

1<sup>st</sup> Quarter 2013

**Private placement completed**

**Full focus on Alzheimer's disease product portfolio development**

Paul de Potocki, CEO

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# Agenda

- Highlights
- Product development
- Financial results
- Outlook

# Highlights

- ♦ Product development of MCItect® and new ADtect® are progressing. Both products are undergoing technical verification studies and calibration trials. Confirmatory validation studies will be initiated during the spring, allowing CE markings in Q3 2013 pending successful validation
- ♦ Patient recruitment for the collaborative clinical study for AMYtect™ with GE Healthcare and Lund's University is progressing as planned. An interim analysis is planned for the summer and results are expected in Q3 this year
- ♦ DiaGenic's study on the 'Prediction of MCI due to AD in an amnesic MCI population' was accepted for publication in the Journal of Alzheimer's Disease
- ♦ DiaGenic signed an agreement with a major U.S. university providing access to additional U.S. patient samples and clinical data to strengthen the validation of MCItect®

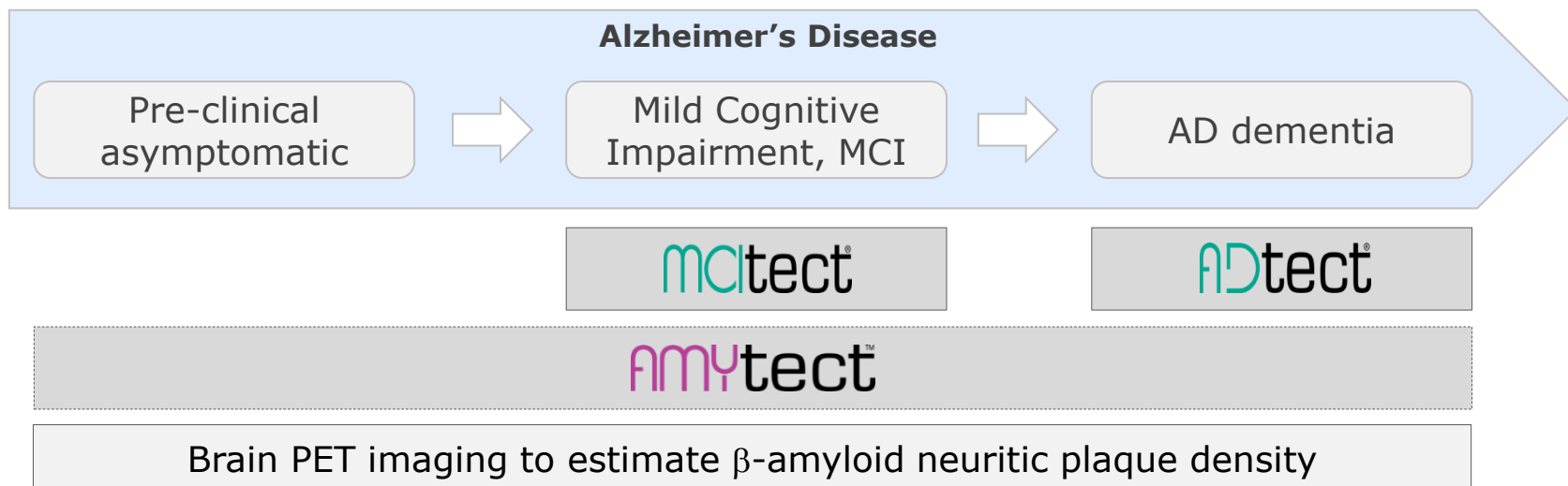
## Highlights cont.

- ♦ Q1 2013 pre-tax earnings were NOK -9.7 million compared with NOK -9.0 million in Q1 2012, in line with estimates
- ♦ On March 7<sup>th</sup> DiaGenic raised NOK 30 million in gross proceeds through a private placement. Registration of the private placement took place after the end of the quarter and the cash balance at the end of March was NOK 9.5 million
- ♦ On 2 April an Extraordinary General Meeting resolved the private placement and a subsequent “repair” offering for the shareholders that did not participate in the private placement. Results of the subsequent offering was NOK 2.8 million in gross proceeds

