# 3rd. Quarter 2008 Presentation

Erik Christensen, MD PhD
Chief Executive Officer

Ruben Ekbråten
Financial Controller

DiaGenic

FOR EARLIER DISEASE DETECTION

## 3rd Quarter Highlights

- Breast cancer test, BCtect™, approved by Super Religare Laboratories Ltd (SRL) following extensive internal testing.
- Commercial launch of BCtect™ in India scheduled for 8 November 2008
- Research grant awarded by the EU Commission
- New patents in Japan, New Zealand and Hong Kong

Post quarter end

- DiaGenic designated DNA Vision as the European clinical reference laboratory

## Core focus of DiaGenic

- First product to be launched i India in one week
- Top priority within the company is then to support the European launch of our tests early next year
- Under present financial markets conditions, future activities will be focused on supporting sales of these products
- Costly clinical studies for new products or new markets are pending external financing
  - Research grants, partner deals, non-dilutive

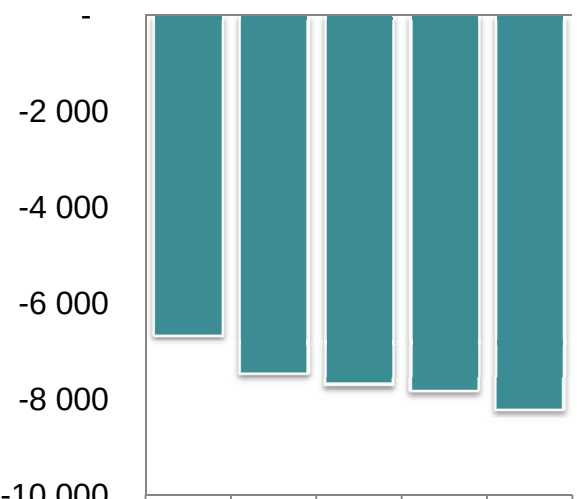
Agenda:

3rd Quarter 2008 Presentation

- 3rd Quarter Highlights
- **3rd Quarter Finance**
- Product Development and Clinical Studies
- Commercial Strategies
- Outlook

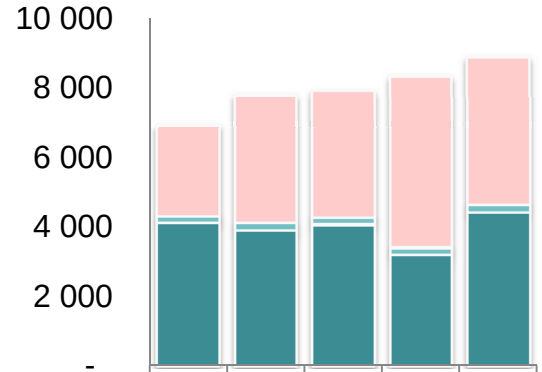
# Finance, Profit & Loss

## Net Income
*(thousand NOK)*



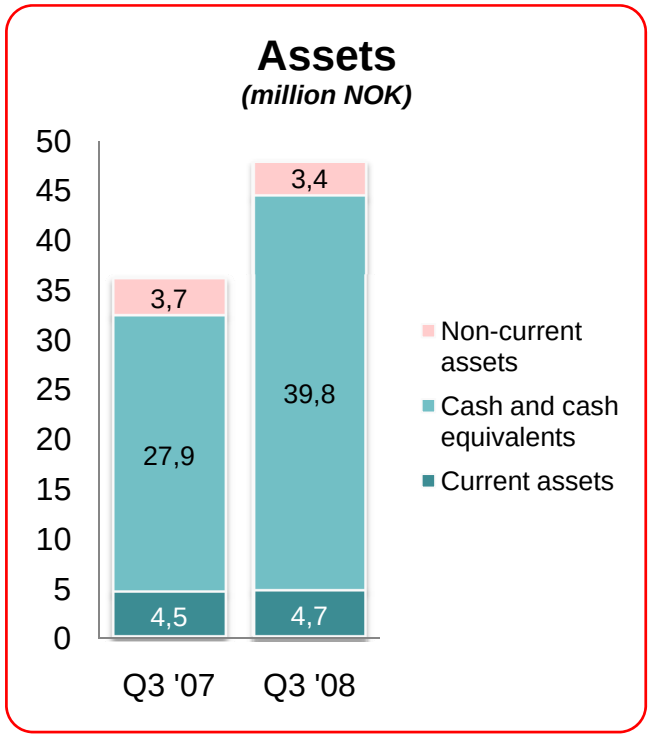

| | Q3 '07 | Q4 '07 | Q1 '08 | Q2 '08 | Q3 '08 |
|---|---|---|---|---|---|
| Net income | -6 662 | -7 471 | -7 712 | -7 852 | -8 239 |

