



**DiaGenic**  
**"Most Innovative Company of the Year"**

-  
**3<sup>rd</sup> Quarter 2009**

**Erik Christensen, MD PhD**

Chief Executive Officer

**Ruben Ekbråten**

Financial Controller

**DiAGENiC**

FOR EARLIER DISEASE DETECTION



# Breaking News:

## Distributor contract for UK and Ireland signed with a world leading diagnostic company



Alzheimer's disease:

**New cases:** 53.000

Breast cancer:

**New cases:** 41.000

**New cases (age 0-44):**8.600

**Total symptomatic women**

**(age 30-49):** 190.000

**Mammograms per annum**

**in women aged 30-49:** 381.000

DiaGenic announces that it has signed an agreement with a world leading provider of diagnostic testing and services to patients and doctors to market its BCtect® for early detection of breast cancer and ADtect® for early detection of Alzheimer's in the UK and Ireland. Both tests uniquely use peripheral blood as the sample material to provide early non-invasive diagnosis of these complex diseases.

“The agreement is a major milestone in DiaGenic's development, making these innovative tests commercially available through this prestigious partner in UK and Ireland,” said DiaGenic CEO Erik Christensen, M.D., Ph.D. “Both tests have already attracted major interest amongst clinicians, researchers and patients. Following CE certification in the summer, we are delighted to be able to offer these tests within the UK and Ireland”.

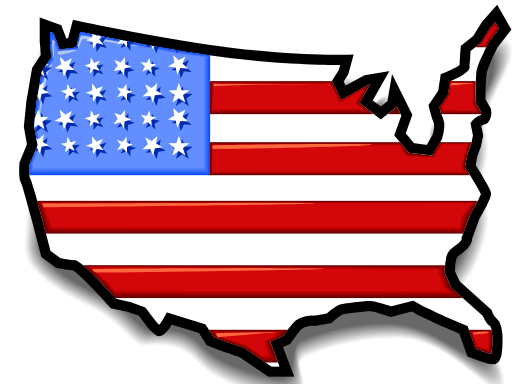
A joint press release on product launch will be published at a later stage.



## DiaGenic Europe strategy



- Signed 5 distributors covering 10 countries, all with minimum volume commitments
  - Aggregated minimum volume for 4 years is 100.000 tests
  - End user price suggested at €600
  - These contracts represents approx 40% of the total European market
- In final stages of negotiating contracts for rest of Europe
- Identifying and preparing partners for new regions



## DiaGenic US strategy

- CLIA route, an intermediate solution for early market access
  - Through a central CLIA certified laboratory
  - Building blocks needed for US entry
    - A partnering central lab, dialogue initiated
    - Sales and marketing support through this partner preferably
    - Reimbursement through CPT code stacking is \$640
    - A CE “light” documentation, including some US samples, needed for a “Lab Developed Test (LDT)”.
- Overall compliance with FDA pursued
  - FDA are currently reviewing IVDMA technology, no immediate changes expected
  - DiaGenic met with FDA March 08
    - Path: PMA vs 510k *denovo*
    - Clinical trial needed, 8 sites, 600-1000 patients
    - FDA cleared instrument
      - Current AB 7900HT is used by FDA cleared tests

## Agenda: 3<sup>rd</sup> Quarter 2009 Presentation

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

# DiaGenic – Norway's Most Innovative Company of the Year



- Over 1,000 Norwegian business leaders voted to crown this developer of a groundbreaking diagnostics method as Norway's Most Innovative Company of the Year for 2009. The biotechnology firm won an overwhelming majority of the votes as industry's own representatives selected the winner from six companies nominated by the Research Council.

# 3<sup>rd</sup> Quarter 2009 Highlights

- ♦ Scientific marketing of ADtect® and BCtect® started in several European countries
- ♦ DNAvision approved for routine use
- ♦ Notice of Allowance for additional European patent on Alzheimer's disease and breast cancer
- ♦ Bridge financing of MNOK 9.35

