



Conference call – Huntexil® Phase III programme and restructuring of operations

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NEUROSEARCH

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- Restructuring of operations
- Design of the Huntexil[®] Phase III programme
- Financial guidance for 2011 and outlook for 2012



NeuroSearch focus resources on Huntexil®



- The aim for NeuroSearch is to create a profitable, specialty pharmaceutical company building on the platform that the company would achieve from a successful development of Huntexil®
- Huntexil® for Huntington's disease is the company's lead asset
- Huntexil® belongs to the new class of 'dopidines' together with ordopidine and seridopidine
- We have an obligation towards patients and shareholders to realise the full potential of Huntexil®
- With an optimised use of resources, NeuroSearch will gain significant financial flexibility



Restructuring of operations



NeuroSearch plans to carry out a comprehensive restructuring of the company's operations

- The employee headcount will be reduced to a size necessary to primarily continue the development of Huntexil[®]. The headcount at NeuroSearch is expected to be reduced from the current number of just under 200 to about 100 employees during Q2 2012, to about 50 employees at the end of Q3 2012 and to about 35 employees when the restructuring is fully and finally implemented in mid-2013. This is expected to reduce fixed and employee-related costs from about DKK 200 million per year to about DKK 50 million per year
- The obligations towards Lilly and Janssen will be met
- NeuroSearch will seek buyers for all drug candidates with the exception of Huntexil[®], ordopidine and seridopidine
- In the months ahead, NeuroSearch will explore the possibilities for the company's research activities to continue under new ownership

Huntexil[®] investment highlights



Huntexil[®] represents a unique opportunity to add significantly to the treatment options for Huntington's disease

- There is no cure or effective treatment of Huntington's disease and Huntexil[®] is the first compound to address the overall motor symptoms
- Large clinical studies have shown significant improvement of patients' overall motor function and a strong tendency towards a positive treatment effect on voluntary movement function
- Safe and well-tolerated in the doses tested and no treatment-related decline detected in other disease symptoms
- Designated orphan drug status with both the FDA and the EMA granting 7 and 10 years market exclusivity, respectively
- NeuroSearch believes there is a large unmet medical need with an estimated approximately 110,000 patients in main markets
- All rights for Huntexil[®] are retained
- Patent protection until 2024 / 2025 in the USA and 2025 in the EU, both including extensions

Huntexil® Phase IIb/III trials



MermaiHD

- Randomised, double-blind and placebo-controlled phase III study
- Conducted in HD centres in Austria, Belgium, France, Germany, Italy, Portugal, Spain and United Kingdom
- Objective: Evaluate efficacy and safety of Huntexil® (45 mg once or twice daily) after 26 weeks with mMS as primary endpoint and TMS among other endpoints
- 437 patients were enrolled

HART

- Randomised, double-blind and placebo-controlled phase IIb study
- Conducted in HD centres in Canada and United States
- Objective: Evaluate efficacy and safety of Huntexil® (10 mg, 22.5 mg or 45 mg – all twice daily) after 12 weeks + establish dose-response relationship with mMS as primary endpoint and TMS among other endpoints
- 227 patients were enrolled

The Total Motor Score, TMS



TMS, part of the Unified HD Rating scale (UHDRS)

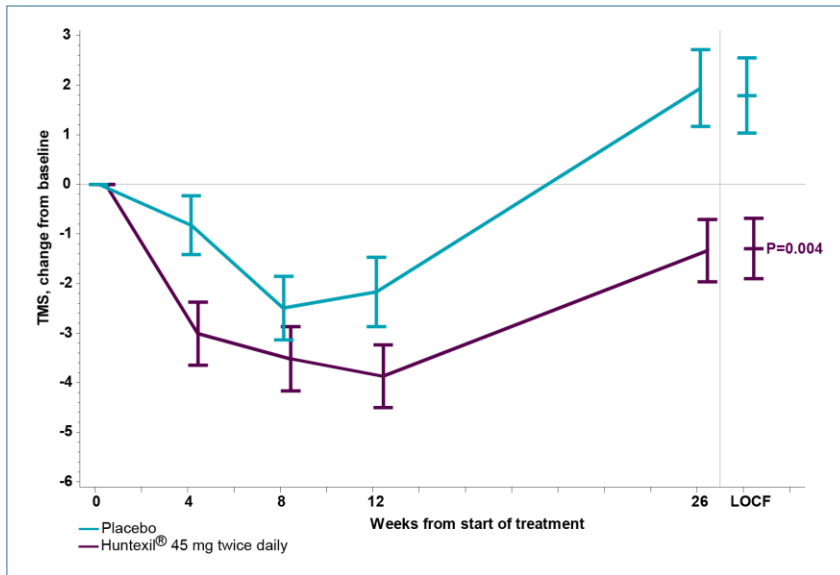
- Measures 15 items related to motor symptoms
- Disease progression: ~4–5 points increase p.a.
- TMS is the most commonly used scale to assess movement disorders related to Huntington's disease

