



Company presentation

Swedish American Life Science Summit 2010 - Stockholm, 29 Sept - 1 Oct 2010

NEUROSEARCH

Forward looking disclaimer



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➤ NeuroSearch - Business overview

- Corporate profile and strategy
- Pipeline
- Share information

➤ Key products

- Huntexil® (Huntington's disease) – Unique orphan drug opportunity
- Tesofensine (Obesity) – Fase III programme in preparation
- Seridopidine (ACR343) & ordopidine (ACR325);
Follow-up speciality drug candidates

➤ Expected 12 months news flow



Business overview

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NeuroSearch – Corporate profile and strategy



Late stage product candidates

- Huntexil® for Huntington's disease: Beneficial effects shown in Phase III study – Clinical program ongoing
- Tesofensine for obesity: Phase III plan in preparation

Pipeline

- 8 novel drugs in clinical development + portfolio of PC candidates
- Pipeline inflow: Own drug discovery and in-licensing/M&A

Solid drug platform and funding

- Well-established research platform, focused on CNS disorders; Drug discovery and development alliances w/ Eli Lilly and Janssen (J&J)
- Capital resources; EUR 110m (end Q2'10) - 240 employees in DK & SE

Building a CNS speciality pharma

- Huntexil® - A unique orphan opportunity, all commercial rights retained
- Aiming for near term company transformation; Ensure profitability through commercialisation of speciality CNS drugs

Pipeline



Indication	Product	Mechanism of action	Partner	PC	Phase I	Phase II	Phase III	Market reg.
Huntington's disease	Huntexil®	Dopidine						
Obesity	Tesofensine	Monoamine RI						
ADHD	ABT-894	NNR modulator	Abbott					
Schizophrenia et al.	ACR343	Dopidine						
PD dyskinesias (LID)	ACR325	Dopidine						
Cognitive dysfunctions	ABT-560	NNR modulator	Abbott					
Depression/anxiety	NSD-788	Monoamine RI						
Social anxiety disorder	NSD-721	GABA modulator						
Preclinical candidates			Lilly Janssen					

Share information



- Number of shares outstanding 24,553,947
- Share price (29 September 2010) DKK 82
- Market Cap DKK ~2.0 bill / € ~ 270 mill / \$ ~360 mill
- Capital resources (end Q2 2010) DKK ~810 mill / € ~ 110 mill / \$ ~140 mill

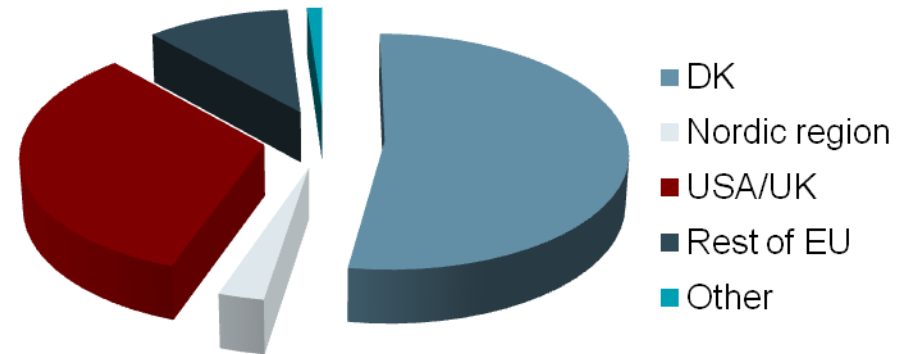


Broad shareholder base

- Corporate shareholders ~11%
- Institutional investors ~ 65%
- Retail investors ~ 24%

100% free float

Geographically well distributed



Key products

Huntexil[®] - Huntington's disease

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A highly attractive product opportunity



- **Huntington's disease: A huge unmet medical need**
 - Prevalence: 1 in 10,000 in most Western countries
 - Market size; ~70,000 pts in NA and Eu, 30,000 – 50,000 pts in RoW
 - Limited treatment options and only very few novel drugs in clinical development

- **Huntexil® - A unique therapeutic offering in Huntington's disease**
 - First ever drug to show beneficial effect on *motor function* in HD patients
 - Results of the MermaiHD study (Phase III study) demonstrate
 - Improvements of both voluntary and involuntary movements
 - No worsening of other disease signs and symptoms
 - Good long-term tolerability and safety profile (after 12 months treatment)
 - Signs of potential disease modifying effect

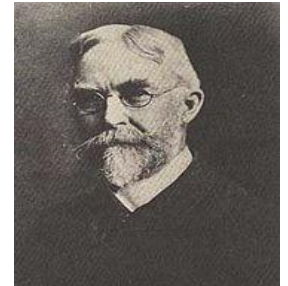
- **Orphan Drug Status with both the FDA and the EMA**

- **Patent protected until 2020 + extension - All commercial rights retained**

What is Huntington's disease?



