



# Investor presentation

# FY 2019

COPENHAGEN, 6 FEBRUARY 2020

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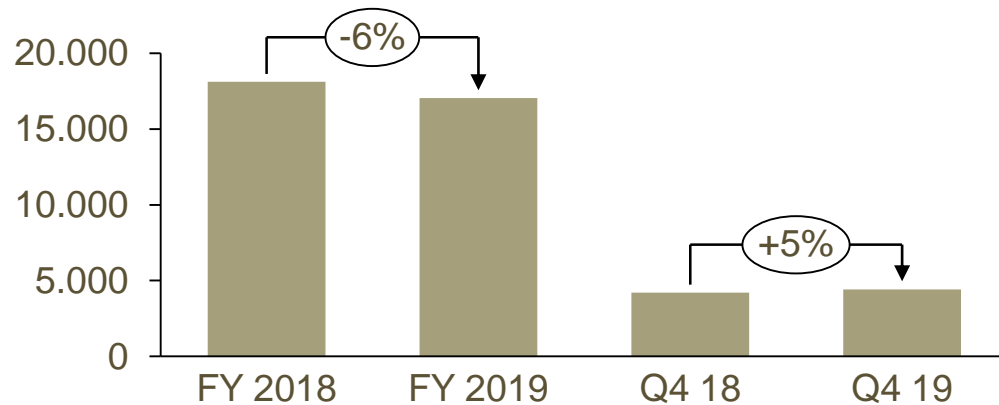
# Lundbeck saw strong progress against *Expand and Invest to Grow* strategy



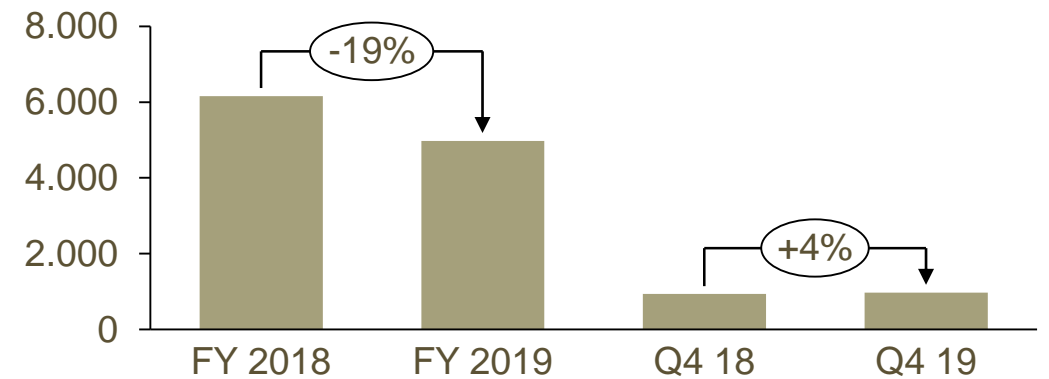
- Strategic brands grew 28% in 2019 with long-term predictable growth
- Two acquisitions expand the indications within neuroscience and add to the pipeline across all phases of development
  - Lundbeck La Jolla Research Center created: Establishing a strong platform for innovation
  - Lundbeck Seattle BioPharmaceuticals builds antibody capabilities
- 8 projects progressed or were added to the pipeline since February 2019
- Solid, stable cash generative base business
- Solid profitability while investing in future growth

# Lundbeck returned to growth in Q4 2019

**Revenue performance**  
(DKKm)

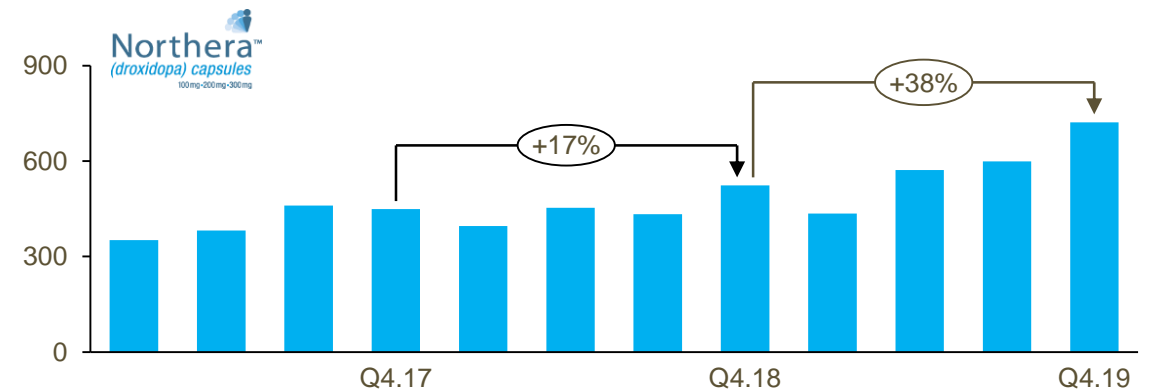
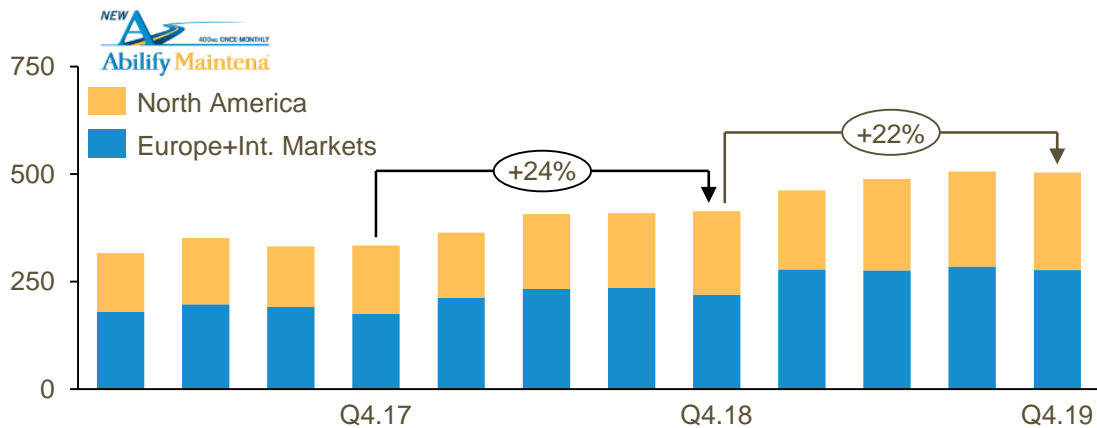
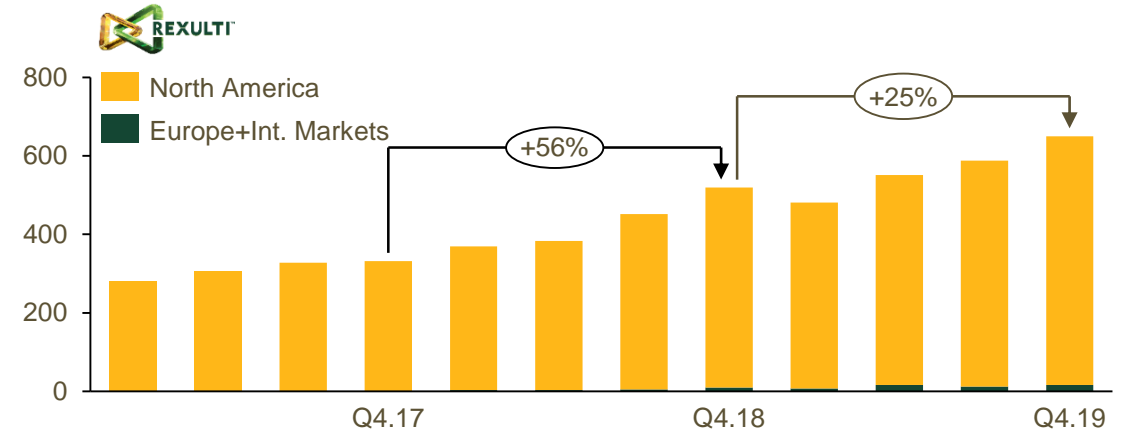
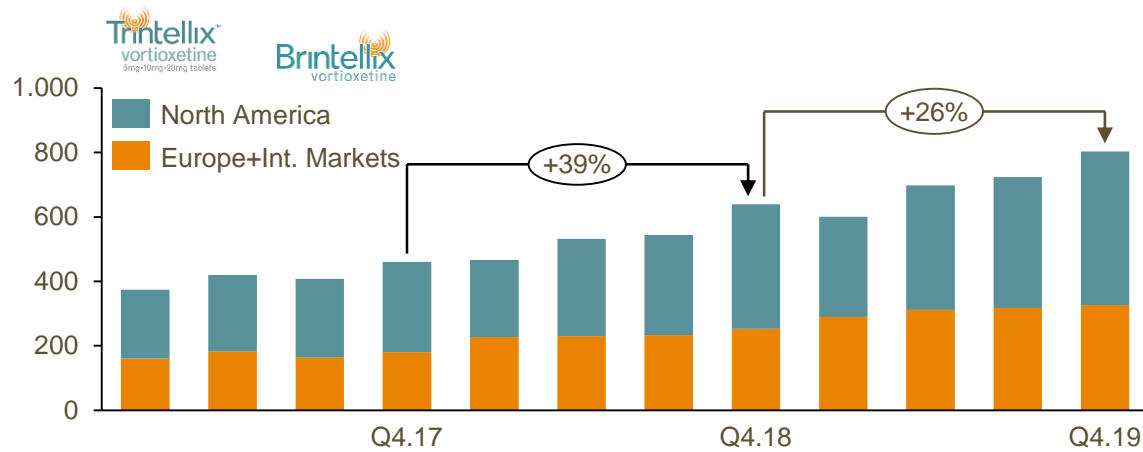


**Core EBIT performance**  
(DKKm)



- The reduced impact from Onfi erosion makes Lundbeck returns to growth in Q4 2019
- In the quarter the core EBIT-margin reaches 21.9% compared to 22.2% the previous year despite investments in commercial infrastructure and added operational costs related to Lundbeck Seattle

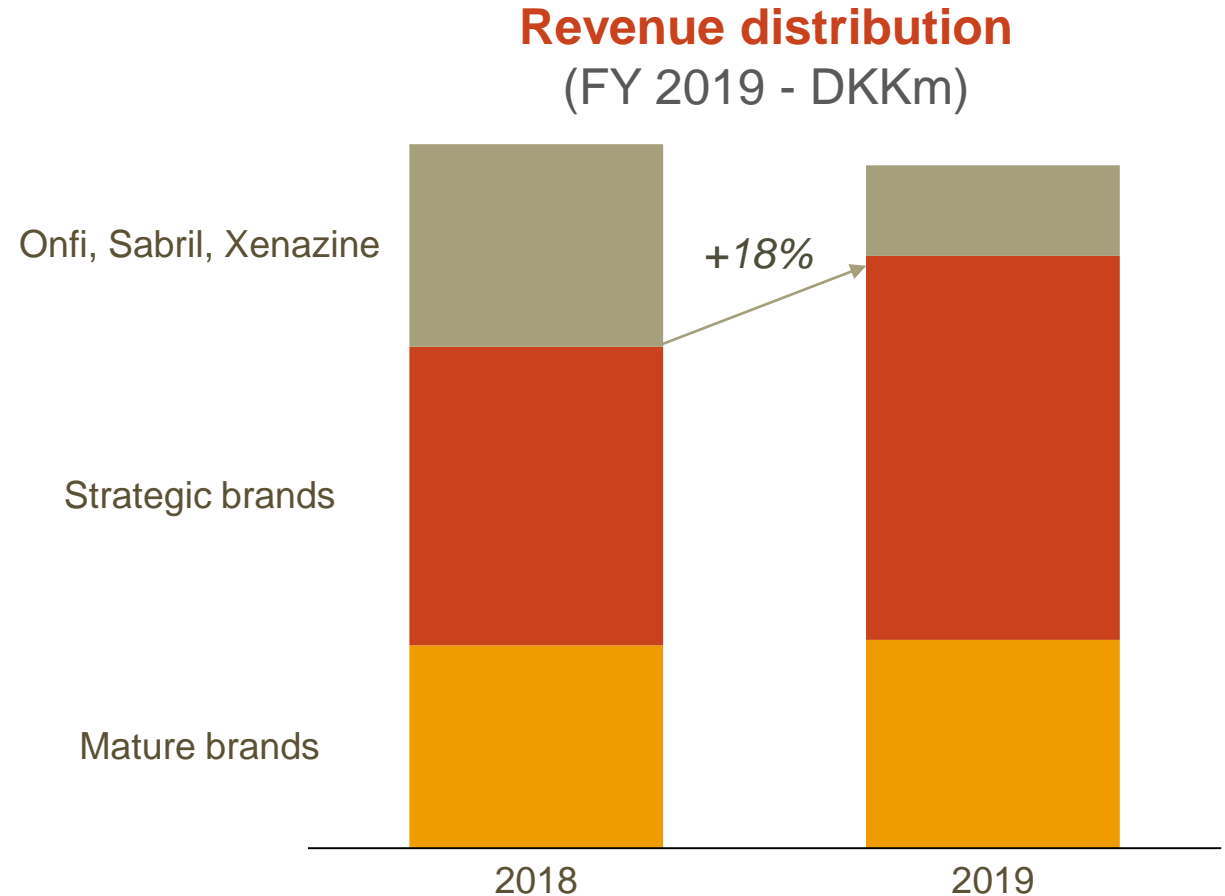
# Continued excellence in commercial execution delivers double-digit revenue growth in all regions for the four strategic brands





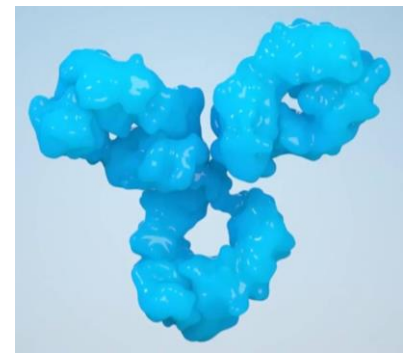
## 2019: A transition year - The strength of our strategic brands significantly mitigates Onfi LoE

- Focus on maximizing existing brands has successfully driven strong growth
- Y/Y revenue decline driven solely by genericization of U.S. neurology products
  - Excluding these products, revenue up by 18%
- Future growth less impacted by decline in mature brands
- Lundbeck ready for a new growth phase



# Eptinezumab: On a path towards launch and global roll-out

- November: Lundbeck Seattle Biopharmaceuticals organization in place
- November 2019: Initiation of *RELIEF* study
- January 2020: U.S. sales reps hired
- U.S. PDUFA: 21 February 2020
- February 2020: Submission in Canada
- H1 2020: Publications of *PROMISE 1* and *PROMISE 2*