TMS	Eye movements	Ocular pursuit Saccade initiation Saccade velocity
	Motor-speech and tongue disorder	Dysarthria Tongue protrusion
	Hand movements	Finger taps Pronate/supinate-hands Luria
	Rigidity and slowness	Rigidity - arms Bradykinesia - body
	Involuntary movements	Maximal dystonia Maximal chorea
	Gait and balance	Gait Tandem walking Retropulsion pull test

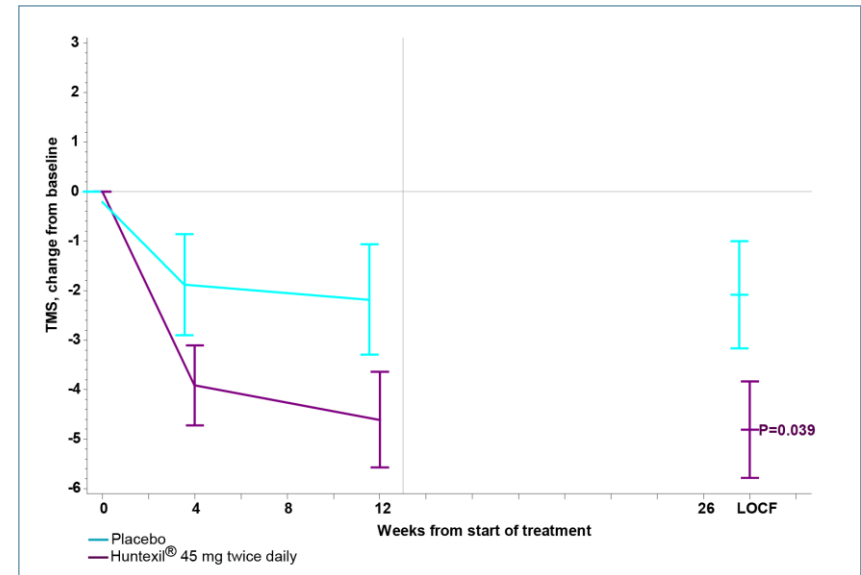
Huntexil[®] effect on TMS



The MermaiHD study



The HART study



The MermaiHD study

- Phase III study with 437 patients in eight European countries
- Significant effects on TMS after 26 weeks
- The primary endpoint (mMS) was not met

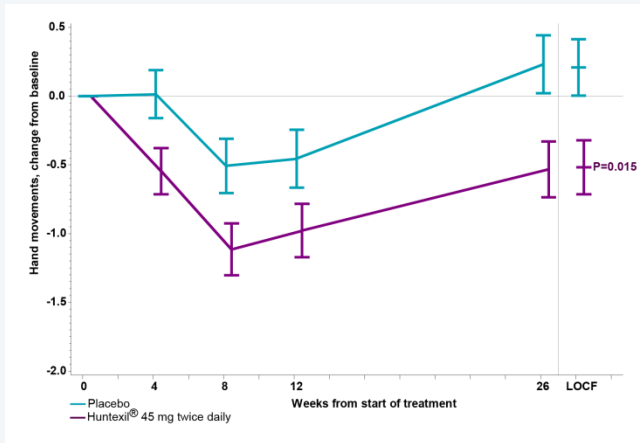
The HART study

- Phase IIb study with 237 patients in the United States and Canada
- Significant effect on TMS after 12 weeks
- The primary endpoint (mMS) was not met



