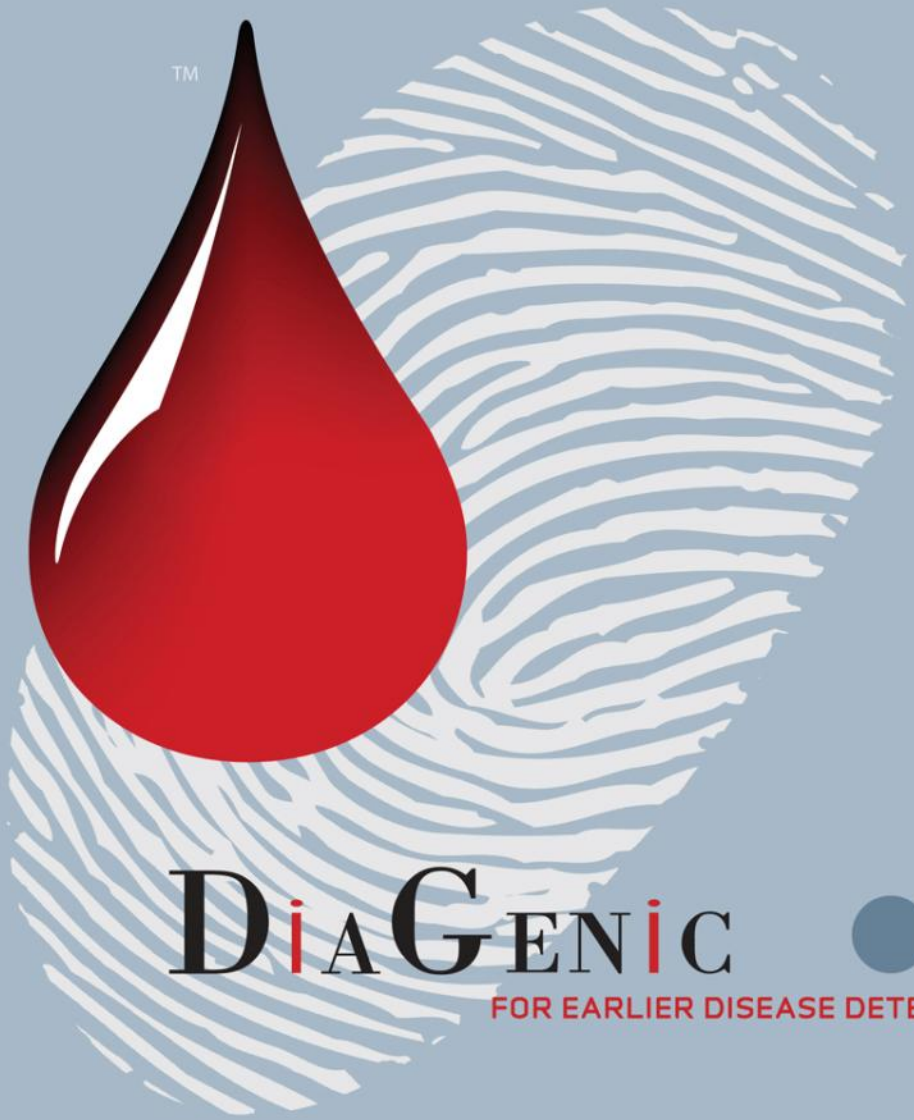

2nd. Quarter 2008 Presentation

Erik Christensen, MD PhD
Chief Executive Officer

Ruben Ekbråten
Financial Controller

DiAGENiC

FOR EARLIER DISEASE DETECTION

Agenda:

2nd Quarter 2008 Presentation

- 2nd Quarter Highlights
- 2nd Quarter Finance
- Product Development and Clinical Studies
- Commercial Strategies
- Outlook

2nd Quarter Highlights

- Agreement on the breast cancer test signed with SRL Ranbaxy
- Indian multi-centre breast cancer study completed
- NOK 44.8 million share issue
- European patent granted for Alzheimer's disease
- Patent granted in Japan for use of gene expression in diagnosis of several different diseases
- Research grant awarded by the EU Commission

Agenda:

2nd Quarter 2008 Presentation

- 2nd Quarter Highlights
- **2nd Quarter Finance**
- Product Development and Clinical Studies
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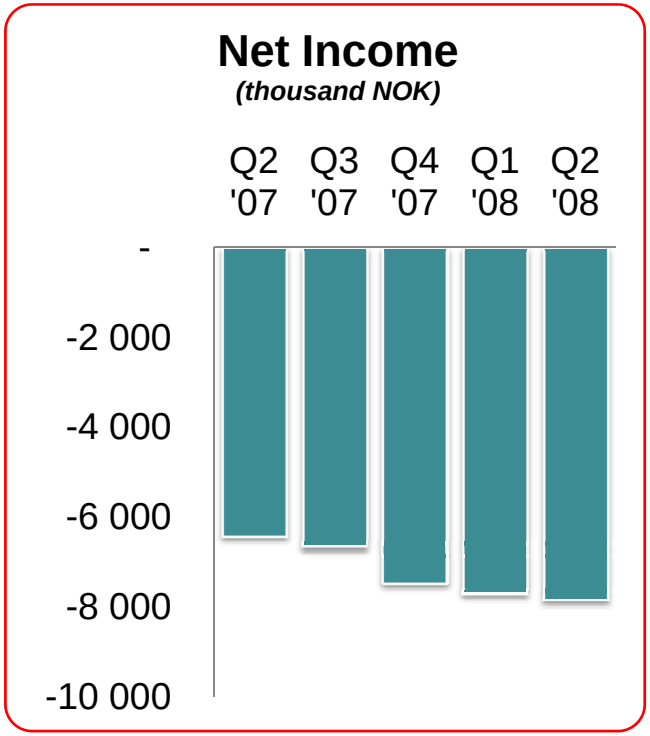
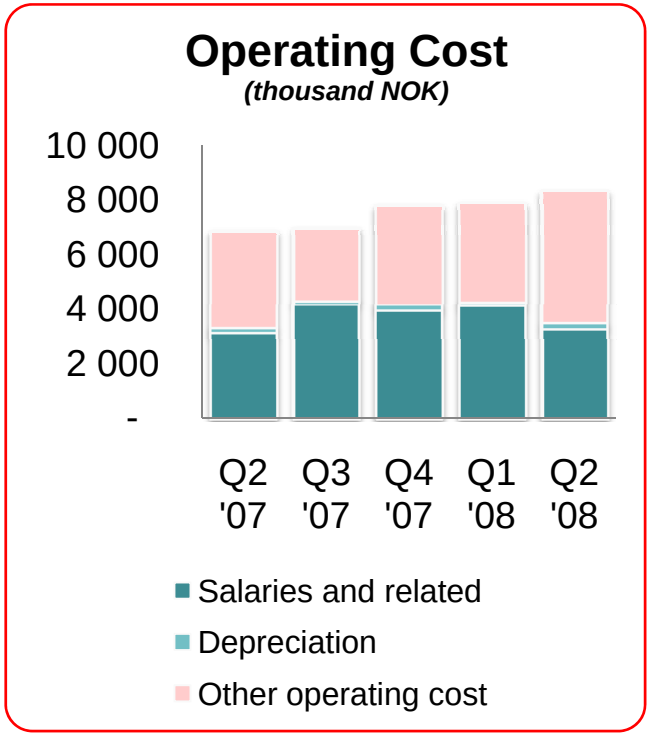
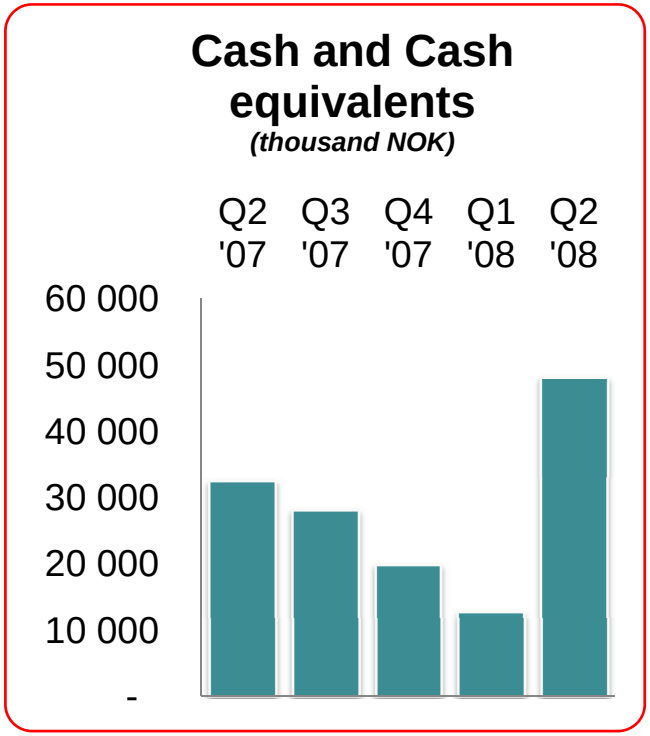
- Outlook

Finance, Profit & Loss





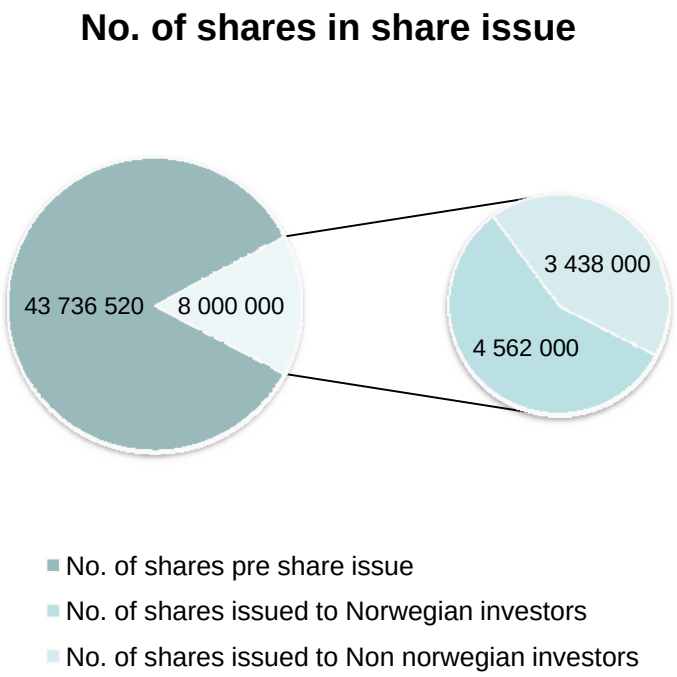
Finance, Cash Position

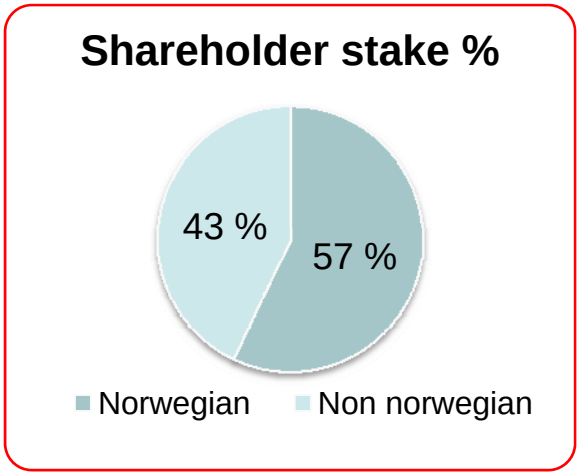


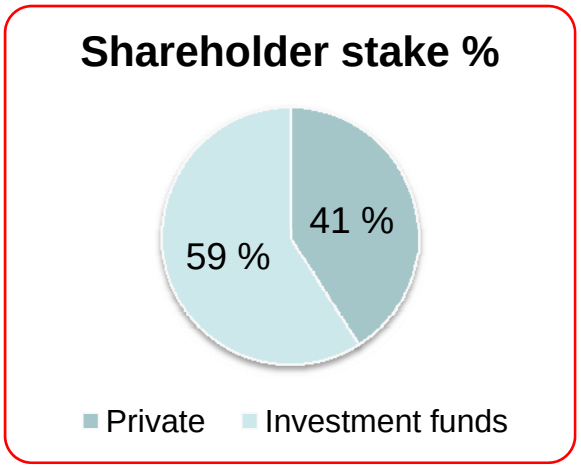
- Share issue completed in May with gross proceeds of NOK 44.8m
- Cash and cash equivalents NOK 48.2m at 30 June 2008

Share issue in May '08

Distribution of shares in share issue:







Finance, 2008 future prospects

- 2H 2008: exciting times ahead with key milestones to deliver on
  - Product launch in India
  - Preparing for the regulatory submission for the European market (CE mark)
- High activity requires more resources, however burn rate is not expected to increase significantly for 2H ’08 compared with 1H ’08

Agenda:

2nd Quarter 2008 Presentation

- 2nd Quarter Highlights
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- **Product Development and Clinical Studies**
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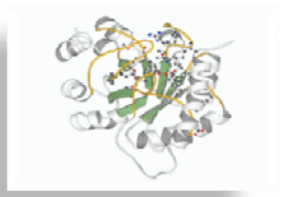
- Outlook

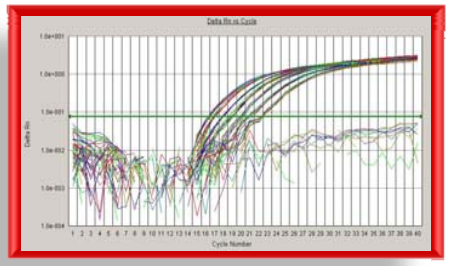
Central Theme in DiaGenic Technology

DNA

RNA



Protein



- RNA plays a central role in translating what is written in our genes to what is expressed in our bloodstream
- RNA expression is measured by qRT-PCR and forms the basis of our proprietary gene signature

DiaGenic's Product Development Focus

Breast Cancer

Alzheimers Disease

Parkinsons Disease

DiaGenic's Product Development Focus

India multicenter study

Objectives

- To measure the efficacy (sensitivity) of the DiaGenic BCT to identify breast cancer in women with stage 0, I, and II and above.
- To measure the specificity of the BCT (i.e. to correctly identify healthy women) from a population of:
  - women with genetic predisposition following a 2 yr. longitudinal study.
  - women with non-malignant findings in the breast
  - age matched healthy controls
- To assess the effect of menopausal status on the efficacy of identifying early stage breast cancer.
- To assess differences in efficacy in populations of women with and without breast cancer in different geographical locations of India.

- 742 enrolled subjects
  - 274 Breast cancer stage 0,1 and 2+
  - 102 High risk – predisposed subjects
  - 225 Healthy controls
  - 141 Benign controls
- Age balanced <50 yrs; >50yrs
- Standard of Truth
  - Subjects with mammographic findings: Cytology or histology
  - Subjects without findings: Mammography alone

Validation process

Patient inclusion

742 females

274 Breast Cancer, 141 benign and 327 controls

Training set

To generate India-specific algorithm

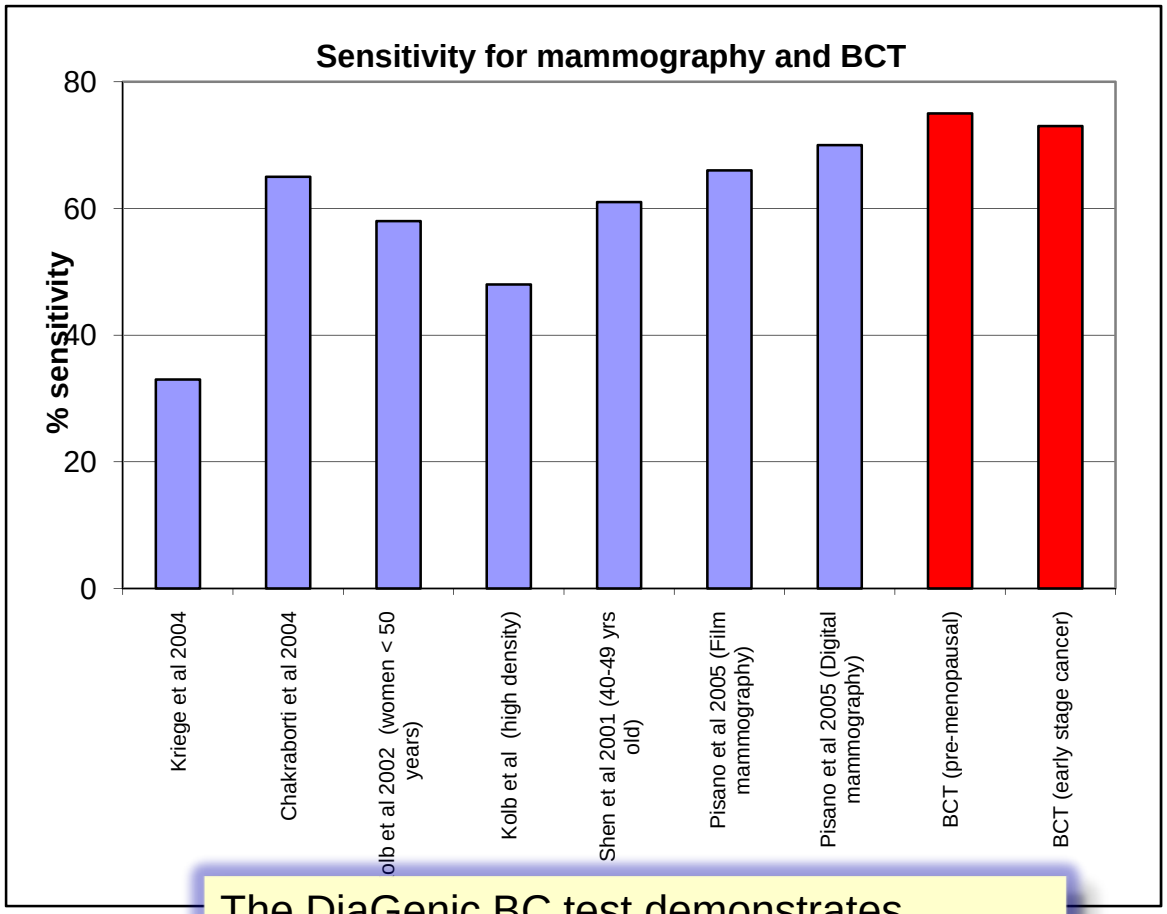
Independent Test set

Sample cohort of 152 samples used for validation of the genes and algorithm

Overall results observed by using an independent test set in the multicenter-study

- The study demonstrated, using a separate test set of 152 females, an overall clinical acceptable performance and in accordance with previous studies
- The test has in premenopausal females 5% higher accuracy than in postmenopausal females
- The test has high accuracy across all cancer stages

