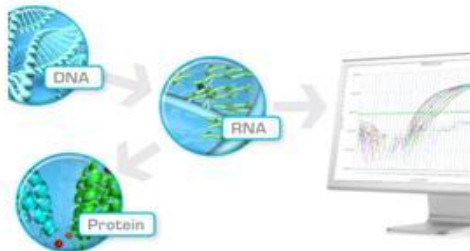


**2<sup>nd</sup> Quarter 2011**

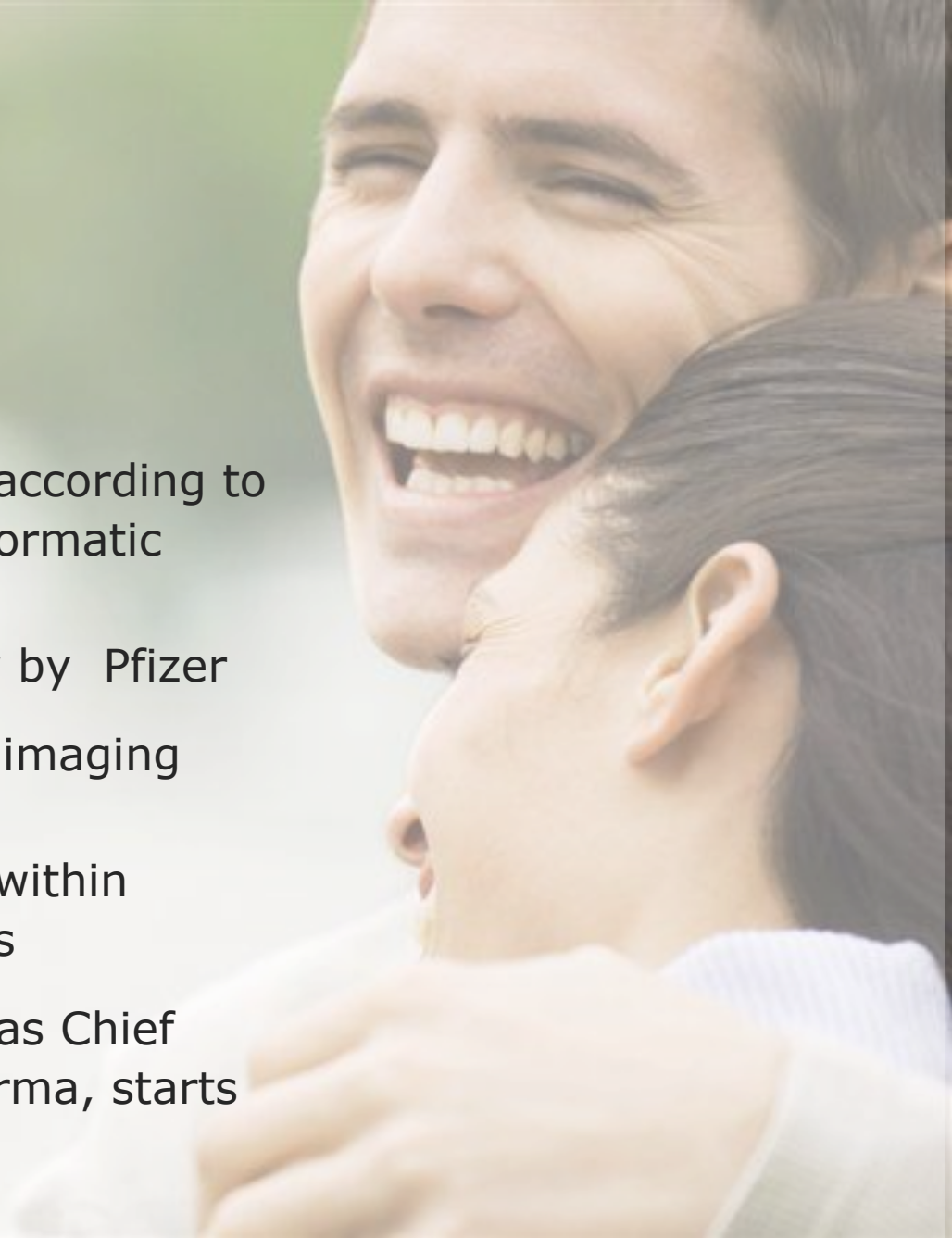
## **Important milestones achieved Read Out of the MCI study ongoing**

Erik Christensen MD PhD, CEO  
Ruben Ekbråten, Finance Director



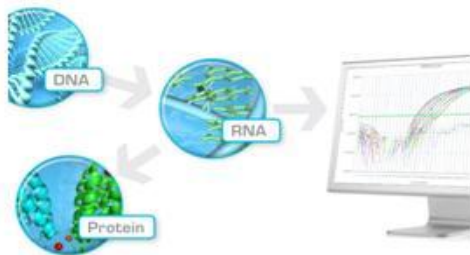
# 2nd Quarter 2011 Highlights

- ♦ Pfizer collaboration proceeds according to plan, all laboratory and bioinformatic analysis finalized
  - Study report under review by Pfizer
- ♦ Discussions with pharma and imaging companies advancing
  - Confirmation of strong IP within Alzheimers by third parties
- ♦ Dr Magnus Sjögren recruited as Chief Medical Officer from UCB Pharma, starts September 1<sup>st</sup>



# DiaGenic – Business Strategy

- The goal of the company is to take a leading position in the area of blood based diagnostics within selected CNS disease areas, through its ability to deliver precise, well-documented tools for early detection.
- This position will be achieved through pharmaceutical partnership, sale of commercial rights and co-development agreements with large pharmaceutical companies.