## Post quarter end

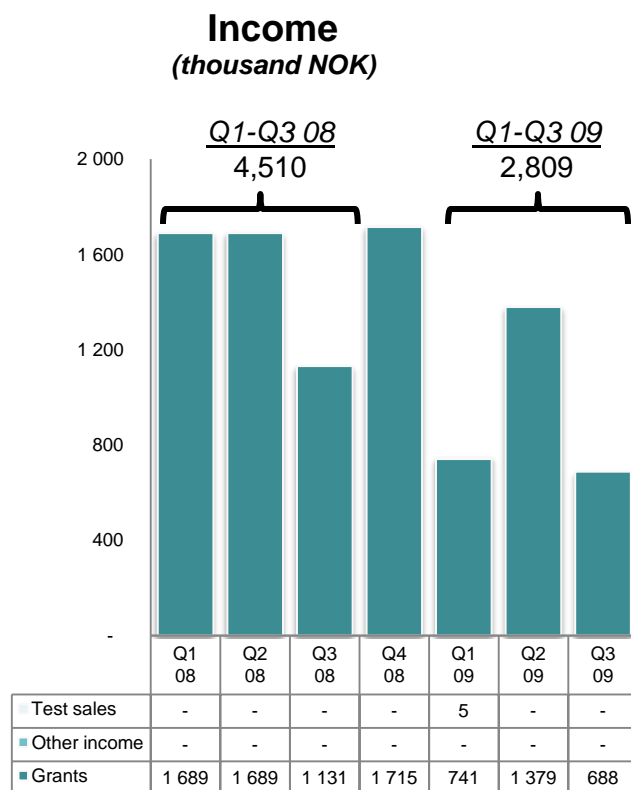
- ♦ Distributor contract for UK and Ireland signed with a world leading provider of diagnostic testing and services
- ♦ Norway's most innovative company prize awarded

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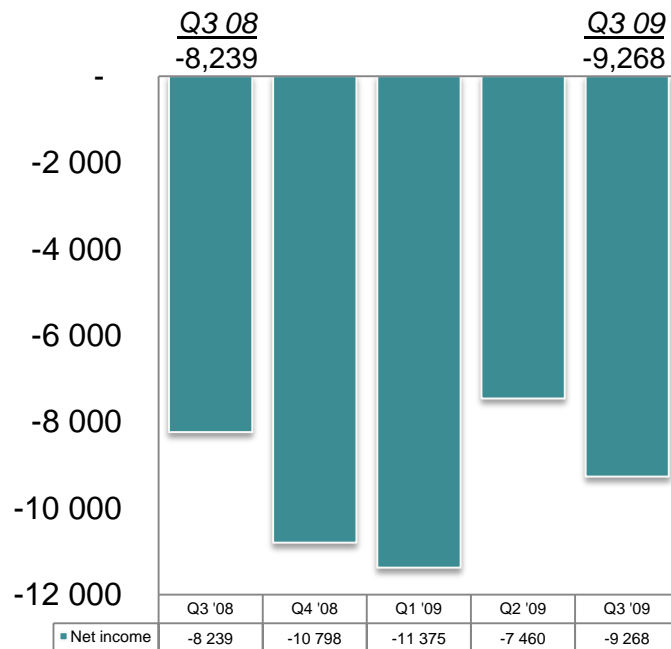
# Finance, Income



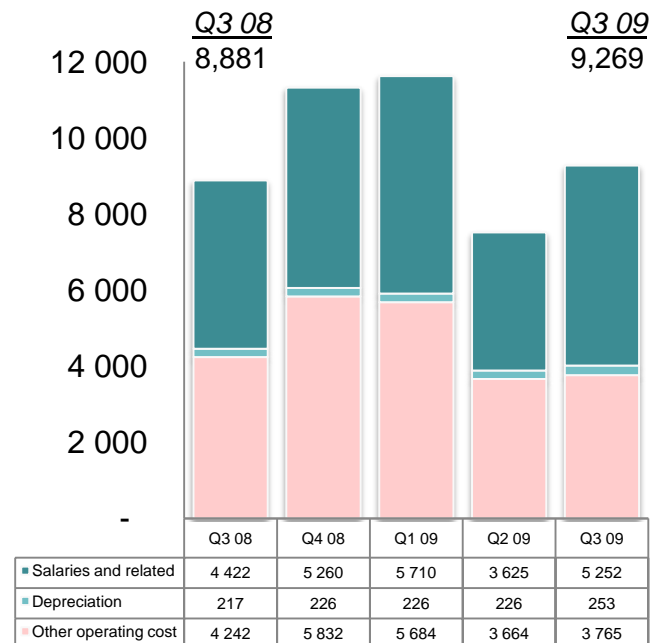
- Research grants in Q3 '09 consist of support from:
  - Michael J. Fox Foundation
  - Innovation Norway
  - EU Commission
  - The Research Council of Norway
- The FUGE Alzheimer's project ended in 2008 and is the main driver for reduced research grants.

