

# Teleconference – Q1 2018

*May 2018*



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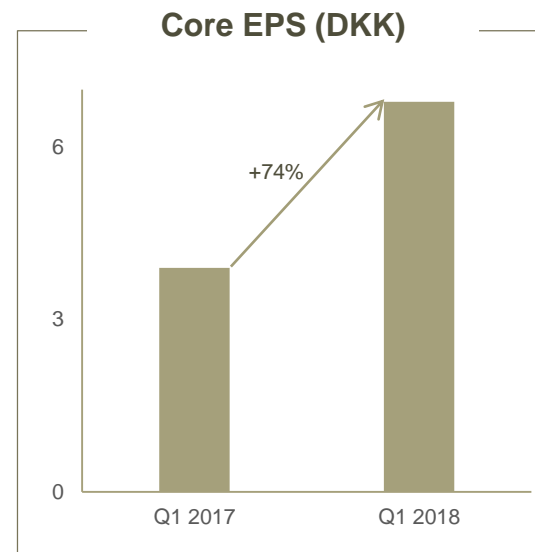
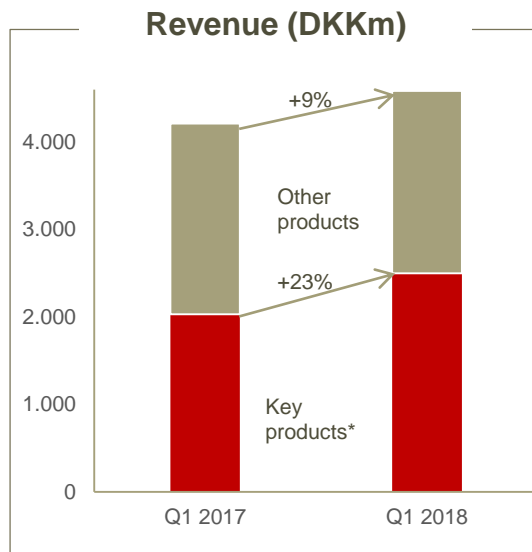
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Certain assumptions made by Lundbeck are required by Danish Securities Law for full disclosure of material corporate information. Some assumptions, including assumptions relating to sales associated with products that are prescribed for unapproved 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 US, prescribe approved drugs for any use they deem appropriate, including unapproved uses, at Lundbeck, promotion of unapproved uses is strictly prohibited.



# Strong financial performance in the first quarter of 2018

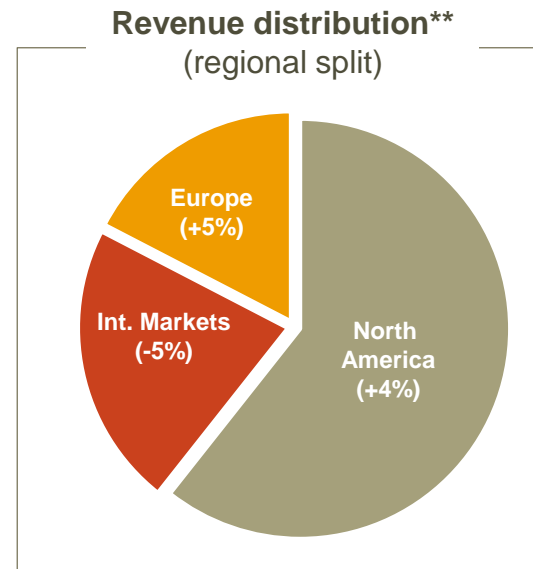
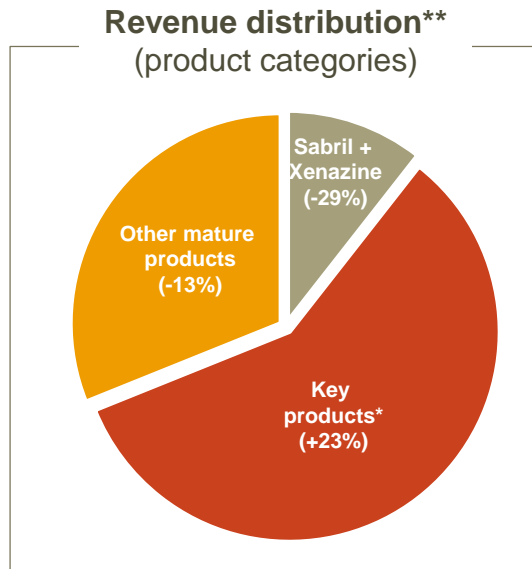
- ★ **Revenue:** +9% (14% in L.C.) to DKK 4.6 billion
- ★ **Hedging** contributed DKK 182 million in the quarter
- ★ **Key products\*:** +23% to DKK 2.5 billion representing 55% of revenue
- ★ **EBIT:** increased 64% to DKK 1.7 billion. EBIT margin significantly improved to 36.1% positively impacted by hedging gains
- ★ **EPS:** +103% to DKK 6.03



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

# Solid revenue growth of 9% to DKK 4.6 billion in Q1 2018 – in local currencies growth reached 14%

- ★ **Key products\*** continue the strong growth momentum
- ★ **Sabril** and **Xenazine** are down 29% combined following generic erosion
- ★ Growth in all regions in local currencies
- ★ Both North America and International Markets see increased currency headwind
- ★ Largest markets are the U.S., Canada, China, France and Japan