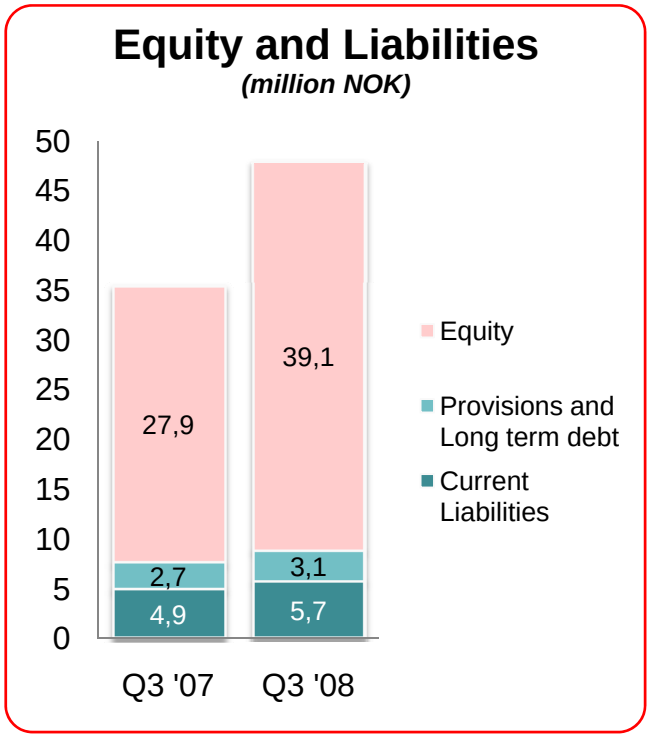
## Operating Cost
*(thousand NOK)*



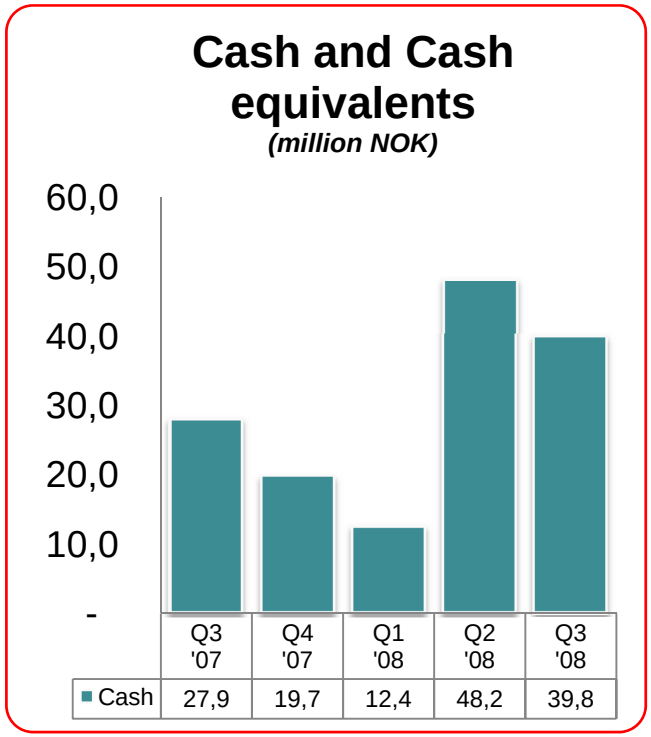

| | Q3 '07 | Q4 '07 | Q1 '08 | Q2 '08 | Q3 '08 |
|---|---|---|---|---|---|
| Other operating cost | 2 629 | 3 678 | 3 605 | 4 933 | 4 242 |
| Depreciation | 185 | 217 | 207 | 209 | 217 |
| Salaries and related | 4 123 | 3 882 | 4 061 | 3 187 | 4 422 |

# Balance sheet



# Finance, Cash Position




- Cash and cash equivalents NOK 39.8m at 30 September 2008
- In the current financial environment we will reinforce the focus on core activities

## Finance, 2008 outlook

- Key drivers for finance Q4 ’08
  - India launch on November 8th
  - CE mark preparations
- Activity will increase slightly in Q4 because of India launch and CE marking, burn rate to be strictly controlled in accordance with DiaGenic’s core strategy