# Potential for multiple new launches the next five years

Project	Area	Status
Eptinezumab	Migraine prevention	<ul style="list-style-type: none"> <li>U.S.: PDUFA on 21 February; Expected launch April 2020</li> <li>Filings in Canada, EU and other selected markets in 2020</li> </ul>
Brexpiprazole	Agitation in Alzheimer's disease	<ul style="list-style-type: none"> <li>Phase III ongoing, Study to finalize in H1 2021</li> <li>February 2016: FDA granted <i>Fast Track Designation</i></li> </ul>
Brexpiprazole	PTSD	<ul style="list-style-type: none"> <li>Phase III ongoing; Two pivotal studies to conclude during 2021</li> </ul>
Aripiprazole 2-months	Schizophrenia	<ul style="list-style-type: none"> <li>Phase Ib ongoing (pivotal); Study expected to finalize mid-2021</li> <li>Filing planned at the turn of 2021</li> </ul>
Lu AG06466	Tourette Syndrome	<ul style="list-style-type: none"> <li>Phase IIa to complete in H1 2020</li> </ul>
Foliglurax	Parkinson's disease	<ul style="list-style-type: none"> <li><i>AMBED</i>-study: Phase IIa to complete in H1 2020</li> </ul>





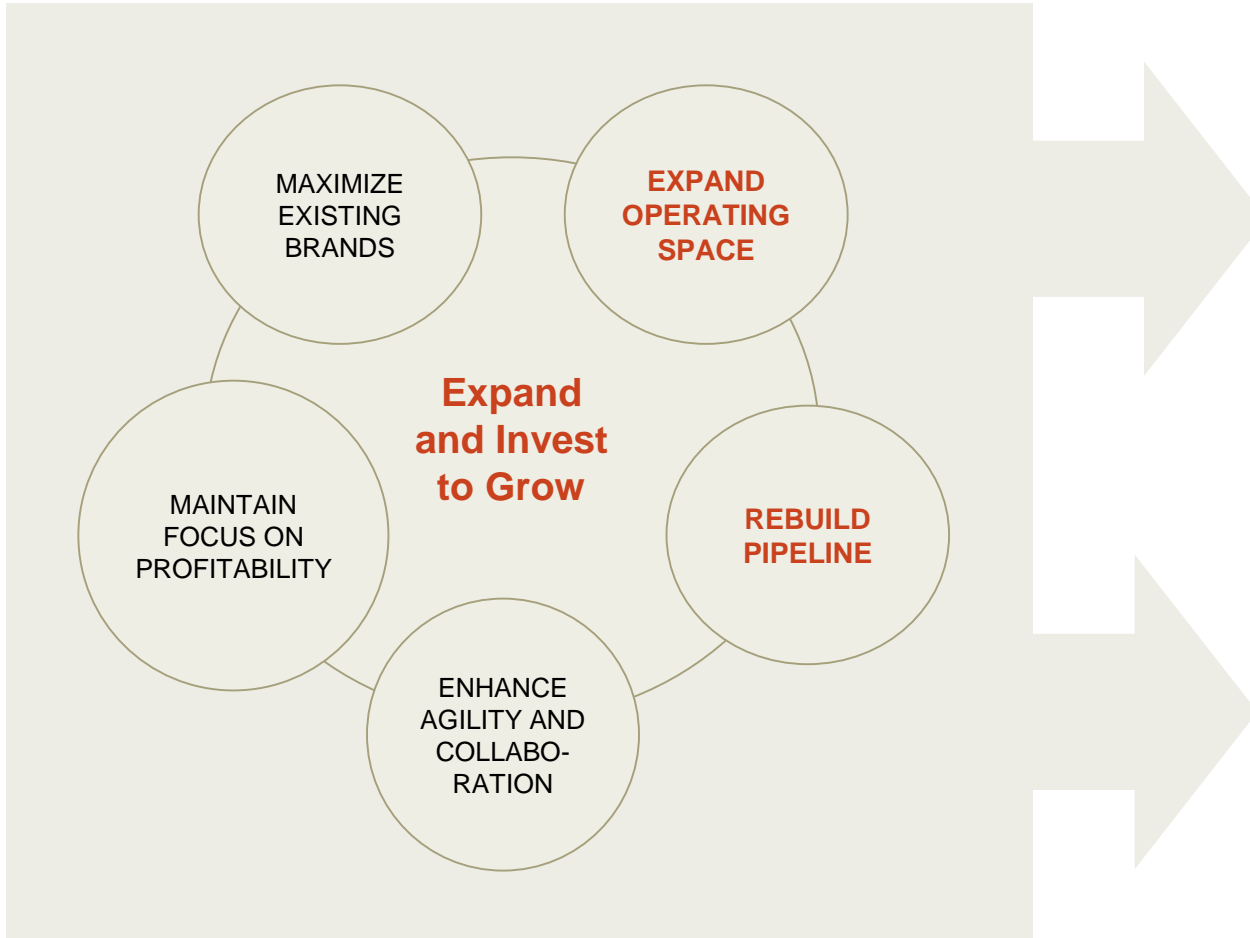
# Readying Lundbeck for a new growth phase – 2020 and beyond

- Strategic brands provide strong, predictable long-term growth
- Highly efficient global infrastructure
- Transformative launch of eptinezumab during 2020
- Expanding pipeline with promising science for future growth
- Solid, stable cash generative base business

**Guided by Lundbeck's Purpose:**  
*Tirelessly dedicated to restoring brain health,  
so every person can be their best*



# Significant progress made in expanding and revitalizing the pipeline



## Progression of internal pipeline

**Brexiprazole**  
PTSD  
(Phase III)

**Lu AF88434**  
Cognitive dysfunction  
(Phase I)

~~**Lu AF76432**  
Schizophrenia  
(Phase I)~~

**Lu AF11167**  
Schizophrenia  
(Phase II)

**Lu AF95245**  
Neuropsychiatric disorders  
(Phase I)

~~**Lu AF20513**  
Alzheimer's Disease  
(Phase I)~~

**Brexiprazole**  
Borderline Personality Disorder  
(Phase II)

**Lu AF87908**  
Alzheimer's Disease  
(Phase I)

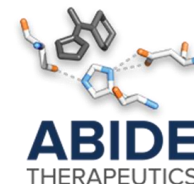
~~**Brexiprazole**  
Bipolar Mania  
(Phase III)~~

## Expansion through acquisitions



**Eptinezumab**  
Migraine prevention  
(Registration)

**Lu AG09222**  
Migraine  
(Phase I)



**Lu AG06466**  
Tourette Syndrome  
(Phase IIa)  
Neuropathic pain  
(Phase I)

# Several late-stage clinical trials initiated in 2019

- **Brexiprazole**

- Two pivotal studies<sup>1)</sup> initiated in October 2019 in adults with PTSD (n = 733 and 577)
- A phase II study<sup>3)</sup> initiated October 2019 in adults with Borderline Personality Disorder (n = 240)
- *ANCHOR* study<sup>4)</sup> initiated October 2019 to investigate the potential benefits and safety in children and adolescent subjects, aged 5 to 17, with irritability associated with autism spectrum disorder (n = 130)

- **Vortioxetine**

- *RECONNECT* study<sup>2)</sup> initiated December 2019 in adult patients with depression coexisting with general anxiety disorder (GAD) (n = 100)

- **Eptinezumab**

- *RELIEF* study<sup>5)</sup> initiated November 2019 to assess the efficacy for acute migraine, defined as an active intercurrent migraine occurring in those patients who are candidates for preventive therapy (n = 450)



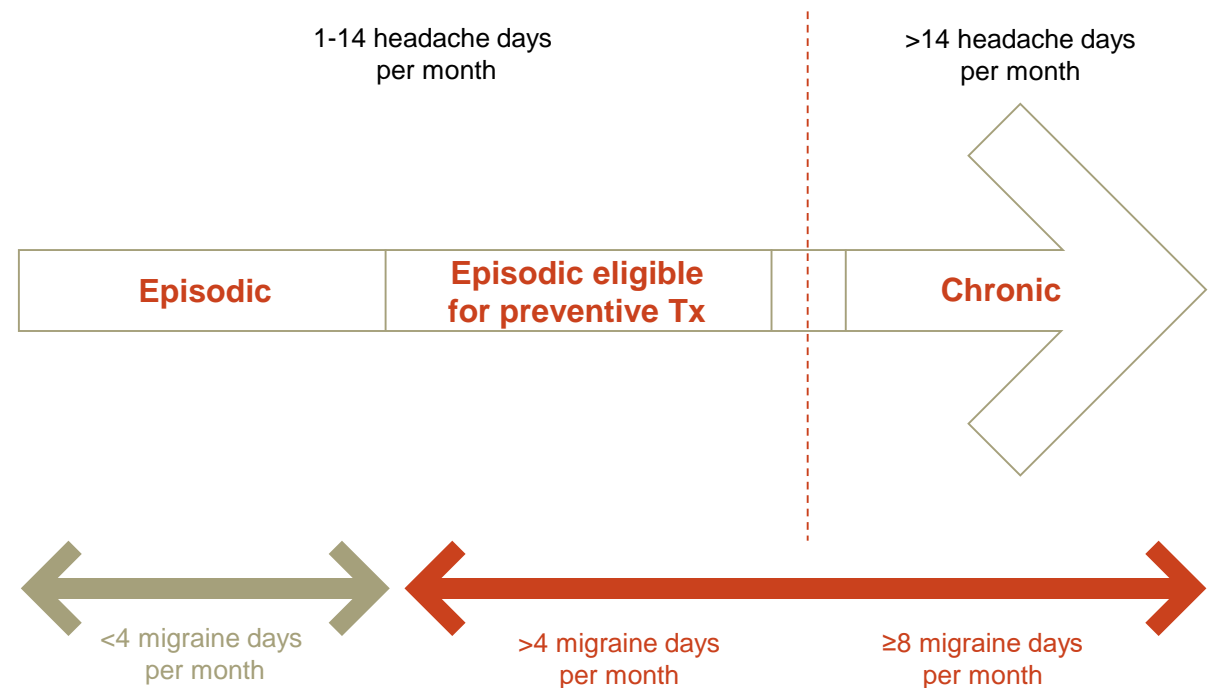
1) NCT04174170 and NCT04124614. 2) NCT04220996. 3) NCT04100096. 4) NCT04174365. 5) NCT04152083

# Migraine prevention represents a large and under served market

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

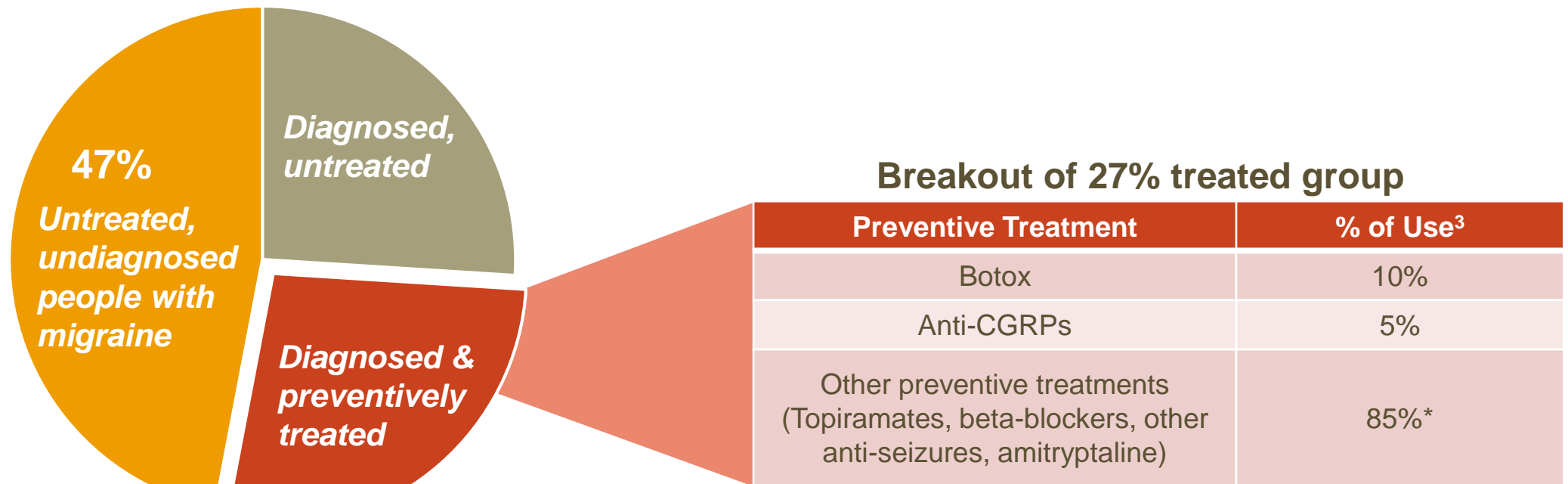
- ~134m – Migraine prevalence
- ~41m – Diagnosed patients (30%)
- ~18m – Eligible for prevention (43%)
- ~9m – Currently on prophylactic treatment

