Driving pharma collaborations and innovation forward

Erik Christensen MD PhD, CEO
Ruben Ekbråten, Finance Director
1st Quarter 2011

Highlights

- Collaboration with Pfizer on developing MCI and AD progression biomarkers proceeds according to the study plan
- Collaborative discussions with multiple leading pharmaceutical and imaging companies on using blood based early AD diagnostics progress satisfactorily
- Appointed the Ferghana Partners Group for support on commercial transactions with pharmaceutical and diagnostic partners
Commercial strategies and products
The value chain
DiaGenic key competencies and assets

DiaGenic has the experience on taking a product from discovery to market
DiaGenic CNS product line

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

MDx
Stand alone IVD assay

ADtect®
Aids in early detection of AD

PDtect®
Aids in early detection of PD

Rx
Integrated biomarkers

ADtect®
Tailor made biomarker with [18F] PET tracer

ADtect®
Tailor made biomarker in CoDX for drug efficacy

MCI tect
MCI to AD progression biomarker

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DiaGenic value proposition

**MDx**
DiaGenic’s blood based biomarkers gives patients broader access to patient friendly diagnostic tools which improves diagnostic quality and ensure optimal treatment.

**Rx**
DiaGenic’s blood based biomarkers and expertise will help the pharmaceutical industry achieve the ambitions of cost-effective and efficacious drug development.
PDtect®

in development

for early Parkinson’s disease detection
Parkinson’s disease

Large unmet medical needs

- Parkinson’s disease affects 5 million patients worldwide
  - Estimated to increase to 9 million in 2030

- No disease modifying drugs available, only symptomatic
  - Since 1966, L-dopa has been the standard treatment to alleviate the symptoms of Parkinson's disease
  - Symptomatic treatment costs $25 billion per year

- No standardized diagnostic work up
  - Commonly misdiagnosed in a community setting (53%*)
  - DaTSCAN radiopharmaceutical agent intended for use with single photon emission computed tomography (SPECT) imaging

- Expanding market
  - 28 ongoing clinical trials for new drugs

- Need for blood based biomarkers
  - Aid in early diagnosis
  - Guide treatment
  - Measure disease progression

DiaGenic PD development program

**Ongoing multicentre study in Europe**

- **Objective:**
  - Develop a Dopamin independent biomarker for early detection of Parkinson’s disease for use in clinical trials and as a diagnostic tool
  - Timeline; a fully validated prototype by mid-2012

- **Whole genome screening completed**
  - 79 PD patients and 105 controls and technical samples has been analyzed by whole genome screening (47,000 probes) to identify disease related probes
  - The preliminary bioinformatic studies support that an accurate diagnostic test can be developed using our technology

- **Technology transfer to a diagnostic analytical platform (e.g. PCR) is planned for in 2nd half of 2011**

- **Funded by external sources**
  - Initial funded through Michael J Fox research grant in co-operation with Harvard Medical School
  - Diagnostic test program
    - Funded by the Norwegian Research Council’s BIA grant, NOK 6 million over 4 years
early detection of Alzheimer’s disease
Alzheimer’s Disease
– A Global Epidemic with a Growing Business Potential

- Affects 34 million worldwide
  - More than 100 million with AD in 2050
  - Worldwide dementia costs 2010: $604 billion
  - Only 50% of AD patients are diagnosed
  - 80% of AD patients receive medication now
    - Aricept (Pfizer) >2 billion dollar revenue

- The market is set to expand as new Alzheimer treatments is expected to reach the market in 2011-2012
  - Approximately 90 experimental therapies in clinical testing
  - Delayed onset and slowed progression is estimated to reduce AD Medicare spending with $88 billions in 2020 (Lewin Group report)

- PET imaging – a multi-billion dollar market
  - Ongoing development of new radioactive imaging biomarkers; key players are GE, Bayer, Siemens and Avid

Sources:
Alzheimer’s Association: 2010 Alzheimer’s Disease Facts and Figures
Development of ADtect®
A multitude of studies successfully performed

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<th>Proof of concept</th>
<th>Whole Genome Array</th>
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<th>Prototype</th>
<th>ADtect® CE marked</th>
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Key publications in the Quarter

