TELECONFERENCE – Q3 2014

5 November 2014

Lundbeck PROGRESS IN MIND

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Q3 – Solid growth in New Products, positive pipeline development and financial outlook maintained

Operations

- Brintellix: Strong branded market share development
- Northera: Launched in the US
- Abilify Maintena/Selincro: European market access going according to plan

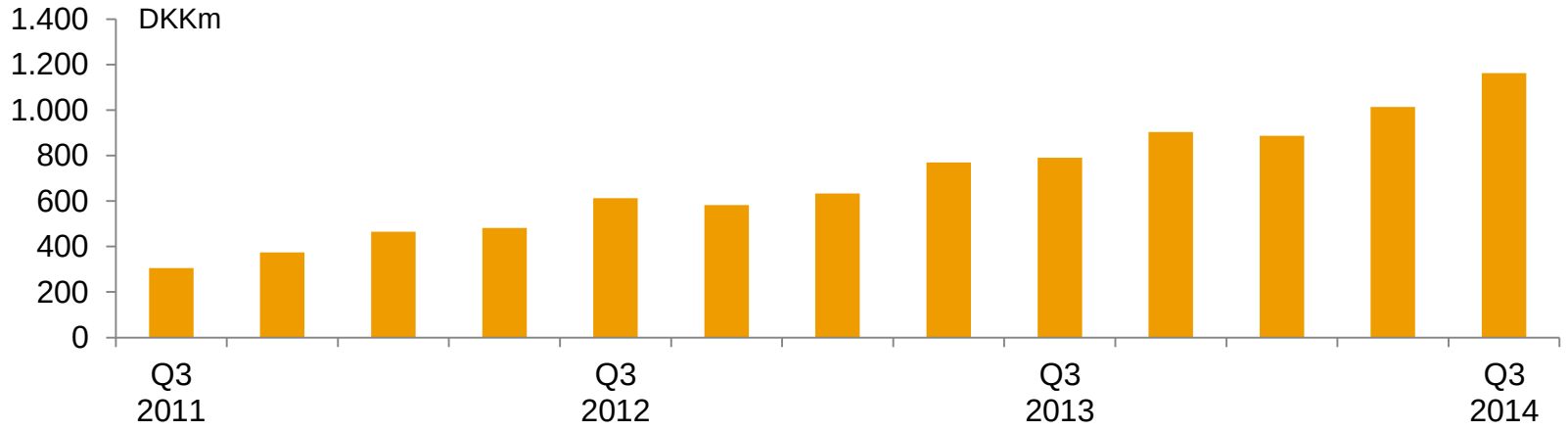
R&D

- Brintellix approved in Canada (Trintellix)
- Brexpiprazole: Robust regulatory package in two indications submitted in the US

Financials

- Core revenue only slightly down in the quarter primarily as a result of strong New Products sales
- 2014 financial guidance maintained
- Preliminary outlook for 2015 provided

Continued robust momentum in New Products' growth



- More than 56% growth (CAGR) in New Products*) since Q3 2011
- Rapid acceleration expected in New Products' growth
- More than 50 launches expected in the next 12 months in various countries

*) New Products include Abilify Maintena, Brintellix, Lexapro (Japan), Northera, Onfi, Sabril, Selincro, Sycrest, Treanda and Xenazine

A new psychiatry portfolio of innovative therapies

Abilify Maintena

- Market access according to plan, with some early success
- *QUALIFY* study
- Encouraging initial uptake in the EU

Brintellix

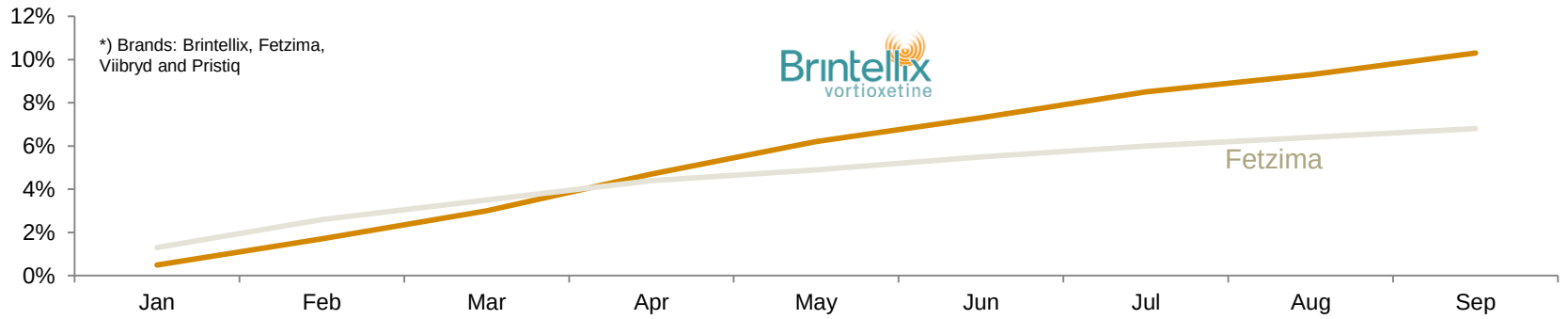
- Positive feedback from US prescribers
- 9 months revenue DKK 105m
- Encouraging initial feedback in the EU