- Fatal, hereditary genetic disorder (mutant Huntingtin gene)
 - ➔ neuronal death and circuit disruptions in several brain centres
- Symptoms onset typically around 30-50 years of age
 - Serious motor disturbances/loss of motor function
 - Cognitive impairment
 - Psychiatric and behavioural changes
- Continuous disease progression over 10-20 years after symptoms onset, eventually leading to the patient's death
- Patients in mid to final disease stages require extensive daily care



Huntington's disease has serious negative implications on quality of life for patients and their families

Current treatment and Huntexil[®] positioning

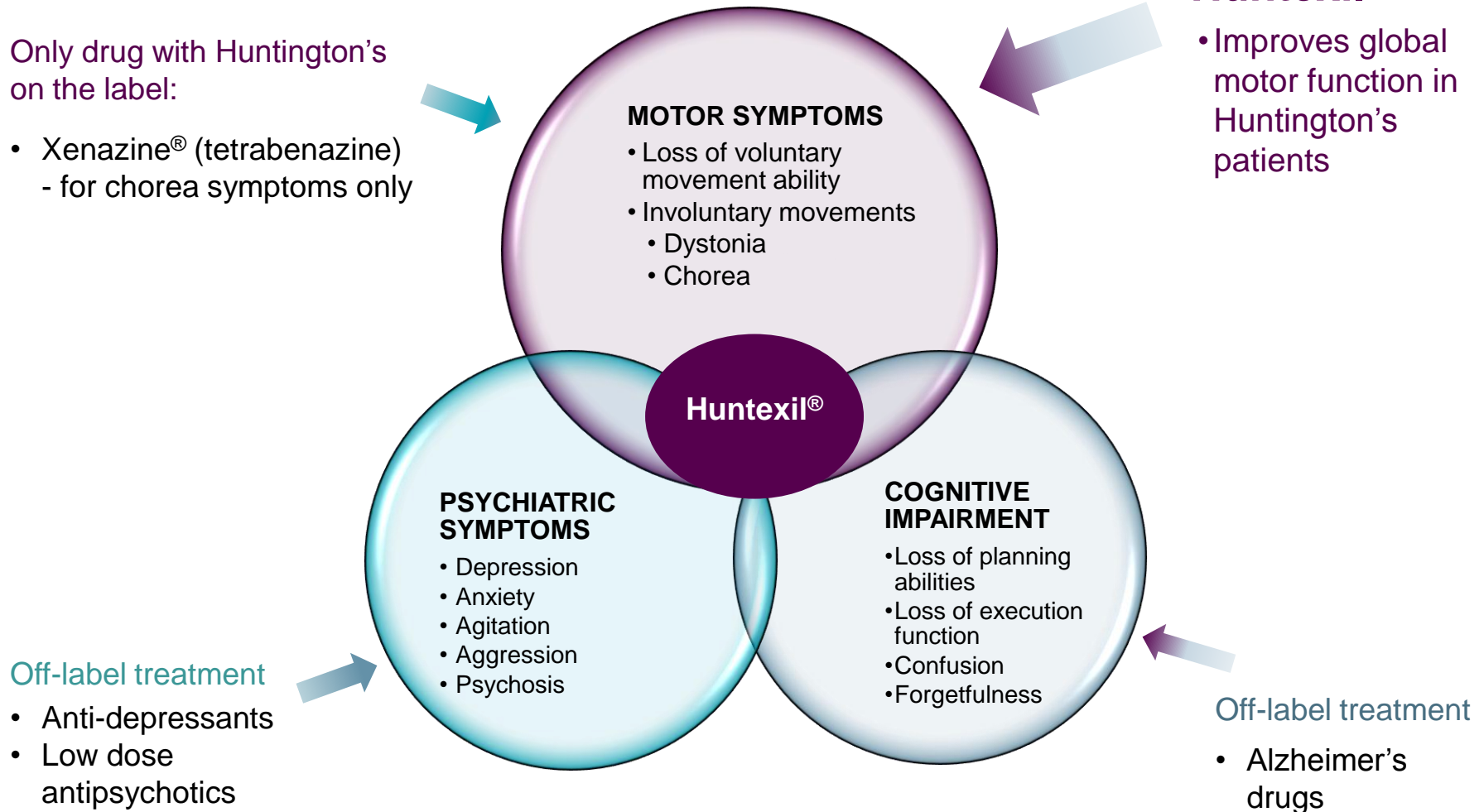


Only drug with Huntington's on the label:

- Xenazine[®] (tetrabenazine)
- for chorea symptoms only

Huntexil[®]

- Improves global motor function in Huntington's patients





➤ Ongoing Phase III programme in Huntington's disease

- ***The MermaiHD study*** (a 26 week European Phase III study in 437 pts);
Completed with results showing a unique efficacy and a good safety profile
- ***The MermaiHD extension*** (a 26 week open-label safety study in 353 pts);
Completed with results showing a good 12m safety and tolerability profile
- ***The HART study*** (a 12 week North American Phase IIB study in 227 pts);
Enrolment completed and results expected mid-October

➤ Other clinical results

Phase II Huntington's disease study (4 week study in 60 pts);

- Significant improvement of voluntary motor function (mMS)
- Positive trends on other symptoms and a benign safety profile

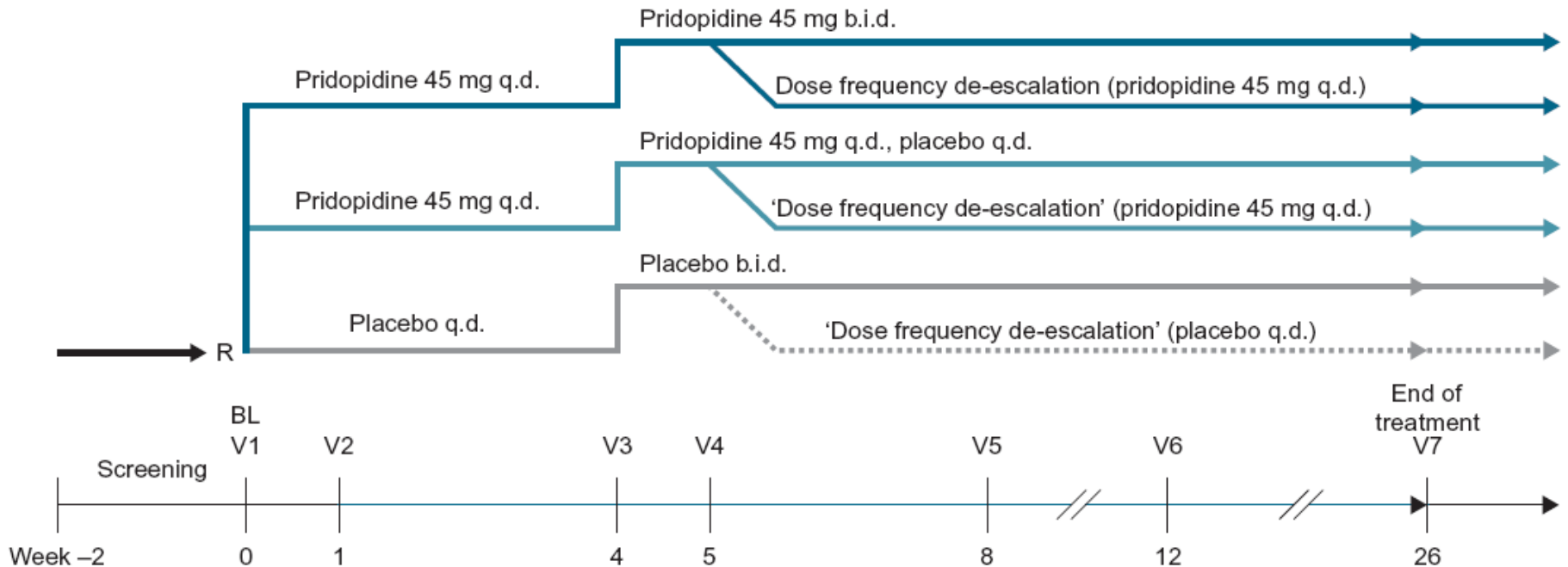
Phase IB studies (Huntington's, Parkinson's and schizophrenia);

- Good safety and consistent, positive effects observed on motor symptoms and cognition

The MermaiHD study – Phase III design



- A 26 weeks randomized, double-blinded, parallel-group study in 437 patients
- Objective: Evaluate Huntexil® (45 mg once or twice daily) versus placebo for the symptomatic treatment of Huntington's disease



BL = baseline; b.i.d.,= twice daily; q.d. = once daily; R = randomization; V = visit.