# Agenda

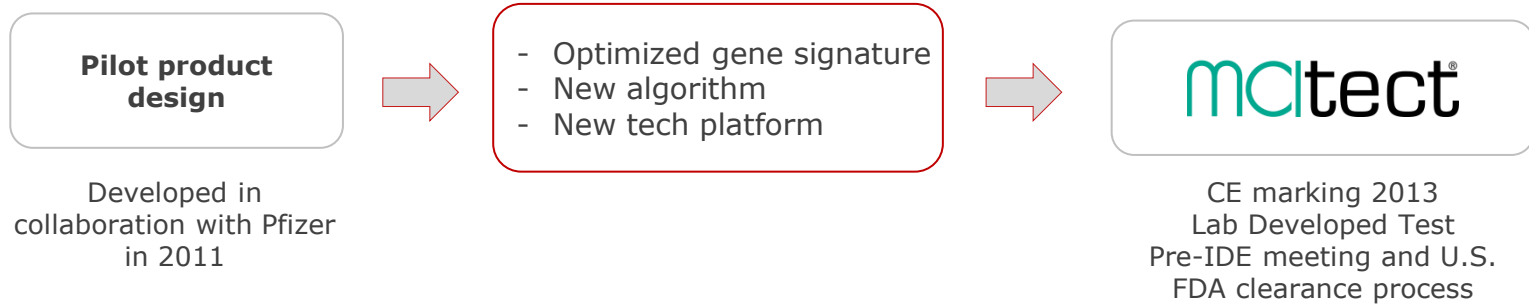
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# Stages of AD and products in development



- ♦ Aid in objective, patient friendly and cost effective diagnosis across Alzheimer's disease progression
- ♦ Respond to the Pharma industry's need to identify patients eligible for treatment with drugs targeting early stage AD
- ♦ Select the appropriate patients for brain amyloid PET imaging

# MCItect® development progress and plans



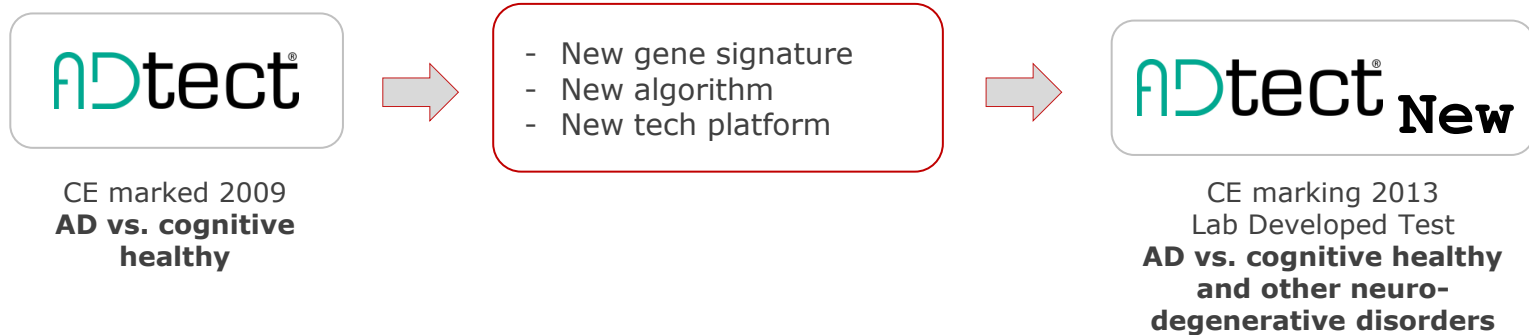
- ♦ To aid in the diagnostic work-up of Mild Cognitive Impairment especially in the identification of individuals who are at risk of developing Alzheimer's disease dementia within two years
- ♦ Technical verification and calibration studies completed. Final validation study in preparation
- ♦ CE marking planned for Q3
- ♦ Pre-submission meeting with the FDA planned



# DiaGenic publication

- “Prediction of Mild Cognitive Impairment that Evolves into Alzheimer’s Disease Dementia within Two Years using a Gene Expression Signature in Blood”
- Recently published in the Journal of Alzheimer’s Disease

# ADtect® development progress and plans



- Ability to differentiate between AD and neurodegenerative disorders implies significantly improved clinical utility
- Current data indicates improved test accuracy
- Technical verification and calibration studies near completion. Final validation study in preparation
- CE marking planned for in Q3

