# IA GENIC FOR EARLIER DISEASE DETECTION

# DiaGenic ASA

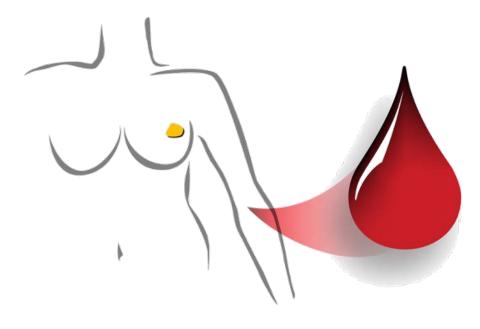
Sweden Bio "Life Science Investment Day" 9 March 2009

Erik Christensen MD PhD **CEO** 





# DiaGenic's Vision



DiaGenic's vision is to offer patient friendly diagnostic tools for the early detection of diseases, thereby leading to an improved quality of life.



# Markets:

- Large, fast growing. Unmet medical needs
- Extensive pharma spending

### DiaGenic:

- Blood based diagnostic tests and biomarkers
- IP based innovative technology with unique benefits & strong scientific validation
- > First product launched, India Nov 2008
- Experienced team
- Backed by Nordic institutional investors
- Listed at Oslo Stock Exchange
  - Market Cap 130M NOK







DiaGenic – Management



Erik Christensen, MD PhD Chief Executive Officer

MD in Denmark 1983. Norway 1985, PhD 1991.

Qualified in Clinical Chemistry 1992.

Abbott Laboratories 1996.- 2006 Medical Director Nordics, ADD and Country Manager Norway, ADD

DiaGenic from January 2007



Anders Lönneborg, PhD Research Director Co founder



Praveen Sharma, PhD Technology Director Co founder



Dag Christiansen Marketing Director



Håkon Sæterøy Chairman of the Board



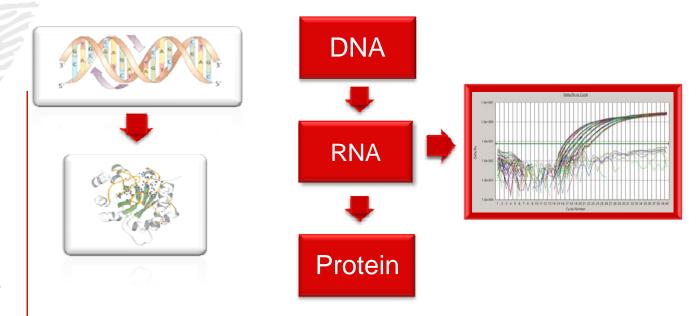
DiaGenic Board of **Directors** 



**Praveen Sharma Anna Malm Bernsten Marie Buchman** 

Ingemar Kihlström Håkon Sæterøy **Ingrid Alfheim** 

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# The Principle

The primary diseased part of the body is not the only part responding to a disease

subtle but systemic impact on gene expression

The disease also leaves a unique "signature" in other parts of the body, including the circulatory system

 response can be detected by measuring the amount of RNA for specific genes from peripheral blood

These signatures can be identified using gene expression technologies

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Product Pipeline







business segments





# **RX**- Business

Biomarker for Prescription drug use

- Biomarkers for pharma studies
  - Use of current tests (ADtect® or BCtect®)
  - R&D cooperation
    - development of new or optimized tests
  - Companion diagnostics

# **MDX**- Business

**Molecular Diagnostics** 

- Invitro Diagnostics
  - Regulatory approved assays
  - ADtect® and BCtect® soon to be approved
  - PDtect<sup>®</sup> in development





# DiaGenic can provide biomarkers for pharma studies

- In dialogue with several large players within the neurology field
  - DiaGenic has a signed term sheet for biomarker development with the first pharmaceutical company
  - A final agreement awaits a decision by the pharmaceutical company based on their ongoing studies.
- Received funding for developing a Parkinson's Disease Biomarker
  - Michael J Fox Foundation and the Norwegian Research Council
  - Collaboration with Harvard Medical School
- Soon fully documented and regulatory (Europe) approved tests
  - Big pharma are already collecting dedicated samples in clinical studies for the potential use on gene expression tests (Alzheimer's Disease)
- Initiated studies needed for new diagnostic assays, like MCI and PD tests
  - Multicentre studies across Europe

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## DiaGenic's position in *Invitro* Diagnostics

