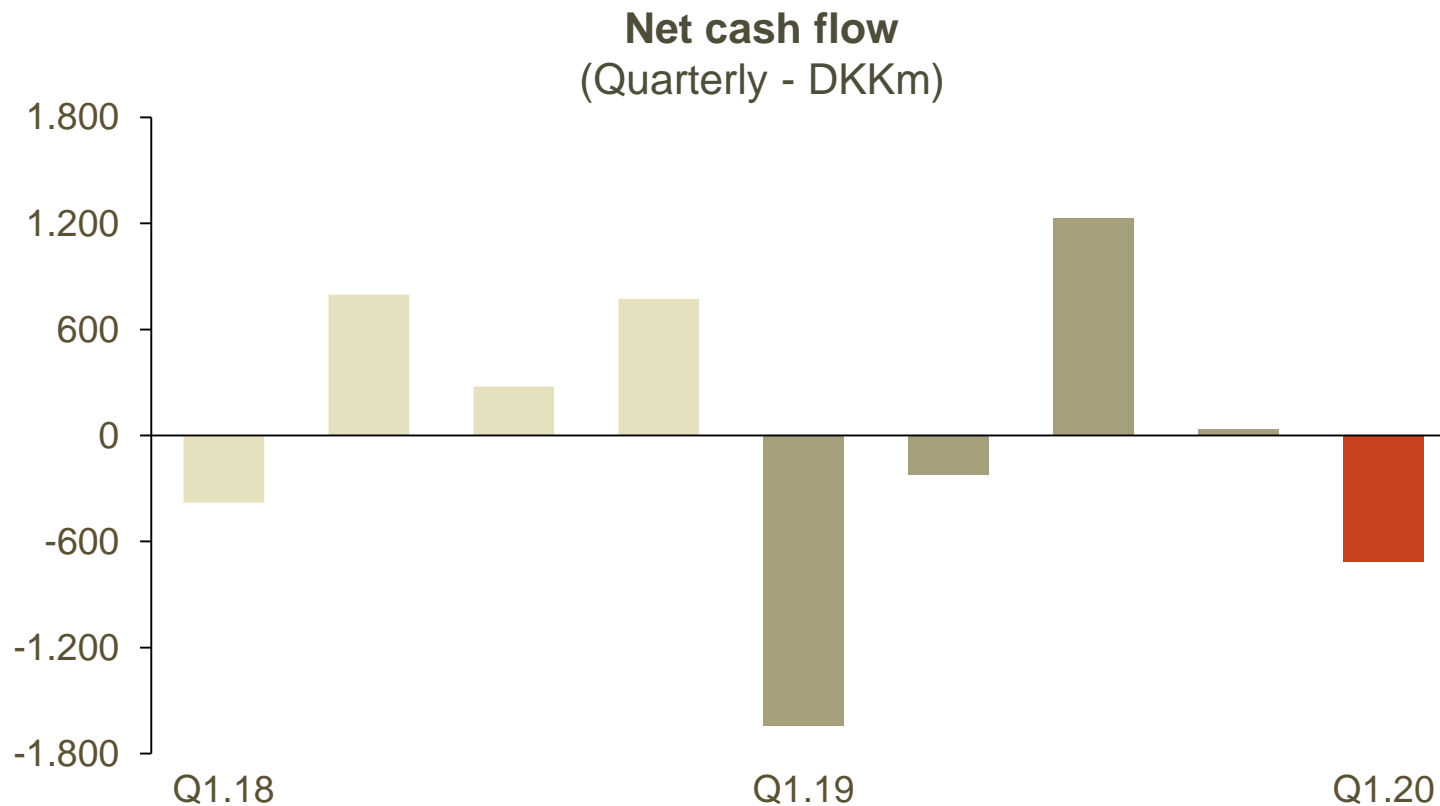
## Lu AF87908

- Tau mAb
- Binding to and inhibition of pathological seeding form of Tau
- Specific and pathology directed mAb
- Retaining the capacity to mediate active clearance of Tau
- FIH study\* initiated in Sep. 2019 in healthy subjects and AD patients

\*) *Clinicaltrials.gov* ID: NCT04149860



# Cash flow impacted by lower EBIT and acquisitions, but solid cash generation still provides flexibility



- **Net cash flow:** Up DKK 928 million to DKK -716 million in Q1 2020 vs. Q1 2019
- FY 2020 cash flow will be negatively impacted by
  - Investments in Vyepti
  - Lower EBITDA
  - Dividend payout for 2019
- **Net debt:** Expected to amount to around DKK 6 billion (USD ~1bn) by end-2020