# AMYtect™ development progress and plans

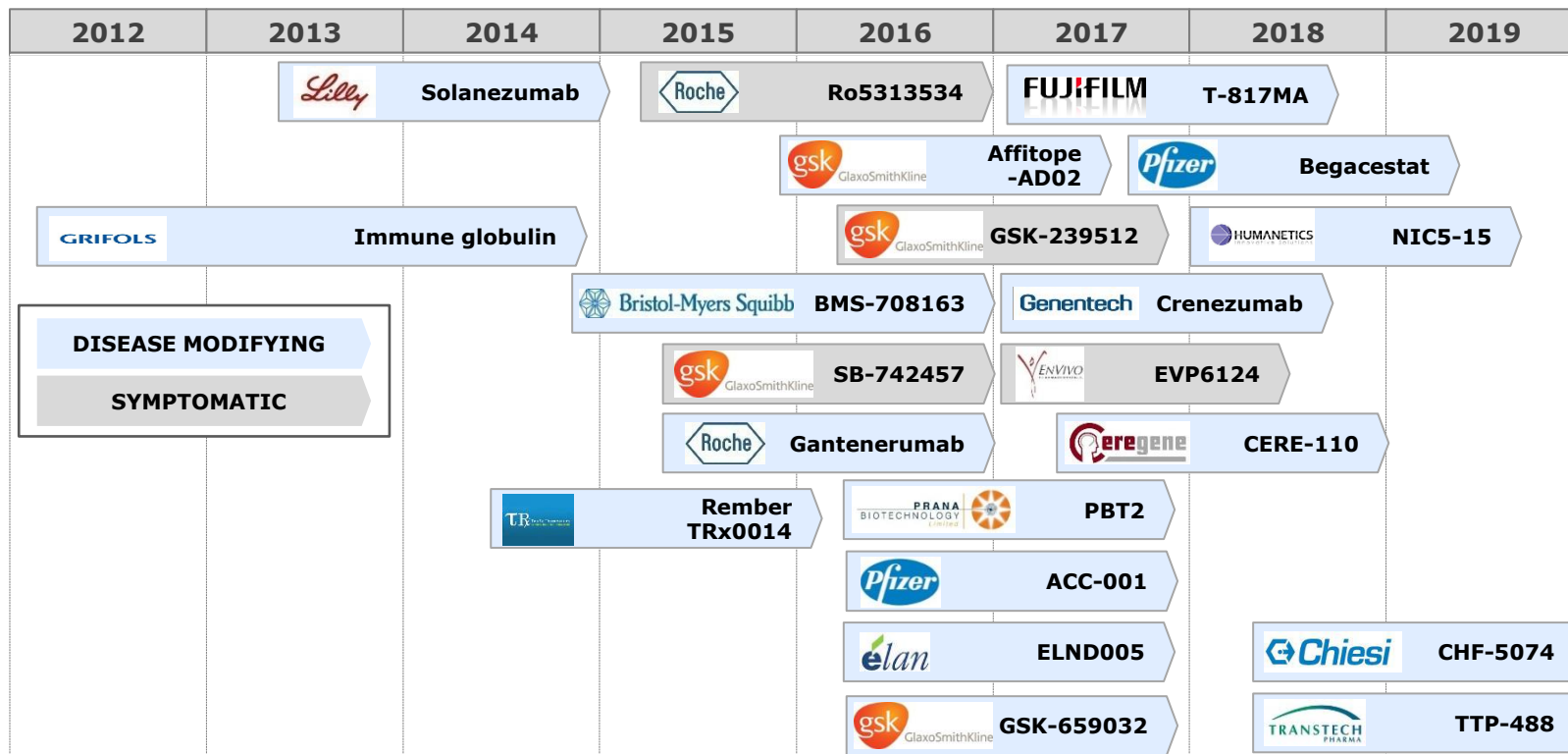
- ♦ An IVD blood test to identify patients with brain amyloid that correlates with brain amyloid PET imaging
- ♦ Developed under a collaborative research and option agreement with GE Healthcare
- ♦ Planned 150 patients, more than half had been scanned at end of quarter
- ♦ Interim analysis during summer, study read-out expected in Q3 2013
- ♦ Ambition to complete product development in industrial partnership