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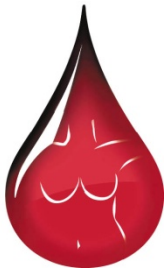
## DiaGenic's New Product Branding

BCtect™

DiaGenic for early Breast Cancer detection



ADtect™

DiaGenic for early Alzheimers Disease detection

## Achieving Regulatory Compliance

- Ongoing projects:
  - ISO 13485:2003 Certification
    - Certification of DiaGenic quality management system by The Norwegian Veritas, first quality review held
    - Full certification can take place when all QMS is in use, including the post launch systems
  - CE-mark of the Alzheimer's Disease and Breast Cancer tests for the EU market

## The *in vitro* diagnostic medical device directive (98/79/EC )


- The EU directive supports free trade in EU, harmonizes country differences in authorization procedures and ensures health protection of patients

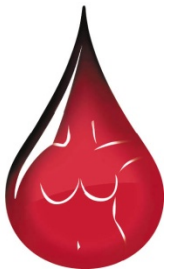
- The studies ongoing to support the CE approval:
  - Calibrating the final version of the test
    - 200-300 patients and controls are analyzed
  - Verification of the model
    - Technical studies using the model
      - Robustness, Interference from other diseases
  - Validating the test with new samples (test set validation)
    - 150-200 patients and controls are analyzed

- All studies compiled into the technical file as the reference for the self-declared EU IVD compliance.

# Product Update

BCtect™

DiaGenic for early Breast Cancer detection



RELIGARE SRL Diagnostics (Formerly SRL Ranbaxy Ltd.)

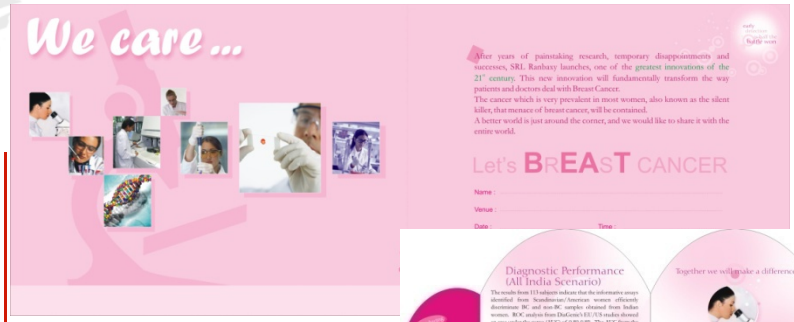
BCtect™ DiaGenic for early Breast Cancer detection

LABINDIA Aiming for the Best

## Preparing for the launch of BCtect™ in India

- DiaGenic performed a large multi centre study demonstrating the clinical accuracy in an Indian population
- SRL have performed thorough quality reviews and blinded testing to ensure quality in throughout the whole process
- SRL have prepared a multitude of different marketing material to support sales activities
- Labindia, our reference laboratory, have relocated testing to a new facility dedicated to BCtect™
- A major launch activity prepared for the November 8th launch in Delhi, supported by DiaGenic
- Subsequent roll out to the larger cities in the coming months

SRL promotion material supporting the launch





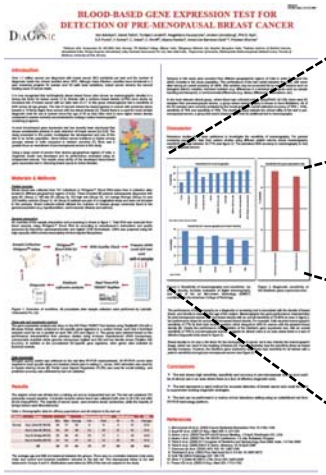





# BLOOD-BASED GENE EXPRESSION TEST FOR DETECTION OF PRE-MENOPAUSAL BREAST CANCER

Ken Bårdsen[1], Derek Tobin[1], Torbjørn Lindahl[1], Magdalena Kauczynska[1], Anders Lönneborg[1], Phil D. Rye[1], D.P. Punia[2], Y. Kumar[3], C. Desai[4], C. Shroff[5], Alpana Razdan[6], Anne-Lise Børresen Dale[7, 8], Praveen Sharma[1]