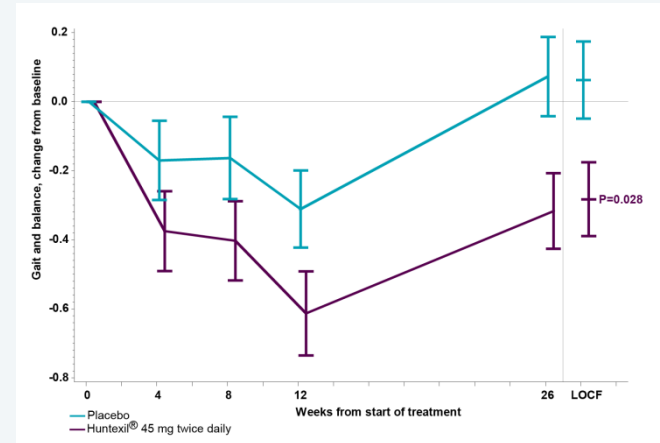
Hand movements

The MermaiHD study

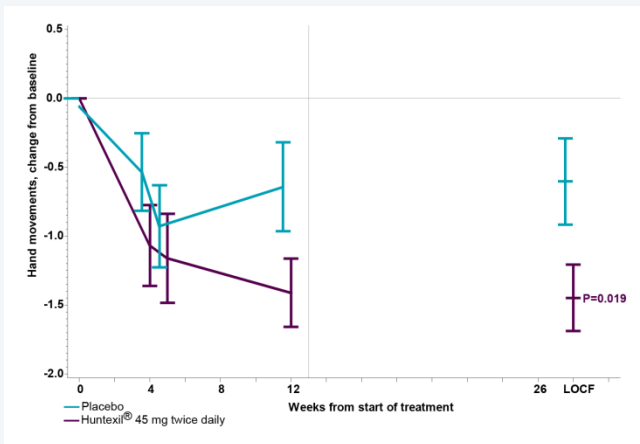


Gait and balance

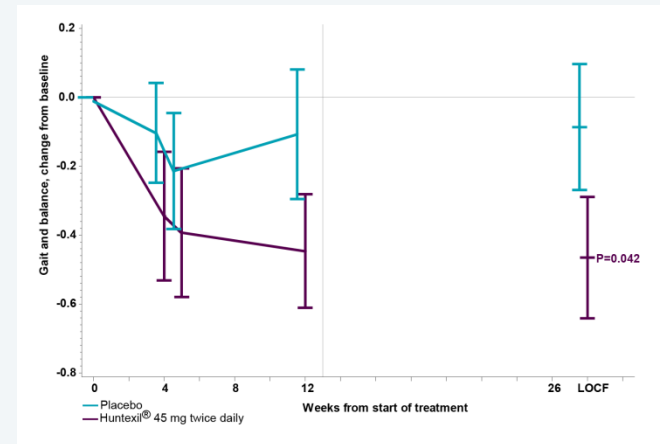
The MermaiHD study

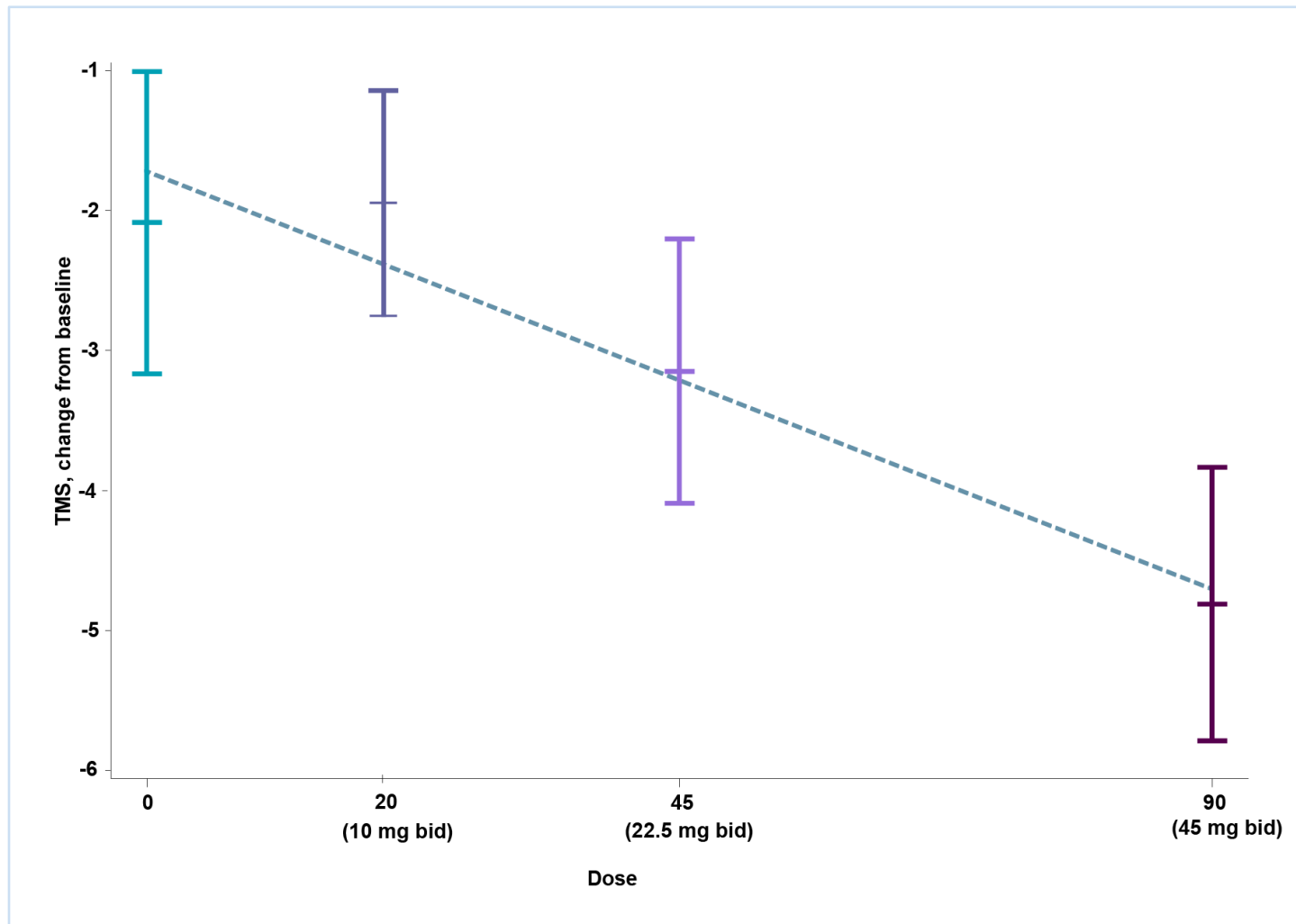


The HART study



The HART study





Huntexil[®] clinical data



The clinical results for Huntexil[®] can be summarised as

- Two independent trials with a total of 664 HD patients demonstrate that 45 mg twice daily improves overall motor function (TMS)
- Strong tendency towards effect on the modified motor score though this primary endpoint was not met
- Effect on TMS corresponds to approximately 6-8 months disease progression
- Dose response relationship established in HART
- Adverse event profile similar to placebo and no worsening of other symptoms such as cognition and behaviour
- Favourable safety profile as demonstrated by 621 HD patients (822 subjects in total) having received Huntexil[®]

Variable	HART (12 weeks)	MermaiHD (26 weeks)
N =	227	437
mMS (PE)	-1.2 points (p = 0.078)	-1.0 points (p = 0.042)
TMS (SE)	-2.8 points* (p = 0.039)	-3.0 points* (p = 0.004)

* Significant improvement from baseline versus placebo

Huntexil® - regulatory status



NeuroSearch has, in the course of H1 2011, had an End of Phase II meeting with the FDA and a scientific advice meeting with the EMA to discuss the results from the HART and MermaiHD studies

- Both agencies require additional Phase III data to confirm efficacy measured on the TMS
- Additional endpoint to support clinical relevance is required
- The FDA also recommended exploring higher doses than 45 mg twice daily