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



# Ready to launch eptinezumab in the U.S.

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



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

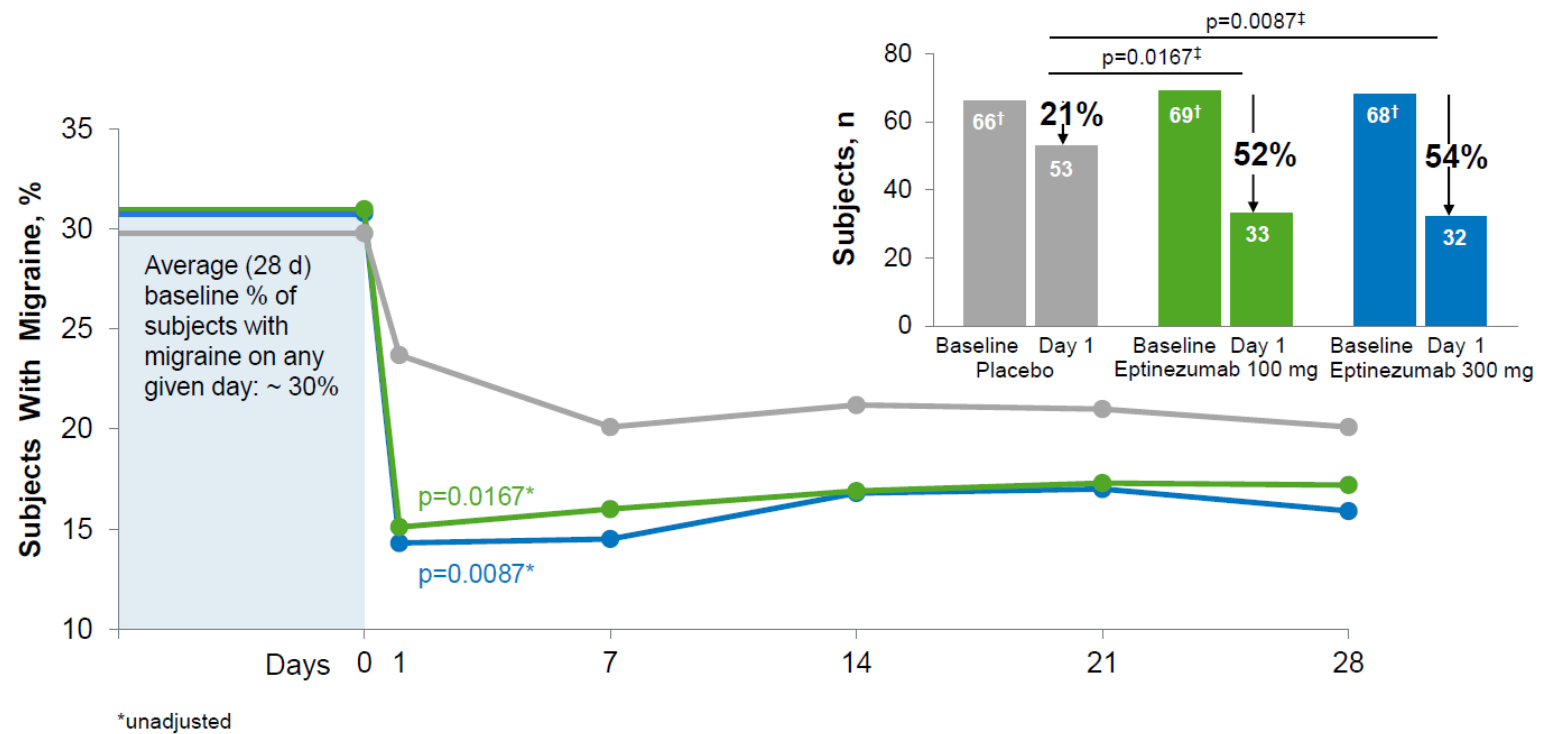
### Meaningful

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

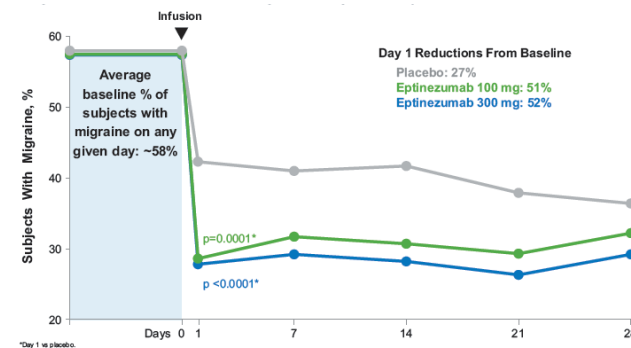


1) Clinicaltrials.gov ID: NCT04082325

# 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

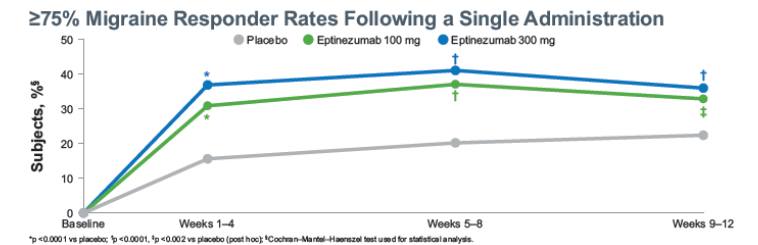
## Day 1 Reductions from baseline in percentages of subjects with a migraine maintained on average through 28 Days



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

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



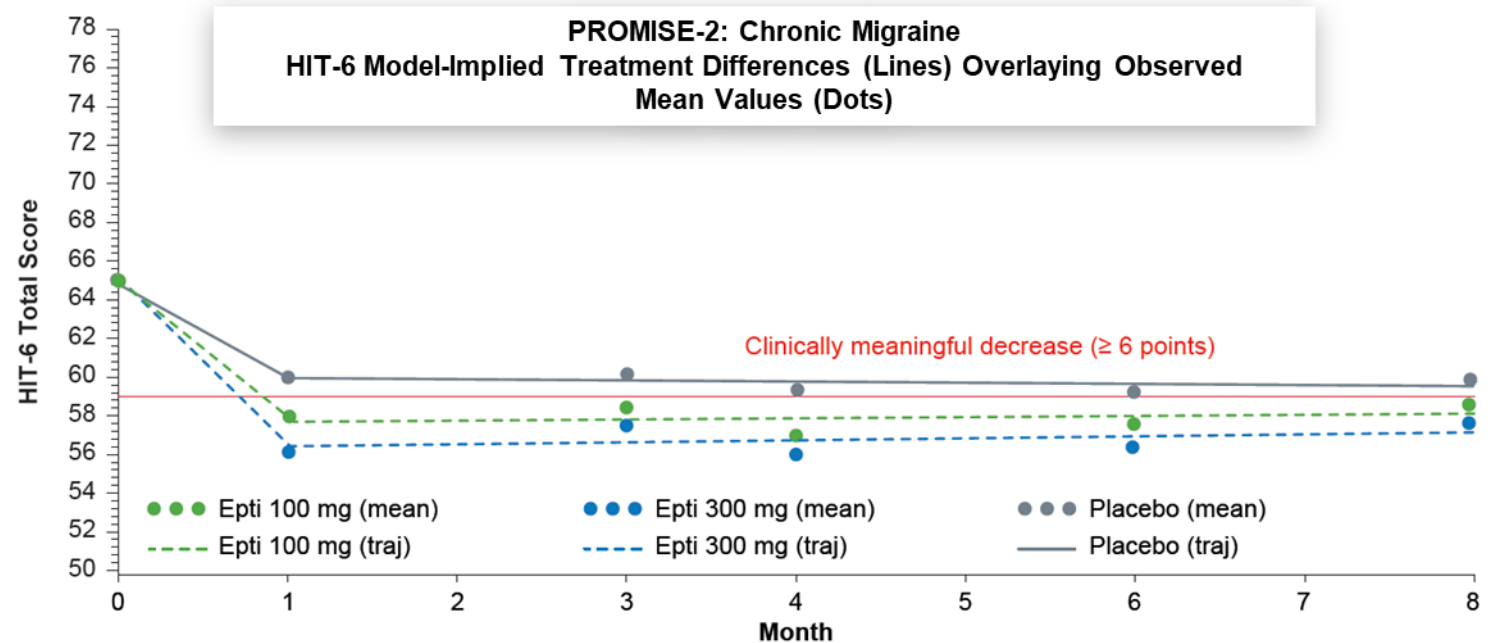
• An average of 38% of subjects treated with eptinezumab achieved a ≥75% reduction in monthly migraine over 3 months

• 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 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

\*) NCT04152083

**100 mg eptinezumab  
vs. placebo**

## Co-primary endpoints

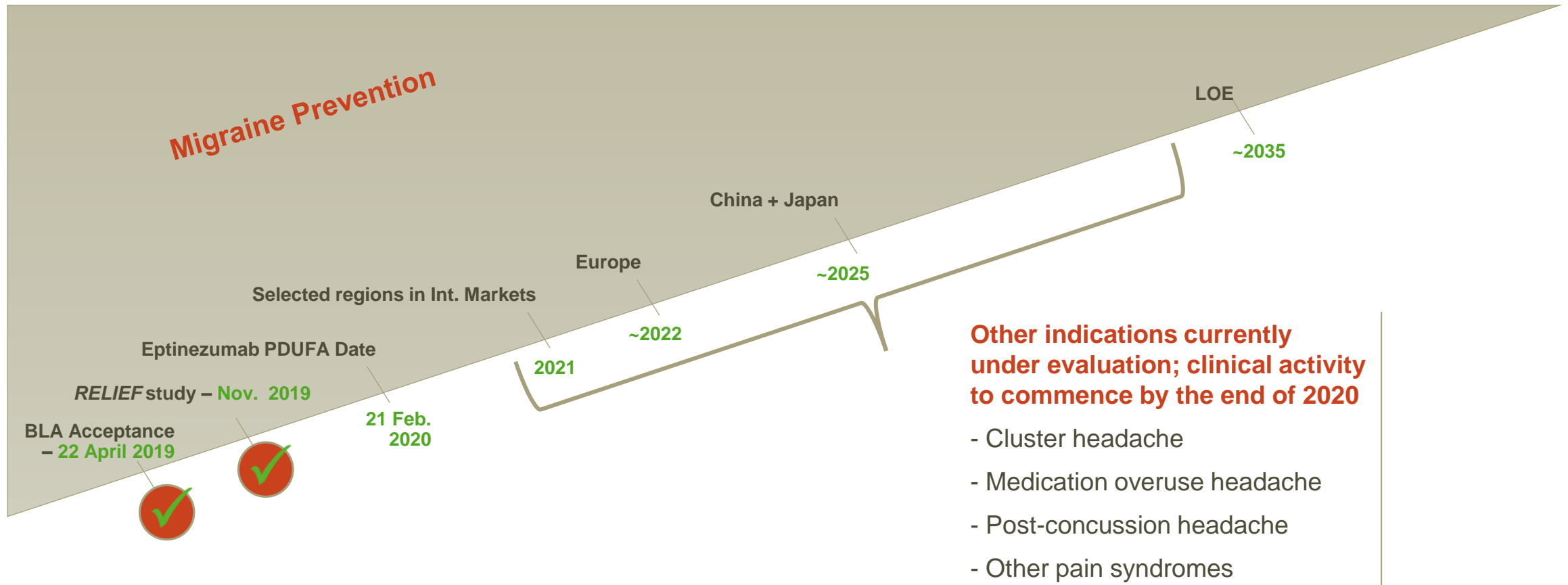
- Time to headache pain freedom
- Time to absence of most bothersome symptom

## Key secondary endpoints

*Measured 2 hours after start of treatment*

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

# Success for eptinezumab 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 - headline results due H1 2021

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>

## 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)

## 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 - headline results due 2022

U.S. dedicated study

1) Clinicaltrials.gov ID: NCT04124614 and NCT04174170

# 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

Headline results due in 2021

Fast Track designation granted 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

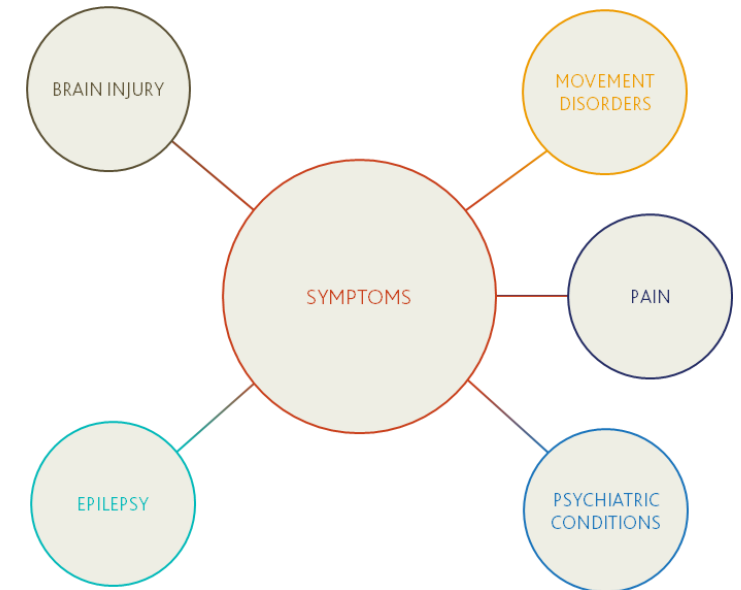
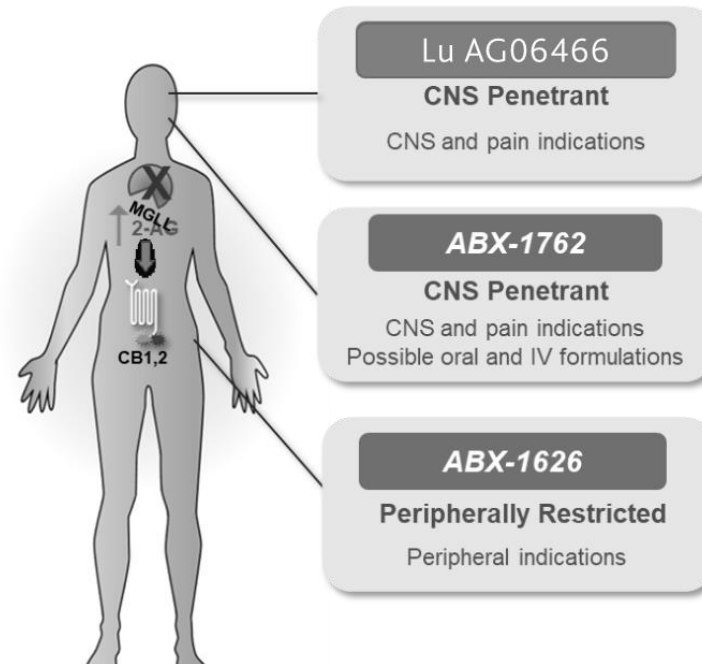
Access to world class MAG-lipase development candidates to bolster our portfolio

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





# Phase IIa study investigating Lu AG06466 near finalization

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

This study will assess the safety, tolerability, and effect on tics Lu AG06466 (previously ABX-1431) in adults with Tourette Syndrome or chronic motor tic disorder in an 8-week study. It is a two-part study

Part 1 is a double-blind, randomized, placebo-controlled study at two target dose levels

Part 2 is an optional, open-label, non-randomized study

## Phase IIa:

Two active arms (10mg and 30mg) + placebo

N = ~48 patients

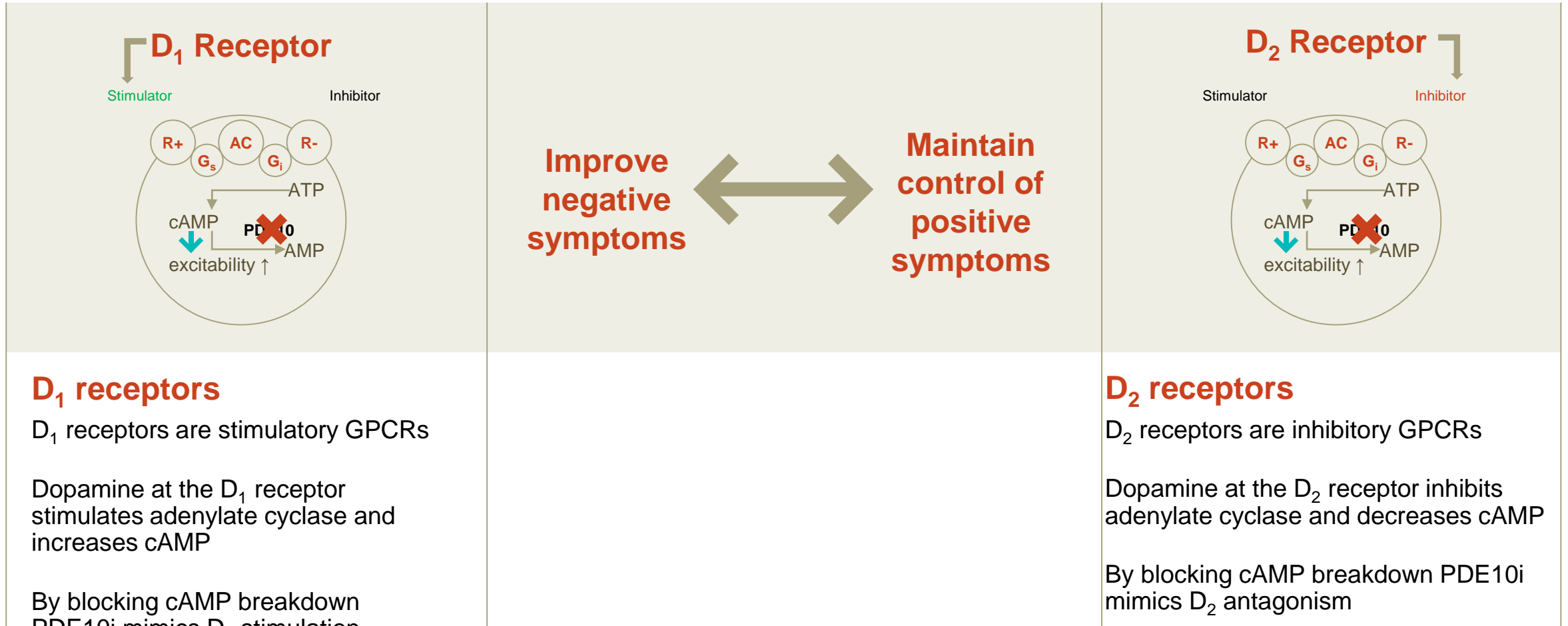
**Primary endpoint:** Change from baseline in Total Tic Score of the Yale Global Tic Severity Scale (YGTSS-TTS) compared with placebo