# Finance, Profit & Loss

**Net Income**  
(thousand NOK)

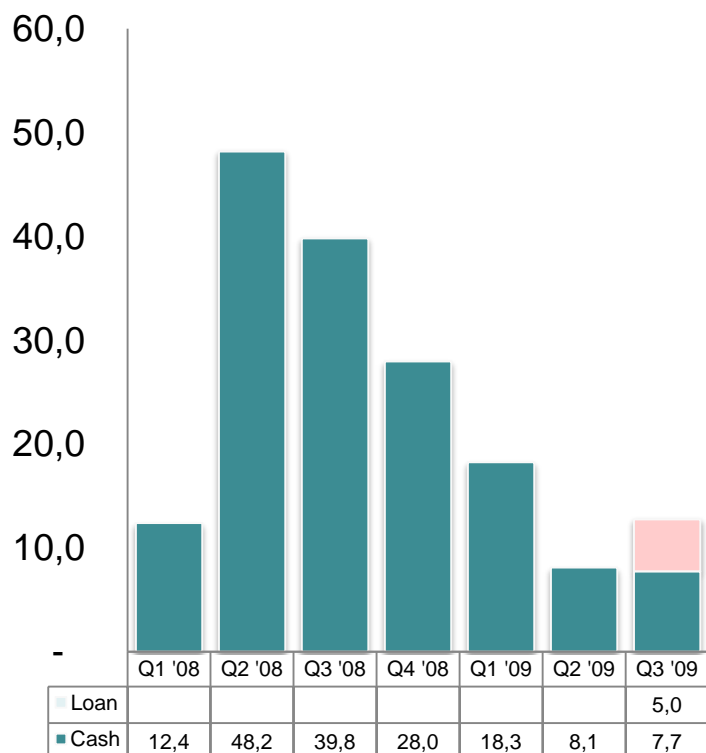


**Operating Cost**  
(thousand NOK)



# Finance, Cash Balance

**Cash and Cash equivalents**  
(million NOK)



- Bridge financing in third quarter
  - Gross proceeds from the issue: NOK 9.4 million
  - Subscribed by large shareholders, Directors and one new institutional investor
- Post quarter: Loan from Innovation Norway
  - 5 million NOK in loan
  - 4 years term
  - Current annual interest rate: 5.75%

# Finance, 2009 Future prospects

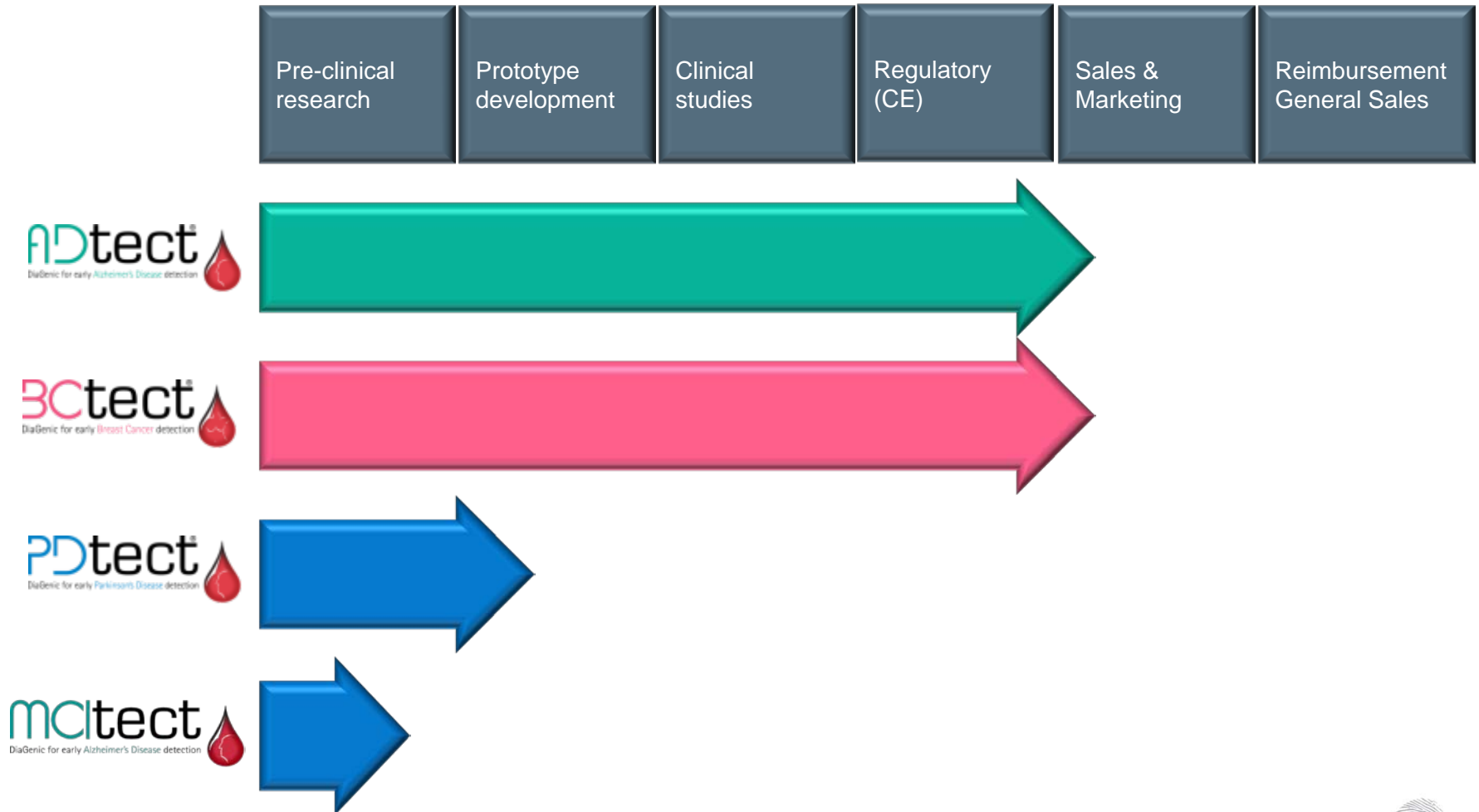
- Burn rate for fourth quarter 2009 expected to be similar to third quarter 2009.
- The Company is funded until the beginning of 2010
- The Board of Directors and its' advisors are working to secure the long term financing of the Company

