

**DiaGenic**  
“Growing market attention;  
Molecular diagnostics and  
biomarkers for Pharma”

-  
**1<sup>st</sup> Quarter 2010**

**Erik Christensen, MD PhD**

Chief Executive Officer

**Ruben Ekbråten**

Financial Controller

**DiaGenic**  
FOR EARLIER DISEASE DETECTION



# Agenda: 1<sup>st</sup> Quarter 2010 Presentation

- ◆ 1<sup>st</sup> Quarter Highlights
- ◆ Commercial Strategies
- ◆ 1<sup>st</sup> Quarter Finance
- ◆ Product Development and Clinical Studies
- ◆ Outlook

# 1<sup>st</sup> Quarter 2010 Highlights

- ◆ Distribution agreement with Ferrer on ADtect®
- ◆ First clinic to use BCtect® in UK presented
- ◆ Improved clinical documentation supporting higher accuracy of ADtect®
- ◆ Share issue of MNOK 9.6

## Post quarter end

- ◆ More clinics in UK and Finland promotes BCtect®

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# Business/Partnering model



RIKSHOSPITALET



BRIGHAM AND  
WOMEN'S HOSPITAL  
A Teaching Affiliate of Harvard Medical School

KAROLINSKA  
Universitetssjukhuset

UCDAVIS  
UNIVERSITY OF CALIFORNIA



AB Applied  
Biosystems



ferrer inCode

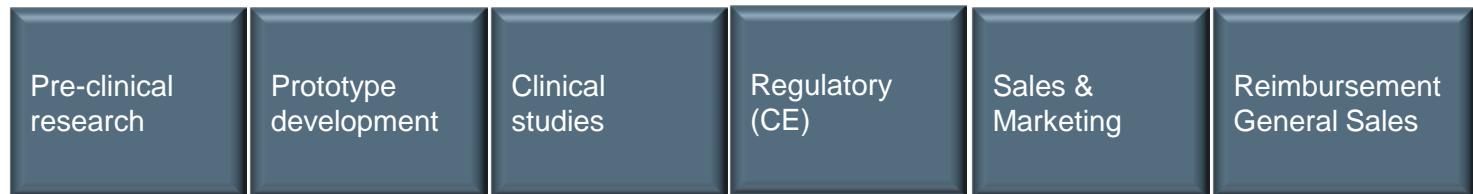


DiAGENIC



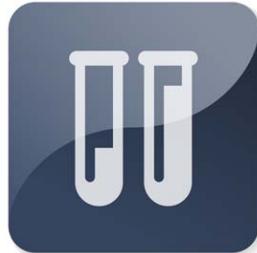
# Product portfolio

## Molecular Diagnostics



FOR EARLY DISEASE SIGNATURES

# Two-segment business model



## MDx-business

Molecular Diagnostics

