

# Teleconference – H1 2018

*August 2018*



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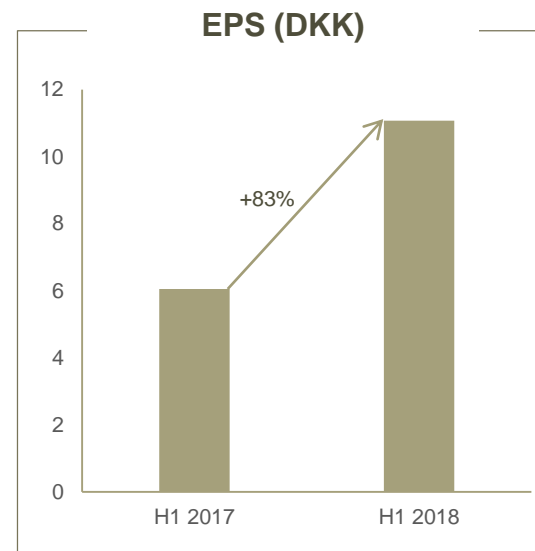
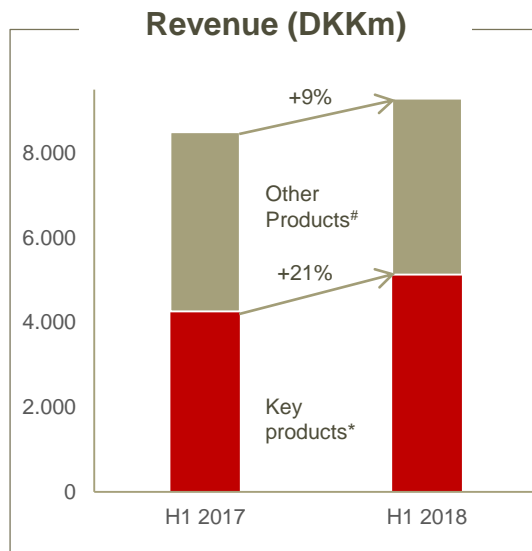
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# Key product growth drives top and bottom line

- ★ **Revenue:** Up 9% (14% in L.C.) to DKK 9.3 billion in H1 2018
- ★ **Hedging:** Contributed DKK 277 million
- ★ **Key products\*:** Up 21% to DKK 5.1 billion representing 55% of revenue
- ★ **EBIT:** Up 46% to DKK 3.0 billion. EBIT margin significantly improved to 32.4%, but positively impacted by hedging gains
- ★ **EPS:** Up 83% to DKK 11.07
- ★ **FY2018:** Guidance revised

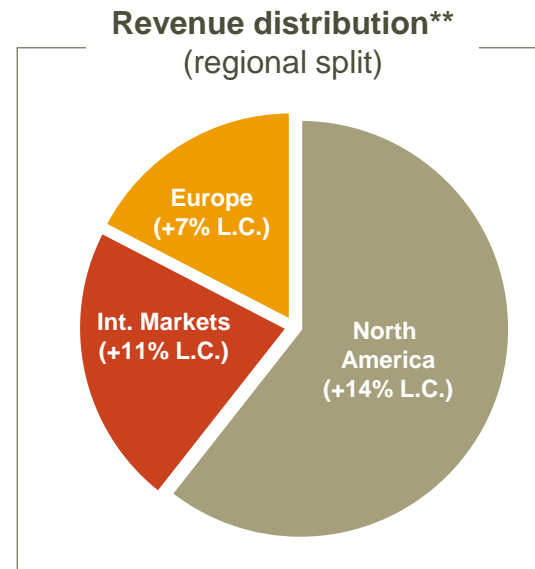
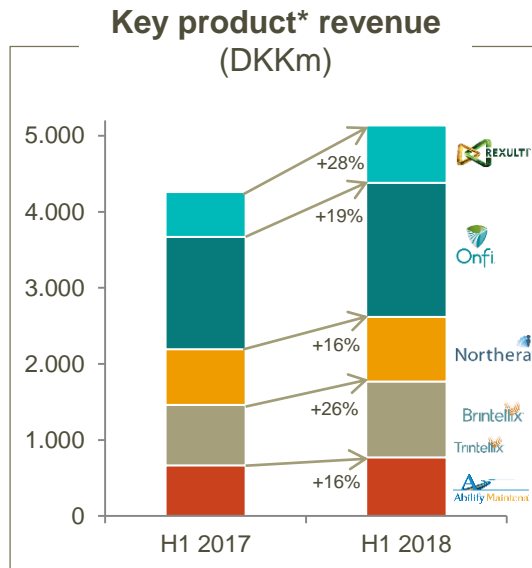


#) Includes Other revenue and effects from hedging

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

# Solid revenue growth of 9% to DKK 9.3 billion in H1 2018 – in local currencies growth reached 14%

- ★ **Key products\*** grew by DKK 874 million or 21% (33% in L.C.) with all products showing double digit growth in H1 2018
- ★ Both **North America** and **International Markets** see significant currency headwind
- ★ Growth in all regions in local currencies
- ★ Largest markets are the U.S., Canada, China, France, Italy, Japan and Spain