The MermaiHD study – Compliance and safety



- Randomised population, Intention to treat (ITT) = 437 pts (100%)
- Completers = 92% (403 pts)
 - Placebo = 90%; 45 mg q.d. = 97%; 45 mg b.i.d = 90%
- Withdrawals due to AE = 4% (17 pts)
 - Placebo = 6%; 45 mg q.d. = 1%; 45 mg b.i.d. = 5%
- AEs similar across study arms
- Completers in full compliance, Per Protocol (PP) = 82% (357 pts)
- Open-label safety extension: 353 patients enrolled
- Anti-psychotic medication
 - 190 patients (43.5%) on and 247 patients (56.5%) not on

Clinical motor scales and efficacy endpoints



The Total Motor Score, TMS

- the motor part of the Unified HD Rating scale (UHDRS)
- Measures 15 items of motor function
- Disease progression: ~4-5 pts increase p. a.



1. Ocular pursuit
2. Saccade initiation
3. Saccade velocity

Eye movements

- 3 items from the TMS

4. Dysarthria
5. Tongue protrusion
6. Finger taps
7. Pronate/supinate hands
8. Fist-hand-palm sequencing
9. Rigidity - arma
10. Body bradykinesia

The modified Motor Score, mMS

- measures voluntary motor function
- 10 items from the TMS
- Disease progression: ~2 pts increase p.a.

Involuntary movements

- 2 items from the TMS

11. Dystonia
12. Chorea

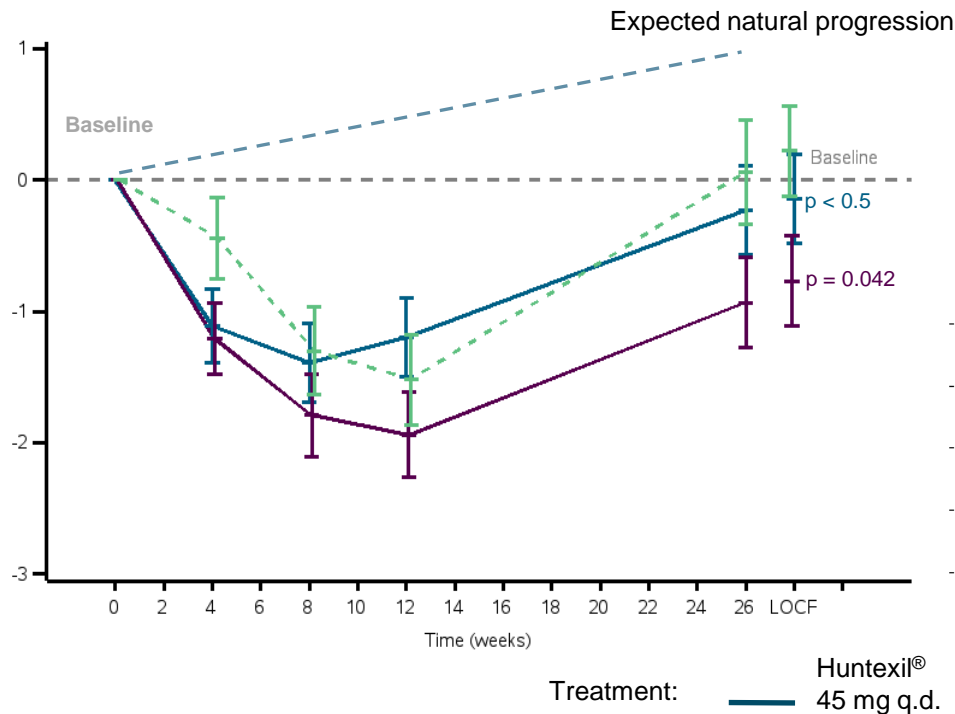
13. Gait
14. Tandem walking
15. Retropulsion pull test