Blood based gene expression – the future in personalized and stratified medicine

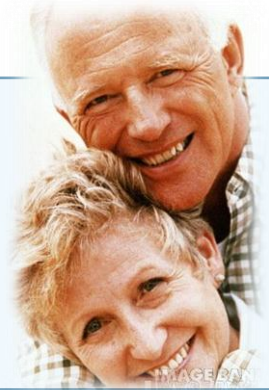
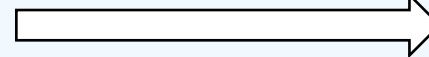
# DiaGenic CNS product line

## MDx

Stand alone IVD assay

ADtect®

Aids in early detection of AD



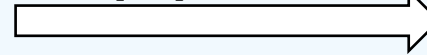
## Rx

Integrated biomarkers

Companion Diagnostics

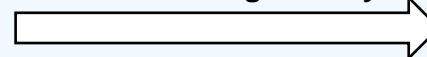
ADtect<sup>PLUS</sup>®

Tailor made biomarker with  
[18F] PET tracer



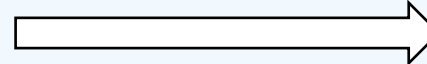
ADtect<sup>ULTRA</sup>®

Tailor made biomarker in  
CoDX for drug efficacy



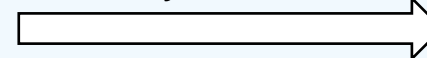
MCitect®

MCI to AD progression biomarker



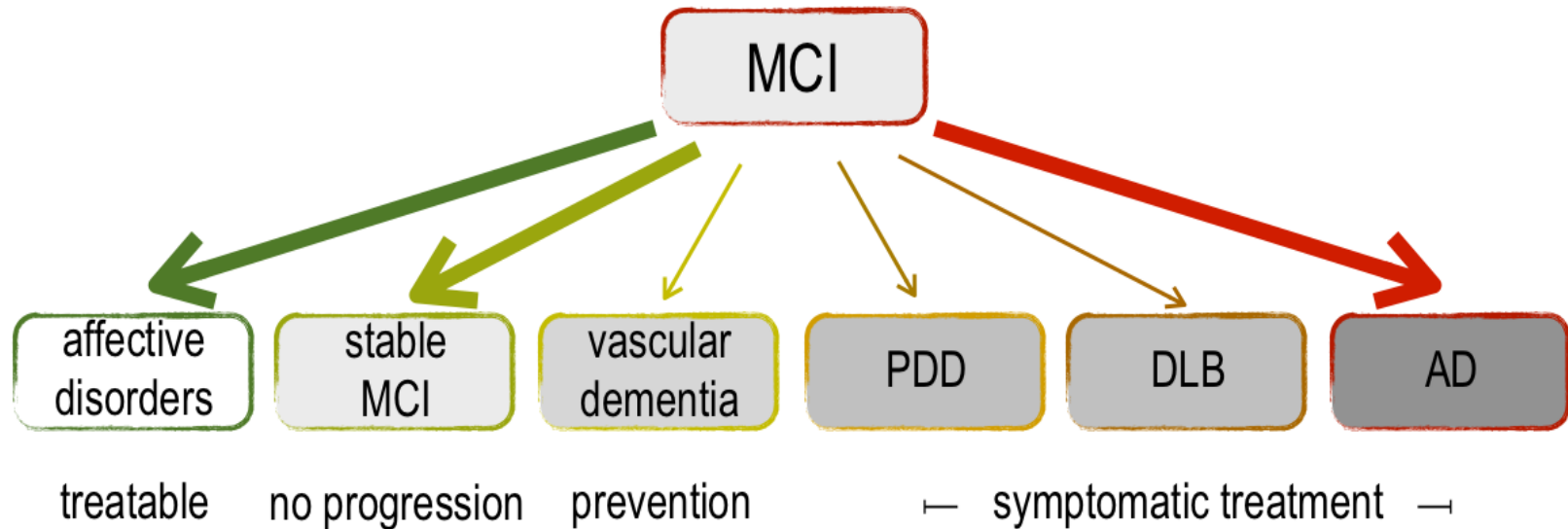
PDtect®

Aids in early detection of PD



# Mild Cognitive Impairment

## MCI – a heterogeneous syndrome



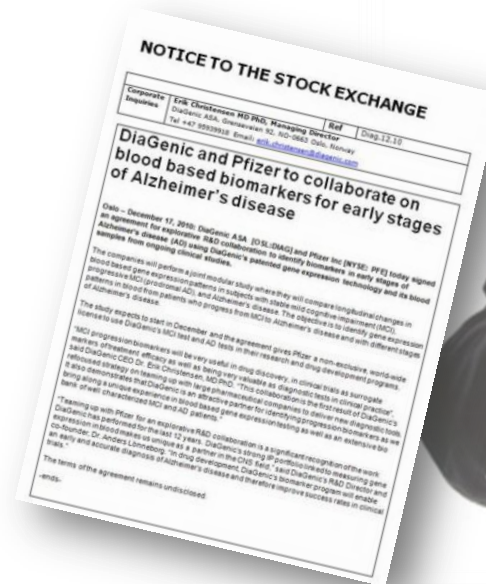
*"The earlier in the disease process that people at risk for developing Alzheimer's are identified, the sooner we can intervene. Earlier detection will be our best opportunity to prevent continuing damage to the brain, once more effective therapies are developed."*

William Thies, PhD,  
Chief Medical and Scientific Officer at the Alzheimer's Association



Product development in collaboration with partners  
**DiaGenic and Pfizer to collaborate on blood based biomarkers for early stages of Alzheimer's disease**

- 🔥 The objective is to identify gene expression patterns in blood from patients
  - who progress from MCI to Alzheimer's disease
  - with different stages of Alzheimer's disease
- 🔥 Compare longitudinal changes in subjects with
  - stable mild cognitive impairment (MCI),
  - progressive MCI (prodromal AD)
  - Alzheimer's disease.