[1]DiaGenic ASA, Grenseveien 92, NO-0663 Oslo, Norway; [2]SP Medical College, Bikaner India, [3]Bhagawan Mahavir Jain Hospital, Bangalore India, [4]Vedanta Institute of Medical Sciences, Ahmedabad India, [5]Shreya Hospital, Ahmedabad, India, [6]Labindia Instruments Pvt. Ltd., New Delhi India, [7]Department of Genetics, Rikshospitalet-Radiumhospitalet Medical Centre, [8]Faculty of



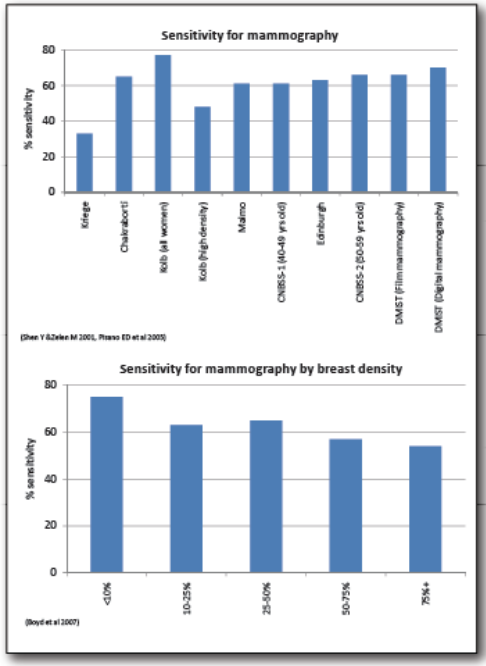




**Figure 2. Sensitivity of mammography and sensitivity by breast density.** Includes evaluation of digital mammography and state of the art film-screen technology (DMIST) coordinated by the American College of Radiology.

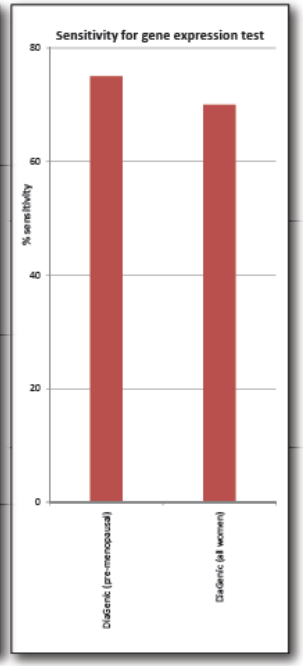



**Figure 3. Diagnostic sensitivity of the DiaGenic gene expression test.**

"International Society of Oncology and Biomarkers" conference

Tokyo
5-9th October.

# Product Update

BCtect™

DiaGenic for early Breast Cancer detection

towards

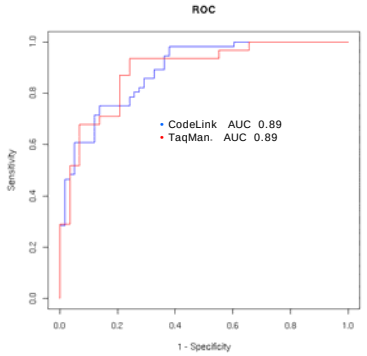
IN VITRO DIAGNOSTIC DIRECTIVE CE

# Prototype vs. BCtect™

## Prototype:

### Study Size

| Study / assay format | N | BC | Non-BC |
|---|---|---|---|
| TaqMan® 384-assay | 60 | 31 | 29 |

