

# **“Pharma and Imaging Companies interactions have progressed”**

**2<sup>nd</sup> Quarter 2010**

**Erik Christensen, MD PhD**

**Chief Executive Officer**

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**Financial Controller**

**Henrik Lund, MD PhD**

**Chairman BoD**



**DiAGENiC**

**FOR EARLIER DISEASE DETECTION**



# Agenda: 2<sup>nd</sup> Quarter 2010 Presentation

- 2<sup>nd</sup> Quarter Highlights
- Product Development & Commercial Strategies
- 2<sup>nd</sup> Quarter Finance
- Outlook

# 2<sup>nd</sup> Quarter 2010 Highlights

- ♦ Distributor sales continue to be slow and below expectations
  - ♦ BCtect<sup>®</sup> is promoted by the first clinic in UK and 6 more is starting after summer
- ♦ Strength of IP and competitive position drives Pharma and PET imaging companies' interest in DiaGenic. Multiple interactions ongoing in Alzheimers area (ADtect<sup>®</sup> /MCItect<sup>®</sup>)
- ♦ New Board of Directors elected – more focus on partnering options for DiaGenic

## Post quarter end

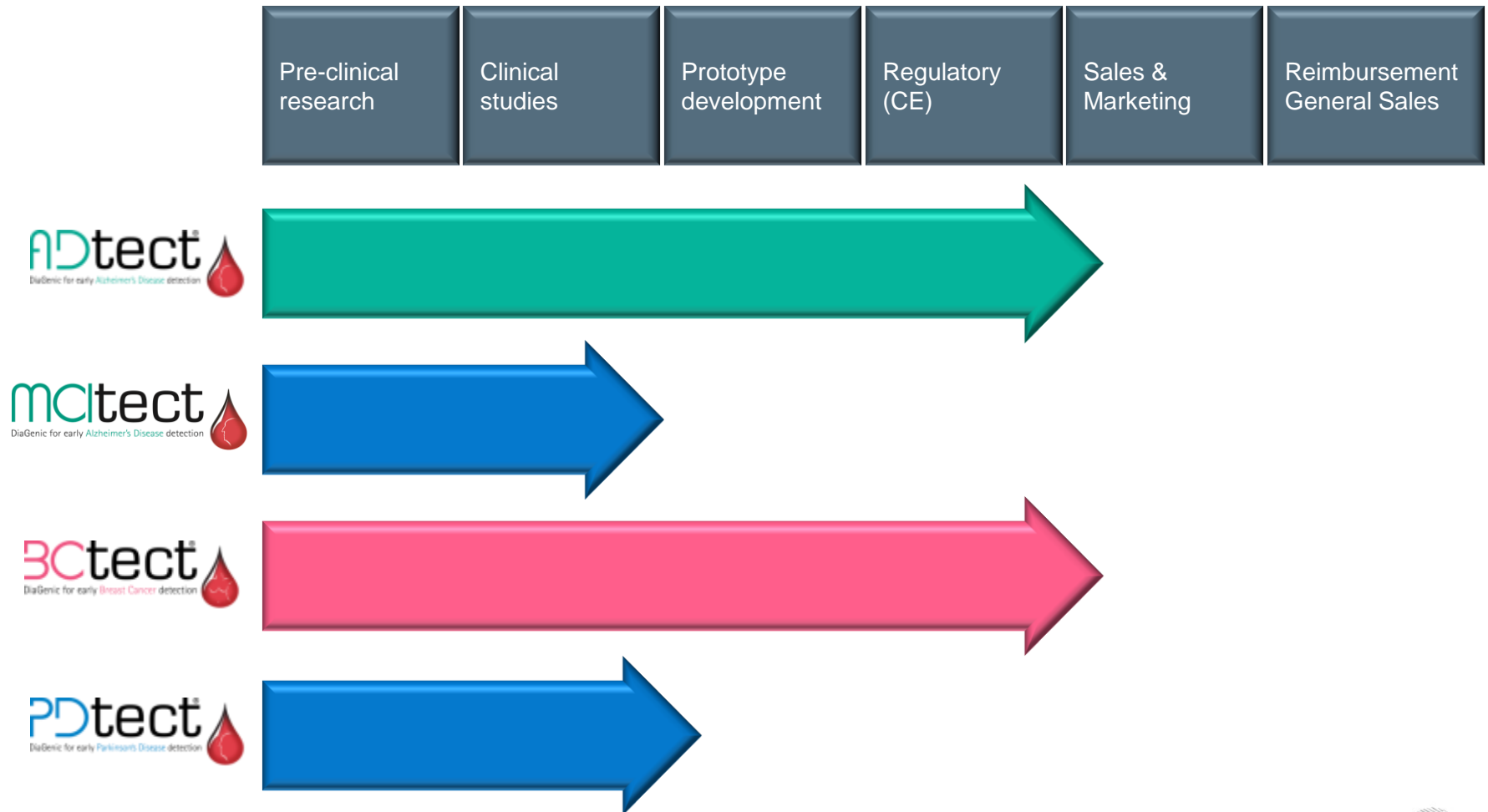
- ♦ Notice of Allowance on a family 3 Patent covering 30 countries in Europe