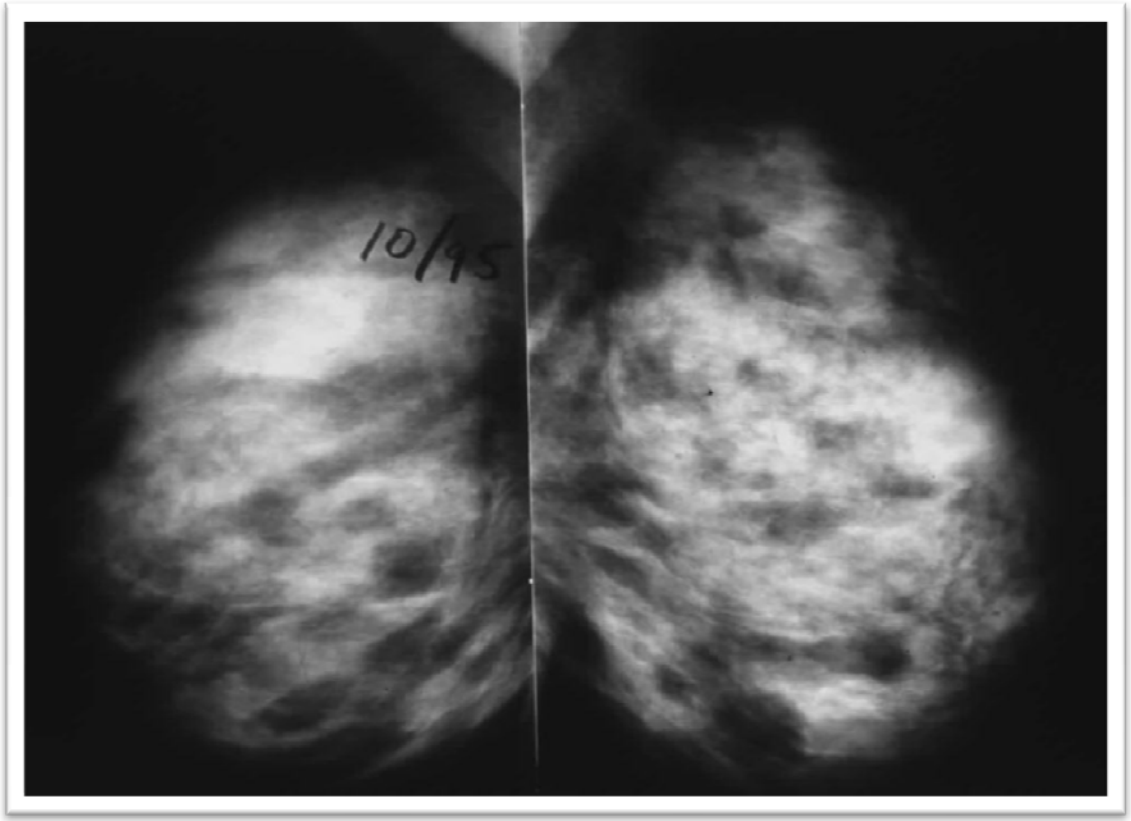
Sensitivity of mammography in younger females from several studies



The DiaGenic BC test demonstrates improved sensitivity in younger females

Disclaimer: For illustrational use only, the studies represents different sample cohorts and are not fully comparable

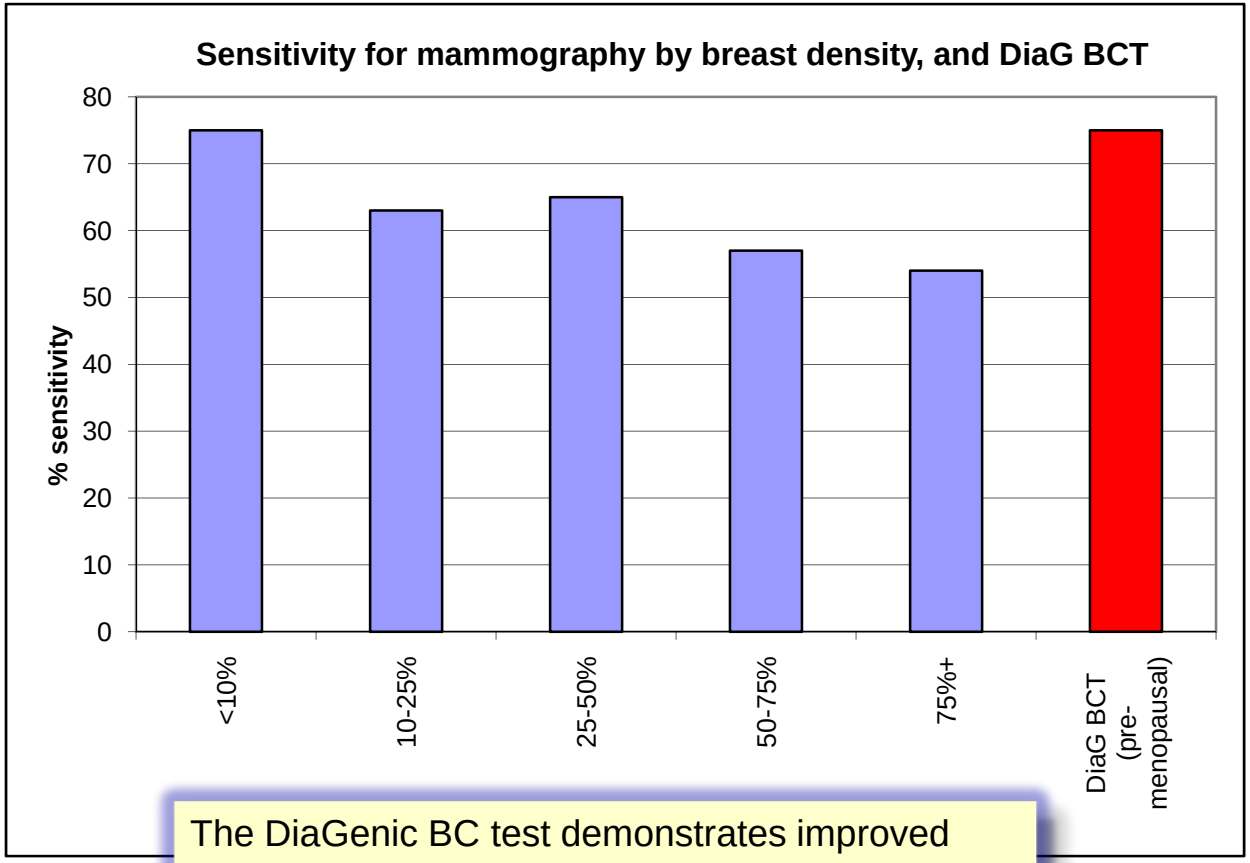
The challenge with Mammo-graphy!