Efficacy results from the MermaiHD study

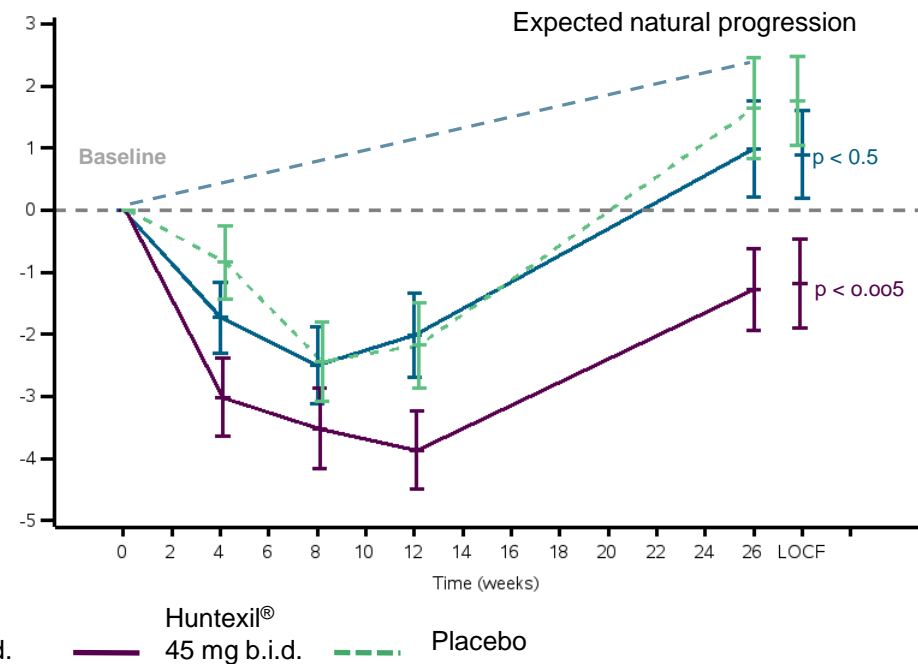


In the MermaiHD study, 26 wk treatment with Huntexil® (45mg twice daily) demonstrated beneficial effect on motor function

Effect on the modified Motor Score, mMS (PE)