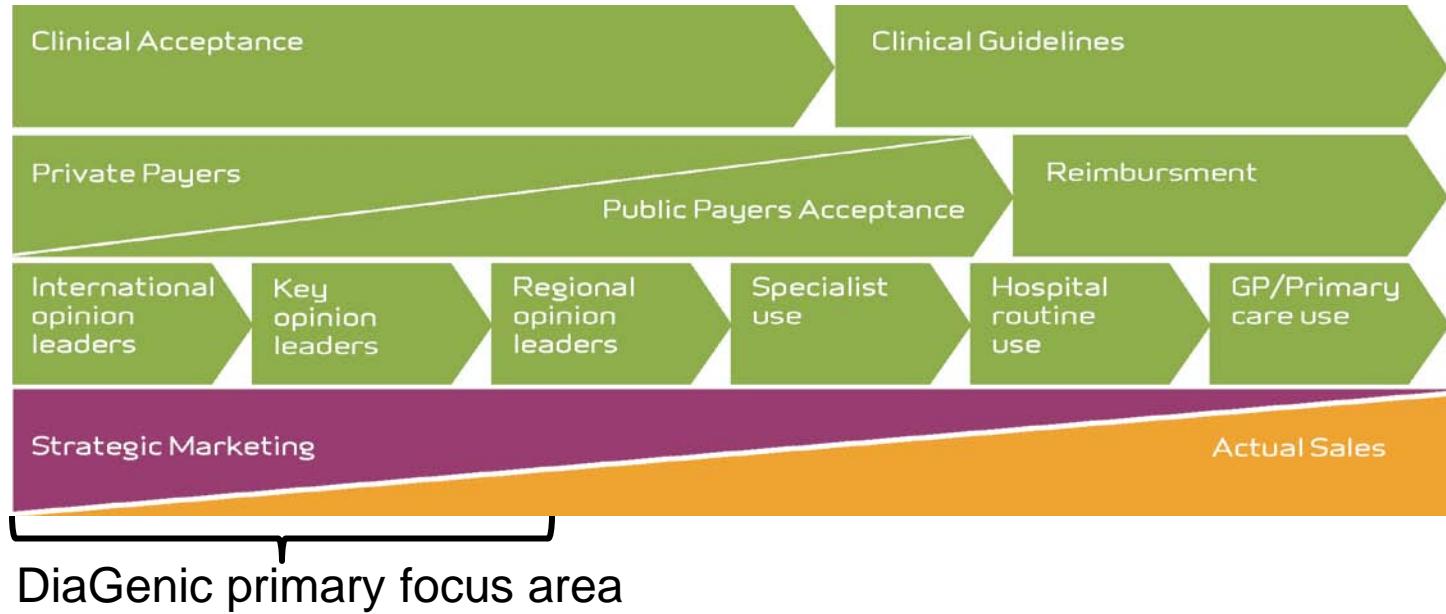


## Rx– business

Biomarker for Prescription drug use



## Generic Scientific Marketing model



DiaGenic primary focus area

### Key activities:

- International Scientific conferences
- Peer reviewed articles
- Building documentation
- Local clinical studies
- Distributor training and support



## ADtect® distribution in Europe



- Signed 6 distributors covering 20 countries, all with minimum volume commitments.
- Key activities
  - Signed distribution contract with Ferrer inCode
  - Step wise roll out:
    - Q2-10: Spain and Germany
    - Q4-10: Benelux, France and Portugal
    - Q1-11: Italy
    - TBD: Latin-America
- 2010 – 2013: Cumulative minimum volumes on ADtect® total approximately 85,000 tests
- Congresses:
  - Alzheimer's Disease International
- Peer review articles
  - 2 submitted



## 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
  - ◆ Private clinics in UK ready to use BCtect:
    - ◆ The London Breast Clinic
    - ◆ Nuffield Bristol
    - ◆ Nuffield Glasgow
  - ◆ Private clinic in Finland ready to use BCtect
- ◆ 2010 – 2013: Cumulative minimum volumes on BCtect® total approximately 60,000 tests
- ◆ Congresses:
  - ◆ European Breast Cancer Congress, Barcelona
  - ◆ IMPACT 2009 Breast Cancer Conference, Brussels