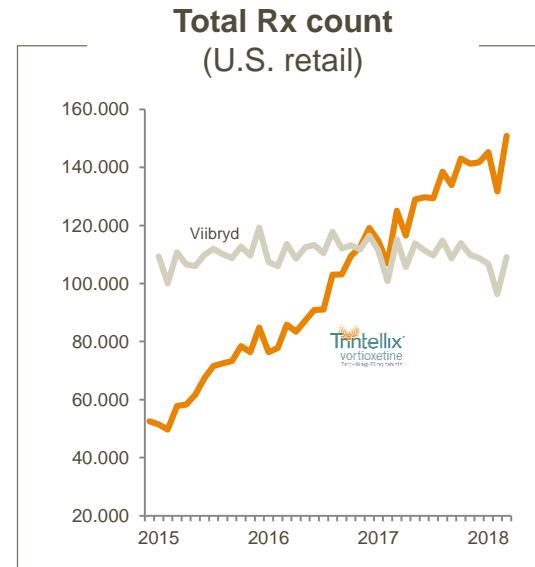
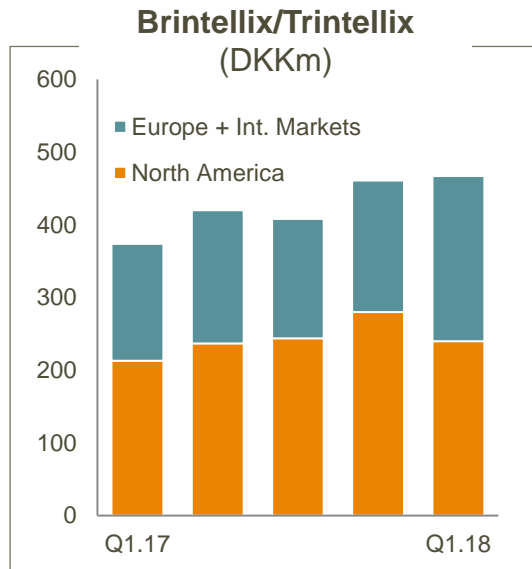


\*) Ability Maintena, Brintellix/Trintellix, Northera, Onfi and Rexulti

\*\*\*) Excluding Other revenue and effects from hedging

# Brintellix/Trintellix grew 25% to DKK 467 million in Q1 2018 – in local currencies the growth was 38%

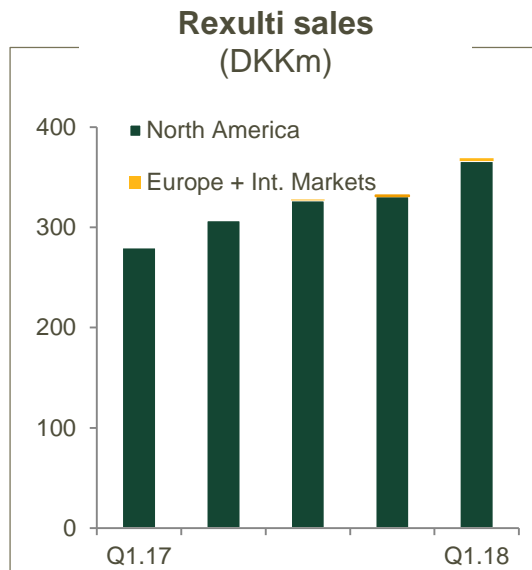
- ★ North America grew by 13% (28% in L.C.) to DKK 240 million
- ★ Europe and Int. Markets grew 41% combined to DKK 227 million
- ★ Largest markets are the U.S., Canada, Spain and Brazil
- ★ Growth mainly driven by France, Saudi Arabia, Spain and the U.S.
- ★ Brintellix continues to gain value share which exceeds 5% in France and Italy
- ★ Trintellix increases value share in Canada and the U.S. to 4.4% and 18.5%, respectively



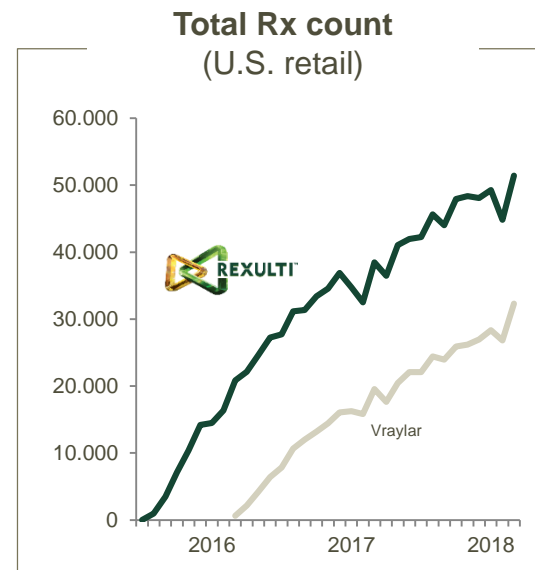
Source: Symphony Health Solutions/Bloomberg (monthly data ending 3/2018)