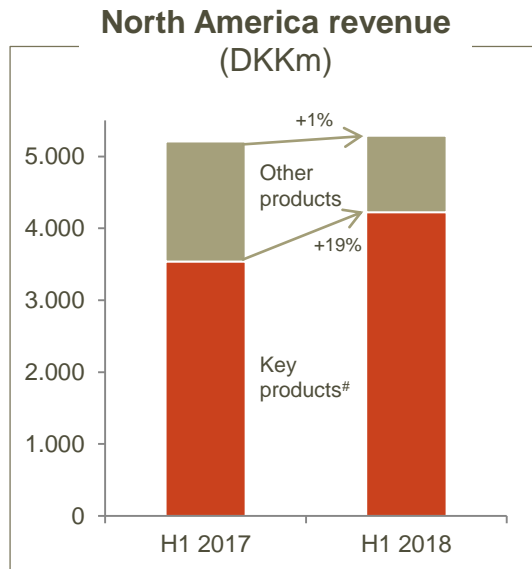


\*) Ability Maintainex, Brintellix/Trintellix, Northera, Onfi and Rexulti

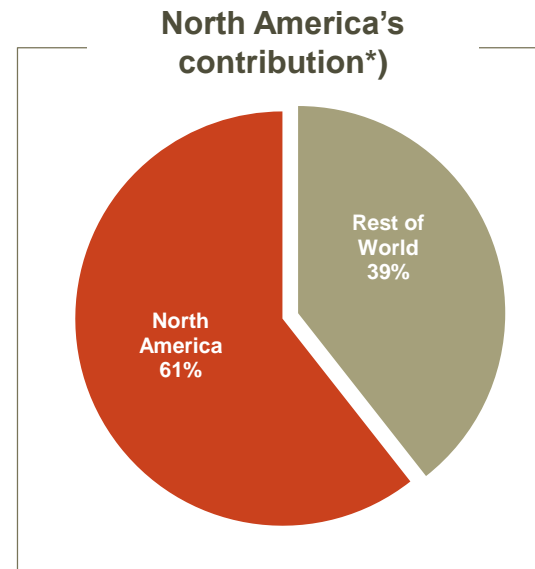
\*\*) Excluding Other revenue and effects from hedging

# North America grew 1% driven by Trintellix, Rexulti, Northera and Onfi – currency headwind had significant negative impact

- ★ North America grew 1% (14% in L.C.) to DKK 5,287 million in H1 2018
- ★ Key products# grew 19% and constituted 80% of revenue in H1 2018
- ★ For FY2018, North America is expected to show growth in local currencies despite LOE on Onfi towards the end of the year



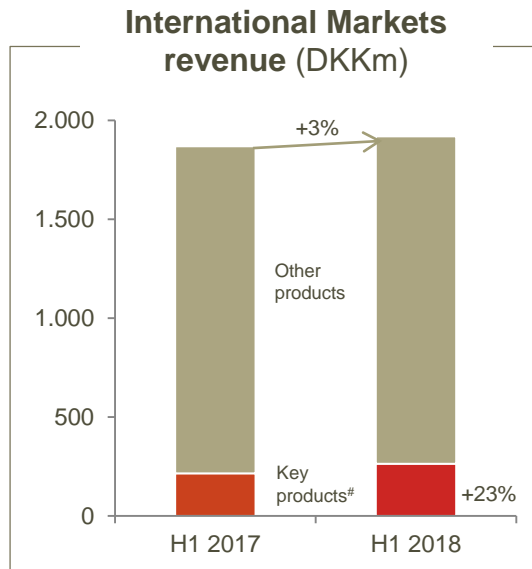
#) Abilify Maintena, Northera, Onfi, Rexulti and Trintellix



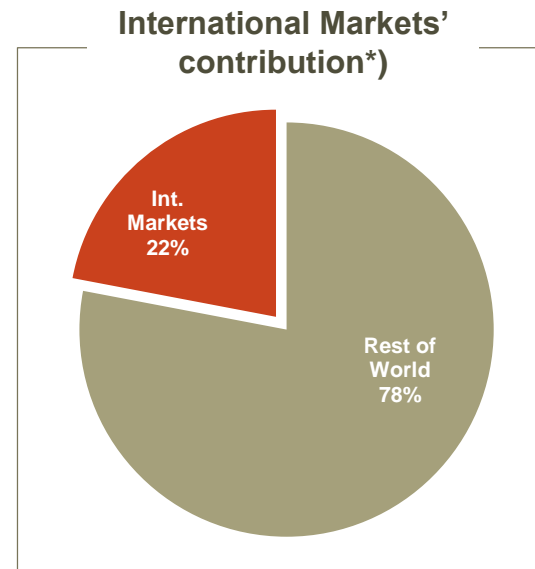
\*) Excluding Other revenue and effects from hedging