- First in the market with blood based diagnostics for Alzheimer's Disease and Breast Cancer
- Strong IP on diagnostic use of gene expression
  - Concept can be applied on a multitude of diseases
- Cooperation with two main technology vendors
  - Qiagen blood sampling RNA extraction
    - DiaGenic participates in a EU project (SPIDIA) together with Qiagen to further develop gene expression methods
  - Life Sciences (formerly Applied Biosystems)
    - cDNA measurements, OEM producer of our gene cards
- Regulatory approved assays
  - ADtect<sup>®</sup> and BCtect<sup>®</sup> soon to be CE-marked
- BCtect<sup>®</sup> launched by SRL Diagnostics in India
  - Successful multicentre study gives clinical documentation
- PDtect<sup>®</sup> in development
- Building a distributor network in Europe





# Compliance studies



### Documenting clinical utility:

- 440 -640 patient samples tested
  - 6-8 sites from several European countries

### Documenting technical robustness

- 15 different studies for each (346 data points x2)
  - · Variability across the whole process documented

### Data analysis

- Calibration model by multivariate regression models
  - More than 75.000 data points to be reviewed for each
- Data and report compilation

All lab analysis completed CE marking pending data analysis







# SRL Diagnostics - Our marketing and sales partner in India:

- The largest pathology laboratory network in India
  - Extensive competencies within molecular diagnostics and experience in launching new diagnostic methods
- BCtect<sup>™</sup> launch in New Delhi November 2008
  - 80 leading gynaecologists and oncologists attended
  - Scientific presentations from radiologists, oncologists and DiaGenic representatives
  - Launch activities ongoing in New Delhi
  - Nationwide rollout to come



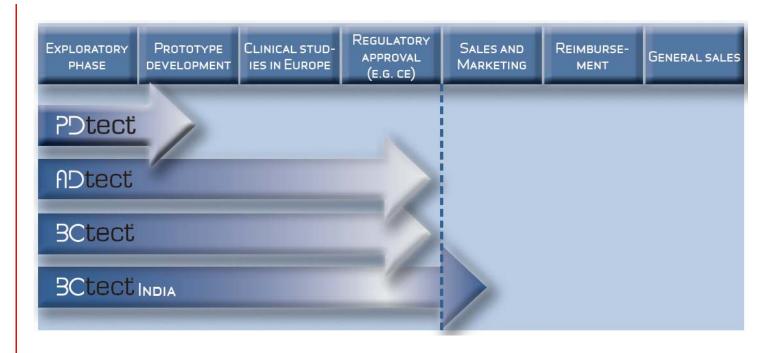
Statement from SRL Diagnostics
CEO Sanjeev Chaudhry:

"The Product Management Team
and Sales and Marketing Teams
at SRL are both optimistic and
enthusiastic and believe in the
potential of this test. "



# MDx-**Business**





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Business segments



RX-business

Biomarker for Prescription drug use



**MDX**-business

**Molecular Diagnostics** 



# Benefits of DiaGenic's innovative diagnostic tests

- •The test is *patient friendly*. A simple blood sample is all that is required.
- •The test is *convenient*. The sample can be taken at Collection Centers and sent to centralized laboratory.
- •The BCtect® test has *high accuracy* with all ages.
  - •Performs equally well for pre and post-menopausal women.
  - Detects very early cancer stages.
  - Detects *lobular cancer* with high accuracy.
- •The ADtect ® test has *high accuracy* with all stages of Alzheimer's Disease.



- 10 years of R&D to be capitalized and backed by a strong IP
  - First diagnostic product in the market
  - First term sheet for biomarker development signed

- Target disease markets are large and with clear medical needs
  - Significant big pharma interest and spend
- Clear marketing strategy via different global territories
  - BCtect® launched last quarter in India
  - CE marking of BCtect® and ADtect® within few months
  - Preparing for distributor network in Europe
- Under present financial markets conditions, future activities will be focused on supporting sales of existing products
- Research & development to be financed by external sources

### Conclusion





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March 6th

Shares	Percent	Name
3 344 000	6.46	Tredje AP-Fonden C/O HANDELSBANKEN AS
3 202 000	6.19	NORDEA BANK SWEDEN A A/C NORDEA HEDGE FUN
2 890 000	5.59	LØNNEBORG ERIK ANDERS
2 800 000	5.41	JPMORGAN LUXEMBOURG CARNEGIE FCP'S'
2 510 000	4.85	SHARMA PRAVEEN
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
1 097 387	2.12	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 003 100	1.94	LIVSFORSIKRINGSSELSK STRATEGISK
872 000	1.69	HAAVIND KARL WILHELM
868 478	1.68	SÆTERØY HÅKON
813 300	1.57	VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS
708 000	1.37	AMFIBIEN AS V/ JOHN HESTAD
650 378	1.26	STORHAUG DAG
535 000	1.03	DnB NOR MARKETS, AKS MARKET-MAKING DERIVA
476 100	0.92	SANDEN A/S C/O JAN PETTER COLLI
422 000	0.82	BRYNILDSEN KJELL-IVAR
410 000	0.79	KIKUT AS
28 762 283	55.60	Sum top 20

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