

**DiAGENIC**

FOR EARLIER DISEASE DETECTION



**“Expanded market reach and first  
product sales in Europe”**

**4<sup>th</sup> Quarter 2009**

**Erik Christensen, MD PhD**

**Chief Executive Officer**

**Ruben Ekbråten**

**Financial Controller**



# Agenda: 4<sup>th</sup> Quarter 2009 Presentation

- ♥ 4<sup>th</sup> Quarter Highlights
- ♥ Commercial Strategies
- ♥ 4<sup>th</sup> Quarter Finance
- ♥ Product Development and Clinical Studies
- ♥ Outlook

# 4<sup>th</sup> Quarter 2009 Highlights

- ◆ First product sales in Europe
- ◆ Distributor contract for UK and Ireland
- ◆ “Norway’s most innovative company” (The Research Council of Norway)
- ◆ Private placement of MNOK 34

## Post quarter end

- ◆ Distribution agreement with Ferrer (32 countries)
- ◆ Share issue of MNOK 9.6

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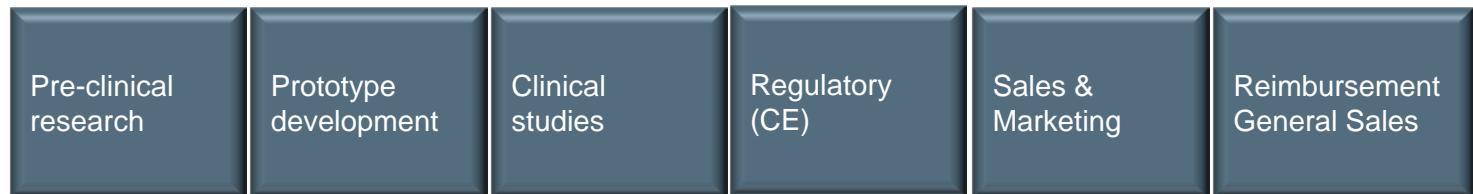
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# Business/Partnering model