# Two-segment business model



## RX– business

Biomarker for Prescription drug use

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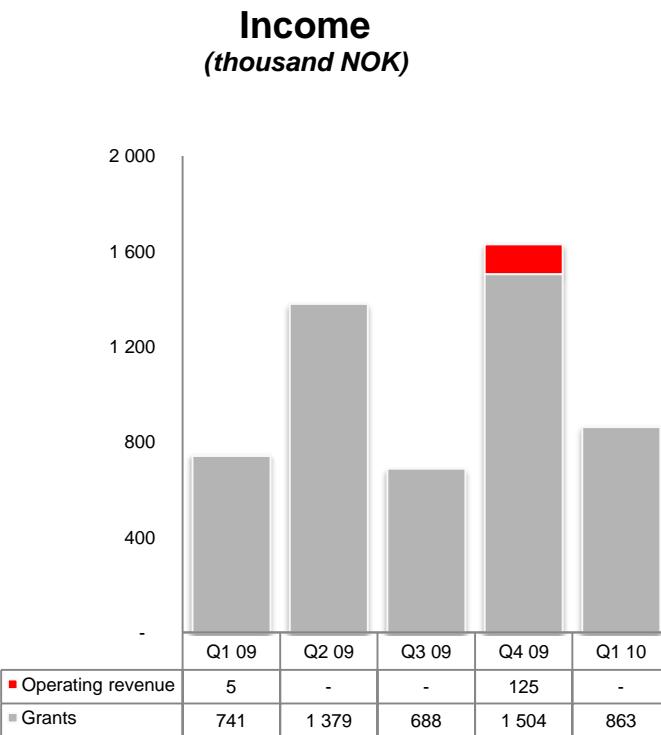
## DiaGenic – growing interest for partnering dialogue

- ◆ Pharmaceutical companies:
  - ◆ Primary focus area is the Mild Cognitive Impairment stage of Alzheimer's disease
    - ◆ Next generation drugs will recruit MCI patients
    - ◆ No applicable tools available today for patient recruitment
      - ◆ CSF is too invasive, thus having low compliance, PET-biomarkers are too expensive for general use. Easy and convenient test needed
- ◆ PET Imaging companies
  - ◆ A number of multinational companies develops new PET ligands as a tool to diagnose MCI and AD
    - ◆ FDA approval expected
    - ◆ Too costly for the payers (>10.000\$/test)
      - ◆ Needs a lower cost triage (patient selection) tool to select the right patients
- ◆ Companion diagnostics opportunity within both areas

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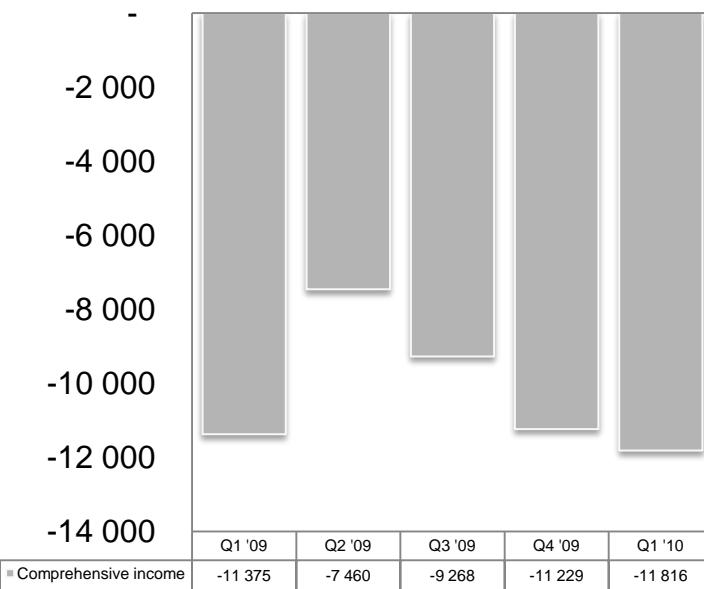
# Finance, Income



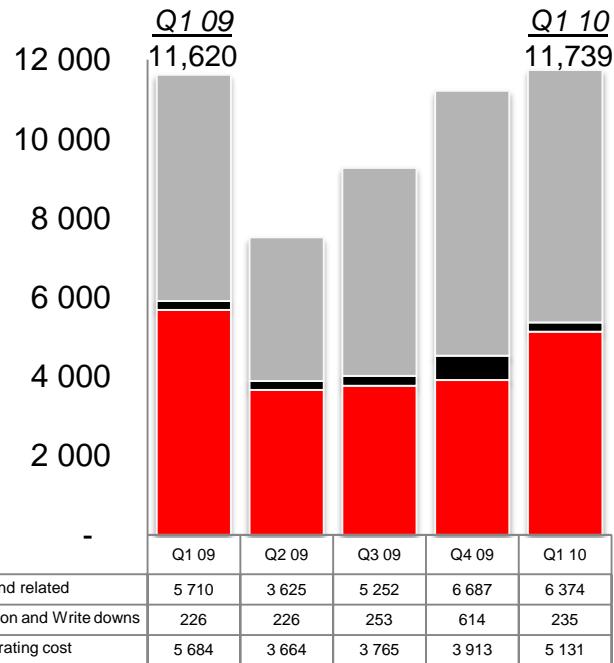
- Research grants in Q1 2010 consist of support from:
  - Innovation Norway
  - EU Commission (SPIDIA)
  - The Research Council of Norway (Parkinson's disease)