- 🔥 DiaGenic's extended gene set from whole genome studies
- 🔥 DiaGenic's blood samples initially from our own clinical studies in the MCI space
- 🔥 Modular extension opportunity



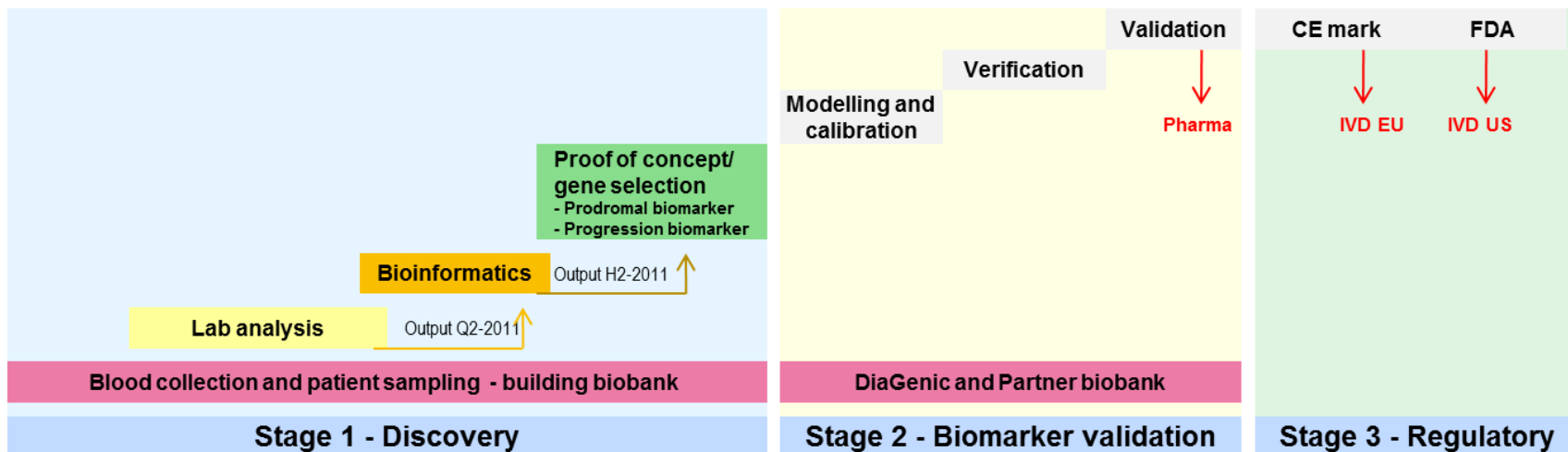
Milestones passed

## **DiaGenic and Pfizer project is advancing according to expected timelines**

- ◆ Sample collection of 120 samples from DiaGenic clinical studies
- ◆ Medical review of the clinical data by external review board
- ◆ Analytical validation of >1100 probes for the gene transcripts
- ◆ Laboratory analysis by DiaGenic of all clinical samples and reference/technical samples on the next generation IVD instrument
- ◆ Bioinformatic analysis of the PCR results on each gene transcript from every patient
  - > 200.000 individual PCR reactions and subsequent biological modeling
- ◆ We have completed all laboratory and bioinformatic analysis as described in the project
- ◆ Comprehensive report currently under review by Pfizer
- ◆ **Communication of the study results in the coming months is thus expected!**
  - ◆ Following contractual obligations between the parties

Milestones passed

## The DiaGenic and Pfizer project creates opportunities



- We have continued promoting our capabilities, core assets and diagnostic tests to multiple large pharma companies who are engaged in the AD field.
- The results from the Pfizer MCI study are key to elevate our commercial discussions beyond R&D collaborations.
- Positive R&D findings from the non-exclusive Pfizer collaboration will enable new momentum to the Pfizer collaboration as well as adding important weight to securing additional revenue generating pharma collaboration with identified partners.