# Rexulti grew 32% to DKK 369 million in Q1 2018 – in local currencies the growth was 51%

- ★ Approved in Saudi Arabia in both depression and schizophrenia – launch expected in H2 2018
- ★ Submitted for approval in markets such as Brazil, Europe, and Mexico in 2017
- ★ Rexulti has 10.3% value share (U.S.)
- ★ Third study in AAD to commence by mid-2018
- ★ Pivotal programme in bipolar mania to conclude H1 2019
- ★ PoC study in PTSD to conclude in H1 2019
- ★ Additional LCM activity progressing



Lundbeck's share of revenue.  
NOTE: Rexulti only launched in Australia outside North America



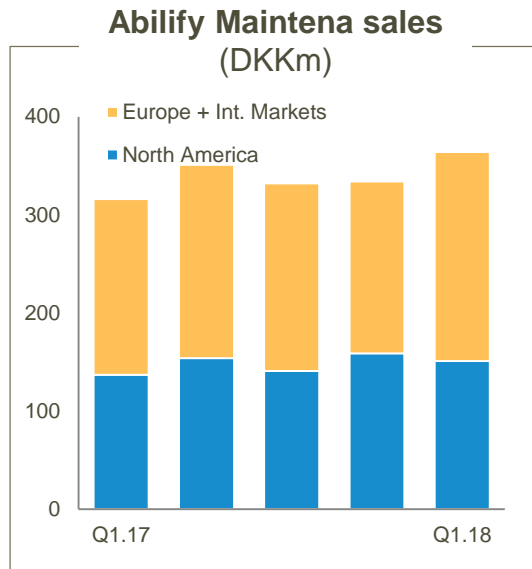
Source: Symphony Health Solutions/Bloomberg (monthly data ending 3/2018)

AAD: Agitation in Alzheimer's disease

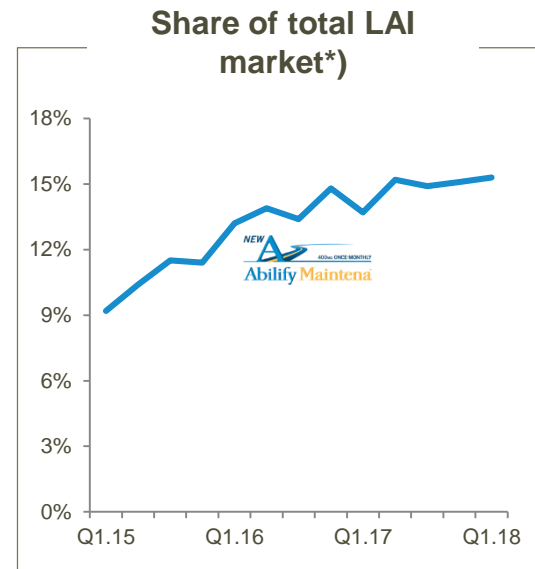
# Abilify Maintena grew 15% to DKK 364 million in Q1 2018

## – in local currencies the growth was 23%

- ✦ Europe up 19% to DKK 184 million
- ✦ International Markets up 16% (26% in L.C.) to DKK 29 million
- ✦ North America up 10% (25% in L.C.) to DKK 151 million
- ✦ Growth driven by Canada, France, Spain and the U.S.
- ✦ Largest markets are the U.S., Canada, Spain and France
- ✦ Market share increasing - >20% volume share (LAI retail) in most markets
- ✦ Total LAI market reached USD 1.1 billion (+13%) in Q1 2018



Lundbeck's share of revenue



\*) Based on quarterly reports from Lundbeck, Otsuka, Alkermes (Bloomberg Q4-consensus) and Johnson & Johnson

LAI: Long-acting injectable anti-psychotics

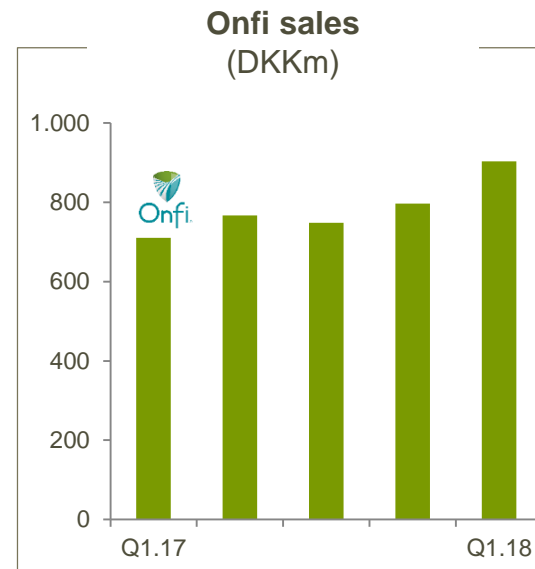
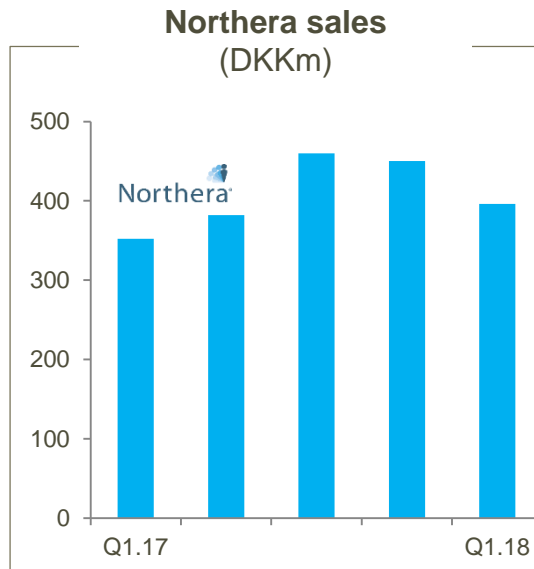
# U.S. neurology products, Northera and Onfi, continue to show solid growth in local currency