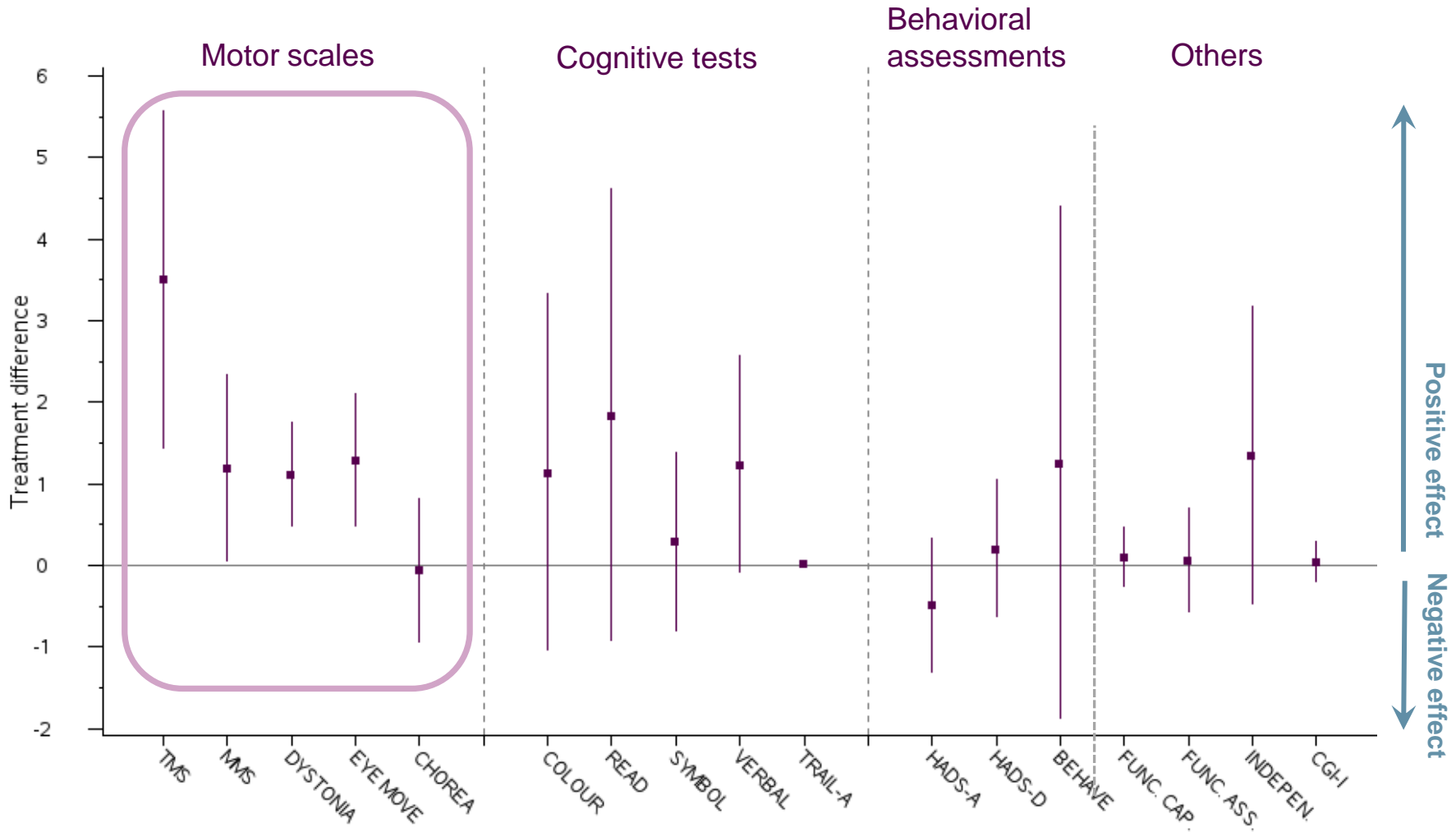


Effect on the Total Motor Score, TMS



The 26 wk effect on mMS and TMS corresponds to an average clinical improvement of 6-8 months

Global motor improvement and no symptoms worsening



Main effects model + adjustment for CAGn* treatment ; n = 393

Conclusions from the MermaiHD study



Results from the 26 week randomised study

- A beneficial effect on motor function in patients with HD
 - Improvement of both voluntary and involuntary motor symptoms
 - Effects corresponding to an average ½ to 1½ years of symptoms set-back
 - Effect on dystonia; indicating potential also for late-stage and juvenile onset pts
- Good safety profile with no apparent therapeutic disadvantages
- Potential disease modifying effect of Huntexil®
 - Increasing placebo contrast effect observed over time
 - Efficacy on symptoms relating to progression of HD (e.g. Eye movements)
 - Reduces the influence of genetic burden (CAGn) on disease progression
- Similar effect and safety in patients “on” and “not on” neuroleptic treatment

Results from the 26 week safety extension

- Confirmed good tolerability and safety profile over 12 months treatment

Clinical study ongoing



- The HART study – a confirmatory Phase IIB study
 - A 12 week randomised, double-blinded, plc controlled North American study (28 centres in the US and Canada)
 - Primary objective: Evaluate the effect of Huntexil on motor symptoms in Huntington's, same endpoints as in the MermaiHD study (mMS, TMS etc)
 - Dose arms: 10 mg, 22.5 mg and 45 mg and placebo – all twice daily
 - Status: The treatment of 227 Huntington patients have been completed
 - Results: Expected mid-October in connection with a clinical HD symposium in La Jolla, US.

Regulatory strategy and other activities



➤ Regulatory plans

- Prepare a combined Huntexil[®] data package (including results from both the MermaiHD and the HART studies)
- Initiate dialogue with FDA and EMA in Q4 2010 to discuss the results
- Define the most appropriate strategy to obtain market registration of the drug as fast as possible

➤ Other activities

- Compassionate Use programme for ex-MermaiHD study patients
- Cost-of-illness study in major markets to help support pricing
- Planning for an Early Access Programme in Europe to cover also patients outside the MermaiHD study
- Publications of the MermaiHD study results in preparation

