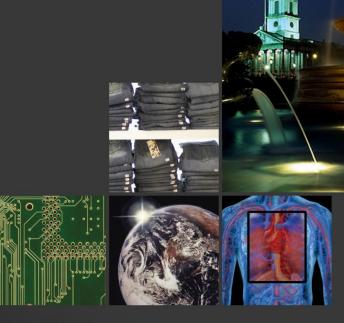
The Third Annual

# Piper Jaffray Europe Conference

June 24-25, 2008



**DiaGenic ASA** 

Guides for the Journey. PiperJaffray.





Slide #2 DiaGenic.com

## Executive Summary

#### Markets:

> Large, fast growing. Unmet medical needs

#### DiaGenic:

- Blood based diagnostic tests
- IP based innovative technology with unique benefits & strong scientific validation
- > First revenues H2 '08
- Experienced team
- Backed by Nordic institutional investors
- Share issue placed May 2008; proceeds of GBP 4 mill. should allow the Company to reach B/E level for BC and AD products





# The DiaGenic Concept

- Diseases leave a unique "signature" in parts of the body besides the affected primary organ(s)
- These signatures can be identified using gene expression technologies
- These signatures can be obtained from easily accessible fluids (blood)



#### **Overview**

**The Commercial Opportunity** 

**The Company** 

The Technology

**The Investment Story** 

Breast Cancer

(India not included)

Cases per Year	High Risk (Family history, extreme dense breast on screening)	Adjuvant to Mammo- graphy (inconclusive results)	Preferred first line test (cultural or psychosocial reasons not to undertake mammography)		
US	4 mill	1,1 mill	1 mill		
Europe	4 mill	1,8 mill	0,7 mill		
Japan	1,5 mill	1,0 mill	0,2 mill		
Total	9,5 mill	3,9 mill	1,9 mill		

"UK Partner expecting a 200-300 GBP per test"
"Gross margin to IP holder (e.g. DiaGenic) ~ 20% (Industry avg)"

Present "burn rate" of DiaGenic only GBP 250' per month; ~ 5.000 tests

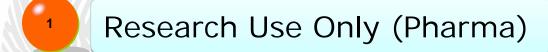
Three product candidates

Potential total market (annually)

	Breast Cancer (Niche Only)	Alzheimer's	Parkinson's
Total	15 m	5 m	2 m

(Does not include India, Pharma companies, and potential for general prevention screening)





Asia Pacific Countries (India)

H2 '08 \( 1\) 1st Revenues

CE (Europe) BC + Alzheimer's H1 '09

Market Entry Strategy with

Revenue Streames

Creating NEWSFLOW

Centralized Lab Testing, US (?)

Ex EU/US Countries

FDA – USA (Alzheimer's first)

Screening Approval US

Screening Approval EU

#### **Overview**

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1997 - Concept discovered

1998 - DiaGenic founded

2000 - Full time research

2002 - Proof of concept

2004 - First patent granted (US/EU) Listed on Oslo Stock Exchange

2005 - Scientific recognition

2006 - Prototype diagnostic tests developed in Breast Cancer and Alzheimer's Disease

> 2007 - Breast Cancer diagnostic test enters clinical trials. Parkinson's Disease project funded





**Erik Christensen Chief Executive Officer** 

Medical Doctor, Odense, DK, 1983 PhD in biochemistry, Oslo 1991 Certified Consultant in Clinical Chemistry 1992

The National Hospital, Oslo, N, 1985 – 93

Ullevål University Hospital, Oslo, N, 1993 – 96

Abbott Laboratories
Nordic Scientific Affairs Manager, 1996 – 2001
Country Manager Norway, 2001 – 06.
CEO DiaGenic from 1.1 2007



Anders Lönneborg
Research Director



Praveen Sharma Technology Director



Dag Christiansen Marketing Director



Håkon Sæterøy Executive Chairman of the Board; Equity financing

DiaGenic Scientific Advisors

#### **Alzheimer's Disease**

#### **Prof. Bengt Winblad**

Karolinska Institutet, Sweden

#### **Prof. Khalid Iqbal**

N.Y. State University, US

#### **Prof. Sam Gandy**

Faber Inst. Philadelphia, US

### Prof. Dag Årsland

Stavanger University Hospital, Norway

#### **Breast Cancer**

### Prof. Anne Lise Børresen Dale

Det Norwegian Radium Hospital, Norway

#### Dr. Alan Hollingsworth

Director, Mercy Women's Center, Oklahoma, US

#### **Prof. Martine Piccart**

Université Libre de Bruxelles, Belgium

#### **Dr. Christos Sotiriou**

Université Libre de Bruxelles, Belgium Molecular
Diagnostics
Value
Chain



DiaGenic provides the missing link in the growing search for applications in the molecular diagnostic market