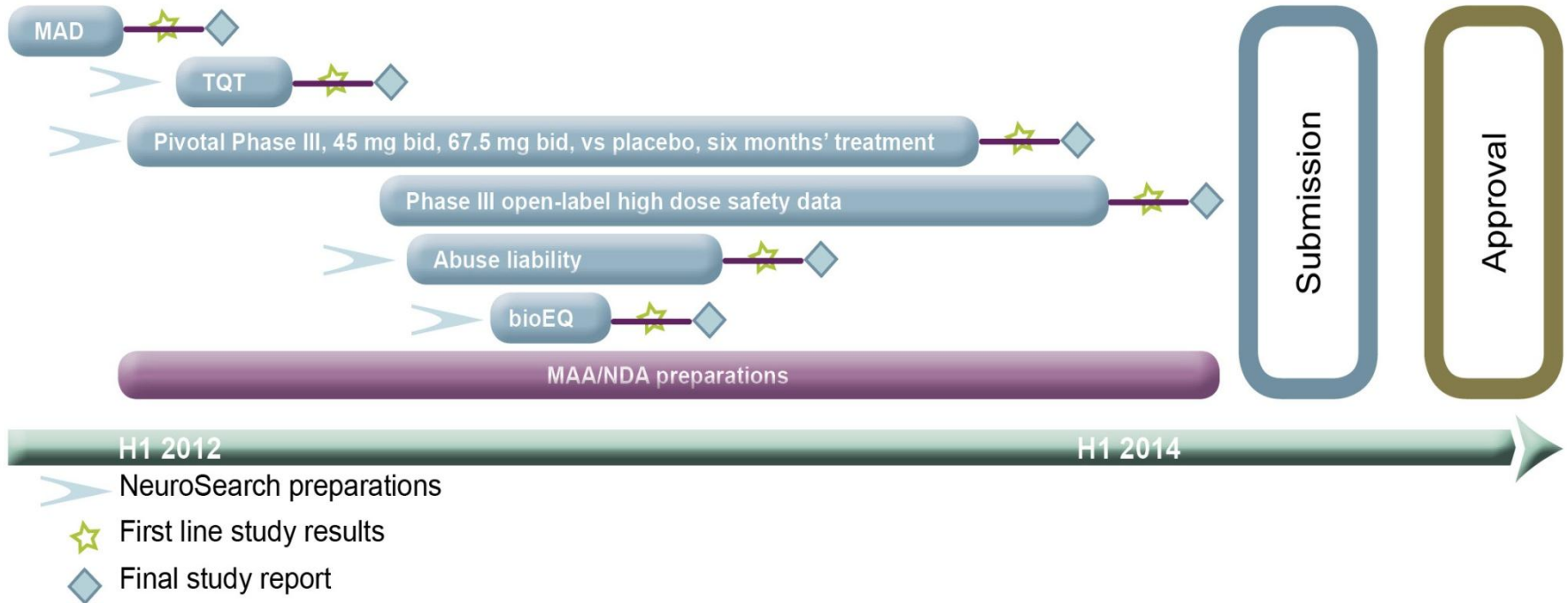


Huntexil® - NeuroSearch development programme



- NeuroSearch has now designed the development programme for Huntexil® based on the recommendations from EMA and the FDA, the results of the HART and MermaiHD studies and discussions with leading experts in the field
- Huntexil® is being developed as a drug for the treatment of impaired motor function associated with Huntington's disease
- The Phase III protocol will be submitted for an informal protocol review at the FDA during Q4 2011 and the feedback will determine the final details of the efficacy study
- Results from the development programme will form the basis for marketing application in Europe and the USA