# Product portfolio

## Molecular Diagnostics



FOR EARLY DISEASE SIGNATURES

# Two-segment business model



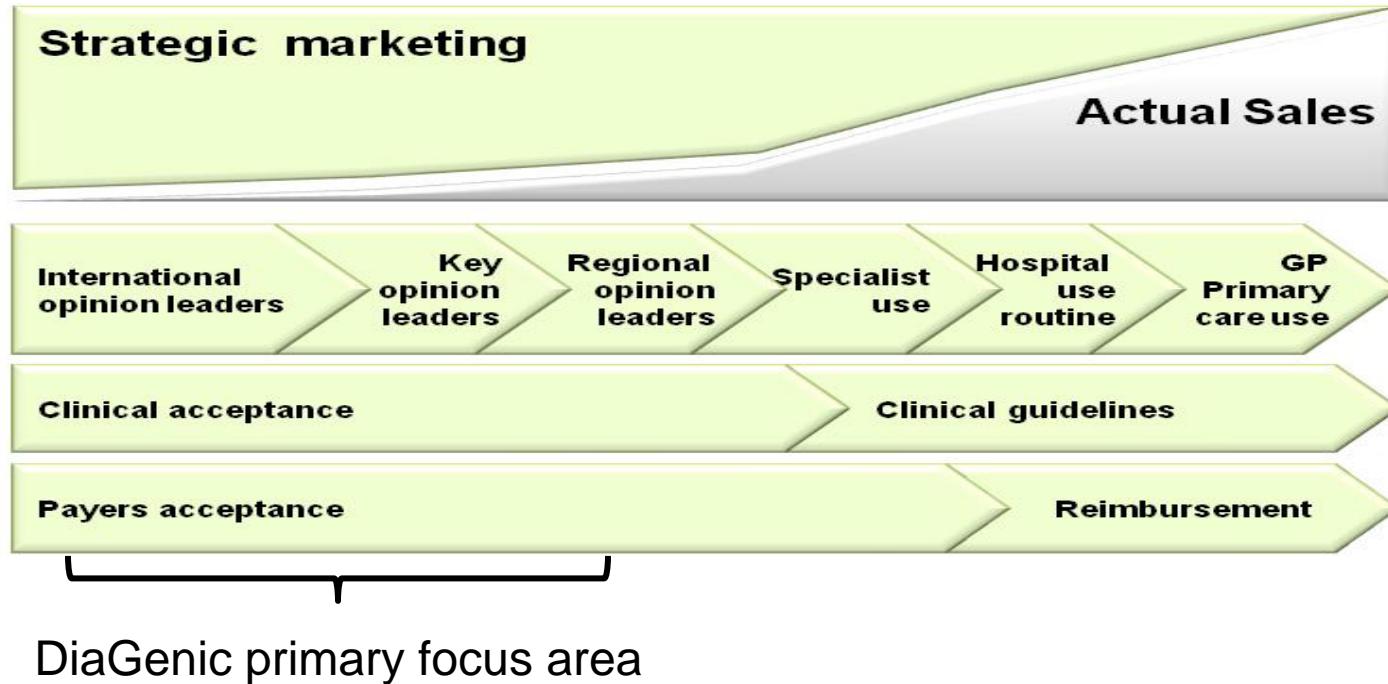
## MDx-business

Molecular Diagnostics



## Rx– business

Biomarker for Prescription drug use





## ADtect® distribution in Europe



- Signed 6 distributors covering 20 countries, all with minimum volume commitments

Key activities last quarter

- Signed up UK and Ireland distributor
- Involved key opinion leaders for introduction of ADtect® in different countries
  - On Local clinical studies to support launch
  - The need for rapid turnaround of results versus cost savings on sample transport
- Prepared article submissions
  - Aiming for leading peer review journals

Contract with Ferrer inCode signed after the quarter



- ◆ Biotech subsidiary of Grupo Ferrer Internacional
- ◆ Privately held company with strong commercial operations in Europe
  - ◆ About 2000 sales representatives worldwide
  - ◆ Dedicated to CNS.

#### Ferrer inCode in personalized medicine

- ◆ Diagnostic, prognostic and prediction services
- ADtect® distribution contract covers 32 countries
  - ◆ Initially Benelux, Germany, Spain and Portugal, France and Italy
  - ◆ Later on also Latin America
- ◆ Competence within CNS, gene expression and sales to clinicians and key opinion leaders