## Northera

- ★ Up 13% (29% in L.C.) to DKK 396 million in Q1 2018
- ★ Northera impacted by seasonal swings in demand
- ★ Expected continued growth

## Onfi

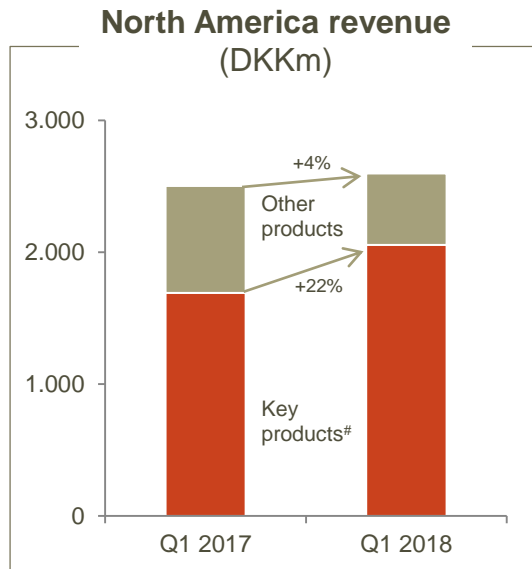
- ★ Up 27% (46% in L.C.) to DKK 903 million in Q1 2018
- ★ Expected to grow until generic clobazam is introduced



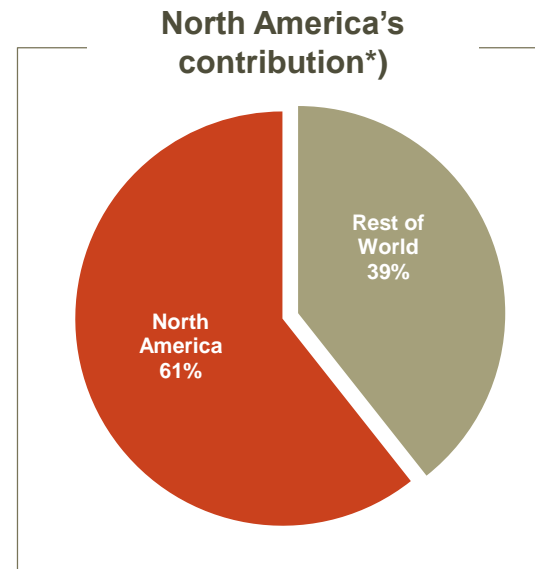


# North America grew 4% driven by Northera, Onfi and Rexulti – currency headwind had significant negative impact

- ★ North America grew 4% (19% in L.C.) to DKK 2,598 million in Q1 2018
- ★ Key products# grew 22% and constitute 79% of revenue in Q1 2018
- ★ North America is expected to continue growing in local currencies despite LOE



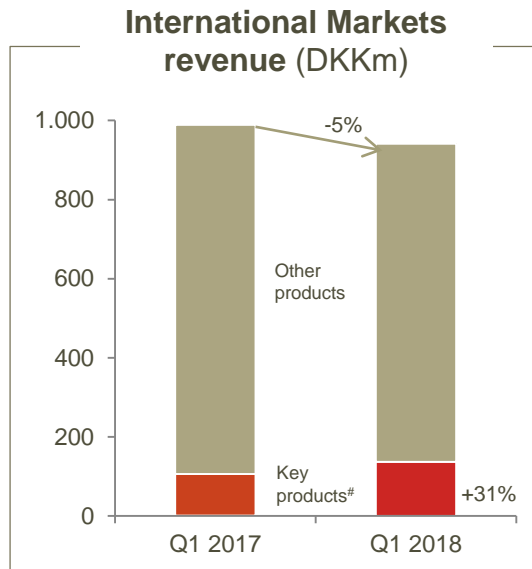
#) Abilify Maintena, Northera, Onfi, Rexulti and Trintellix



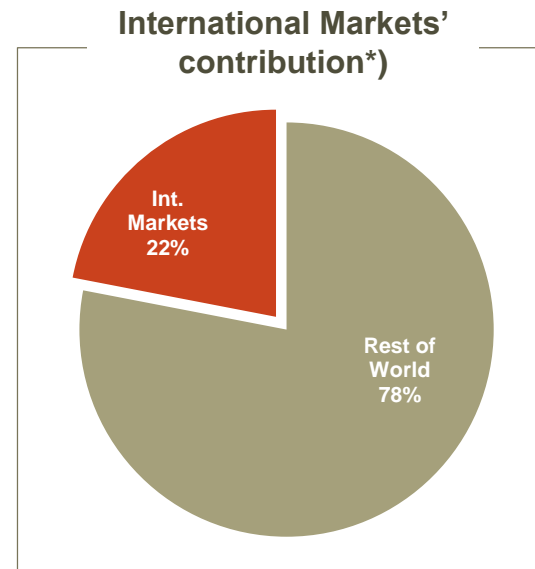
\*) Excluding Other revenue and effects from hedging