**A Gene Expression Pattern in Blood for the Early Detection of Alzheimer’s Disease**

Birgitte Boesnstra Bosisj1,2, Torbjørn Lindahl3, Peter Wetterberg4, Nina Voss Skaane5, Solve Sarbe6, Guri Feiser7, Phil D. Rye7,8, Lena Iren Kristiansen9, Nina Hagen9, Marianne Jensen9, Ken Bárdseth9, Bengt Winblad10, Praveen Sharma11 and Anders Lönneborg12,13

1Diagnostic ASA, Gremene, Oslo, Norway
2Memory Clinic, Ullevål University Hospital, Oslo, Norway
3National Institute of Public Health, Oslo, Norway
4Department of Chemistry, Biotechnology and Food Science, Norwegian University of Life Sciences, Ås, Norway
5Department of Neurology, University of Oslo, Oslo, Norway
6Department of Geriatrics, Medical Division, Ullevål University Hospital, Oslo, Norway
7Department of Neurology, Care Sciences and Society, Karolinska Institute, Stockholm, Sweden
8Department of Neurology, University of Oslo, Oslo, Norway
9Department of Geriatric Medicine, Section for Geriatric Medicine, University of Bergen, Bergen, Norway
10Department of Geriatric Medicine, School of Nursing, University of Bergen, Bergen, Norway
11Department of Clinical Sciences, Lund University Hospital, Lund, Sweden
12Department of Psychiatry, Division of Mental Health Services, and Institute of Clinical Medicine, Skåne University Hospital, and Malmö University Hospital, University of Oslo, Lunnestad, Norway

Accepted 16 September 2010

**A Novel Blood Test for the Early Detection of Alzheimer’s Disease**

Phil. D. Rye1,2,3, Birgitte Boesnstra Bosisj4,5, Cilde Grave6, Torbjørn Lindahl7, Lena Kristiansen8, Hilde Marie Andersen9, Peter O. Bondalavicius10, Hans G. Nygaard11, Håkon Eide1,2, and Praveen Sharma11

1Department of Geriatric Medicine, Section for Geriatric Medicine, University of Bergen, Bergen, Norway
2Telemark Hospital, Telemark, Norway
3Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
4Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
5Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
6Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
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8Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
9Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
10Section for Geriatric Medicine, Department of Public Health and Primary Health Care, University of Bergen, Bergen, Norway
11Department of Clinical Sciences, Lund University Hospital, Lund, Sweden
12Department of Psychiatry, Division of Mental Health Services, and Institute of Clinical Medicine, Skåne University Hospital, and Malmö University Hospital, University of Oslo, Lunnestad, Norway

Accepted 16 September 2010

Alzheimer’s disease is a neurodegenerative disorder affecting an estimated 30 million people worldwide. The diagnosis of Alzheimer’s is often delayed, and there is currently no cure for the disease. Early detection of Alzheimer’s disease is crucial for effective intervention and management. A novel blood test for the early detection of Alzheimer’s disease has been developed and validated in a series of studies. The test is based on the analysis of gene expression patterns in blood samples, and it has shown promise in detecting Alzheimer’s disease at an early stage.

**Keywords:** Alzheimer’s disease, biomarker, blood, diagnostic test, gene expression, RNA
The ADtect® test includes at least 44 genes that encode proteins closely connected to known AD biology.

- Four of them (GRB2, TARDBP, TCF12, TNF) are in the AlzGene list.
- Several are also associated with oxidative stress, mitochondrial function, inflammation, calcium regulation, neuronal or brain function.

The systemic response of AD detected in peripheral blood contains information connected to known biology of the disease.
Providing CNS biomarkers for Clinical trials and prescription drug use

Creating one–to–one relationships
There is an increasing demand for new and innovated therapies by both patients and payers.

CNS clinical trials are confounded with a heterogenic patient population, appearance of placebo response, subjective patient evaluation, and lengthy durations.

Only 7% of development candidates in the field of CNS have the probability of reaching the market, compared to the industry average of 15%.

- One reason for the low success rate of CNS drugs is the presence of the blood-brain barrier, which can be difficult for a drug to penetrate.
- Another reason is the fact that the brain is a complex organ and there is much biology that is not completely understood, which is why many drugs have the problem of side effects.

CNS drugs have on average taken twice as long to reach approval compared to drugs for cardiovascular and gastrointestinal indications.

A validated biomarker or biomarker signature that is more objective greatly helps this process.