## Companion diagnostic value proposition

### **DiaGenic develops key solutions for Amyloid PET producers**

#### **High end imaging diagnostics (PET)**



#### **Characteristics**

- ♦ PET imaging diagnostics are the most accurate diagnostic tool for Alzheimer Disease
- ♦ Expensive equipment and procedures

#### **Challenges**

- ♦ High cost per patient
- ♦ Capacity constraints – limited no of scanners available due to cost
- ♦ Lack of objective selection criteria for reimbursements

**DiAGENiC**

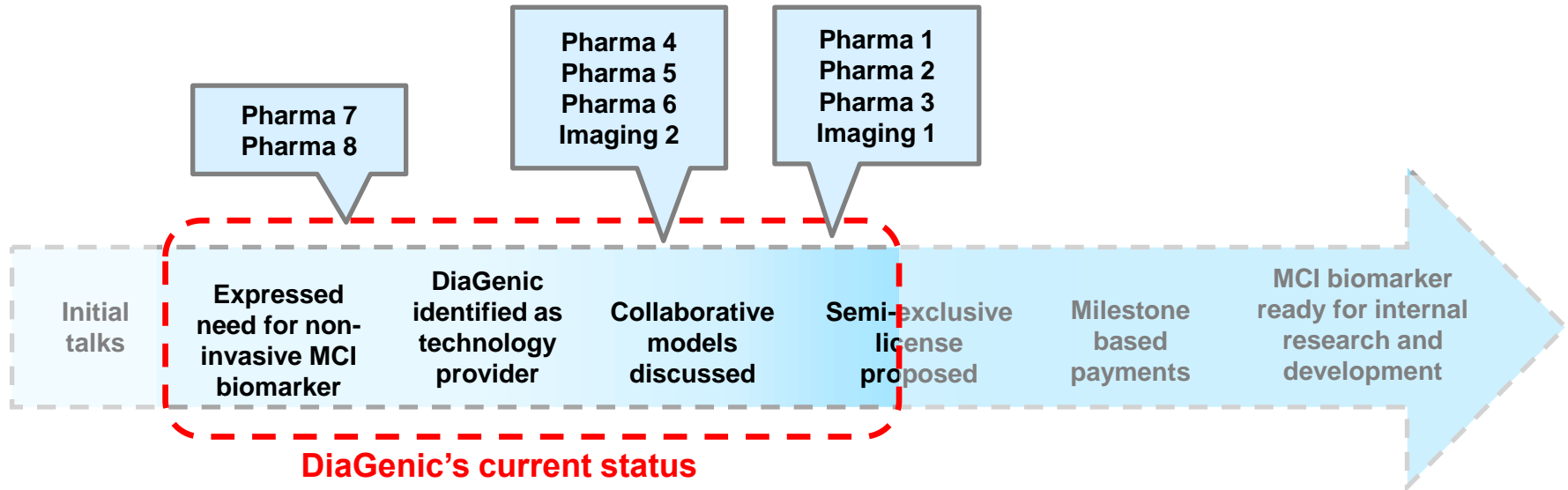
#### **Value proposition**

- ♦ Blood-based diagnostics as a tool for pre-selecting patients for PET
- ♦ Increases hit-rates
- ♦ Reduces capacity constraints
- ♦ Validates reimbursement

- ♦ Advancing dialogues with producers of amyloid PET tracers on R&D collaborations
  - Joint development of study protocols, clinical site reviews and funding scenarios.
  - These dialogues also address a potential use of blood based biomarkers together with high cost PET imaging as part of a multimodal approach of future AD management.

Funneling pharma and imaging customers for negotiations on MCI licenses and strategic collaborations

## Driving collaborative agreements forward



- ◆ Collaborative partner deals yielding R&D service fees, licensing and milestone payments, and ultimately product revenue from companion diagnostics
- ◆ Pharma validation to drive stand-alone MDx revenue
- ◆ Multiple interactions with pharma and imaging companies advancing according to plan
  - ◆ First R&D deal signed with Pfizer
- ◆ Ferghana Partners group acts as advisors on potential commercial transactions

Chief Medical Officer

## **Dr Magnus Sjögren**

- ♦ DiaGenic organization has adjusted to the new strategy and strengthened its capabilities by recruiting Magnus Sjögren MD PhD as Chief Medical Officer.
  - Magnus has an extensive background within the neuroscience area from both pharmaceutical companies and academia. He was most recent Vice President Global Exploratory Development at UCB Pharma, and has held Senior Director positions in Schering Plough and Organon and director (neuroscience disease area expert) at AstraZeneca.
  - Magnus is also an Affiliated Lecturer/Professor at Karolinska Institutet. His academic research has included studies on biomarkers in neurological diseases and he is a specialist in neurology and psychiatry (PhD 1999).