# International Markets grew 3% in H1 2018 – up 11% in local currencies

- ★ International Markets increased 3% (11% in L.C.) to DKK 1.9 billion in H1 2018
- ★ Positive impact from stocking of DKK ~150 million
- ★ Key products# grew by 23% and constituted 14% of sales
- ★ Market exclusivity for Lexapro extended by two years in Japan
- ★ Main markets are Brazil, China, Japan and South Korea
- ★ For FY2018, International Markets is expected to show growth in local currencies



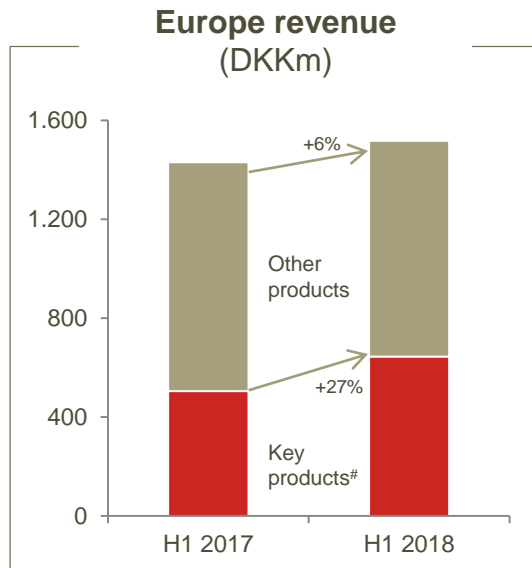
#) Abilify Maintena, Brintellix and Rexulti



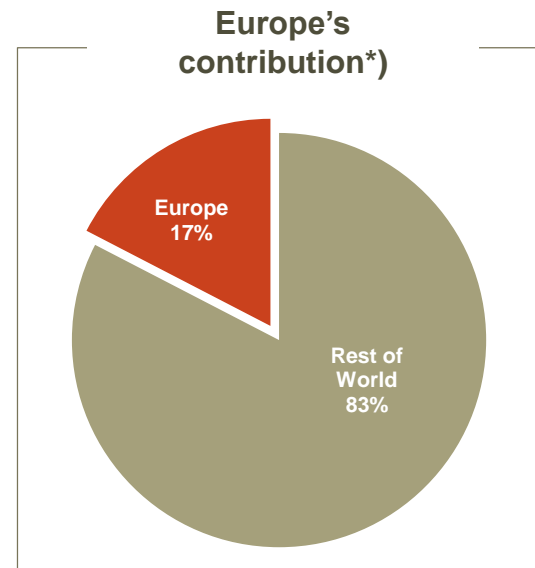
\*) Excluding Other revenue and effects from hedging

# Europe grew 6% in H1 2018 driven by Abilify Maintena and Brintellix – up 7% in local currencies

- ★ Europe grew 6% to DKK 1.5 billion in H1 2018
- ★ Key products# grew 27% and constituted 42% of sales
- ★ Largest markets are France, Italy and Spain
- ★ Continued strong performance for Brintellix, especially in France, Italy and Spain
- ★ Profitability significantly improved
- ★ Rxulti approved in Europe with launch commencing in H1 2019
- ★ For FY2018, Europe is expected to show growth in local currencies



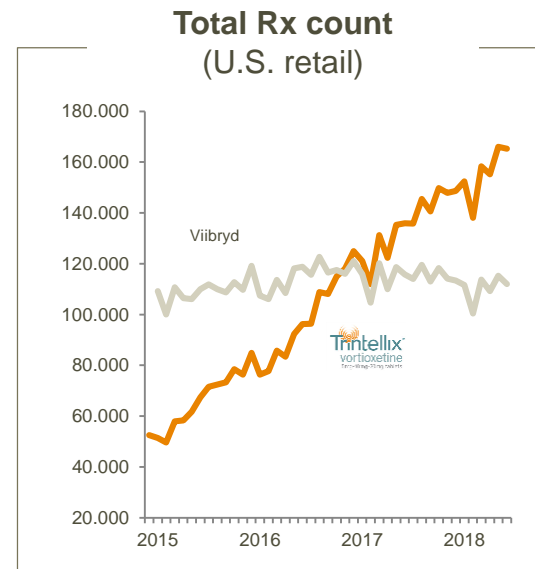
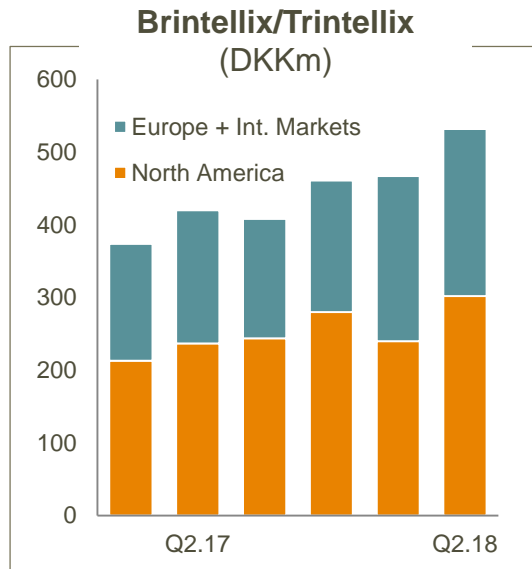
#) Abilify Maintena and Brintellix