Slide #13 DiaGenic.com



Award from
Michael J.
Fox
Foundation
&
Cooperation
Harvard
Medical
School

- Statement from member of our Scientific Board, professor Dag Aarsland:
  - "I like to congratulate DiaGenic with this very prestigious award.
  - The competition is paramount and only the very best projects receive funding
  - I also like to emphasis that very few non-US research groups ever get this award.
  - It is also recognition of the importance of identifying new biomarkers that can help in the early diagnosis of this disease"



Commercial Launch summer 2008





research







custome

- South East Asia's & India's fastest growing Pathology Services
  - 750 collection centres
  - 321 laboratories
  - 1.100 employees
  - 5 mill patients per year
- Extensive competencies within molecular diagnostics and experience in launching new diagnostic methods
  - A strategic and broad cooperation

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#### **Overview**

**The Commercial Opportunity** 

**The Company** 

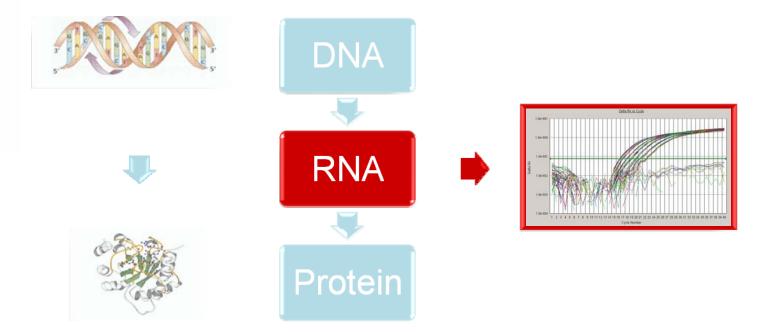
The Technology

**The Investment Story** 



DiaGenic

Technology



- RNA plays a central role in translating what is written in our genes to what is expressed in our bloodstream
- RNA expression is measured by qRT-PCR and forms the basis of our proprietary gene signature

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### Patent Status

	Family 1 (WO 98/49342)			(WO 2	mily 2004/04		Family 3 (WO 2005/118851)			
Expiry year	20	17		2023				2024		
Countries/										
Region	G	Α	Р	G	Α	Р	G	Α	Р	
US	Alz	0	BC, MS	0	0	G	0	0	С	
Europe*	G, nSB	0	Alz	0	0	0	0	0	0	
Europe**	0	0	0	0	0	G	0	0	С	
Norway	G, nSB	0	G, dD	0	0	G	0	0	С	
Japan	0	0	G, dD	0	0	G	0	0	С	
Canada	0	0	0	0	0	G	0	0	С	
Hong Kong	G, nSB	0	0	0	0	G	0	0	С	
China	0	0	0	0	0	G	0	0	С	
Australia	0	0	0	0	0	G	0	0	С	
New Zealand	0	0	0	0	0	G	0	0	С	
					Alz					
India	0	0	0	0	, BC	0	0	0	С	
South Africa	0	0	0	G	0	0	0	0	С	
ARIPO*	0	0	0	0	0	G	0	0	С	

G = Granted

A = Accepted by examiner

P = In-process

#### **Abbreviations**

Alz: Alzheimer's Disease

BC: Breast cancer

C: Cancer

G: No disease limitation.

G, dD: No disease limitation. Samples collected distant to the area of the disease

G, nSB: No disease limitation. Limited to **onl**y non-sequence based methods.

MS: Multiple sclerosis.