Large palpable cancer 5 cm is not visible due to density in the breast parenchym!

Courtesy of Prof. Per Skaane

Sensitivity of mammography Impact of Breast density



The DiaGenic BC test demonstrates improved sensitivity in groups with high breast density

Source: The New England Journal of Medicine, 2007, Boyd et al: "Mammographic Density and the Risk and Detection of Breast Cancer"
Disclaimer: For illustrational use only, the studies represents different sample cohorts and are not fully comparable

Overall conclusion

- The present study is one of the largest studies performed to determine the efficacy of a blood-based gene expression test for diagnostic use.
  - BCT has high diagnostic performance for pre-menopausal women, providing a viable alternative to mammography
  - BCT has clinical utility for pre- and post-menopausal women
  - BCT detects early stage cancer
  - BCT detects ductal cancer and lobular cancer with high accuracy
- This study confirms applicability of the DiaGenic BCT in India for women of various ages and ethnic background, independent of menopausal status and stage of breast cancer or type of benign disease.
- The BCT shows good accuracy for pre-menopausal women, which constitutes a group of women for which mammography is known to have poor efficacy due to high breast density.
- Consequently, the BCT may offer a valuable alternative to women that require an alternative that is efficacious, comfortable and painless.

Our marketing and sales partner in India

- SRL Ranbaxy is the largest and most trusted pathology laboratory network in India, servicing nearly 2,000 hospitals/path labs and over 25,000 doctors. SRL Ranbaxy performs over 34,000 tests/day and caters to approximately 5 million patients in a year offering a comprehensive range of over 3,500 tests, from the routine to the highly specialized tests.

- Extensive competencies within molecular diagnostics and experience in launching new diagnostic methods
  - A strategic and broad cooperation between the parties
  - A major marketing investment from SRL Ranbaxy

Pre Launch activities ongoing:

- To be done from DiaGenic: Approval of the patient sample logistics in SRL Ranbaxy.

DIAGENIC

SRL RANBAXY

DiaGenic receives research grant from the European Commission

SPIDIA = Standardisation and improvement of generic pre-analytical tools and procedures for in vitro diagnostics

Approach and methodology:

SPIDIA is organised into three activities, each consisting of multiple Work Packages (WPs):

- 1. Evidence-based, international guidelines and quality-assurance schemes.
- 2. Research leading to pre-analytical tools for molecular in vitro diagnostics and classical pathology.

3. Management, ethics and spreading of excellence:

Coordinator: **QIAGEN GmbH**

Partners:

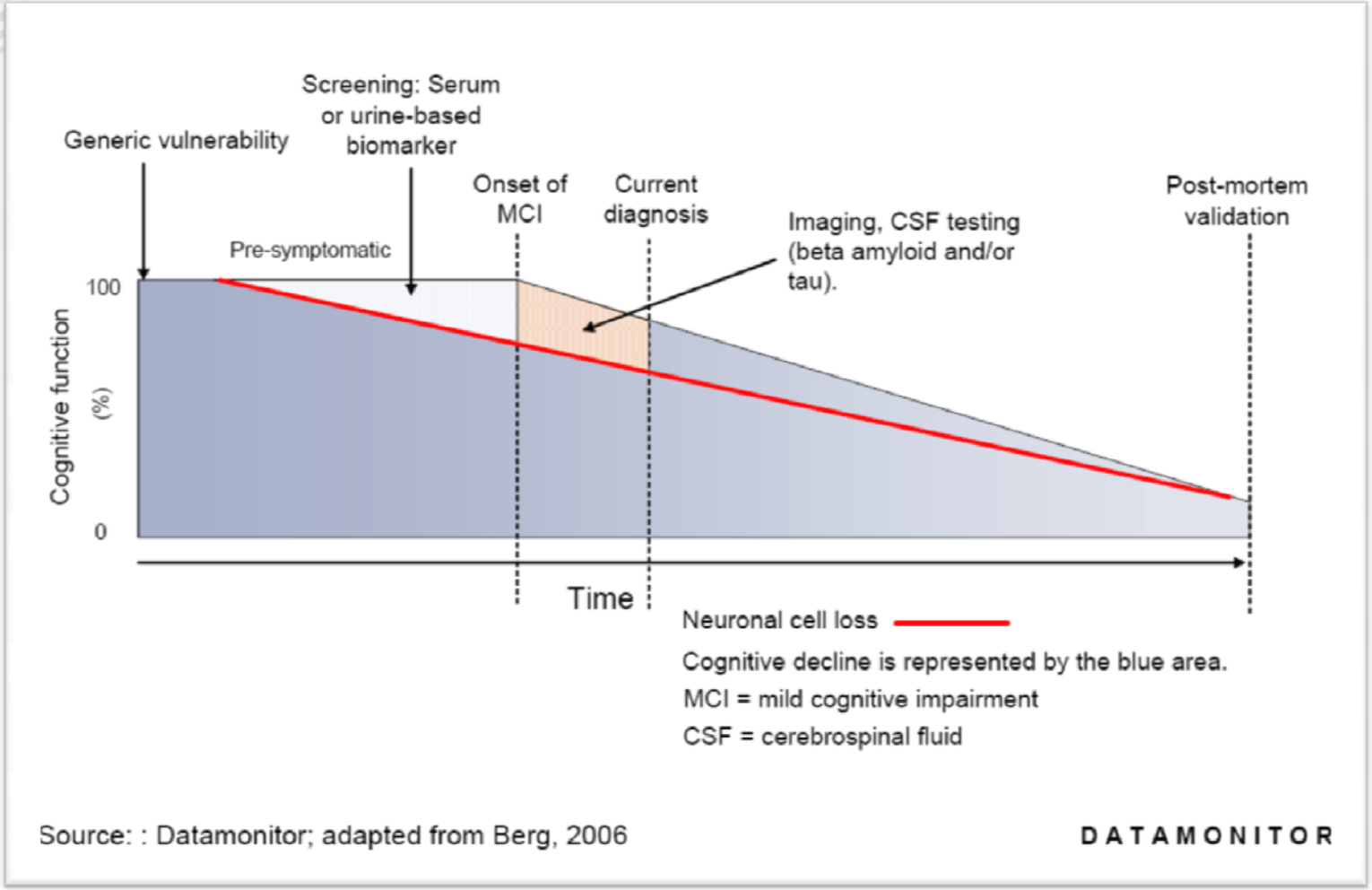
- 6 Universities and research institutions
- 4 Small and medium sized enterprises:
  - PreAnalytiX GmbH, **DiaGenic ASA**, AROS Applied Biotechnology AS, Dako Denmark AS
- 4 private research organizations, including International Agency for Research on Cancer
- European Committee for Standardization (CEN)