# Third party collaborations providing unique access to patient data supporting product development

- Study on going with Lund University
- Collaboration since 2011 with UC Davis, US
- Collaborative agreement with Harvard Medical school
- Agreement with AP-HP and Baltazar in France, a major multi-centre prospective study on MCI
- Agreement recently signed with major American university

# Significant drug development investments

Illustrative overview of AD drug pipeline



- The Alzheimer's disease drug market was worth \$5.8bn in 2011, forecasted to grow to \$14.5bn - 20bn by 2020<sup>1</sup>
- New and expensive drug therapies expected to increase need and value of early diagnostics

<sup>1</sup> Deutsche Bank, May 2012.

Source: DataMonitor, [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.alzforum.org](http://www.alzforum.org) and company estimates.

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# Finance, Profit & Loss

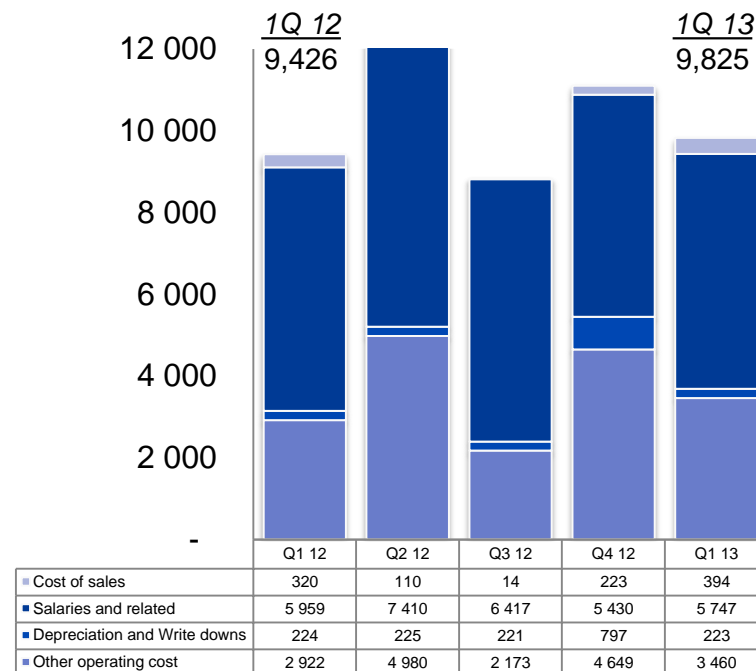
## P&L 1Q

(thousand NOK)

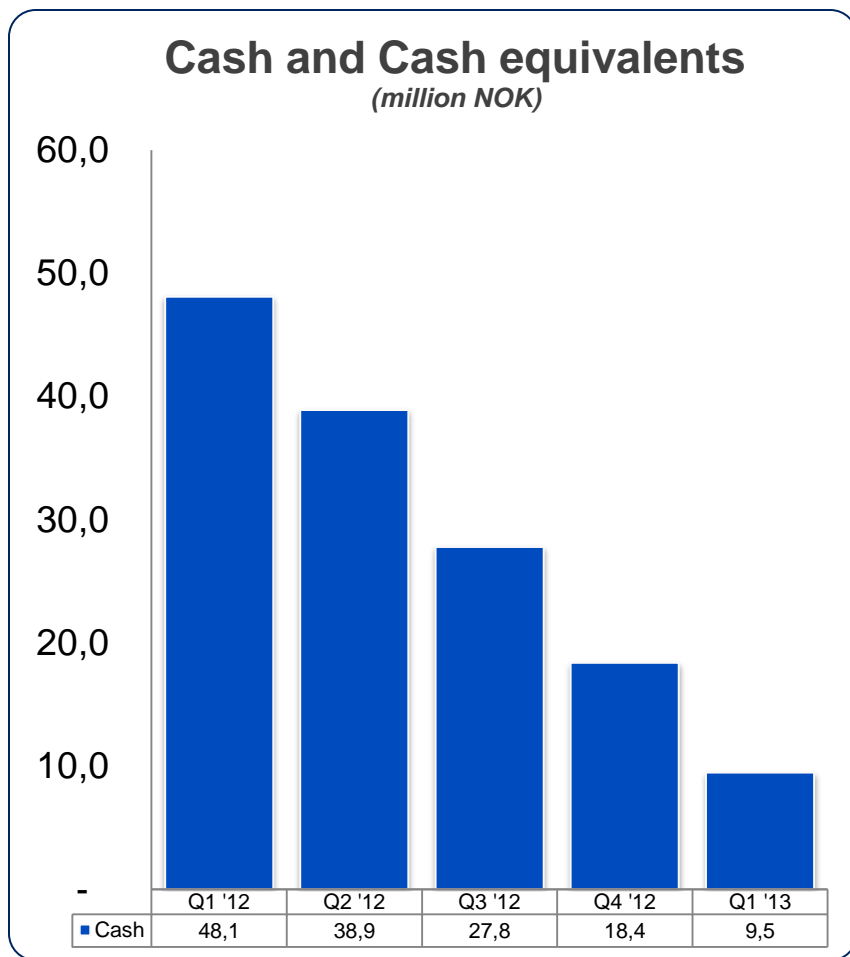
	1Q '13	1Q '12
Revenue	69	23
Grants	325	785
Operating Cost net of Grants	9,825	9,426
Operating loss	(9,755)	(9,403)
Net finance	54	423
Net income	(9,701)	(8,980)