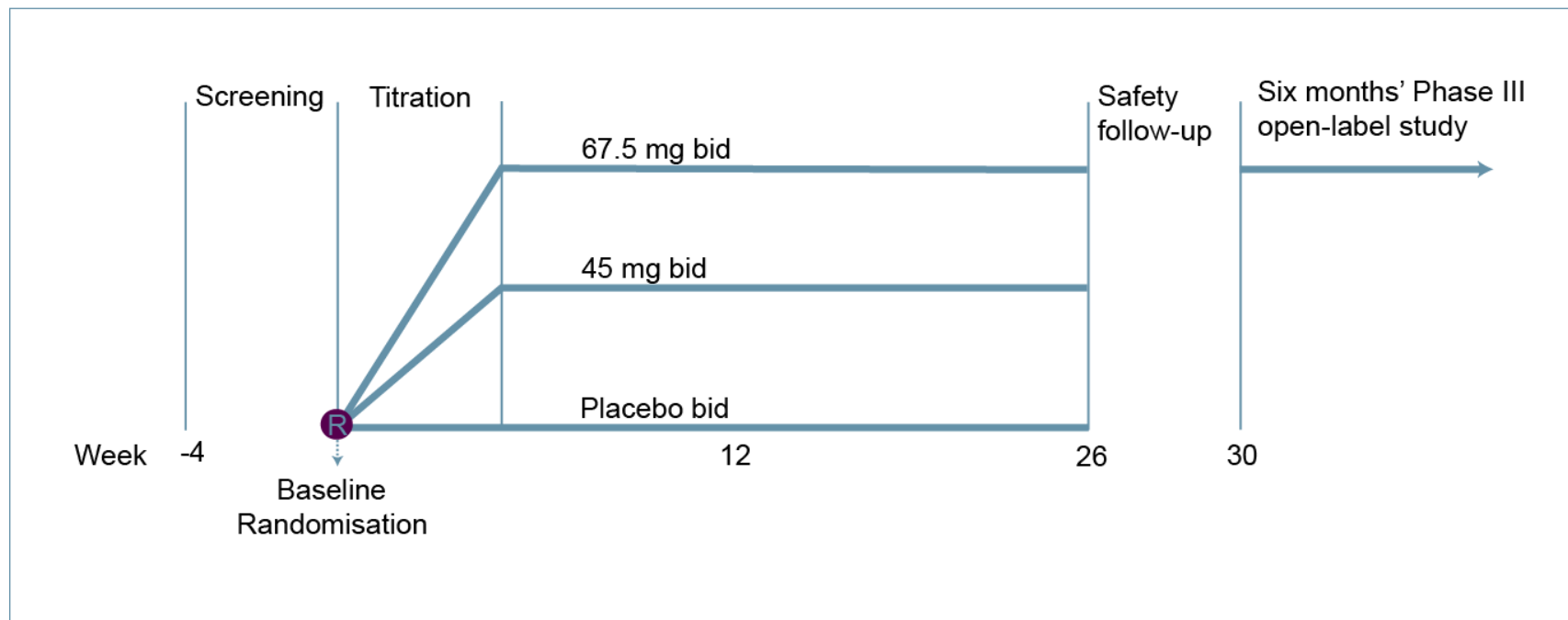
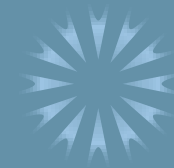
Huntexil[®] Phase III programme overview



- MAD, TQT and bioEQ are performed in healthy volunteers
- Abuse liability is performed in recreational drug abusers

Prime-HD for Huntexil®

Confirmatory Phase III efficacy study design



Confirmatory Phase III efficacy study

- Global study with 630 patients in three treatment arms
- Primary endpoint is TMS. The primary objective is to show efficacy of Huntexil® 45 mg twice daily on TMS
- Other endpoints include Clinical Global Impression (CGI), activities on daily living (ADCS-ADL) and non-motor scales from UHDRS

Prime-HD for Huntexil®

Other programme information



- Patients will be recruited in Europe and the United States and possibly also in South America and Australia
- Patient enrolment criteria will be similar to those in the HART and MermaiHD studies
- Patient enrolment is expected to take 12 months
- First patient is expected to be dosed during H1 2012 provided NeuroSearch has secured financing to complete Prime-HD
- The efficacy of the two Prime-HD doses measured on the TMS and CGI scales will be tested within a closed testing procedure to ensure an overall significance level of 5%

Complementary studies



- **Multiple Ascending Dose (MAD) study**
 - Increasing doses to test the safety and tolerability of Huntexil®
 - Select a supra-therapeutical dose for the TQT heart study
 - Enrolling up to 36 healthy volunteers – first patient recently dosed
 - Interim analyses of the data will be used in the other studies
- **TQT heart study**
 - Mandatory study of Huntexil®'s effect on the heart's conductive properties (electrocardiogram)
 - The study will be conducted in healthy volunteers
- **Abuse potential study**
 - Mandatory abuse liability study for CNS-active compounds
 - The study will be conducted in subjects classified as recreational drug abusers
- **Bioequivalence study**
 - Study to confirm the bio-equivalence between Huntexil® capsules and Huntexil® tablets that will be developed for commercial use
 - Study will be performed in healthy volunteers