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# Product portfolio

## Molecular Diagnostics



FOR EARLY DISEASE SIGNATURES



# Solid IP, backed by 10 years of R&D

## > 100 patents accepted or granted

### Patent overview

17th of August 2010

Expiry year	Family 1 (WO 98/49342)			Family 2 (WO 2004/046382)			Family 3 (WO 2005/118851)		
	2017			2023			2024		
	G	A	P	G	A	P	G	A	P
US	1	0	2	0	0	1	0	0	1
Europe*	2	0	1	0	0	0	0	0	1
Europe**	0	0	0	1	0	0	0	1	0
Norway	2	0	0	0	0	1	0	0	1
Japan	1	0	0	0	0	1	0	0	1
Canada	0	0	0	0	0	1	0	0	1
Hong Kong	2	0	0	0	0	1	0	0	1
China	0	0	0	0	0	1	0	0	1
Australia	0	0	0	1	0	0	0	0	1
New Zealand	0	0	0	1	0	0	1	0	0
India	0	0	0	1	0	0	0	0	1
South Africa	0	0	0	1	0	0	1	0	0
ARIPO*	0	0	0	0	0	1	0	0	1

- G** Number of patents granted
- A** Number of patents accepted by examiner
- P** Number of patents in progress

#### Europe\*

##### Designated countries

Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, The Netherlands, Portugal and Sweden

#### Europe\*\*

##### Designated countries

Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Romania, Sweden, Slovenia, Slovakia and Turkey

#### ARIPO\* (African Regional Intellectual Property Organization)

##### Designated countries

Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe

#### List of granted patents/allowed patent applications

US 6720138; EP 0979308; EP 1323728;  
NO 317247; NO 20040371; JP 4163758;  
HK 1026003; HK 03109502.9; AU 2003286262;  
NZ 540750; IN 2701/DELNP/2005;  
ZA 2005/03797; ZA 2006/10644; HK 1057217;  
NO 327084; EP 156557431