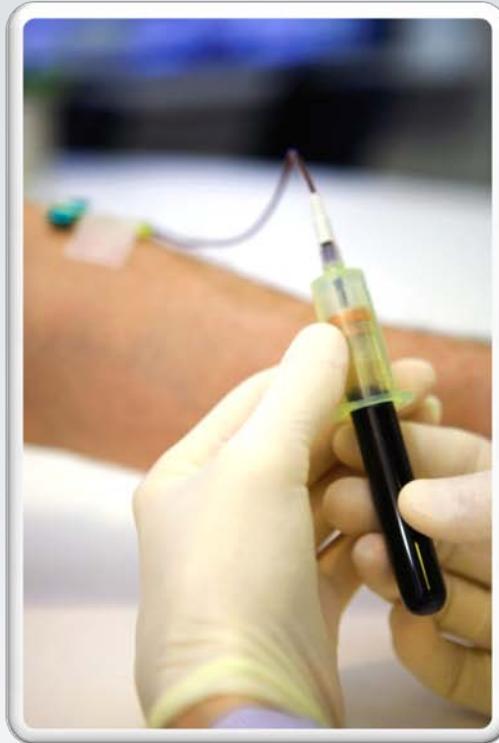


## Current BCtect® distribution in Europe



- ❖ 5 distributors covering 10 countries, all with minimum volume commitments
  - ❖ Identifying and in dialogue with partners for new countries
- ❖ Key activities last quarter
  - ❖ Signing up with the UK and Ireland distributor
  - ❖ Private London clinics ready to use BCtect
  - ❖ Dialogue with key opinion leaders on country/region specific use of BCtect® for
    - ❖ Local clinical studies to support launch
    - ❖ Pricing and payment structures
  - ❖ Preparing and submitting for article publications
    - ❖ Aiming for leading peer review journals
    - ❖ Published article in Breast Cancer Research
      - ❖ *Gene expression profiling of peripheral blood cells for early detection of breast cancer* by J Aaroe et al

# Collection kits



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# Collection kits

- DiAGenic has developed, and are now offering collection kits containing the necessary equipment and consumables for collecting blood samples from the patients.
  - Ensure easy availability of our tests in clinics and in doctor offices
  - Makes the tests more visible and works as an appealing sales tool for the distributors.
  - Ensuring correct blood sampling by using the certified consumables
  - Revenue making
    - The margins in line with the other products from DiAGenic.



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# Two-segment business model



## Rx– business

Biomarker for Prescription drug use

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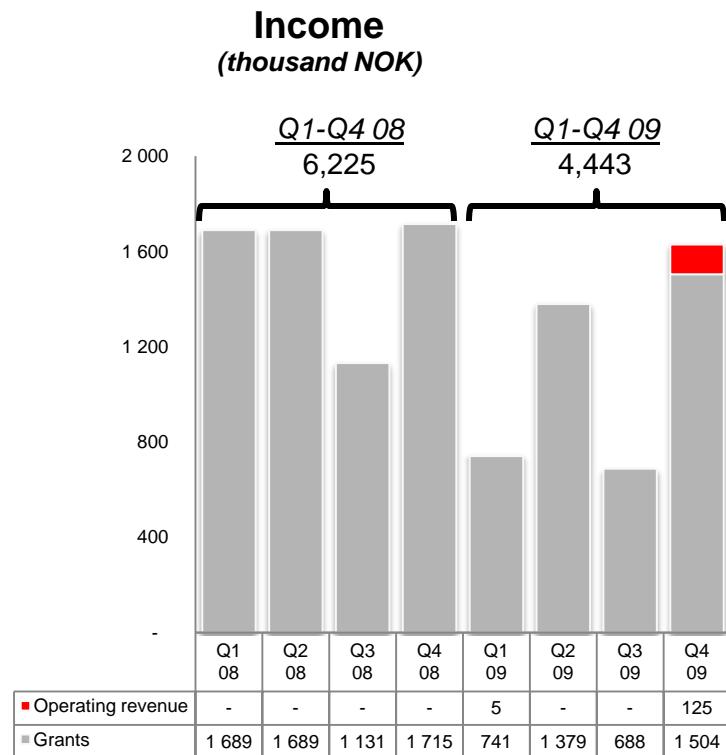
## DiaGenic can provide biomarkers for pharma studies

- Fully documented and regulatory (Europe) approved tests
  - ADtect® can improve clinical trial performance
  - Represented at the Alzheimer Association Research Roundtable, on "Global issues in drug development for Alzheimer's disease" in Washington
  - Presented and was highlighted at Stephen Burrills annual "The Burrill Personalized Medicine Meeting" in San Francisco
- Research & development to be financed by external sources
  - Non exclusive option contract with Merz Pharmaceuticals
    - US research activities increased
      - Collaboration with University of California, Davis. on development of an Mild Cognitive Impairment test, MCItect®.
    - External funding for developing PDtect®, a Parkinson's Disease Biomarker
- Ultimate goal: Companion Diagnostics
  - Joint drug and diagnostic test development for combined clinical use