# Finance, Profit & Loss

**Comprehensive income**  
(*thousand NOK*)



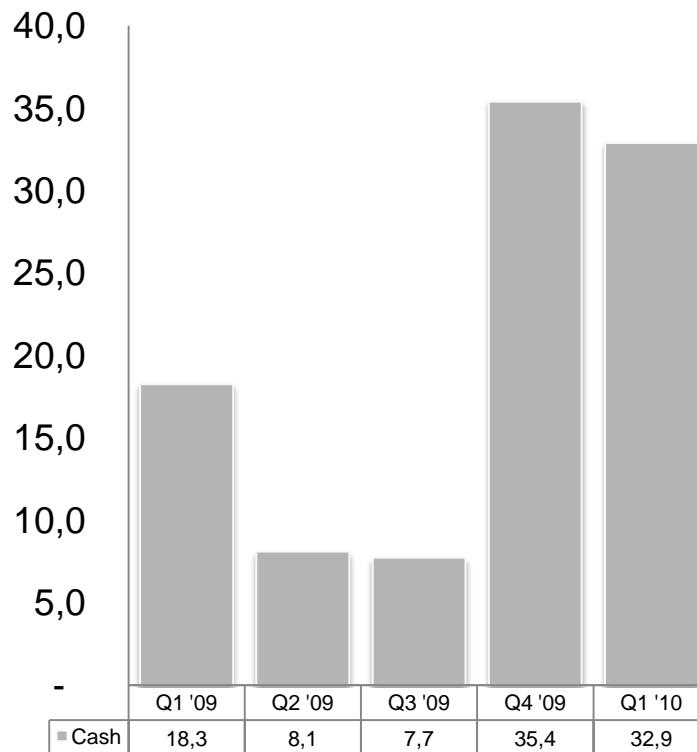
**Other Operating Cost**  
(*thousand NOK*)



# Finance, Financing

## Cash and Cash equivalents

(million NOK)



- Share issue completed in the first quarter
  - Issue of 3,5 million shares with gross proceeds of NOK 9,6 million
- Warrants issued in the first quarter
  - 16 million warrants issued the first quarter
  - Subscription price: NOK 3,25 per share
  - May be exercised up to 30 September 2010

# Finance, Process to exercise warrants

- Process for exercising warrants
  - Reference is made to Prospectus dated 21 January 2010, section 4.12.
  - Information regarding exercising warrants will be listed on our web page: [www.diagenic.com](http://www.diagenic.com) under Investor Relations
  - Key dates for exercising warrants are shown below:

Dates when share capital increases are reported to the Norwegian Register of Business Enterprises:

30 June



30 September

Due dates for requests to exercise warrants and due dates for when payment for new shares shall be made:

• 22 June

• 22 Sept.

# Finance, 2010 Future prospects

- Gradual increase of top line is expected
- Burn rate for second quarter 2010 is expected to be similar to first quarter 2010.