# Impact of Clinical Accuracy

ADtect®

early detection of

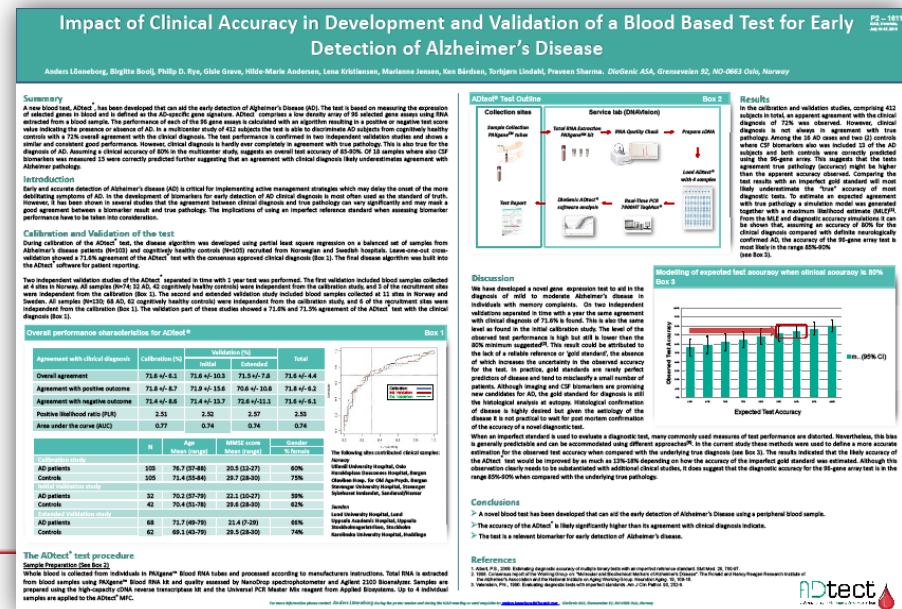
Alzheimer's disease



- Two independent validation studies of ADtect® showed a 71.6% and 71.5% agreement of the ADtect® test with the clinical diagnosis
- Clinical diagnosis is not always in agreement with true pathology
- Among the 16 AD cases and two (2) controls where CSF biomarkers also was included 13 of the AD subjects and both controls were correctly predicted
- Assuming an accuracy of 80% for the clinical diagnosis compared with definite neurologically confirmed AD, the agreement of the 96-gene array test is most likely in the range 85%-90%

FOR EARLY DISEASE SIGNATURES

Slide 7





# How closely is the gene expression in blood of Alzheimer's disease patients associated with the known biology of the disease?

ADtect®

early detection of  
Alzheimer's disease



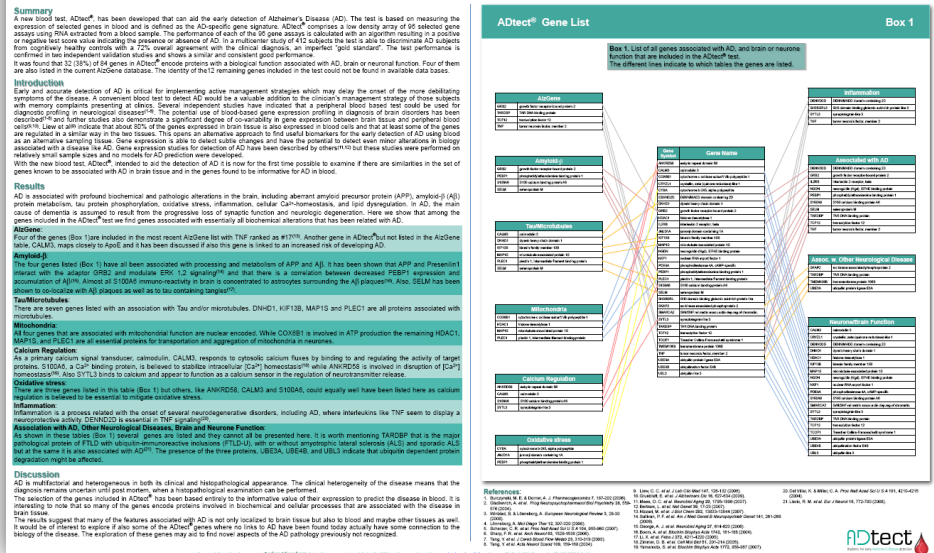
It was found that 32 of 84 genes in ADtect® encode proteins with a biological function associated with AD, brain or neuronal function.

Four of them are also listed in the current AlzGene database.

The identity of 12 genes included in the test could not be found in available databases.

## How closely is the gene expression in blood of Alzheimer's disease patients associated with the known biology of the disease?