#### ACCURATE AND EARLY DETECTION OF ALZHEIMER'S DISEASE USING A GENE EXPRESSION SIGNATURE

<u>Anders Lönneborg ',</u> Birgitte Booij ', Marianne Jensen ', Ken Bårdsen ', Nina Hagen ', Lena Kristiansen ', Torbjørn Lindahl

†) Dia Genic ASA, Grenseveien 92, NO-0661 Oslo, Norway; 2) Dept. of Chemistry, Biotechnology and Food Science, Norwegian University of L Karolinska Institutet, Novum, Floor 5, SE-141 57 Huddinge, Sweden Wew York State Inst. #r Basic Res. in I

With potential disease modifying drugs for Alzheimer's soon to come we early identification techniques for Alzheimer's so that we can initiate treatmen for diagnosis of Alzheimer's Disease (AD) involved close rela e, and tests to determine disease

presented results from a pilot study. ssion based test can be developed for AD<sup>6</sup>. We have more

A novel blood-based gene expression signature was identified that could discriminate AD patients and agematched controls with high accuracy, sensitivity, and specificity. The signature also accurately distinguished AD patients from those having Parkinson disease, another neuro-degenerative disease. In an initial validation with a subset of identified informative gene probes on the quantitiative real-time PCR (gRT-PCR) based TagMan® Low Density Arrays® (LDA Applied Riesystes) showed that high diagnostic accuracy. based TagMan® Low Density Arrays® (LDA, Applied

was retained and the platform potentially car customized arrays

age-matched controls and 8 control samples from young individuals to rule out any possibility of AD, see Table 1. The same samples were used both in the TagManOD LDA and in the CodellinOD stroy.

Total RNA was extracted from blood samples asing PAXgene™ Blood RNA htt (figure 2) and quality assessed by NanoDrop spectrop to breter and Higure 1. Taq Man⊚ LDA (left) and Agilent 2100 Bloanalyzer.



Codelink \*\*\* (right) custom i zed arrays

Table 1. Demographic information of patient and control samples.

AD and age-matiled controls amples were the same for Tag Man and Cook Link, 26 young control samples were different Sample in the Tag Man is slown.

	Age (years)			MM SE soore			Gender dichribution			
	Average	8 D	Min	Max	Average	8D	Min	Max	Fernale (%)	Male (%)
Al zhelm er's disea se (N=63)	77,4	7,0	55	88	21,1	4,6	5	28	64 %	36 %
Age-matched controls(N=68)	75,8	7,6	59	93	29,2	0,8	27	30	79 %	21%
Young confrois (H=8)	22,6	2,4	20	28				-	100 %	0 %

hybrideson and backing steps. It care of Trapitation LDA, assays with other hissing states or having an average CT- 30 (160 assays in both) were removed prior to data analysis. Partial Least Square Regiession (PLSR) and Leave one out cross-callisation (LOCCV) were used for model by titing and to estimate the prediction accuracy. A novel approach combining double and triple cross-validation (CV) routing was used to select a smaller number of genes which could fit within a 95-assay format and the prediction accuracy of these genes was estimated. However, during gene selection, data from only 112 samples were used for modeling. The samples that were

2 the gene expression signature developed correctly predicted the class of 89/112 samples (accuracy 70%) including 36/49 AO samples (sensitivity, 74%) and 63/63 Non-Alzhemer controls (specificity, 84%). The ROC curve and AUC of this signature is presented in Figure 3.

In case of CodeLink customized arrays, the Alzheimer's specific gene expression signature was developed using complete pre-processed data. As shown in Table 2, the developed gene expression signature correctly predicted the class of 97 samples (accuracy, 85%), including 42 AD samples. (sensitivity, 82%) and 49 non-Alzheimer's controls (specificity, 87%).

The prediction results reported here are comparable to those previously presented using AB1700 Human Whole Genome Microarrays. The comparative ROC and AUC obtained in these studies is presented in Figure 3. The AUC in these studies ranged between 0.89 to 0.93 thus demonstrating improved diagnostic value compared to existing clinical diagnostic practice.

Table 2. Prediction results from AB1700 Human whole genome array, TaqMan $\otimes$  LDA and Codelink <sup>TM</sup> BioArray, LR+; positive likelihood ratio. (%) 95% Confidence interval.

Sensitivity	Specificity	Accuracy	LR+
85 %	88 %	87 % (5 %)	7.3
74 %	84 %	79 % (7 %)	4.6
82 %	87 %	85 % (7 %)	6.5
	85 % 74 %	85 % 88 % 74 % 84 %	85 % 88 % 87 % (5 %) 74 % 84 % 79 % (7 %)



etabolism. These were also the largest calculories represented

Figure 3, ROC curves for AB1700 WGA, Tag Man⊚ LDA within a 96-assay format and Codelink BloArrays data. The respective AUC's are shown.