\*) Excluding Other revenue and effects from hedging

# Brintellix/Trintellix grew 26% to DKK 999 million in H1 2018 – in local currencies the growth was 36%

- ★ **North America** grew by 20% (34% in L.C.) to DKK 542 million
- ★ **Europe and International Markets** grew 33% (40% in L.C.) combined to DKK 457 million
- ★ Largest markets are the U.S. Brazil, Canada, France, Italy, and Spain
- ★ Growth mainly driven by France, Italy, Spain and the U.S.
- ★ Brintellix continues to gain both volume and value share
- ★ **PDUFA** on 21 October regarding **TESD** in patients with depression



Source: Symphony Health Solutions/Bloomberg (monthly data ending 6/2018)

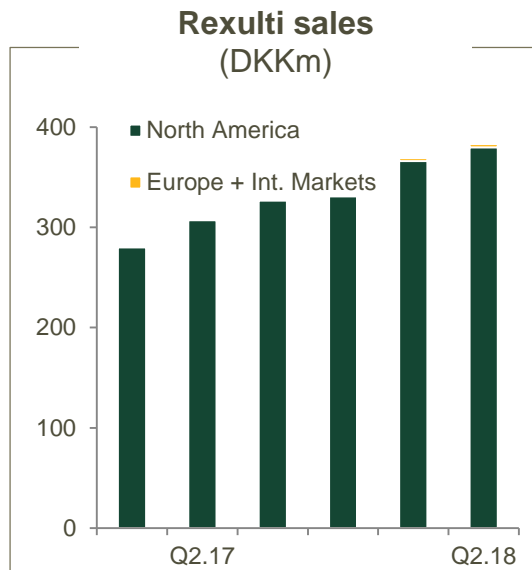
PDUFA: Prescription Drug User Fee Act (FDA).  
TESD: Treatment-Emergent Sexual Dysfunction



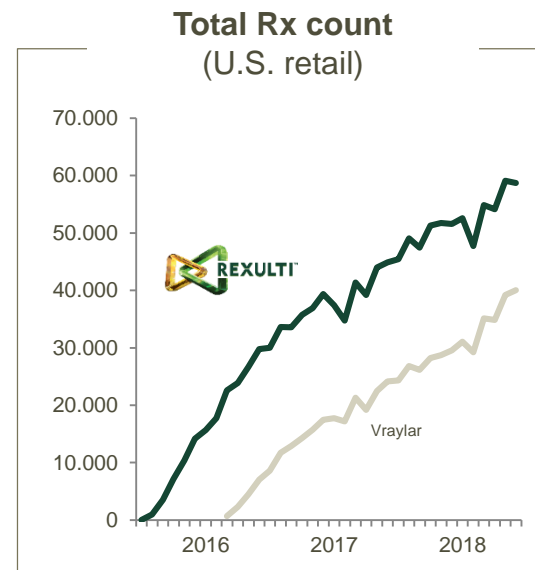
# Rexulti grew 28% to DKK 752 million in H1 2018 – in local currencies the growth was 44%

- ★ **Rxulti** approved in Europe
- ★ Recently also approved in Honduras and Saudi Arabia
- ★ Rexulti has 11.3% value share (U.S.)
- ★ Third study in **AAD** commenced
- ★ Pivotal programme in **bipolar mania** to conclude H1 2019
- ★ PoC study in **PTSD** to conclude around year-end 2018
- ★ Additional LCM activity progressing

AAD: Agitation in Alzheimer's disease; PoC: Proof of Concept; PTSD: Post-Traumatic Stress Disorder; LCM: Life-Cycle Mgmt.



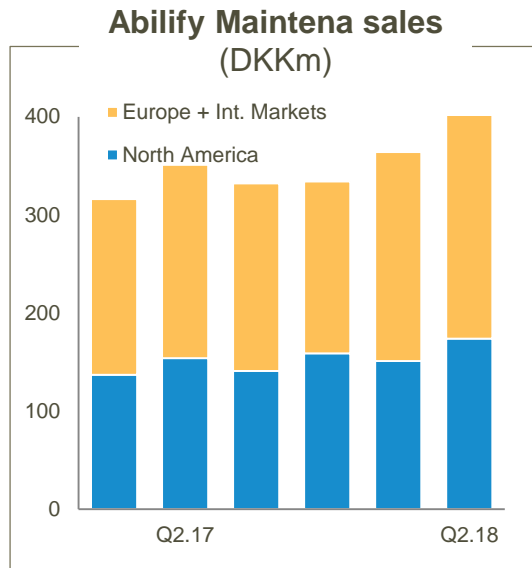
Lundbeck's share of revenue.  
NOTE: Outside North America, Rexulti has only been launched in Australia