# ADtect<sup>®</sup>

early detection of

Alzheimer's disease



# Started promoting ADtect®, a stepwise market approach

## Ferrer Spain

- Training of a team of sales reps focusing on ADtect®
  - Covering all major cities in Spain
  - Next phase of the product launch will include their 80 person strong CNS sales force
- Established dedicated scientific advisory board of internationally recognized KOL's
- Product documentation in Spanish developed, including Spanish collection kit
- Established sample collection centers throughout Spain
  - Teamed up with a Spanish laboratory chain
- Marketing of ADtect® in key national journals
- Focus on private sector, already signed agreement with leading hospitals
- Initial feedback from clinicians are positive
  - Still early days



# Ongoing technological and clinical studies

## 💧 Improving **accuracy**

- Optimization of ADtect® gene and assay set
  - For current intended use
  - For other indications like prodromal AD/MCI



## 💧 Improving **robustness**

- Participating in EU funded study aiming to standardize the pre-analytical phase of IVD (SPIDIA)



## 💧 Improving **logistics**

- Shipping study to simplify process and reduce costs of sample shipment, collaboration with Becton Dickinson

## 💧 Improving **market access**

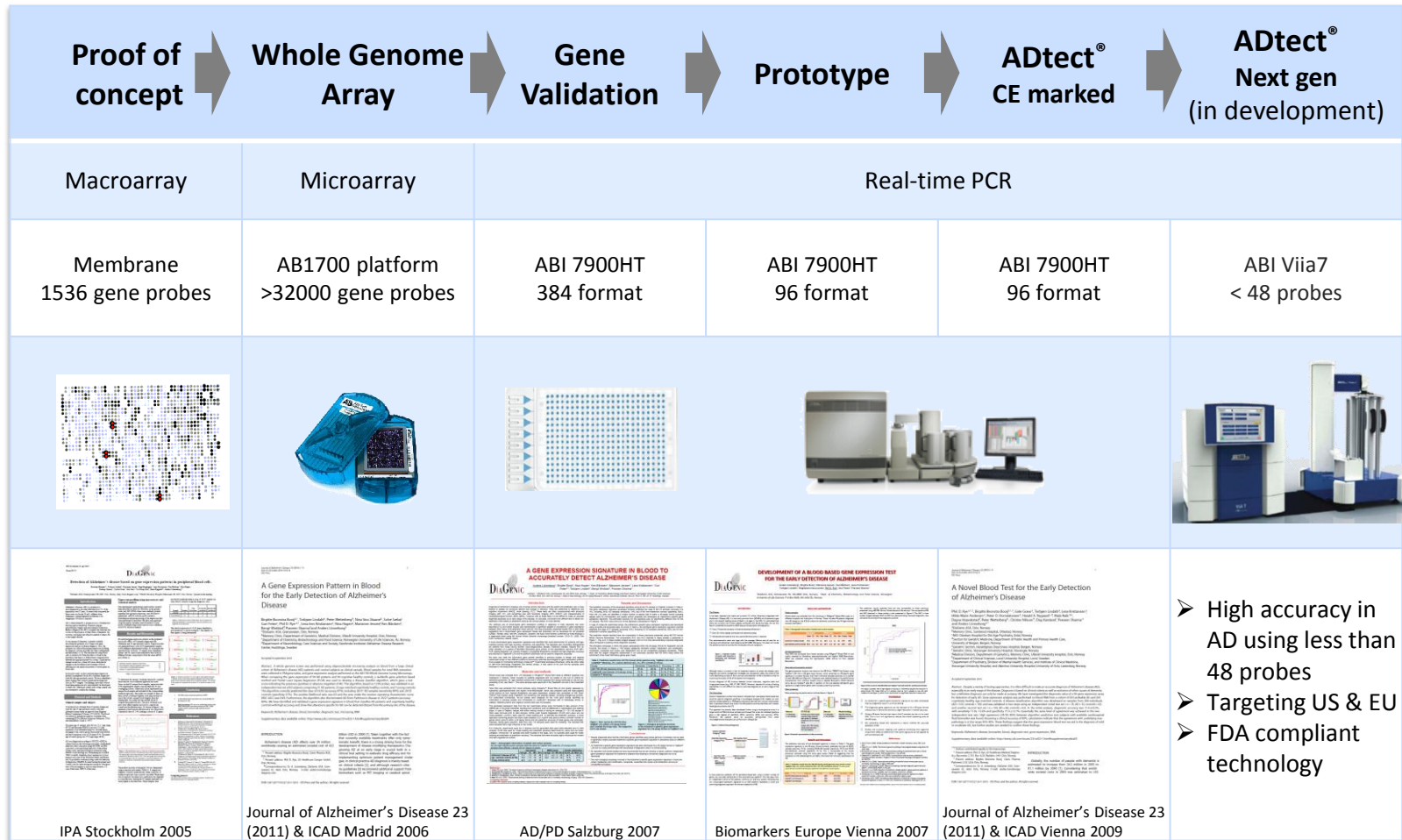
- Transfer to new instrument platform CE marked for IVD use (ViiA7)
  - Targeting US & EU
  - FDA compliant technology
  - High accuracy in various AD stages using less than 48 probes