## Product distribution of revenue – Q1 2020 and FY 2019

DKKm	FY 2019	FY 2018	Q1 2020	Q1 2019	Growth	Growth in local currencies	% of total
<b>TOTAL:</b>							
Abilify Maintena	1,961	1,595	<b>612</b>	462	33%	30%	13%
Brintellix/Trintellix	2,826	2,182	<b>817</b>	601	36%	34%	18%
Cipralex/Lexapro	2,314	2,257	<b>722</b>	619	17%	16%	16%
Northera	2,328	1,806	<b>538</b>	435	24%	20%	12%
Onfi	1,052	3,165	<b>153</b>	325	(53%)	(54%)	3%
Rexulti/Rxulti	2,270	1,723	<b>713</b>	481	48%	43%	16%
Sabril	847	1,342	<b>177</b>	254	(30%)	(33%)	4%
Other pharmaceuticals	3,100	3,143	<b>781</b>	869	(10%)	(11%)	17%
Other revenue	660	662	<b>139</b>	236	(41%)	(41%)	3%
Effects from hedging	(322)	242	<b>(88)</b>	(48)	-	-	-2%
<b>Total revenue</b>	<b>17,036</b>	<b>18,117</b>	<b>4,564</b>	<b>4,234</b>	<b>8%</b>	<b>7%</b>	<b>100%</b>

# Cash generation

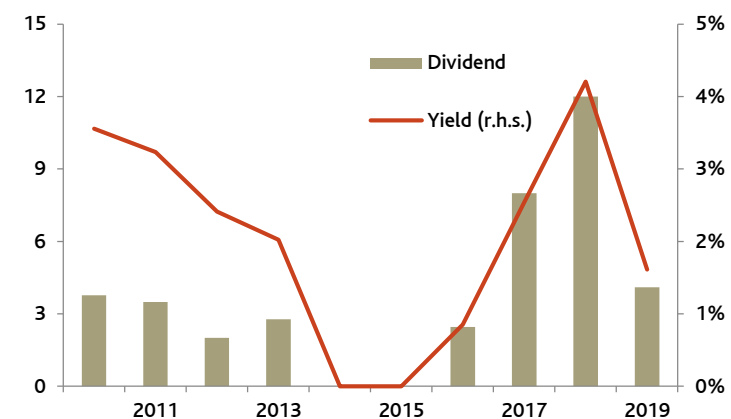
DKKm	Q1 2020	Q1 2019	FY 2019	FY 2018
Cash flows from operating activities	188	837	2,609	5,981
Cash flows from investing activities	(68)	(63)	(7,755)	(2,907)
<b>Cash flows from operating and investing activities (free cash flow)</b>	<b>120</b>	<b>774</b>	<b>(5,146)</b>	<b>3,074</b>
Cash flows from financing activities	(836)	(2,418)	4,548	(1,607)
<b>Net cash flow for the period</b>	<b>(716)</b>	<b>(1,644)</b>	<b>(598)</b>	<b>1,467</b>
Cash, bank balances and securities, end of period	2,287	5,014	3,012	6,635
Interest-bearing debt	(9,638)	(462)	(9,578)	-
<b>Net cash/(net debt)</b>	<b>(7,351)</b>	<b>4,552</b>	<b>(6,566)</b>	<b>6,635</b>



# Balance sheet and dividend

DKKm	31.03.2020	31.12.2019
Intangible assets	22,652	23,399
Other non-current assets	3,554	3,320
Current assets	8,661	9,038
<b>Assets</b>	<b>34,867</b>	<b>35,757</b>
Equity	14,074	14,554
Non-current liabilities	12,928	10,923
Current liabilities	7,865	10,280
<b>Equity and liabilities</b>	<b>34,867</b>	<b>35,757</b>
Cash and bank balances	2,283	3,008
Securities	4	4
Interest-bearing debt	(9,638)	(9,578)
<b>Interest-bearing debt, cash, bank balances and securities, net, end of year</b>	<b>(7,351)</b>	<b>(6,566)</b>

## Dividend (DKK)



- ✱ Dividend payout of DKK 4.10 per share for 2019, corresponding to a payout ratio of 31%
- ✱ A total of DKK 816 million and a yield of 1.6%\*
- ✱ Dividend policy: Payout ratio of 30-60% from 2019