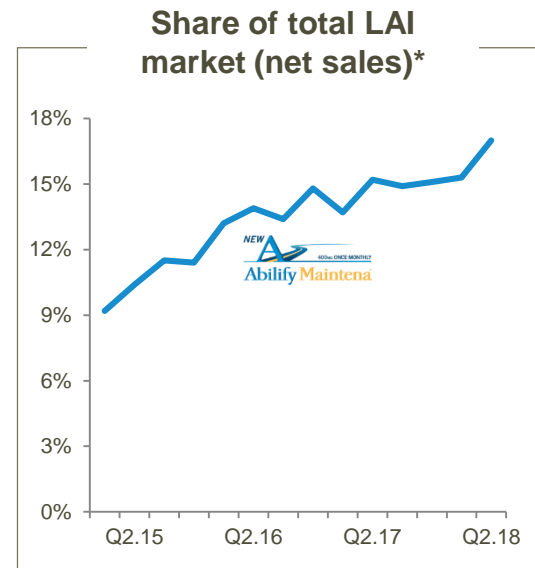
Source: Symphony Health Solutions/Bloomberg (monthly data ending 6/2018)

# Abilify Maintena grew 16% to DKK 771 million in H1 2018 – in local currencies the growth was 22%

- ★ **Europe and International Markets** grew 19% (21% in L.C.) combined to DKK 446 million
- ★ **North America** up 12% (24% in L.C.) to DKK 325 million
- ★ Growth driven by Australia, Canada, France, Spain and the U.S.
- ★ Largest markets are Australia, Canada, France, Spain and the U.S.
- ★ Market share increasing - >20% volume share (LAI retail) in most markets
- ★ **Total LAI market** reached USD 2.2 billion (+13%) in H1 2018



Lundbeck's share of revenue



\*) Based on quarterly reports from Lundbeck, Otsuka, Alkermes and Johnson & Johnson

LAI: Long-acting injectable anti-psychotics

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

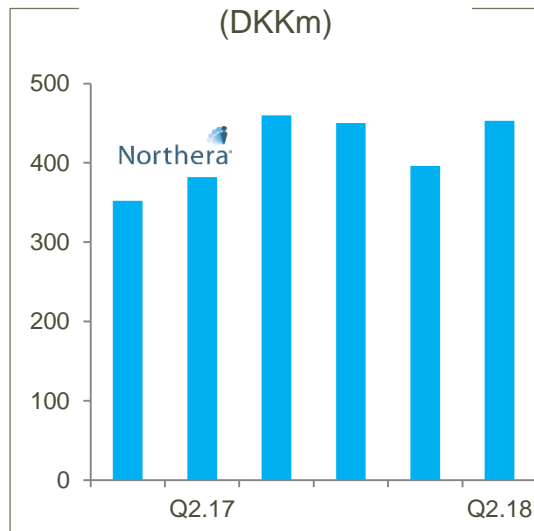
## Northera

- ★ Up 16% (30% in L.C.) to DKK 849 million in H1 2018
- ★ Northera impacted by seasonal swings in demand
- ★ Expected continued growth

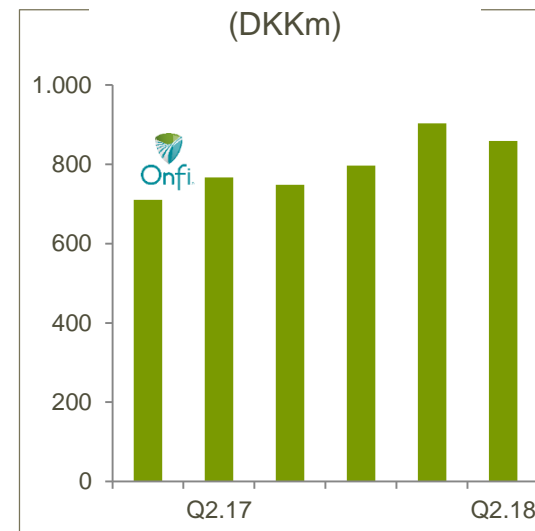
## Onfi

- ★ Up 19% (34% in L.C.) to DKK 1,762 million in H1 2018
- ★ Expected to grow until generic clobazam is introduced, expectedly in Q4 2018

Northera sales  
(DKKm)

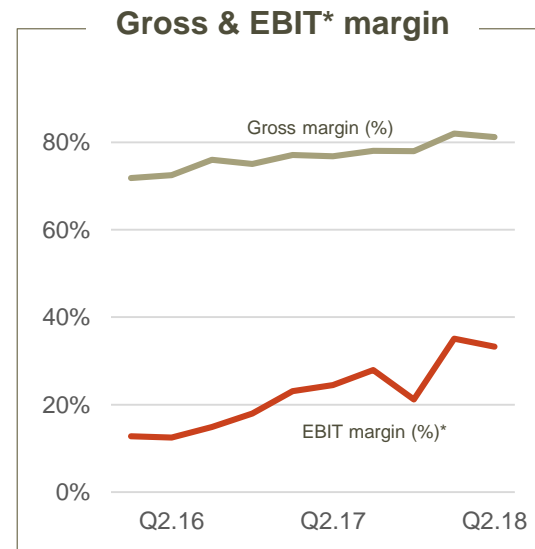
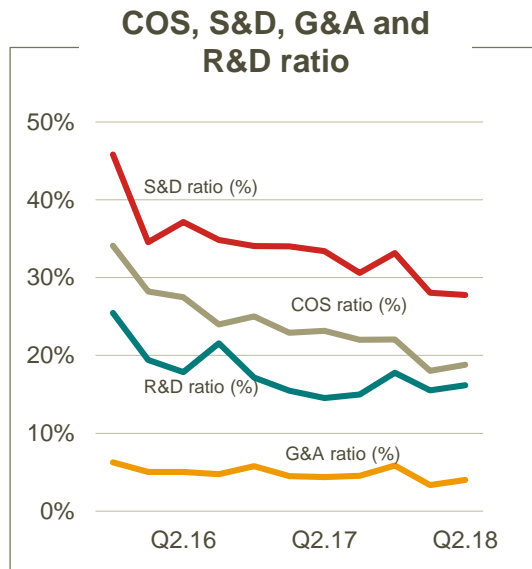