**Secondary endpoint:** Adult Tic Questionnaire (ATQ); Premonitory Urge for Tics Scale (PUTS); Clinical Global Impressions Scale for Improvement (CGII) and several AE related endpoints

Phase IIa started in October 2018; headline results due in H1 2020

1) Clinicaltrials.gov ID: NCT03625453

# 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

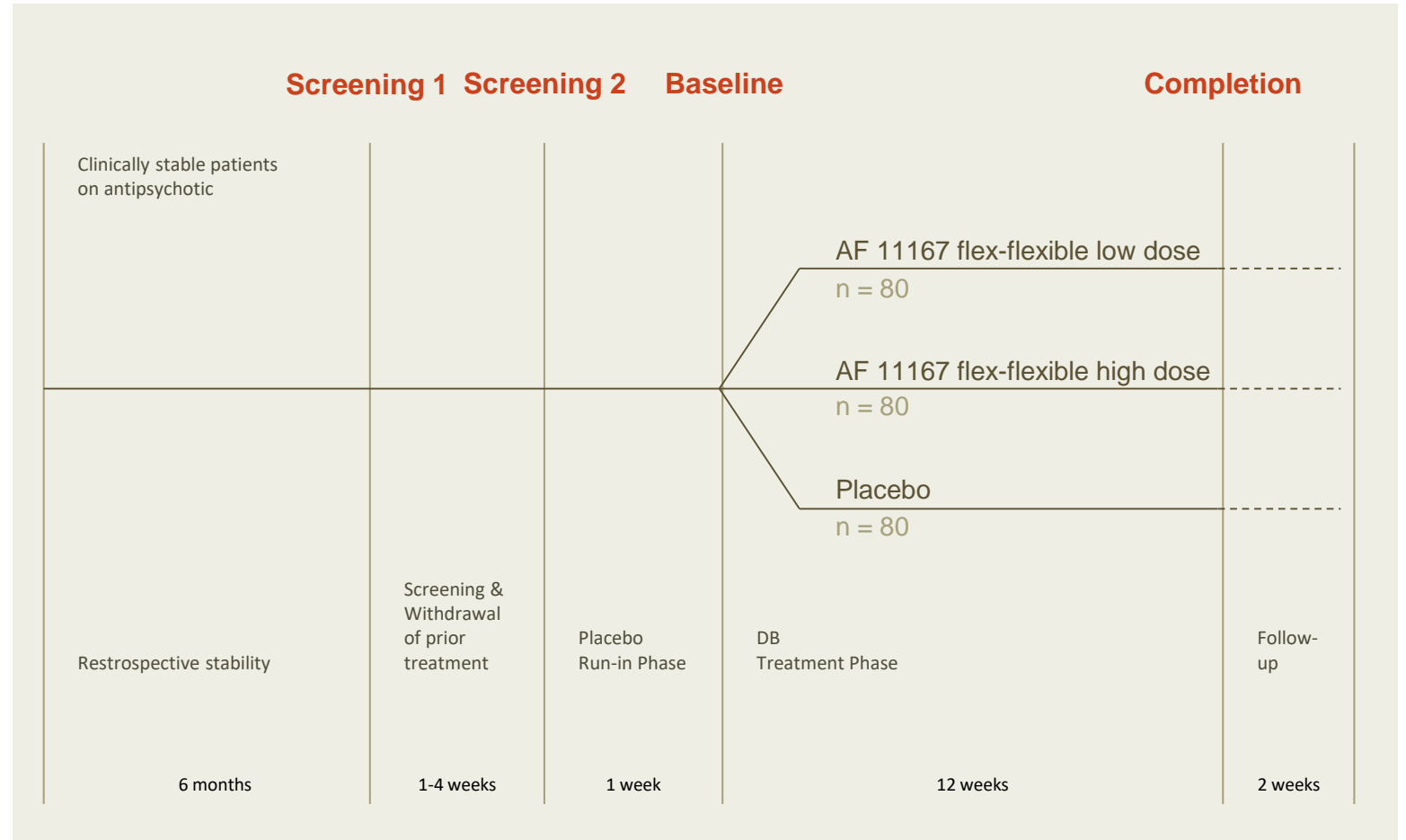
**Primary endpoint:** Change from baseline to Week 12 in BNSS total score\*\*

Several secondary endpoints

Expected completion: 2021

\*) ClinicalTrials.gov Identifier: 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 (major countries)

**4.7m**

Prevalence of schizophrenia (G7)

**3.5m**

Treatment prevalence (75%)

**1.7m**

Clinical stable outpatients (50%)

**0.8m**

Negative symptoms (40%)

# Pipeline - >50% of current projects are new since February 2019

Project	Area	Phase I	Phase II	Phase III	Filing
<b>Eptinezumab (anti-CGRP mAb)</b>	Migraine prevention				★
Brexpirazole	Agitation in Alzheimer's disease			★	~2021
Brexpirazole	PTSD			★	≥2023
<b>Brexpirazole</b>	Borderline Personality Disorder		★		≥2025
Foliglurax (mGluR4 PAM)	Parkinson's disease		★		~2025
Lu AF11167 (PDE 10 inhibitor)	Schizophrenia		★		≥2025
<b>Lu AG06466 (MAGLi)</b>	Tourette Syndrome		★		≥2025
Aripiprazole 2-month injectable	Schizophrenia+bipolar I disorder	★			~2021
Lu AF82422 (alpha-synuclein mAb)	Synucleinopathies	★			>2025
Lu AF28996 (D <sub>1</sub> /D <sub>2</sub> agonist)	Parkinson's disease	★			>2025
<b>Lu AG06466 (MAGLi)</b>	Neuropathic pain	★			>2025
<b>Lu AF88434 (PDE1B inhibitor)</b>	Cognitive dysfunction	★			>2025
<b>Lu AG09222 (PACAP mAb)</b>	Migraine	★			>2025
<b>Lu AF87908 (Tau mAb)</b>	Tauopathies	★			>2025
<b>Lu AF95245 (Kv7 activator)</b>	Neuropsychiatric disorders	★			>2025

Most advanced stage shown

# 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> 

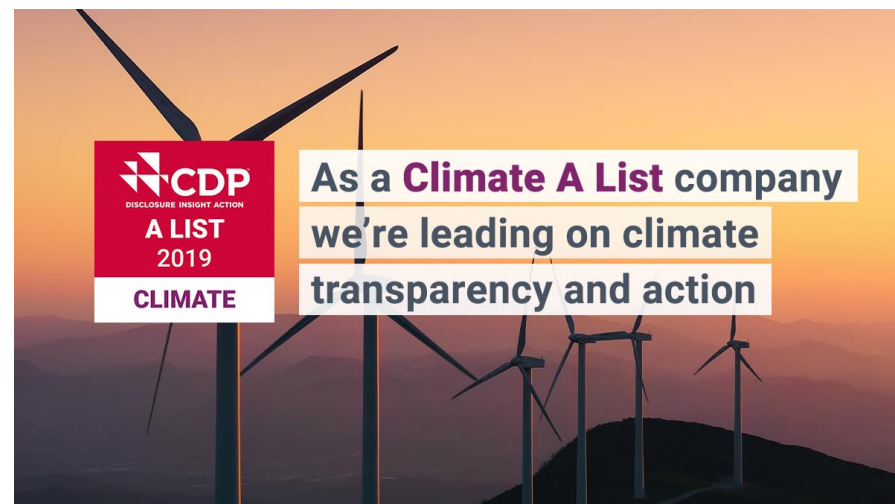
## Overview of our ambitions, initiatives and targets

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)

# Achieves Climate A List top 2% of more than 8,400 companies evaluated for their actions against climate change

Category	2019	2018	Change (%)
Energy (MWh)	93,137	94,312	(1.2)
CO <sub>2</sub> (tonnes)	15,254	15,973	(4.5)
Work related accidents with absence (accidents per 1 mill working hours)	6.2	7.5	(17.3)
Number of employees (FTE)	5,806	5,143	12.9



- Lundbeck joins “Business Ambition for 1.5°C” a global alliance of leading companies aligning their business actions with the Paris Agreement’s ambitions
- Lundbeck joins “Climate Panel for Life Science and Biotech” in Denmark, helping to provide industry-wide recommendations



# Robust financial performance in 2019 - Investments in new products and reduced exposure to generic erosion

## FY2019

- Revenue impacted by Onfi erosion
- Gross margin in line with expectations
- Operational costs up 2% to DKK 9.5 billion
- EBIT margin mainly impacted by Onfi erosion
- Tax rate positively impacted by alder related tax benefits

DKKm	FY 2019	Δ% y/y	Q4 2019	Δ% y/y
Revenue	17,036	(6%)	4,421	+5%
<i>Gross margin</i>	80.1%	-0.8pp	78.5	-1.2pp
Operating expenses	9,529	+2%	2,667	+2%
SG&A	6,413	+6%	1,777	+9%
R&D	3,116	(5%)	890	(10%)
Other operating items, net	(514)	-	(514)	-
EBIT	3,608	(32%)	291	(66%)
<i>EBIT margin</i>	21.2%	-8.1pp	6.6%	-13.6pp
Net financials	(127)	-	(149)	-
<i>Effective tax rate</i>	23.4%	-2.7pp	-	-
EPS	13.42	(32%)	1.16	(65%)

## Q4.2019

- Return to revenue growth
- Strategic brands up 28%
- Mature U.S. neurology products constitute less than 11% of total revenue
- Profits impacted by acquisition and integration costs
- Underlying profitability strong with core EBIT margin reaching 21.9%

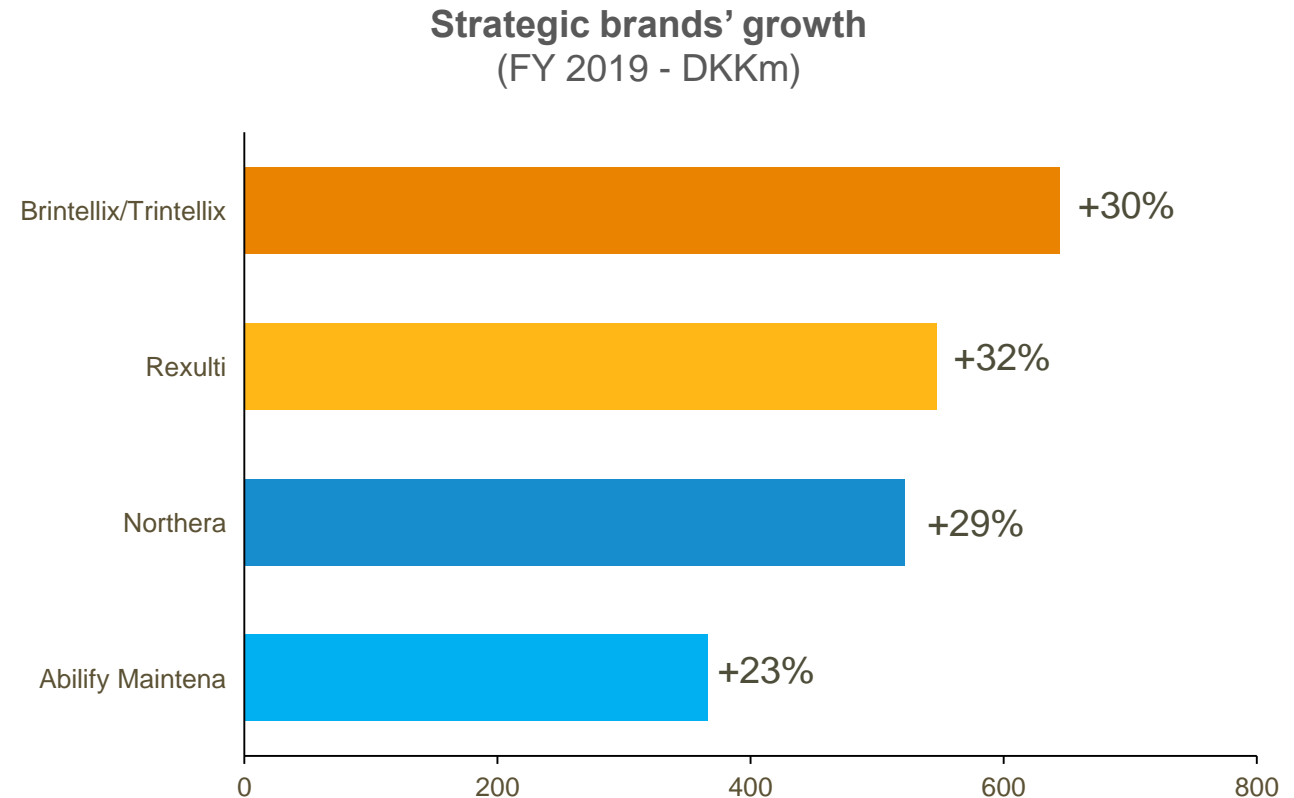
## Core P&L shows solid underlying financial performance

- Gross margin fairly stable as expected
- Core EBIT mainly impacted by investments in commercial infrastructure
- Core EPS benefitting from reduced tax payments following the Alder transaction

DKKm	FY 2019	% change	% total revenue	Q4 2019	% change	% total revenue
Revenue	17,036	(6%)	100	4,421	+5%	100
<i>Gross margin</i>	<b>85.1%</b>	-0.3pp	-	<b>83.4%</b>	-1.2pp	-
Operating expenses	9,529	+2%	56	2,722	+4%	61
- SG&A expenses	6,413	+6%	38	1,832	+12%	41
- R&D expenses	3,116	(5%)	18	890	(10%)	20
Core EBIT	4,976	(19%)	29	966	+4%	22
<i>Core EBIT-margin</i>	<b>29.2%</b>	-4.8pp	-	<b>21.9%</b>	-0.3pp	-
<i>Tax rate</i>	<b>20.3%</b>	-	-	<b>1.2%</b>	-	-
Core EPS	19.46	(18%)	-	4.06	+9%	-