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# Product portfolio

## Molecular Diagnostics



FOR EARLY DISEASE SIGNATURES

**DiA**GENIC

# ADtect™

early detection of

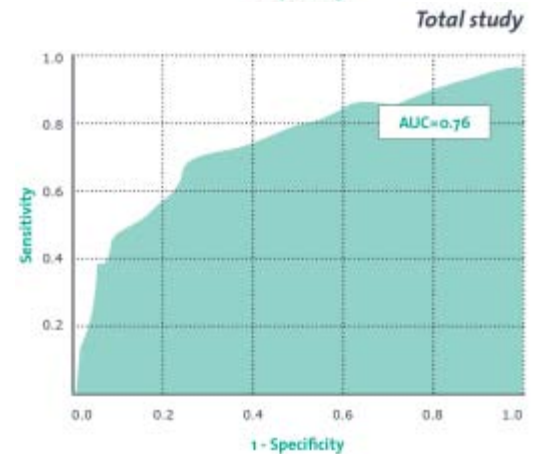
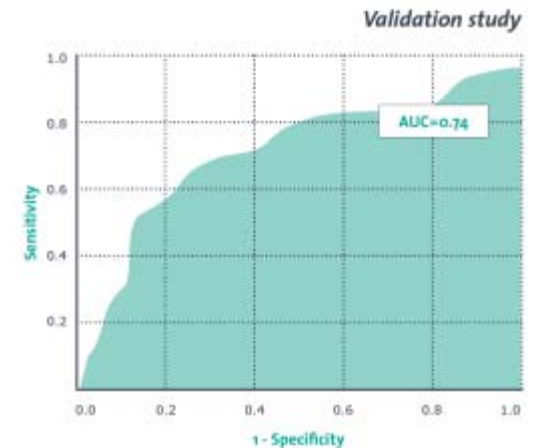
Alzheimer's disease



# Multi-centre study for ADtect® CE-marking

Performance Data	Independent cohort	Total Study Intended use population
Number	74	248
Accuracy	71.6%	72.6%
Sensitivity	71.9%	73.3%
Specificity	71.4%	72.0%