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# ADtect™

early detection of

## Alzheimer's disease



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# Multi-centre study for ADtect® Data



Demographic data	Independent Validation Cohort		Total Study Intended use population	
	AD Patients (N=100)	Cognitively Healthy (N=104)	AD Patients (N=173)	Cognitively Healthy (N=205)
Age	<b>71.2 (49-79)</b>	<b>69.6 (43-79)</b>	<b>72.5 (49-79)</b>	<b>70.3 (43-79)</b>
MMSE	<b>21.6 (7-29)</b>	<b>29.6 (28-30)</b>	<b>21.0 (7-29)</b>	<b>29.6 (28-30)</b>

- ◆ 11 clinical sites for patient recruitment
  - ◆ More than 550 samples collected
  - ◆ No significant effect observed for most common co-morbidities included in study
    - ◆ e.g. diabetes, coronary disease, depression, previous strokes, hypertension, cancer, rheumatoid arthritis
- ◆ Independent validation cohort
  - ◆ All samples (N=204) independent from calibration study
  - ◆ Samples from 5 sites independent from the calibration study

# Multi-centre study for ADtect®



## Results

Performance Data	Independent cohort	Total Study Intended use population
Number	204	378
Accuracy	71.6%	72.2%
Sensitivity	71.0%	72.3%
Specificity	72.1%	72.2%
Accuracy early AD MMSE 20-27	73,5%	73,0%
Accuracy late AD MMSE 10-19	74,1%	75,4%

- Overall 72% accuracy of ADtect® in this clinical study,
  - Using only one blood sample at first patient visit
  - As good in early AD as in later stages
- Clinical accuracy of the study centers is estimated to 80%;
  - Our real accuracy towards a true gold standard is thus 85-90%

# Multi-centre study for ADtect®

## Spinal Fluid (CSF) results

ADtect®

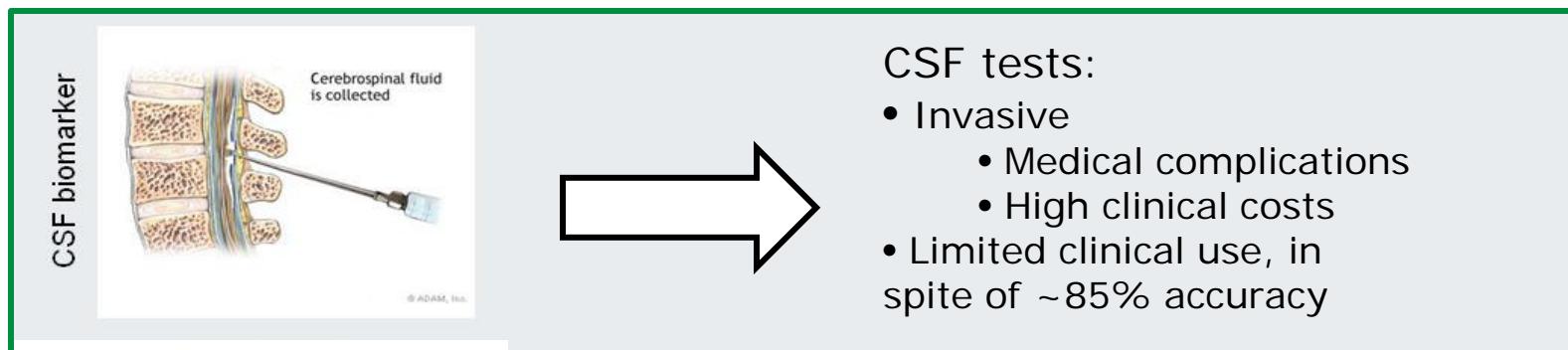
early detection of

Alzheimer's disease



- 44 out of the 51 AD patients and controls included from Sweden were correctly predicted with ADtect® (>85% accuracy)
- 14 Clinical samples contained CSF biomarker data ( $A\beta_{1-42}$ , t-tau, p-tau)
  - 11 of 12 positive CSF samples were correctly predicted with ADtect®
  - 2 of 2 negative CSF samples on controls were correctly predicted with ADtect®

Additional studies initiated to increase study size for comparison ADtect® and CSF biomarkers





- Challenges with Alzheimer's disease (AD) and diagnosing patients:
  - Diagnosing AD takes time; from 10 months in Germany to 32 months in UK
  - AD diagnosis requires multiple visits to specialists
  - Limited access to expensive imaging (PET/SPECT)
  - One new AD patient every 70 seconds in USA.
  