Brexpiprazole

- US regulatory process initiated
- Clinical data to be presented later in 2014
- PDUFA date mid-July 2015

Brintellix continues its solid TRx uptake – feedback from physicians is very positive

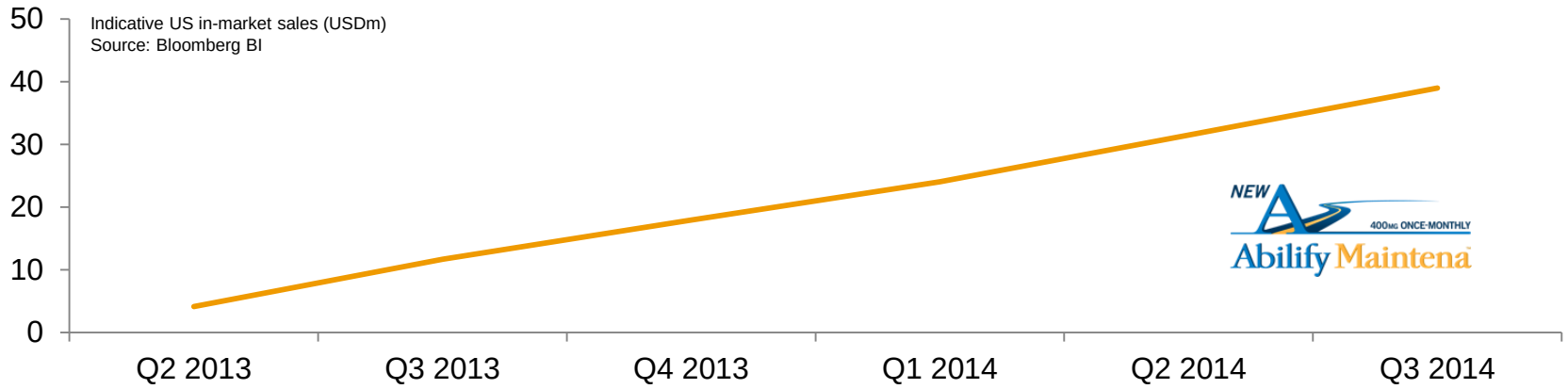
US branded value share* (monthly)



- Solid market share gains
- Brintellix is **outperforming** Viibryd and Fetzima in value by **27% and 74%** respectively

- Approved in Canada (Trintellix)
- Launched in e.g. Chile, Denmark and South Africa
- Initial feedback encouraging

Abilify Maintena on track – has >9% of US long-acting injectable market



- Dual-chamber syringe approved
- Deltoid administration submitted
- *Assure* access programs

- Unrestricted reimbursement in 17 European countries
- Access preparations ongoing in International Markets
- Launched in 11 countries

US neurology franchise up 36%* YTD – to be further strengthened by Northera

Current neurology franchise (9mth):

Onfi (clobazam) 5, 10, and 20 mg Tablets

- Up 71%* to DKK 606m

Xenazine (tetrabenazine) 12.5 and 25 mg Tablets

- Up 21%* to DKK 1,190m

Sabril vigabatrin 500 mg tablet 500 mg powder for oral solution

- Up 36%* to DKK 519m

Northera (droxidopa) capsules 100 mg • 200 mg • 300 mg

- FDA approved for nOH**
- Launched in September 2014
- Significant unmet medical need
- Growing market with aging US population
- DKK ~15m in Q3 - peak sales potential of DKK >2bn annually

* Local currency, first nine months

**nOH = neurogenic orthostatic hypotension

Selincro is getting to the end of the market access phase

Optimal market access	Work in progress
	

- NICE recommendation and French ASMR IV
- Launched in key markets: France, Germany and Spain
- Very good product understanding in the first markets