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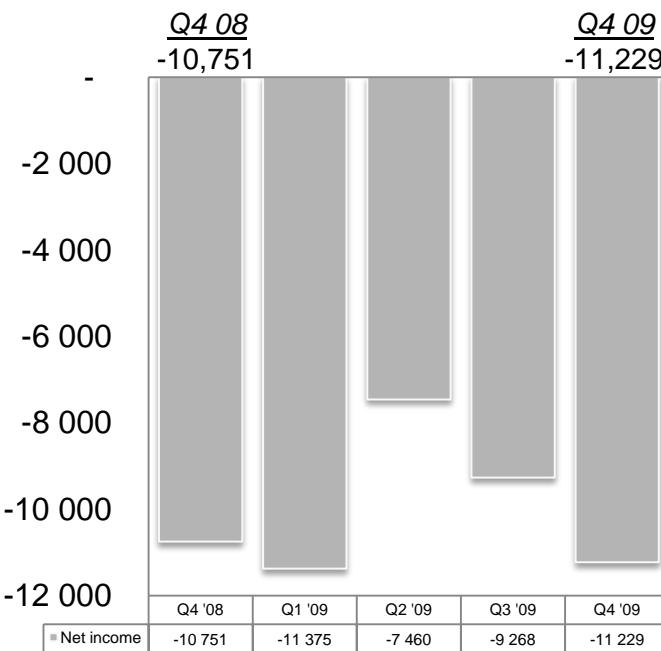
# Finance, Income



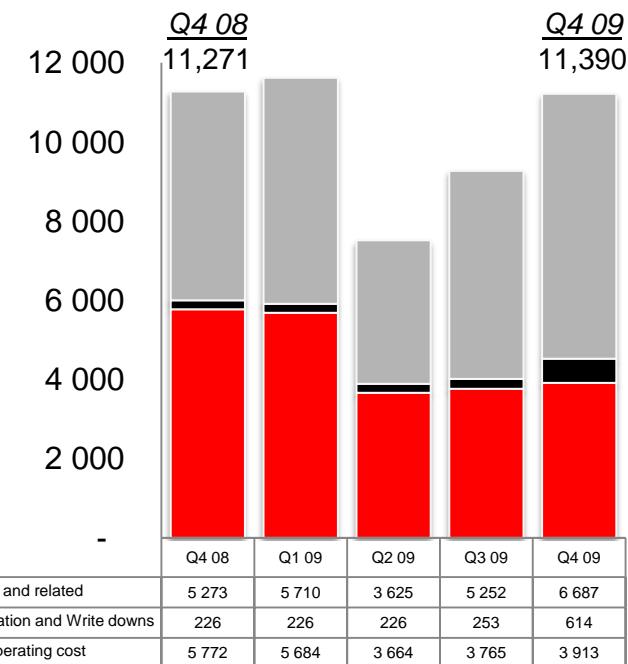
- Operating revenue NOK 125k in 4<sup>th</sup> quarter 2009:
  - Sale of collection kits
- Research grants in Q4 '09 consist of support from:
  - Michael J. Fox Foundation
  - Innovation Norway
  - EU Commission
  - The Research Council of Norway
- The FUGE Alzheimer's project ended in 2008 and is the main driver for reduced research grants.