# Lundbeck's four strategic brands added DKK 2.1 billion in additional revenue in 2019

- **Strategic brands\*:** Up 28% (24% in L.C.) to DKK 9,385 million representing 55% of total revenue
- **Brintellix/Trintellix:** Up 30% to DKK 2,826 million
- **Rexulti/Rxulti:** Up 32% to DKK 2,270 million
- **Northera:** Up 29% to DKK 2,328 million
- **Abilify Maintena:** Up 23% to DKK 1,961 million

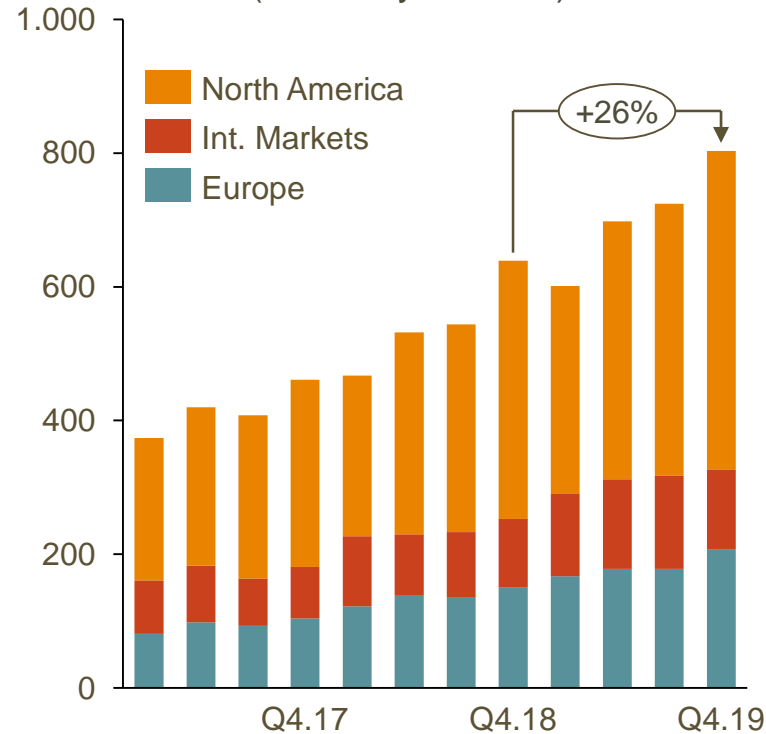


\*) Abilify Maintena, Brintellix/Trintellix, Northera and Rexulti/Rxulti

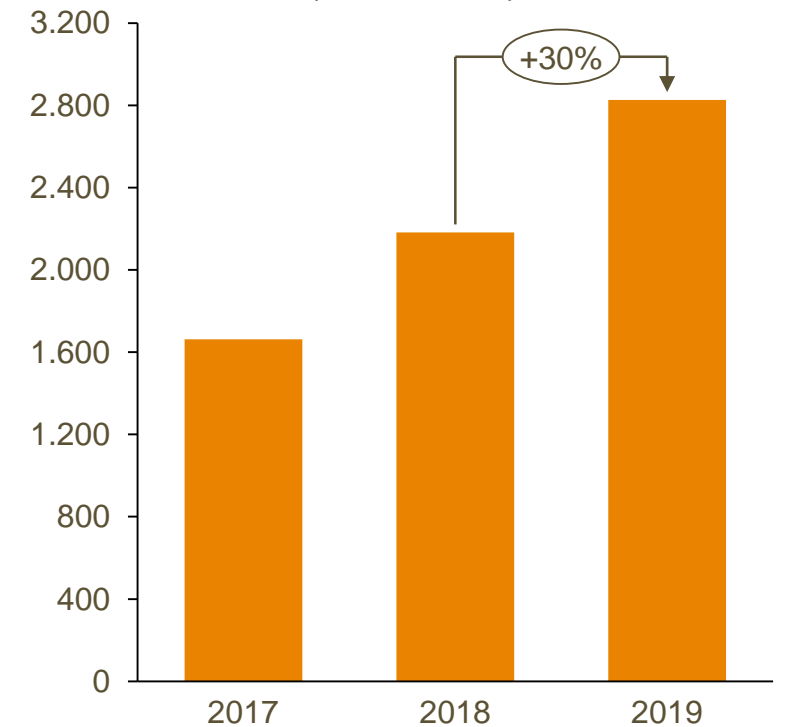
# Brintellix/Trintellix continues its significant growth momentum

- Grew 30% (26% in L.C.) to DKK 2,826 million in 2019
- Continued solid traction in value share gains<sup>1)</sup>
  - >8.0%: Denmark, Finland, France, Italy, Norway, Spain and Sweden
  - >5.0%: Canada, Switzerland and Turkey
- In the U.S., volume is up 17% y/y in Q4 2019<sup>2)</sup>
  - U.S. value share of 22.5%<sup>1)</sup>
- Trintellix launched in Japan in November

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



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

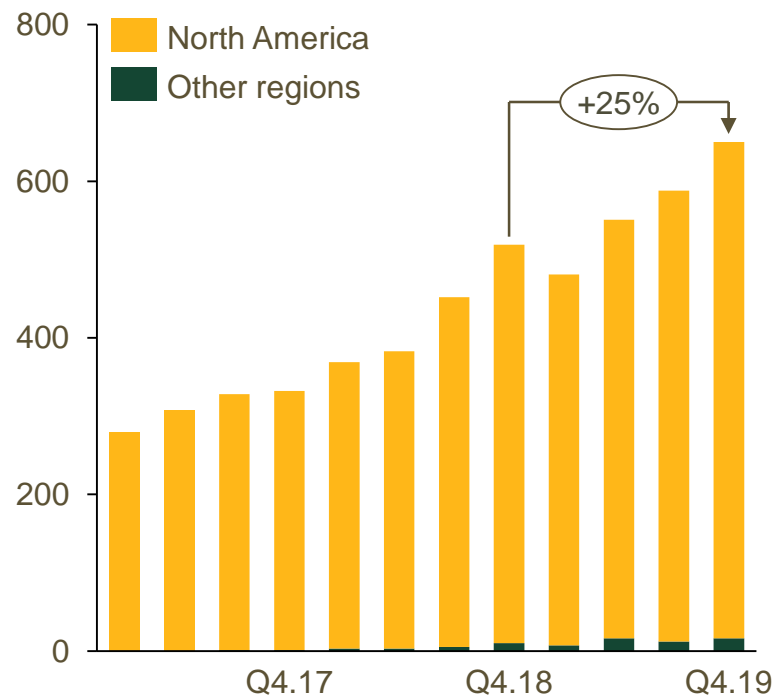


1) IQVIA. 2) Symphony Health (cf. Bloomberg)

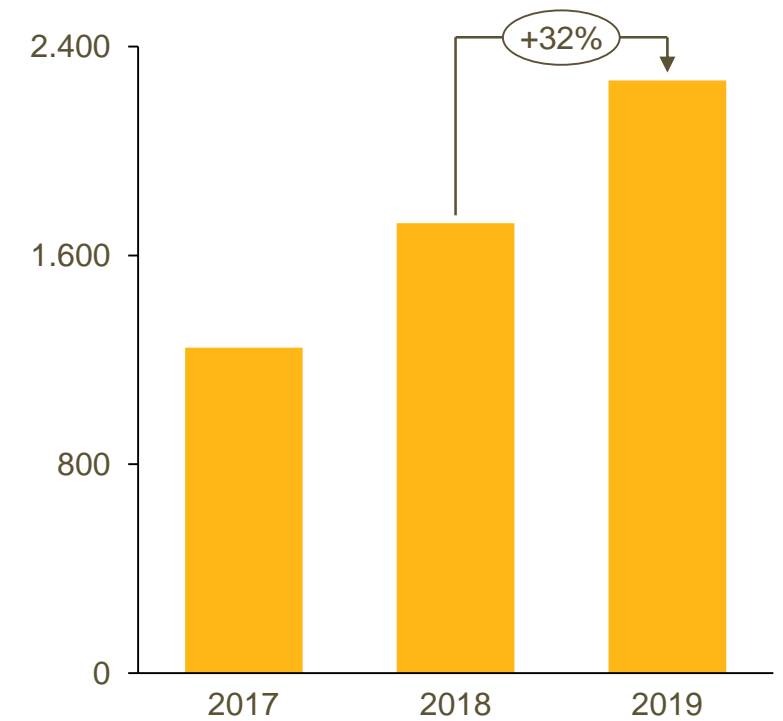
# Rexulti shows significant growth driven by demand - roll-out in new markets continues

- Grew 32% (25% in L.C.) to DKK 2,270 million in 2019
- In the U.S., volume is up 19% y/y in Q4<sup>1)</sup>
- Launched in North America, selected European markets, Australia, Chile, Mexico and Saudi Arabia
- Phase III programme in PTSD<sup>2)</sup> commenced in October 2019
- Phase II study in BPD<sup>3)</sup> commenced in October 2019

Rexulti sales per region\*  
(Quarterly - DKKm)



Rexulti sales\*  
(FY - DKKm)



1) Symphony Health (cf. Bloomberg)

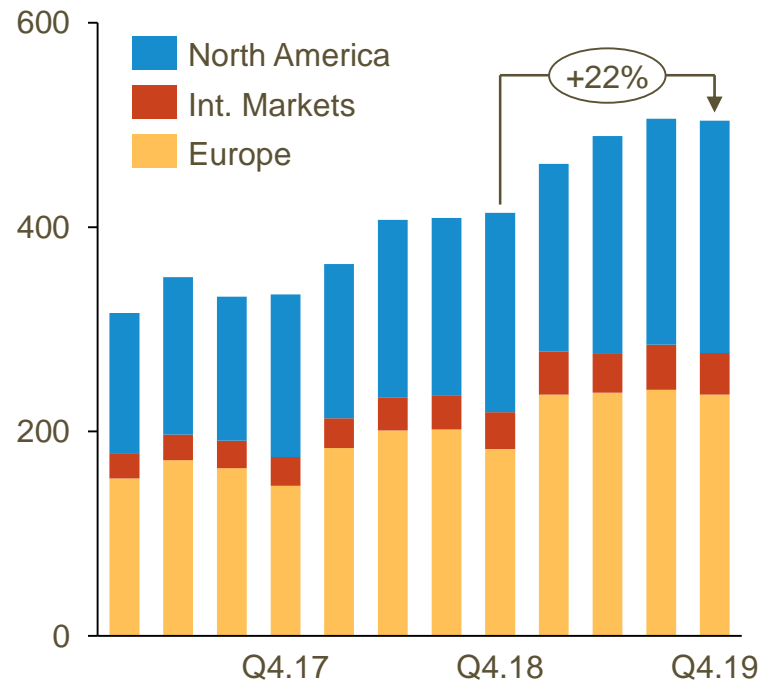
2) Borderline Personality Disorder. 3) Post-Traumatic Stress Disorder

\*) Lundbeck's share of revenue

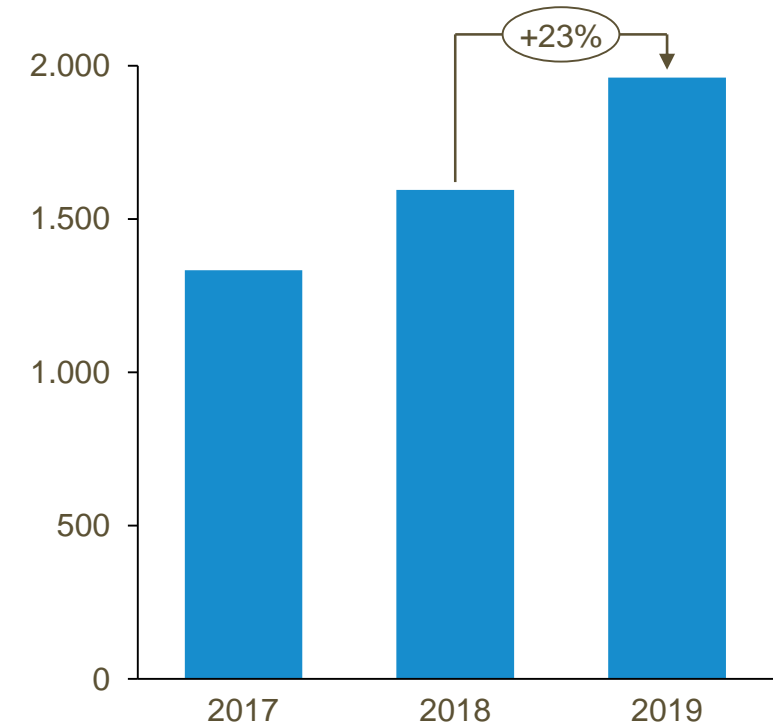
# Abilify Maintena continues its robust growth

- Grew 23% (20% in L.C.) to DKK 1,961 million in 2019
- 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 5bn (2019)
- Abilify Maintena’s share of the LAI market is 17% compared to 16% in FY2018<sup>1)</sup>

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



Abilify Maintena sales\*  
(FY - DKKm)



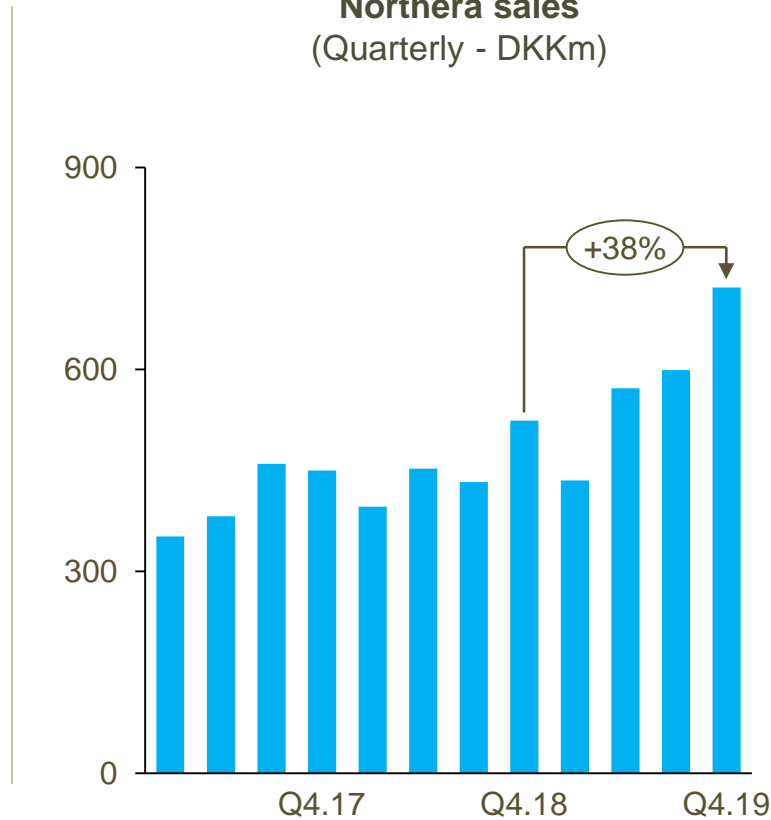
1) Reported net sales of atypical LAIs

\*) Lundbeck’s share of revenue

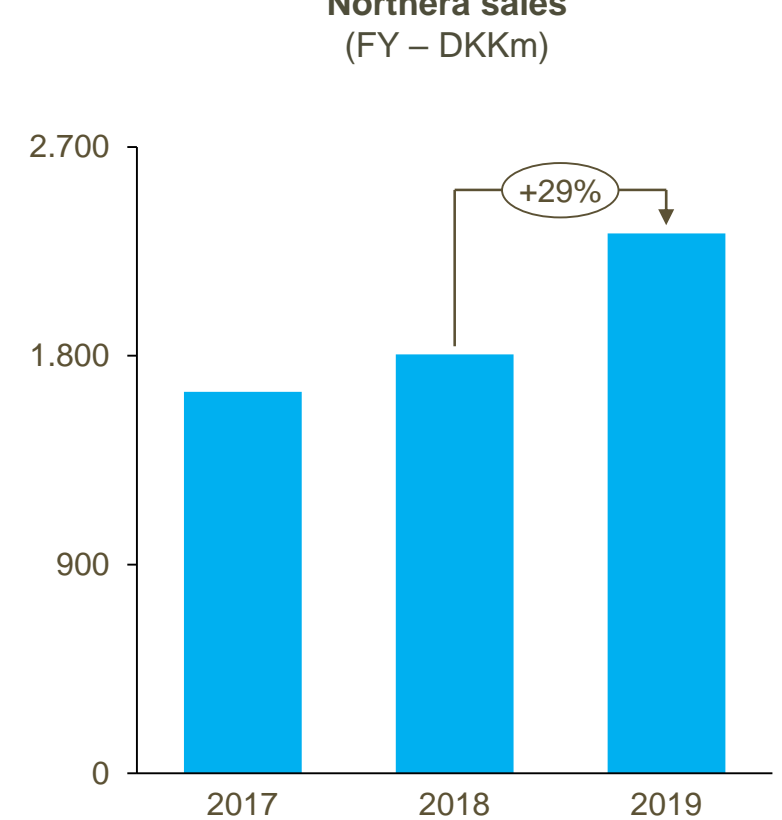
# Northera shows solid growth in sales and demand