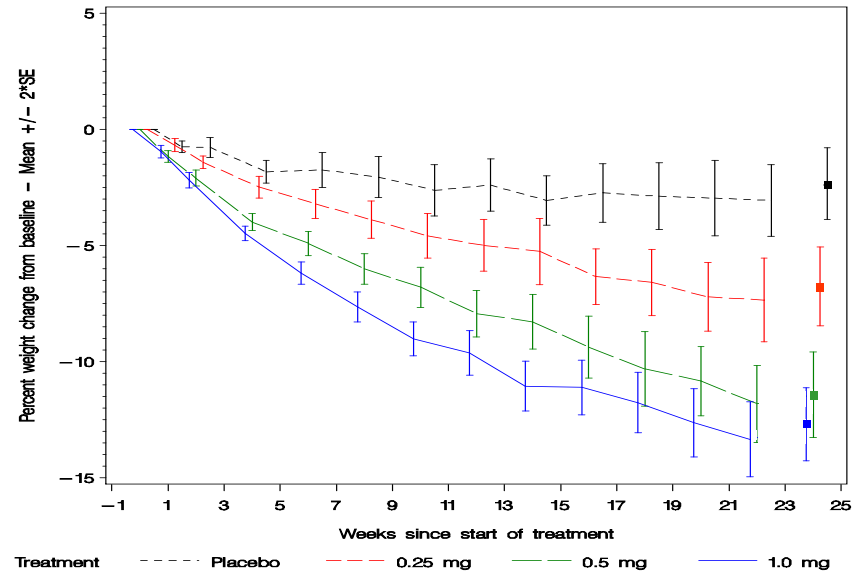
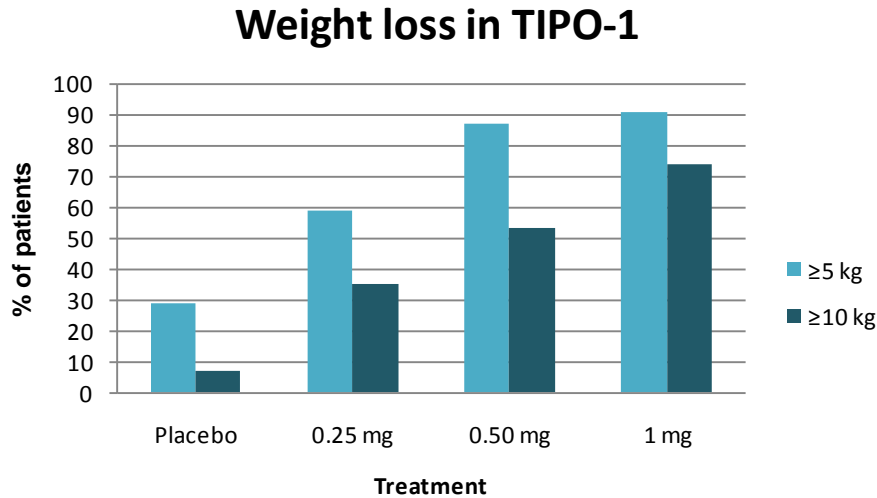
Huntexil[®] – Aiming for market registration as fast as possible

Key products

Tesofensine – A highly efficacious weight-loss drug

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Very strong weight loss effect



In the Phase II study, TIPO-1, 24 wk treatment with therapeutic relevant doses of tesofensine; 0.25 mg and 0.5 mg resulted in

- An average weight loss of ~ 6.5% and 11.2%, respectively (PLC: 2%)
- On 0.5 mg: 87% lost $\geq 5\%$ (≥ 5 kg) and 53% lost $\geq 10\%$ (≥ 10 kg)
- On 0.25 mg: 59% lost $\geq 5\%$ (≥ 5 kg) and 35% lost $\geq 10\%$ (≥ 10 kg)
- Good tolerability and acceptable safety profile; non-significant increase in blood pressure

Take on the current regulatory environment



- Increased transparency regarding the regulatory environment for weight-loss drugs in general
 - Approval based on an evaluation of the combined risk/benefit profile of a new drug
 - Modest efficacy; i.e. weight-loss of < 5% over 12m negatively influence the risk/benefit balance
 - Strong focus on proper measures to ensure post approval risk management – in particular CV related risks
 - Weight-loss should be combined with improved cardiac and metabolic parameters and improved QoL
 - The Phase 3 study population should be diverse and reflect the background population

- Current obesity drug guidelines under revision and likely to include increased pre-approval requirements

Plans for the Phase III programme



Design tesofensine Phase III with the objective of demonstrating

- More than 5% PLC corrected weight-loss over 12 months
- Significant improvement of metabolic parameters and QoL
- An acceptable safety profile in the obesity population including high risk patients
 - diabetics
 - cardiovascular disease patients

Outlook

- Plan to meet and discuss a new Phase III plan with regulators in the US and Europe in Q4
- In parallel, continue dialogue with potential license partners

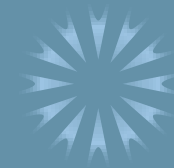
Key products

Seridopidine (ACR343) and ordopidine (ACR325)

– Other speciality drug candidates

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Two novel speciality drug candidates



Seridopidine (ACR343) – Schizophrenia a.o.

- Phase II PoC study as add-on treatment in schizophrenia is in preparation
- Parallel evaluation of potential in speciality neurologic disorders; Tourette's, dystonia, initiation of gait in Parkinson's etc.