Onfi sales  
(DKKm)



# Maintaining strong cost focus while also investing in the business

- ★ **Total costs** down 5% while growing topline by 9% in H1 2018
- ★ **EBITDA margin** of 38.2% vs. 31.2% in H1 2017
- ★ **EBIT margin** of 32.4% vs. 24.3% in H1 2017
- ★ **COS%:** Expected to show continued improvements vs. 2017
- ★ **S&D%:** Stable or modest additional improvements vs. 2017
- ★ **G&A%:** Stable or modest additional improvements vs. 2017
- ★ **R&D%:** Slightly increasing vs. 2017 depending on project execution



\*) Data adjusted for Other operating items, net

# Strong growth in earnings

- ★ Significant negative impact from FX reducing revenue growth
  - ★ Growth for all key products and in all regions in L.C.
- ★ EPS growth of 83%
- ★ Significant EPS improvement driven by
  - ★ Solid revenue growth
  - ★ Strong improvement of profitability
  - ★ Reduced tax rate as the U.S. tax reform has decreased the group tax rate from 40% in H1 2017 to 27%

## Financial results

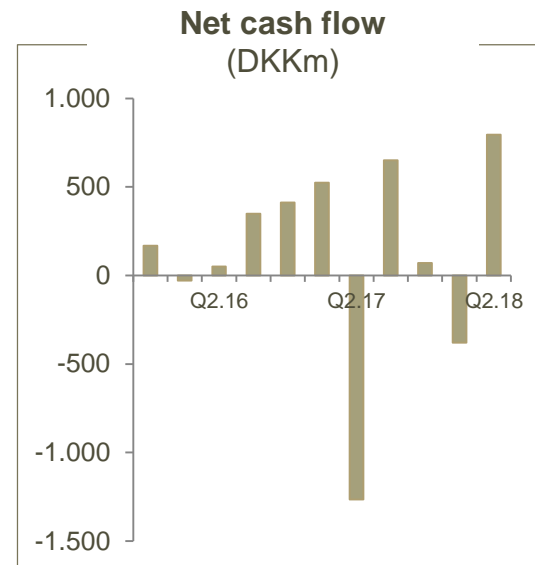
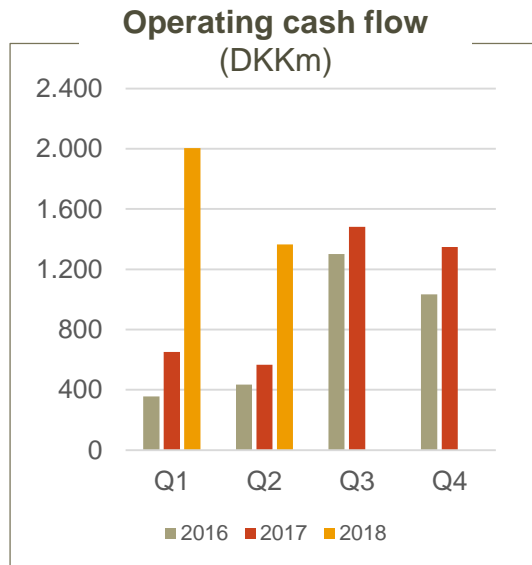
DKKm	H1.18	H1.17	Δ%
Revenue	<b>9,288</b>	8,494	9%
Gross margin	<b>81.6%</b>	76.9%	-
EBIT	<b>3,006</b>	2,061	46%
EBIT margin	<b>32.4%</b>	24.3%	-
Core EBIT	<b>3,578</b>	2,500	43%
Net profit	<b>2,198</b>	1,195	84%
EPS	<b>11.07</b>	6.05	83%

## Revenue (reported vs. L.C.)

DKKm	H1.18	Δ DKKm	Δ% L.C.
Revenue	<b>9,288</b>	+794	+14%
- Abilify Maintena	<b>771</b>	+104	+22%
- Brintellix/Trintellix	<b>999</b>	+205	+36%
- Northera	<b>849</b>	+115	+30%
- Onfi	<b>1,762</b>	+285	+34%
- Rexulti	<b>752</b>	+165	+44%
North America	<b>5,287</b>	+77	+14%
Int. Markets	<b>1,920</b>	+51	+11%
Europe	<b>1,518</b>	+87	+7%