# Finance, Profit & Loss

**Net Income**  
(*thousand NOK*)



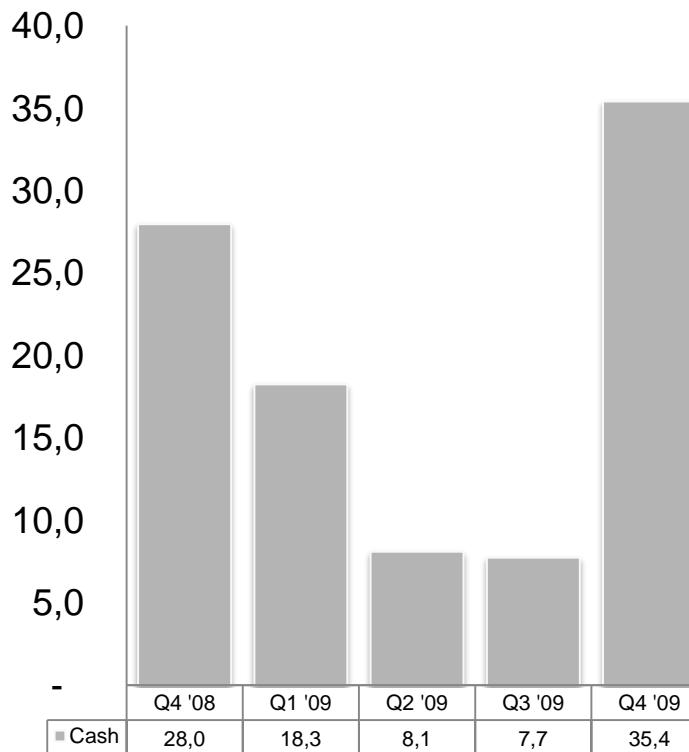
**Operating Cost**  
(*thousand NOK*)



# Finance, Financing

## Cash and Cash equivalents

(million NOK)



- Private placement completed in fourth quarter
  - Issue of 12,5 million shares with gross proceeds of NOK 34.4 million
- Accepted a NOK 5 million loan from Innovation Norway
- Repair issue oversubscribed post quarter
  - Subscription for 7.8 million shares of 3.5 million on offer
  - Subscription price of NOK 2.75 per share with gross proceeds of NOK 9.6 million

# Finance, 2010 Future prospects

- ◆ Warrants to be issued
  - ◆ One warrant for each share allotted in the private placement and in the public offering.
  - ◆ Subscription price: NOK 3.25 per share
  - ◆ May be exercised up to 30 September 2010
- ◆ Costs for first quarter 2010 expected to be similar to fourth quarter 2009.

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# ADtect™

early detection of

## Alzheimer's disease



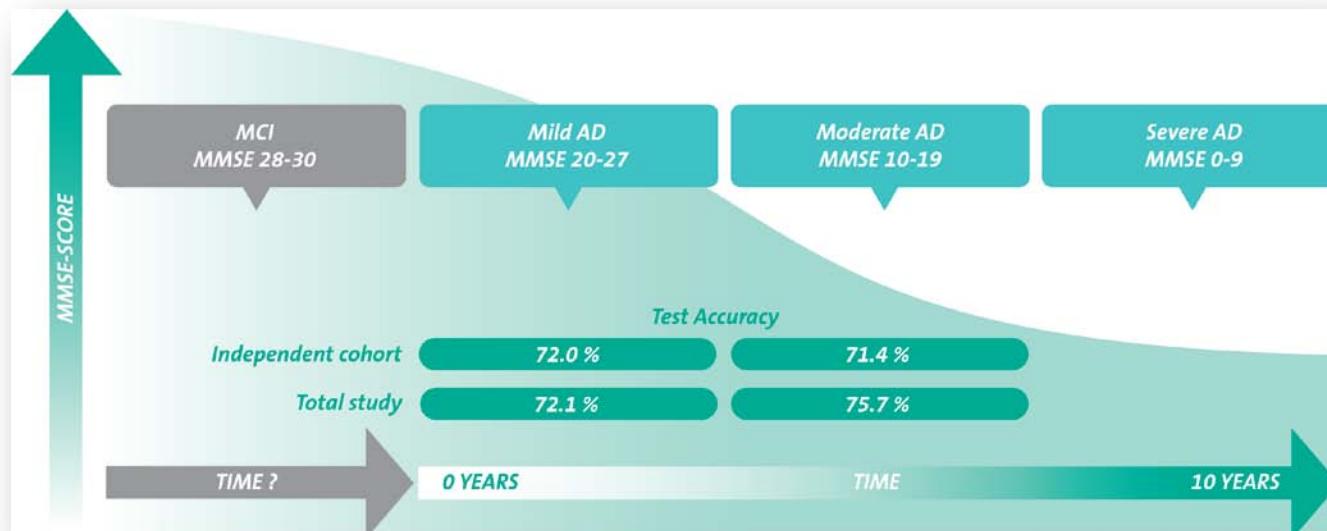
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## Multi-centre study for ADtect® CE-marking