- Grew 29% (22% in L.C.) to DKK 2,328 million in 2019
- Volume is up 8%<sup>1)</sup> compared to Q4 2018
- Northera impacted by normal quarterly fluctuations driven by e.g. seasonality and pharmacies' buying pattern
- Lundbeck only promotes Northera in the U.S.

Northera sales  
(Quarterly - DKKm)



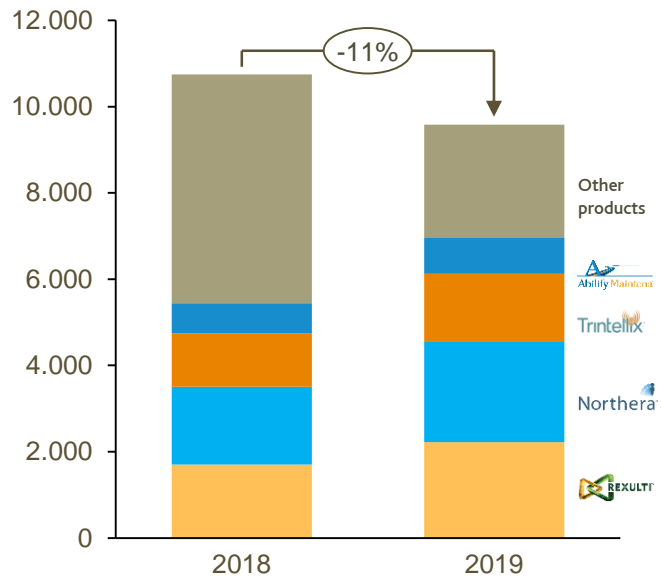
Northera sales  
(FY – DKKm)



<sup>1)</sup> Symphony Health (cf. Bloomberg)

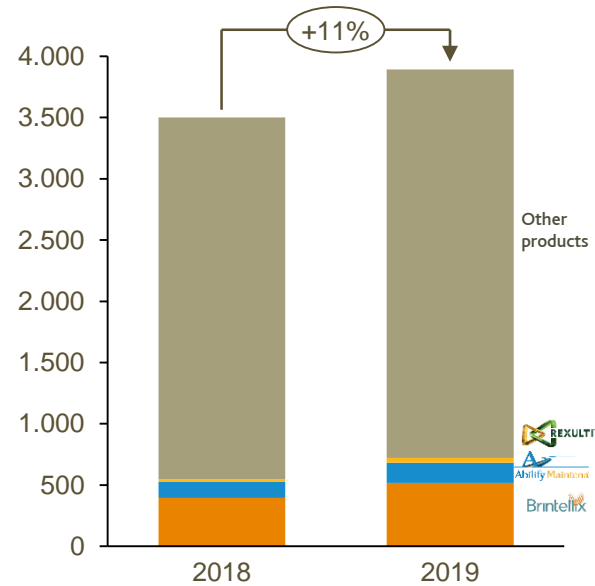
# Solid growth in both Europe and International Markets, and North America grew when adjusted for Onfi

North America revenue  
(FY - DKKm)



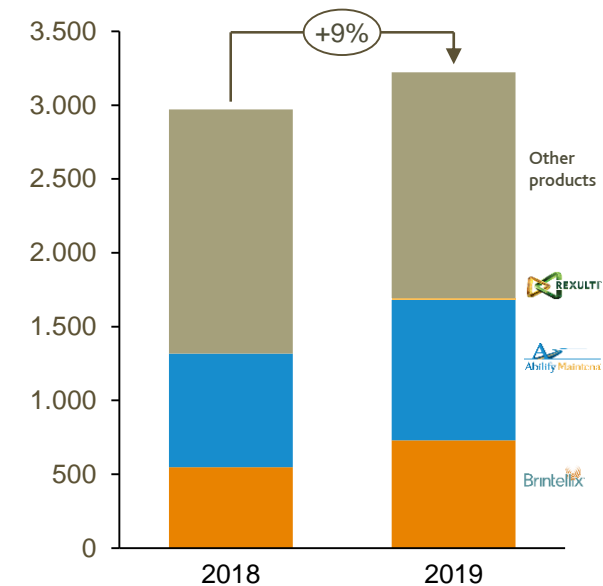
- Strategic brands up 28% to DKK 6,971m
- 13% growth ex. Onfi
- Eptinezumab will add to growth in 2020

International Markets revenue  
(FY - DKKm)



- Strategic brands up 32% to DKK 722m
- CipraleX/Lexapro still strong
- Trintellix progresses as planned in Japan

Europe revenue  
(FY - DKKm)



- Strategic brands up 29% to DKK 1,692m
- CipraleX in Q4 benefitted from quarterly fluctuations



## 2-6% revenue growth expected for 2020 - earnings impacted by investments in eptinezumab

- Continued strong growth for strategic brands
- Increased uncertainty in China following the corona virus outbreak
- Substantial investments in launch and R&D activities for eptinezumab
- Effects from hedging is a loss of around DKK 200 - 250 million
- Net financial expenses of DKK 300-400 million expected in 2020
- Financial guidance based on currency levels from mid-January 2020\*

### 2020 financial guidance

DKK	FY 2019 actual	FY 2020 guidance
Revenue	17,036m	17.4 – 18.0bn
EBITDA	4,823m	3.9 – 4.4bn
Core EBIT	4,976m	3.5 – 4.0bn
EBIT	3,608m	2.2 – 2.7bn
<i>Effective tax rate</i>	23.4%	22 – 24%

A positive outcome of the foliglurax phase IIa *AMBLEMED*-study can result in milestone payments of up to EUR 100 million in 2020. A milestone payment of EUR 25 million is payable if primary and key secondary endpoint are met and an additional EUR 75 million is payable if improvement in OFF time exceeds two hours. A negative outcome of the study might result in a write-down of the product rights whereby EUR 100 million will be recognized in the income statement.

\*) Lundbeck's main trading currencies are the USD, JPY, CNY and CAD. The financial guidance is based on the current hedging rates for our main currencies; i.e. USD/DKK (6.40), JPY/DKK (0.0615), CAD/DKK (4.93) and CNY/DKK (0.94)

# Financial position solid despite acquisitions and elevated investment levels

## Selected cash flow figures

DKKm	FY 2019	Q4 2019
Cash flows from operating activities	2,609	394
Cash flows from investing activities	(7,755)	(7,357)
Free cash flow	(5,146)	(6,963)
Cash flows from financing activities	4,548	6,997
Net cash flow for the period	(598)	34

## Selected balance sheet figures

DKKm	31.12.2019	31.12.2018
Intangible assets	23,399	8,023
Total assets	35,757	23,011
Equity	14,554	14,251
Non-current liabilities	10,923	1,184
Current liabilities	10,280	7,576
Cash, bank balances and securities	3,012	6,635
Interest-bearing debt	(9,578)	-
Net debt	(6,566)	6,635

- **Dividend pay-out:** DKK 816m proposed for 2019 or DKK 4.10 per share
- **Net debt:** Net debt position of DKK 6-6.5 bn 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

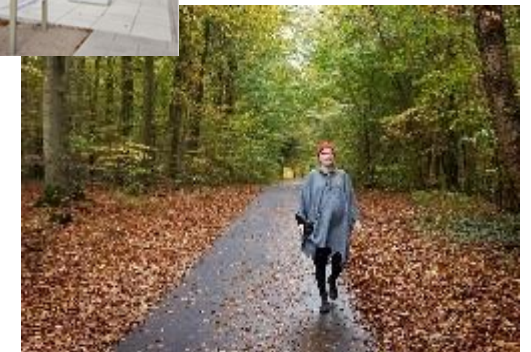
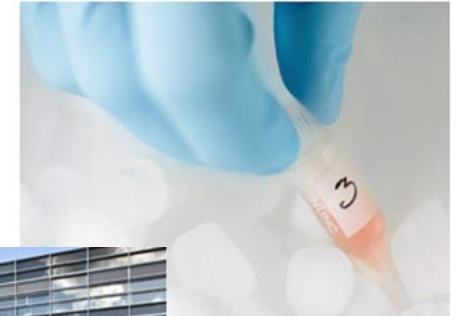
# Selected deliverables for 2020

## H1 2020:

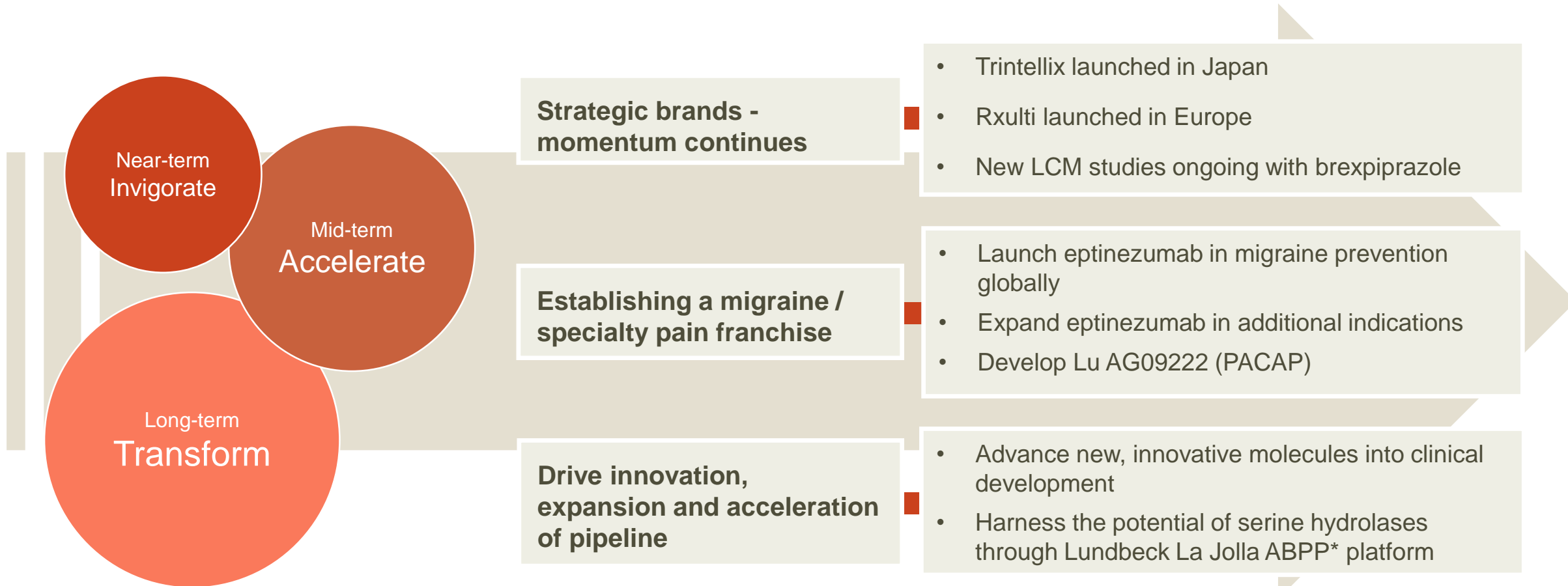
- Canadian submission for eptinezumab
- U.S. PDUFA action date on eptinezumab (21 February)
- Launch eptinezumab in the U.S (April)
- Phase IIa headline results (*AMBLEMED*) for foliglurax (Parkinson's)
- Phase IIa headline results for Lu AG06466 (Tourette's)

## H2 2020:

- EU submission of eptinezumab
- Headline results from *RELIEF* study (eptinezumab)
- 1-2 additional new molecules in clinical development