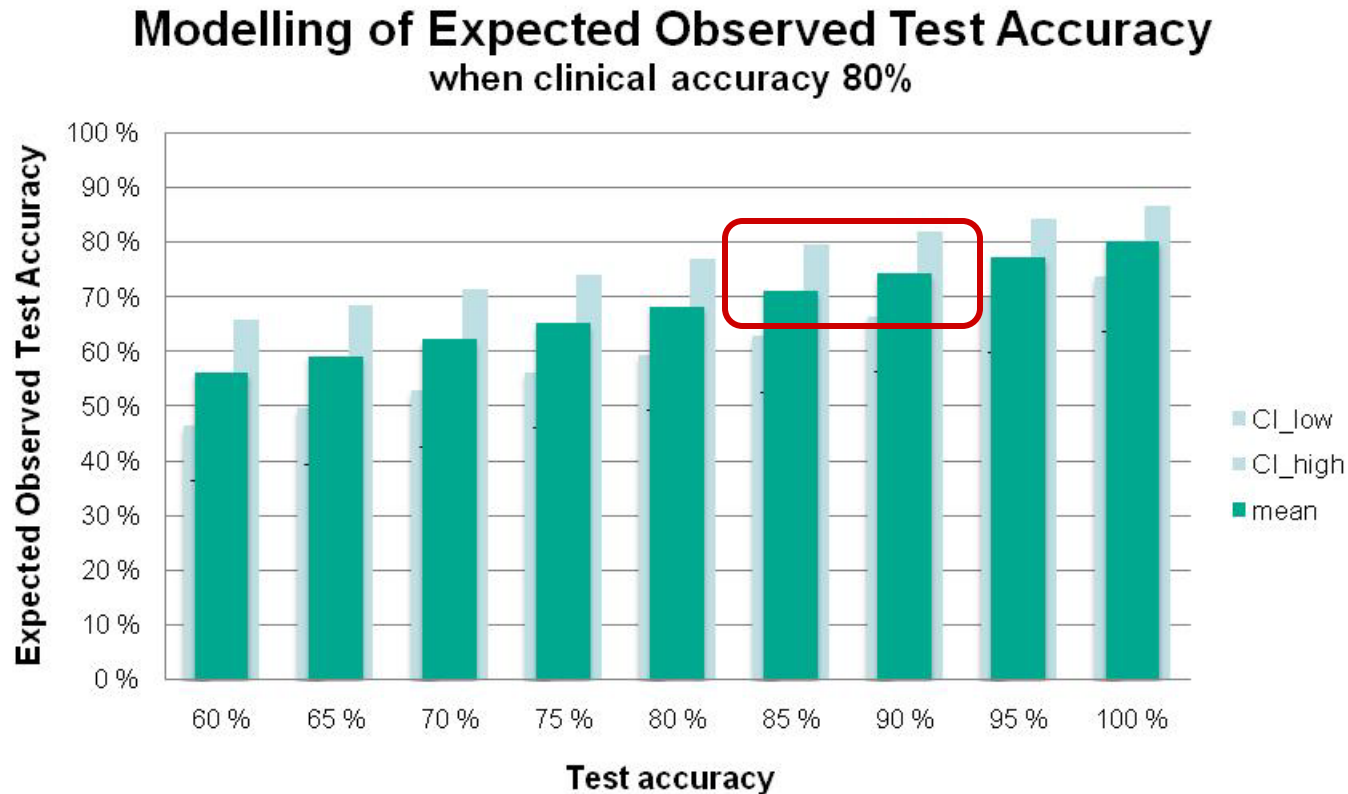
- Using only one blood sample at first patient visit
- Overall 73% accuracy of ADtect® across sites
- Accuracy independent of disease stage, early diagnosis needed for early treatment
- Clinical accuracy varies between sites (67%-82%);
  - From ~60% at GP's, to ~85% at top Universities in Sweden where data from MRI imaging, clinical testing and CSF samples are combined before final diagnosis
  - Estimated clinical accuracy in this study is 80%





# Implication of imperfect gold standard

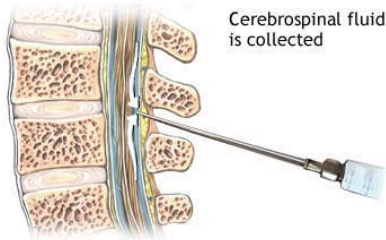
Example: Assumed clinical accuracy of 80%



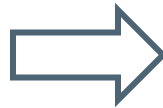
# Multi-centre study – Spinal fluid (CSF) results

- Some of the clinical samples from our CE study contained CSF information on 3 different proteins
- 9 out of 10 CSF was correctly predicted by ADtect®
- Additional studies initiated to increase study size

## CSF biomarker



Cerebrospinal fluid  
is collected



- Invasive
  - Medical complications
  - High clinical costs
- Limited clinical use, in spite of ~85% accuracy

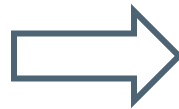
© ADAM, Inc.



- Non invasive
- Objective
- Less Expensive
- Patient friendly

# ADtect™ Clinical Benefit and Value

- The challenges with Alzheimer's disease (AD) and diagnosing patients:
  - AD is a large burden on patients, their relatives and to the society
  - Diagnosing AD in Europe ranges from 32 months in UK to 10 months in Germany
  - AD diagnosis requires multiple visits to specialists for monitoring of disease progression and current techniques has low clinical accuracy
  - Uncertainty on mild AD cases delays referral to specialists
  - Limited access to expensive imaging (PET/SPECT)
- Early detection of Alzheimer's disease...
  - Enables treatment schemes (medication, nutrition, exercise etc) that could delay placement of patients in nursing homes by preserving higher function levels, and allow more time to plan for the future.



- Fast turn around time
- Non invasive
- Patient friendly
- Objective
- Less Expensive

*ADtect® ensures that Alzheimer 'spatients are diagnosed early, thereby improving quality of life and saving costs for the society*

# 3Ctect<sup>TM</sup>

early detection of

Breast Cancer



# Multi-centre study for BCtect® CE-marking

Cohort	N	Accuracy
BCtect® accuracy (total study)	332	72%
Menopausal status		
Pre-menopausal	140	71%
Post-menopausal	192	73%
Breast cancer stage		
Early stages (0-I)	89	71%
Late stages (II+)	87	72%