Anders Linnéberg, Birgitte Bevil, Philip D. Ryan, Glade Greve, Hilde Marie Andersen, Lena Kristiansen, Torbjørn Lindahl, Puneet Sharma, Diagenic ASA, Grønveien 92, NO-0663 Oslo, Norway





# Business/Partnering model



# Two-segment business model



## MDX-business

Molecular Diagnostics



## Rx-business

Biomarker for Prescription drug use



**MDX-business**  
Molecular Diagnostics

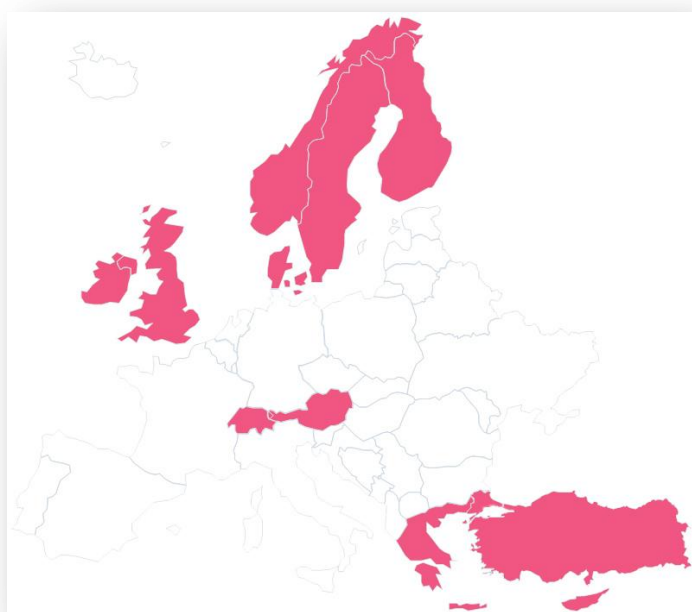
**BCtect**<sup>™</sup>

early detection of

Breast Cancer



## BCtect<sup>®</sup> distribution in Europe



- ♦ 5 distributors covering 10 countries
- ♦ Key activities
  - ♦ Private clinics in UK ready to promote BCtect:
    - The London Breast Clinic.
    - The London Clinic,
    - The Harley Street Breast Clinic,
    - Nuffield Health, Bristol and Glasgow,
    - Aspen Healthcare, Parkside Hospital Wimbledon,
    - BMI Healthcare, Syon.
  - ♦ Private clinic in Finland signed contract
- ♦ Congresses:
  - ♦ European Cancer Research Association, Oslo
  - ♦ IMPACT 2009 Breast Cancer Conference, Brussels



**MDX-business**  
Molecular Diagnostics

**ADtect™**

early detection of

Alzheimer's disease



## ADtect® distribution in Europe



- ♦ 6 distributors covering 20 countries
  - ♦ Main support focus area:
    - ♦ Ferrer Step wise roll out:
      - ♦ Q2-10: Spain and Germany
      - ♦ Q4-10: Benelux, France and Portugal
  - ♦ The distributors follows the scientific sales model
    - ♦ Scientific and commercial advisor board initiated
- ♦ Congresses:
  - ♦ International Congress on Alzheimer's Disease
    - ♦ 2 presentations, one in hot topic section

# Two-segment business model



## Rx– business

Biomarker for Prescription drug use

# Pharma Strategy



Development

Partnering

Commercialization

# DiaGenic's Partner Approach

August 2010

Development status

**Potential pharma partner:**  
96 gene signature + expanded gene set  
Progression markers – longitudinal - drug effects