- Patient recruitment into the study was from memory clinics
- ADtect® demonstrated the same accuracy among the challenging group of early AD patients as in moderate AD.
- Supports the use of ADtect® as an aid in the diagnosis of Alzheimer's disease in this patient population.

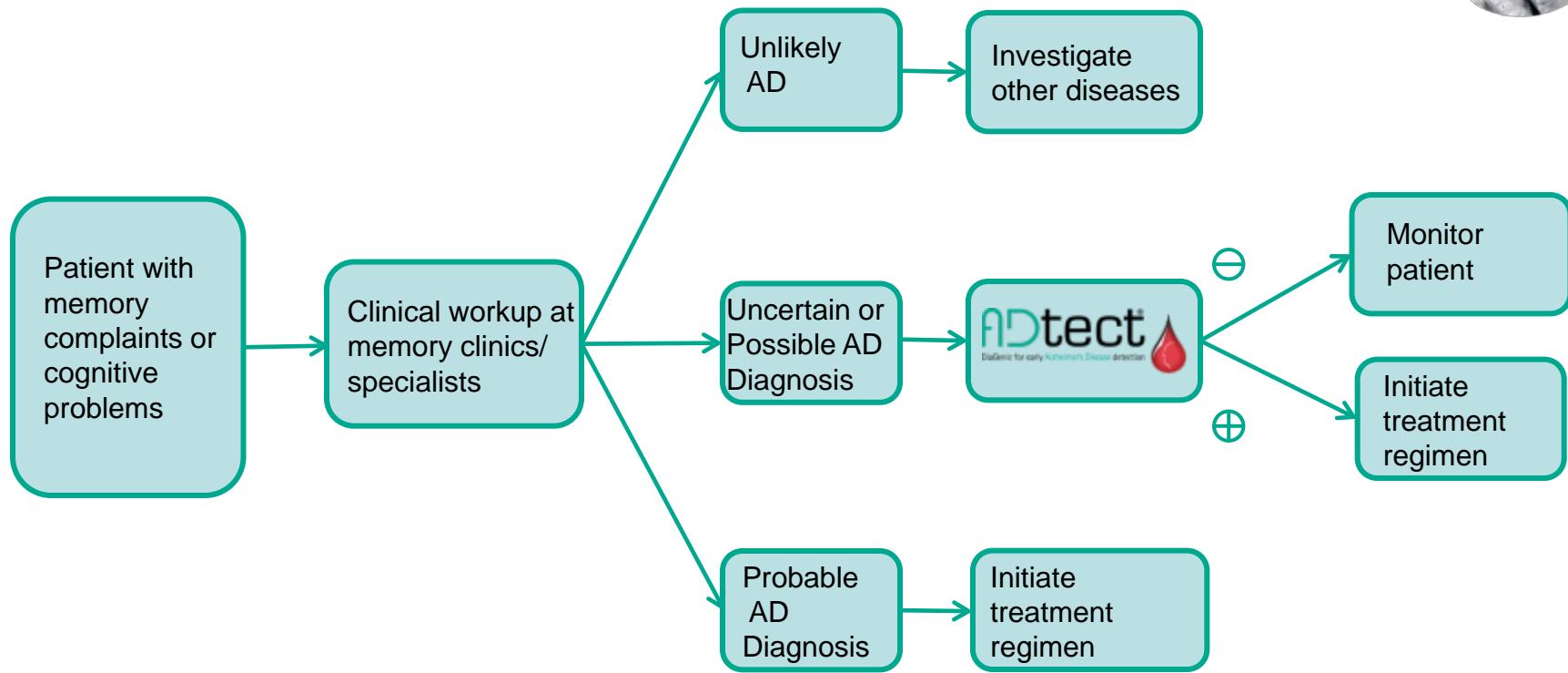


# ADtect® as problem solver for memory clinics

ADtect®

early detection of

Alzheimer's disease



# A need for new test to detect early Alzheimer's disease pathology

ADtect®

early detection of

Alzheimer's disease



## The challenge

- Patients referred to memory clinics are getting younger and younger
- Symptoms are often vague and diffuse
- Higher education may mask underlying AD pathology
- Cognitive test are often normal or inconclusive

## ADtect® as problem solver

- Well educated young patients, sixty to early 70 with early symptoms, but negative/inconclusive on cognitive tests