# International Markets declined 5% – 5% growth in local currencies

- ★ International Markets declined 5% (up 5% in L.C.) to DKK 941 million in Q1 2018
- ★ Key products# grew by 31% and contributed 15% of sales
- ★ Market exclusivity for Lexapro extended by two years in Japan
- ★ Main markets are China, Japan, Brazil and South Korea
- ★ International Markets is expected to continue growing in 2018 in local currencies



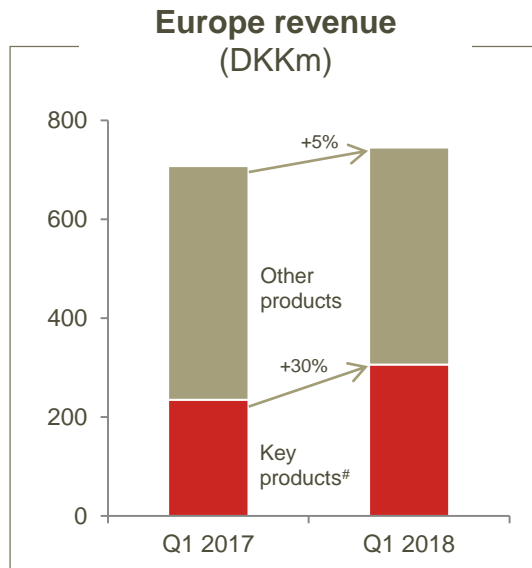
#) Abilify Maintena, Brintellix and Rexulti



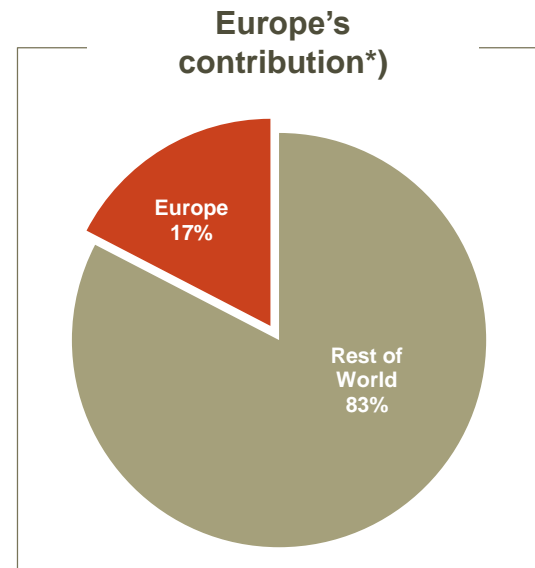
\*) Excluding Other revenue and effects from hedging

# Europe is up 5% in Q1 2018 driven by key products

- ★ Europe grew 5% to DKK 745 million in Q1 2018
- ★ Key products# grew 30% and contribute 41% of sales
- ★ Largest markets are France, Italy and Spain
- ★ Continued strong performance for Brintellix, especially in France, Italy and Spain
- ★ Profitability significantly improved
- ★ Europe is expected to continue growing in 2018



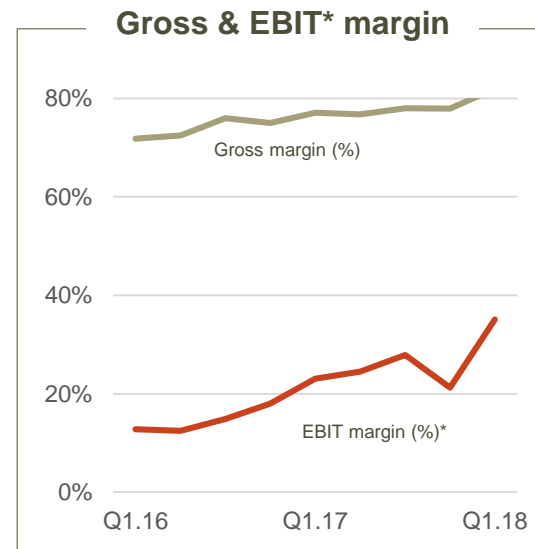
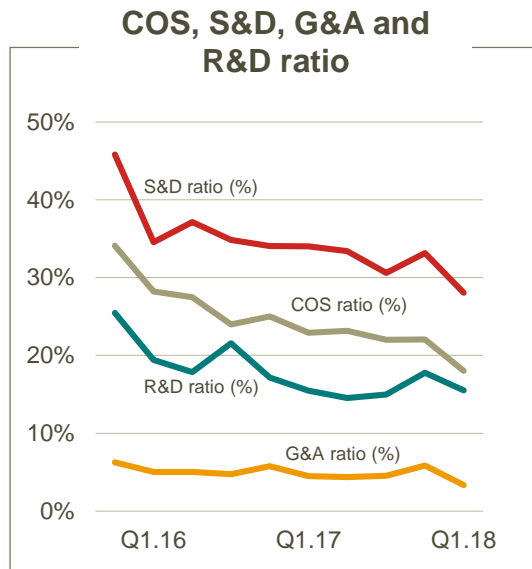
#) Abilify Maintena and Brintellix