- BCtect® shows similar good performance with pre- and post-menopausal women
  - In comparison, mammography sensitivity as low as 40-50% in pre-menopausal females
- BCtect® shows similar good performance with early and late stage breast cancer
  - Detected tumours as small as 4mm!
- All tumour types detected
  - Including Lobular carcinomas that often is invisible on mammograms
  - No relationship to receptor status, the most aggressive tumour type, triple negative, are detected with equal efficacy as entire population

# BCtect<sup>TM</sup> Clinical Use and positioning

- Use of BCtect<sup>®</sup> ensures improved cancer diagnosis
  - BCtect<sup>®</sup> as a problem solver:
    - 3.500.000 mammograms annually in Europe, best suited for post-menopausal females
    - 16% of referred cases are false positive from the screening mammograms
    - 3 out of 4 biopsies are negative
    - 10% of referred cases are inconclusive - Increased breast density and difficult tumour types
  - BCtect<sup>®</sup> as a first-line test; asymptomatic, pre-menopausal females:
    - High-risk market: 250,000 tests in Europe p.a.
    - Symptomatic market: 250,000 tests in Europe p.a.
    - BCtect<sup>®</sup> - a first line test for asymptomatic females with worries due to family history, resistance to mammography or who is not part of a screening program
  - Early diagnosis improves patients survival and quality of lives



DiaGenic for early Alzheimer's Disease detection

# MCI tect multi-center study

- Aim: To identify and validate a blood based gene expression signature to identify MCI that go on to develop AD.
- Ongoing multicentre in Scandinavia since 2007, starting in 2009 also in the US
  - To include 500 MCI patients and 200 controls
  - Sites Norway and Sweden
    - Ullevål University Hospital, Oslo, Dr. Nina Voss Skaane
    - Haraldsplass Diakonale Hospital, Bergen, Dr. Mala Naik
    - Geriatric Dept. Stavanger University Hospital, Dr. Dagne Hoprekstad
    - Sanderud Memory clinic, Sykehuset Innlandet, Dr. Peter Horndalsveen
    - Karolinska University Hospital, Stockholm, Prof. Lars-Olof Wahlund
    - Lund University Hospital, Dr. Christer Nilsson
    - Stockholmsgeriatriken, Stockholm, Dr. Eva Pilenvik
    - Uppsala Akademiska Hospital, Prof. Lars Lannfelt
  - US site
    - UC Davis, Prof. Charles deCarli (PI), to include 200 MCI and 50 controls





DiaGenic for early Parkinsons Disease detection

## Early stage development

- In early stage of development of a biomarker and a diagnostic test for early detection of Parkinson's disease
- Fully funded by external sources
  - Michael J. Fox project
    - Aims to develop a biomarker for pharma use is on schedule
    - Diagnostic accuracy on blinded samples from Harvard with similar high accuracy as our other tests (ROC AUC >0.80)
  - The Norwegian Research Council IVD project
    - Aims for a CE approved diagnostic test
    - Multi-centre trials with university hospitals in Norway, Sweden, and other European countries
    - Ahead of schedule; after less than one year 204 out of 250 patients enrolled

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# Two-segment business model



## Rx– business

Biomarker for Prescription drug use

# "Blood biomarkers for Alzheimer's disease"

Winblad B., Lönneborg A. European Neurological Review 2008; 3(2)



## Biomarkers for the Future

"In the field of biomarkers, there may be particular merit for the use of approaches that simultaneously assay multiple biological markers and their interactions.

These approaches have the potential to take into account the fact that AD is a multifactorial disease and that it is both clinically and histopathologically heterogeneous."

"Biomarkers that include only one or a few of these processes are less likely to be AD-specific and sensitive enough to detect all subgroups of the disease."

Prof. Bengt Winblad

Karolinska Institute's Alzheimer's Disease Research Centre

# Possible utilities and positioning for pharma

## ADtect® in clinical trials

- Triage of patients
  - Use as stand alone test for “clean-up” of AD population
- Triage of controls
  - Ensure no AD pathology in control group
- Benefits :
  - Triage based on broader biological coverage than single pathway markers (t-tau, P-tau, A $\beta$ <sub>1-42</sub>)
  - Homogenous Clinical Cohorts
  - More cost-effective
  - Increases likelihood of successful studies



**Rx-business**

Biomarker for Prescription drug use

## DiaGenic can provide biomarkers for pharma studies

- ♦ **Fully documented and regulatory (Europe) approved tests**
  - ADtect® can ensure a more homogenous study population thus saving costs and improves success rates
- ♦ **Research & development to be financed by external sources**
  - DiaGenic has signed an option contract for biomarker development with the first pharmaceutical company, Merz Pharmaceuticals
  - Received funding for developing a Parkinson's Disease Biomarker
    - Michael J Fox Foundation and the Norwegian Research Council, collaboration with key opinion leaders at Harvard Medical School.
- **Ultimate goal: Companion Diagnostics**
  - A majority of new drugs will need blood based diagnostic tests to identify the right subgroup of patients that will respond to therapy.
  - The regulatory approval of these drugs will depend upon the use of a diagnostic test
  - Further clinical use of the drug is based on the results from the diagnostic test.