- Patients with contraindications to MRI/CT/CSF investigations
- Patients where there is suspicion of an underlining depression
- Stroke patients with aphasia

# BCtect™

early detection of

## Breast Cancer



FOR EARLY DISEASE SIGNATURES

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# Multi-centre study for BCtect® CE-marking

BCtect®

early detection of

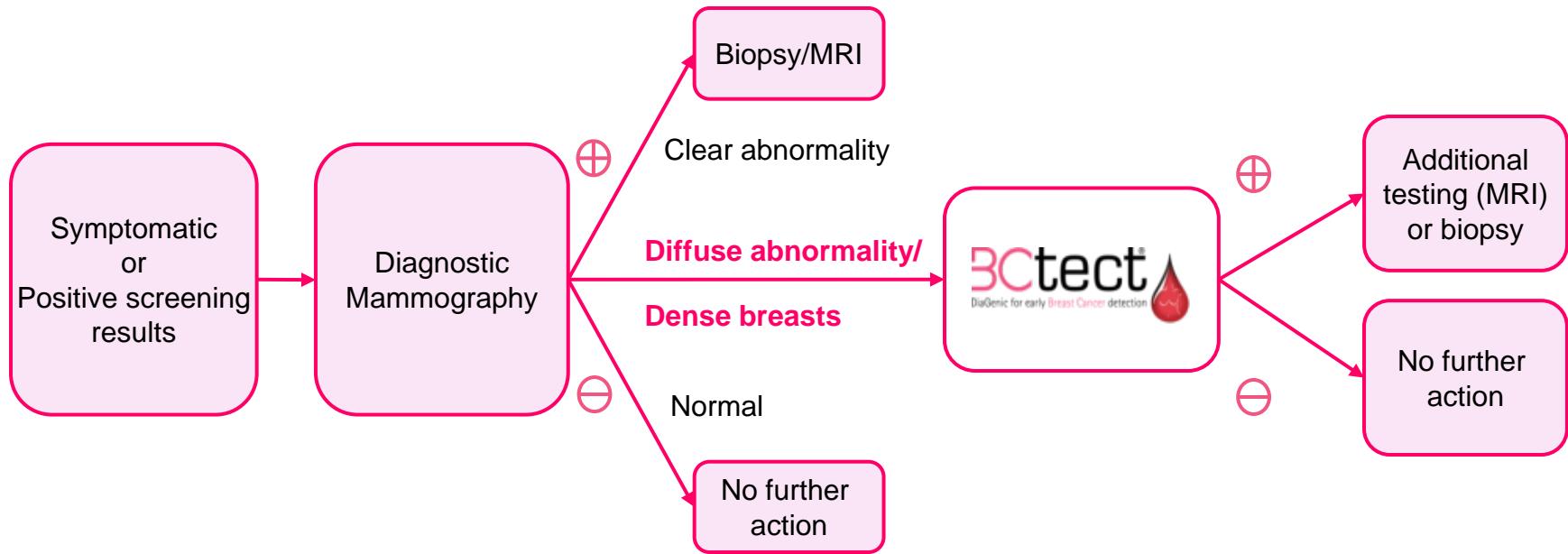
Breast Cancer



- Patient recruitment in the study was from specialist centres at hospitals
- Patients were positive on screening mammograms or had clinical symptoms
- BCtect® shows similar good performance with pre- and post-menopausal women
- Supports the use of BCtect® as an aid in the diagnosis of breast cancer in patients on diagnostic workup of suspected cancer.