Selincro® nalmefene

Lundbeck's geographical expansion well under way

- US up 48%* in Q3
- US constitutes ~31% of total revenue in Q3
- Northera has been launched
- Brexpiprazole expected to be launched H2 2015
- US revenue approaching USD 1 billion in 2015

- International Markets up 16%* in Q3
- International Markets constitutes ~33% of total revenue in Q3
- Lexapro leading brand in China
- Brintellix approved in Canada
- In Europe, Abilify Maintena launch off to a good start
  - Brintellix and Selincro well under way

* Local currency

Solid financial performance in Q3 2014

- **Core revenue**
  - Modest decline due to strong generic competition
  - New Products up 47%

DKK 3.2bn

- **Core EBIT**
  - Continued focus on operational and sourcing efficiencies

DKK 0.3bn

- **Core EBIT margin**
  - Increased investments in launch activities

9%

- **Operating cash flow**
  - Positive development in working capital

DKK 0.8bn

Guidance for 2014 maintained, preliminary 2015 guidance provided

- An **unusual number** of variables
- Strong increase in **investments** in sales, promotion and R&D
- Amortization will increase to DKK **~800 million**
- **Preliminary outlook for 2015**
  - Revenue indicated to be on **level of or slightly below 2014**
  - Core EBIT is expected to be **close to zero or slightly negative**

Financial guidance 2014

DKK billion	2013 - Actual	9M 2014 - Actual	2014 - Forecast
Revenue	15.3	10.2	~13.5
Core EBIT	2.3	1.5	0.9 - 1.4
EBIT	1.6	0.9	0.0 - 0.5

Lundbeck invests to develop late-stage pipeline

Regulatory processes

- Brintellix approved in Canada

Brexpiprazole

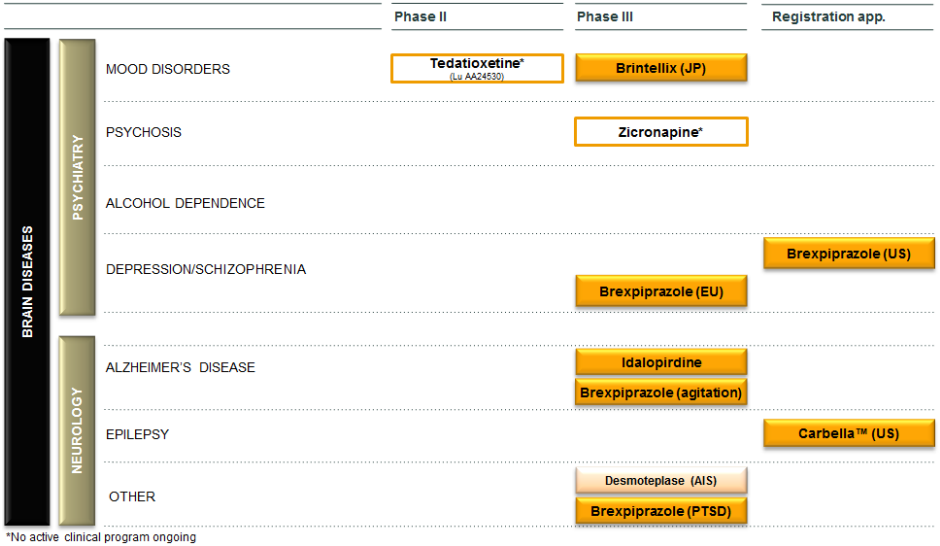
- Brexpiprazole NDA accepted for filing
- Significant data presentation at medical conferences later in 2014

Desmoteplase

- DIAS 3 data presented at WSC
- Evaluation of next step ongoing

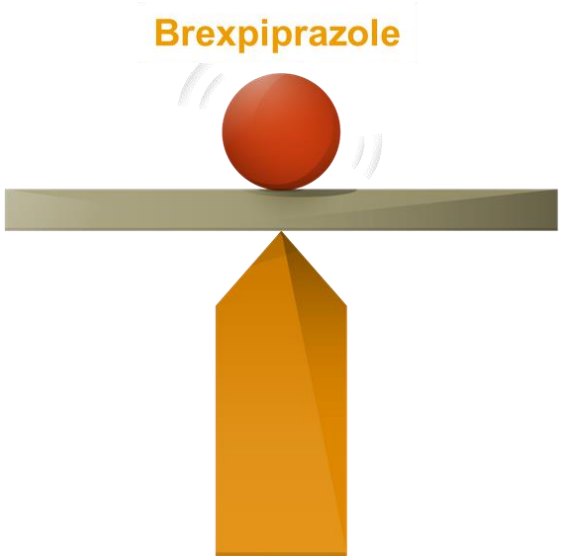
Abilify Maintena

- *QUALIFY*: Strong data on quality of life



Brexpiprazole - existing therapies leave an unmet need for a safe and well-tolerated treatment