Next steps in development of Huntexil®



- Results from MAD are expected during Q1 2012
- The Prime-HD protocol will be submitted for an informal protocol review by the FDA during Q4 2011
- Interaction with KOLs and CROs for planning of TQT and abuse liability studies will be initiated during Q4 2011
- Publications of the results from the MermaiHD and the HART studies
- Operational preparations for Prime-HD will be initiated Q4 2011
- Tablet formulation is planned to be available Q4 2012
- Continuation of the Open-HART study (98 patients enrolled) and compassionate use programme (129 patients participating)
- Key results from Prime-HD are expected H1 2014

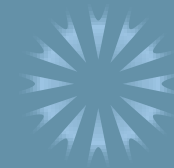
External cost of Huntexil[®] development programme



- Total external costs for completion of the Huntexil[®] development programme, consisting of Prime-HD and four additional studies, are estimated to be about DKK 200 million of which the majority relates to Prime-HD
- Most of the external costs are expected to be incurred in 2012 and 2013 provided that the study is initiated in the first half of 2012



Revised financial guidance for 2011



Previous guidance for 2011

DKK million

Operating loss (EBIT) 300

Adjusted guidance for 2011

DKK million

Continuing operations	130
Restructuring costs (related to continuing operations)	240 (no cash effect)
Operating loss (EBIT)	370

Loss on discontinuing activities	345 (140 in cash effect)
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The value of cash and cash equivalents and securities is expected to be approximately DKK 230 million at the end of 2011

Basis for guidance and reporting

The financial guidance and reporting will, going forward, distinguish between loss from continuing operations, being primarily Huntexil® related activities, and loss from discontinuing activities

Outlook for 2012



Outlook for 2012

DKK million

Continuing operations 150 -175

Restructuring 0

Operating loss (EBIT) 150 - 175

Loss on discontinuing activities 0
(~70 in cash effect)

- The costs relate primarily to the Phase III programme for Huntexil[®], provided it progresses according to plan, but also include costs for continuing the Open HART study, the compassionate use programme, development of a tablet formulation for commercial use, preparation of product registration and marketing, further development of seridopidine and ordopidine and costs of a significantly reduced organisation

Conclusions on financials



- With an optimised use of resources, NeuroSearch will gain significant financial flexibility
- NeuroSearch will be a going concern until beginning of 2013, should the Prime-HD study not be initiated
- Our ambition is to secure funding to be able to enrol the first patient in Prime-HD in H1 2012
- We are actively assessing different funding options, including a partnership agreement for Huntexil® and a rights issue



For more information, please visit; www.neurosearch.com
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Pipeline



Product	Indication	Mechanism of action	Partner	Phase	PC	I	II	III	Reg.
Huntexil®	Huntington's disease	Dopidine		Phase III					
<div style="border: 1px solid purple; padding: 10px;"> <div style="display: flex; align-items: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); background-color: purple; color: white; padding: 5px; font-weight: bold; margin-right: 10px;">Project activities</div> <div style="flex-grow: 1;"> <div style="margin-bottom: 5px;">MAD</div> <div style="margin-bottom: 5px;">TQT</div> <div style="margin-bottom: 5px;">Pivotal Phase III, 45 mg bid, 67.5 mg bid, vs placebo, six months' treatment</div> <div style="margin-bottom: 5px;">Phase III open-label high dose safety data</div> <div style="margin-bottom: 5px;">Abuse liability</div> <div style="margin-bottom: 5px;">bioEQ</div> </div> </div> </div>									
Seridopidine	Movement disorders	Dopidine		Phase I					
Ordopidine	Movement disorders	Dopidine		Phase I					

Portfolio of assets



Product	Indication	Mechanism of action	Partner	Phase	PC	I	II	III	Reg.
Tesofensine	Obesity	MRI		Ready for Phase III					
ABT-894	ADHD	NNR modulator	Abbott	Phase II					
ABT-560	CNS diseases	NNR modulator	Abbott	Phase I					
NSD-788	Anxiety / depression	MRI		Phase I					
NSD-721	Social anxiety disorder	Ion channel modulator		Phase I					
NSD-726	Inflammatory CNS diseases	Ion channel modulator		Preclinical					
NSD-801	Ataxias	Ion channel modulator		Preclinical					