Overall performance			
	Validation (N=109)	Calibration (N=223)	Combined (N=332)
Accuracy	72 %	73 %	72 %
Sensitivity	69 %	73 %	72 %
Specificity	74 %	73 %	73 %
Pre-menopausal accuracy	73 %	70 %	71 %
Post-menopausal accuracy	70 %	74 %	73 %

# BCtect® as problem solver for specialists



## Population estimates

Negative: 75% of those referred for diagnostic mammography

Positive: 15% of those referred for diagnostic mammography, 3 to 4 biopsies taken for 1 cancer

Inconclusive: 10% of those referred for diagnostic mammography



# A need for new tests to detect early breast cancer

## The challenge

- ◆ Mammography misses too many tumours in young women and women with dense breasts
- ◆ Tumours in younger women are normally more aggressive so early detection is vital for successful treatment
- ◆ Breast cancer of the lobular type are especially difficult to detect

## BCtect® as the problem solver

- ◆ High sensitivity with young women and women with dense breasts
- ◆ Detects tumours as small as 4 mm
- ◆ Detects lobular breast cancer as well as ductal with high sensitivity
- ◆ Is an attractive alternative for those females who do not wish to use or have access to established imaging methods

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# Outlook

- ◆ Launch of ADtect® in European countries covered by the Ferrer contract.
- ◆ Launch of ADtect® and BCtect® in UK and Ireland
- ◆ Strengthen the sales and marketing organization in order to increase distributor support capabilities.
- ◆ Proceed with US market entry plan
- ◆ Proceed with the companion diagnostics strategy, including marketing of our biomarkers towards the pharmaceutical industry.

# Conclusion

- ♥ Clinical need for our products confirmed by clinicians and international diagnostic companies.
- ♥ Important minimum volumes in current contracts
  - ♥ In total 150.000 tests over 4 years, with end user price of >600€ each
- ♥ 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 – Norway's Most Innovative Company of the Year**



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# 20 Largest Share Holders - February 15th 08:00

Shares	Percent	Name
4 143 795	6.21	Tredje AP-Fonden C/O HANDELSBANKEN AS
3 399 742	5.09	NORDEA NORDIC EQUITY
2 900 000	4.35	LØNNEBORG ERIK ANDERS
2 295 000	3.44	SHARMA PRAVEEN
1 892 178	2.84	HOLBERG NORDEN V/HOLBERG FONDSFORVALTNING
1 885 000	2.82	A/S SKARV
1 877 224	2.81	ARGO SECURITIES AS EMISJONSKONTO INNLAN D
1 421 959	2.13	HOLBERG NORGE V/HOLBERG FONDSFORVALTNING
1 382 600	2.07	JPMORGAN CHASE BANK NORDEA TREATY ACCOUNT
1 090 000	1.63	HAAVIND KARL WILHELM
1 003 100	1.50	LIVSFORSIKRING.NORDE JP MORGAN CHASE BANK
1 000 000	1.50	SKAGEN VEKST
813 300	1.22	VPF NORDEA SMB C/O JPMORGAN EUROPE
808 000	1.21	AMFIBIEN AS V/ JOHN HESTAD
688 000	1.03	DnB NOR MARKETS, AKS
684 000	1.02	HESTAD JOHN
655 000	0.98	KIKUT AS
621 000	0.93	NARMO SIGRID
558 378	0.84	STORHAUG DAG
529 545	0.79	SÆTERØY HÅKON
<b>29 647 821</b>	<b>44.41</b>	<b>Sum</b>