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



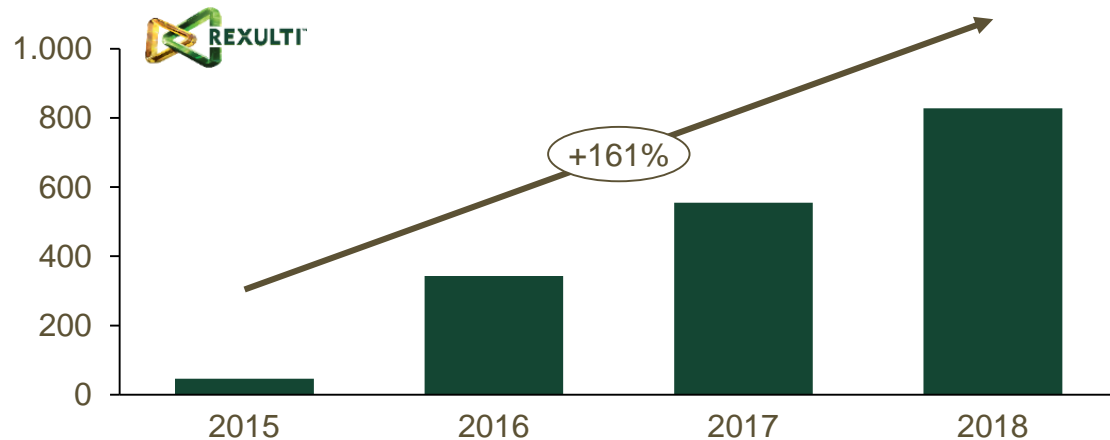
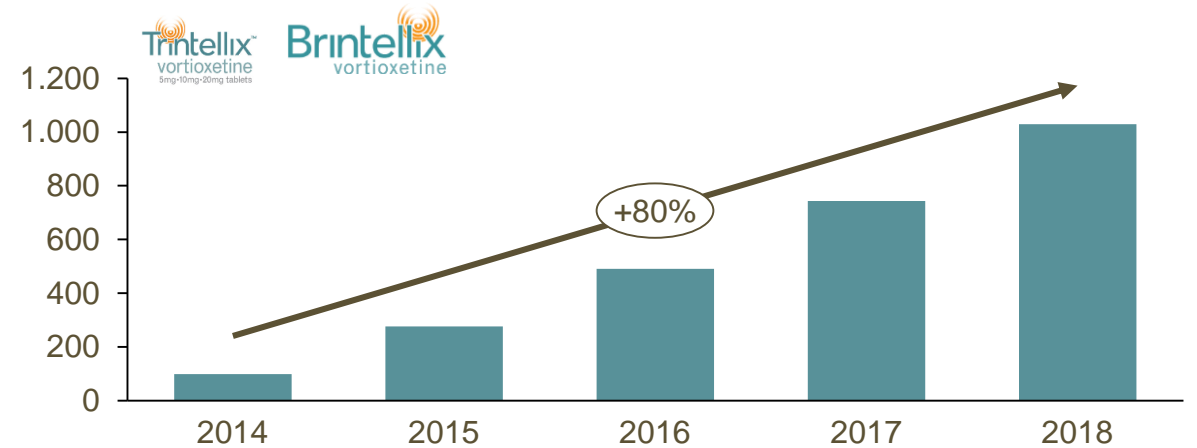
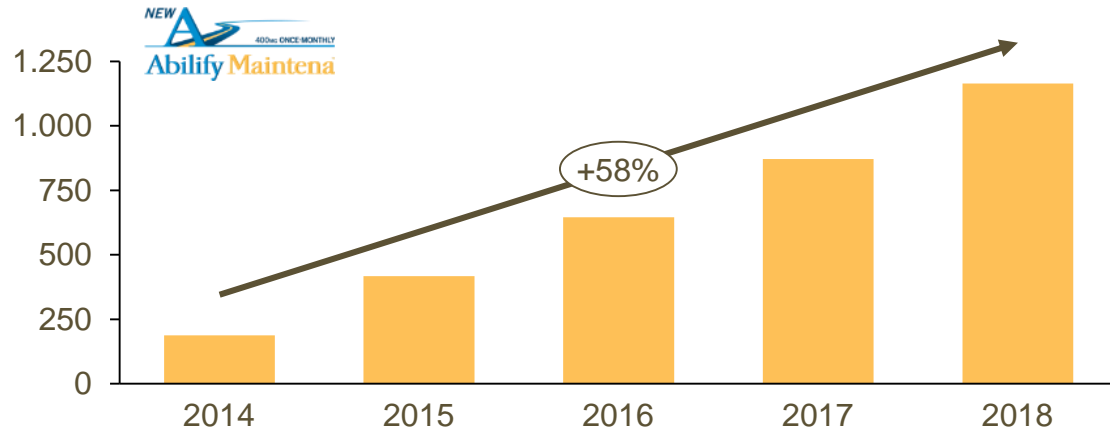
\*) Activity-Based Protein Profiling

Thank you

Lundbeck



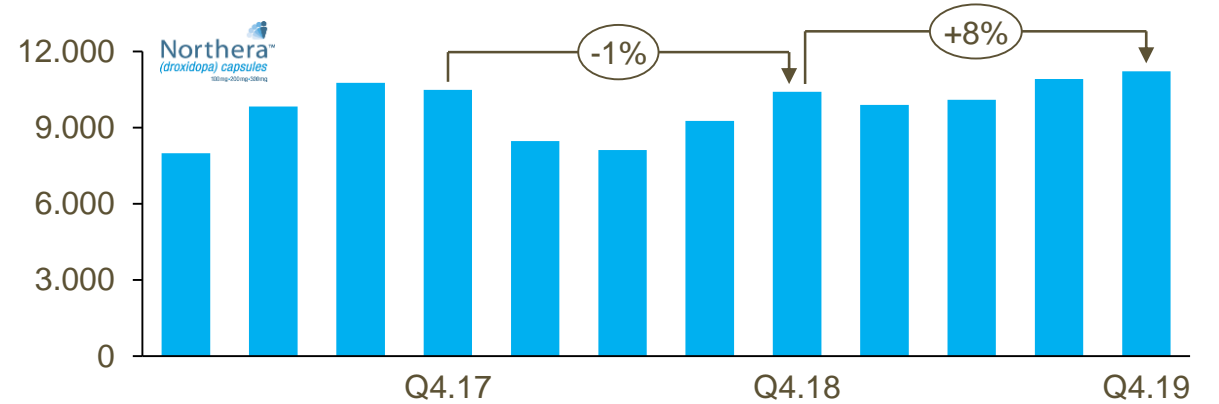
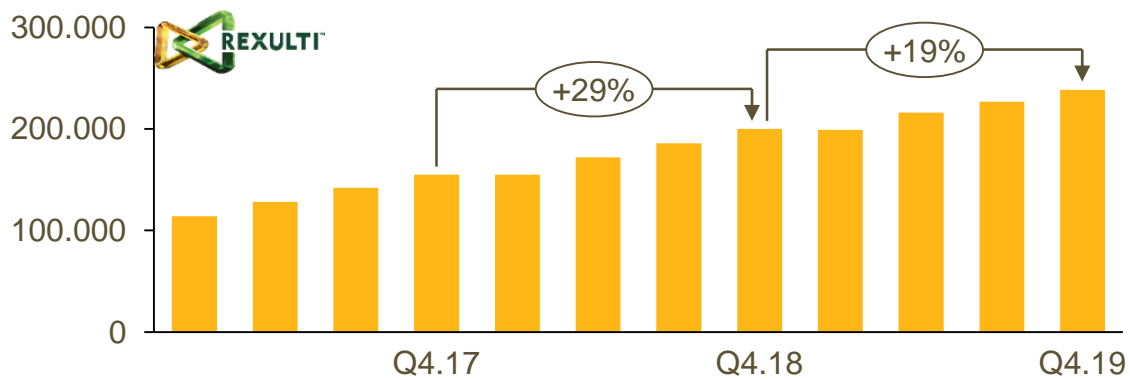
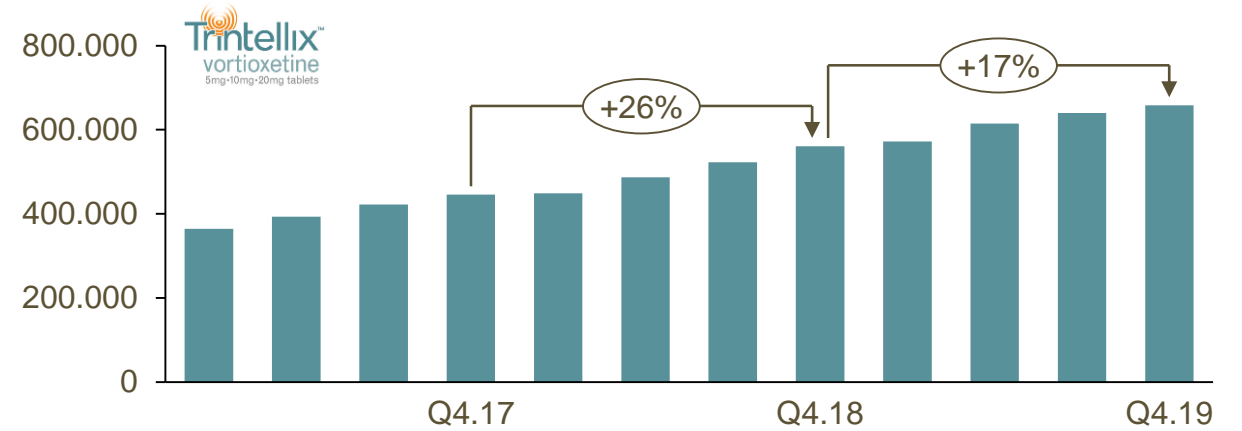
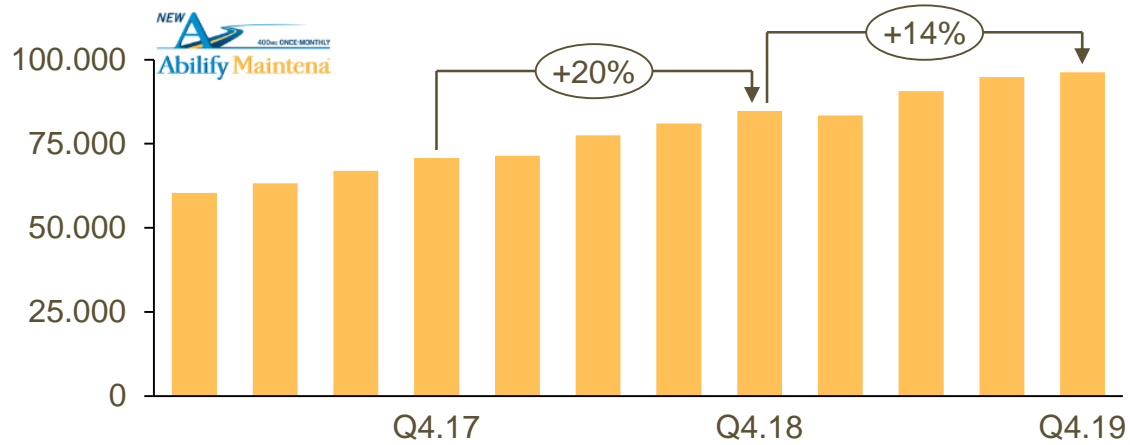
# Total molecule sales (gross) - USDm



- **Abilify Maintena:** US approval (Feb. 2013); EU approval (Nov. 2013)
- **Brintellix/Trintellix:** US approval (Oct. 2013); EU approval (Dec. 2013); Japan approval (Sep. 2019)
- **Rexulti:** US approval (Jul. 2015); EU approval (Jul. 2018); Japan approval (Jan. 2018 – NOT Lundbeck territory)

Source: IMS

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



Source: Symphony Health (ref Bloomberg)

# Foliglurax is a potential new treatment for Parkinson's disease

PD-LID is the most important unmet medical need after disease modification in Parkinson's<sup>1)</sup>

PD-LID affects ~50% after 5-10 years increasing to ~90% after 10-15 years of L-DOPA therapy

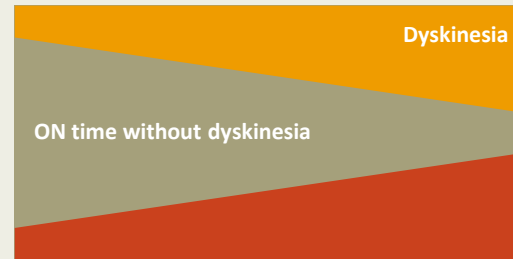
170-200,000 patients in the U.S. with PD-LID<sup>2)</sup>

Once established, PD-LID is difficult to treat

Foliglurax increases the sensitivity of the mGluR4 receptor towards glutamate and hence reduces, in a physiologically relevant manner, the abnormal glutamate stimulation that is believed to develop during levodopa dosing

1) Datamonitor. 2) PD-LID = Parkinson's Disease – Levodopa-Induced Dyskinesia. 3) Modified based on Jankovic, Mov. Disorder 2005

## Levodopa-induced dyskinesia<sup>3)</sup>

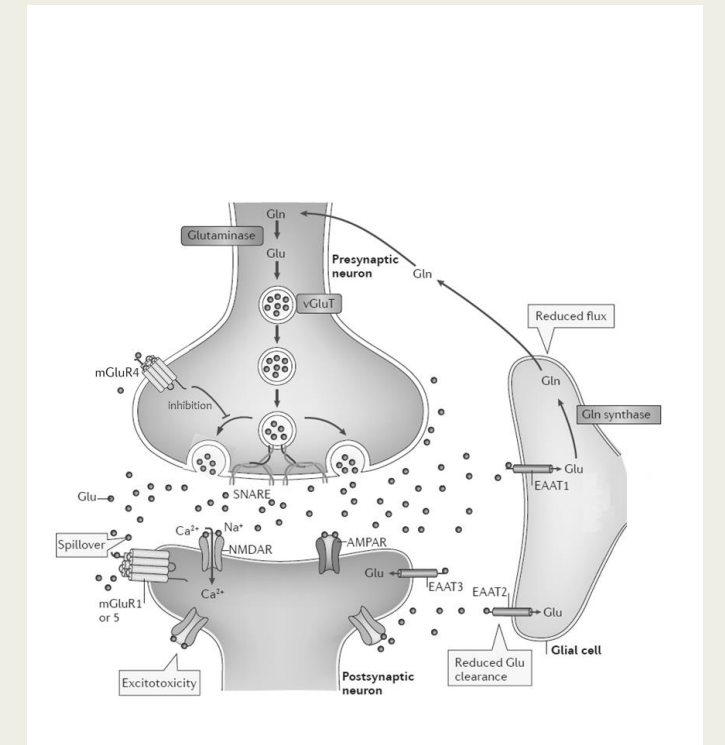


Disease progression in patients with motor fluctuations



With addition of foliglurax (illustrative)

## mGluR4 PAM





# Phase IIa study (*AMBLEMED*) investigating foliglurax near final recruitment

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

Evaluate the efficacy, safety and tolerability of 28-Day oral treatment with foliglurax in reducing motor complications of levodopa therapy in subjects with Parkinson's disease experiencing end-of-dose wearing off and levodopa-induced dyskinesia (*AMBLEMED*)

## Phase IIa

Two active arms (10mg and 30mg) + placebo

~165 patients (Europe)

**Primary endpoint:** Change from baseline to end of Treatment Period in the daily awake *OFF* time based on subject Hauser diary entries

Phase IIa started in July 2017; headline results due in H1 2020

Clinicaltrials.gov ID: NCT03162874

# 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 to be initiated Q1 2020

1) NCT03565094

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

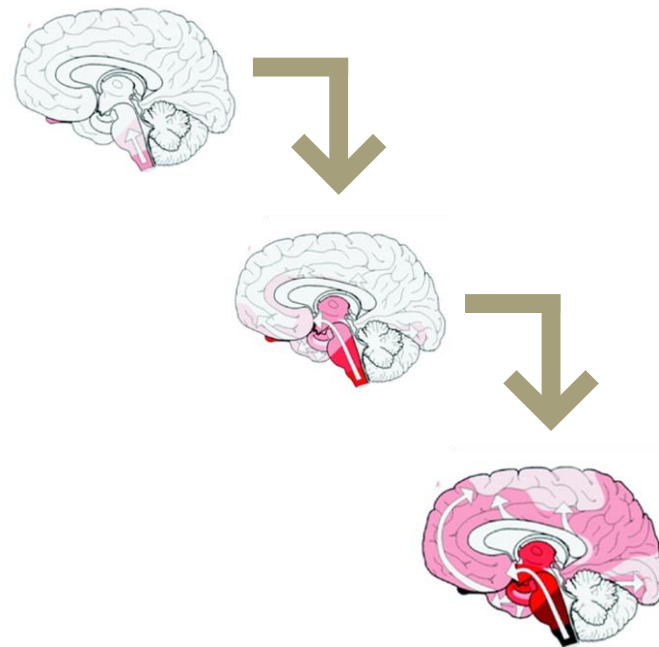
Pathological alpha-synuclein is released to extracellular space upon cell death and can mediate seeding and aggregation of alpha-synuclein in healthy neurons<sup>1</sup>