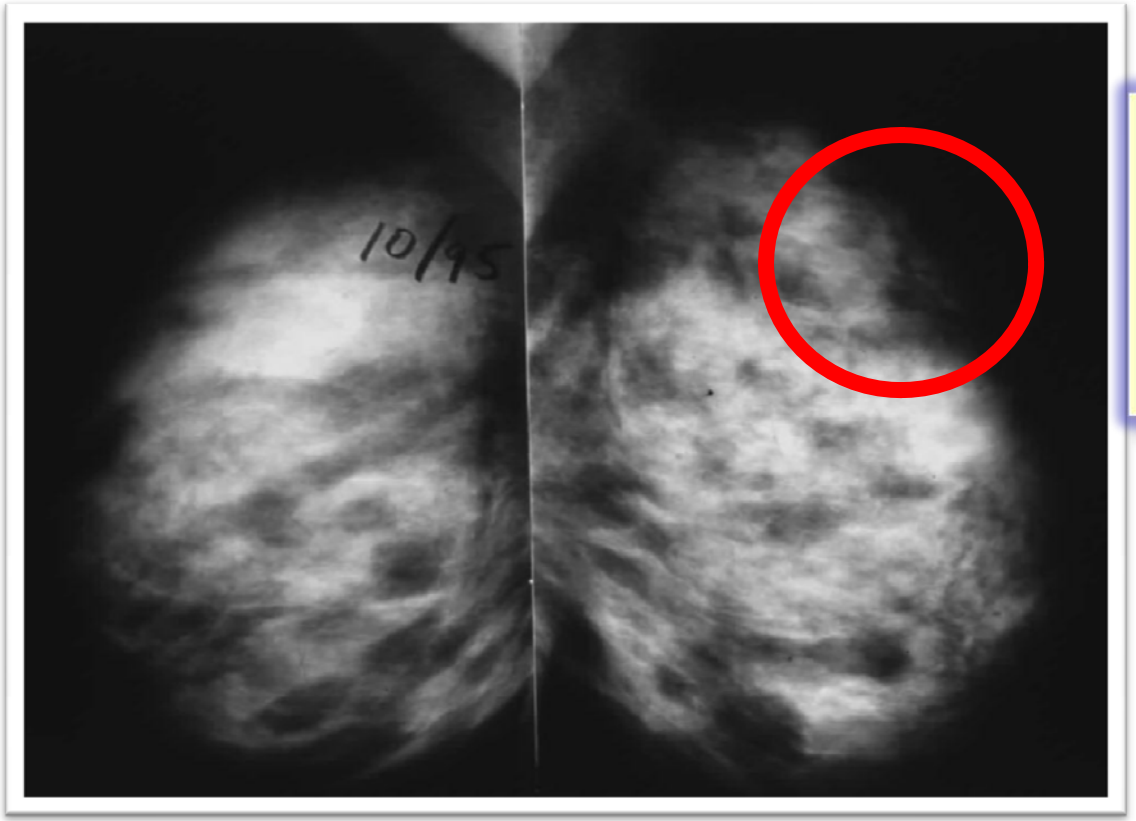



### Study Results

| Study / Signature | Sensitivity | Specificity | Accuracy | AUC |
|---|---|---|---|---|
| TaqMan® 74 genes | 87% | 76% | 82% (10%) | 0.89 |

The ongoing CE studies on BCtect™ encompass more than 700 cases and controls, thus >10 times the size of the prototype study.

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**

Positioning

–

BCtect™
DiaGenic for early Breast Cancer detection

after

IN VITRO DIAGNOSTIC DIRECTIVE CE

- Early diagnosis of Breast cancer
  - Premenopausal females
    - Symptomatic patients
    - High Risk
  - ILC detection (often negative on mammography)
  - Optional first line test if warranted
- Support other diagnostic modalities
  - Problem solver for inconclusive mammography or fine needle aspiration cytology
- Future positioning (to be developed pending financing)
  - Screening in high risk/younger females
  - Post surgery verification of treatment success
  - Monitoring of disease relapse after initial treatment
  - Companion diagnostics w. pharma

# ADtect™

DiaGenic for early Alzheimers Disease detection

## Product Update

towards

IN VITRO DIAGNOSTIC DIRECTIVE CE

Positioning

–

ADtect™
DiaGenic for early Alzheimers Disease detection

after

IN VITRO DIAGNOSTIC DIRECTIVE CE

- Early diagnosis of Alzheimer's Disease
  - Memory clinics / Neurology clinics
  - (GPs – who should be referred to specialists)
- Support other diagnostic modalities
  - Select patients for advanced imaging (MRI, PET) in AD workup
  - Confirm imaging findings
    - Most imaging are not sensitive/specific for AD and are used to exclude other diseases
- Future positioning (to be developed pending financing)
  - Diagnosis of Mild Cognitive Impairment
    - Ongoing FUGE and EU projects
  - Monitoring of disease progression
  - Companion diagnostics w. pharma

# DiaGenic receives 580 thousand Euro in research grant from the European Commission


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

- **QIAGEN GmbH** to coordinate development of improved preanalytical and RNA extraction methods for diagnostics
- **DiaGenic**, as the only company, to develop blood based tests
  - Identify RNA probes indicating sample quality
  - Using the improved process in our ADtect™ test
    - Optimize accuracy
    - Optimize sample handling and logistics
    - Reduce technology costs
- **European Committee for Standardization (CEN)** to develop evidence-based, international guidelines and quality-assurance schemes.