# Development of ADtect®

## A multitude of studies successfully performed



- High accuracy in AD using less than 48 probes
- Targeting US & EU
- FDA compliant technology

# PDtect<sup>®</sup>

in development

for early

Parkinson's disease detection

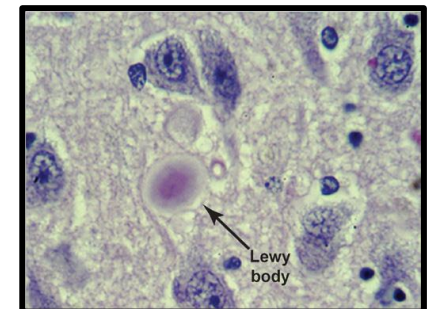
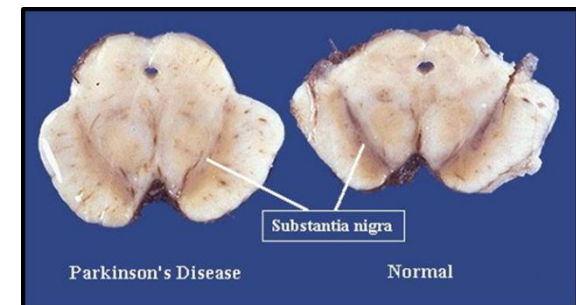


4-6 million PD patients world wide

# Unmet medical need for PD biomarkers

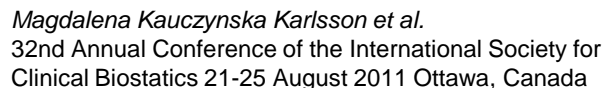


- Degeneration of dopaminergic neurons have started years before symptoms become apparent
- No disease modifying drugs available, only symptomatic
  - 28 ongoing clinical trials for new drugs
- Today's conventional diagnostic work up:
  - Commonly misdiagnosed in a community setting (53%\*)
  - By GPs and then by Neurologists
    - Clinical exam
    - Imaging
      - CT and MRI to rule out other conditions
      - DaTSCAN detects loss of functional dopaminergic neurons
    - Lewy bodies in autopsy is considered the gold standard for diagnosing PD
- Need for blood based biomarkers
  - Pharma use
    - Aid in early diagnosis, patient stratification into clinical trials
    - Measure disease progression
  - Clinical use
    - Clinical diagnosis in early disease stages



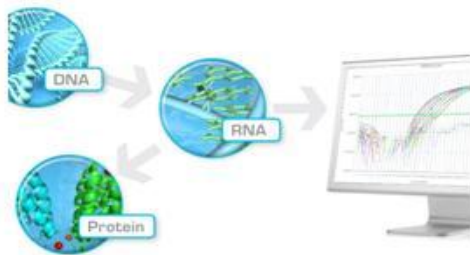
\*) Meara, J., B. K. et al. (1999). Accuracy of diagnosis in patients with presumed Parkinson's disease. *Age Ageing* 28(2): 99-102.

**PDtect® identifies Parkinson patients with high accuracy**



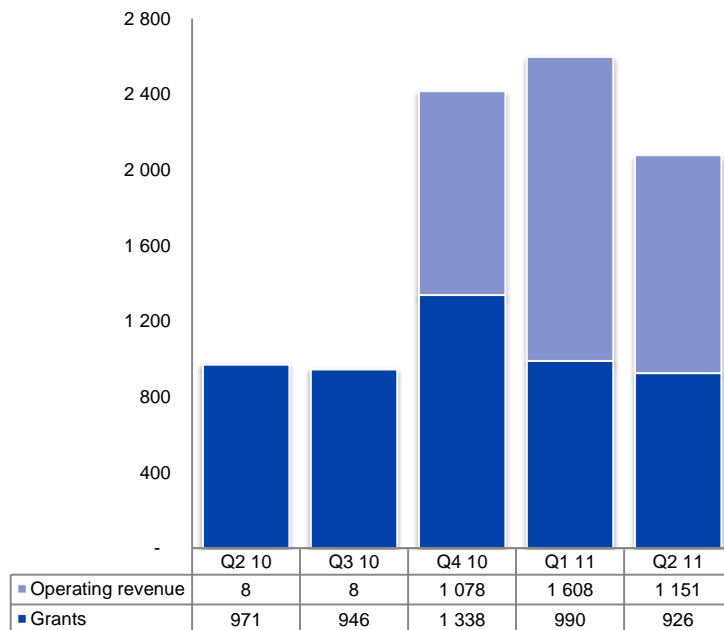
- for early disease detection **DiAGENiC**

# 2<sup>nd</sup> quarter 2011 financials



# Finance, Income

**Income**  
(thousand NOK)



- Operating revenue in Q2: mainly recognition of milestone revenue from R&D collaboration with pharma
- NOK 1 million recognised as milestone revenue in Q2
- Research grants in Q2 totalled NOK 0.9 million