- Accuracy independent of disease stage
  - Overall 73% accuracy
  - Challenge with imperfect Gold standard:  
Clinical accuracy is 80%; our real accuracy is then 85-90%
  - Accuracy independent of disease stage; early diagnosis needed for early treatment



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

# BCtect™

early detection of

## Breast Cancer



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# Multi-centre study for BCtect® CE-marking



- 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 %



- ❖ Challenges with Breast Cancer (BC) and diagnosing patients:
  - ❖ Mammography in younger females and females with dense breasts has low sensitivity
    - ❖ as low as 50-60% in pre-menopausal females
  - ❖ Falling compliance on mammography screening
    - ❖ Inconvenient, cultural resistance, radiation fear++
- ❖ BCtect has same performance (accuracy 72%) in
  - ❖ pre- and post-menopausal women
  - ❖ early and late stage breast cancers (detects tumours as small as 4mm)
  - ❖ all tumour types (Including Lobular carcinomas that often is invisible on mammograms)
- ❖ BCtect® as a problem solver when mammography is inconclusive.
  - ❖ First line test if warranted by the clinicians
    - ❖ Clinical findings, Family history of BC, Cultural resistance etc.



- ❖ Fast turn around time
- ❖ Non invasive
- ❖ Patient friendly
- ❖ Improved sensitivity

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# Outlook

- ◆ Launch of ADtect® in European countries covered by the Ferrer contract.
- ◆ Gain market acceptance of ADtect® and BCtect® in Europe from a growing customer base followed by gradual increase of sales revenue
- ◆ Continue with US market entry plan
- ◆ Continue with the companion diagnostics strategy, including marketing of our biomarkers toward the pharmaceutical industry.

# Conclusion

- Clinical need for our products confirmed by clinicians; awaits topline
- BCtect®
  - Available now in private clinics in UK and Finland
- ADtect®
  - Signed agreement with Ferrer
    - Launching first in Spain and Germany
  - Clinical trials ongoing or in preparation in Norway, Switzerland and Greece
  - Several European and US university hospitals included in the development of MCItect
- Rx – Companion Diagnostics
  - Growing interest from multinational imaging and pharmaceutical-companies for dialogue with DiaGenic.

*“DiaGenic offers a patient friendly tool for early detection of diseases to be used for research and for aid in diagnosis; thereby leading to an improved quality of life”*



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# 20 Largest Share Holders - May 19th 17:00

Shares	Percent	Name
3 963 795	5.64	Tredje AP-Fonden C/O HANDELSBANKEN AS
2 907 370	4.14	LØNNEBORG ERIK ANDERS
2 599 670	3.70	NORDEA NORDIC EQUITY
2 490 764	3.55	SHARMA PRAVEEN
1 892 178	2.69	HOLBERG NORDEN V/HOLBERG FONDSFORVA
1 885 000	2.68	A/S SKARV
1 877 224	2.67	ARGO SECURITIES AS EMISJONSKONTO INNLAN
1 421 959	2.02	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 383 538	1.97	JPMORGAN CHASE BANK NORDEA TREATY ACCOUN
1 267 667	1.80	SKAGEN VEKST
1 230 000	1.75	HAAVIND KARL WILHELM
1 003 100	1.43	LIVSFORSIKRING.NORDE JP MORGAN CHASE BANK
848 000	1.21	AMFIBIEN AS V/ JOHN HESTAD
813 300	1.16	VPF NORDEA SMB C/O JPMORGAN EUROPE
740 000	1.05	NARMO SIGRID
712 000	1.01	GJØRLING KENNETH RAYMOND
691 000	0.98	HESTAD JOHN
669 301	0.95	GEZINA AS
665 678	0.95	STORHAUG DAG
580 000	0.83	DIEDRICHSEN TAGE
<b>29 641 544</b>	<b>42.18</b>	<b>Sum</b>