- Results presented show that the informative genes identified using whole genome microarrays can be used to generate a highly accurate Alzheimer's specific gene expression signature in peripheral blood on different platforms
- An Alzheimer's specific gene expression signature has been developed within a 90-assay formation.
   TaqMan® LDA and on CodeLink. Bio Arrays with accuracies of diagnostic value in a clinical setting.
- By repeated multi-centre studies we have documented that we can develop a robust inlatform. independent gene expression signature for Alzheimer's disease thus enabling a convenient diagnostic tool
- The main biological processes involved in the Alzheimer's specific gene expression signature in blood are protein metabolism and modification, nucleoside, nucleotide and nucleic

- Charp FR, of al. (2006). Arch Neurd. 63: 1529-1536.

  Buro and di ME, Dorner AJ (2006). Pharmacogenomics. 7. (2:187-202.

  Gladke viol. A, Kauffman HF, Korf.J. (2004). Prog. Neuropsychoptomacol. Bid. Psychiaty. 28: 559-576.
- Gaariev von A, Kaumian HF, Korto (2006). Prog Neuropsychopromocos aid PS Sharma P, Lônneborg A (2006). Uriled Stales Palenti 8,709, 188. Mae d OC *et al.* (2005). Neurobidogy of Ajrig. 1559-1437. Sharma P, *et al.* (2005). Als fact number: 162960, 12th PA, Slockholm , Sweden
- Lönneborg A of al. (2005) Abs traci#: 03-01-01, 10th ICAD Conference, Madrid, Spain
- http://www.preanalvtir.com/RNA.asp

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### Benefit to users

- Easy, convenient peripheral blood samples, compared to:
  - Tissue based tests (cancer)
  - Mammograms (Breast cancer)
  - Battery of neuropsychiatry tests, Spinal Fluid (Alzheimer's disease)
- Processing time comparable with other blood tests (e.g. PSA)
- High accuracy
- Early stage of the disease; better prognosis
- Technology well suited for "Point of Care" and screening

#### **Overview**

**The Commercial Opportunity** 

**The Company** 

The Technology

**The Investment Story** 

## Well controlled burn rate

- 16 mill GBP invested since year 2000
  - Norwegian State FUGE grants: 2 mill GBP
  - Equity (financial investors): 14 mill GBP
- New: Private placement May 2008; net proceeds 4 mill GBP should allow the Company to reach break even level for BC and AD diagnostic products\*
- Market cap: 25 mill GBP

<sup>\*</sup> Includes: AD and BC CE approval, BC Launch in India and FDA studies on AD

# Interesting Pipeline Opportunity

- Further growth capital to be raised to finance FDA studies on BC and roll out to new verticals:
  - Pipeline within CNS
  - Biomarkers for pharma industry
- The Company is seeking alternative sources of financing; Equity (from partners) and non dilutive solutions





Shares	Percent	Name
3 589 135	6.94	VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS
2 910 000	5.62	SHARMA PRAVEEN
2 890 000	5.59	LØNNEBORG ERIK ANDERS
2 844 100	5.50	NORDEA BANK SWEDEN A
2 344 000	4.53	Tredje AP-Fonden C/O HANDELSBANKEN AS
1 914 000	3.70	A/S SKARV
1 444 870	2.79	HOLBERG NORDEN V/HOLBERG FONDSFORVA
1 406 500	2.72	NORDEA BANK PLC FINL
1 400 000	2.71	SKAGENVEKST
1 389 400	2.69	JPMBLSA NORDEA LUX LENDING A
1 097 387	2.12	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 003 100	1.94	LIVSFORSIKRINGSSELSK STRATEGISK
828 933	1.60	INVESTOR CORPORATE A
773 300	1.49	VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS
702 000	1.36	AMFIBIEN AS
646 000	1.25	ANDERSENRUBEN
476 100	0.92	SANDEN A/S C/O JAN PETTER COLLI
460 000	0.89	HAAVIND KARL WILHELM
428 378	0.83	STORHAUGDAG
28 957 203	55.98	Sum

20 Largest Share Holders - June 20th 20:00



 Innovative molecular diagnostics company, strong IP

#### Conclusion

- Experienced management team
- Target disease markets are large
- Clear marketing strategy via different global territories
- First Sales Q3 08
- Intensive Newsflow 2008/09







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