DiaGenic's Product Development Focus

Impact of improved diagnostics on key stakeholders

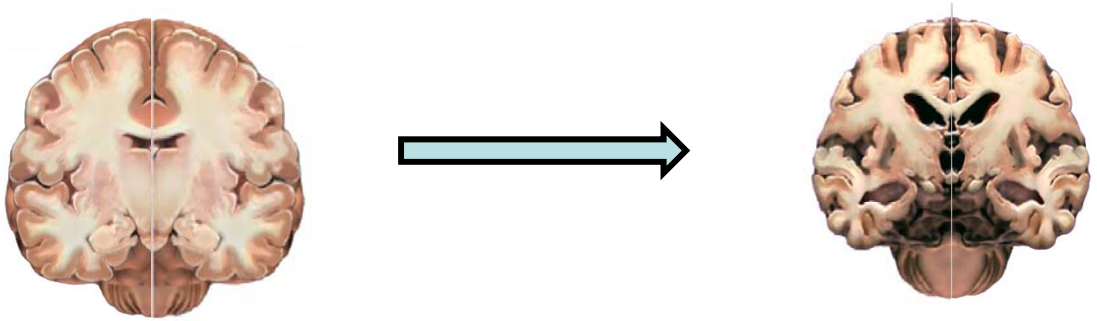
Patients	Diagnostic companies	Pharmaceutical companies	Payers
Better treatment outcome, via pre-symptomatic identification and treatment before significant neurodegeneration has occurred	Screening greatly increases commercial potential. Serum/urine based biomarker companies benefit from large demand	Earlier treatment equals more drug revenue for pharmaceutical companies. Increasing the revenue potential per patient e.g. $5 billion in Alzheimer's disease	Biomarkers can be used as tools for pharmaco-economics. Quantitatively showing the effect of treatment in each patient
Less anxiety for patients and their families regarding uncertainty	Increased use of imaging scanners (e.g. PET/SPECT) increases demand for these expensive machines from manufacturers	Threat: cost-effectiveness studies may become more quantitative once biomarkers are incorporated as endpoints in trials	It will be difficult for payers to justify not paying for incorporation of biomarkers into the diagnosis of these diseases. A clear pharmaco-economic benefit of early treatment is likely

Points of diagnosing of Alzheimer's disease



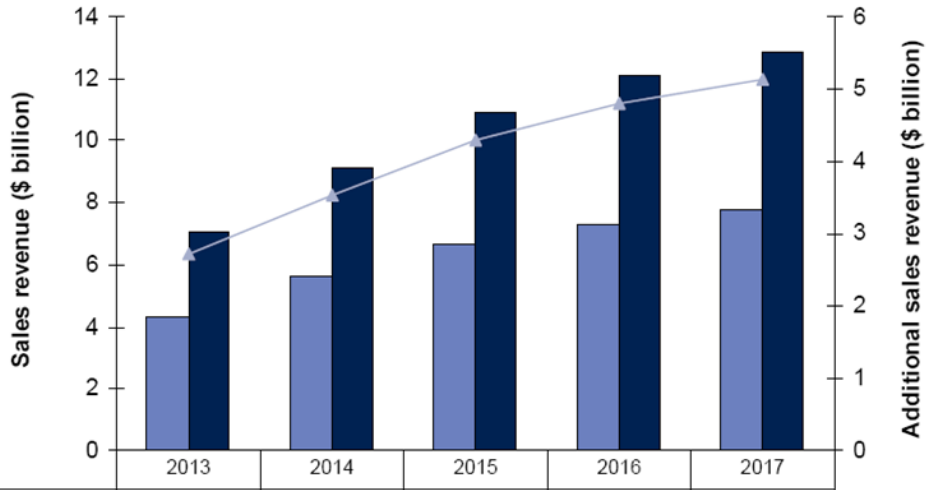
Mild Cognitive Impairment (MCI)

- Mild Cognitive Impairment is a condition with reduced cognitive functions, but retained the levels needed for normal functions in daily life
- MCI is regarded as a risk factor for developing Alzheimer's disease
- An approximate 15% of MCI progress to AD annually
  - A subgroup, called amnestic MCI, has the highest conversion rates
- Some MCI patients exhibit full blown AD pathology demonstrated by modern imaging techniques
- Increased interest on diagnostics for MCI from pharma
  - New clinical studies on disease modifying drugs are all targeted in this patient group



AD pharma-market development and MCI

Revenue gain in the Alzheimer's disease market value with the inclusion of patients with amnestic mild cognitive impairment (amMCI), 2013–17



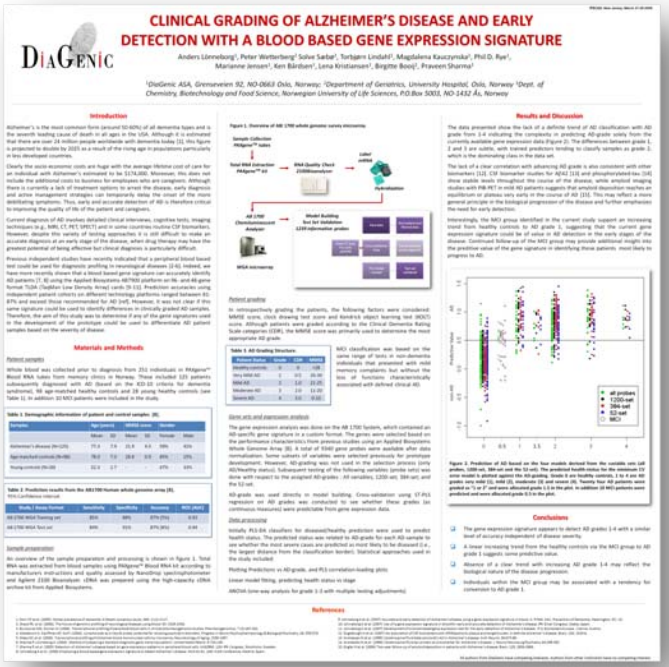
	2013	2014	2015	2016	2017
AD market value ($ billion)	4.3	5.6	6.6	7.3	7.7
AD + amMCI market value ($ billion)	7.1	9.2	10.9	12.1	12.9
Additional revenue ($ billion)	2.7	3.5	4.3	4.8	5.1