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## Market Entry Strategy with Revenue Streams

1. Biomarker (R&D Pharma)
2. India – BCtect™ — H2 '08
3. Europe - BCtect™ + ADtect™ — H1 '09

- Initial focus:
  - Establish centralized lab testing for our tests

DNA VISION sa
YOUR GENETIC SOLUTION

DNAVISION
YOUR GENETIC SOLUTION

- A leading European service provider of genetic analyses for industry and healthcare professionals.
- To provide new genetic tests based genetic markers
- DNAVISION has a full range of services within the molecular diagnostics field
- A service provider for top 10 pharma companies, several diagnostic and biotech companies
- Experience with RNA extraction with the PAXgene™ system
- Certified by Applied Biosystems as TaqMan™ service provider
- Full range of quality system documentation
  - Accredited by BELAC, ISO certified, CLIA and CAP approved



1. Biomarker (R&D Pharma)
2. India – BCtect™ — H2 '08
3. Europe - BCtect™ + ADtect™ — H1 '09

## Market Entry Strategy with Revenue Streams

- Establish centralized lab testing for our tests
- Establish a distributor network
  - UK: Dr James MacKay, former Medical Director of Opaldia, is a consultant for DiaGenic and his team is currently preparing the logistical network for UK access to our tests in the private health care segment

  - No change in DiaGenic's overall marketing strategy in UK, we expect to have the network in UK in place when our tests are CE marked.

1. Biomarker (R&D Pharma)
2. India – BCtect™ — H2 '08
3. Europe - BCtect™ + ADtect™ — H1 '09

## Market Entry Strategy with Revenue Streams

- Establish centralized lab testing for our tests
- Establish a distributor network in countries with a sizeable private payer segment.
  - Ongoing discussions with several distributors across Europe, with an initial focus on market access to the private payer segment.

## Market Entry Strategy with Revenue Streams

1. Biomarker (R&D Pharma)
2. India – BCtect™ — H2 '08
3. Europe - BCtect™ + ADtect™ — H1 '09
4. Other Countries excluding US — H2 '09
5. US – FDA approval of AD
   US – Centralized Lab Tests
6. *Screening Approval EU & US*

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# Outlook

- DiaGenic will launch the BCtect™ test in New Delhi in collaboration with our partners Super Religare Laboratories and Labindia on 8 November 2008. The other major cities in India will follow in early 2009. DiaGenic will actively contribute to support the launch and marketing of the test.

- In light of the global financial turbulence DiaGenic has chosen to give priority to activities that are necessary to bring forward products for sale. In addition to the launch in India these are activities that are necessary to obtain the CE mark in Europe for BCtect™ and ADtect™.

- The company is in process to establish a distribution network for Europe and expects that such a network will be in place for the most important countries when CE marking of the products is obtained. When the tests have been launched in Europe the company will have diagnostic tests on sale in two important geographic regions.

- DiaGenic will continue to seek external funding (research grants, partner deals and non dilutive financing) of costly clinical studies for development of new products and for entry into new geographic markets.


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# 20 Largest Share Holders

October 30th 17:00

| Shares | Percent | Name |
|---|---|---|
| 3 439 135 | 6.65 | VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS |
| 3 182 000 | 6.15 | NORDEA BANK SWEDEN A A/C NORDEA HEDGE FUN |
| 2 890 000 | 5.59 | LØNNEBORG ERIK ANDERS |
| 2 510 000 | 4.85 | SHARMA PRAVEEN |
| 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 |
| 1 401 670 | 2.71 | NORDEA BANK PLC FINL |
| 1 400 000 | 2.71 | SKAGEN VEKST |
| 1 318 330 | 2.55 | JPMBLSA NORDEA LUX LENDING A |
| 1 097 387 | 2.12 | HOLBERG NORGE V/HOLBERG FONDSFORVA |
| 1 003 100 | 1.94 | LIVSFORSIKRINGSSELSK STRATEGISK |
| 868 478 | 1.68 | SÆTERØY HÅKON |
| 862 000 | 1.67 | AMFIBIEN AS |
| 783 300 | 1.51 | VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS |
| 654 378 | 1.26 | STORHAUG DAG |
| 590 000 | 1.14 | HAAVIND KARL WILHELM |
| 535 000 | 1.03 | DnB NOR MARKETS, AKS MARKET-MAKING DERIVA |
| 476 100 | 0.92 | SANDEN A/S C/O JAN PETTER COLLI |
| 410 238 | 0.79 | SEB ENSKILDA ASA EGENHANDELSKONTO |
| 29 123 986 | 56.29 | 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.