\*) Excluding Other revenue and effects from hedging

# Continued cost discipline

- ★ **Total costs** down 8% while growing topline by 9% in Q1 2018
- ★ **EBITDA margin** of 41.2% vs. 30.6% in Q1 2017
- ★ **EBIT margin** also improved significantly
- ★ **COS%:** Expected to show continued improvements
- ★ **S&D%:** Stable or modest additional improvements
- ★ **G&A%:** Stable or modest additional improvements
- ★ **R&D%:** Stable or slightly increasing depending on project execution



\*) Data adjusted for gain from divestment of properties in the U.S. and Denmark included in EBIT (recognized in Q1.2017, Q3.2017 and Q1.2018)

# Strong growth in earnings with more than a doubling of net profits

- ★ Significant negative impact from FX reducing revenue growth
  - ★ Growth for all key products and in all regions in L.C.
- ★ EPS growth of 103%
- ★ Significant EPS improvement driven by
  - ★ Solid revenue growth
  - ★ Strong improvement of profitability
  - ★ Reduced tax rate as the U.S. tax reform has decreased the tax rate from 41% in Q1 2017 to 27%

## Financial results (Quarterly)

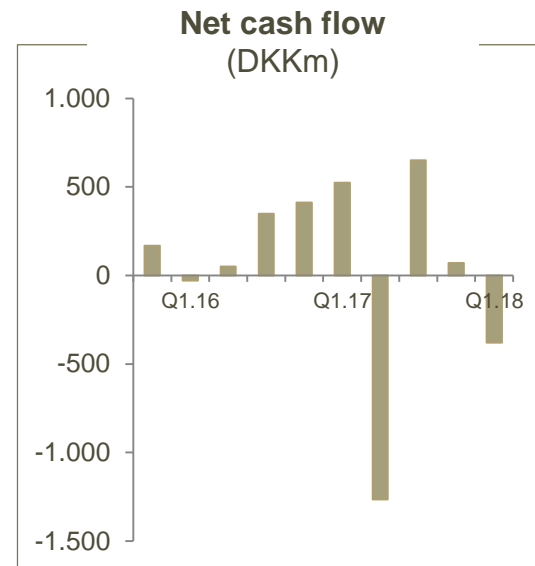
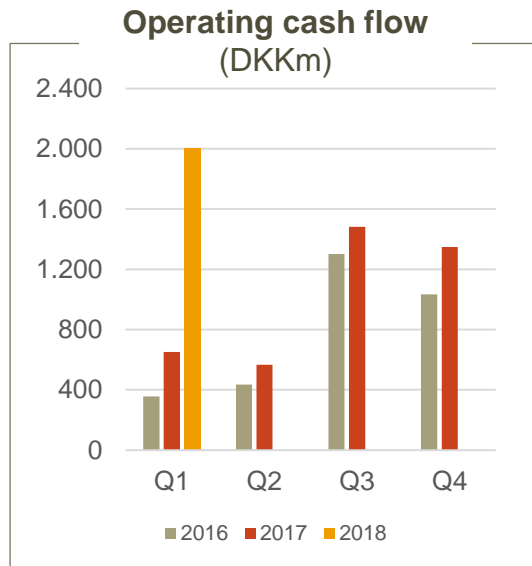
DKKm	Q1.18	Q1.17	Δ%
Revenue	<b>4,585</b>	4,211	9%
Gross margin	<b>82.0%</b>	77.1%	-
EBIT	<b>1,656</b>	1,011	64%
EBIT margin	<b>36.1%</b>	24.0%	-
Core EBIT	<b>1,818</b>	1,213	50%
Net profit	<b>1,199</b>	587	104%
EPS	<b>6.03</b>	2.97	103%

## Financial results (reported vs. L.C.)

DKKm	Q1.18	Δ DKK	Δ% L.C.
Revenue	<b>4,585</b>	+374m	+14%
- Abilify Maintena	<b>364</b>	+48m	+23%
- Brintellix/Trintellix	<b>467</b>	+93m	+38%
- Northera	<b>396</b>	+44m	+29%
- Onfi	<b>903</b>	+193m	+46%
- Rexulti	<b>369</b>	+89m	+51%
North America	<b>2,598</b>	+95m	+19%
Int. Markets	<b>941</b>	-47m	+5%
Europe	<b>745</b>	+37m	+6%

# Strong cash flow generation and improved ROIC

- ★ Cash flows from operating activities increased from DKK 651 million in Q1 2017 to DKK 2,003 million in Q1 2018
- ★ Acquisition of Prexton impacts net cash flow by DKK 745 million
- ★ Dividend payout increased to DKK 1.6bn
- ★ ROIC increased from 30.8% in 2017 to 57.6% in Q1 2018