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 with expected completion H2 2020

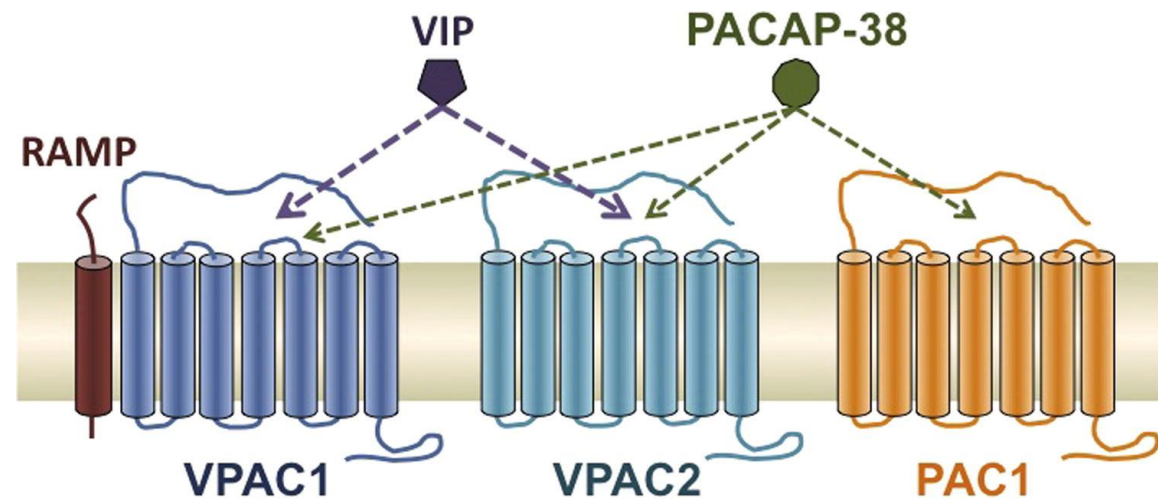
3) NCT03611569

# 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



# Several new projects 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

\*) NCT04149860

## Lu AF95245

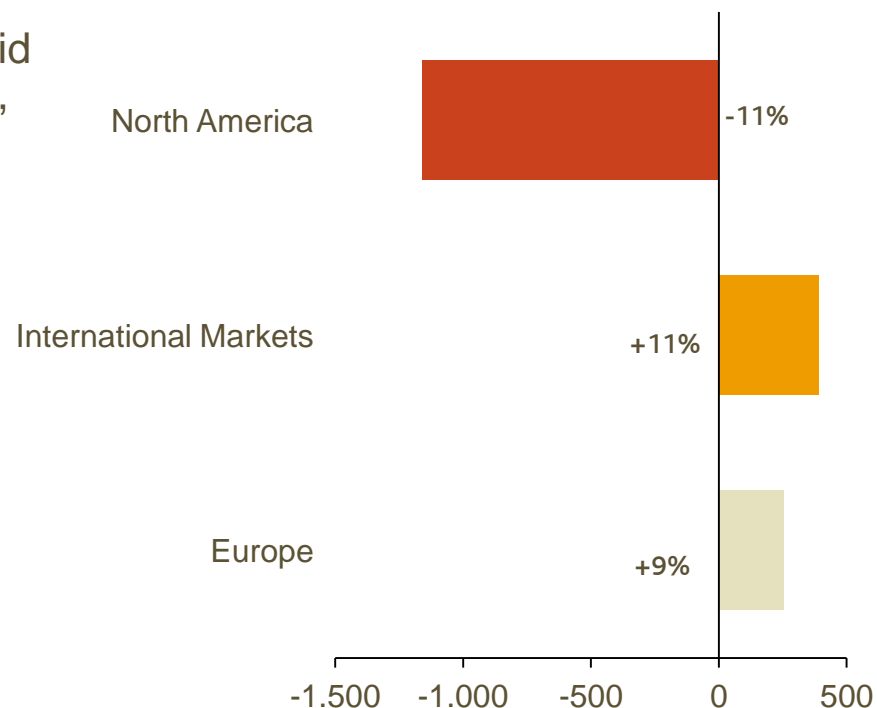
- Kv7 (KCNQ) ion channels are important regulators of neuronal excitability
- Activation of Kv7 channels dampens neuronal repetitive / burst firing
- Kv7 activators are effective in broad range of in vivo models/assays relevant to depression, psychosis, epilepsy and pain
- FIH study\* initiated January 2020

\*) NCT04199585

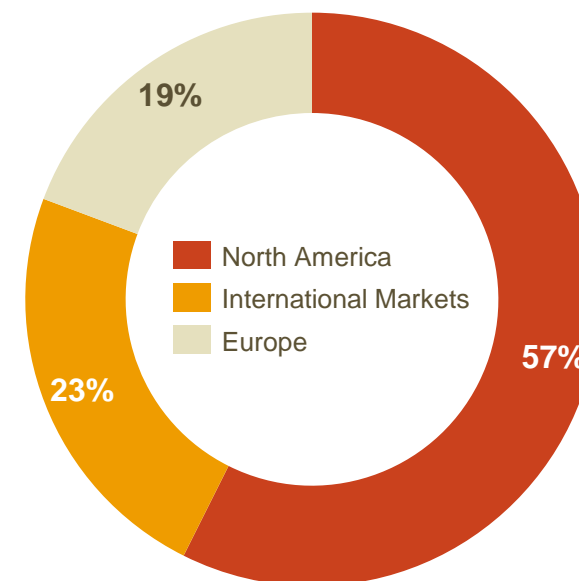
# Europe and International Markets have returned to strong dynamic growth

- Strong improvement in both growth and profitability in **Europe**
- **International Markets** shows solid growth driven by Australia, Japan, Korea and South East Asia
- **North America** impacted by generic erosion, mainly Onfi
  - Growth of 13% excluding Onfi
- Largest markets are the U.S., China, Canada, Spain, Italy, France and Japan constituting >70% of sales<sup>#</sup>

**Regional growth**  
(FY 2019 - DKKm)

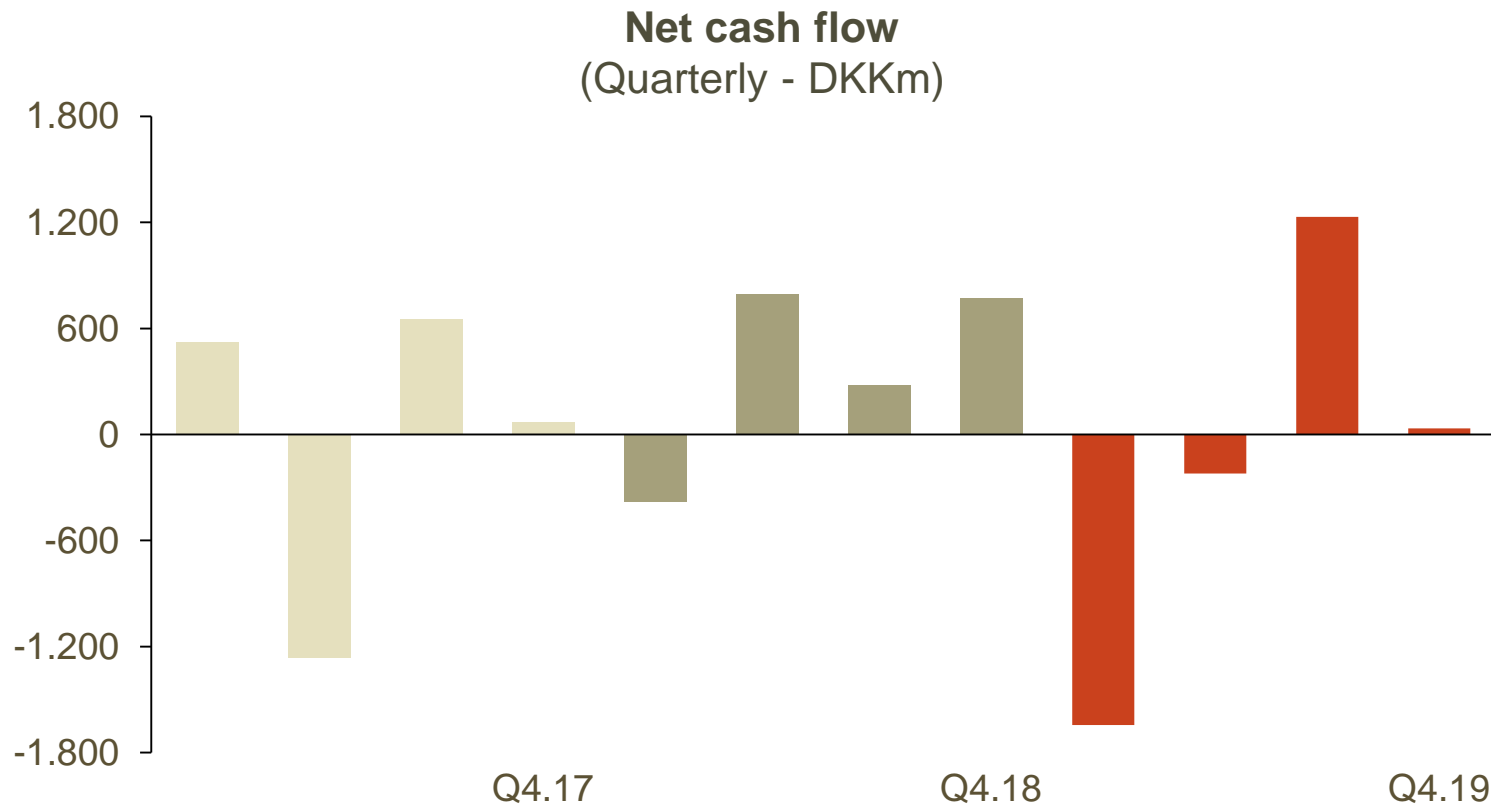


**Sales by region<sup>#</sup>**  
(FY 2019)



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

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



- **Net cash flow:** Down DKK 2,065 million to DKK -598 million in 2019
- FY 2020 cash flow will be negatively impacted by
  - Investments in eptinezumab
  - Lower EBITDA
  - Dividend payout for 2019
  - Potential milestones
- **Net debt:** Expected to amount to DKK 6-6.5 billion (USD ~1bn) by end-2020

# Product distribution of revenue – Q4 and FY 2019

DKKm	FY 2019	FY 2018	Q4 2019	Q4 2018	Growth	Growth in local currencies	% of total
<b>TOTAL:</b>							
Abilify Maintena	1,961	1,595	504	415	22%	20%	11%
Brintellix/Trintellix	2,826	2,182	803	639	26%	23%	18%
Cipralex/Lexapro	2,314	2,257	505	363	39%	36%	12%
Northera	2,328	1,806	722	524	38%	33%	16%
Onfi	1,052	3,165	212	496	(57%)	(59%)	5%
Rexulti/Rxulti	2,270	1,723	650	519	25%	21%	15%
Sabril	847	1,342	204	359	(43%)	(45%)	5%
Other pharmaceuticals	3,100	3,143	722	751	(4%)	(5%)	16%
Other revenue	660	662	227	196	16%	15%	5%
Effects from hedging	(322)	242	(128)	(66)	-	-	-3%
<b>Total revenue</b>	<b>17,036</b>	<b>18,117</b>	<b>4,421</b>	<b>4,196</b>	<b>5%</b>	<b>4%</b>	<b>100%</b>



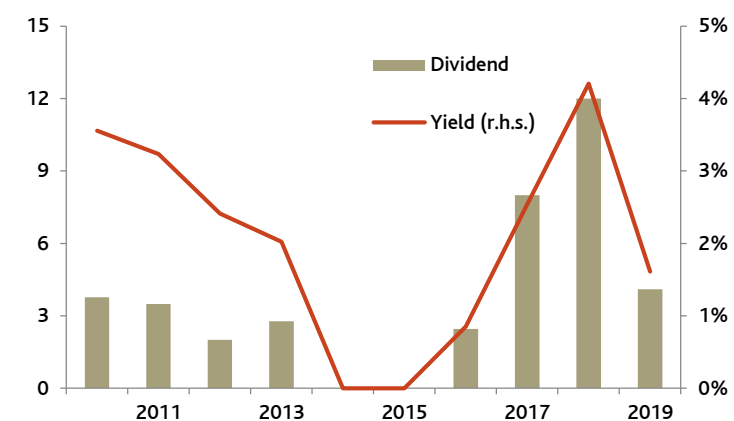
# Cash generation

DKKm	Q4 2019	Q4 2018	FY 2019	FY 2018
Cash flows from operating activities	394	1,406	2,609	5,981
Cash flows from investing activities	(7,357)	(609)	(7,755)	(2,907)
<b>Cash flows from operating and investing activities (free cash flow)</b>	<b>(6,963)</b>	<b>797</b>	<b>(5,146)</b>	<b>3,074</b>
Cash flows from financing activities	6,997	(24)	4,548	(1,607)
<b>Net cash flow for the period</b>	<b>34</b>	<b>773</b>	<b>(598)</b>	<b>1,467</b>
Cash, bank balances and securities, end of period	3,012	6,635	3,012	6,635
Interest-bearing debt	(9,578)	-	(9,578)	-
<b>Net cash/(net debt)</b>	<b>(6,566)</b>	<b>6,635</b>	<b>(6,566)</b>	<b>6,635</b>

# Balance sheet and dividend

DKKm	31.12.2019	31.12.2018
Intangible assets	23,399	8,023
Other non-current assets	3,320	3,339
Current assets	9,038	11,649
<b>Assets</b>	<b>35,757</b>	<b>23,011</b>
Equity	14,554	14,251
Non-current liabilities	10,923	1,184
Current liabilities	10,280	7,576
<b>Equity and liabilities</b>	<b>35,757</b>	<b>23,011</b>
Cash and bank balances	3,008	3,605
Securities	4	3,030
Interest-bearing debt	(9,578)	-
<b>Interest-bearing debt, cash, bank balances and securities, net, end of year</b>	<b>(6,566)</b>	<b>6,635</b>

## Dividend (DKK)



- ✦ Proposed dividend payout of DKK 4.10 per share for 2019, corresponding to a payout ratio of 30.6%
- ✦ 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

# 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	366,019 (0.2%)
Insider holdings	122,665 (0.06%)
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

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[polesen3@bloomberg.net](mailto:polesen3@bloomberg.net)

## Financial calendar

<b>AGM</b>	24 March 2020
<b>Q1 2020</b>	12 May 2020
<b>6M 2020</b>	13 August 2020
<b>9M 2020</b>	3 November 2020