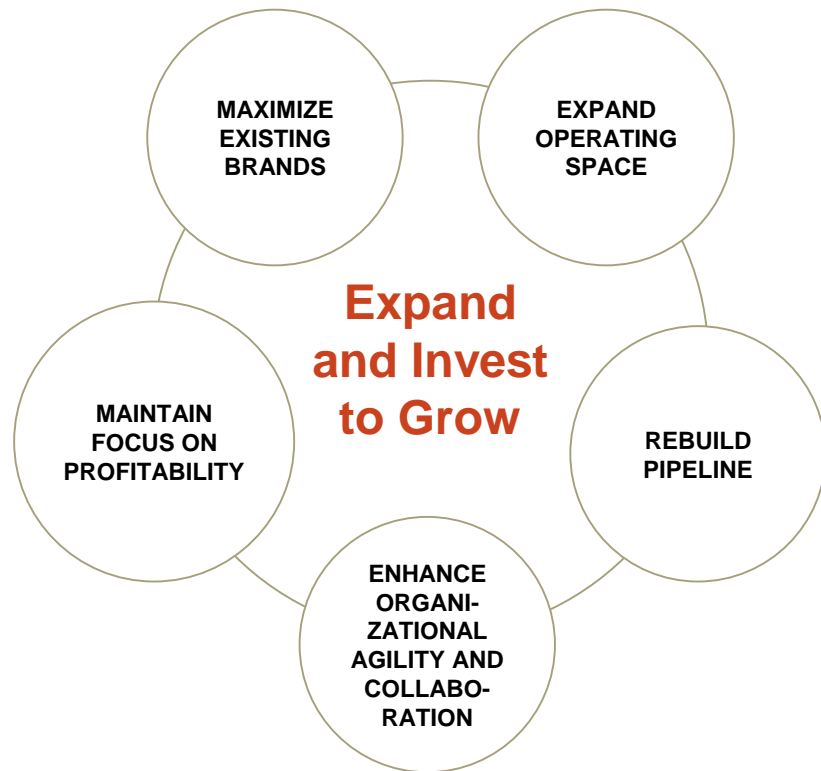
\*Based on the share price of DKK 254.40

# Costs – Full year figures

DKKm	2019	2018	2017	2016	2019 ( $\Delta\%$ )	2018 ( $\Delta\%$ )
Revenue	17,036	18,117	17,234	15,634	(6%)	5%
Cost of sales	3,385	3,456	3,881	4,082	(2%)	(11%)
Sales & Distribution costs	5,514	5,277	5,649	5,488	4%	(7%)
Administrative expenses	899	762	833	805	18%	(9%)
R&D costs	3,116	3,277	2,705	2,967	(5%)	21%
<b>Total costs</b>	<b>12,914</b>	<b>12,772</b>	<b>13,068</b>	<b>13,342</b>	<b>1%</b>	<b>(2%)</b>
EBIT <sup>1)</sup>	3,608	5,301	4,408	2,292	(32%)	20%
Core EBIT	4,976	6,158	5,115	3,477	(19%)	20%
<i>Cost of sales</i>	<b>19.9%</b>	19.1%	22.5%	26.1%	-	-
<i>Sales &amp; Distribution costs</i>	<b>32.3%</b>	29.1%	32.8%	35.1%	-	-
<i>Administrative expenses</i>	<b>5.3%</b>	4.2%	4.8%	5.1%	-	-
<i>R&amp;D costs</i>	<b>18.3%</b>	18.1%	15.7%	19.0%	-	-
<i>EBIT margin</i>	<b>21.2%</b>	29.3%	25.6%	14.7%	-	-

1) Includes Other operating items, net

# Lundbeck has seen strong progress against *Expand and Invest to Grow* strategy announced in February 2019



- Solid growth across strategic brands
- Global footprint with growth in all regions of the world
- Two acquisitions made in 2019 expand the indications within neuroscience and add to the pipeline across all phases of development
  - Lundbeck La Jolla Research Center created: Establishing a strong platform for innovation
  - Lundbeck Seattle BioPharmaceuticals builds antibody capabilities
- Long-standing reputation with patient communities and physicians
- Deep scientific heritage and capabilities in CNS
- Demonstrated track record of partnering relationships
- Solid, stable cash generative base business
- Solid profitability while investing in future growth

# For more information, please contact Investor Relations

- Listed on the Copenhagen Stock Exchange since 18 June 1999
- Deutsche Bank sponsored ADR programme listed on NASDAQ (U.S. OTC) effective from 18 May 2012
- For additional company information, please visit Lundbeck at: [www.lundbeck.com](http://www.lundbeck.com)

Number of shares	199,136,725
Treasury shares	435,019 (0.22%)
Insider holdings	130,339 (0.07%)
Classes of shares	1
Restrictions	None
ISIN code	DK0010287234
Ticker symbol	LUN DC/LUN.CO (Bloomberg/Reuters)
ADR programme	Sponsored level 1
ADR symbol	HLUYY
Ratio	1:1

## IR contact

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## Financial calendar

<b>6M 2020</b>	13 August 2020
<b>9M 2020</b>	3 November 2020
<b>FY 2020</b>	February 2021
<b>Q1 2021</b>	May 2021