# 2018 financial outlook maintained

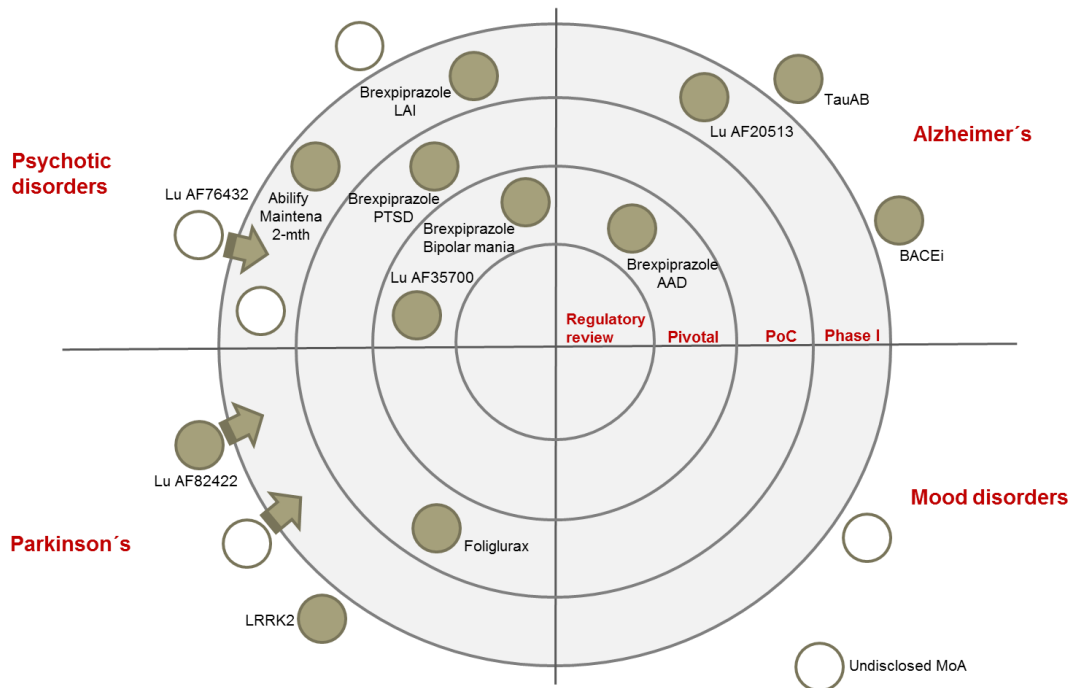
- ✦ Growth in all three regions in local currencies
- ✦ Continued growth for key products to outpace the decline from generic erosion
- ✦ Net financial items of DKK ±50 million expected in 2018
- ✦ No known one-off income and/or expenses
- ✦ Unchanged currencies from end-April 2018

## 2018 financial guidance

DKKbn	2016	2017	2018 guidance	~Δ% (y/y)
Revenue	15.6	17.2	<b>17.2-18.0</b>	0-5%
EBIT	2.3	4.4	<b>4.8-5.2</b>	9-18%
Implied EBIT margin	14.7%	25.6%	<b>~27-30%</b>	-
Tax rate	43.9%	38.7%	<b>26-28%</b>	-

# Continued progression in our R&D pipeline

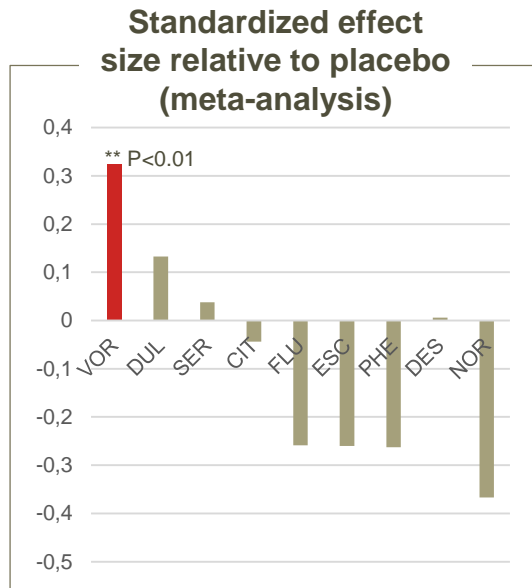
- ★ **Trintellix:** U.S. label update to include DSST data and sNDA accepted for TESD
- ★ **Foliglurax:** Acquired in March 2018. Clinical phase II initiated in 2017
- ★ **Brexpiprazole AAD:** Third study (n=~300) to commence by mid-2018
- ★ **New projects:**
  - ★ Lu AF76432 FIH planned to start in Q2 2018 (schizophrenia)
  - ★ Lu AF82422 FIH planned to start in Q3 2018 (Parkinson's)
  - ★ A third project likely to enter clinical testing in 2018





# Trintellix is the first FDA-approved treatment for MDD to have data on processing speed, an aspect of cognitive function that is impaired in many patients with MDD

- ★ FDA updates Trintellix label to include data showing improvement in processing speed, an important aspect of cognitive function
- ★ Comparative studies have not been conducted to demonstrate a therapeutic advantage over other antidepressants on the DSST
- ★ MDD is a multidimensional disorder consisting not only of mood, but also physical and cognitive symptoms
- ★ Cognitive symptoms in MDD are highly prevalent and persistent even after treatment