66% increase in the market

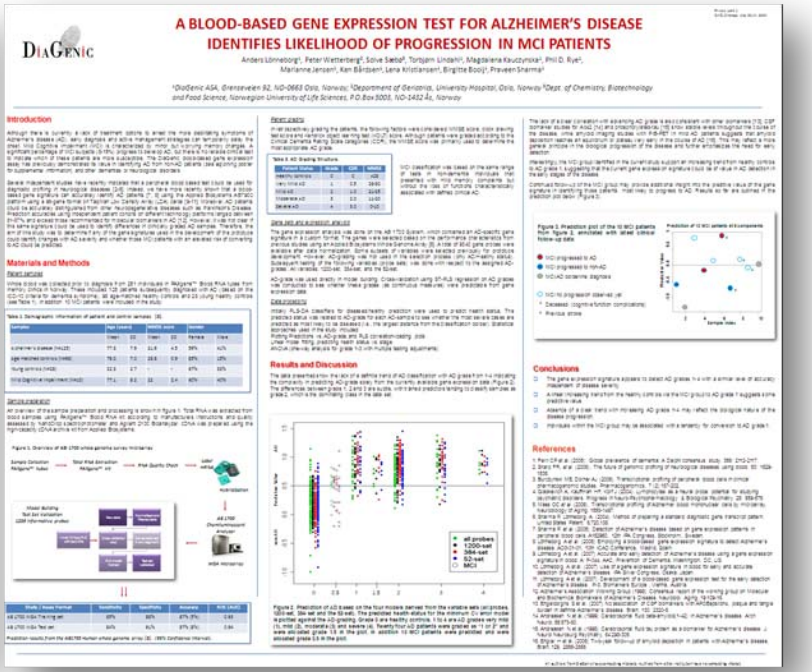
Source: Datamonitor. AD base scenario market value, and methodologies associated with it, can be found in Datamonitor's report *Pipeline and Commercial Insight 2008: Alzheimer's disease (DMHC2376).*

DATAMONITOR

5th International Pharmaco-Economic Conference on AD, Newark, and International Conference on AD, Chicago



CLINICAL GRADING OF ALZHEIMER'S DISEASE AND EARLY DETECTION WITH A BLOOD BASED GENE EXPRESSION SIGNATURE



A BLOOD-BASED GENE EXPRESSION TEST FOR ALZHEIMER'S DISEASE IDENTIFIES LIKELIHOOD OF PROGRESSION IN MCI PATIENTS

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2nd Quarter 2008 Presentation

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- **Commercial Strategies**
- Outlook

Intellectual Property update

US 20020022222A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2002/0022222 A1**

SHARMA et al. (43) **Pub. Date: Feb. 21, 2002**

(54) **METHOD OF PREPARING A STANDARD DIAGNOSTIC GENE TRANSCRIPT PATTERN**

(76) Inventors: **PRAVEEN SHARMA**, OSLO (NO); **ANDERS LONNEBORG**, AAS (NO)

Correspondence Address:
SUGHRUE MION ZINN MACPEAK & SEAS PLLC
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 200373213

(*) Notice: This is a publication of a continued prosecution application (CPA) filed under 37 CFR 1.53(d).

(21) Appl. No.: **09/429,803**

(22) Filed: **Oct. 29, 1999**

Related U.S. Application Data

(63) Continuation of application No. PCT/GB98/01261, filed on Apr. 30, 1998.

(30) **Foreign Application Priority Data**

Apr. 30, 1997 (NO) ..... NO 972006

Publication Classification

(51) **Int. Cl.**[7] **C12Q 1/68**; C07H 21/02; C07H 21/04; C12P 19/34

(52) **U.S. Cl.** **435/6**; 536/23.1; 435/91.2

(57) **ABSTRACT**

A method for preparing a gene transcript pattern probe kit characteristic of a disease or condition or a stage thereof in a prokaryotic or eukaryotic organism using mRNA which is differentially expressed in the disease or condition or stage as probes, methods of diagnosis using the method and kits for performing the same are disclosed.

US 20070134656A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2007/0134656 A1**

Sharma et al. (43) **Pub. Date: Jun. 14, 2007**

(54) **PRODUCT AND METHOD**

(76) Inventors: **Praveen Sharma**, Oslo (NO); **Narinder Singh Sahni**, Oslo (NO); **Anders Lonneborg**, Aas (NO)

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WASHINGTON, DC 20037 (US)

(21) Appl. No.: **10/535,414**

(22) PCT Filed: **Nov. 21, 2003**

(86) PCT No.: **PCT/GB03/05102**

§ 371(c)(1),
(2), (4) Date: **May 1, 2006**

(30) **Foreign Application Priority Data**

Nov. 21, 2002 (GB) 0227238.3

Publication Classification

(51) **Int. Cl.**
C12Q 1/68 (2006.01)
G06F 19/00 (2006.01)
C07H 21/04 (2006.01)

(52) **U.S. Cl.** **435/6**; 702/20; 536/24.3

(57) **ABSTRACT**

The present invention relates to oligonucleotide probes, for use in assessing gene transcript levels in a cell, which may be used in analytical techniques, particularly diagnosis techniques and kits containing the same.

Patent Development H1 2008

	Family 1 (WO 98/49342)			Family 2 (WO 2004/046382)			Family 3 (WO 2005/118851)		
Expiry year	2017			2023			2024		
Countries/ Region	G	A	P	G	A	P	G	A	P
US	Alz		BC, MS			G			C
Europe*	G, nSB	Alz							
Europe**						G			C
Norway	G, nSB		G, dD			G			C
Japan		G, dD (AD-BC)			Alz, BC	G			C
Canada						G			C
Hong Kong	G, nSB					G			C
China						G			C
Australia					Alz, BC				C
New Zealand					Alz, BC				C
India					Alz, BC				C
South Africa				G				G	
ARIPO*						G			C

Q1

Q2

Abbreviations
Alz: Alzheimer's Disease
BC: Breast cancer
C: Cancer
G: No disease limitation.
G, dD: No disease limitation. Samples collected distant to the area of the disease
G, nSB: No disease limitation. Limited to **onl**y non-sequence based methods.
MS: Multiple sclerosis.