# Two-segment business model

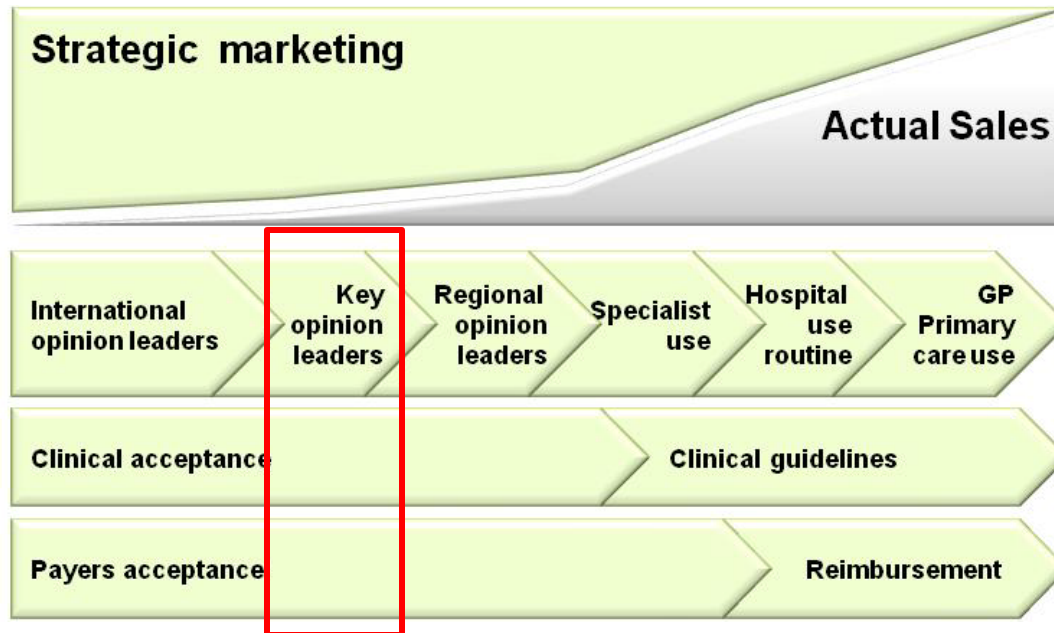


## MDx-business

Molecular Diagnostics

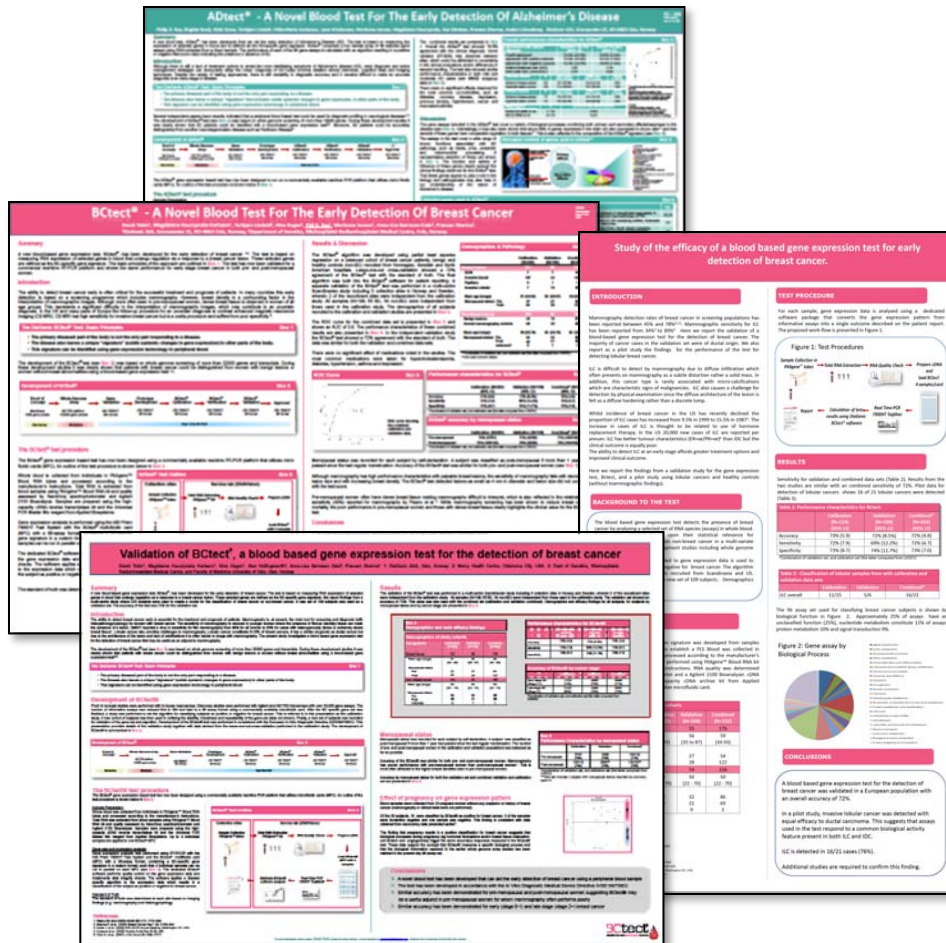


# Scientific Marketing



- DiaGenic and distributors now in the early phase of strategic marketing in Europe
  - KOL meetings to ensure acceptance, although they will not be high volume customers
  - Initiating post launch independent studies to support local needs
  - Local scientific meetings arranged by distributors
  - Promotional material distributed
  - Early adopters identified

# DiaGenic presents CE studies internationally



- The International Alzheimer's disease congress (ICAD) in Vienna, Austria, July 2009
  - "ADtect® - A novel blood test for the early detection of Alzheimer's disease".
- ECCO 15 and 34th ESMO Multidisciplinary Congress in Berlin, Germany Sept. 2009
  - "Efficacy of a novel blood based gene expression test for early detection of breast cancer".
- ISOBM, 37th Congress of the International Society of Oncology and Biomarkers in Amsterdam, the Netherlands Sept 2009
  - "BCtect® - A novel blood test for the early detection of breast cancer".
- ASCO Breast Cancer Symposium 2009 in San Francisco, USA, September 2009
  - "Validation of a blood-based gene expression test for the detection of breast cancer".

All available at [www.dia-genic.com](http://www.dia-genic.com)

# DiaGenic marketing material



FOR EARLY DISEASE SIGNATURES

  
DiaGenic

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# Outlook

- ◆ Complete the distributor network for the larger European markets.
- ◆ Support the distributors in sales and marketing of ADtect® and BCtect®.
- ◆ Proceed with accelerated US market entry plan.
- ◆ Promote ADtect® and companion diagnostics to major pharmaceutical companies by presenting the clinical data from the CE studies and our ongoing MCI studies.