Baune BT, et al. *Int J Neuropsychopharmacol*; 2018 Feb 1;21(2):97-107

## The prevalence of cognitive symptoms in MDD

### Acute phase – 94%

Cognitive problems dominate the course of depression and were present for up to 94% of the time during depressive episode

### Remission – 44%

Even patients thought to be in remission, cognitive symptoms were present in depressed patients for an average of 39-44% of the time

Conradi HJ et al. *Psychol Med* 2011; 41: 1165-1174

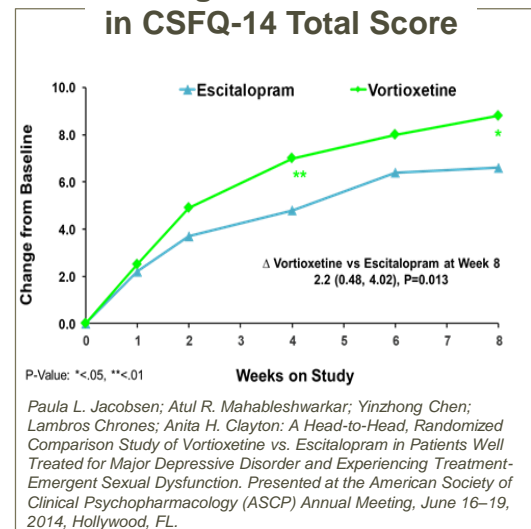
# Further potential strengthening of Trintellix label

- ★ FDA acceptance of sNDA for Trintellix for Treatment-Emergent Sexual Dysfunction (TESD)
- ★ PDUFA on 21 October 2018
- ★ The prevalence of TSED reach 25-80% (SSRIs) and 40-80% (SNRIs)
- ★ Sexual dysfunction ranked as the most bothersome adverse event (AE), followed by drowsiness, weight gain, and insomnia

## Completed studies in TSED

Study #1 (NCT01364649)	Study #2 (NCT02932904)
<b>Completed enrollment:</b>	
450 patients included	352 healthy volunteers
<b>Intervention:</b>	
10-20mg vortioxetine, 10-20mg escitalopram and placebo	10-20mg vortioxetine, 20mg paroxetine and placebo
<b>Treatment duration:</b>	
8 weeks	8 weeks
<b>Primary outcome measures:</b>	
Change From Baseline in the CSFQ-14 Total Score <sup>1</sup>	

## Change from baseline in CSFQ-14 Total Score



Serretti, A: Treatment-Emergent Sexual Dysfunction Related To Antidepressants – A Meta-Analysis. *Journal of Clinical Psychopharmacology*. Vol. 29, No. 3, June 2009  
 Kennedy, SH: Sexual Dysfunction, Depression, and the Impact of Antidepressants. *Journal of Clinical Psychopharmacology*. Vol. 29, No. 2, April 2009  
 Clayton AH, Montejo AL. Major depressive disorder, antidepressants, and sexual dysfunction. *J Clin Psychiatry*. 2006;67 Suppl 6:33-37.

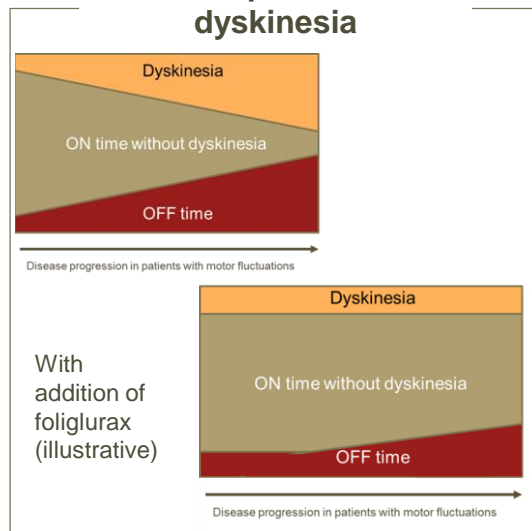
# Foliglurax – an interesting new pipeline asset currently in PoC testing in Parkinson's patients

## Foliglurax (PXT002331)

- ✦ Increase activity of a specific glutamatergic target (mGluR4)
- ✦ Symptomatic treatment of *OFF*-time in Parkinson's and levodopa induced dyskinesia
- ✦ Strong IP
- ✦ Global rights to foliglurax and full control of asset
- ✦ Phase II started in July 2017 and will be concluded H1 2019<sup>1)</sup>
- ✦ Two active arms + placebo (BID)
- ✦ ~165 patients (Europe)
- ✦ Change in awake *OFF* time based on subject diary entries

1) NCT03162874

## Levodopa-induced dyskinesia



Source: Jankovic, *Mov. Disorder* 2005,

## Motor complications of levodopa

- ✦ PD-LID is the most important unmet medical need after disease modification in Parkinson's<sup>2)</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
- ✦ Once established, PD-LID is difficult to treat

PD-LID: Parkinson's Disease – Levodopa-Induced Dyskinesia  
2) Datamonitor

Thank you!

Lundbeck