G = Granted
A = Accepted by examiner
P = In-process

Achieving Regulatory Compliance

- Ongoing projects:
  - ISO 13485:2003 Certification
    - Certification of DiaGenic quality management system
  - CE-mark of the Alzheimer's Disease and Breast Cancer tests for the EU market
  - Preparations for a multicenter study in the US ongoing, in dialogue with Food and Drug Administration (FDA).
    - Recruitment of key centres ongoing
    - Evaluation of technical platforms supporting FDA PMA demands ongoing

1 Biomarker (R&D Pharma)

Biomarker

-

Research Use

- R&D tool ensuring
  - Documentation for:
    - Marketing acceptance
    - Pharma communication
- Biomarker for the pharma industry in new drug development and life cycle management
  - Early disease diagnostics, recruitment strategies, find responders and monitoring the effects
  - Fine tuning the gene signature to our customers needs
    - R&D collaborations and joint synergies

1. Biomarker (R&D Pharma)
2. India – Breast Cancer — H2 '08
3. Europe - BC + Alzheimer's — H1 '09

Market Entry Strategy with Revenue Streams

- Initial focus:
  - Establish a distributor network in countries with a sizeable private payer segment.
    - Selected distributors that covers larger areas are preferred
  - Establish centralized lab testing for our tests

Market Entry Strategy with Revenue Streams

1. Biomarker (R&D Pharma)
2. India – Breast Cancer — H2 '08
3. Europe - BC + Alzheimer's — H1 '09
4. Ex US Countries with IP
5. US – FDA approval of AD
   US – Centralized Lab Tests
x x x
6. *Screening Approval EU & US*

Agenda:

2nd Quarter 2008 Presentation

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- **Outlook**

Outlook

- DiaGenic will actively support SRL Ranbaxy in the launch of the breast cancer test in India. Initial target group will be younger females and their gynaecologists.
- The Company will continue to prepare for a distribution network in Europe, focusing on countries where the private payer segment on healthcare and diagnostics is significant.
- The ongoing projects to ensure European CE approval for diagnostic use for the breast cancer and the Alzheimer's test continues.

Conclusion

- Innovative diagnostics company
- Target disease markets are large
- Clear medical needs
- Significant big pharma interest and spend
- Products in and near the clinic
- Clear marketing strategy via different global territories
- Experienced management team

DIAGENIC

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Tel +47 23 24 89 50
Mail: diagenic@diagenic.com
www.diagenic.com

20 Largest Share Holders

August 21th 16:00

Shares	Percent	Name
3 589 135	6.94	VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS
2 910 100	5.62	NORDEA BANK SWEDEN A A/C NORDEA HEDGE FUN
2 910 000	5.62	SHARMA PRAVEEN
2 890 000	5.59	LØNNEBORG ERIK ANDERS
2 344 000	4.53	Tredje AP-Fonden C/O HANDELSBANKEN AS
1 914 000	3.70	A/S SKARV
1 444 870	2.79	HOLBERG NORDEN V/HOLBERG FONDSFORVA
1 403 120	2.71	NORDEA BANK PLC FINL
1 402 780	2.71	JPMBLSA NORDEA LUX LENDING A
1 400 000	2.71	SKAGEN VEKST
1 097 387	2.12	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 003 100	1.94	LIVSFORSIKRINGSSELSK STRATEGISK
828 933	1.60	INVESTOR COPORATE AS
816 000	1.58	AMFIBIEN AS
783 300	1.51	VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS
646 000	1.25	ANDERSEN RUBEN
620 378	1.20	STORHAUG DAG
496 000	0.96	HAAVIND KARL WILHELM
476 100	0.92	SANDEN A/S C/O JAN PETTER COLLI
410 000	0.79	KIKUT AS
29 385 203	56.79	Sum

Breast cancer

- Breast cancer is the most common for of cancers among women with more 600,000 new cases and 150,000 deaths in Europe and the US alone. Early diagnosis and treatments holds the key to survival. This has lead most western countries to establish a screening program for BC. However, the current testing methods - mammography, ultrasound and MRI - all have increasingly recognized limitations. The too low accuracy of mammography especially in women below the age of 50 and in women with dense breasts results in too many missed cancers. There is a clear need for additional and better diagnostic tools, both to improve the detection rate when using conventional mammography, and to select the appropriate patients for the new and costly MRI method. DiaGenic's concept is ideal – peripheral blood is a convenient and easily accessible clinical sample

Parkinson's disease

- Parkinson's disease (PD) is a chronic, degenerative neurological disorder and belongs to a group of conditions called motor system disorders. There is no objective test, or biomarker, for Parkinson's, so the rate of misdiagnosis can be relatively high, especially when the diagnosis is made by a non-specialist. Estimates regarding the number of people in the United States with Parkinson's range from 500,000 to 1,500,000 with 50,000 new cases reported annually. Since Parkinson's is more common in people 60 years old and older, it is expected that the incidence of Parkinson's will increase with the ageing of the baby boomers. Although PD is more common in older persons, some people begin to show symptoms before reach the age of 40. The diagnostic accuracy is only 47% in a community setting, 74% in standard geriatric and neurological practice. Experts in neurological movements disorders achieve 92-98% accuracy.
- The MJ Fox Foundation is funding a DiaGenic study together with Dr Clemens R Scherzer, Assistant Professor of Neurology at Brigham and Womens Hospital and Harvard Medical School to develop the first blood test for Parkinson's disease. This involves identification of, and independent validation of a unique gene expression signature for Parkinson using peripheral blood. Since blood samples have already been collected, the immediate start of the analytical and bioinformatics studies will ensure a rapid development of a prototype of the blood test preceding an approved diagnostic test

Alzheimer's disease

- Alzheimer's disease is the leading cause of dementia and a recent update estimates that more than 20 million people currently have the disease. Even more threatening is that these figures expect to triple in the next 30-40 years. Diagnosis of AD involves a large battery of assessments, including clinical interviews, cognitive function, and, sometimes, also functional imaging and measurements of neurophysiological function. However, with all these tests it is still difficult to make an accurate diagnosis, especially at an early stage of the disease. There are today more that 14 disease modifying drugs in clinical phase III and it is expected that several of them will be on the market in 2 - 4 years time. Efficacy of the new drugs will depend on early diagnosis and thus boost the diagnostic market.