**IVD**  
96 gene signature  
Bi-nomic AD

**ADtect**  
CSF-18F PET support

**MCItect**  
Bi-nomic  
MCI to AD

**IVD**  
Multi-nomic AD  
MCI  
AD

**Potential imaging partner**  
pre-qualification  
into high end imaging?

**Potential imaging partner**  
pre-qualification  
into high end imaging?

**Merz:**  
non-exclusive  
option  
for MCItect  
co-development

Pre 2010

August 2010

2011

FOR EARLY DISEASE SIGNATURES





# DiaGenic's Partner Discussions

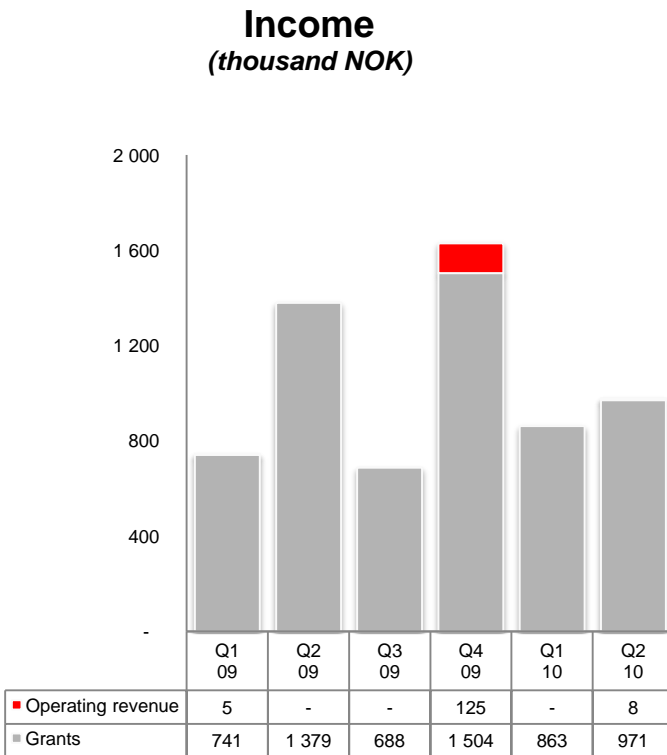
## August 2010

- Multiple ongoing pharma interactions
  - Therapeutics
  - High-end Diagnostics
- DiaGenic invited into Phase II and Phase III development (R&D collaboration)
- Protocols exchanged for new progression and drug effect marker (expanded gene signature)
- Strong IP position: Freedom to operate
  - Freedom to operate as an independent 3 party provider of IVD in AD
  - Expansion of gene signatures and to piggy back on DiaGenic main patent classes/claims

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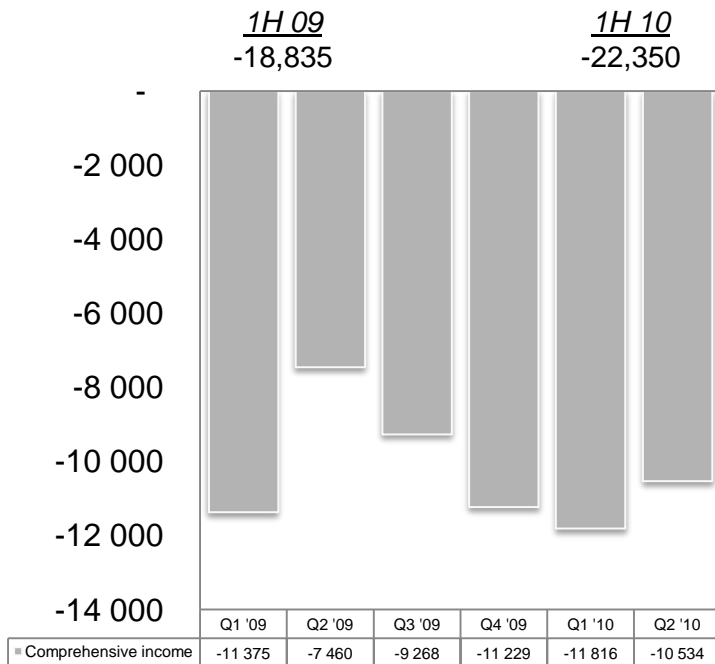
# Finance, Income