## Operating Cost

(thousand NOK)



# Finance, Cash position

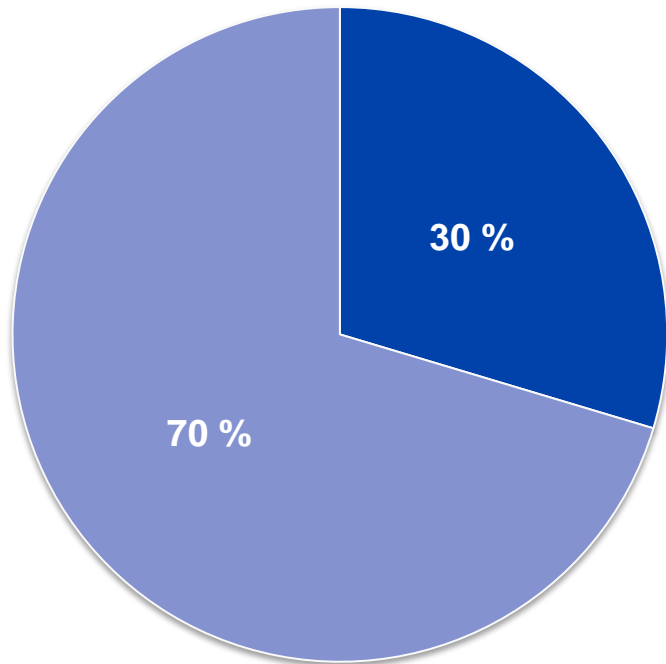


- NOK 9.5 million in cash at end of March 2013
- NOK 32.8 million in gross proceeds from share issues as resolved by the Extraordinary General Meeting on 2 April 2013
- According to estimate the Company's working capital is funded to April 2014



# Finance, Share issue

**Shareholder participation in share issue**



■ New shareholders ■ Existing shareholders

- Share issues of NOK 32.8 million resolved by the Extraordinary General Meeting on 2 April 2013:
  - Private placement of NOK 30 million and subsequent repair issue of NOK 2.8 million
  - Subscription price NOK 0.60 per share
  - A total of 54,575,078 new shares were issued, bringing the total number of shares in DiaGenic up to 81,598,730

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# Outlook and Deliverables

- Achieve CE marking of MCItect® and new ADtect®
- Conclude ongoing clinical study for AMYtect™
- Conduct pre-submission meeting with the FDA
- Evaluate strategic options for final product development and commercialization, including strategic collaborations and asset or trade sale
- Establish additional R&D collaborations with Pharma

# Thank you!

- Q&A

## Financial calendar 2013:

- **23 May at 10 CET - DiaGenic Annual General Meeting 2013**  
(Please see [www.diagenic.com](http://www.diagenic.com) for notice and participation and proxy forms)
- 23 August - Second quarter 2013 results presentation
- 31 October – Third quarter 2013 results presentation

# DiaGENic

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