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**AD/CNS drug development challenges**

- There is an increasing demand for new and innovated therapies by both patients and payers.
- CNS clinical trials are confounded with a heterogenic patient population, appearance of placebo response, subjective patient evaluation, and lengthy durations.
- Only 7% of development candidates in the field of CNS have the probability of reaching the market, compared to the industry average of 15%.
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**BCC Research October 2010: BIO074A – Central Nervous System (CNS) Biomarkers: Technologies and Global Markets**
New drugs target very early stages of AD

Mild cognitive deficits (MCI)  Mild dementia  Moderate dementia  Severe dementia

Disease-modifying therapies
DiaGenic MCI development program

**Ongoing multicentre study in Europe and US**

- **Objectives**
  - Develop a blood based gene expression test to identify MCI that go on to develop AD

- **Study setup**
  - Annual monitoring of MCI patients, controls and other dementias over 3-4 years, to include 500 MCI cases and 200 controls
  - Multicentre study with hospitals in Europe and the US
  - Now included recently initiated MCI study in Southern Sweden, PI is Prof Oskar Hansson,
    - Access to 300 MCI patients + controls
    - Access to all clinical data, including CSF biomarkers and PET optionally.
  - Timeline; a fully validated prototype by Q1/2 2012

- **Funding**
  - Initial funded through The National Research Council (FUGE Platform)
  - Pharma collaborations (Pfizer) and DiaGenic

- **Aim**
  - To develop companion diagnostic products for use together with a new drug or imaging product (PET)
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 option

- The terms of the agreement remains undisclosed
Milestones

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

- Sample collection and medical review of clinical data
- Analytical validation of >1200 probes for the gene transcripts
- Laboratory analysis by DiaGenic of all clinical samples and reference/technical samples on the next generation IVD instrument, ABI Viia7

- Bioinformatic analysis of the PCR results on each gene transcript from every patient
  - > 200,000 individual PCR reactions and subsequent biological modeling

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**Stage 1 - Discovery**
- Blood collection and patient sampling - building biobank
- Lab analysis
- Output Q2-2011

**Stage 2 - Biomarker validation**
- DiaGenic and Partner biobank
- Proof of concept/ gene selection
  - Prodromal biomarker
  - Progression biomarker
- Modelling and calibration
- Output H2-2011

**Stage 3 - Regulatory**
- Validation
- Verification
- Pharma
- CE mark
- FDA
- IVD EU
- IVD US

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**Output H2-2011**
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DiaGenic business model
Integrating IP, technology and partners

MCI biomarker licenses to pharma

- Use test to qualify the right patients into clinical trials
- Limited number of licenses
  - Secures a few selected pharma companies access to unique biomarkers for their R&D and drug development
  - A few licenses retains the value of DiaGenic’s proposition
- Co-funding of DiaGenic’s biomarker development
- Agreements with upfront and milestone based payments
- DiaGenic retains IP linked to Diagnostics tools
Aim to retain multiple revenue streams from new business model

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

First R&D deal signed with Pfizer

Multiple interactions with pharma and imaging companies advancing according to plan
1st quarter 2011 financials
Finance, Income

- Operating revenue in Q1: mainly recognition of milestone revenue from R&D collaboration with pharma

- NOK 1.6 million recognised as milestone revenue in Q1

- Research grants in Q1 totalled NOK 1 million
## Finance, Profit & Loss

### P&L 1Q

*(thousand NOK)*

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<td>Operating loss</td>
<td>(11,933)</td>
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<td>Net income</td>
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### Other Operating Cost

*(thousand NOK)*

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<td>4,202</td>
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<td>Depreciation and Write downs</td>
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<td>Other operating cost</td>
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For early disease detection...
Finance, Cash position

Cash and Cash equivalents
(million NOK)

- Long term financing secured in Q4 2010
- Cash balance end of March 2011: NOK 87 million

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<th>Quarter</th>
<th>Cash and Cash equivalents (million NOK)</th>
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<tr>
<td>Q1 '11</td>
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Outlook & Summary
2011 - Outlook

- Execute on the companion diagnostics initiative closing R&D and licensing agreements with pharmaceutical and imaging companies operating in the CNS field.
- Successfully deliver and leverage the Pfizer collaboration in 2011.
- Strengthen and align the organization to support to the company’s pharma strategy.
DiaGenic
Your preferred partner for gene expression profiling in blood

Core competence and assets:

- 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 ASA
Grenseveien 92, N-0663 Oslo, Norway
Tel +47 23 24 89 50
Mail: diagenic@diagenic.com
www.diagenic.com
# Shareholders

11 May 2011

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For more information, see www.diagenic.com
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