# Finance, Profit & Loss

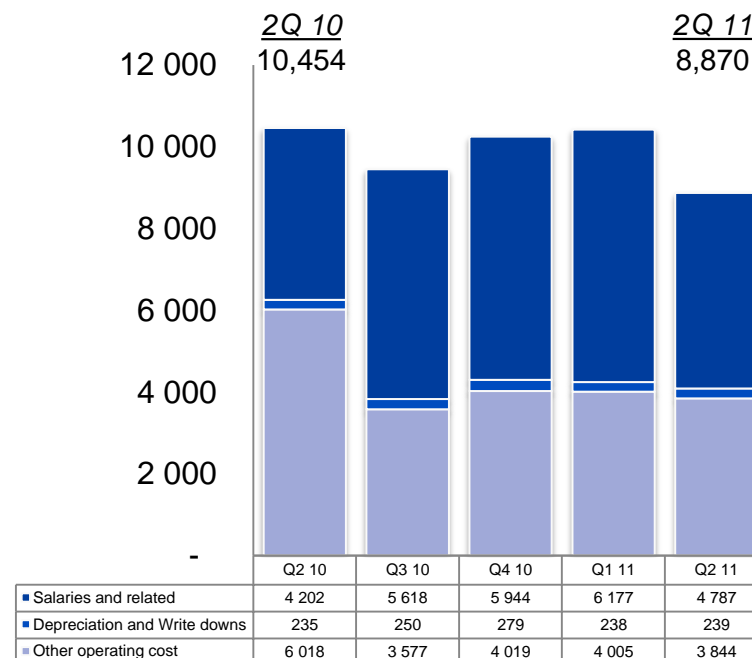
## P&L 2Q

(thousand  
NOK)

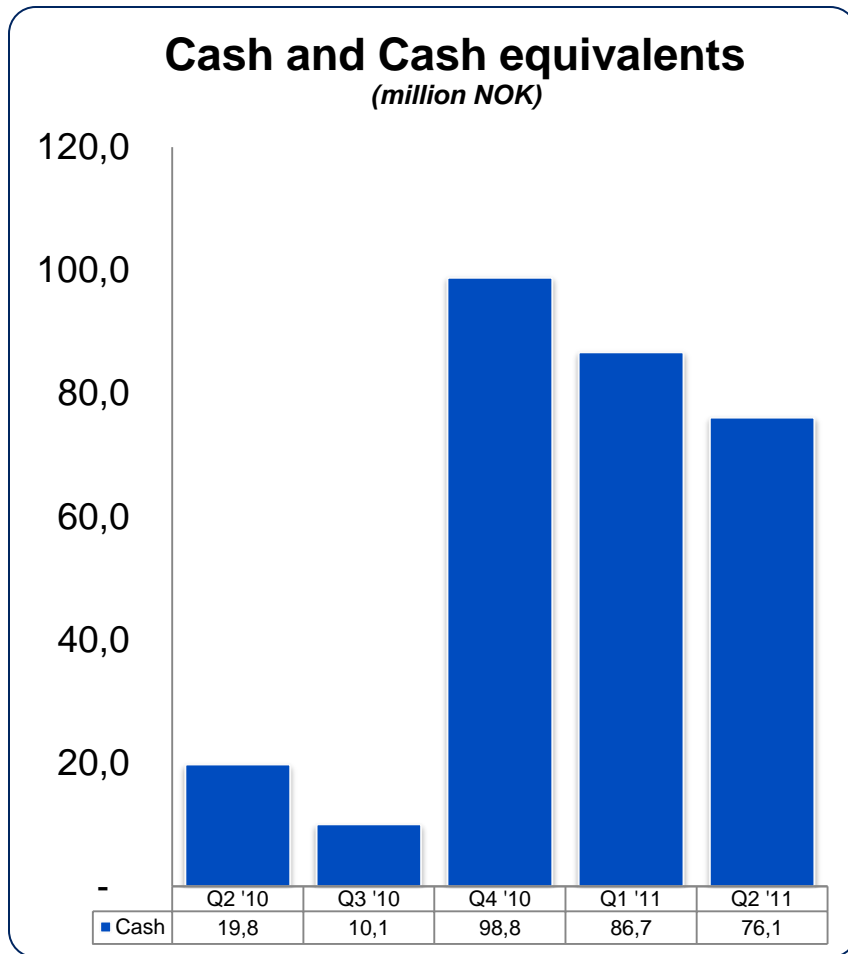
	2Q '10	2Q '11
Revenue	8	1,151
COGS	71	951
Other Operating Cost	10,454	8,870
Operating loss	(10,518)	(8,670)
Net finance	(16)	603
Net income	(10,534)	(8,067)

## Other Operating Cost

(thousand NOK)