Ordopidine (ACR325) – Dyskinesias in Parkinson's disease-

- Phase Ib safety study ongoing in Parkinson's patients with dyskinesias
- Phase II PoC study in L-Dopa induced Parkinson's dyskinesias in preparation

Like Huntexil®, seridopidine and ordopidine belong to a newly established class of CNS active pharmaceutical agents: **dopidines** (earlier designated dopaminergic stabilisers),

- Act primarily on dopamine D₂-receptors with unique pharmacodynamic actions
- Able to regulate both hyper- and hypo-dopaminergic functioning
- Display state-dependent behavioural effects with only subtle effect on normal behaviour

Expected news flow

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Expected 12 months news flow



- **Huntington's disease - Huntexil®**
 - Oct' 10: Results from the 12-week HART study
 - Regulatory interactions (FDA and EMA) and decision on registration strategy
 - Publications of MermaiHD study results
 - Potential initiation of Early Access programme
- **Obesity - Tesofensine**
 - Completion of new Phase III plan
 - Regulatory interactions (FDA and EMA)
 - Licensing
- **Schizophrenia – Seridopidine (ACR343)**
 - Initiation of Phase II study
- **Parkinson's dyskinesias – Ordopidine (ACR325)**
 - Initiation of Phase II study
 - Completion of Phase Ib study
- **Other news**
 - Appointment of new Chief Medical Officer
 - Advances for associated companies
 - Pipeline inflow



Appendices

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New CEO of NeuroSearch: Patrik Dahlen



Professional background

- More than 10Y of top managerial experience from the international Life Science industry
 - PerkinElmer, DAKO A/S and BiImage A/S
- Leadership experience from both smaller venture-backed companies and large, global organisations
- Proven track-record in the optimisation and growing of commercially oriented companies



Key NeuroSearch related competences

- Strong and proven managerial and organisational skills
- Commercially savvy and market oriented
- Performance driven and scientifically founded

Personal data

Born: 1962

Nationality: FIN

Civil status:

Married, living in
DK

The clinical relevance of genetic disease burden



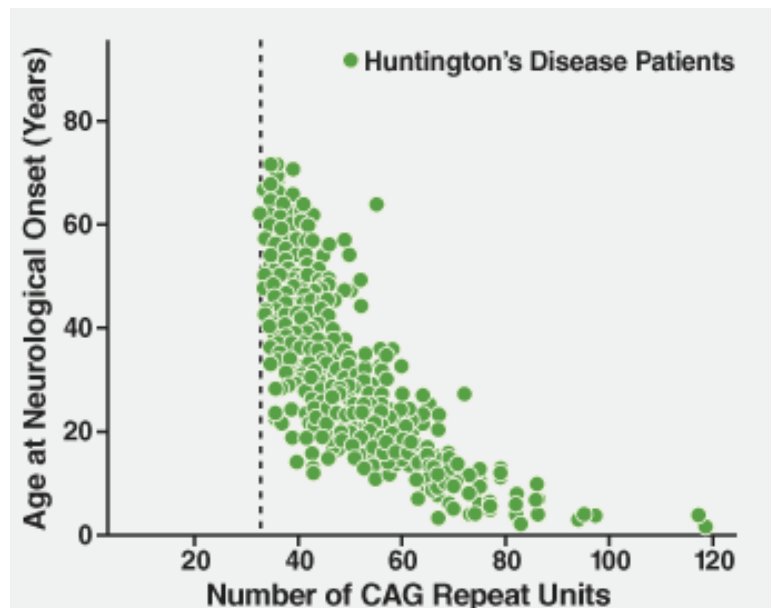
- The Huntington's disease gene (the huntingtin gene) contains a CAG repeat (CAG_n) sequence;
 - In normal individuals:
CAG_n of between 10 and 30
 - In Huntington patients (mutated):
CAG_n > 36
- The CAG_n score (the length of the diseased gene) correlates with onset of symptoms and disease progression:

The longer the CAG_n,
 - the faster the onset of symptoms and
 - the poorer the disease prognosis and symptoms progression

External references:

Aziz et al., "Normal and mutant HTT interact to affect clinical severity and progression in Huntington's disease"; *Neurology*, 2009; 73; 1280-1285

Ravina et al., "The Relationship Between CAG Repeat Length and Clinical Progression in Huntington's Disease"; *Movement Disorders*, vol. 23, No. 9, 2008, pp. 1223–1227



Source:
The Gladstone Institute of Neurological Disease



The MermaiHD study AE reporting

The MermaiHD study – Reported adverse events:

	Placebo (%)	Huntexil® 45 mg q.d. (%)	Huntexil® 45 mg b.i.d. (%)
Full analysis set, patients	144 (100%)	148 (100%)	145 (100%)
Any adverse event(s)	64%	61%	68%
Fall	6%	5%	9%
Dizziness	4%	7%	5%
Huntington's chorea	6%	5%	7%
Diarrhoea	3%	7%	6%
Nausea	6%	7%	3%
Nasopharyngitis	3%	5%	6%
Depression	6%	4%	4%
Fatigue	6%	5%	3%
Insomnia	3%	3%	6%



For more information, please visit www.neurosearch.com or write
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