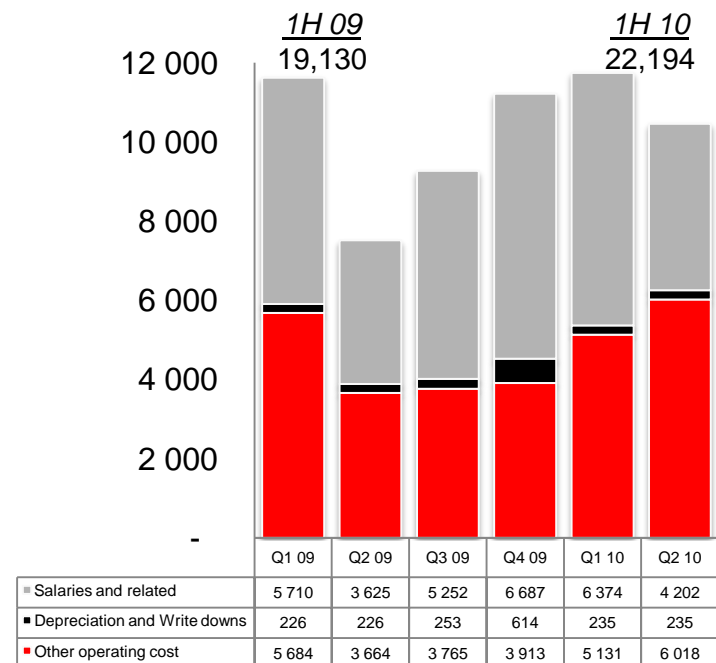
- Research grants in 1H 2010 consisted of support from:
  - Innovation Norway
  - EU Commission (SPIDIA)
  - The Research Council of Norway (Parkinson's disease)

# Finance, Profit & Loss

## Comprehensive income (thousand NOK)

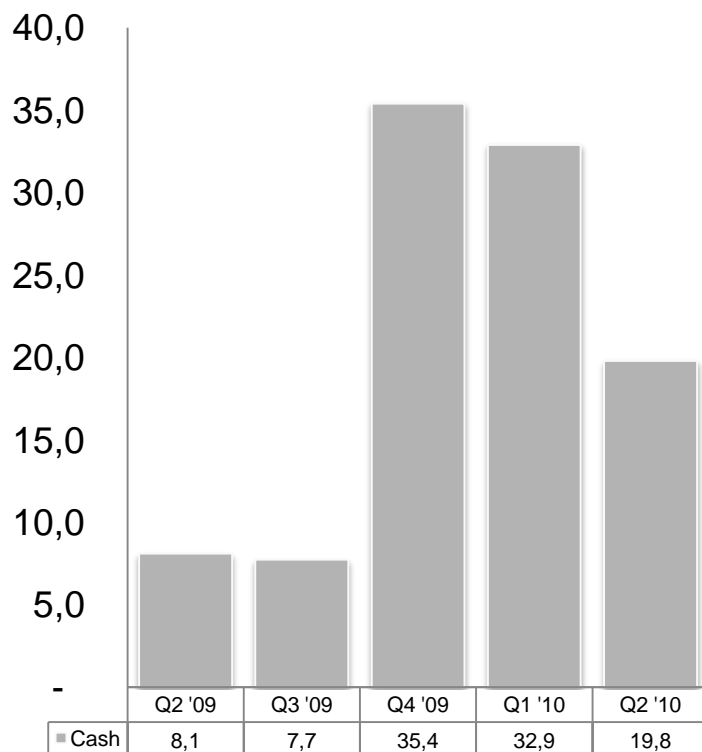


## Other Operating Cost (thousand NOK)



# Finance, Financing

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



- Share issue completed in the first half of 2010
  - Issue of 3,5 million shares with gross proceeds of NOK 9.6 million
- Warrants issued in the first half of 2010
  - 16 million warrants issued
  - Subscription price: NOK 3.25 per share
  - May be exercised up to 22 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:

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

30 September

• 22 Sept.