# Strong cash flow generation and improved ROIC

- ★ Cash flows from operating activities increased from DKK 1,217 million in H1 2017 to DKK 3,369 million in H1 2018
- ★ Acquisition of **Prexton Therapeutics** in Q1 impacts net cash flow by DKK 745 million
- ★ **Dividend payout** for 2017 increased to DKK 1.6 billion
- ★ **ROIC** increased from 26.6% in FY2017 to 53.2% in H1 2018



## 2018 financial outlook revised

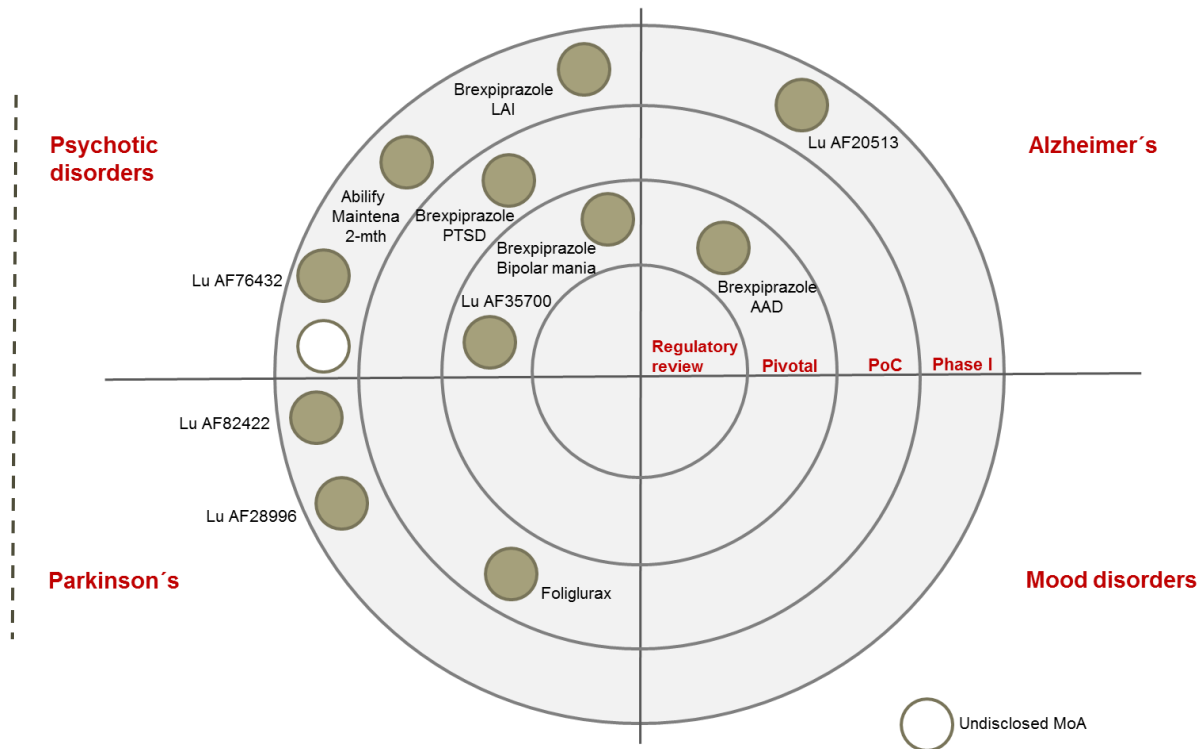
- ★ Growth in all three regions in local currencies
- ★ Continued growth for key products to outpace the decline from generic erosion
- ★ Onfi revenue is expected to decline 40-50% compared to prior quarters in 2018
- ★ Net financial items of DKK ±50 million expected in 2018
- ★ No known additional one-off income and/or expenses
- ★ Unchanged currencies from end-July 2018

### 2018 financial guidance

DKKbn	2016	2017	Previous 2018 guidance	Revised 2018 guidance	~Δ% (y/y)
Revenue	15.6	17.2	17.2-18.0	<b>17.6-18.0</b>	2-5%
EBIT	2.3	4.4	4.8-5.2	<b>4.9-5.2</b>	11-18%
Implied EBIT margin	14.7%	25.6%	~27-30%	<b>~27-30%</b>	-
Tax rate	43.9%	38.7%	26-28%	<b>26-28%</b>	-

# The value of Lundbeck's R&D pipeline is increasing

- ★ **Brexpiprazole:** Approved by the European Commission and in Switzerland
- ★ **Vortioxetine:** Strong pivotal data in Japanese patients
- ★ **Lu AF35700:** Finished recruiting in *DAYBREAK I*
- ★ **Abilify Maintena 2-month:** Single dose study finished now moving into multi-dose study
- ★ **Lu AF76432:** Phase I initiated in May 2018 (schizophrenia)
- ★ **Lu AF28996:** Phase I initiated in June 2018 (Parkinson's)
- ★ **Lu AF82422:** Phase I initiated in August 2018 (Parkinson's)