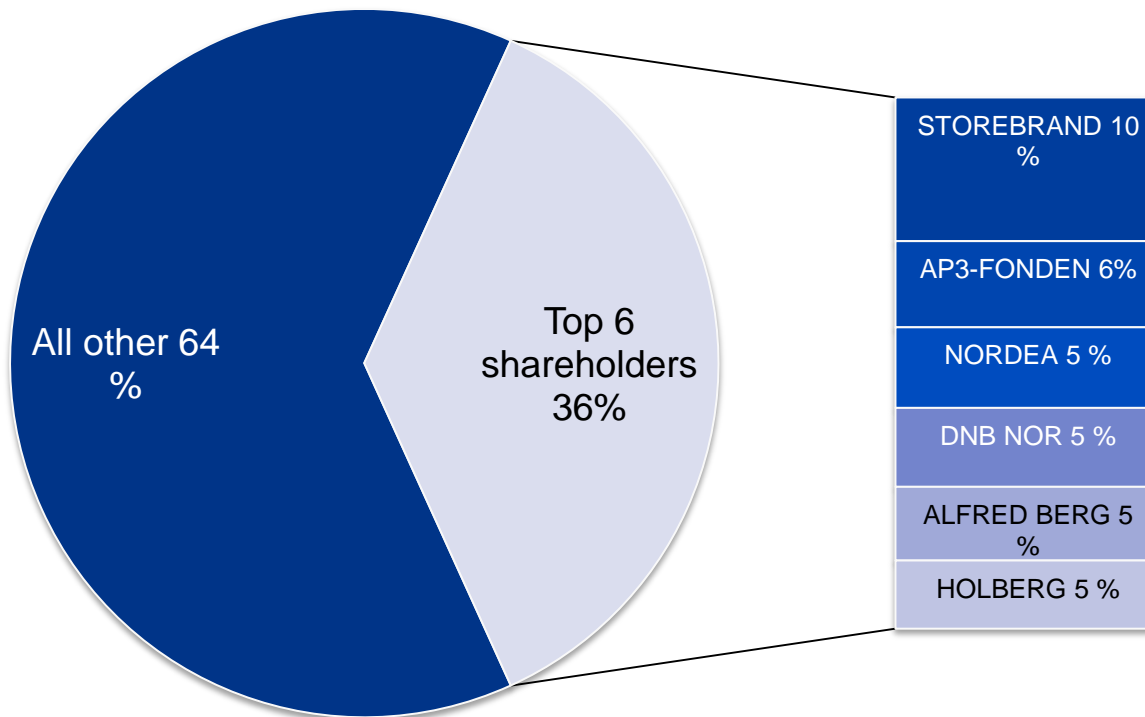
# Finance, Cash position



- Long term financing secured in Q4 2010
- Cash balance end of June 2011: NOK 76 million

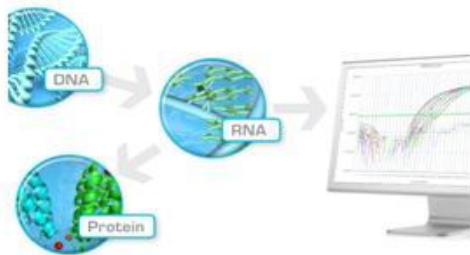
# Finance, Shareholders and the share

## Shareholder composition



- Largest shareholders:
  - Top 6 shareholders control 36 % of share capital/ voting rights.
- Reverse share split in the ratio 10:1 effective from 30 May:
  - Total number of shares post share consolidation: 27,023,652 shares
  - Face value per share increased from NOK 0.05 to 0.50 after reverse share split.

# Outlook & Summary



## 2nd Quarter 2011 Outlook

- ♦ Successfully leverage on and expand the Pfizer collaboration further
- ♦ Communicate the results from the Pfizer study in the coming months
- ♦ Execute on the companion diagnostics initiative, closing R&D and licensing agreements with pharmaceutical and imaging companies operating in the CNS field

# Your preferred partner for gene expression profiling in blood

## Core competence and assets:

- 🔥 Delivers unique biomarkers in a well defined market characterized by a large unmet medical need
- 🔥 World's first company with approved blood based test in AD diagnosis
- 🔥 Strong IP protection within blood based AD diagnosing and monitoring. Broad claims protects against infringement.
- 🔥 Competence and experience in all aspects of product development from discovery to regulatory
  - Strong knowhow on technologies and platforms
  - Strong competence in bioinformatics
  - R&D collaboration with reputable university hospitals in US and Europe
    - World Class Biobank
  - CE marked products that are commercially available in Europe
- 🔥 Good track record on receiving public grants
- 🔥 Overall aim is to provide Companion Diagnostics tools for pharma and imaging companies



# DiaGENic

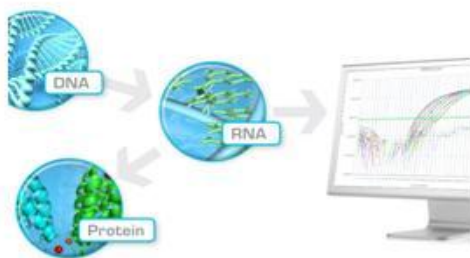
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