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# Outlook

- ♦ Accelerate the companion diagnostics strategy, including marketing of our biomarkers to the pharmaceutical and imaging industry, leading to partnering agreements.
- ♦ Gain market acceptance of BCtect® and ADtect® in selected countries in Europe.
- ♦ Continue with ADtect® US market entry plan

# Conclusion

- ◆ Rx – Companion Diagnostics – Key focus area
  - ◆ Expressed interest from multinational imaging and pharmaceutical-companies for partnership with DiaGenic.
    - ◆ Active dialogue on supporting phase II and III studies
    - ◆ New tools pursued on disease progression and on early disease stage
    - ◆ Through the development of MCItect® DiaGenic has a leading biobank of samples
    - ◆ DiaGenic has unique competitive advantage and capabilities in developing biomarkers
- ◆ MDx – Molecular diagnostics
  - ◆ BCtect® - Available now in private clinics in UK and Finland
  - ◆ ADtect® - Signed agreement with Ferrer, launching first in Spain and Germany
  - ◆ Marketing barriers remains high, large players are instrumental to drive revenue and income
- ◆ At current cost levels the company is financed for a period of less than one year. Work is thus proceeding to secure financing of the Company, including but not limited to exercise of warrants and equity financing.

For more information, see [www.diagenic.com](http://www.diagenic.com)





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# Disclaimer

This presentation includes forward-looking statements regarding DiaGenic ASA, including projections and expectations, which involve risk and uncertainty. Such statements are included without any guarantees to their future realization. Although DiaGenic believes that the expectations regarding the Company reflected in such forward-looking statements are based on reasonable assumptions, no assurance can be given that such projections will be fulfilled. Any such forward-looking statement must be considered along with knowledge that actual events or results may vary materially from such predictions due to, among other things, political, economic, financial or legal changes in the markets in which DiaGenic does business, and competitive developments or risks inherent to the Company's business plans. Many of these factors are beyond DiaGenic's ability to control or predict. Given these uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. The Company does not intend, and does not assume any obligation, to update the forward-looking statements included in this presentation as of any date subsequent to the date hereof.

# Solid IP, backed by 10 years of R&D

## > 100 patents accepted or granted

### 4 patent families granted, accepted by examiner, or in process

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Family 1	<ul style="list-style-type: none"><li>a. Method to identify diseases using blood samples and gene expression technology, where the sample is collected distant to the area of the disease</li><li>b. Method to identify diseases using non-sequence based gene expression methods</li></ul>	<ul style="list-style-type: none"><li>a. Covers both sequence based and non-sequence based gene expression methods. Granted for Alzheimer in US, Europe, and Hong Kong. Broad patent, including Alzheimer, in Japan and Norway.</li><li>b. No disease limitations, no sample limitations. Granted in Europe, Norway and Hong Kong</li></ul>
Family 2	Describes sets of gene sequences that can be used to develop expression signature for the detection of diseases	Granted in South Africa. Granted in Australia, New Zealand and Europe for Alzheimer and Breast Cancer, and for breast cancer in India
Family 3	Describes gene families and genes expressed in blood which can be used to detect cancer	Accepted in Europe, Granted in South Africa and New Zealand
Family 4	Describes oligonucleotide probes in kit form that can be used to identify, diagnose and monitor breast cancer	Application filed 2010

## 20 Largest Share Holders - August 18th 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
1 903 224	2.71	SIX SIS AG 25PCT
1 892 178	2.69	HOLBERG NORDEN V/HOLBERG FONDSFORVA
1 421 959	2.02	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 363 600	1.94	JPMORGAN CHASE BANK NORDEA TREATY ACCOUN
1 267 667	1.80	SKAGEN VEKST
1 220 000	1.74	HAAVIND KARL WILHELM
1 003 100	1.43	LIVSFORSIKRING.NORDE JP MORGAN CHASE BANK
1 000 000	1.42	A/S SKARV
923 082	1.31	STOREBRAND VEKST JPMORGAN EUROPE LTD,
848 000	1.21	AMFIBIEN AS V/ JOHN HESTAD
820 000	1.17	NARMO SIGRID
813 300	1.16	VPF NORDEA SMB C/O JPMORGAN EUROPE
804 231	1.15	NORDNET BANK AB
755 000	1.07	GJØRLING KENNETH RAYMOND
693 278	0.99	STORHAUG DAG ERIK
655 000	0.93	KIKUT AS
<b>29 345 218</b>	<b>41.77</b>	<b>Sum</b>