- Current atypical antipsychotics are associated with a risk of activation or sedation
- Brexpiprazole NDA filed in the US for schizophrenia and adjunctive treatment of MDD
  - Robust data package
  - Solid tolerability data
  - Data planned to be presented at ACNP
- Phase III studies ongoing for PTSD and for agitation associated with dementia of the Alzheimer's type



Additional analysis on desmoteplase presented at WSC – next steps under evaluation

- In the PP population desmoteplase showed **better functional** outcome vs placebo as assessed by the mRS
- **MRI seems more sensitive than CT** scanning in identifying appropriate patients likely to benefit from desmoteplase
- The safety profile of desmoteplase was **similar** to that of placebo
- Lundbeck to **discuss next steps** with KOLs and regulatory authorities

Idalopirdine received positive FDA and EMA feedback and strong support for the development program

- Phase III program ongoing
  - >2,500 patients
  - Primary end-point agreed with FDA and in accordance with guidelines
  - Receptor occupancy data supports lower dose-range[1)]
  - Data read-out 2016/17
- Phase II data published in The Lancet Neurology
  - "*Stat-sig*" on ADAS-cog
  - Trend toward improvement on ADL and global impression (CGIC)

Articles

Safety and efficacy of idalopirdine, a 5-HT$_6$ receptor antagonist, in patients with moderate Alzheimer's disease (LADDER): a randomised, double-blind, placebo-controlled phase 2 trial

David Wilkinson, Kristian Windfeld, Eskild Colding-Jørgensen

Summary

Background In human beings, 5-HT$_6$ receptors are almost exclusively expressed in the brain, particularly in areas relevant for cognition, such as the hippocampus and frontal cortex. We assessed the effect on cognitive performance of Lu AE58054 (idalopirdine), a selective 5-HT$_6$ receptor antagonist, in donepezil-treated patients with moderate Alzheimer's disease.

Methods For this randomised, double-blind, placebo-controlled phase 2 trial (LADDER), we recruited patients from 48 outpatient clinical sites in seven countries. Patients were 50 years or older, had moderate Alzheimer's disease (a mini-mental state examination score of 12–19), and had been stably treated with donepezil 10 mg per day for 3 or more months. Using a computer-generated sequence, we randomly assigned patients (1:1, stratified by site) to receive either idalopirdine 90 mg per day (30 mg thrice daily) or placebo. The primary endpoint was change from baseline in the 13-item Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) at week 24. We analysed all efficacy endpoints in the full-analysis set (modified intention-to-treat analysis). This trial is registered with ClinicalTrials.gov, number NCT01019421.

Findings Between Dec 8, 2009, and Dec 23, 2011, we randomly allocated 278 patients to treatment: 133 to placebo and 145 to idalopirdine. 132 patients in the placebo group and 140 in the experimental group were included in the final analysis. At week 24, the change from baseline in ADAS-cog total score was +1·38 (SD 0·53) in the placebo group and −0·77 (0·55) in the idalopirdine group (treatment difference of −2·16 points, 95% CI −3·62 to −0·69; p=0·0040). 25 patients (seven taking placebo and 18 taking idalopirdine) discontinued treatment because of adverse events, the difference between groups being mainly due to asymptomatic transient increases in transaminase concentrations in some idalopirdine-treated patients. The most common adverse events (occurring in >3% of patients) were increased γ-glutamyltransferase (14 [10%] patients in the idalopirdine group vs two [2%] in the placebo group), diarrhoea (six [4%] vs nine [7%]), urinary tract infection (three [2%] vs nine [7%]), fall (three [2%] vs eight [6%]), increased alanine aminotransferase (nine [6%] vs none), and benign prostatic hyperplasia (two [5%] vs none). Serious adverse events were reported by 14 (10%) patients in the idalopirdine group and 13 (10%) patients in the placebo group. One death occurred in each treatment group, neither were regarded as being related to treatment.

Interpretation Idalopirdine improved cognitive function in donepezil-treated patients with moderate Alzheimer's disease. Larger studies [illegible] population of patients are ongoing to substantiate the effects reported here.

1) Schmidt et al, Alzheimer's & Dementia, Volume 10, Issue 4, Supplement, July 2014, Page P925

ON TRACK TO DELIVER LONG-TERM GROWTH

- New Products continues the solid momentum
- US psychiatry infrastructure established
- US neurology franchise expanded with Northera
- Expansion in International Markets