# Conclusion

- ◆ Clinical need for our products confirmed by clinicians and an international diagnostic company.
- ◆ Important minimum volumes in current contracts.
- ◆ Targeting large disease markets.
  - ◆ High unmet medical needs, high big pharma interest.
- ◆ Well defined international marketing strategy.
  - ◆ MDx - Molecular Diagnostics
    - ◆ Launching ADtect® and BCtect® in Europe.
    - ◆ Strategy for accelerated entry into the US market.
  - ◆ Rx – Companion Diagnostics
    - ◆ First contract signed for R&D collaboration.
    - ◆ Developing new biomarkers, PDtect & MCItect.
    - ◆ Promoting our CE marked tests for immediate use.



DiaGenic ASA

Grenseveien 92, N-0663 Oslo, Norway

Tel +47 23 24 89 50

Mail: [diagenic@diagenic.com](mailto:diagenic@diagenic.com)

[www.diagenic.com](http://www.diagenic.com)



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# 20 Largest Share Holders

October 29, 2009

Shares	Percent	Name
3 379 000	6.23	Tredje AP-Fonden C/O HANDELSBANKEN AS
3 050 000	5.62	NORDEA BANK SWEDEN A A/C NORDEA HEDGE FUN
2 900 000	5.35	LØNNEBORG ERIK ANDERS
2 035 000	3.75	SHARMA PRAVEEN
1 969 000	3.63	A/S SKARV
1 646 000	3.03	SKAGEN VEKST
1 584 870	2.92	HOLBERG NORDEN V/HOLBERG FONDSFORVA
1 197 387	2.21	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 024 000	1.89	HAAVIND KARL WILHELM
1 003 100	1.85	LIVSFORSIKRING.NORDE JP MORGAN CHASE BANK
1 000 000	1.84	DNB NOR BANK ASA, EM
868 478	1.60	SÆTERØY HÅKON
829 000	1.53	DnB NOR MARKETS, AKS MARKET-MAKING DERIVA
813 300	1.50	VPF NORDEA SMB JPMORGAN EUROPE LTD,
808 000	1.49	AMFIBIEN AS V/ JOHN HESTAD
650 378	1.20	STORHAUG DAG
640 000	1.18	HESTAD JOHN
526 100	0.97	SANDEN A/S C/O JAN PETTER COLLI
474 227	0.87	GEZINA AS
445 200	0.82	HOLBERG NORDEN III V/HOLBERG FONDSFORVA
<b>26 843 040</b>	<b>49.48</b>	
<b>54 250 000</b>	<b>100%</b>	<b>Total number of shares outstanding</b>