# Major clinical programme ongoing with Lu AF35700 – first results to be reported in Q4 2018

## Lu AF35700

- For the treatment of treatment-resistant schizophrenia (TRS) which represents a major unmet medical need
- Antagonist at dopaminergic, serotonergic, and  $\alpha$  adrenergic receptors. Unlike all currently available antipsychotics, Lu AF35700 has higher affinity for the human dopamine D<sub>1</sub> receptor than it has for the human dopamine D<sub>2</sub> receptor

## Clinical studies in TRS

- *DAYBREAK I* evaluates the efficacy of 10 and 20 mg/day of Lu AF35700 on schizophrenia symptoms in patients with treatment-resistant schizophrenia (n = 964) (NCT02717195)
- *ANEW* evaluates the efficacy of 10 mg/day Lu AF35700 on symptoms of schizophrenia in patients with early-in-disease or late-in-disease treatment-resistant schizophrenia (n = 285) (NCT03230864)

## Supportive clinical studies

- Study to evaluate the pharmacokinetics of Lu AF35700 after a single dose tablet to subjects with renal impairment and compare that with healthy subjects (n = 32) (NCT03241147)
- Study to investigate the effect of multiple doses of the strong P450 enzyme inhibitor itraconazole on the pharmacokinetics of Lu AF35700 in healthy subjects (n = 23) (NCT03103646)
- Study to establish bioequivalence of Lu AF35700 between the clinical formulation and the commercial formulation for three tablet strengths; 5, 10 and 20 mg (n = 90) (NCT03394482)

## Upcoming events

- Communicate headline results from first study (*DAYBREAK I*) in the pivotal programme during Q4 2018

# Comprehensive LCM programme ongoing for brexpiprazole for further product value expansion

## Brexpiprazole

- Several clinical programmes ongoing to address unmet medical needs and aiming for product value maximation

## Bipolar I disorder

- Two studies to demonstrate the efficacy in acute treatment of manic episodes, with or without mixed features, in subjects with a diagnosis of Bipolar I disorder (n = 320 in both studies) (NCT03257865, NCT03259555)
- Evaluating the safety and tolerability in the treatment of subjects with Bipolar I disorder (n = 384) (NCT03287869)

## Agitation in Alzheimer's

- Programme to compare the efficacy of 2 doses (2 mg and 3 mg) of brexpiprazole with placebo in subjects with agitation associated with dementia of the Alzheimer's type (n = 225) (NCT03548584, NCT03594123 (12-week extension study))

## PTSD

- Evaluating the safety, efficacy and tolerability of brexpiprazole (with placebo) as monotherapy or combination therapy (Zoloft) in adults with PTSD (n = 332) (NCT03033069)

## Adolescents

- To determine the safety and efficacy of brexpiprazole monotherapy in the treatment of adolescents with schizophrenia (n = 387) (NCT03198078)
- To further characterize the long-term safety and tolerability of brexpiprazole in adolescents with schizophrenia (n = 350) (NCT03238326)

## Upcoming events

- Headline results from the PoC study in PTSD to be reported in Q1 2019
- Headline results from the pivotal programme in Bipolar mania to be reported in Q1 2019

## Lu AF20513 to enter proof of concept-study during H1 2019

### Lu AF20513

- An active vaccine inducing high affinity polyclonal antibodies that target beta-amyloid (“Abeta”), for the potential injectable prevention of progression of Alzheimer's dementia

### Ongoing activities

- Open label study to determine if multiple immunizations with Lu AF20513 is tolerable and safe in patients with mild Alzheimer's disease (n = 50) (NCT02388152)
- Investigating if subjects are generating antibodies

### Upcoming events

- PoC study expected to commence in H1 2019

# Foliglurax is an innovative and highly attractive phase II compound being developed for symptomatic treatment of Parkinson's disease

## Foliglurax

- A small-molecule positive allosteric modulator of group III metabotropic glutamate receptor 4 (mGluR4 PAM), for the potential oral treatment of Parkinson's disease

## Ongoing activities

- Phase II proof of concept study in subjects with Parkinson's treated with a stable dose of levodopa who are experiencing both end-of-dose wearing off and Levodopa-Induced Dyskinesia (n = 165) (NCT03162874)

## Upcoming events

- PoC study expected to finalize in Q3 2019

# Pipeline progressing with further newsflow expected in the next 12 months

- ★ **Lu AF35700: Data from first pivotal study**
  - ★ Headline results from *DAYBREAK I* (Q4 2018)
- ★ **Brexpiprazole: Data from life cycle management programme**
  - ★ PoC headline results in PTSD (Q1 2019)
  - ★ Pivotal data in bipolar mania (Q1 2019)
- ★ **Trintellix sNDA**
  - ★ The U.S. FDA accepted an sNDA for the drug to treat MDD in patients with treatment-emergent sexual dysfunction in February 2018. PDUFA is set to 21 October 2018
- ★ **Lu AF20513: Entering clinical Proof of Concept study**
  - ★ Based on the data from phase I, Lundbeck intends to advance Lu AF20513 into a phase II clinical study in Alzheimer's disease patients (H1 2019)
- ★ **Foliglurax: Clinical proof of concept**
  - ★ Headline results from PoC study (Q3 2019)

Thank you!

Lundbeck

